European Food Safety Authority

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SCIENTIFIC OPINION[1]

Evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC

Guidance of the Panel on Plant Health

(Question No EFSA-Q-2008-259)

Adopted May 13 2009

This opinion, published on 30th October 2009, replaces the previous version published on 12th June 2009[2].

PANEL MEMBERS*

Richard Baker, David Caffier, James William Choiseul, Patrick De Clercq, Erzsébet Dormannsné-Simon, Bärbel Gerowitt, Olia Evtimova Karadjova, Gábor Lövei, Alfons Oude Lansink, David Makowski, Charles Manceau, Luisa Manici, Dionyssios Perdikis, Angelo Porta Puglia, Jan Schans, Gritta Schrader, Robert Steffek, Anita Strömberg, Kari Tiilikkala, Johan Coert van Lenteren and Irene Vloutoglou.

SUMMARY

The European Food Safety Authority requested the Panel on Plant Health to produce a guidance document on the evaluation of documents prepared by EU Member States or third parties to justify requests for phytosanitary measures to be considered under Council Directive 2000/29/EC[3].

The Panel reviewed the 36 opinions published in the period 2006-2008, and in particular considered the evaluation process for 30 pest risk analysis documents prepared by France on organisms considered harmful for the overseas Departments of Guadeloupe, French Guiana, Martinique and Reunion. It also considered the International Standards for Phytosanitary Measures (ISPMs) and the evaluation process is presented with reference to the elements of

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[2] The EFSA journal number has been corrected.

* One member declared an interest and did not vote on the adoption of the opinion

[3] 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, 112 pp

ISPM No. 11: Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms[4] .

This guidance confirms the criteria used by the Panel in evaluating whether the evidence presented in the submitted documents supports the conclusion that an organism may pose a risk to plant health and therefore be considered as a harmful organism. The following elements are used as the basis of the conclusions reached by the Panel:

- the potential for consequences to cultivated and managed plants and environmental consequences following the introduction of the organism to a specified area
- the likelihood of establishment and spread
- the likelihood of entry by analysis of the potential pathways presented
- the uncertainties which may influence the conclusions reached.

If requested, the Panel may also identify and evaluate the effectiveness of potential risk management options a) in reducing the risk of entry and b) in reducing the magnitude of the potential consequences following the introduction of an organism considered to pose a risk to plant health in the European Community.

Keywords: Guidance, opinion, evaluation, pest risk assessment, European Community, phytosanitary measures

[4] FAO 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.

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BACKGROUND AS PROVIDED BY THE EUROPEAN FOOD SAFETY AUTHORITY[5]

The Scientific Panel on Plant Health provides independent scientific advice on the risks posed by organisms that can cause harm to plants, plant products or biodiversity in the EU. 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.

The Agreement on the Application of Sanitary and Phytosanitary Measures (WTO, 1994) requires that decision-making for phytosanitary measures should be based on assessment of the risks to plant life or plant health taking into account risk assessment techniques developed by the relevant international organisations.

Guidance for conducting a pest risk assessment for phytosanitary purposes is provided by the International Plant Protection Convention and is outlined in the International Standards for Phytosanitary measures (ISPM): 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). Pest risk assessment for quarantine pests is defined in the ISPM No. 5 Glossary of Phytosanitary Terms (FAO, 2007c) as *"evaluation of the probability of the introduction and spread of a pest and magnitude of the associated potential economic consequences"*. The standards provide a broad rationale for the analysis of the scientific evidence and the elements needed in order to assess the risk posed by an organism of potential quarantine pest status, but do not provide detailed guidance on the level of detail and assessment methodology required to provide an adequate basis for decision-making.

Protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community are established by Council Directive 2000/29/EC.

Within the framework of harmonisation of the EU plant health regime, the Panel was requested by the European Commission to provide scientific opinions on 30 pest risk analysis documents prepared by France on organisms considered harmful for four of its overseas Departments (Guadeloupe, French Guiana, Martinique and Réunion). A transparent evaluation procedure is required, based on scientific principles, to ensure an objective and consistent approach for the evaluation of pest risk assessments to support decision-making by EU risk managers on organisms potentially harmful to plants or plant products. Currently there is no clear and shared consensus on the criteria by which a pest risk assessment dossier should be reviewed.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN FOOD SAFETY AUTHORITY

In view of the above, the Panel is requested to produce a guidance document on the evaluation of pest risk assessments prepared by third parties to justify phytosanitary measures under the Council Directive 2000/29/EC.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank members of the Working Group for the preparation of this opinion: David Caffier, Patrick De Clercq, Gábor Lövei, David Makowski, Jan Schans, Gritta Schrader, Kari Tiilikkala, Johan Coert van Lenteren.

[5] Submitted by the European Food Safety Authority, ref (2008) EBC/2706586.

INTRODUCTION

1. Purpose and scope of the guidance document

The purpose of this document is to outline the process and scientific principles followed by the EFSA Scientific Panel on Plant Health (referred to hereafter as the Panel) when evaluating documents prepared for organisms proposed for regulation under Council Directive 2000/29/EC. This Directive provides for "protective measures against introduction into and spread within the European Community of organisms harmful to plants and plant products". The Panel is requested to evaluate these documents in order to assist EU risk managers with a sound scientific basis for phytosanitary regulations under Directive 2000/29/EC.

This guidance document describes the evaluation process i.e. the process of independent scientific review used by the Panel when considering risk assessment documents. A pest risk analysis is requested (Article 16.3 and 5 of Council Directive 2000/29/EC) to support claims for phytosanitary measures. The scientific data requirements to support such claims are not specified within the EU legislation and documents submitted to the Panel may include qualitative or quantitative assessments which follow national or regional (e.g. the European and Mediterranean Plant Protection Organisation (EPPO, 2007)) standards.

This guidance presents the process by which the Panel evaluates the documents presented and reaches its conclusions.

This document does not have any regulatory status.

2. Requests for a scientific opinion of the EFSA Panel on Plant Health

The Panel on Plant Health was established in 2006 by Commission Regulation No 575/2006 amending Regulation (EC) No 178/2002 to provide independent scientific advice on the risk posed by organisms which can cause harm to plants, plant products or biodiversity in the EU.

EFSA addresses requests for scientific opinions from the European Commission, Member States and European Parliament. The EFSA administrative procedure for handling requests is described at the following link:

http://www.efsa.europa.eu/EFSA/1178718048624/efsa_locale-1178620753812_ReceiptOfRequest.htm

The Panel evaluates the evidence presented with regard to the specific terms of reference of the request. The request should specify the scope and objectives for the evaluation, which may relate to evaluation of documents prepared by:

- Member States with reference to their own territory
- Member States with reference to more than one Member State, and which may include the whole EU territory
- The European and Mediterranean Plant Protection Organisation (EPPO) which covers a wider geographical area than the EU territory. The Panel restricts its evaluation to the EU territory
- Non-EU countries to support claims for consideration or revision of Community phytosanitary measures.

The documents submitted for evaluation are most commonly entitled "pest risk analyses". The elements described in the documents submitted may include aspects relevant for risk managers. This guidance provides clarification on the scope of the Panel evaluation in each section below.

3. Terminology and methodology

3.1. Terms and Definitions used by the Panel

Within 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 terminology used in Directive 2000/29/EC is used in reference to the plant health regulatory framework in the European Community. In line with EFSA's commitment for transparency in risk assessment (EFSA, 2008a) the Panel also uses, where appropriate, phytosanitary terms and definitions as listed by the International Plant Protection Convention (IPPC) in ISPM No.5 Glossary of Phytosanitary Terms (FAO, 2007c). This is referred to as the IPPC Glossary.

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 and considers pest risk assessment to be the process by which it is determined whether a "pest" has the characteristics to be considered as a "harmful organism" for potential inclusion in Council Directive 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" as defined in the IPPC Glossary.

Pest risk assessment is defined within the IPPC Glossary as the "evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences". Within this definition, "economic" is noted as including both environmental and social consequences. The Sanitary and Phytosanitary Agreement of the World Trade Organisation (WTO, 1994) similarly defines risk assessment as "the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing member country according to the sanitary and phytosanitary measures which might be applied, and of the associated potential biological and economical consequences". A pest risk analysis is defined in the IPPC Glossary as "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." 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 refrain from using neither the term "pest risk analysis" nor its acronym PRA.

A pest risk assessment is conducted with reference to a defined geographical area ("PRA area" in IPPC standards). This area may be the whole European Community, one or more Member States, or a defined region within one Member State or within several Member States. The Commission may request the Panel to consider the risk posed by an organism to the whole European Community, as phytosanitary decision-making at the EU level is taken with consideration of the whole EU area. If the Panel is asked to evaluate a document prepared for a restricted area and extend its scope to the whole EU area, the Panel needs to collect additional information and perform the appropriate risk assessment.[6]

[6] Guidance for the assessment of plant health risks in the EU is in preparation http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=PLH (Question number Q-2008-704)

The Panel evaluates the potential consequences to cultivated and managed plants and environmental consequences arising from introduction of a pest. It evaluates whether appropriate risk management options have been identified and the level to which the risk is reduced by the management options proposed.

An "endangered area" is defined in the IPPC Glossary as "an area where ecological factors favour the establishment of a pest whose presence in an area will result in economically important loss". However, the monetary value and importance of the loss is not determined by the Panel, and therefore, an endangered area is interpreted as an area where ecological factors favour the establishment of a pest whose presence in that area is likely to result in negative consequences to plants.

3.2. Comparison of EFSA and IPPC risk assessment processes

The Panel acknowledges the International Standards for Phytosanitary Measures ISPM No. 2 Framework for pest risk analysis (FAO, 2007a), and No. 11 Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms (FAO, 2007b) as the internationally agreed framework for risk assessment relating to plant health. Following a review of existing international standards, and in line with EFSA's commitment to the transparency of risk assessment (EFSA, 2008a) the Panel uses ISPM No. 11 as the reference for its evaluation.

EFSA founding regulation (Regulation (EC) 178/2002) describes risk assessment as a scientifically based process consisting of four steps:

a) hazard identification

b) hazard characterisation

c) exposure assessment

d) risk characterisation.

ISPM No. 11 also describes four steps of the pest risk assessment process and the relationship to the steps described in the EFSA pest risk assessment process is shown in Table 1 below. Hazard identification" is considered to correspond to the "pest categorisation stage". Within the IPPC pest risk assessment process, a distinction is made between the assessment of the probability of introduction (entry and establishment) and spread, and the assessment of potential impacts. These elements cannot be considered as entirely equivalent but are considered by the Panel to relate to "exposure assessment" and "hazard characterisation", respectively, for a defined geographical area.

"Risk characterisation" provides the conclusion of the pest risk assessment stage and includes consideration of the uncertainties and their significance in influencing the outcome of the risk assessment.

Table 1. **Relationship between EFSA and IPPC (ISPM No. 11) components of risk assessment**

IPPC pest risk assessment steps	EFSA risk assessment steps
Pest categorisation	Hazard identification
Potential consequences	Hazard characterisation
Probability of introduction and spread	Exposure assessment
Conclusion of pest risk assessment	Risk characterisation

4. Evaluation of documents submitted to EFSA

4.1. General review of the document presented

The documents presented for evaluation by the Panel may be prepared in a number of different formats, e.g. following international, national or regional standards (e.g. those of the IPPC or European and Mediterranean Plant Protection Organisation (EPPO, 2007)) within the EU and using risk assessment schemes which may comprise short qualitative assessments, or detailed quantitative analyses.

The Panel reviews the methodology and associated terms, including descriptions of the ratings used in the document provided. When the Panel disagrees with the ratings given in the submitted document, it may ascribe new ratings, based on additional information or on different reasoning. In such situations it will present its justification for the ratings given in the opinion in a transparent manner.

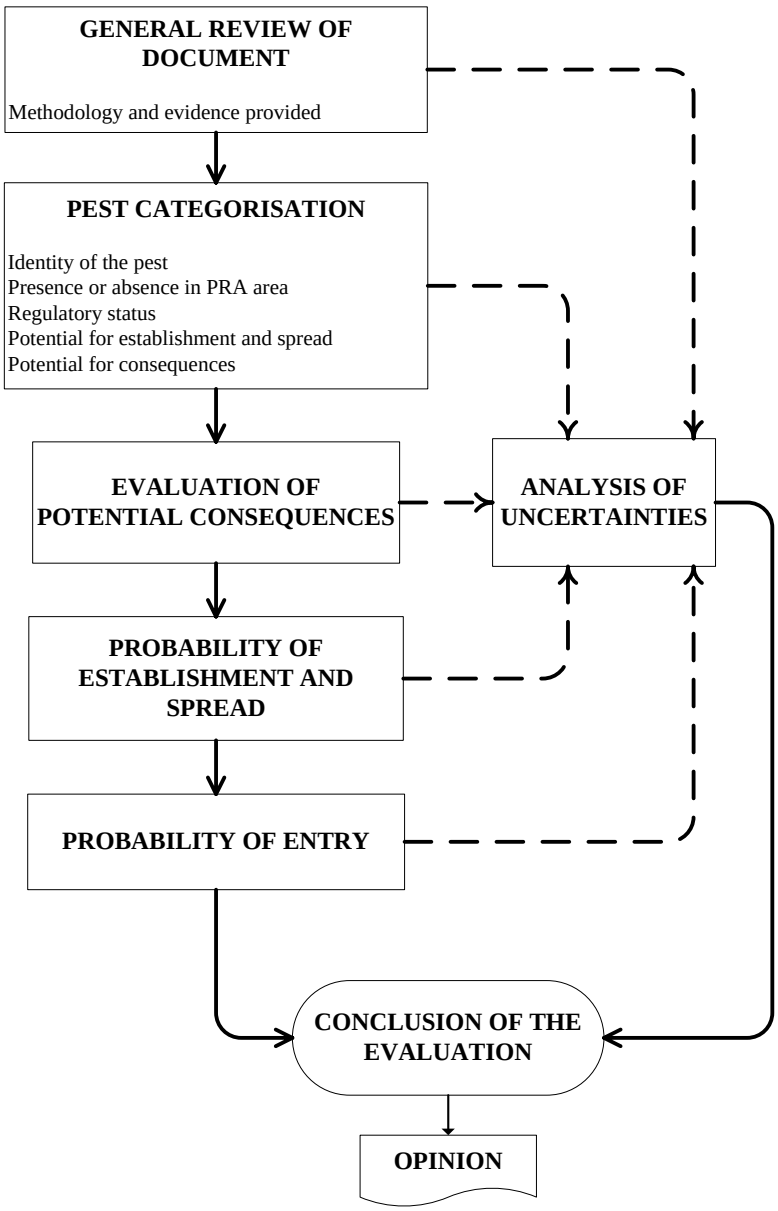
The Panel evaluates the evidence provided to support the arguments presented. It considers whether references are correctly cited and interpreted, and whether the conclusions are clearly formulated and derived from scientific reasoning. The quality of the evidence, including unpublished data and personal communications (supported by written documentation) are evaluated and taken into account within the overall evaluation of uncertainty. Supporting data are evaluated according to their relevance to the assessment. The Panel will consider both published and unpublished information. Higher weight is given to published information from peer-reviewed journals and information from official sources where available. The Panel notes where expert judgement has been used in the assessment provided, and evaluates whether statements are justified by the argumentation and supporting evidence provided.

The Panel will also determine whether additional evidence exists which may contradict the conclusions reached in the assessment provided. In the absence of published evidence to support statements made by the Panel, the reasoning and argumentation will be presented to ensure that the basis of its expert judgement is made explicit.

Where adequate evidence is not provided to support the conclusions or when the Panel finds evidence which may alter the conclusions of the assessment, it may undertake an exploratory

analysis and identify key areas which may require further study to reduce the level of uncertainty and enable a conclusion to be reached.

Figure 1. **Flowchart of Evaluation Process**



4.2. Pest categorisation

The Panel considers the following aspects described below, which equate to the first step known as "pest categorisation" in the pest risk assessment process outlined in ISPM No. 11. This step, considered broadly equivalent to "hazard identification", enables the Panel to conduct a preliminary evaluation to determine at an early stage of the evaluation process, whether a pest has the potential for further consideration as a harmful organism for inclusion in 2000/29/EC.

4.2.1. Pest identity

The Panel reviews the evidence presented in the document to confirm the taxonomy of the organism under evaluation allows for its unambiguous identification. The taxonomic unit is generally a species. The Panel considers the evidence presented to justify evaluation of a higher (e.g. species complex) or lower (sub-species, races) taxonomic unit. If the causal agent has not yet been fully identified, then evidence should be presented to enable the Panel to confirm the agent produces consistent symptoms and is transmissible. Taxonomic uncertainties relating to the organism are highlighted.

Symptoms and the availability of reliable detection techniques are also considered by the Panel, as relevant.

4.2.2. Presence or absence of the pest in the PRA area

The Panel reviews the available literature to confirm whether the information provided in the document accurately reflects the occurrence of the pest in the PRA area and to identify any uncertainties arising. The document should clearly state whether the organism is absent from the PRA area, or if present, should present evidence to indicate its occurrence and distribution.

4.2.3. Regulatory status

The Panel evaluates whether the regulatory status of the organism in the PRA area has been correctly specified. Where the pest is present, evidence should be presented to confirm that official measures are being undertaken in and around an infested area to reduce or eradicate pest populations and prevent further spread.

4.2.4. Potential for establishment and spread

The Panel evaluates the evidence presented to confirm there is a potential for the organism to establish and spread in the PRA area. Evidence should be provided to confirm the suitability of eco-climatic conditions and the presence of host species, alternate hosts and vectors.

4.2.5. Potential for consequences

The Panel evaluates the evidence presented for potential effects on cultivated and managed plants and environmental consequences following establishment and spread of the organism in the PRA area. Evidence includes published reports of direct and/or indirect effects such as yield loss, reduction in host quality, consequences to ecosystem services and effects of implementing additional control measures directly arising as a consequence of the pest incursion.

4.2.6. Conclusion of the pest categorisation stage

The Panel examines the evidence presented to verify from a preliminary examination of the above elements whether the organism has the potential for further consideration as a harmful organism for inclusion in 2000/29/EC.

If the organism has a potential for establishment spread and negative consequences, the Panel continues with a more detailed evaluation as appropriate to the specific request.

4.3. Evaluation of potential consequences

The Panel evaluates the evidence provided on the risk posed to plants, plant products and biodiversity. The evidence for potential consequences of pest introduction is examined in the absence of any measures against the introduction of the pest. A conclusion is formulated on the quality of the information and argumentation provided within this section, listing any shortcomings and uncertainties and whether they may influence the conclusions reached.

4.3.1. Consequences to cultivated and managed plants

The Panel evaluates the evidence presented on the potential reduction of yield and/or quality of cultivated and managed plant species in the PRA area. This evidence can be related to quantitative information on the yield and quality levels attained in the PRA area in the absence of the pest concerned and information of yield and quality reduction in areas where the pest occurs naturally or has been introduced. Effects of biotic and abiotic factors existing in the PRA area that may influence the level of yield and quality reduction by the pest are included in the evaluation.

4.3.2. Environmental consequences

The Panel evaluates the evidence presented concerning the influence (direct as well as indirect) of the harmful organism on species providing ecosystem services. These services are described in the Millennium Ecosystem Assessment[7] (MEA, 2005).

The Panel will evaluate the indirect effects by the harmful organism on species connected to the above ecosystem functions and services, including those arising from pest management measures such as the application of pesticides and via competition, changes in mutualism, impact on natural enemies or pathogens of the above organisms that may result in a negative effect for other species providing the ecosystem function.

The Panel also evaluates the impacts on biodiversity itself, especially on rare species, including effects on their genetic diversity, on population viability, and habitat fragmentation.

4.3.3. Other consequences

Potential impacts on human or animal health are not within the scope of the Council Directive 2000/29/EC and not within the scope of the Panel's evaluation. Where evidence is presented to suggest that the organism under consideration presents a risk to human or animal health, this will be noted in the opinion but will not be evaluated further by the Panel.

[7] These services are described in terms of a) Provisioning services such as genetic resources, food, fiber, water and soil; b) Regulating services, including biological control by natural enemies, mitigation of local weather extremes, soil erosion mitigation including shoreline and river channel stability; and c) Sustaining services including pollination, soil fertility maintenance, decomposition. Cultural services, among them psychological benefits, maintenance of health and well-being.This last aspect is not evaluated by the Panel.

Where evidence is provided to indicate potential consequences of pest incursions, the Panel considers effects on local communities such as threats to food security arising from yield reduction of staple crops. The Panel evaluates the evidence provided for other potential consequences of pest introduction including effects on infrastructure (e.g. blocking of waterways by invasive weeds).

4.4. Evaluation of probability of establishment

The Panel evaluates the evidence presented in the document to determine whether the pest can establish in the assessment area.

The following elements are considered by the Panel and a conclusion is formulated on the quality of the information and argumentation provided within this section, listing any shortcomings. Uncertainties are highlighted where these may influence the conclusions reached.

4.4.1. Characteristics of the pest affecting the probability of establishment

- Information on the life cycle, host range, potential number of generations per year (in the PRA area), reproductive strategies, dormancy and other survival strategies.
- Information on the adaptability of the organism (genotypic or phenotypic variability), including the occurrence of strains or races with different host ranges, records of climatic adaptation or the ability to develop pesticide resistance.
- Information on likelihood that a transient population (i.e. a population surviving during part of the year, but not capable of establishment) would occur upon entry.

4.4.2. Availability of suitable hosts, alternate hosts and vectors

- Presence, abundance, geographic area of distribution and taxonomic position of cultivated and wild host plants of the organism in the assessment area if the organism is an animal pest or a pathogen.
- Geographic proximity of alternate hosts to allow the organism to complete its life cycle.
- The host range, including additional plant species which could prove to be suitable hosts in the absence of the usual host species (secondary hosts).
- If relevant, area of protected cultivation of host plants in the PRA area, and earlier records of the organism in protected cultivation elsewhere.
- If the organism requires a vector or another intermediate host that is essential for part of the life cycle or spread of the organism, presence, abundance, distribution and taxonomic position of the vector(s)/host(s).
- Likelihood of introduction of a vector(s)/host(s) needed for dispersal or presence of another closely related vector species in the PRA area.

4.4.3. Suitability of the environment

The Panel evaluates the evidence presented on the similarity between the climatic and other abiotic conditions of the assessment area and the area of current distribution of the organism.

Where the evidence provided is based on calculations or mathematical models, transparency requires that relevant elements of the reasoning, assumptions, calculation or mathematical modelling should be described so that it can be evaluated by the Panel.

4.4.4. Evaluation of current cultural practices and control measures

- Impact of existing cultivation and production practices (e.g. crop rotation, water and soil management, use of resistant varieties) in the assessment area, compared with practices in the area of origin of the pest.
- Occurrence and impact of natural enemies or antagonists in the assessment area.
- Existing pest control programmes in the assessment area which reduce the probability of establishment.
- Availability of suitable methods for eradication. Pests for which eradication is not likely to be successful are considered to present a greater risk than those with records of successful eradication.

4.5. Evaluation of probability of spread after establishment

The Panel reviews the evidence presented to determine if all relevant aspects have been addressed as listed below, and whether areas of uncertainty have been highlighted in the assessment provided. A conclusion is formulated on the quality of the information and argumentation provided within this section, listing any shortcomings and areas of uncertainty which may affect the conclusions reached:

- suitability of the natural and/or managed environment for spread of the pest
- dispersal potential of the pest (no. of generations, dispersal per generation, presence and importance of dispersal stages, active and/or passive dispersal)
- presence of natural barriers
- potential vectors of the pest
- potential natural enemies of the pest
- potential for passive movement with commodities or conveyances, including water and animals
- production practices aiding spread of the pest e.g. vegetative reproduction, grafting
- intended use of the commodity.

4.6. Identifying the endangered area

The Panel reviews the document to determine whether the endangered area has been accurately identified on the basis of the evidence presented and whether areas of uncertainty have been highlighted in the assessment provided. This is evaluated by consideration of a) the ecological or other factors favouring establishment of the pest and b) the potential consequences arising from the introduction of the pest into that area. The endangered area may comprise the whole assessment area or specified areas within it.

4.7. Evaluation of probability of entry

The Panel evaluates the evidence presented for the pathways identified, and determines if all relevant aspects of this item have been addressed. Uncertainties are highlighted where these may influence the conclusions reached. By evaluation of the available evidence, the Panel will note additional potential pathways which should be included in the assessment by undertaking exploratory analysis and identifying key areas which may require further studies, but no new pathway analysis will be conducted.

Pest interception data should be included in the evidence presented where available as such data provides valuable evidence of the ability of a pest to be associated with a pathway and to survive in transport or storage. Factors considered in the evaluation process are:

4.7.1. Identification of pathways

- Consignments of plants and plant products moving in international trade
- Other pathways such as other types of commodities, packing materials, persons, baggage, mail, conveyances and the exchange of scientific material
- Entry by natural means

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

- Prevalence of the pest in the source area
- Occurrence of the pest in a life-stage that would be associated with commodities, containers, or conveyances
- Volume and frequency of movement along the pathway
- Seasonal timing (transport versus life cycle of the organism)
- Pest management, cultural and commercial procedures applied at the place of origin that may reduce or prevent the possibility of the pest being associated with the pathway at origin

4.7.3. Probability of survival before, during and after transport or storage

- Speed and conditions of transport and duration of the life cycle of the pest in relation to time in transport and storage
- Vulnerability of the life-stages during transport or storage
- Prevalence of pest likely to be associated with a consignment
- Commercial procedures (e.g. refrigeration) applied to consignments in the country of origin, country of destination, or in transport or storage
- Existing pest management procedures (including phytosanitary procedures)
- The probability of detection of visual symptoms

4.7.4. Probability of transfer to a suitable host

- Dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host
- Whether the imported commodity is to be sent to a few or many destination points
- Proximity of entry, transit and destination points to suitable hosts
- Time of year at which import takes place
- Intended use of the commodity (e.g. for planting, processing and consumption)
- Risks from by-products and waste

The probability to be associated with any growth, processing, or disposal of the commodity in the vicinity of suitable hosts is also considered by the Panel.

4.8. Analysis of uncertainty

To ensure transparency in risk assessment, uncertainties should be identified, characterised and documented in the assessment provided. 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 the assessment of the potential consequences is based on the scientific data available and, where relevant, model simulations (e.g. climatic matching and epidemiological models). All these sources of information have uncertainties.

The Panel evaluates whether uncertainties have been clearly identified in the document and whether their potential influence on the conclusions of the pest risk assessment has been discussed. Based on a list of the uncertainties in each section of the pest risk assessment, the Panel addresses uncertainty as a separate step in the evaluation process. The Panel concludes on the level of uncertainty and its influence on the conclusions reached.

The Panel considers it important to distinguish between uncertainty due to inadequate 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 consulting further experts. Uncertainty due to natural variability is an inherent characteristic of biological systems and generally cannot be reduced.

Several studies have proposed classifications for uncertainty, (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 (e.g. from one species to another)
- 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.

For qualitative pest risk assessments, the Panel evaluates whether key sources of uncertainty have been identified and discussed. A qualitative characterisation of uncertainty can be provided for each source (e.g. low, high, etc.) as an aid to risk managers. When quantitative models are used, the Panel evaluates whether sensitivity analysis has been performed in order to analyse the sensitivity of the model outputs to uncertain model parameters. Where possible the Panel may use a tiered approach, combining qualitative and quantitative evaluations of uncertainty, as developed by EFSA's Scientific Committee (EFSA, 2006) and applied in several opinions of other EFSA Scientific Panels (e.g. EFSA, 2008b).

4.9. Conclusion of the pest risk assessment stage

The Panel completes its evaluation of the pest risk assessment by summarising whether the evidence presented in the submitted document supports the conclusions reached but only in so far as this evidence falls within the remit of the Panel. The Panel concludes the evaluation by reference to the conclusions reached for each of the components of the pest risk assessment, including:

- potential consequences of introduction

- probability of establishment
- probability of spread
- probability of entry.

The uncertainties associated with each of the components above are described separately, indicating whether the level of uncertainty in each case may influence the conclusions reached. The conclusion of the evaluation includes identification of the endangered area, which may be the whole PRA area or a defined part thereof, where ecological factors favour the establishment of a pest whose presence in that area is likely to result in a negative consequences to cultivated and managed plants and environmental consequences to plant health.

Following its evaluation of the evidence presented, the Panel will clearly state where it considers the evidence supports the conclusions reached. Where the Panel does not support the conclusions stated, it presents evidence and reasoning to justify a different rating or a revised conclusion. At the end of the evaluation of the pest risk assessment, the Panel formulates a conclusion in response to the terms of reference of the request.

Where the level of uncertainty is high, the Panel may not be able to reach a conclusion on whether an organism is potentially eligible for phytosanitary risk management measures. In this case additional studies will be identified where possible to assist in reducing the level of uncertainty.

Where the Panel is requested to evaluate whether an organism can be considered as a harmful organism, in the meaning of the definition in Article 2.1 (e) of Council Directive 2000/29/EC, the Panel concludes stating whether the organism is considered appropriate for subsequent analysis of pest risk management options.

5. Evaluation of risk management options

The conclusions of the risk assessment stage are used by risk managers to decide whether risk management is required and the strength of measures to be used. Upon request, the Panel evaluates whether the options for risk management have been identified and whether the following aspects have been discussed:

- the level to which the risk is reduced by each risk management option or proposed combinations of risk management options should be indicated
- where different risk management options lead to the same or equivalent effect and level of risk reduction, they will be indicated as alternatives
- if existing phytosanitary measures reduce the risk of the pest, the added effect of each risk management option proposed to the reduction of risk should be demonstrated.

The Panel evaluation does not address cost-effectiveness of management options but includes their technical feasibility. The IPPC principles of “minimal impact” and “non-discrimination” are not addressed by the Panel.

The Panel may also be requested to identify and evaluate additional risk management options and/or to evaluate the scientific basis for existing measures in terms of the characteristics described above.

Risk management options may include:

- options for consignments including specified treatment
- 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

– options for surveillance, eradication, containment and control measures in the importing country.

The uncertainties are described, indicating whether the level of uncertainty may influence the conclusions reached.

At the end of the evaluation of the risk management options, the Panel formulates a conclusion in response to the terms of reference of the request.

6. Adoption and publication of the opinion

The output of the evaluation is a draft opinion which is reviewed by the Panel for adoption according to EFSA procedures. The opinion is published on the EFSA website.

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