SCIENTIFIC OPINION

Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA[1]

EFSA Panel on Plant Health (PLH)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Scientific Panel on Plant Health was requested by EFSA to develop a guidance document on a harmonised framework for risk assessment of organisms harmful to plants and plant products and the identification and evaluation of risk management options. The document provides guiding principles on assessment practices and approaches when assessing risks to plant health to support the decision-making process under Council Directive 2000/29/EC. The framework aims at implementing the fundamental principles of risk assessment as laid down in Regulation (EC) No 178/2002, most importantly the independence and transparency of risk assessments carried out by EFSA. The document discusses the main issues of the pest risk assessment process: terminology, data requirements and data-related uncertainties. Furthermore, the document provides a framework for pest risk assessment and evaluation of pest risk management options. For the assessment of entry, establishment and spread of pests; both qualitative and quantitative approaches are recommended. An EFSA-adapted EPPO scheme is proposed should a qualitative approach be followed. The assessment of potential consequences of pest introduction and spread considers direct and indirect effects on all affected plant species as well as on the environment. The assessment of economic impacts falls outside the remit of EFSA. For the characterization of the overall risk, the use of risk matrices is proposed to combine qualitative scores. Upon request by the risk manager, risk management options may be identified. Potential changes in risk level resulting from different management options may also be assessed. Uncertainty and sensitivity analysis should be performed for the whole assessment process. For transparency reasons, the process of data collection should be recorded and included in the assessment. Principal requirements for the documentation of the pest risk assessment process are also discussed.

KEY WORDS

---

[1] On request of EFSA, Question No EFSA-Q-2008-704, adopted on 20 January 2010.

[2] Panel members: Richard Baker, Thierry Candresse, Erzsébet Dormannsné Simon, Gianni Gilioli, Jean-Claude Grégoire, Michael John Jeger, Olia Evtimova Karadjova, Gábor Lövei, David Makowski, Charles Manceau, Maria Navajas, Angelo Porta Puglia, Trond Rafoss, Vittorio Rossi, Jan Schans, Gritta Schrader, Gregor Urek, Johan Coert van Lenteren, Irene Vloutoglou, Stephan Winter and Marina Zlotina. Correspondence: plh@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on a harmonised framework for pest risk assessment in the EU for the preparation of this opinion: Richard Baker, David Caffier, Erzsébet Dormannsné-Simon, Olia Evtimova Karadjova, Gábor Lövei, David Makowski, Charles Manceau, Françoise Petter, Angelo Porta Puglia, Vittorio Rossi, Jan Schans, Gritta Schrader, Johan Coert van Lenteren, furthermore former panel (2006-2009) members for their contributions: James William Choiseul, Patrick De Clercq, Bärbel Gerowitt, Alfons Oude Lansink, Luisa Manici, Dionyssios Perdikis, Robert Steffek, Anita Strömberg, Kari Tiilikkala, and EFSA's staff members Virág Kertész and Sara Tramontini for the support provided to this EFSA scientific output.

Suggested citation: EFSA Panel on Plant Health (PLH); Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA. EFSA Journal 2010; 8(2):1495. [66 pp.]. doi:10.2093/j.efsa.2010.1495. Available online: http://www.efsa.europa.eu/en/efsajournal.htm

EFSA guidance document, pest risk assessment, transparency, independence, data requirements, risk management options

SUMMARY

The European Food Safety Authority (EFSA) requested the Panel on Plant Health to develop a guidance document on a harmonised framework for risk assessment of organisms harmful to plants and plant products and the identification and evaluation of risk management options.

The framework aims at implementing the fundamental principles of risk assessment as laid down in Regulation (EC) No 178/2002[4], most importantly, the independence and transparency of risk assessments carried out by EFSA.

The framework described addresses risks presented by non-indigenous living organisms harmful to plants and/or plant products that are associated with the movement of plants, plant products and other objects, and that may enter, establish, spread and cause harmful effects on plants and/or plant products and biodiversity. In fulfilling this mandate, the Panel reviewed the internationally recognised standards for pest risk analysis and compared the risk related terminology and the process with those of EFSA. Recognising the International Plant Protection Convention (IPPC) standards as the primary source of guidance, the Panel notes that the process, as outlined in the relevant international standards for phytosanitary measures (ISPM Nos 2, 5 and 11), engages both risk assessors and risk managers without specific differentiation of their roles and responsibilities in this process. The Panel therefore, after careful analysis has adapted the IPPC guidelines to the requirements of independent and transparent assessment of pest risk set out in Regulation (EC) No 178/2002. The principal differences between the EFSA framework for pest risk assessment and the identification and evaluation of pest risk management options and the IPPC standards on pest risk analysis are that EFSA does not (i) describe the process as pest risk analysis and use the acronym PRA, (ii) assess economic impacts in monetary terms, (iii) assess the consequences for markets, employment or tourism, (iv) assess social impacts, (v) evaluate the cost effectiveness of phytosanitary measures or (vi) evaluate the acceptability of risk.

The framework also recognises the “Guidelines on pest risk analysis – Decision-support scheme for quarantine pests” developed by the European and Mediterranean Plant Protection Organization (EPPO) as a possible option for conducting pest risk assessment and the identification and evaluation of pest risk management options. In the EFSA framework, the scheme developed by EPPO has been adapted for this purpose following the principles of independence and transparency.

As a result, the Panel has the following conclusions regarding the elements of the risk assessment process.

(i) Assessment of introduction and spread of organisms harmful to plants and/or plant products

For the assessment of the entry, establishment and spread of harmful organisms both qualitative and quantitative approaches may be used, however, in most cases a qualitative approach is followed, that may include quantitative elements. The Panel proposes to use the EFSA-adapted EPPO scheme. Transparency requires that the scoring system to be used is described in advance, including the number of ratings, the description of each rating, the method for combining scores and the classification of final risk level. However, to include these elements in the scheme, there is a need for further development.

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

(ii) Assessment of potential consequences associated with the introduction and spread of harmful organisms

Potential direct and indirect consequences of entry, establishment and spread of harmful organisms on all affected plant species as well as environmental consequences should be assessed. The Panel recognises that quantification of economic losses in monetary values or other related economic quantifications do not belong to its remit. Therefore, the Panel will not assess economic impacts in monetary terms, export markets, employment and tourism. Consequently these aspects are not included in the risk assessment scheme developed by the Panel.

(iii) Incorporation of the risk components into the overall characterization of the risk of a plant pest

When only quantitative approaches are used in pest risk assessment, the overall risk may be obtained by computation. Risk matrices are frequently used by risk assessors for combining qualitative scores. Although risk matrices should be used with caution, recognising that the combination of qualitative scores is still an active area of research, the Panel proposes the use of this technique for combining qualitative scores.

(iv) Assessment of the effect of risk management options on the level of risk

Upon request by the risk manager, the Panel can identify risk management options and/or evaluate the potential changes in risk resulting from different management options. Risk management options should be formulated in line with the considerations listed in ISPM No 11. Costs of risk management options are considered to be in the realm of risk management, i.e. the European Commission.

With quantitative risk assessment methods, the Panel proposes that methods be developed to ensure that the effectiveness of a risk management option is expressed as the expected change of each risk element, should the management option be applied. With qualitative risk assessment methods, the Panel recommends that methods be developed to ensure that effectiveness of a risk management option is expressed as the expected new score for each risk element, should the management option be applied.

The changes in uncertainty of each risk element, associated with the risk management option, should be assessed according to the methods proposed by the Panel for the analysis of uncertainty. The combination of several risk management options should be identified wherever possible.

(v) Harmonised methodologies to allow for consistent characterization of risk and evaluation of pest risks

To ensure transparency in risk assessment, uncertainties should be identified, characterized and documented in the assessment process. Documentation of the areas and degree of uncertainty enables risk managers to take the level of uncertainty into account in the decision-making process. The assessment of the capability of the organism to enter, to establish, to spread, and of its impact is based on scientific data, as well as, in some cases, on model simulations (e.g. climate matching and epidemiological models). All these sources of information have uncertainties. The relative importance of these uncertainties and their influence on the assessment outcome should be described.

The Panel considers that uncertainty and sensitivity analysis should be performed for the pest risk assessment as a whole, in addition to the consideration of uncertainty for each question in the assessment scheme. The most appropriate techniques will depend on the risk assessment

method implemented by the risk assessor, the number of uncertain factors and the computational time of the model.

(vi) Definition of data requirements allowing for transparent assessment of pest risks

A risk assessment requires a comprehensive evaluation of the data considered and the experimental and/or environmental conditions under which the data were generated. The information required for pest risk assessment is outlined in the international standard ISPM No 11. Each step of the risk assessment process requires its own data input.

The Panel suggests that the phase of data collection, searching, documenting the results of data searches and their validation be recorded and included in the assessment itself. These should follow normal protocols of evidence-based methods.

(vii) Principal requirements for documentation of pest risk assessment process and submission of dossiers

The main elements of documentation are:

- summary (including keywords);
- the background and terms of references as provided by the originator of the risk assessment request;
- the strategy of data searching;
- the assessment;
  - pest(s), pathways, risk assessment area, endangered area,
  - assessment of the probability of entry, establishment and spread (description of the scoring system, if a qualitative approach was used; description of mathematical model(s), if a quantitative approach was applied),
  - assessment of the potential consequences (direct and indirect),
  - if relevant, description of the uncertainty and sensitivity analysis methods,
  - conclusion of risk assessment (if relevant, description of the method used to combine individual scores),
- identification and evaluation of risk management options;
  - identification of risk management options and assessment of the effect of risk management options on the level of risk,
  - conclusion of the identification and evaluation of risk management options,
- final conclusions and recommendations;
- confidential data and information if any;
- list of references and documentation.

The EFSA pest risk assessments should respect the EFSA fundamental principles as laid down in Regulation (EC) No 178/2002. The opinion produced by the Panel should be fully and systematically

documented and communicated to the risk manager. Understanding any limitations that influenced the Panel's final conclusion is essential for the transparency of the process.

The conduct of a pest risk assessment requires a team effort in which there is a need for communication with the risk manager. Even though the roles of the risk assessor and the risk manager are distinct, a close collaboration between the two is essential to optimise results.

The EFSA procedures for pest risk assessment and the identification and evaluation of risk management options in this document should be kept under review to take into account the experiences of the EFSA Plant Health Panel and development work funded by EFSA under Article 36 and by other organizations worldwide.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN FOOD SAFETY AUTHORITY

The Scientific Panel on Plant Health provides independent scientific advice on the risks posed by harmful organisms which can cause harm to plants, plant products or biodiversity in the European Community. The Panel reviews and assesses those risks with regard to the safety and security of the food chain to assist risk managers in taking effective and timely decisions on protective measures against the introduction and spread of harmful organisms in the European Community.

On the request of the European Commission, the Panel carries out scientific evaluations of pest risk assessment documents prepared by Member States or other parties with the aim of advising the European Commission on claims for regulation of organisms considered harmful to plants or plant products under the Council Directive 2000/29/EC[5].

The current framework for conducting risk assessment for phytosanitary regulatory purposes is outlined by the International Plant Protection Convention (IPPC) in the international standards for phytosanitary measures (ISPMs): ISPM No 2 Framework for pest risk analysis (FAO, 2007a) and ISPM No 11 Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms (FAO, 2007b). The standards provide a broad rationale for the analysis of the scientific evidence to be taken into consideration when assessing the risk posed by an organism of potential quarantine pest status. While the IPPC standards cover basic principles to be followed by all its members, additional clarifications and adaptations may be required in view of various systems the member countries employ in their risk analysis activities.

The experience arising from the 40 opinions, on a variety of PRA documents evaluated and delivered so far by the Panel, as well as the results of 10th EFSA Scientific Colloquium (EFSA, 2008b), illustrate that the process of risk assessment of harmful organisms broadly varies in terms of scientific approaches, methodologies and data applied. In addition, consultations at the level of the Council Working Party of Chief Officers of Plant Heath Services show the demand for concerted efforts to address the process of risk assessment of harmful organisms at the EU level. Therefore, it becomes inevitable that EFSA contributes to harmonisation of the process of assessment of risks of harmful organisms at the European level. The aim is to facilitate and coordinate the activities in this area to fulfil the objective of provision of high quality, independent, scientific advice for decision-making in the European Community.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN FOOD SAFETY AUTHORITY

The Panel on Plant Health is requested to produce a guidance document on a harmonised framework for the assessment of risks of organisms harmful to plants and plant products in the European Community and in particular whether the organisms concerned may be considered harmful organisms, as defined in Article 2.1.(e) of Council Directive 2000/29/EC and thus potentially eligible for addition to the list of harmful organisms in Council Directive 2000/29/EC.

The brief for the Panel is to develop a proposal for a harmonised approach to pest risk assessment at EFSA. More specifically, the guideline document should provide a transparent and science-based framework regarding:

(i) assessment of introduction and spread of organism harmful to plants and/or plant products;

(ii) assessment of potential consequences associated with the introduction and spread of harmful organisms;

[5] 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, 10.7.2000, p. 1–112. (Consolidated version of 03.03.2009)

(iii) incorporation of the risk components into the overall characterization of the risk of a plant pest;

(iv) identification of risk management options and assessment of their effect on the level of risk;

(v) harmonised methodologies to allow for consistent characterization of risk and evaluation of pest risks;

(vi) definition of data requirements allowing for transparent assessment of pest risks;

(vii) principal requirements for documentation of pest risk assessment process and submission of dossiers.

In fulfilling the mandate the Panel should make the best use of the recommendations of the 10th EFSA Scientific Colloquium, the deliverables of the EFSA mandate Q-2008-259 on Guidance document for evaluation of pest risk assessments (EFSA, 2009a) as well as the results produced by the on-going projects funded both by EFSA and the European Commission (PRASSIS and PRATIQUE, respectively). Particular attention should be given to the issue of potential consequences associated with introduction of plant pests. Harmonised approach is needed in (i) distinguishing between direct and indirect impacts of pests, (ii) identifying the range of direct and indirect impacts, (iii) defining data requirements for their evaluation and (iv) incorporating these impacts into the overall characterization of the risk of a plant pest.

The working groups created for the purpose of this mandate should collaborate fully with each other and report regularly to the Panel.

The guidance document should be subjected to further consultation involving all parties concerned in the issue.

GUIDANCE DOCUMENT

1. Introduction

The European Food Safety Authority (EFSA) is the keystone of the European Union risk assessment regarding food and feed safety. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In all these fields, EFSA's most critical commitment is to provide objective and independent science-based advice grounded in the most up-to-date scientific information and knowledge.

The Scientific Panel on Plant Health of the European Food Safety Authority was established in 2006 by Regulation (EC) No 575/2006[6] amending Regulation (EC) No 178/2002[7]. The mandate of the Panel as adopted by the EFSA Management Board[8] is to address the increasing demand for assessing the risks of organisms harmful to plants, plant products and/or biodiversity. In response to requests for scientific opinions from the European Commission, the European Parliament, the Member States, or on its own initiative, the Panel provides independent scientific advice on issues related to organisms harmful to plants and plant products and biodiversity.

During its first three years of activity, the Panel delivered 40 opinions, contributing to the overall activity of EFSA as the EU's independent risk assessor.

1.1. Purpose and scope of the document

The purpose of this document is to develop a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA, to be used by the Panel when responding to requests for scientific advice on issues related to phytosanitary risks within the European Community. This document provides guiding principles on assessment practices and approaches when assessing risks to plant health in order to support the decision-making process under Council Directive 2000/29/EC.

The framework described below aims at implementing in plant health the fundamental principles of risk assessment laid down in Regulation (EC) No 178/2002, most importantly the principle of separation of risk assessment and risk management, independence and transparency of risk assessments carried out by EFSA (EFSA, 2009b).

Specific guidelines for pest risk analysis are provided by the International Plant Protection Convention (IPPC) in International Standards for Phytosanitary Measures (ISPMs) No 2 (FAO, 2007a) and No 11 (FAO, 2007b). The relevant terminology is included in ISPM No 5 (FAO, 2009). Recognising the IPPC documents as the primary source of guidance, the Panel notes that the process as outlined in the ISPMs engages both risk assessors and risk managers without specific differentiation of their roles and responsibilities in this process. The Panel therefore, after careful analysis adapts the IPPC guidelines to the requirements of independent and transparent assessment of risk.

The framework is based on an adapted version of "Guidelines on pest risk analysis – Decision-support scheme for quarantine pests" developed by the European and Mediterranean Plant Protection

[6] Regulation (EC) No 575/2006 of 7 April 2006 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority. OJ L 100, 8.4.2006, p. 1.

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

[8] EFSA Management Board decision 15.12.2005-3 adopted. Available from: http://www.efsa.europa.eu/en/events/documents/mb_23rdmeeting_managementplan_en1,0.pdf

Organization (EPPO, 2007) (referred to hereafter as: "EPPO scheme") for conducting pest risk assessment and the identification and evaluation of risk management options. For this purpose, in the EFSA framework, the scheme developed by EPPO has been adapted following the principles of independence, transparency and separation of risk assessment and risk management.

1.2. Context of risk assessment in plant health

The Council Directive 2000/29/EC recognises the importance of plants to the Community and the negative effects that harmful organisms have on plant yields. Protective measures against the introduction of such organisms into the Members States from other Member States or third countries are considered essential to safeguarding the Community's plant production.

In this context, the framework described addresses risks presented by non-indigenous living organisms harmful to plants and/or plant products that are associated with the movement of plants, plant products and other objects, and that may enter, establish, spread and have harmful effects on plants and/or plant products and biodiversity. The range of the organisms of concern includes plant pathogenic microorganisms (viruses, bacteria, fungi and other yet unidentified pathogenic agents), phytophagous invertebrates, parasitic plants and weeds.

1.3. Comparison of terminology between EFSA founding Regulation 178/2002 and IPPC

The Panel observes that the terminology of the IPPC pest risk analysis differs from the EFSA terminology of risk analysis as defined in EFSA founding Regulation No 178/2002.

The differences in terminology between EFSA (Regulation (EC) No 178/2002), IPPC and the PLH Panel approach are described in Appendix A and summarized in a table as presented in Appendix B, for each step of the risk analysis process.

2. Definition of data requirements

2.1. Data quality

2.1.1. Data needed for pest risk assessment

As recognised in EFSA's "Transparency in Risk Assessment" document, a risk assessment requires a comprehensive description of the data considered and the experimental and/or environmental conditions under which the data were generated (EFSA, 2009b).

The information required for pest risk assessment is outlined in the international standard ISPM No 11 (FAO, 2007b). Each step of the risk assessment process requires its own data inputs:

- pest categorization;
- assessment of the probability of entry, establishment and spread, and
- assessment of potential consequences and their magnitude.

More specifically, the PLH Panel collects information about:

- taxonomy and biological characteristics of pests;
- occurrence, distribution and prevalence of pests in various geographical areas;
- characteristics of diagnostic techniques;

- environmental data (e.g. climate, soil, geography) that could affect establishment and spread;
- farming practices and crop characteristics;
- transport and storage conditions of commodities that can potentially carry pests;
- trading patterns and other pathways relevant to spread of pests (e.g. tourist flows).

2.1.2. Availability of data

Information and summarized data on pests may be available from peer-reviewed scientific literature, reports and other documents. When searching for relevant literature, the procedure published in protocols of systematic reviews (e.g. Sargeant *et al.*, 2005) is considered very useful. The key components and requirements of such reviews are:

- identification of a search strategy;
- generation of a complete list of all primary research (published and unpublished) that could potentially answer the research question;
- construction of effective combinations of search terms using the key components of the review question(s);
- identification of relevant literature by initially searching electronic databases, then searching reference lists of publications identified, and obtaining data from unpublished studies when necessary.

When searching for relevant literature, a suitable combination of key word searches and combined keyword searches (using Boolean operators) should be performed. The search strategy should be recorded and documented. 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). Electronic database searches may not identify all of the relevant literature, and additional search strategies (hand search, checking the reference lists of identified primary information sources, searching personal information) should be considered. If appropriate, a relevance screening procedure should be introduced. The literature identified should be assessed for relevance, using minimum criteria (check-sheet). Information that does not meet these pre-defined criteria should be excluded from the review. Following this, the database should be characterized, its composition documented, and data should be extracted and synthesised.

These sources often do not provide the level of detail and scope of EU-coverage, required for risk assessment. Essential data for pest risk assessment may be present in specific databases with restricted access. These databases are of utmost importance for EFSA. To facilitate the conduct of pest risk assessment, an inventory of international and national data sources is generated by the projects PRASSIS funded by EFSA under Article 36 of Regulation (EC) No 178/2002 (Rossi *et al.*, 2009), and PRATIQUE funded by the 7th Framework Programme (PRATIQUE, online; Baker *et al.*, 2009). These projects cooperate with each other to improve the organization of available data and their acquisition.

Technical information such as data from surveys and interceptions may be relevant for pest risk assessment (FAO, 2007a). Member States collect data on organisms that are (i) mandatory for the whole EU, (ii) mandatory for their own territory, (iii) considered for yearly monitoring programmes, (iv) monitored following establishment and in support of eradication programmes. These data are currently not shared but may be available on request.

2.1.3. Uncertainties related to data

Uncertainty is a component of risk and therefore important to recognise and document when performing pest risk assessment. As described in ISPM No 2 (FAO, 2007a), "Sources of uncertainty may include: missing, incomplete, inconsistent or conflicting data; natural variability of biological systems; subjectiveness of analysis; and sampling randomness. Symptoms of uncertain causes and origin and asymptomatic carriers of pests may pose particular challenges". Uncertainty is the inability to determine the true state of affairs of a system (Haimes, 2009).

To ensure transparency in risk assessment, uncertainties should be identified, characterized and documented in the assessment process. Documentation of the areas and degree of uncertainty enables risk managers to take the level of uncertainty into account in the decision-making process. The assessment of the capability of the organism to enter, establish and spread, and of its impact is based on scientific data, including in some cases data based on model simulations (e.g. climate matching and epidemiological models). All these sources of information have uncertainties (EFSA, 2009a). The relative importance of these uncertainties and their influence on the assessment outcome should be described (EFSA, 2009b).

The Panel considers it important to distinguish between uncertainty due to imperfection of data and uncertainty arising from the natural variability and randomness which is associated with biological/physical data. Uncertainty due to a lack of knowledge is sometimes reduced through further measurements, studies or through further consultation with experts. Uncertainty due to natural variability is an inherent characteristic of biological systems and thus often cannot be easily reduced.

Several studies have proposed classifications for uncertainty due to imperfection of data (e.g. Vose, 2000). The Panel specifically considers the following forms of uncertainty relevant for pest risk assessments:

- limitations in the data, e.g. lack of data, conflicting or outdated data;
- limitations in terminology, e.g. ambiguous or imprecise definitions;
- experimental and observational limitations, e.g. sampling uncertainty, measurement uncertainty;
- extrapolation beyond the range of a dataset, or from one type of data to another (surrogacy);
- the selection of the line of reasoning, simulation model, or mathematical distribution for data fitting, when alternative approaches are available and the selected approach might influence the conclusion of the assessment.

In qualitative risk assessments, it is important to identify and discuss the key sources of uncertainty. A qualitative characterization of uncertainty can be provided for each source (e.g. low, high, etc.) as an aid to risk managers. When quantitative models are used in risk assessment, it is recommended to perform an uncertainty and sensitivity analysis (see 3.4.). Where possible a tiered approach may be applied, combining qualitative and quantitative evaluations of uncertainty, as developed by EFSA's Scientific Committee (EFSA, 2006) and applied in several opinions of EFSA Scientific Panels (e.g. EFSA, 2008a).

3. Framework for pest risk assessment

3.1. Assessment of the probability of entry, establishment and spread of pests

The probabilities of entry, establishment and spread of pests may be assessed by quantitative or qualitative approaches.

The Panel recognises that in most cases a qualitative approach will be followed, that may include quantitative elements. The Panel proposes to use the EFSA-adapted EPPO scheme (Appendix C). Transparency requires that the scoring system to be used is described in advance. This includes the number of ratings, the description of each rating, the method for combining scores and the classification of final risk levels (EFSA, 2008b). To include these elements in the EFSA-adapted EPPO scheme, the Panel recognises the need for further development. Where quantitative elements are included, transparency requires that every element of the calculation or mathematical modelling is communicated and justified, with a clear description of the model used, its accuracy and the parameter estimation (EFSA 2008b, 2009b).

3.2. Assessment of potential consequences

The Panel assesses potential direct and indirect consequences of entry, establishment and spread of pests on all affected plant species as well as environmental consequences.

Pests that principally have effects on crop yield or quality may also have environmental side effects. In accordance with current ecological concepts, two orders of considerations should be analysed: impacts on ecosystem services and impacts on biodiversity itself (Millenium Ecosystem Services, 2005). If the main effects are already large and unacceptable, detailed consideration of such side effects may not be necessary.

The Panel recognises that quantification of economic losses in monetary values or other related economic quantifications do not belong to its remit. Therefore, the Panel will not assess effects on economic impacts in monetary terms, export markets, employment and tourism.

3.3. Conclusion of risk assessment

3.3.1. Combination of qualitative scores using risk matrices

The Panel proposes to investigate the use of risk matrices as a method for combining ratings given to questions in the EFSA-adapted EPPO scheme. Risk matrices are frequently used by risk assessors for combining qualitative scores. A risk matrix is a table with several categories of likelihood for its row, and several categories of consequence for its columns (Cox, 2008; Engert and Lansdowne, 1999). Each cell of the table indicates the overall level of risk R associated with a given combination of likelihood (L) and consequence (C). In pest risk assessment, risk matrices can be used to combine the likelihood of entry, establishment, and spread of pests, and their consequence (e.g. Anonymous, 2002).

The definition of a risk matrix is not straightforward because it implies several choices:

- the matrix size i.e. the number of rows and columns (4 by 4, 5 by 5 etc.);
- the possible levels taken by the overall risk R, often represented by different colours (e.g. green, yellow, red);
- the risk level (e.g. colour) associated with each likelihood/consequence combination and with each cell of the matrix.

There is no fully objective way to choose the best matrix, but 5 by 5 matrices are frequently used in practice (Cox, 2008; EPPO, 2007). The two possible 5 by 5 matrices proposed by Cox (2008) and consistent with the formula R = L*C are presented below in the section. Although risk matrices should be used with caution, the PLH Panel proposes to explore the use of this technique for combining qualitative scores because:

- risk matrices are easy to understand;
- they provide risk assessors with a transparent way for combining scores;
- they can be used to improve the consistency of pest risk assessment;
- they allow the estimation of overall risk levels which can be used to rank different pests;
- they can be used to perform uncertainty analysis with qualitative scores (see next section).

The combination of qualitative scores is still an active area of research. Research is currently being carried out on this topic by the EU project PRATIQUE.

Two examples are presented below of possible colourings of a 5 by 5 risk matrix compatible with the formula R = L*C and consistent with the properties 1) weak consistency, 2) betweenness, and 3) consistent colouring. The order of the overall levels of risk is Red>Yellow>Green. (Cox, 2008).

Table 1: Example 1 for possible colouring of a 5 by 5 risk matrix

Likelihood/Consequence	0-0.2	0.2-0.4	0.4-0.6	0.6-0.8	0.8-1
0.8-1	Green	Green	Yellow	Red	Red
0.6-0.8	Green	Green	Yellow	Yellow	Red
0.4-0.6	Green	Green	Green	Yellow	Yellow
0.2-0.4	Green	Green	Green	Green	Green
0-0.2	Green	Green	Green	Green	Green

Table 2: Example 2 for possible colouring of a 5 by 5 risk matrix

Likelihood/Consequence	0-0.2	0.2-0.4	0.4-0.6	0.6-0.8	0.8-1
0.8-1	Green	Green	Yellow	Yellow	Red
0.6-0.8	Green	Green	Yellow	Yellow	Yellow
0.4-0.6	Green	Green	Green	Yellow	Yellow
0.2-0.4	Green	Green	Green	Green	Green
0-0.2	Green	Green	Green	Green	Green

3.4. Uncertainty and sensitivity analysis in pest risk assessment

Uncertainties arise in different stages of pest risk assessment due to lack of knowledge and to natural variability. Currently there is limited experience with uncertainty and sensitivity analysis in the practice of pest risk assessment, both at EFSA and other institutions. The Panel proposes to explore methods of uncertainty and sensitivity analysis to enhance the scoring, summarizing and communication of risk and uncertainty. This section shows how uncertainty and sensitivity analysis can be used to analyse the effect of various sources of uncertainties in the conclusion of a pest risk assessment.

3.4.1. Definition

Uncertainty and sensitivity analysis have two different purposes (Helton *et al*., 2006; Monod *et al*., 2006). Uncertainty analysis refers to the determination of the uncertainty in the output that derives from the uncertainty in inputs. Sensitivity analysis aims at determining the contributions of individual uncertain inputs to the uncertainty of the output. Consider, for a quantitative example, the calculation of the overall risk level R associated with a pest from the likelihood of entry, establishment and spread (L) and its consequence (C), R = L * C. The inputs are L and C, and the output is R. In this example, the purpose of the uncertainty analysis is to determine the uncertainty in the overall risk R induced by the uncertainties in L and C. The purpose of the sensitivity analysis is different; it aims at determining if R is more sensitive to the value of L than to the value of C (or the opposite) when these values vary over their uncertainty ranges. Uncertainty analysis is thus useful for communicating the uncertainty to the decision makers, whereas sensitivity analysis can be used to identify and prioritize key sources of uncertainty.

A number of methods have been developed to perform uncertainty and sensitivity analysis. Techniques are available for qualitative and quantitative approaches in risk assessment. These methods have been reviewed by many authors, for example by Chowdhury *et al*. (2009) in the context of risk assessment in drinking water and by the World Health Organization (2008) for exposure assessment. Uncertainty analysis proceeds in four steps:

i. characterization of the uncertainty in the inputs;

ii. generation of values of the inputs;

iii. computation of the outputs;

iv. presentation of the uncertainty analysis results.

Sensitivity analysis methods include an additional step which consists in computing sensitivity indices for each input and to rank the inputs according to these indices. A number of techniques have been proposed for each one of these steps. The advantages and disadvantages of several of these techniques are currently studied within the framework of the PRATIQUE Project. We briefly present the purpose of each step below.

3.4.1.1. Characterization of the uncertainty in the inputs

Several approaches can be used to characterize the uncertainty in the inputs (L and C in the example presented above). A simple approach is to define intervals i.e. to express the inputs in ranges with upper and lower limits. Another approach consists in using possibility and necessity functions in order to indicate values that are possible and values that are required to be satisfied. Finally, uncertainty can be described using continuous or discrete probability distributions.

In qualitative risk assessments such as the EFSA-adapted EPPO scheme (Appendix C), discrete probability distributions can be used to characterize the uncertainty in qualitative scores. Intervals, possibility/necessity functions, and probability distributions can be defined from experimental data and/or expert review process depending on the source of uncertainty (Budnitz *et al*., 1998). All these approaches have their advantages and disadvantages (Chowdhury *et al*., 2009).

In the example described above, the result of this step would be intervals of values for L and C, probability distributions for L and C, or possibility and necessity functions for L and C.

3.4.1.2. Generation of values of the inputs

When the uncertainty in the inputs is characterized by probability distributions and when the inputs are not combined using a linear model, it is often necessary to sample values from the input probability distributions. Several sampling strategies are available, including Monte Carlo sampling, importance sampling, and Latin hypercube sampling. The best strategy depends on the computational time of the model and on the probability distribution characteristics (McKay *et al*., 1979; Helton *et al*., 2006). In the example considered above, the result of this step would be a set of values of L and C.

3.4.1.3. Computation of the outputs

When a sample of input values is generated from a probability distribution, the purpose of this step is to compute the corresponding output values. If we consider our simple example, the result of this step is the mapping [L_i, C_i, R_i], i=1, …, N, where L_i and C_i are the i^{th} values of L and C generated at the previous step, N is the number of generated input values, and $R_i = L_i * C_i$.

When the uncertainty is not characterized by a probability distribution but by intervals, the outputs can be computed using the specific rules presented by Chowdhury *et al*. (2009). For example, if we consider the relation R = L*C and if we define the uncertainty of L and C by the intervals [a, b] and [d, e] respectively, the corresponding uncertainty interval for R is defined by [min(ad, ae, bd, be), max(ad, ae, bd, be)]. Specific rules are also defined when the uncertainty is characterized by possibility and necessity functions (Chowdhury *et al*., 2009).

These techniques can be applied with both quantitative and qualitative risk analysis. However, a prerequisite is the definition of an explicit relationship between the output and the uncertain inputs. Without such relationship, it is not possible to compute the output from generated input values or uncertainty intervals. The relationship between output and inputs can be a simple function like R = L*C, can be a complex function (e.g. EFSA, 2008a), or can be a risk matrix like those shown in section 3.3.1. For example, if the uncertainty intervals [0.2-0.6] and [0.4-0.8] are defined for L and C respectively, the uncertainty interval of the output R is [Green-Yellow] when the matrices displayed under 3.3.1 are used.

3.4.1.4. Presentation of the uncertainty analysis results

This step consists in displaying the output values. Presentation possibilities are numerous and include simple statistics such as means, standard deviation, confidence interval, minimum, maximum, quantiles, and graphic presentations like cumulative probability distributions and boxplots (e.g. Elith *et al*., 2002; Helton *et al*., 2006; Holland *et al*., 2009).

3.4.2. Computation of sensitivity indices

The purpose of sensitivity analysis is to assess the effects of individual uncertain inputs on the output. The results of a sensitivity analysis can be used to identify the inputs that deserve an accurate estimation. They can also be used for model reduction purposes; when an input does not have any effect on outputs either on its own or in combination with other inputs, it can be considered as non-influential and can be fixed to any value within its range of uncertainty (Saltelli and Tarantola, 2004). Sensitivity analysis consists of computing one or several sensitivity indices for each uncertainty input. The inputs are then ranked according to the indices values. A number of approaches have been proposed in the literature and the most appropriate technique depends on the computational time of the model, on the number of uncertain inputs, and on the characteristics of the input uncertainties (e.g. Saltelli *et al*., 2000, 2008). Sensitivity analysis techniques were implemented in various areas. An example of application to a model predicting the risk of establishment of *Guignardia citricarpa* in Europe is presented in Scientific Opinion of the Panel of Plant Health (EFSA, 2008a).

3.4.3. Uncertainty and sensitivity analysis for the EFSA-adapted EPPO scheme

The Panel considers that uncertainty and sensitivity analysis should be performed in pest risk assessment to the extent that is possible. The most appropriate techniques must be chosen according to the risk assessment method implemented by the risk assessor, notably according to the number of uncertain factors and to the computational time of the model (Cariboni *et al*., 2007). It is not currently possible to perform an uncertainty and sensitivity analysis with the EFSA-adapted EPPO scheme because this scheme does not propose any explicit rule for combining scores. Such rules are being explored in the PRATIQUE project. The Panel proposes that risk matrices are used to combine scores in order to facilitate uncertainty and sensitivity analysis.

4. Identification and evaluation of risk management options

4.1. Data requirements for identification and evaluation of risk management options

The international standard ISPM No 11 (FAO, 2007b) distinguishes broad categories of risk management options, but provides no information on the data required for their evaluation. Each category requires its own data inputs. The Panel considers that evidence or reasoned estimates need to be provided in order to demonstrate the effect of each management option on reducing the probability of entry, establishment, spread and/or the magnitude of impacts.

The principles on data quality and availability, discussed in section 2.1., are valid for identification and evaluation of risk management options.

4.2. Methodology for identification and evaluation of risk management options

Upon request by the risk manager, the Panel identifies risk management options and/or evaluates the potential changes in risk resulting from different management options, in line with the considerations listed in ISPM No 11 (FAO, 2007b).

The Panel identifies risk management options according to the following categories:

- options for consignments;
- options preventing or reducing infestation in the crop;
- options ensuring that the area, place or site of production or crop is free from the pest;
- additional options for specified pathways;
- additional options within the importing country.

The Panel evaluates identified risk management options with respect to:

- effectiveness, i.e. the level to which the risk is reduced by the risk management option;
- technical feasibility, i.e. whether technology and knowledge exists that is necessary for practical application of measure(s) proposed.

However, the Panel notes that:

- the decision on acceptability of the risk;
- the selection of risk management options for implementation, and

- the evaluation of risk management options in terms of their cost-effectiveness, minimal impact and non-discrimination;

fall outside of the Panel's remit.

Uncertainties associated with risk management options will be considered, and expressed in particular with respect to how they may influence the effectiveness of the measures in reducing the level of risk.

According to these considerations, the Panel analysed and adapted the section on "Pest Risk Management" in the EPPO scheme and proposes to identify and evaluate risk management options according to the EFSA-adapted EPPO scheme in Appendix C.

4.3. Conclusion of risk management section

The conclusions from the identification and evaluation of risk management options are presented.

5. Principal requirements for documentation of the risk assessment process and submission of dossiers

The principle of transparency requires that the risk assessor(s) make available the rationale for their assessment. The whole process of pest risk assessment (and the identification and evaluation of risk management options upon request) should be appropriately documented, so that the sources of information and rationale used to make the final conclusion are clearly shown.

The main elements of documentation are:

- summary (including keywords) – a technical summary reflecting the content of the assessment (the questions addressed, the information evaluated, the key issues which resulted in the conclusion);
- the background and terms of references as provided by the originator of the risk assessment request (European Commission, European Parliament, Member States, or EFSA;
- the strategy of data searching (identity of data bases, data banks and information systems, key search terms and strategies applied, and the time period covered should be provided;
- the risk assessment section, addressing what information was evaluated, how the information was evaluated and which issues were considered of key-relevance for the assessment. Main elements to be included are:
  - pest(s), pathways, risk assessment area, endangered area,
  - assessment of the probability of entry, establishment and spread (description of the scoring system, if a qualitative approach was used; description of mathematical model(s), if a quantitative approach was applied),
  - assessment of the potential consequences (direct and indirect),
  - if relevant, description of the uncertainty and sensitivity analysis methods,
  - conclusion of risk assessment (if relevant, description of the method used to combine individual scores),
- identification and evaluation of risk management options;

- assessment of the effect of risk management options on the level of risk,
- conclusion of the identification and evaluation of risk management options,

- final conclusions and recommendations;
- confidential data and information, if any. The reasons for confidentiality must be provided (EFSA, 2009b)
- list of references and documentation.

CONCLUSIONS

The Panel has reached the following conclusions regarding the elements of the risk assessment process:

(i) Assessment of introduction and spread of organisms harmful to plants and/or plant products

For the assessment of the entry, establishment and spread of harmful organisms both qualitative and quantitative approaches may be used, however, in most cases a qualitative approach is followed, that may include quantitative elements. The Panel proposes to use the EFSA-adapted EPPO scheme. Transparency requires that the scoring system to be used is described in advance, including the number of ratings, the description of each rating, the method for combining scores and the classification of final risk level. However, to include these elements in the scheme, there is a need for further development.

(ii) Assessment of potential consequences associated with the introduction and spread of harmful organisms

Potential direct and indirect consequences of entry, establishment and spread of harmful organisms on all affected plant species as well as environmental consequences should be assessed. The Panel recognises that quantification of economic losses in monetary values or other related economic quantifications do not belong to its remit. Therefore, the Panel will not assess economic impacts in monetary terms, export markets, employment and tourism. Consequently these aspects are not included in the risk assessment scheme developed by the Panel.

(iii) Incorporation of the risk components into the overall characterization of the risk of a plant pest

When only quantitative approaches are used in pest risk assessment, the overall risk may be obtained by computation. Risk matrices are frequently used by risk assessors for combining qualitative scores. Although risk matrices should be used with caution, recognising that the combination of qualitative scores is still an active area of research, the Panel proposes the use of this technique for combining qualitative scores.

(iv) Assessment of the effect of risk management options on the level of risk

Upon request by the risk manager, the Panel can identify risk management options and/or evaluate the potential changes in risk resulting from different management options. Risk management options should be formulated in line with the considerations listed in ISPM No 11. Costs of risk management options are considered to be in the realm of risk management, i.e. the European Commission.

With quantitative risk assessment methods, the Panel proposes that methods be developed to ensure that the effectiveness of a risk management option is expressed as the expected change

of each risk element, should the management option be applied. With qualitative risk assessment methods, the Panel recommends that methods be developed to ensure that effectiveness of a risk management option is expressed as the expected new score for each risk element, should the management option be applied.

The changes in uncertainty of each risk element, associated with the risk management option, should be assessed according to the methods proposed by the Panel for the analysis of uncertainty. The combination of several risk management options should be identified wherever possible.

(v) Harmonised methodologies to allow for consistent characterization of risk and evaluation of pest risks

To ensure transparency in risk assessment, uncertainties should be identified, characterized and documented in the assessment process. Documentation of the areas and degree of uncertainty enables risk managers to take the level of uncertainty into account in the decision-making process. The assessment of the capability of the organism to enter, to establish, to spread, and of its impact is based on scientific data, and, in some cases, on model simulations (e.g. climate matching and epidemiological models). All these sources of information have uncertainties. The relative importance of these uncertainties and their influence on the assessment outcome should be described.

The Panel considers that uncertainty and sensitivity analysis should be performed for the pest risk assessment as a whole in addition to the consideration of uncertainty for each question in the assessment scheme. The most appropriate techniques will depend on the risk assessment method implemented by the risk assessor, the number of uncertain factors and the computational time of the model.

(vi) Definition of data requirements allowing for transparent assessment of pest risks

A risk assessment requires a comprehensive evaluation of the data considered and the experimental and/or environmental conditions under which the data were generated. The information required for pest risk assessment is outlined in the international standard ISPM No 11. Each of the steps of the risk assessment process requires its own data inputs.

The Panel suggests that the phase of data collection, searching, documenting the results of data searches and their validation be recorded and included in the assessment itself. These should follow normal protocols of evidence-based methods.

(vii) Principal requirements for documentation of pest risk assessment process and submission of dossiers

The main elements of documentation are:

- summary (including keywords);
- the background and terms of references as provided by the originator of the risk assessment request;
- the strategy of data searching;
- the assessment;
    - pest(s), pathways, risk assessment area, endangered area,

  - assessment of the probability of entry, establishment and spread (description of the scoring system, if a qualitative approach was used; description of mathematical model(s), if a quantitative approach was applied),
  - assessment of the potential consequences (direct and indirect),
  - if relevant, description of the uncertainty and sensitivity analysis methods,
  - conclusion of risk assessment (if relevant, description of the method used to combine individual scores),
- identification and evaluation of risk management options;
  - identification of risk management options and assessment of the effect of risk management options on the level of risk,
  - conclusion of the identification and evaluation of risk management options,
- final conclusions and recommendations;
- confidential data and information if any;
- list of references and documentation.

The EFSA pest risk assessments should respect the EFSA fundamental principles as laid down in Regulation (EC) No 178/2002. The opinion produced by the Panel should be fully and systematically documented and communicated to the risk manager. Understanding any limitations that influenced the Panel's final conclusion is essential for the transparency of the process.

The conduct of a pest risk assessment requires a team effort in which there is a need for communication with the risk manager. Even though the roles of the risk assessor and the risk manager are distinct, a close collaboration between the two is essential to optimise results.

RECOMMENDATIONS

It is recommended by the Panel that the present guidance document is revised and updated based upon:

- the outcome and experience gained from the currently ongoing PRATIQUE project;
- results of EFSA calls on the development of pest risk assessment methodology;
- results of horizontal harmonisation activities within EFSA;
- any relevant new information which may have an impact on the current opinion.

DOCUMENTATION PROVIDED TO EFSA

Letter, dated 21 October 2008 with ref. EFSA/PLH/EBC/ac/out-2008-3392664 from C. Geslain-Lanéelle to J. Schans.

REFERENCES

Anonymous, 2002. The importation of fresh bananas in the Philippines. Technical information paper, Biosecurity Australia.

Baker RHA, Battisti A, Bremmer J, Kenis M, Mumford J, Petter F, Schrader G, Bacher S, De Barro P, Hulme PE, Karadjova O, Lansink AO, Pruvost O, Pyšek P, Roques A, Baranchikov Y and Sun J-H, 2009. PRATIQUE: a research project to enhance pest risk analysis techniques in the European Union. EPPO Bulletin, 39(1), 87–93.

Budnitz RJ, Apostolakis G, Boore DM, Cluff LS, Coppersmith KJ, Cornell CA and Morris PA, 1998. Use of technical expert panels: applications to probabilistic seismic hazard analysis. Risk analysis, 18, 463–469.

Cariboni J, Gatelli D, Liska R and Saltelli A, 2007. The role of sensitivity analysis in ecological modelling. Ecological modelling 203, 167–182.

Chowdhury S, Champagne P and McLellan PJ, 2009. Uncertainty characterization approaches for risk assessment of DBPs in drinking water: a review. Journal of Environmental Management 90: 1680–1691.

Cox LA Jr 2008. What's wrong with risk matrices? Risk analysis 28, 497–511.

EFSA (European Food Safety Authority) 2006. Guidance of the Scientific Committee on a request from EFSA related to uncertainties in dietary exposure assessment, EFSA Journal, 438, 1–54.

EFSA (European Food Safety Authority), 2008a. Scientific Opinion of the Panel on Plant Heath on a request from the European Commission on *Guignardia citricarpa* Kiely. The EFSA Journal, 925, 1–108.

EFSA (European Food Safety Authority), 2008b. Pest Risk Assessment. Science in support of phytosanitary decision-making in the European Community. EFSA Scientific Colloquium 10.

EFSA (European Food Safety Authority), 2009a. Guidance of the Panel on Plant Health on the evaluation of pest risk assessments and risk management options prepared by third parties to justify requests for phytosanitary measures under Council Directive 2000/29/EC, EFSA Journal, 2654, 1–18.

EFSA (European Food Safety Authority), 2009b. Transparency in Risk Assessment – Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General principles. The EFSA Journal, 1051, 1–22.

Elith J, Burgman MA and Regan HM, 2002. Mapping epistemic uncertainties and vague concepts in predictions of species distribution. Ecological Modelling, 157, 313–329.

Engert P and Lansdowne Z, 1999. Risk Matrix User's Guide Version 2.2. The MITRE Corporation; 52 pp.

EPPO (European and Mediterranean Plant Protection Organization) Standards 2007. Guidelines on Pest Risk Analysis, Decision-support scheme for quarantine pests. EPPO/OEPP, PM 5/3(3), Paris. Available from: http://archives.eppo.org/EPPOStandards/pra.htm

FAO (Food and Agriculture Organization of the United Nations) 1995. International standards for phytosanitary measures 1 to 29 (2007 edition). ISPM No 4 Requirements for the establishment of pest free areas (2007), Rome, 55-62.

FAO (Food and Agriculture Organization of the United Nations) 1998. International standards for phytosanitary measures 1 to 29 (2007 edition). ISPM No 8 Determination of pest status in an area (2007), Rome, 103-113.

FAO (Food and Agriculture Organization of the United Nations) 1999. International standards for phytosanitary measures 1 to 29 (2007 edition). ISPM No 10 Requirements for the establishment of pest free places of production and pest free production sites (2007), Rome, 125-133.

FAO (Food and Agriculture Organization of the United Nations) 2002. International standards for phytosanitary measures 1 to 29 (2007 edition). ISPM No 14 The use of integrated measures in a systems approach for pest risk management (2007), Rome, 183-193.

FAO (Food and Agriculture Organization of the United Nations) 2007a. International standards for phytosanitary measures 1 to 29 (2007 edition). ISPM No 2 Framework for pest risk analysis (2007), Rome, 27–41.

FAO (Food and Agriculture Organization of the United Nations) 2007b. International standards for phytosanitary measures 1 to 29 (2007 edition). ISPM No 11 Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms (2004), Rome, 135–160.

FAO (Food and Agriculture Organization of the United Nations) 2009. International standards for phytosanitary measures 1 to 29 (2009 edition). ISPM No 5 Glossary on phytosanitary terms (2009), Rome, 63–86.

Haimes YY, 2009. Risk modeling, management and assessment. 3rd ed. John Wiley and Sons.

Helton JC, Johnson JD, Sallaberry CJ and Storlie CB, 2006. Survey of sampling-based methods for uncertainty and sensitivity analysis. Reliability Engineering and System Safety, 91, 1175–1209.

Holland EP, Burrow JF, Dytham C and Aegerter JN, 2009. Modelling with uncertainty: introducing a probabilistic framework to predict animal population dynamics. Ecological Modelling, 220, 1203–1217.

McKay MD, Beckman RJ and Conover WJ, 1979. A comparison of three methods for selecting values of input variables in the analysis of output of computer code. Technometrics, 21, 239–245.

Millennium Ecosystem Assessment, 2005. Ecosystems and Human Well-being: Biodiversity Synthesis. World Resources Institute, Washington, DC. Available from: http://www.millenniumassessment.org/documents/document.354.aspx.pdf

Monod H, Naud C and Makowski D, 2006. Uncertainty and sensitivity analysis for crop models. In: Working with dynamic crop models. D. Wallach, D. Makowski, J. Jones Eds, Elsevier, 55–100.

PRATIQUE, online. Enhancements of pest risk analysis techniques (2008-2011). European Commission's 7th Framework Programme for Research and Technological Development: Grant Agreement No 212459. Available from: https://secure.fera.defra.gov.uk/pratique/index.cfm

Rossi V, Giosuè S, Bernazzani R, 2009. Pest risk assessment in the European Community: inventory of data sources. Scientific Report submitted to EFSA. Available at: http://www.efsa.europa.eu/en/scdocs/scdoc/29e.htm

Saltelli A, Ratto M, Andres T, Campolongo F, Cariboni J, Gatelli D, Saisana M and Tarantola S, 2008. Global sensitivity analysis. The primer. Wiley, New York.

Saltelli A and Tarantola S, 2004. Sensitivity analysis in practise. Wiley, New York.

Saltelli A, Tarantola S and Campolongo F 2000, Sensitivity analysis as an ingredient of modelling. Statistical Science, 15(4), 377–395.

Sargeant JM, Amezcua MDR, Rajic A and Waddell L, 2005. A guide to conducting systematic reviews in agri-food public health. Public Health Agency of Canada (Ottawa), 84 pp.

Vose D, 2000. Risk analysis, a quantitative guide. Wiley & Sons, New-York, 2nd edition.

WHO (World Health Organization), 2008. Uncertainty and data quality in exposure assessment, 1-159.

APPENDICES

A. TERMS AND DEFINITIONS USED BY THE PANEL

In line with EFSA's commitment for transparency in risk assessment (EFSA, 2009b) the Panel uses terms and definitions as listed by the International Plant Protection Convention (IPPC) in ISPM No 5 Glossary of Phytosanitary Terms (FAO, 2009) unless otherwise stated. This is referred to as the 'IPPC Glossary'. The use of some particular terms needs further explanation:

"Economic evidence" and "potential economic consequences"

The evaluation of economic evidence is essential to pest risk assessment. "Economic evidence" is also referred to as "potential economic consequences" and includes potential economic, environmental and social consequences. Since economic assessments are interpreted to be outside the scope of Regulation (EC) No 178/2002, the Panel addresses the "potential economic consequences" as two separate categories: impacts on (i) cultivated and managed plants and (ii) the environment.

Equivalence of "harmful organism" (Council Directive 2000/29/EC) and "pest" (IPPC)

In the European Community, Council Directive 2000/29/EC provides the legal basis for "protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community". The term "harmful organism" is defined in Article 2.1. (e) of the Directive as "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products". The Panel notes that this definition is identical to the definition of "pest" within the IPPC Glossary. Pest risk assessment is the process by which it is determined whether a "harmful organism" has the characteristics to be considered for potential listing in 2000/29/EC.

Council Directive 2000/29/EC does not refer to the term "quarantine pest" and the Panel does not use the term in this document or in its opinions. However, a species listed, or under consideration for potential listing in 2000/29/EC as a "harmful organism" is noted to comply in broad terms with the characteristics of a "quarantine pest" which is defined in the IPPC Glossary (FAO, 2009) as "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".

"Pest risk assessment area" and "endangered area"

A pest risk assessment is conducted with reference to a defined geographical area. This is referred to by the Panel as the "pest risk assessment area" in line with the definition within the IPPC Glossary (FAO, 2009). This area may be the whole European Community, one or more Member States, or a defined region within one Member State or within several adjacent Member States.

An "endangered area" is defined in the IPPC Glossary as "an area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss". However, "economically important loss" is not clearly defined and the Panel, therefore, interprets endangered area as "the area where ecological factors favour the establishment of a pest whose presence in the area will result in harmful consequences to cultivated and managed plants and the environment".

B. DIFFERENCES IN TERMINOLOGY BETWEEN EFSA (REGULATION (EC) NO 178/2002), IPPC AND THE PLH PANEL APPROACH

TERM	REGULATION (EC) NO 178/2002	IPPC	PLH Panel approach
		TERMINOLOGY	
Hazard	**Hazard** A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect. **[Art. 3(14)]**	**Pest** Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. **[ISPM No 5]**	The PLH Panel notes the similarity between the terms "hazard" and "pest": • "*A biological, chemical or physical agent in, or condition of, food or feed*" is equivalent to "*Any species, strain or biotype of plant, animal or pathogenic agent*" • *"The potential to cause an adverse health effect"* is equivalent to *"injurious to plants or plant products"* Council Directive 2000/29/EC uses the term "harmful organism", which is synonymous with the term "pest". However, with respect to the process of defining a harmful organism, 2000/29/EC refers to IPPC terminology, i.e. "pest risk analysis' and "pest free area". The PLH Panel will use the term "**pest**" in association with risk assessment methodology, and he term "**harmful organism**" when referring in general to organisms that are injurious to plants and/or plant products.

Risk	**Risk** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard. **[Art. 3(9)]**	**Pest risk (for quarantine pests)** The probability of introduction and spread of a pest and the magnitude of the associated potential economic consequences. **[ISPM No 5]**	**Pest risk** The PLH Panel notes the similarity between the terms 'risk' and 'pest risk', with the IPPC definition specifying the relevant probability for pests. The PLH Panel will use the term "**pest risk**". The Panel defines the pest risk as function of the probability of entry, establishment and spread and the magnitude of the associated potential consequences. Monetary aspects of potential consequences are considered by EFSA as the risk manager's responsibility.
Risk Analysis	**Risk analysis** A process consisting of three interconnected components: risk assessment, risk management and risk communication. **[Art. 3(10)]**	**Pest risk analysis (acronym: PRA)** (agreed interpretation) The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it. **[ISPM No 5]** The pest risk analysis process consists of	**Pest risk assessment and evaluation of risk management options** The PLH Panel notes that the specific feature of the risk analysis process in the European Community is the separation of risk assessment from risk management. The PLH Panel considers that the following elements of the IPPC risk analysis process fall within the Panel's remit: • The process of evaluating scientific evidence to determine whether an organism can be considered harmful.

		three stages: - Stage 1: Initiation - Stage 2: Pest risk assessment - Stage 3: Pest risk management. **[ISPM No 2]**	• On request identification of risk management options and evaluation of their effect on the level of risk and of their technical feasibility. The evaluation of economic impact, decision whether an organism should be regulated and decision on the strength of any phytosanitary measures to be taken against it fall outside the EFSA PLH Panel's remit. Therefore the Panel will not use the term pest risk analysis or its acronym PRA. Instead it will refer to "pest risk assessment and identification and evaluation of risk management options".
RISK ANALYSIS PROCESS			
Initiation	There is no clear provision in the Regulation for the initiation of the risk analysis process, but Article 29 provides the possibility for EFSA to initiate risk assessment via self-tasking. **[Art. 29]**	The pest risk analysis process may be initiated as a result of: (i) the identification of a pathway that presents a potential pest hazard (ii) the identification of a pest that may require phytosanitary measures (iii) the review or revision of phytosanitary policies and priorities.	The Panel considers initiation of risk analysis process to be ordinarily the responsibility of the risk manager. Although in some cases this process may be initiated by self-tasking according to Regulation (EC) No 178/2002.

		[ISPM No 11]	
Risk Assessment	A scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization. **[Art. 3(11)]**	Pest risk assessment: Evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences. **[ISPM No 5]**	To improve consistency with IPPC, the PLH Panel will use the term "**pest risk assessment**". The Panel notes that evaluation of the probability of entry, establishment and spread of a harmful organism and the magnitude of the associated potential consequences falls within the Panel's remit. The Panel considers impacts on cultivated and managed plants and environmental consequences. However, decision on the acceptability of risk and evaluation of monetary aspects of economic consequences is considered by EFSA as the risk manager's responsibility. The Panel does not address potential social consequences either. In relation to the area to which this assessment applies the Panel will use the term "**pest risk assessment area**".
	Hazard identification	**Pest categorization**	To be consistent with IPPC, the Panel will use the term "**pest categorization**".
	Hazard characterization Hazard characterization is not further defined in Regulation (EC) No 178/2002.	**Assessment of potential economic consequences.**	The PLH Panel notes the similarity between these terms and interprets the assessment of potential economic consequences as equivalent to hazard characterization. The PLH Panel notes that hazard

			characterization involves the potential direct and indirect consequences of entry, establishment and spread of the harmful organisms on all affected plant species as well as environmental consequences. The PLH Panel recognises that quantification of economic losses in monetary values or other related economic quantifications do not belong to its remit. Therefore effects on export markets, employment and tourism will not be assessed by the Panel. The Panel considered a term according to EFSA terminology as "hazard characterization for harmful organisms". However, to improve consistency with IPPC, the Panel proposes to refer to this step as "**Assessment of potential consequences**".
	Exposure assessment Exposure assessment is not further defined in Regulation (EC) No 178/2002.	**Assessment of probability of introduction and spread** Introduction of a pest is comprised of entry and establishment. **[ISPM No 11]**	The PLH Panel notes the similarity between these terms and interprets "exposure assessment" as equivalent to "assessment of probability of introduction and spread". In assessment of the exposure of an area to a harmful organism, the PLH Panel distinguishes between entry, establishment and spread of harmful organisms.
	Risk characterization	**Conclusion of pest risk assessment** "summarizing the overall pest risk on the basis of assessment results regarding introduction, spread and potential	The PLH Panel notes the similarity between these terms. To be consistent with IPPC, the Panel proposes to refer to this step as "**conclusion of pest risk**

		economic impacts for quarantine pests, or economically unacceptable impacts for regulated non-quarantine pests". The outputs from pest risk assessment are used to decide if the pest risk management stage is required. **[ISPM No 2]**	**assessment**". As the monetary values of risk are not considered by the Panel, summarizing the overall pest risk will be done on the basis of the results of assessment of probability of entry, establishment, spread and impacts on cultivated and managed plants as well as environmental consequences. The decision whether pest risk management is required should be done by the risk manager.
Decision on the need to explore risk management options	The decision on the need to explore risk management options is part of risk management.	As a result of the pest risk assessment, all or some of the categorized pests may be considered appropriate for pest risk management. **[ISPM No 11]**	The decision whether an organism should be regulated and decision on the strength of any phytosanitary measures to be taken against it fall outside the EFSA PLH Panel's remit.
Identification and evaluation of risk management options	Regulation (EC) No 178/2002 does not provide for the identification and evaluation of risk management options.	ISPM No 11 refers to this process step as "Pest Risk Management", described as: "the process of identifying ways to react to a perceived risk, evaluating the efficacy of these actions, and identifying the most appropriate options". According to ISPM No 11 these are risk management options that reduce risk to an acceptable level. In ISPM No 2 it is formulated as: "The conclusion of the pest risk management stage will be whether or not appropriate phytosanitary measures adequate to reduce the pest risk to an acceptable level are	The Panel recognises the risk manager's demand for scientific advice on risk management options. Therefore identification and evaluation of risk management options in terms of their effectiveness on reducing the level of risk is considered to be in the Panel's remit. The Panel will provide scientific advice on risk management options if requested so by the risk manager. The Panel will, upon request, identify risk management options and/or evaluate the potential changes in risk resulting from

		available, cost-effective and feasible." **NB.** The decision on selection of risk management options to be implemented is outside the Pest Risk Management process	different management options. The Panel will refer to these activities as "**identification and evaluation of risk management options**".
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. **[Art. 3(12)]** Identification and selection of risk management options are not addressed in Regulation (EC) No 178/2002.	Pest risk management for quarantine pests: "Evaluation and selection of options to reduce the risk of introduction and spread of a pest". **[ISPM No 5]** "The regulatory decision is beyond the Pest Risk Analysis process." **[ISPM No 2]**	The Panel notes that (i) the decision on acceptability of the risk, (ii) the selection of risk management options and, (iii) evaluation of risk management options in terms of their cost-effectiveness and economic feasibility, minimal impact, and non-discrimination fall outside of the Panel's remit. The EFSA PLH Panel will not take part in the risk management activities as described in Regulation (EC) No 178/2002.
Risk Communication	Risk communication is carried out in all above stages.	Risk communication (ISPM No 2) is carried out in all above stages.	EFSA PLH Panel contributes to risk communication through its opinions or other types of scientific outputs.

C. EPPO SCHEME ADAPTED BY THE EFSA PANEL ON PLANT HEALTH FOR PEST RISK ASSESSMENT AND THE IDENTIFICATION AND EVALUATION OF PEST RISK MANAGEMENT OPTIONS

The PLH Panel adapted the EPPO scheme, version 2007(EPPO, 2007) in order to follow the fundamental principles of risk assessment as laid down in Regulation (EC) No 178/2002, most importantly the independence and transparency of risk assessments carried out by EFSA.

A summary of the main modifications is as follows:

- Recognising that the IPPC pest risk analysis differs from the EFSA concept of risk analysis, the EFSA does not use the term pest risk analysis or its acronym PRA. For more details on terminology, please consult Appendix B.

- For EFSA pest risk assessments, the risk assessment area may be the whole European Community, one or more Member States, or a defined region within one Member State or within several adjacent Member States. If the risk assessment is requested by the Commission/is going to be used for Community legislation then the risk assessment area will always be the Community territory addressed by Council Directive 2000/29/EC.

- The term “economic” has been removed or replaced by biological components of the impact, since quantification of economic losses in monetary values or other related economic quantifications do not belong to EFSA remit. Questions regarding increases in production costs, reduction in consumer demand, losses in export markets, other costs resulting from introduction, e.g. to government, and social impacts have also been removed for the same reason.

- In stage 2, section 2 “Assessment of potential consequences”, EFSA will focus the analysis on the adverse effects of a pest on crop yield and/or quality and on the environment.

- Recognising that pests which principally have effects on crop yield or quality may also have environmental side-effects, the environmental consequences section (2.4) has been updated with current concepts in ecology regarding impacts on ecosystem services and biodiversity. A detailed note has been added in order to provide due attention to ecosystem services. The question “How likely is it that genetic traits can be carried to other species, modifying their genetic nature and making them more serious plant pests?” has also been removed.

- In “Stage 3: Evaluation of risk management options”, a decision on the acceptability of the risk is in the realm of the risk manager. It has also been made explicit that decisions on adoption of measures, which are out of the EFSA remit, will not be analysed as these are the domain of risk decision makers/risk managers. However, upon specific request from them, the Panel may analyse the effect of management options on the level of risk and state whether they may be effective, practical and reproducible. To this end, one question (Question 3.1. in the original EPPO scheme) has been removed and other questions, particularly question 3.34 which relates to the cost-effectiveness of measures, have been adapted where relevant.

- Figures 1, 2 and 3 of the EPPO scheme (2007) (presenting a flow diagram of the sequence of the scheme) have been removed.

- Minor changes have been made, mostly to make the text fit with the changes required for EFSA risk assessments and the identification and evaluation of risk management options.

Both the introductory part of the scheme as well as the introduction to its three stages have been modified. The modified parts of the text are underlined.

Guidelines on Pest Risk Assessment and evaluation of risk management options

Scheme for pest risk assessment and the identification and evaluation of pest risk management options in the EFSA framework

Specific scope

This scheme is based on the ISPM No 11 "*Pest Risk Analyses for Quarantine Pests including analysis of environmental risks and living modified organisms"*. It provides detailed instructions, for the following stages of pest risk analysis for organisms potentially eligible for addition to the list of harmful organisms in Council Directive 2000/29/EC: initiation, pest categorization, probability of introduction, assessment of potential harmful consequences to cultivated and managed plants, and the identification and evaluation of pest risk management options. It provides a simple scheme based on a sequence of questions for deciding whether an organism has harmful characteristics, and if appropriate to identify potential management options. The scheme can also be used for pest risk assessments initiated by the identification of a pathway or the review of a policy. Expert judgement may be used in answering the questions.

INTRODUCTION

The EPPO decision-support scheme for quarantine pests, as adapted to EFSA risk assessment and evaluation of risk management options, is intended to be used to assess the potential importance of a particular pest for the territory of the EU (presently subject to the Community plant health regime) as the risk assessment area, unless otherwise specified.

The scheme concentrates on the assessment of individual pests[1]; if a risk assessment is being performed on a particular pathway, the scheme can be used once the individual pests likely to be associated with the pathway have been identified.[2]

The scheme provides detailed instructions for the following stages of pest risk analysis: initiation, pest categorization, probability of introduction, potential harmful consequences to cultivated and managed plants and the environment, and the identification and evaluation of pest risk management options.

Pest risk assessment is divided into two major sections. The assessment in section A is in the form of a binary decision tree, constructed from a sequence of questions based largely on decision points with two alternative options. If the scheme leads to the conclusion that an organism may have the necessary characteristics of a pest for possible listing in Council Directive 2000/29/EC, the pest is then evaluated in greater detail, in section B. From this evaluation, it should be possible to arrive at a conclusion concerning the level of "pest risk" presented by the pest. At the request of the risk manager, an evaluation of pest risk management options may then be conducted. Before beginning the pest risk management stage or at certain points throughout the process, it may be advisable to consult other interested bodies. For example, discussions may be needed with government officials concerning international trade issues and with pest-control experts to determine which methods of control are available, their effectiveness and the extent to which eradication is possible.

[1] The term "pest" is defined as "any species, strain or biotype of plant, animal or pathogenic agent injurious to plant or plant products" within the IPPC Glossary. This definition is identical to the definition of "harmful organism" within Council Directive 2000/29/EC Article 2.1. (e) (EFSA Guidelines, 2009).

[2] In the case of a detection of a pest in an imported consignment, it may be necessary first to make a rapid evaluation (i.e. within the time that the consignment can be detained) and, for this purpose, EPPO Standard PM 5/2 Pest risk analysis to decide immediate action to be taken on detection of a pest in a consignment should be followed. Such a process will only allow a decision as to what action to take with regard to the consignment in question (e.g. destruction, treatment, return to origin, no action, etc.). It may be followed by a full PRA in order to decide on permanent measures.

Information requirements

Before beginning the pest risk assessment and/or the identification and evaluation of risk management options, information should be collected on the various characteristics of the pest that will be evaluated in the procedure. EPPO Standard PM 5/1(1): "*Check-list of information required for pest risk analysis*" provides an aide mémoire to indicate which information will be of relevance. For pathway initiated risk analysis a list of the pests likely to be associated with the pathway (e.g. carried with the commodity) may be generated by any combination of official sources, databases, scientific and other literature, or expert consultation. It is preferable to prioritize the listing, based on expert judgement on pest distribution and types of pests.

A preliminary evaluation may be done using any information already available to make a clear decision immediately one way or the other. In particular, if a high risk is immediately identified for one or more important pathways or important hosts, it may be superfluous to search for information for and reply to other questions, or to consider other pathways or hosts. Expert judgement will be used to decide this, and the preliminary assessment will thus provide guidance on the information which will be needed for the full assessment. On the other hand, it can quickly be obvious in section A that a particular pest does not have all the essential characteristics to be listed in Council Directive 2000/29/EC, so that there is no purpose in continuing with a full assessment.

In going through the scheme, the assessor will probably find that certain questions cannot be answered. This may be because the question is not relevant in the particular case (N/A), in which case the question can be ignored and the absence of a reply will not affect the value of the pest risk assessment. Alternatively, it may prove impossible to obtain the information, in which case its absence will to a certain degree reduce the value of the assessment depending on the importance of the question. A meaningful pest risk assessment or evaluation of risk management options cannot be performed without adequate information, and at the end of this scheme the assessor is asked to indicate whether the quantity and quality of the information was satisfactory.

In cases where particular information is lacking about a pest, useful information may sometimes be obtained by reference to closely related organisms. Where such indirect information is used, this should be recorded during the assessment and taken into account in the final evaluation.

Documentation

It is important for any possible future re-evaluation of the pest risk assessment or the risk management options that all steps of the procedure should be fully documented, indicating who performed the evaluation, how each decision was reached and on what information it was based. It is also important to indicate the date on which the information was collected in case subsequent data on the pest may influence the final decision. Any uncertainties regarding data or conclusion should be noted.

More details on documentation are provided in chapter 5.

Special situation of pest plants

The organism undergoing risk assessment or for which risk management options are identified and evaluated may be a pest plant. Pest plants may be primarily damaging to crops and managed vegetation, in which case they are generally referred to as "weeds". Weeds do not have "host plants", but the damage they do can be evaluated in similar terms to those used for pest animals or microorganisms. Apart from their effects on cultivated plants, weeds may also have effects on the environment. A few pest plants may be primarily damaging to natural or semi-natural vegetation. These are often referred to as "invasive". Their effects are on the environment (including indirect effects on man and animals). Although they can be evaluated in quantitative terms, they are generally described in qualitative terms. Other pest plants are directly parasitic on a host plant; these can be assessed in the risk assessment in the same way as plant pathogens.

Like pest animals and microorganisms, pest plants may be introduced accidentally, especially as seeds or other propagules contaminating various imported commodities. However, it is a particular feature of plants that they are very often intentionally imported, for agricultural or horticultural purposes. In that case, the pathway of entry ceases to be of interest for pest risk assessment or risk management options. Instead the analysis is concerned with the pathway from the "intended habitat" (where the plant does not necessarily establish, but may simply be sustained by human activity) to various possible "unintended habitats", where it may establish.

Pest animals and microorganisms are often known by the analyst to be pests before the start of the pest risk assessment. The same is true for many weeds and invasive plants. However, most plants are not pests, and the risk assessment should establish this quickly and simply. It should be noted that cases are known of plants which are not harmful in their native area, but become weedy or invasive when introduced into new areas. Newly bred or selected ornamentals may also have potential for harm.

For definitions of terms used in this scheme see FAO (2009) *Glossary of phytosanitary terms*. ISPM No 5 in International Standards for Phytosanitary Measures.

Stage 1: Initiation

The initiation of the pest risk assessment process is considered by EFSA to be ordinarily the responsibility of the risk manager. Although in some cases this process may be initiated by self-tasking according to Regulation (EC) No 178/2002.

The aim of the initiation stage is to identify the pest(s) and pathways which are of phytosanitary concern and should be considered for risk analysis in relation to the identified risk assessment area.

1. Give the reason for performing the pest risk assessment

The pest risk assessment may be initiated for one or several reasons, the most common being:

Pest risk assessment initiated by the identification of a pathway:

- international trade is initiated in a commodity not previously imported into the EU, or a commodity from a new area or new country of origin;
- new plant species are imported for breeding or research purposes or cultivation;
- a pathway other than a commodity import is identified (natural spread, packing material, mail, garbage, passenger baggage, etc).

Pest risk assessment initiated by the identification of a pest:

- an established infestation or an incursion of a pest has been discovered in the risk assessment area;
- a pest has been detected in an imported consignment;
- a pest has been identified as a risk by scientific research;

- a pest has invaded a new area, other than the risk assessment area;
- a pest is reported to be more damaging in a new area than its area of origin;
- a pest is observed to be detected more frequently in international trade;
- a request is made for the intentional import of a pest;
- a previous pest risk assessment is being re-evaluated;
- an organism has been identified as a vector for other pests.

In some cases, a pest risk assessment may be initiated as above by an organism which is not known to be a pest, but whose pest potential in the risk assessment area needs to be evaluated.

Pest risk assessment initiated by the review or revision of a policy:

- phytosanitary regulations are being revised, e.g. following a EU decision or new information on treatments or processes;
- a proposal made by another country or by an international organization (RPPO, FAO) is assessed;
- a dispute arises on phytosanitary measures.

Go to 2

2. Specify the pest or pests of concern and follow the scheme for each individual pest in turn. For intentionally introduced plants specify the intended habitats.

If no pest of concern has been identified the pest risk assessment may stop at this point.

Go to 3

3. Clearly define the risk assessment area.
   Note: The risk assessment area can be a complete country, several countries or part(s) of one or several countries. These areas do not need to be continuous. Risk assessment performed in the EFSA framework concern EU Member States. For risk assessments to be used for decision making at the Community level the risk assessment area should be the territory of the Community addressed in Council Directive 2000/29/EC.

Go to 4

Earlier analysis

The pest, or a very similar one, may have been subjected to the risk assessment process before, nationally or internationally. This may partly or entirely replace the need for a new pest risk assessment.

4. Does a relevant earlier pest risk assessment exist?
   if yes **Go to 5**
   if no **Go to 6**
5. Is the earlier pest risk assessment still entirely valid, or only partly valid (out of date, applied in different circumstances, for a similar but distinct pest, for another area with similar conditions)?
   if entirely valid **End**

if partly valid proceed with the pest risk assessment, but compare as much as possible with the earlier pest risk assessment **Go to 6**
if not valid **Go to 6**

6. Specify the host plant species (for pests directly affecting plants) or suitable habitats (for non parasitic plants) present in the risk assessment area.

   Note: the taxonomic level at which hosts are considered should normally be the species. The use of higher or lower taxonomic levels should be scientifically justified. The pest should be able to complete its life cycle or multiply on the hosts considered. Some other plant species might also prove to be suitable hosts in the absence of the usual host species. Additionally, it may be appropriate to distinguish between major and minor hosts when answering this question. If the pest risk assessment is conducted on a pest which is indirectly injurious to plants through effects on other organisms, these organisms should also be present in the risk assessment area. Habitats may be considered according to the CORINE land cover classification (see appendix I). It may be useful to consider associations with key-stone or dominant species of plants. For intentionally introduced plants, indicate the unintended habitats.

Go to 7

7. Specify the distribution of the pest

Go to Stage 2

Stage 2: Pest Risk Assessment

Section A: Pest categorization

At the outset, it may not be clear which pest(s) identified in Stage 1 require(s) a risk assessment. The categorization process examines for each pest whether the criteria for being listed in Council Directive 2000/29/EC are satisfied. In the evaluation of a pathway associated with a commodity, a number of individual risk assessments may be necessary for the various pests potentially associated with the pathway. The opportunity to eliminate an organism or organisms from consideration before in-depth examination is undertaken is a valuable characteristic of the categorization process.

An advantage of pest categorization is that it can be done with relatively little information; however information should be sufficient to adequately carry out the categorization.

There is no need to answer these questions in cases where it is clear from the outset that a full pest risk assessment is required.

Identify the pest (or potential pest)

The identity of the pest (or potential pest) should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological and other information used in the assessment is relevant to the organism in question. If this is not possible because the causal agent of particular symptoms has not yet been fully identified, then it should have been shown to produce consistent symptoms and to be transmissible.

In cases where a vector is involved, the vector may also be considered a pest to the extent that it is associated with the causal organism and is required for its transmission.

8. Is the organism clearly a single taxonomic entity and can it be adequately distinguished from other entities of the same rank?
   if yes indicate the correct scientific name and taxonomic position **Go to 10**
   if no **Go to 9**
   Note: The taxonomic unit for the pest is generally the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In the case of levels below the species, this should include evidence demonstrating that factors such as differences in virulence, host range or vector relationships are significant enough to affect phytosanitary status.

9. Even if the causal agent of particular symptoms has not yet been fully identified, has it been shown to produce consistent symptoms and to be transmissible?
   if yes **Go to 10**
   if no **Go to 19**

Determining whether the organism is a pest

10. Is the organism in its area of current distribution a known pest (or vector of a pest) of plants or plant products?
    if yes, the organism is considered to be a pest **Go to 12**
    if no **Go to 11**

11. Does the organism have intrinsic attributes that indicate that it could cause significant harm to plants?
    Note: Some organisms may not be known to be harmful in their area of current distribution, but may nevertheless have the potential to become pests in the risk assessment area. This possibility may have to be considered in certain circumstances.

    if yes, the organism may become a pest of plants in the risk assessment area **Go to 12**
    if no **Go to 19**

Presence or absence in the risk assessment area and regulatory status (pest status)

12. Does the pest occur[3] in the risk assessment area?
    if yes **Go to 13**
    if no **Go to 14**

13. Is the pest widely distributed in the risk assessment area?
    Note: a pest which is eligible for listing in Council Directive 2000/29/EC may be 'present but not widely distributed'. This means that the pest has not reached the limits of its potential area of distribution either in the field or in protected conditions; it is not limited to its present distribution by climatic conditions or host-plant distribution. There should be evidence that, without phytosanitary measures, the pest would be capable of additional spread. If the pest is present but not widely distributed in the risk assessment area, it may already be under official control, with the aim of eradication or containment. If it is not already under official control, the conclusion of this risk assessment is that it should be listed in Council Directive 2000/29/EC.

[3] Occurrence: the presence in an area of a pest officially recognised to be indigenous or introduced and/or not officially reported to have been eradicated [FAO, 1990; revised FAO, 1995; formerly occur]. This includes organisms which have been introduced intentionally and which are not subject to containment (notably cultivated plants). Organisms present for scientific purposes under adequate confinement (e.g. in botanic gardens) are not included.

if not widely distributed **Go to 14**
if widely distributed **Go to 19**

Potential for establishment and spread in the risk assessment area

For a pest to establish, it should find host plants or suitable habitat in the risk assessment area. Natural hosts should be of primary concern but, if such information is lacking, plants which are recorded as hosts only under experimental conditions or accidental/very occasional hosts may also be considered. The pest should also find environmental conditions suitable for its survival, multiplication and spread, either in natural or in protected conditions.

14. Does at least one host-plant species (for pests directly affecting plants) or one suitable habitat (for non parasitic plants) occur in the risk assessment area (outdoors, in protected cultivation or both)?
    Note: if the risk assessment is conducted on a pest which indirectly affects plants through effects on other organisms, these organisms should also be present in the risk assessment area. Some pests require more than one host plant species to complete their life cycle and this should be taken into account when answering this question.

    if yes **Go to 15**
    if no **Go to 19**

15. If a vector is the only means by which the pest can spread, is a vector present in the risk assessment area? (if a vector is not needed or is not the only means by which the pest can spread **go to 16**)
    if yes **Go to 16**
    if no **Go to 19**
    Note: if a vector is the only means by which the pest can spread and when it is absent from the risk assessment area, a separate pest risk assessment to determine the risk of introduction of the vector may be needed.

16. Does the known area of current distribution of the pest include ecoclimatic conditions comparable with those of the risk assessment area or sufficiently similar for the pest to survive and thrive or is there any indication that the pest adapt to the ecoclimatic conditions in the risk assessment area (consider also protected conditions)?
    if yes **Go to 17**
    if no **Go to 19**

Potential for consequences in risk assessment area

There should be clear indications that the pest is likely to have an undesirable impact in the risk assessment area. Climatic and cultural conditions in the risk assessment area should be considered to decide whether important consequences (including environmental) or loss to plants may occur in the risk assessment area. In some cases, the pest may only be potentially harmful, as suggested by its intrinsic attributes.

17. With specific reference to the plant(s) or habitats which occur(s) in the risk assessment area, and the damage or loss caused by the pest in its area of current distribution, could the pest by itself, or acting as a vector, cause significant damage or loss to plants or other negative impacts on the environment through the effect on plant health in the risk assessment area?
    If yes or uncertain **Go to 18**
    If no **Go to 19**

Conclusion of pest categorization

18. This pest could present a risk to the risk assessment area (Summarize the main elements leading to this conclusion)

Go to section B

19. The pest does not qualify as a harmful organism for possible listing in Council Directive 2000/29/EC for the risk assessment area and the assessment for this pest can stop (summarize the main reason for stopping the analysis).

For a pathway analysis, go to 4 and proceed with the next pest. If no further pests have been identified the risk assessment may stop at this point.

Section B: Assessment of the probability of introduction and spread and of potential consequences

This part of the risk assessment process firstly estimates the probability of the pest being introduced into the risk assessment area (its entry and establishment) and secondly makes an assessment of the likely impact if that should happen. From these assessments, it should be possible to estimate the level of risk associated with the pest, which can then be used when evaluating pest risk management options.

The evaluation is based on the replies to a series of questions, mostly expressed in the first instance as the choice of an appropriate phrase out of a set of five alternatives (e.g. very unlikely, unlikely, moderately likely, likely, very likely). It is important to identify especially high or especially low risks. The user of the scheme should add to all replies any details which appear relevant indicating the source of information used. In addition the level of uncertainty attached to each answer should be given.

Answer as many of the following questions as possible. If any question does not appear to be relevant for the pest concerned, it should be noted as "irrelevant". If any question appears difficult to answer no judgement should be given but the user should note whether this is because of lack of information or uncertainty.

Probability of introduction and spread

Introduction, as defined by the FAO Glossary of Phytosanitary Terms, is the entry of a pest resulting in its establishment.

Probability of entry of a pest

Identification of pathways

Pathway is defined in the Glossary as "any means that allows the entry or spread of a pest" [FAO, 1990; revised FAO, 1995].

Pathways can be identified principally in relation to the geographical distribution and host range of the pest. Consignments of plants and plant products moving in international trade are the principal pathways of concern and existing patterns of such trade will, to a

substantial extent, determine which pathways are relevant. Other pathways such as other types of commodities, packing materials, persons, baggage, mail, conveyances and the exchange of scientific material should be considered where appropriate. Entry by natural means should also be assessed, as natural spread is likely to reduce the effectiveness of phytosanitary measures.

Closed pathways may also be considered, as the pests identified may support existing phytosanitary measures. Furthermore, some pathways may be closed by phytosanitary measures which might be withdrawn at a future date. In such cases, the risk assessment may need to be continued. Data on detections in imported consignments may indicate the ability of a pest to be associated with a pathway. For a pest risk assessment initiated by the identification of a pathway, this is the main pathway to be considered.

If the pest risk assessment is being conducted on a pest that is intentionally imported, e.g. a plant for planting or a biological control agent, and this is the only pathway of entry, an assessment of its entry potential is not required. However, it is still important to record the volume, frequency and distribution of imports. If other pathways of entry also exist, these should be assessed following standard procedures. Spread from the intended habitat to the unintended habitat which is an important judgement for intentionally imported plants is covered by questions 1.33 to 1.35.

1.1. Consider all relevant pathways and list them.
Relevant pathways are those with which the pest has a possibility of being associated (in a suitable life stage), on which it has the possibility of survival, and from which it has the possibility of transfer to a suitable host. Make a note of any obvious pathways that are impossible and record the reasons.

Go to 1.2

1.2. Estimate the number of relevant pathways, of different commodities, from different origins, to different end uses.

very few, few, moderate number, many, very many

Level of uncertainty:	**Low**	**Medium**	**High**

Go to 1.3

1.3. Select from the relevant pathways, using expert judgement, those which appear most important. If these pathways involve different origins and end uses, it is sufficient to consider only the realistic worst-case pathways. The following group of questions on pathways is then considered for each relevant pathway in turn, as appropriate, starting with the most important.

Go to 1.4

Probability of the pest being associated with the individual pathway at origin.

1.4. How likely is the pest to be associated with the pathway at origin taking into account factors such as the occurrence of suitable life stages of the pest, the period of the year?

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

Go to 1.5

1.5. How likely is the concentration of the pest on the pathway at origin to be high, taking into

account factors like cultivation practices, treatment of consignments?
Note: these are practices mainly in the country of origin, such as plant protection product application (including herbicides for plants), removal of substandard produce, kiln-drying of wood, cultural methods, sorting and cleaning of commodities. Note that cultivation practices (including choice of crop cultivars) may change over time. Phytosanitary measures are not considered in this question (see 1.10).

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

Go to 1.6

1.6. How large is the volume of the movement along the pathway?
Note: This should be evaluated or estimated on the basis of quantities of the traded commodity, packing materials, persons, baggage, mail and conveyances, on a yearly basis. For natural spread, movement of the pest should be estimated as far as possible (usually little information is available).

minimal, minor, moderate, major, massive

Level of uncertainty:	**Low**	**Medium**	**High**

Go to 1.7

1.7. How frequent is the movement along the pathway?
Note: This should be evaluated or estimated on the basis of quantities of the traded commodity, packing materials, persons, baggage, mail and conveyances, on a yearly basis. For natural spread, movement of the pest should be estimated as far as possible (usually little information is available).

very rarely, rarely, occasionally, often, very often

Level of uncertainty:	**Low**	**Medium**	**High**

Go to 1.8

<u>Probability of survival during transport or storage</u>

1.8. How likely is the pest to survive during transport /storage?
Note: consideration should be given to:

- speed and conditions of transport;
- vulnerability of the life-stages likely to be transported (for plants: viability of seeds or other propagules);
- whether the life cycle is of sufficient duration to extend beyond time in transit;
- commercial procedures (e.g. refrigeration) applied to consignments in transport or at destination.

Data on detections in imported consignments may be used to indicate the ability of a pest to survive in transit.

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	Low	Medium	High

Go to 1.9

1.9. How likely is the pest to multiply/increase in prevalence during transport /storage?
Note: Some pests do not multiply/increase in prevalence during transport/storage, in this case it should be rated impossible.

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	Low	Medium	High

Go to 1.10

Probability of the pest surviving existing pest management procedures

1.10. How likely is the pest to survive or remain undetected during existing management procedures (including phytosanitary measures)?
Note: existing phytosanitary measures (e.g. inspection, testing or treatments) are most probably required as a protection against other pests listed in 2000/29/EC and applied in the exporting country or the importing country. **The assessor should bear in mind that such measures could be removed in the future if the other pests are re-evaluated.**
The likelihood of detecting the pest during inspection or testing will depend on a number of factors including:

- ease of detection of the life stages which are likely to be present. Some stages are more readily detected than others, for example insect adults may be more obvious than eggs or seeds and bulbs for plants;
- location of the pest on the commodity - surface feeders may be more readily detected than internal feeders;
- symptom expression - many diseases may be latent for long periods, at certain times of the year, or may be without symptoms in some hosts or cultivars and virulent in others;
- distinctiveness of symptoms - the symptoms might resemble those of other pests or sources of damage such as mechanical or cold injury;
- the intensity of the sampling and inspection regimes;
- distinguishing the pest from similar organisms;
- availability of specific identification methodologies (for certain microorganisms).

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	Low	Medium	High

Go to 1.11

Probability of transfer to a suitable host or habitat

1.11. In the case of a commodity pathway, how widely is the commodity to be distributed throughout the risk assessment area?

Note: the more scattered the destinations, the more likely it is that the pest might find suitable habitats.

very limited, limited, moderately widely, widely, very widely

Level of uncertainty:	**Low**	**Medium**	**High**

Go to 1.12

1.12. In the case of a commodity pathway, do consignments arrive at a suitable time of year for pest establishment?

Note: introduction at many different times of the year will increase the probability that entry of the pest will occur at a life stage of the pest or the host which is suitable for establishment or when habitat or environmental conditions are favourable.

if yes **Go to 1.13**
if no **Go to 1.15**

1.13. How likely is the pest to be able to transfer from the pathway to a suitable host or habitat?

Note: consider innate dispersal mechanisms or the need for vectors, and how close the pathway on arrival is to suitable hosts or habitats.

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

Go to 1.14

1.14. In the case of a commodity pathway, how likely is the intended use of the commodity (e.g. processing, consumption, planting, disposal of waste, by-products) to aid transfer to a suitable host or habitat?

Note: Some uses are associated with much higher probability of introduction (e.g. planting) than others (e.g. processing). Consider whether the intended use of the commodity would destroy the pest or whether the processing, planting or disposal might be done in the vicinity of suitable hosts or habitats.

N/A, very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

Go to 1.15

Consideration of further pathways

In principle, all the relevant pathways selected at point 1.3 may in turn be considered. However, the replies given for the pathway(s) so far considered may indicate that it is not necessary to consider any more.

1.15. Do other pathways need to be considered?

if yes **Go back to 1.3**
if no **Go to conclusion on the probability of entry and then to 1.16**

Conclusion on the probability of entry

The overall probability of entry should be described and risks presented by different pathways should be identified.

Probability of Establishment

For plants which are intentionally imported, the assessment of the probability of establishment concerns the unintended habitat.

Availability of suitable hosts or suitable habitats, alternate hosts and vectors in the risk assessment area

1.16. Estimate the number of host plant species or suitable habitats in the risk assessment area (see question 6).

very few, few, moderate number, many, very many

Level of uncertainty:	**Low**	**Medium**	**High**

1.17. How widespread are the host plants or suitable habitats in the risk assessment area? (specify)

very limited, limited, moderately widely, widely, very widely

Level of uncertainty:	**Low**	**Medium**	**High**

1.18. If an alternate host or another species is needed to complete the life cycle or for a critical stage of the life cycle such as transmission (e.g. vectors), growth (e.g. root symbionts), reproduction (e.g. pollinators) or spread (e.g. seed dispersers), how likely is the pest to come in contact with such species?

Note: Is the species present, widespread and abundant or could it be introduced or could another species be found ?

N/A, very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

Suitability of the environment

Specify the area where host plants (for pests directly affecting plants) or suitable habitats (for non parasitic plants) are present (cf. Questions 1.16-1.18). This is the area for which the environment is to be assessed in this section. If this area is much smaller than the risk assessment area, this fact will be used in defining the endangered area.

1.19. How similar are the climatic conditions that would affect pest establishment, in the risk assessment area and in the current area of distribution?

Note: the climatic conditions in the risk assessment area to be considered may include those in protected cultivation. When comparing climates in a pest's current distribution with those in the risk assessment area, it is important to ensure that, as far as possible, the variables selected are relevant to the pest's ability to exploit conditions when these are favourable for growth and reproduction and to survive unfavourable periods, such as those of extreme cold, heat, wetness or drought.

not similar, slightly similar, moderately similar, largely similar, completely similar

Level of uncertainty:	**Low**	**Medium**	**High**

1.20. How similar are other abiotic factors that would affect pest establishment, in the risk assessment area and in the current area of distribution?

Note: one of the major abiotic factor to be considered is soil type and other soil characteristics; others are, for example, environmental pollution, topography/orography. For organisms having an aquatic stage pH, salinity, current and temperature are important factors to consider.

not similar, slightly similar, moderately similar, largely similar, completely similar

Level of uncertainty:	**Low**	**Medium**	**High**

1.21. If protected cultivation is important in the risk assessment area, how often has the pest been recorded on crops in protected cultivation elsewhere?

N/A, never, very rarely, rarely, occasionally, often, very often

Level of uncertainty:	**Low**	**Medium**	**High**

1.22. How likely is it that establishment will occur despite competition from existing species in the risk assessment area?

Note: For pest plants, how likely is the pest plant to build up monospecific stands? Is the species a freshwater macrophyte? Is the species allelopathic? Is the species able to fix nitrogen?

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

1.23. How likely is it that establishment will occur despite natural enemies already present in the risk assessment area?

Note: natural enemies include antagonists. For pest plants, the assessor should consider if the species is unpalatable to grazing animals or toxic.

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

Cultural practices and control measures

1.24. To what extent is the managed environment in the risk assessment area favourable for establishment?

Note: factors that should be considered include cultivation practices such as the time of year that the crop is grown, soil preparation, method of planting, irrigation, whether grown under protected conditions, surrounding crops, time of harvest, method of harvest, soil water balance, fire regimes, disturbance, etc.

not at all favourable, slightly favourable, moderately favourable, highly favourable, very highly favourable

Level of uncertainty:	**Low**	**Medium**	**High**

1.25. How likely is it that existing pest management practice will fail to prevent establishment of the pest?

Note: for pest plants is the species poorly controlled by herbicides? Is the species tolerant of mutilation, cultivation or fire?

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

1.26. Based on its biological characteristics, how likely is it that the pest could survive eradication programmes in the risk assessment area?

Note: Some pests can be eradicated at any time (survival is very unlikely), others at an early stage (moderately likely) and others never (very likely). Similarly, incursions of some pests may be difficult to find and/or delimit (very likely). Note that intentionally imported plants may need to be eradicated from the intended habitat as well as from the unintended habitat. Some plants should be eradicated before fructification.

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

Other characteristics of the pest affecting the probability of establishment

1.27. How likely is the reproductive strategy of the pest and the duration of its life cycle to aid establishment?

Note: consider characteristics which would enable the pest to reproduce effectively in a new environment, such as parthenogenesis/self-crossing, short life cycle, number of generations per year, resting stage, high intrinsic rate of increase, self fertility, vegetative propagation, production of viable seeds, prolific seed production, formation of a persistent seed bank or offspring bank. For a pest transmitted by a vector the reproductive strategy of the vector should also be taken into account.

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

1.28. How likely are relatively small populations to become established?

Note: if very small populations are known to survive for long periods in their area of current distribution, such evidence may be used to answer this question. For plants, is the species able to hybridise freely? Is the species polymorphic, with, for example, subspecies? Is the species self-compatible? Does the species reproduce by vegetative fragmentation?

no judgment, very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	Low	Medium	High

1.29. How adaptable is the pest?

Note: is the species polymorphic, with, for example, subspecies or pathotypes? Is it known to have a high mutation rate? Does it occur in a wide range of climate and habitats? Such evidence of variability may indicate that the pest has an ability to withstand environmental fluctuations, to adapt to a wider range of habitats or hosts, to develop resistance to plant protection products and to overcome host resistance.

Adaptability is:
very low, low, moderate, high, very high

Level of uncertainty:	Low	Medium	High

1.30. How often has the pest been introduced into new areas outside its original area of distribution? (specify the instances, if possible)

Note: if this has happened even once before, it is important proof that the pest has the ability to pass through most of the steps in this section (i.e. association with the pathway at origin, survival in transit, transfer to the host or habitat at arrival and successful establishment). If it has occurred often, it suggests an aptitude for transfer and establishment.

never, rarely, occasionally, often, very often

Level of uncertainty:	Low	Medium	High

1.31. If establishment of the pest is very unlikely, how likely are transient populations to occur in the risk assessment area through natural migration or entry through man's activities (including intentional release into the environment)?

Note: Non applicable applies when establishment has already been observed in the risk assessment area. Transience is defined as the presence of a pest that is not expected to lead to establishment [ISPM No 8, 1998]

N/A, very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	Low	Medium	High

Conclusion on the probability of establishment

The overall probability of establishment should be described.

Probability of spread

Spread potential is an important element in determining how quickly impact is expressed and how readily a pest can be contained. In the case of intentionally imported plants, the assessment of spread concerns spread from the intended habitat or the intended use to an unintended habitat, where the pest may establish. Further spread may then occur to other unintended habitats. The nature and extent of the intended habitat and the nature and amount of the intended use in that habitat will also influence

the probability of spread. Some pests may not have injurious effects on plants immediately after they establish, and in particular may only spread after a certain time. In assessing the probability of spread, this should be considered, based on evidence of such behaviour.

1.32. How likely is the pest to spread rapidly in the risk assessment area by natural means?
Note: consider the suitability of the natural and/or managed environment, potential vectors of the in the risk assessment area, and the presence of natural barriers. Spread depends on the capacity of a pest to be dispersed (e.g. wind dispersal) as well as on the quantity of pest that can be dispersed (e.g. volume of seeds).

Natural spread can result from movement of the pest by flight (of an insect), wind or water dispersal, transport by vectors such as insects, birds or other animals (internally through the gut or externally on the fur), natural migration, rhizomial growth.

Spread is defined as the expansion of the geographical distribution of a pest within an area [FAO, 2007]

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

1.33. How likely is the pest to spread rapidly in the risk assessment area by human assistance?
Note: consider the potential for movement with commodities or conveyances, the fact that the species is intentionally dispersed by people, the ability of the pest to be unintentionally dispersed along major transport routes. As for 1.32, consider the capacity to be spread as well as the quantity that can be spread. For intentionally introduced plants consider spread to the unintended habitat.

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

1.34. Based on biological characteristics, how likely is it that the pest will not be contained within the risk assessment area?
Note: consider the biological characteristics of the pest that might allow it to be contained in part of the risk assessment area. For intentionally introduced plants consider spread to the unintended habitat.

very unlikely, unlikely moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

Go to conclusion on the probability of spread

Conclusion on the probability of spread

The overall probability of spread should be described.

Go to Conclusion on the probability of introduction and spread

Conclusion on the probability of introduction and spread

The overall probability of introduction and spread should be described. The probability of introduction and spread may be expressed by comparison with pest risk assessments on other pests.

Go to 1.35

Conclusion regarding endangered areas

1.35. Based on the answers to questions 1.16 to 1.34 identify the part of the risk assessment area where presence of host plants or suitable habitats and ecological factors favour the establishment and spread of the pest to define the endangered area.

Note: The risk assessment area may be the whole EU territory or part of it. The endangered area may be the whole of the pest risk assessment area, or part or parts of the area (i.e. the whole EU territory region or whole or part of several countries of the EU territory). It can be defined ecoclimatically, geographically, by crop or by production system (e.g. protected cultivation such as glasshouses) or by types of ecosystems.

Go to 2 Assessment of potential consequences

ASSESSMENT OF POTENTIAL CONSEQUENCES

The main purpose of this section is to determine whether the introduction of the pest will have harmful consequences. It may be possible to do this very simply, if sufficient evidence is already available or the risk presented by the pest is widely agreed. Start by answering Questions 2.1 - 2.9. If the responses to question 2.2 is "major" or "massive" and the answer to 2.3 is "with much difficulty" or "impossible" or the response to question 2.5 is "major" or "massive" ", the evaluation of the other questions in this section may not be necessary and you can go to 2.9 unless a detailed study is required or the answers given to these questions have a high level of uncertainty. In cases where the organism has already entered and is established in part of the risk assessment area, responses to questions 2.1and 2.4, which refer to impacts in its area of current distribution, should be based on an assessment of current impacts in the risk assessment area in addition to impacts elsewhere.

Expert judgement is used to provide an evaluation of the likely scale of impact. If precise impact evaluations are available for certain pest/crop plant combinations, it will be useful to provide details.

The replies should take account of both short-term and long-term effects.

In any case, providing replies for all hosts (or all habitats) and all situations may be laborious, and it is desirable to focus the assessment as much as possible. The study of a single worst-case may be sufficient. Alternatively, it may be appropriate to consider all hosts/habitats together in answering the questions once. If a selection is made, it should be justified. Only in certain circumstances will it be necessary to answer the questions separately for specific hosts/habitats.

Consider potential hosts/habitats identified in question 6 when answering the following questions:

Pest effects

2.1. How great a negative effect does the pest have on crop yield and/or quality to cultivated plants or on control costs within its current area of distribution?

Note: factors to consider are types, amount and frequency of damage and crop losses in yield and quality.

minimal, minor, moderate, major, massive

2.2. How great a negative effect is the pest likely to have on crop yield and/or quality in the risk assessment area without any control measures?

Note: the ecological conditions in the risk assessment area may be adequate for pest survival but may not be suitable for pest populations to build up to levels at which significant damage is caused to the host plant(s). Rates of pest growth, reproduction, longevity and mortality may all need to be taken into account to determine whether these levels are exceeded. Consider also effects on non-commercial crops, e.g. private gardens, amenity plantings.

minimal, minor, moderate, major, massive

Level of uncertainty:	**Low**	**Medium**	**High**

2.3. How easily can the pest be controlled in the risk assessment area without phytosanitary measures?

Note: Consider the existing control measures and their efficacy against the pest. Difficulty of control can result from such factors as lack of effective plant protection products against this pest, resistance to plant protection products, difficulty to change cultural practices, occurrence of the pest in natural habitats, private gardens or amenity land, simultaneous presence of more than one stage in the life cycle, absence of resistant cultivars.

very easily, easily, with some difficulty, with much difficulty, impossible

Level of uncertainty:	**Low**	**Medium**	**High**

2.4. How important are environmental consequences caused by the pest within its current area of distribution?

Note: Pests which principally have effects on crop yield or quality may also have environmental side-effects. If the main effects are already large, detailed consideration of such side-effects may not be necessary.

On the other hand, other pests principally have environmental effects and the replies to this and the following question are then the most important of this part of the analysis.

In accordance with current ecological concepts, two orders of considerations should be analysed:

(1) Impacts on ecosystem services, considering the four main classes of ecosystem services one by one;

- are there any possible impacts on organisms providing **Provisioning services**? (genetic resources, food, fiber, water and soil),
- are there any possible impacts on organisms providing **Regulating services**? (biological control by natural enemies and antagonists,

mitigation of local weather extremes, shoreline stability, river channel stability),

- are there any possible impacts on organisms providing **Sustaining services**? (pollination, soil fertility maintenance, decomposition),
- are there any possible impacts on organisms providing **Cultural services**?(these are psychological benefits from contact with nature).

Consider indirect impacts on species connected to the above function/s, also via direct, indirect, and apparent competition, changes in mutualism, mesopredator release (when a predator of a smaller predator becomes rare, the smaller predator's impact may be higher on its prey), impact on natural enemies or antagonists of the above organisms that may result in considerable negative effect for the above species providing the ecosystem function, or, if an important species cannot be identified, assess the impact on the function itself.

(2) Impacts on biodiversity itself, especially on rare species, culturally important species, their genetic diversity, population viability, fragmentation. Consider the different levels of biodiversity: within-individual diversity (genetic diversity), species-level diversity, guild (functional group), landscape and ecosystem diversity.

minimal, minor, moderate, major, massive

Level of uncertainty:	**Low**	**Medium**	**High**

2.5. How important are the environmental consequences likely to be in the risk assessment area (see note for question 2.4)?

minimal, minor, moderate, major, massive

Level of uncertainty:	**Low**	**Medium**	**High**

As noted in the introduction to section 2, the evaluation of the following questions may not be necessary if the response to question 2.2 is "major" or "massive" and the answer to 2.3 is "with much difficulty" or "impossible" or the response to question 2.5 is "major" or "massive". You may go directly to point 2.9 unless a detailed study of impacts is required or the answers given to these questions have a high level of uncertainty.

2.6. How likely is it that natural enemies, already present in the risk assessment area, will not reduce populations of the pest below the damage threshold?

Note: For pest plants, natural enemies include herbivores and pathogens.

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

2.7. How likely are control measures to disrupt existing biological or integrated systems for control of other pests or to have negative effects on the environment e.g. biodiversity (at various levels), reduce population sizes, or increase their fragmentation?

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

2.8. How likely is the pest to cause a significant increase in the impact of other pests by acting as a vector or host for these pests?

very unlikely, unlikely, moderately likely, likely, very likely

Level of uncertainty:	**Low**	**Medium**	**High**

19.1.1. Conclusion of the assessment of consequences

2.9. Referring back to the conclusion on endangered area (1.35), identify the parts of the risk assessment area where the pest can establish and which are most at risk.

Go to degree of uncertainty

Degree of uncertainty

Estimation of the probability of introduction of a pest and of its consequences involves many uncertainties. In particular, this estimation is an extrapolation from the situation where the pest occurs to the hypothetical situation in the risk assessment area. It is important to document the areas of uncertainty (including identifying and prioritizing of additional data to be collected and research to be conducted) and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs. It should be noted that the assessment of the probability and consequences of environmental hazards of pests of uncultivated plants often involves greater uncertainty than for pests of cultivated plants. This is due to the lack of information, additional complexity associated with ecosystems, and variability associated with pests, hosts or habitats.

For Pest-Initiated Risk Assessments:	**Go to conclusion of the risk assessment**
For Pathway-Initiated Risk Assessments:	**Go to back to 1.4 to evaluate the next pest, if all pests have been evaluated go to conclusion of the risk assessment**

Conclusion of the pest risk assessment

Entry

Evaluate the probability of entry and indicate the elements which make entry most likely or those that make it least likely. Identify the pathways in order of risk and compare their importance in practice.

Establishment

Evaluate the probability of establishment, and indicate the elements which make establishment most likely or those that make it least likely. Specify which part of the risk assessment area presents the greatest risk of establishment.

Impact

List the most important potential impacts, and estimate how likely they are to arise in the risk assessment area. Specify which part of the risk assessment area is most at risk.

Overall conclusion of the pest risk assessment

The risk assessor should give an overall conclusion on the pest risk assessment, an estimation of the level of risk posed by the pest or pathway under assessment, and upon request from the risk manager identify management options and evaluate their effect on the level of risk and on their technical feasibility.

Stage 3: Identification of management options and evaluation of their effect on the level of risk and of their technical feasibility

The EFSA-adapted EPPO scheme takes into consideration that:

- the decision on acceptability of the risk,
- the selection of risk management options and
- the evaluation of risk management options in terms of their cost-effectiveness and economic feasibility, minimal impact and non-discrimination

fall outside of the remit of the Panel on Plant Health.

While in the original EPPO scheme the third stage in pest risk analysis is called the pest risk management stage, in the EFSA-adapted EPPO scheme this stage, taking into consideration the above limitations, concentrates solely on the identification of management options and evaluation of their effect on the level of risk and of their technical feasability.

The scheme provides a structured analysis of the measures that can be recommended to minimize the risks posed by a pest or pathway. This stage may be used to consider measures to prevent entry, establishment or spread of a pest and the magnitude of impacts. It explores options that can be implemented (i) at origin or in the exporting country, (ii) at the point of entry or (iii) within the importing country or invaded area.

In the scheme, the methods whereby risk management options are selected differ according to whether the introduction is intentional or unintentional, whether the organism is absent or already present in the risk assessment area and the type of entry pathway. The options are structured so that, as far as possible, the options considered to be most effective in reducing the level of risk are considered first. Options to prevent unintentional entry on commodities are distinguished from options to prevent natural spread/movement or entry with other pathways such as passenger luggage. It should be noted that measures recommended for intentional introductions are often restricted to prohibiting imports and to actions that can be taken in the importing country.

The scheme requires a judgement on the reliability of each potential measure identified. A reliable measure is understood to mean one that it is effective, and reproducible. Limitations of application in practice should be noted. Once the potential measures have been identified, the extent to which they are effective and can be combined with other measures is evaluated. A pest may enter by many different pathways and a pathway may transport many pests. It is therefore important to repeat the process for all relevant pests and pathways of concern.

In considering your responses to the following questions, please note that helpful information may be obtained from the pest risk assessment stage, particularly from the section concerning the entry of a pest (1.1-1.15). References to the relevant sections of the risk assessment stage have been added.

Risk associated with major pathways

Acceptability of the risk

A decision has to be made by risk managers to determine whether the risk from any pest/pathway combination is an acceptable risk. This decision will be based on the relationship between the level of risk identified in the pest risk assessment stage (i.e. the combination of the probability of introduction and the potential impact) and the importance/desirability of the trade that carries the risk of introduction of the pest.

The scheme will proceed following the instructions below when the risk managers conclude that the risk identified in the pest risk assessment stage for all pest/pathway combinations is unacceptable, or when the risk manager/the Commission is clearly requesting the evaluation of management options.

Types of pathways

In most cases, the pathways to be studied will be particular commodities of plants and plant products, of stated species, moving in international trade and coming from countries where the pest is known to occur, and the questions are intended primarily for these situations. However, the pathways identified in the pest risk assessment may also include other types of pathways, e.g. natural pathway (pest spread), transport by human travellers, conveyances, packing material and traded commodities other than plants and plant products, and these also need to be assessed for suitable measures. Therefore, this section explains how to analyse the other types of pathways. For plants, it is particularly important to prioritize the pathways and to identify their relative importance, as some important pathways may not currently be regulated (grain, wool, hides, sand, gravel...).

Instructions for working through the stage of identification and evaluation of management options

Pest-initiated analysis

In the case of an analysis concerning an unintentional introduction of a pest, go to question 3.1 and proceed through steps 3.1-3.9, which relate to different pathways on which the pest being analysed may be carried. Thereafter continue with the questions concerned with the measures that might be applied to each pathway. Repeat the process for every major pathway.

For the intentional import of pest plants, the focus should be on measures preventing the establishment and spread of the organism in unintended habitats within the risk assessment area. The main pathway for these plants is usually the trade with ornamental plants intended for planting. For such cases go directly to question 3.27 (measures that can be taken in the importing country). This still allows the option of prohibiting import (3.35) to be considered by risk managers. However, if the organism is also entering the area unintentionally, then measures to prevent introduction through unintentional pathways may be examined and steps 3.1-3.26 should also be followed. Options for managing the

unintentional introduction of pest plants are covered by following the procedures for pathway-initiated analysis.

Pathway-initiated analysis for a commodity of plants and plant products

In the case of a pathway-initiated analysis for a commodity of plants and plant products, since the precise pathway is already known, begin with question 3.9 to consider possible measures for this pathway and repeat the process as far as question 3.39 for each of the pests identified in the pest risk assessment as presenting a risk to the risk assessment area. When all the pests have been considered, go to 3.41 to integrate the measures for the commodity. (Note that the probabilities for entry of a particular harmful organism with other pathways, including existing pathways, may also need to be investigated).

In considering responses to the following questions, please note that helpful information may be obtained from the pest risk assessment stage, particularly from the section concerning entry (1.1-1.15). References to the relevant sections of the risk assessment stage have been added.

3.1. Is the pathway that is being considered a commodity of plants and plant products?
If yes **Go to 3.10**
If no **Go to 3.2**

3.2. Is the pathway that is being considered the natural spread of the pest? (see answer to question 1.32)
Note: Natural spread includes movement of the pest by flight (of an insect), wind or water dispersal, and transport by vectors such as insects or birds, natural migration, rhizomial growth.
If yes **Go to 3.3**
If no **Go to 3.8**

3.3. Is the pest already entering the risk assessment area by natural spread or likely to enter in the immediate future? (see answer to question 1.32)
If yes **Go to 3.4**
If no **Go to 3.37**

3.4. Is natural spread the major pathway?
If yes **Go to 3.28**
If no **Go to 3.5**

3.5. Could entry by natural spread be reduced or eliminated by control measures applied in the area of origin?
If yes **Possible measures: control measures in the area of origin**
Go to 3.6

3.6. Could the pest be effectively contained or eradicated after entry? (see answer to question 1.26, 1.34)
If yes **Possible measures: internal containment and/or eradication campaign**
Go to 3.7

3.7. Was the answer “yes” to either question 3.5 or question 3.6?
If yes **Go to 3.28**

If no **Go to 3.37**

3.8. Is the pathway that is being considered the entry with human travellers?

If yes **Possible measures: inspection of human travellers, their luggage, publicity to enhance public awareness on pest risks, fines or incentives. Treatments may also be possible**
Go to 3.28

If no **Go to 3.9**

3.9. Is the pathway being considered contaminated machinery or means of transport?

If yes **Possible measures: cleaning or disinfection of machinery/vehicles**
Go to 3.28

For other types of pathways (e.g. commodities other than plants or plant products, exchange of scientific material, packing material, grain, wool, hides, sand, gravel ...), not all of the following questions may be relevant; adapt the questions to the type of pathway.

Go to 3.11

Existing phytosanitary measures

Phytosanitary measures (e.g. inspection, testing or treatments) may already be required as a protection against other pests listed in Council Directive 2000/29/EC (see stage 2: question 1.10). The assessor should list these measures and identify their effect on the level of risk. The assessor should nevertheless bear in mind that such measures could be removed in the future if the other pests are re-evaluated.

3.10. If the pest is a plant, is it the commodity itself?

If yes **Go to 3.28**

If no (the pest is not a plant or the pest is a plant but is not the commodity itself) **Go to 3.12**

3.11. Are there any existing phytosanitary measures applied on the pathway that could prevent the introduction of the pest?

If appropriate, list the measures and identify their efficacy against the pest of concern.
Go to 3.12

Identification of appropriate risk management options

This section (questions 3.12 to 3.30) examines the characteristics of the pest to determine if it can be reliably detected in consignments by inspection or testing, if it can be removed from consignments by treatment or other methods, if limitation of use of the commodity would prevent introduction, or if the pest can be prevented from infecting/infesting consignments by treatment, production methods, inspection or isolation. “Reliably” should be understood to mean that a measure is effective and reproducible. Measures can be reliable without being sufficient to reduce the risk to a level that risk managers consider as acceptable. In such cases their combination with other measures to reach the desired level of protection against the pest should be considered (see question 3.31). When a measure is considered reliable but not sufficient, the assessor should indicate this. The effective, practical and

reproducible nature of the measures should be evaluated by the assessor for each potential management option identified. Limitations of application of measures in practice should be noted. **Effectiveness and impact on trade are considered in the section "evaluation of risk management options" (questions 3.33 to 3.35).**

Options for consignments

Detection of the pest in consignments by inspection or testing

3.12. Can the pest be reliably detected by a visual inspection of a consignment at the time of export, during transport/storage or at import?

If yes — **Possible measure: visual inspection. Go to 3.13**

3.13. Can the pest be reliably detected by testing (e.g. for pest plant, seeds in a consignment)?

If yes — **Possible measure: specified testing. Go to 3.14**

3.14. Can the pest be reliably detected during post-entry quarantine?

Note: ISPM No 5 "*Glossary of Phytosanitary Terms*" defines quarantine as "*official confinement for observation and research or for further inspection, testing and/or treatment of a consignment after entry*".

If yes — **Possible measure: import under special licence/permit and post-entry quarantine. Go to 3.15**

Removal of the pest from the consignment by treatment or other phytosanitary procedures

3.15. Can the pest be effectively destroyed in the consignment by treatment (chemical, thermal, irradiation, physical)?

If yes — **Possible measure: specified treatment. Go to 3.16**

3.16. Does the pest occur only on certain parts of the plant or plant products (e.g. bark, flowers), which can be removed without modifying the intrinsic nature of the consignment? (This question is not relevant for pest plants)

If yes — **Possible measure: removal of parts of plants from the consignment. Go to 3.17**

3.17. Can infestation of the consignment be reliably prevented by handling and packing methods?

If yes — **Possible measure: specific handling/packing methods. Go to 3.18**

Prevention of establishment by limiting the use of the consignment

3.18. Could consignments that may be infested be accepted without risk for certain end uses, limited distribution in the risk assessment area, or limited periods of entry, and can such limitations be applied in practice?

If yes — **Possible measure: import under special**

licence/permit and specified restrictions.
Go to 3.19

Options for the prevention or reduction of infestation in the crop

Prevention of infestation of the commodity

3.19. Can infestation of the commodity be reliably prevented by treatment of the crop?
If yes **Possible measure: specified treatment and/or period of treatment.**
Go to 3.20

3.20. Can infestation of the commodity be reliably prevented by growing resistant cultivars? (This question is not relevant for pest plants)
If yes **Possible measure: consignment should be composed of specified cultivars.**
Go to 3.21

3.21. Can infestation of the commodity be reliably prevented by growing the crop in specified conditions (e.g. protected conditions such as screened greenhouses, physical isolation, sterilized growing medium, exclusion of running water, etc.)?
If yes **Possible measure: specified growing conditions.**
Go to 3.22

3.22. Can infestation of the commodity be reliably prevented by harvesting only at certain times of the year, at specific crop ages or growth stages?
If yes **Possible measure: specified age of plant, growth stage or time of year of harvest.**
Go to 3.23

3.23. Can infestation of the commodity be reliably prevented by production in a certification scheme (i.e. official scheme for the production of healthy plants for planting)?
If yes **Possible measure: certification scheme.**
Go to 3.24

Establishment and maintenance of pest freedom of a crop, place of production or area

Note that in this set of questions the spread capacity is considered without prejudice to any other measure that can be recommended. For some pests, growing the plant in specific conditions can prevent natural spread (e.g. production in a glasshouse may provide protection against pest with high capacity for natural spread). These measures should have been identified in question 3.22. In answering questions 3.24 to 3.28 refer to the answer to question 1.32 of the risk assessment section.

3.24. Has the pest a very low capacity for natural spread?
If yes **Possible measure: pest freedom of the crop, or pest-free place of production or pest-free area.**
Go to 3.27

If no **Go to 3.25**

3.25. Has the pest a low to medium capacity for natural spread?

If yes **Possible measure: pest-free place of production or pest-free area.**
Go to 3.27

If no **Go to 3.26**

3.26. The pest has a medium to high capacity for natural spread.

Possible measures: pest-free area.
Go to 3.27

3.27. Can the freedom of the crop, place of production or an area from the pest be reliably guaranteed?

Note: In order to guarantee freedom of a crop, place of production, place of production and buffer zone, or area, it should be possible to fulfil the requirements outlined in ISPM No 4 (1995) and ISPM No 10 (1999). Consider in particular the degree to which unintentional movement of the pest by human assistance could be prevented (see answer to question 1.33).

If no **Possible measure identified in question 3.24-3.26 would not be suitable.**
Go to 3.28

Consideration of other possible measures

3.28. Are there effective measures that could be taken in the importing country (surveillance, eradication) to prevent establishment and/or economic or other impacts?

Note: For intentionally imported plants, see the EPPO Standard PM/3 67 on Guidelines for the management of invasive alien plants or potentially invasive alien plants which are intended for import or have been intentionally imported. When natural spread is the major pathway, international measures are not justified and risk should be accepted because it is not manageable.

If yes **Possible measures: internal surveillance and/or eradication campaign.**
Go to 3.29

Evaluation of risk management options

This section evaluates the risk management options selected and considers in particular their biological effectiveness.

3.29. Have any measures been identified during the present analysis that will reduce the risk of introduction of the pest? List them.

If yes **Go to 3.30**
If no **Go to 3.37**

3.30. Does each of the individual measures identified reduce the risk to the level required by the risk manager?

If yes **Go to 3.33**
If no **Go to 3.31**

3.31. For those measures that do not reduce the risk to the level required by the risk manager, can two or more measures be combined to reduce the risk to the level required by the risk manager?

Note: The integration of different phytosanitary measures at least two of which act independently and which cumulatively achieve the Appropriate Level of Protection against regulated pests are known as Systems Approaches (see ISPM No 14 (2002) The use of integrated measures in a systems approach for Pest Risk Management). It should be noted that Pest free places of production identified as phytosanitary measures in questions 3.24 to 3.26 may correspond to a System Approach.

If yes **Go to 3.33**
If no **Go to 3.32**

3.32. If the only measures available reduce the risk but not down to an acceptable level as indicated by risk manager, such measures may still be indicated, as they may at least delay the introduction or spread of the pest. In this case, a combination of phytosanitary measures at or before export and internal measures (see question 3.28) should be considered.

Go to 3.33

3.33. Estimate the effect of the measures (or combination of measures) being considered on international trade.

Note: If this analysis concerns a pest already established in the risk assessment area but under official control, measures that are applied for international trade should not be more stringent than those applied domestically/internally.

Go to 3.34

3.34. Estimate to what extent the measures (or combination of measures) being considered have undesirable environmental consequences.

Go to 3.35

3.35. Have measures (or combination of measures) been identified that reduce the risk for this pathway, are effective and have no undesirable environmental consequences?

If yes **For pathway-initiated analysis, go to 3.38**
For pest-initiated analysis, go to 3.37
If no **Go to 3.36**

3.36. Indicate the option of prohibiting the pathway.

Note: Prohibition should be viewed as a measure of last resort. If prohibition of the pathway is the only measure identified for a commodity-initiated analysis, there may be no need to analyse any other pests that may be carried on the pathway. If later information shows that prohibition is not the only measure for this pest, analysis of the other pests associated with the pathway will become necessary.

For pathway-initiated analysis, go to 3.42 (or 3.38)
For pest-initiated analysis, go to 3.37

3.37. Have all major pathways been analysed (for a pest-initiated analysis)?

If yes **Go to 3.40**
If no **Go to 3.1 to analyse the next major pathway**

3.38. Have all the pests been analysed (for a pathway-initiated analysis)?

If yes **Go to 3.39**

If no **Go to 3.1 to analyse next pest**

3.39. For a pathway-initiated analysis, compare the measures appropriate for all the pests identified for the pathway that would qualify eligible for listing in Council Directive 2000/29/EC, and select only those that provide phytosanitary security against all the pests.

Note: the minimum effective measures against one particular pest may reduce the risk from other far more than estimated necessary by the risk managers, but these measures would be the only ones appropriate for the pathway as a whole.

Go to 3.40

3.40. Consider the relative importance of the pathways identified in the conclusion to the entry section of the risk assessment

Note: the relative importance of the pathways is an important element to consider in formulating phytosanitary regulation. Indications about regulation of pathways presenting similar risks should be consistent.

Go to 3.41

3.41. All the measures or combination of measures identified as being appropriate for each pathway or for the commodity can be considered in indications for inclusion in phytosanitary regulations in order to offer a choice of different measures to trading partners.

Note: When indicating management options upon request by risk managers it must be considered that only the most practical measure (or measures) capable of performing the task should be identified. Thus, if inspection is truly reliable, it should not be necessary to consider treatment or testing. Note also that some measures may counteract each other; for example the requirement for resistant cultivars may make detection more difficult. It may be that some or all of these measures are already being applied to protect against one or more other pests, in which case such measures need only be applied if the other pest(s) is/are later withdrawn from the legislation. The minimum phytosanitary measure applied to any pest is the listing in Council Directive 2000/29/EC.

Go to 3.42

3.42. In addition to the measure(s) selected to be applied by the exporting country, a phytosanitary certificate (PC) may be required for certain commodities. The PC is an attestation by the exporting country that the requirements of the importing country have been fulfilled. In certain circumstances, an additional declaration on the PC may be needed (see EPPO Standard PM 1/1(2): Use of phytosanitary certificates).

Go to 3.43

3.43. If there are no measures that reduce the risk for a pathway, or if the only effective measures are considered by risk managers to have undesirable environmental consequences, the conclusion of the pest risk management stage may be that introduction cannot be prevented. In the case of pest with a high natural spread capacity, regional communication and collaboration is important.

Conclusion of the identification and evaluation of management options

Summarize the conclusions of the identification and evaluation of risk management options. List all potential management options and indicate their effectiveness. Uncertainties should be identified.

Monitoring and review

Performance of measure(s) should be monitored to ensure that the aim is being achieved. This is often carried out by inspection of the commodity on arrival, noting any detection in consignments or any entries of the pest to the risk assessment area.

Information supporting the pest risk analyses should be reviewed periodically by the pest risk analysts to ensure that any new information that becomes available does not invalidate the decision taken. The analysts should in particular be aware that new international trade may be initiated, host plants may newly be grown in the risk assessment area which were not grown at the time the pest risk assessment was conducted, climate may change, new policy decisions may influence the result of a previous analysis.

Appendix I

Categories of habitat (adapted from Corine Land Cover nomenclature)

Arable land

Protected agriculture (e.g. glasshouses)

Permanents crops (e.g. vineyards, fruit tree and berry plantations, olive)

Pastures

Natural grassland

Mixed forests

Conifer forests

Broad-leaved forests

Deserts (sparsely vegetated areas)

Cold lands (e.g. tundra, ice, high altitudes)

Moors and heathland

Sclerophyllous vegetation (e.g. garrigue, maquis)

Inland wetlands (marshes, peat bogs)

Coastal wetlands

Marine waters (coastal lagoons, estuaries)

Continental waters (water courses, water bodies)

Banks of continental water, Riverbanks / canalsides (dry river beds)

Road and rail networks and associated land

Other artificial surfaces (wastelands)

Green urban areas, including parks, gardens, sport and leisure facilities

Scrub

GLOSSARY / ABBREVIATIONS

(of terms not defined by the IPPC (2009) or redefined by EFSA)

EPPO	European and Mediterranean Plant Protection Organization
EPPO scheme	Guidelines on pest risk analysis – Decision-support scheme for quarantine pests developed by the European and Mediterranean Plant Protection Organization [EPPO, 2007].
evaluation of risk management options	The process of identifying risk management options and/or evaluating the potential changes in risk resulting from different management options [Plant Health Panel approach].
FAO	Food and Agriculture Organization of the United Nations
harmful organism	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [2000/29/EC].
IPPC	International Plant Protection Convention
ISPM	International standards for phytosanitary measures [FAO, 2007]
pest	See harmful organism. In the context of plant health, "pest" and "harmful organism" are considered equivalent terms [Plant Health Panel approach].
pest risk	A function of the probability of entry, establishment and spread and the magnitude of the associated potential consequences [PLH Panel approach].
pest risk assessment	The evaluation of the probability of entry, establishment and spread of a harmful organism and the magnitude of the associated potential consequences [Plant Health Panel approach].
PRASSIS	Pest Risk Assessment in the European Community: inventory of data sources – a project initiated with the aim to produce an inventory of national and international data sources necessary to conduct the risk assessment of harmful organisms for the EC.
PRATIQUE	Enhancement of Pest Risk Analysis Techniques - EU collaborative project
risk analysis	A process consisting of three interconnected components: risk assessment, risk management and risk communication [Regulation (EC) No 178/2002].
risk assessment	A scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization [Regulation (EC) No 178/2002].

risk assessment area	The area to which the risk assessment applies [Plant Health Panel approach].
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 matrix	A table with several categories of likelihood for its row, and several categories of consequence for its columns; a tool used by risk assessors for combining qualitative scores [Cox, 2008].
sensitivity analysis	The determination of the contributions of individual uncertain inputs to the uncertainty of the output [Helton *et al*., 2006].
transparency	An essential operating principle of the EFSA [Regulation (EC) No 178/2002; EFSA, 2009b] referring to an environment in which data, information, decisions and their rationale are provided to the public in a comprehensible, accessible, and timely manner.
uncertainty	The inability to determine the true state of affairs of a system [Haimes, 2009]; may arise in different stages of risk assessment due to lack of knowledge and to natural variability.
uncertainty analysis	The determination of the uncertainty in the output that derives from the uncertainty in inputs [Helton *et al*., 2006].