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STATEMENT

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Standard protocols for plant health scientific assessments

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Abstract

In accordance with the EFSA Strategy 2027 outlining the need for fit-for-purpose protocols for EFSA generic scientific assessments, the EFSA Panel on Plant Health (PLH Panel) developed standard protocols to harmonise the problem formulation process and outputs for mandates addressing recurrent scientific questions. Three types of recurring EFSA plant health mandates require generic scientific assessments: (i) pest categorisation; (ii) commodity risk assessment for the purpose of derogation to provisions of the EU plant health law and (iii) quantitative pest risk assessment. The three standard protocols are tailored to the appropriate level of detail and build on the existing guidance documents laying out the methods for conducting risk assessment in the plant health domain. To develop a standard protocol for pest categorisation, the PLH Panel adapted the latest version of the standard template reporting the evidence needs and the assessment questions to conclude whether a pest fulfils the criteria for being considered a potential quarantine pest for the EU. To develop a standard protocol for commodity risk assessment, the PLH Panel adapted the procedure and standard templates used for commodity risk assessment of high risk plants. To develop a standard protocol for quantitative pest risk assessments (qPRA), the Panel reviewed the existing guidance document on qPRA and the qPRAs published by the PLH Panel. The hierarchy of assessment questions and sub-questions used were identified and extracted. Based on this, a hierarchically organised IT-tool was formulated as protocol for the planning and documentation of future qPRAs.

KEYWORDS

commodity risk assessment, generic opinions, methodology, pest categorisation, quantitative pest risk assessment

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SUMMARY

In October 2023, EFSA published the Guidance on protocol development for EFSA generic scientific assessments (EFSA Scientific Committee, 2023). For mandates addressing recurrent scientific questions, standard protocols can be developed and reused over time upon minor, ad hoc adaptations, when needed, depending on the specific question.

The EFSA Plant Health Panel (PLH Panel) developed standard protocols for its recurring mandates. Recurring mandates are those that answer standardised questions of the risk managers on risk, but applied to different plant pests and/or to different plant commodities.

The plant health mandates received from the European Commission have well defined aims and scope that may be grouped in three main categories (pest categorisation, commodity risk assessment and pest risk assessment) and the outputs that the Plant Health Panel prepares in response to these mandates have a standard and recurring structure. Therefore, the development of protocols was based on the existing procedures, Panel guidelines and templates, and the relevant international phytosanitary standards that the PLH Panel already uses to address these three types of mandate.

The pest categorisation aims to determine whether a pest should be considered to be a potential quarantine pest and the conclusion is based on the fulfilment of a set of criteria translated into assessment questions and sub-questions: '*Is the identity of the pest clearly defined, or has it been shown to produce consistent symptoms and to be transmissible?*', '*Is the pest present in the EU territory? and "If present, is the pest in a limited part of the EU or is it scarce, irregular, isolated or present infrequently?"*', "*Is the pest able to enter into, become established in, and spread within, the EU territory?*", '*Would the pests' introduction have an economic or environmental impact on the EU territory?*', '*Are there measures available to prevent pest entry, establishment, spread or impacts?*'. For the development of the protocol for generic mandates on pest categorisation, the Panel revised the standard template currently in use for pest categorisation. This template includes the information and evidence needed to answer the assessment questions and therefore, assess whether the pest meets each criterion for being considered to be potential quarantine pest.

The commodity risk assessment can be conducted to investigate the plant health risk of a plant commodity, or the efficacy of a risk reduction option applied to prevent such risk. The process is usually initiated following a request from a third country to export plants or plant products to the EU where restrictions are in place and aims to identify the pest(s) of potential concern that could be present in plants or plant products imported from non-EU countries into the EU territory. In the commodity risk assessments, the probability of pest freedom is the only assessment question and similarly to the pest categorisations, a template exists to aid the systematic identification and collection of the evidence needed to answer the relevant sub-questions and inform the elicitation of the likelihood of pest freedom.

Quantitative pest risk assessments answer assessment questions regarding entry (incl. transfer), establishment (incl. climate suitability), spread and impact. A quantitative answer is obtained for each question, based on several sub-questions. The Panel reviewed the existing guidance document by the EFSA PLH Panel, along with several published quantitative pest risk assessment output documents. From this review, the Panel identified a common structure in the quantitative methodology and developed a logical hierarchy of sub-questions. Recognising that mandated quantitative pest risk assessments may involve varying levels of detail, the Panel organised this list of questions and sub-questions into a hierarchical protocol that supports each question to be addressed at the level of detail that is in accordance with the available data. This protocol allows on a case-by-case basis for a flexible representation of assessment questions and sub-questions that were addressed.

1 | INTRODUCTION

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

1.1.1 | Background

The Plant Health Regulation (EU) 2016/2031, on the protective measures against pests of plants, is applying from 14 December 2019. Conditions are laid down in this legislation for pests to qualify for listing as Union quarantine pests, protected zone quarantine pests or Union regulated non-quarantine pests. The lists of the EU regulated pests together with the associated import or internal movement requirements of commodities are included in Commission Implementing Regulation (EU) 2019/2072. Additionally, as stipulated in the Commission Implementing Regulation 2018/2019, certain commodities are provisionally prohibited to enter in the EU (high risk plants, HRP). EFSA is performing the risk assessment of the dossiers submitted by exporting to the EU countries of the HRP commodities, as stipulated in Commission Implementing Regulation 2018/2018. Furthermore, EFSA has evaluated several requests from exporting to the EU countries for derogations from specific EU import requirements.

In line with the principles of the new plant health law, the European Commission with the Member States are discussing monthly the reports of the interceptions and the outbreaks of pests notified by the Member States. Notifications of an imminent danger from pests that may fulfil the conditions for inclusion in the list of the Union quarantine pest are included. Furthermore, EFSA has been performing horizon scanning of media and literature.

As a follow-up of the above-mentioned activities (reporting of interceptions and outbreaks, HRP, derogation requests and horizon scanning), several pests of concern have been identified. EFSA is requested to provide scientific opinions for these pests, in view of their potential inclusion by the risk manager in the lists of Commission Implementing Regulation (EU) 2019/2072 and the inclusion of specific import requirements for relevant host commodities, when deemed necessary by the risk manager.

1.1.2 | Terms of Reference

EFSA is requested, pursuant to Article 29(1) of Regulation (EC) No 178/2002, to provide scientific opinions in the field of plant health.

EFSA is requested to deliver 53 pest categorisations for the pests listed in Annex 1A, 1B, 1D and 1E (for more details see mandate M-2021-00027 on the Open.EFSA portal). Additionally, EFSA is requested to perform pest categorisations for the pests so far not regulated in the EU, identified as pests potentially associated with a commodity in the commodity risk assessments of the HRP dossiers (Annex 1C; for more details see mandate M-2021-00027 on the Open.EFSA portal). Such pest categorisations are needed in the case where there is no risk assessment available for the EU.

When the pests of Annex 1A are qualifying as potential Union quarantine pests, EFSA should proceed to phase 2 risk assessment. The opinions should address entry pathways, spread, establishment, impact and include a risk reduction options analysis.

Additionally, EFSA is requested to develop further the quantitative methodology currently followed for risk assessment, to have the possibility to deliver an express risk assessment methodology. Such methodological development should take into account the EFSA Plant Health Panel Guidance on quantitative pest risk assessment and the experience obtained during its implementation for the Union candidate priority pests and for the likelihood of pest freedom at entry for the commodity risk assessment of high risk plants.

1.2 | Interpretation of the Terms of Reference

In October 2023, the EFSA Scientific Committee (SC) published the Guidance on protocol development for EFSA generic scientific assessments (EFSA Scientific Committee, 2023), proposing a harmonised and flexible framework for planning generic scientific assessments. In this Statement, the EFSA Scientific Panel on Plant Health (PLH Panel), following the abovementioned SC guidance, developed standard protocols to be applied to the main types of EFSA plant health risk assessments: pest categorisation (PC); quantitative pest risk assessment (qPRA); and commodity risk assessment (CRA). For developing these protocols, the PLH Panel considered the experience gained from the application of its guidance documents (EFSA PLH Panel, 2018a, 2019a), as well as the flexibility needed to deal with new and emerging plant pests (i.e. different extents of planning depending on the knowledge on the pest and/or the commodity and also on the character of urgency of the mandate).

1.2.1 | EFSA SC guidance on protocols development for generic scientific assessments

The scope of the SC guidance (2023) was to provide all EFSA Scientific Panels and Units/Teams with a harmonised but flexible framework for developing protocols for 'generic mandates'. Generic mandates (as defined by Art. 29 and Art. 31 of Regulation (EC) 178/2002 and Art. 43 of Regulation (EC) 396/2005) are mandates not related to processes of regulated products.

This SC guidance encourages the development of protocols when domain-specific guidance does not yet exist laying out the methods for conducting the assessment. To ensure the delivery of fit-for-purpose and efficient scientific advice, EFSA protocols must be adapted to the mandate requirements, tailoring, to each mandate (i) the level of detail of the protocol and (ii) the approach to publishing and disseminating the protocol. Therefore, EFSA protocols can range from being brief summaries of the assessment questions and sub-questions and of the approach to perform the assessment, to documents that detail, for example, the final search strategies, the tools for appraising evidence or the statistical analysis plan. In addition to the mandate requirements, several reasons can reduce the possibility of developing highly detailed protocols. These include, for instance, the impossibility to fully formulate the problem upfront that is inherent in some types of scientific assessments; the limited knowledge of the available evidence at the time of protocol development; the unavailability of or lack of expertise in applying certain methods; or time constraints. For mandates addressing recurrent scientific questions, standard protocols can be developed and reused over time. When such a standard protocol is applied minor ad hoc adaptations may still be made, when needed, depending on the specific question (EFSA Scientific Committee, 2023).

1.2.2 | Protocols for recurrent plant health scientific assessments

The PLH Panel therefore developed protocols for its recurring mandates on plant health risk assessment. Recurring mandates are those that answer standardised questions of the risk managers on risk, but applied to different plant pests and/or to different plant commodities.

The plant health risk assessment mandates received from the European Commission (EC) have well defined aims and scope that may be grouped in three main categories (PC, qPRA and CRA) and the outputs the PLH Panel prepares in response to these mandates have a standard and recurring structure. Therefore, the development of protocols was based on the existing procedures, Panel guidance documents and templates, and the relevant international phytosanitary standards that the PLH Panel yet uses to address these three types of mandates.

EFSA plant health generic scientific assessments address the risk of new and emerging plant pests for the EU territory. The risk assessment of new and emerging plant pests is often characterised by the scarcity of published scientific literature on the pest and urgency of the requested advice, hence strengthening the need for standard approaches to assess the risk as well as the uncertainties. The assessments are conducted following international phytosanitary standards (FAO, 2017) and PLH Panel specific guidance documents (EFSA PLH Panel, 2018a, 2019a). The PLH Panel guidance on quantitative pest risk assessment (EFSA PLH Panel, 2018a) provides guidance for PC and qPRA, including already the key aspects of protocol development, such as problem formulation and the specification of evidence needs and methods. The PLH Panel has developed a guidance for commodity risk assessment of high risk plants (EFSA PLH Panel, 2019a). CRA of high risk plants is conducted based on dossiers submitted by Third Countries (considered, in the EFSA context, as applications, for which SC guidance does not require protocol development); however, the same guidance is also applied in case of mandates to assess derogations to provisions of the EU plant health law – which are currently considered by EFSA as generic scientific assessments. Hence, the current document also covers CRA as a type of generic scientific assessment.

The proposed APRIO framework (Agent, Pathway, Receptor, Intervention and Output) can be applied directly with generic assessments. However, in the EFSA PLH Panel several assessment mandates are of reoccurring structure while being different regarding the individual hazard assessed. For mandates addressing recurrent scientific questions, a standard protocol can be developed and reused over time with minor, ad-hoc adaptations, when needed, depending on the specific question.

The purpose of this document refers to the documentation of the standard protocol approaches followed by the PLH Panel when addressing PC, CRA and qPRA. The proposed protocols aid delivery of generic PLH Panel scientific opinions. Their design took into account existing guidance documents of the Panel (EFSA PLH Panel, 2018a, 2019a), template-based protocols currently used, and the lessons learned in implementing previous assessments.[1]

PC follows a standard pest risk assessment approach with no or limited effort towards quantification of risk. The categorisations comprise the assessment questions on entry, establishment, spread and impact. The PC is conducted for a specific pest organism at the request of the EC.

CRA can be initiated by EC when it needs to assess phytosanitary requirements on a specific plant or plant product commodity, or by a request from a Third Country to modify existing EU phytosanitary requirements on a specific plant or plant product commodity. Past CRA of PLH Panel for derogation purposes have largely followed the protocol used for high-risk plants CRA, with modifications needed.

The qPRA implements the generic logic of import risk assessment guidelines of the International Plant Protection Convention (IPPC) (FAO, 2017) as well as of other international standard setting organisations in food safety and animal health (FAO/WHO, 2015; WOAH, 2022). These guidelines propose main assessment questions regarding entry [import], establishment [exposure], spread and impact [consequences]. In the context of a plant health qPRA, with an identified entry pathway the questions of the assessment protocol according to the APRIO (Agent, Pathway, Receptor, Intervention and Output) would repetitively list identical data for every sub-question but for the interventions and the output. Nonetheless the proposed sub-structure of the APRIO approach is congruent with the logic of quantitative pathway models often

[1]The EFSA PLH Panel assessments are published on the related EFSA Journal Virtual Issues; for PC at https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.Pest-categorisations; for qPRA at https://efsa.onlinelibrary.wiley.com/doi/toc/10.2903/(ISSN)18314732.Quantitative-pest-risk-assessments; for CRA at https://efsa.onlinelibrary.wiley.com/doi/toc/10.2903/(ISSN)1831-4732.Commodity-risk-assessment-for-plant-health-risks.

applied as technique for a pest risk assessment reflecting the chain of conditional events leading to pest risk (i.e. entry, establishment, spread and impact). In this document, spread and impact are addressed independently in accordance with the reviewed PLH Panel outputs. However, the spread capacity and resulting losses over time since establishment could be integrated using pragmatic approaches. The additional effort implied would lead, in line with risk assessment concepts, to quantification of the magnitude of the impact respecting the mandated time horizon of the assessment. qPRA according to the protocol can differ by the number of assessment questions considered: a full risk assessment, which addresses entry (including import, distribution, transfer), establishment (including climate suitability), spread and impact, or a partial risk assessment, which focuses on selected questions according to the Terms of Reference (ToR).

2 | DATA AND METHODOLOGIES

The three standard protocols for recurring assessment questions were derived from the guidance documents, working templates and published output of the PLH Panel. Recurring assessment questions presented to the EFSA PLH Panel can be classified into three main types of scientific documents: PC, CRA and qPRA.

2.1 | Pest categorisation

PC aim to answer the assessment question of whether the categorised pest fulfils the criteria to be potentially listed as a Union quarantine pest. There is no hierarchy of the five sub-questions addressing these criteria: (i) Is the identity of the pest clearly defined, or has it been shown to produce consistent symptoms and to be transmissible? (ii) Is the pest absent or with a limited presence in the EU? (iii) Is the pest able to enter into, become established in and spread within, the EU? (iv) Would the pests' introduction have an economic and/or environmental impact in the EU? and (v) Are measures available to prevent pest entry, establishment, spread or impacts? The five sub-levels must be fulfilled for the pest to be potentially listed as a Union quarantine pest. The PC includes a statement as to whether (1) all assessed criteria are met and (2) if not, which one(s) are not met. In the pest categorisations, uncertainties are listed, but not quantified.

For the protocol the most up to date template for PC was revisited that comprises the current practise.

2.2 | Commodity risk assessment

CRA aims to identify the pests of potential concern ('actionable pests') that could be present in plants or plant products imported from non-EU countries into the EU territory.

This type of assessment was initially designed for the CRA for High Risk Plants (a series of plant genera/species listed in Commission Implementing Regulation (EU) 2018/2019) and it can be applied and adapted also to assess the risk of plant commodities on the base of requests of derogation from specific provisions of the EU Plant Health law.

The first step consists in the identification of all the pests potentially associated with the plant species/genus (pest list).

The second step is the identification of the pests of potential concern (actionable pests) following the evaluation of a set of criteria for each pest: (i) pest is present in the exporting country; (ii) pest is absent or has a limited distribution in the EU or it is a regulated pest in the EU; (iii) pest is associated with the commodity and (iv) there is evidence that the pest causes significant impact.

The third step is the preparation of the pest datasheets for the actionable pests, that will constitute the 'evidence dossier' for the subsequent step.

The fourth step is the assessment of the likelihood of pest freedom of the commodity based on the evidence provided by the applicant and reviewed/supplemented by EFSA. This assessment can be done by an Expert knowledge elicitation (EFSA, 2014; EFSA PLH Panel, 2019a) following a prespecified set of questions and sub-questions.

Depending on the specific question received in the mandate, a request of derogation to a provision of the EU plant health law can also be addressed by means of PC (see Section 2.1 above) or of qPRA (see Section 2.3 below). In this case, the relevant protocol should be applied.

2.3 | Quantitative pest risk assesment

First, **conceptual definitions** were collated from the PLH panel guidance on quantitative pest risk assessment (EFSA PLH Panel, 2018a) and the qPRAs listed in Annex A.1 to harmonise assessment questions and sub-questions (see Section 3.3.1).

Then, the **quantitative models** described in past qPRAs were analysed and reverted to the inherent hierarchical structure (Annex A.2). This process facilitates the harmonised representation across past outputs using nested items and the identification of the hierarchical questions [i.e. from assessment questions (AQ) to different levels of sub-questions (SQ)].

The **assessment questions and sub-questions** answered in the PLH Panel output documents were recorded and similar ones harmonised.

The structure of assessment questions and sub-questions was implemented into a **hierarchical protocol.** To achieve this, the outline functionalities of Microsoft tools (e.g. Excel) were used. Each assessment question and sub-question was represented together with the expected quantitative outcome, the quantitative evidence and possible methodological approaches, which are: literature – using evidence from scientific literature and study reports; data – data from databases other than bibliographic; EKE – expert judgement informally collected or elicited via semi-formal or formal expert knowledge elicitation processes; modelling – mathematical/statistical tools. Where appropriate, the mathematics of aggregation of sub-level output to the next higher hierarchy level is specified.

The protocol is hierarchical in the sense that not all scientific assessments mandated in the future will need to be addressed at the same level of detail, and hence, selecting or unselecting individual sub-questions can flexibly represent the protocol decisions during assessment planning.

In qPRAs, **model inputs** are often parameterised by means of EKE in which the median and percentiles of the probability distribution characterising the uncertainty of the parameter value are elicited. Elicitation of model parameters requires precise questions. For certain parameters, these questions can coincide with the assessment or sub level questions. The Panel compiled a list of the parameters elicited in the previous qPRAs together with the EKE questions and provided a suggested wording for recurrent EKE questions.

3 | ASSESSMENT

3.1 | Pest categorisation

PC documents answer the assessment questions on possible entry, establishment, spread and impact following a standard template. The template used in previous PC outputs was updated and proposed as the standard protocol for PC (Kertesz et al., 2024).

3.2 | Commodity risk assessment

Most of the CRA done so far were on high-risk plants and have followed the protocol elaborated for those specific plants (EFSA PLH Panel, 2019a). Modifications to this protocol have been introduced to adapt the methodology to requests of derogation of import provisions of specific plant commodities (Table 1).

TABLE 1 Modifications applied to the high risk plant guidance in the different CRAs.

Document	Modification to HRP guidance
Commodity risk assessment of *Petunia* spp. and *Calibrachoa* spp. unrooted cuttings from Guatemala (EFSA PLH Panel, 2024a)	It generally follows HRP guidance, but has been specifically modified to include all Solanaceae pests and also includes Regulated Non-Quarantine Pest (RNQP)
Commodity risk assessment of *Petunia* spp. and *Calibrachoa* spp. unrooted cuttings from Kenya (EFSA PLH Panel, 2024b)	It generally follows HRP guidance, but has been specifically modified to include all Solanaceae pests and also includes RNQP
Efficacy of a postharvest treatment aiming at eradication of all developmental stages of *Tecia solanivora* in ware potatoes (EFSA PLH Panel, 2023a)	This mandate requested the assessment of a single treatment (elevated carbon dioxide) against a single pest (*Tecia solanivora*). Evidence of the efficacy of this treatment was from one published study, but due to limitations in the study design and execution, it was not possible to conclude that all stages of the insect would be eradicated. No EKE was performed, this was based solely on a review of the methodology and analysis of the reported results (Lobo et al., 2021).
Commodity risk assessment of black pine (*Pinus thunbergii* Parl.) bonsai from Japan (EFSA PLH Panel, 2019d)	The interpretation of the TOR indicated specifically that this assessment was to be based on the Guidance for High Risk Plants (HRP) commodity risk assessment (EFSA PLH Panel, 2019a).
Commodity risk assessment of bonsai plants from China consisting of *Pinus parviflora* grafted on *Pinus thunbergii* (EFSA PLH Panel, 2022c)	The interpretation of the TOR indicated specifically that this was to be based on the Guidance for HRP (EFSA PLH Panel, 2019a).
Commodity risk assessment of *Citrus* L. fruits from South Africa for *Thaumatotibia leucotreta* under a systems approach (EFSA PLH Panel, 2021b)	This request focused on a single pest of citrus fruit but with a systems approach for risk reduction. There were three options (primarily related to sampling intensity and temperature during shipment) that led to three scenarios, and a separate EKE was generated for each of them.
Commodity risk assessment of *Citrus* L. fruits from Israel for *Thaumatotibia leucotreta* under a systems approach (EFSA PLH Panel, 2021a)	Similar question was assessed for citrus fruit from Israel, but with only one scenario and a single EKE.
Commodity risk assessment of ash logs from the US treated with sulfuryl fluoride to prevent the entry of the emerald ash borer *Agrilus planipennis* (EFSA PLH Panel, 2023b)	Single pest (emerald ash borer) and single Risk Reduction Option (RRO); two commodities (logs with and without bark); two EKE.
Commodity risk assessment of oak logs with bark from the US for the oak wilt pathogen *Bretziella fagacearum* under an integrated systems approach (EFSA PLH Panel, 2020)	Single pest (*Bretziella fagacearum*) and control with a systems approach where methyl bromide (MB) is replaced with sulfuryl fluoride (SF); three variations in the systems approach led to three different EKE (MB, SF and no fumigant).

3.2.1 | CRA – protocol

Within the APRIO model, the CRA has the following logic:

- Agent: Single or several plant pests which may infect or infest a commodity.
- Pathway: Mode(s) of movement of a commodity which may be infected or infested with the plant pests(s).
- Receptor: Plants in the EU which may be affected by the pest or pests in question.
- Interaction: Risk reduction options that may be in place.
- Outcome: Probability distribution of commodity pest freedom.

In CRAs the probability of pest freedom is the only assessment question and is normally elicited with the elicitation being informed by the answers to a set of sub-questions.

The approach of CRA is translated into a protocol listing the sub-level assessment questions and the decision tree to evaluate the evidence (Gardi et al., 2024). The protocol additionally includes the forms for standard presentations of the pest information (pest sheet) and the list of relevant risk reduction options.

3.3 | qPRA

The qPRA comprises a standard sequence of main questions referring to entry (including transfer), establishment (including climate suitability), spread and impact. Being a quantitative assessment, the answers will usually be expressed as event probability or frequency per unit of time. The more informative data is accessible, and the more precise assessment is required, the more sub-levels (i.e. sub-questions, sub-sub-questions etc.) can be addressed. Finally, the multi-component outcome is connected to calculate quantitative answers to main questions.

3.3.1 | Conceptual definitions

In the protocol for qPRAs, in accordance with the EFSA guidelines (EFSA PLH Panel, 2018a, 2019a), the following definitions are used:

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 or individual plants/fruit. 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 infested by the pest.

Disaggregation/aggregation (of pathway units): The process to aggregate or disaggregate pathway units into transfer units if not the same.

Transfer unit: The unit of product or pest that moves as a cluster within the risk assessment area post-entry and reaches the final destination as a whole and which can result in a single founder population. Depending upon the problem and the modelling choices made in relation to the available data, a transfer unit could be a single seed, fruit or insect, but it could also be composed of a large number of such individual items, e.g. all the maize seeds or all the potato tubers required to plant a single field. If a single pathway unit gives rise to multiple transfer units, disaggregation is applied. If on the other hand a single transfer unit is composed of multiple pathway units, aggregation is applied.

Distribution (of transfer units): Following entry into the EU the (infested) transfer units are distributed to different final destinations. The distribution pattern may reflect quantitative characteristics, e.g. number of inhabitants, administrative units, e.g. NUTS2.

Potential founder populations: A potential founder population is an infested transfer unit that achieves an encounter with a host at an appropriate developmental stage.

Founder population: A founder population is a potential founder population in a suitable area/environment and therefore originates a population that can persist and spread after a lag period.

3.3.2 | Hierarchical protocol tool for qPRA

A hierarchical version of qPRA protocol is proposed (Crotta et al., 2024).

The hierarchal protocol is designed as a dynamic organised IT-tool for the planning of a qPRA. The tool supports explicit identification of parameters to be considered and quantitatively described in the risk assessment model.

The hierarchical protocol is meant to translate mandated ToR into scientifically answerable assessment sub-questions. For every assessment (sub-) question, the hierarchical protocol collates the evidence needs and the methods that could be applied for answering, including uncertainty analysis.

The structure of the protocol tool underpins the logic of a pathway model.

The tool is organised into a logical series of assessment questions (AQ) and different levels of sub-questions (SQ) according to the protocol guidance document (EFSA Scientific Committee, 2023). The tool visually supports inclusion or exclusion of sub-questions (scalability) so that the resulting protocol reflects the details necessary to address individual mandates.

The protocol intentionally does not prescribe a specific level of detail as there will be different data- and knowledge-driven limitations for different qPRAs. Rather it will guide till the most used level of resolution from past qPRA outputs, leaving an open space for future refinements while still maintaining the protocol in principle.

In principle, e.g. by using EKE directly answering the main assessment questions, the minimal protocol includes only the assessment questions that address the components of the qPRA i.e. entry, establishment, spread and impact.

To address a component of the qPRA i.e. answering the associated assessment questions in greater detail, the hierarchical protocol tool comprises logical series of sub-questions. Including more sub-questions makes the model more detailed, allowing for a deeper analysis of the biological phenomena. This leads to a better understanding of the key influencing events.

The formulation of the SQs requires a quantitative answer (e.g. uncertainty distribution, functional relationship or fixed value). The tool provides guidance regarding the potential sources and knowledge needed to answer the (sub-level) question. The logical connection with, or the intended calculation to answer the question on the next higher level is suggested.

Recognising the importance of minimising complexity and aiming to develop parsimonious models, the Panel believes that the current version of the template is suited to accommodate standard qPRA questions. The protocol tool is intended to be a dynamic document. On a case-by-case basis, the Panel could assess whether the template is sufficiently comprehensive, or whether additional SQs should be added to satisfy new needs and update the tool accordingly.

3.3.3 | Standard versions of EKE questions

Following the revision of the EKE questions used to elicit parameters in the qPRAs published so far by the PLH Panel, a standard version of the questions, addressing the common main and sub-questions, is proposed and presented in Table 2.

TABLE 2 Suggested wording for recurring EKE questions.

EKE n#	Parameter	Proposed EKE question
Entry (including transfer)		
1	Number of pathway units imported per year	What is the average volume of import (into the EU during the [timeframe for the risk assessment]) of the commodities from the countries with reported presence of the [pest]? [expressed in number of pathway units / year (or similar)]
2	Conversion factor	What is the factor to convert the number of pathway units into the number of transfer units? [expressed as factor]
Infestation rate; alternative1: direct elicitation of the infestation rate of the pathway units entering the EU (EKE n#3)		
3	Infestation rate at entering the EU	What is the average proportion of pathway units, that are infested with the [pest], when entering the EU (passing the border control) from the countries with reported presence of the [pest]? [expressed in 1 per 10,000 (or similar)]
Infestation rate; alternative 2: elicitation of the parameters needed to estimate the infestation rate of the pathway units entering the EU (EKE n#4 → n#7)		
4	Infestation rate at harvest in the countries of origin	What is the average proportion of the [commodities] just before harvest, that is infested with the [pest] in the production systems in the countries with reported presence of the [pest]? [expressed as % (or similar)]
5	Change of infestation by e.g. sorting, grading, handling and storing until departure	What is the factor converting the infestation rate of the [commodities] just before harvest into the infestation rate of the [commodities] just before departure from the countries with reported presence of the [pest], e.g. reduction of the infestation by sorting, grading, handling and storing? [expressed as % (or similar)]
6	Change of the infestation by transporting to the EU border	What is the average factor converting the infestation rate of the [commodities] just before departure from the countries with reported presence of the [pest] into the infestation rate at the EU border, just before the border control, e.g. reduction of the infestation by transporting? [expressed as % (or similar)]
7	Reduction at the border control	What is the average reduction of the infestation rate of the [commodities] due to the border control (before and after inspection)? [expressed as % (or similar)]
Aggregation/disaggregation		
8	Aggregation/disaggregation factor	What is the average factor converting the infestation rate of the [commodities] into the infestation rate of the [transfer units]? [expressed as factor]
Transfer; alternative 1: elicitation of the transfer rate		
9	Transfer rate	What is the factor describing the average number of initiated, established founder population per infested transfer unit, which entered the suitable area of the EU? [expressed as factor (or similar)]

(Continues)

TABLE 2 (Continued)

EKE n#	Parameter	Proposed EKE question
		Transfer rate; alternative 2: elicitation of the parameters needed to estimate the transfer rate (EKE n#10 → n#11)
10	Release rate	What is the factor describing the average number of released [pest] (e.g. from disposal) per infested transfer unit, when entered the suitable area of the EU? [expressed as factor (or similar)]
11	Mating rate	What is the proportion of released [pest], which is able to complete a reproductive cycle, e.g. by getting mated, reaching a host and initiating a potential founder population? [expressed in % (or similar)]
Establishment		
12	Establishment rate	What is the proportion of initiated, potential founder population, which establishes, e.g. persist a certain time? [expressed in % (or similar)]
Spread		
13	Lag phase	The 'natural' spread of an established founder population can be described in three phases: • The lag phase from the initiation of an (established) founder population until the start of its constant expansion. (The spread rate is increasing) • The expansion phase, this is the linear phase of the spatial spread (The spread rate is nearly constant). • The saturation phase, with decreasing spread rate due to limitation of resources What is the average duration of the lag phase? [expressed in years (or similar)]
14	Expansion rate	What is the average (constant) spread rate during the expansion phase? [expressed in km/year (or similar)]
Impact		
15	Yield loss	What is the average reduction of marketable yield in the production systems of suitable areas in the EU, due to the infestation with the [pest] on a steady-state level (saturation phase in the kernel of an infested area, compared to pest free areas)? [expressed in % (yield without the pest) (or similar)]
16	Quality loss	What is the average proportion of marketable yield in the production systems of suitable areas in the EU, which has reduced quality, due to the infestation with the [pest] on a steady-state level (saturation phase in the kernel of an infested area, compared to pest free areas)? [expressed in % (marketable yield) (or similar)]

4 | CONCLUSIONS

Three standard protocols for the recurring generic scientific assessments of the EFSA PLH Panel are proposed addressing pest categorisation, commodity risk assessment and quantitative pest risk assessment.

The assessment questions of a pest categorisation are intended to indicate whether a pest fulfils the criteria for being considered to be a potential quarantine pest.

Commodity risk assessments address one main assessment question regarding the likelihood of pest freedom of an imported plant commodity if certain import requirements apply.

Quantitative pest risk assessments answer four assessment questions regarding entry (including transfer), establishment (including climate suitability), spread and impact. Quantitative pest risk assessments result in quantitative risk estimates, based on several sub-questions addressing nested quantitative parameters.

Pest categorisation is the most prescriptive of the three types of assessment. The protocol comprises a working template of assessment questions with dedicated sub-questions, following existing PLH Panel guidance.

The commodity risk assessment protocol for generic scientific assessments is adapted from the high-risk plants commodity risk assessment guidance. The protocol proposes sub-questions necessary to be addressed in a tabular format with the table heading providing once the APRIO data for the assessment question.

The quantitative risk assessment protocol follows existing PLH Panel guidance and published output documents and is implemented as a hierarchical table (Excel appendix) listing the assessment and sub-questions in a flexible tool to foster the procedure of assessment planning.

The hierarchical aspect of the protocol implies that sub-levels of assessment questions can be hidden or unfolded visually when planning a qPRA. While reviewing the sub-questions, they can be adjusted based on the available data and the specific requirements of individual qPRAs. Therefore, the hierarchical protocol seems suitable for designing the qPRA in advance.

The risk assessment models prepared in previous qPRAs of the Panel can be visualised using a common nested structure. The scheme (including possible colour coding) comprises the essential logic of the protocol and therefore would be an option to harmonise protocol documentation of future qPRAs.

ABBREVIATIONS

APRIO agent pathway receptor intervention output
AQ assessment question

CRA commodity risk assessment
EKE expert knowledge elicitation
HRP high risk plants
PC Pest Categorisation
PLH plant health
qPRA quantitative Pest Risk Assessment
RNQP Regulated Non Quarantine Pest
RRO risk reduction option
SC Scientific Committee
SQ sub question
ToR Terms of Reference

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

AMENDMENT

Panel member Philippe Lucien Reignault was inadvertently omitted from the author list. An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the original version of the output has been removed from the EFSA Journal, but is available on request.

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MAP DISCLAIMER

The designations employed and the presentation of material on any maps included in this scientific output do not imply the expression of any opinion whatsoever on the part of the European Food Safety Authority concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

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ANNEX A

A.1 | Review of past qPRAs

List of pests, date of adoption and reference of the qPRAs published by the PLH Panel (period 2016–2024), which have been reviewed when writing this document

TABLE A.1 List of pests, date of adoption and reference of the qPRA published by the PLH Panel (2016–2024) – reviewed for this statement.

Pest	Date of adoption	Reference
Phlyctinus callosus	22/04/2024	EFSA PLH Panel (2024d)
African *Leucinodes spp.*	14/03/2024	EFSA PLH Panel (2024e)
Retithrips syriacus	14/03/2024	EFSA PLH Panel (2024f)
Leucinodes orbonalis	30/11/2023	EFSA PLH Panel (2024c)
*Thaumatotibia leucotreta**	28/04/2023	EFSA PLH Panel (2023e)
Resseliella citrifrugis	30/03/2023	EFSA PLH Panel (2023f)
Elasmopalpus lignosellus	30/03/2023	EFSA PLH Panel (2023c)
*Citripestis sagittiferella**	26/01/2023	EFSA PLH Panel (2023d)
Xanthomonas citri pv. *viticola*	24/10/2022	EFSA PLH Panel (2022a)
*Amyelois transitella**	08/07/2022	EFSA PLH Panel (2022b)
Pantoea stewartii subsp. *stewartii*	26/09/2019	EFSA PLH Panel (2019b)
Xylella fastidiosa	28/04/2019	EFSA PLH Panel (2019c)
Spodoptera frugiperda	21/06/2018	EFSA PLH Panel (2018b)
Diaporthe vaccinii	28/06/2017	EFSA PLH Panel (2017a)
Radopholus similis	24/05/2017	EFSA PLH Panel (2017b)
Eotetranychus lewisi	24/05/2017	EFSA PLH Panel (2017c)
Atropellis spp.	24/05/2017	EFSA PLH Panel (2017d)
Cryphonectria parasitica	30/10/2016	EFSA PLH Panel (2016a)
Ceratocystis platani	30/10/2016	EFSA PLH Panel (2016b)
Flavescence dorée	28/09/2016	EFSA PLH Panel (2016c)

*Examples of qPRA used in Annex A.2 to represent the general pathway structure.

A.2 | Example documents visualised

Schematic representation of the recurring structure of qPRAs published by the EFSA Panel for plant health. Colours are used to identify the internal dependence of different outcomes of assessment questions addressed by the reviewed qPRAs:

Entry [Importation, Distribution and Transfer] – Establishment incl. climate suitability – [Spread] – [Impact].

The different (intermediate) assessment results are displayed and coloured according to their quantitative interdependence. For example, one objective is to estimate the number of founder populations established during the assessment horizon. The scheme shows how the estimated number of pathogen units imported (Importation) is a prerequisite for their distribution in the risk assessment area (Distribution), and only then can the number of resulting potential founder populations that reach a host and reproduce (Transfer) be estimated. From the number of potential founder populations distributed throughout the EU, the final number of founder populations is estimated area-wise as the proportion that land in an area with a suitable climate for the pest and its hosts (Establishment).

For the Spread and the Impact, most of the reviewed documents, did not consider an integration; both estimations were presented independently without reference to the number of founder populations estimated before. However, other approaches can be found in literature or in previous PLH qPRA outputs (EFSA PLH Panel, 2016a) and a pragmatic approach to integrate both estimations in a time dependent impact quantification is given as an example in the coloured scheme below.

With the integration of spread and impact, the qPRA can combine a frequency-like outcome i.e. number of events per time units (founder population) and a magnitude-outcome i.e. the spread-based impact. The product of the two is a risk outcome.

Entry [Import, Distribution and Transfer] – [Establishment including climate suitability] – [Spread] – [Impact]

Number of FOUNDER populations
Number of POTENTIAL FOUNDER populations
Number of INFESTED TRANSFER UNITS
Number of INFESTED PATHWAY UNITS passing the EU border
Number of PATHWAY UNITS EXPORTED to EU
* Proportion of pathway units infested at the place of production
* Proportion of infested pathway units undetected, i.e. pest not removed, between leaving the place of production until before crossing the border of the export country
* Proportion of infested pathway units being infested during shipment, i.e. between leaving the border of the export country and arriving at the EU point of entry (proportion can be smaller or larger than 1)
* Proportion of infested pathway units undetected between arrival and departure of the EU entry point.
* Disaggregation of pathway units into number of transfer units & distribution across admin units
* Proportion of pest surviving after leaving the point of entry till transfer to the host (regional + local transfer + disposal)
* Proportion of pest that completes the reproductive cycle on the host e.g. mating and egg laying)
* Proportion of pest that is in an area suitable to complete multiple generations
Impact
Number of occupied spatial units
Number of spatial units with founder populations of the pest (e.g. NUT2 area)
+ [(Time horizon e.g. number of years - Lag phase)
* Spread rate *(e.g. annual number of newly occupied units)]*
* loss(es) in occupied spatial units

*In the latest output the Panel did not consider integrating spread and loss estimates. Instead for impact quantification, the necessary assumption was made that all suitable area already affected was endemically stable, and the impact was quantified in percent i.e. valid on arbitrary spatial dimension. Hence, in this approach the estimation of lag and spread has no relevance for impact estimation. Nonetheless, the explicit estimation of lag phase and spread rate can be used to inform surveillance planning.

As an example, three of the reviewed previous qPRA outputs of the Panel are represented using the visualisation scheme.

A.2.1 | *Thaumatotibia leucotreta*

In the assessment of the probability of introduction of *Thaumatotibia leucotreta* [the false codling moth (FCM)] into the EU with import of cut roses (EFSA PLH Panel, 2023e), the model calculates how many *T. leucotreta* individuals infesting cut roses would survive and emerge as adults from commercial or household disposal in the EU NUTS2 regions where the establishment is possible based on physiologically based demographic modelling.

The model consisted of three components to determine the number of adults that would escape from cut roses imported from countries with reported occurrence of *T. leucotreta*:

- A cut rose distribution model describing the proportion of the imported infested roses distributed in NUTS2 regions of the EU (see figure 6 of the Opinion for details);
- A development model describing the proportion of adult *T. leucotreta* that would emerge from infested cut roses as a function of the number of days after importation into the EU (see figure 7 of the Opinion);
- A waste model describing the proportion of *T. leucotreta* adults that would survive and escape prior to different types of waste treatment (see figure 8 of the Opinion).

Using the colour scheme presented in Annex A.2, the qPRA of *T. leucotreta* could be visualised as:

Geographically distributed mated females in climatically suitable areas (#FOUNDER POPULATION):

Number of mated FCM escaping waste treatment (#POTENTIAL FOUNDER POPULATION):

Number of INFESTED cut roses distributed into NUTS2 of the EU:

Number of INFESTED cut roses passing the EU border:

Number of cut roses imported into EU by season; PATHWAY UNITS

["entry"]

* Infestation$_{AF}$ (INFESTATION LEVEL in Africa)
* (Proportion of infested roses infested with eggs at EU border.
+ Proportion of infested roses with young larvae (L1 or L2) at EU border)
* Loss of 2–5% of infested roses at grading

["disaggregation and distribution"]

* Proportion infested transfer units where pest survives transport+distribution & arrives in correct stage to escape (Developmental model).
* Population$_{NUTS2}$ (potentially escaping pest assigned at NUTS2 proportional to population)

["transfer"]

* Probability of FCM surviving development time and waste processing until escape
* Probability to find a mate (FCM clustering)

["Establishment"]

NUTS2 (EU Risk Area) identified by physiologically based demographic model based on climate suitability

No Spread

No Impact

A.2.2 | *Citripestis sagittiferella*

In the Risk assessment of *Citripestis sagittiferella* for the EU (EFSA PLH Panel, 2023d), the number of potential founder populations was calculated as:

Number of founder populations = [Number of pathway units imported = (Annual weight imported * Disaggregation factor dividing annual flow into pathway units)] * Proportion of all harvested fruit being infested * Proportion of infested fruit NOT removed by postharvest treatment (RRO) * Proportion of infested fruit NOT removed at pre-export inspection * Probability that the pest in batch is transferred to suitable hosts.

Using the colour scheme presented in Annex A.2, the qPRA of *C. sagitiferella* could be visualised as:

Number of founder populations per year

Number of potential founder populations per year (i.e. pest-host encounters in the EU territory)

Number of transfer units

Infestation level when entering the EU

N_{trade} - import weight

* Prevalence at the origin
* $P_{sorting}$ i.e. [1- (1 - PSorting_Packing) * (1 - PSorting_Border)]
* d - Disaggregation of weights into transfer units
* $P_{transfer}$ - probability that an infested transfer unit results in a potential founder population.
* P_{estab} - probability that a potential founder population will establish

Spread

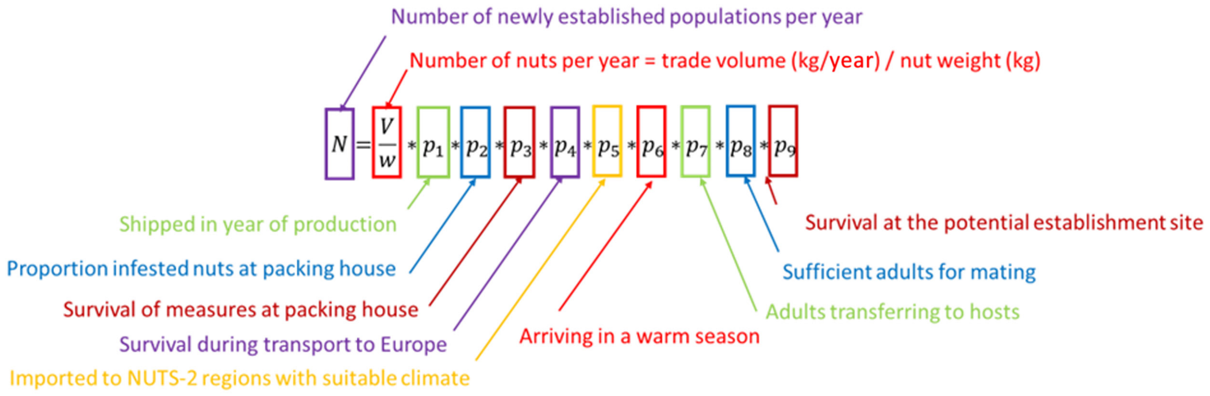
lag period & spread rate apply to the EU host-growing area,

Impact

yield loss estimated for the EU citrus-growing area once the pest has spread to its entire extent.

A.2.3 | *Amyelois transitella*

In the Risk assessment of *Amyelois transitella* for the EU (EFSA PLH Panel, 2022b), the number of potential founder populations was calculated as outlined in the annotated pathway model in figure 1 (Figure A.1).



Using the colour scheme presented in Annex A.2, the qPRA of *A. transitella* could be visualised as:

(N) Established (FOUNDER POPULATIONS)
- POTENTIAL FOUNDER POPULATIONS
  - Distribution of import to NUT-2 regions (ignore the one in non-suitable NUTS2)
    - Nuts entering the EU
      - (V/w) Trade volume / Weight of one nut
      - * (p1) Proportion of units traded in the year of production ## no cold treatment
      - * (p2) Proportion of infested units at packing house
      - * (p3) Proportion surviving measures at packing house
      - * (p4) Proportion surviving transport to the EU
    - * (p5) Proportion of units allocated to NUTS-2 regions that are suitable for establishment
  - * (p6) Proportion of units imported during climatically suitable seasons
  - * (p7) Probability of finding a suitable site
  - * (p8) Probability of successfully mate finding at the site (p8)
- * (p9) Probability of surviving measures, practices and biological control at the site

Spread
- Lag phase and Spread rate of expansion

Impact
- yield loss mean percentage