INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 2

FRAMEWORK FOR PEST RISK ANALYSIS

(2007)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in March 2007.

INTRODUCTION

SCOPE

This standard provides a framework that describes the pest risk analysis (PRA) process within the scope of the IPPC. It introduces the three stages of pest risk analysis – initiation, pest risk assessment and pest risk management. The standard focuses on the initiation stage. Generic issues of information gathering, documentation, risk communication, uncertainty and consistency are addressed.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Glossary of phytosanitary terms, 2007. ISPM No. 5, FAO, Rome.
Glossary supplement No. 2: Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations. ISPM No. 5, FAO, Rome.
Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms, 2005. ISPM No. 3, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.
Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006. ISPM No. 1, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

The pest risk analysis (PRA) process is a technical tool used for identifying appropriate phytosanitary measures. The PRA process may be used for organisms not previously recognized as pests (such as plants, biological control agents or other beneficial organisms, living modified organisms), recognized pests, pathways and review of phytosanitary policy. The process consists of three stages: 1: Initiation; 2: Pest risk assessment; and 3: Pest risk management.

This standard provides detailed guidance on PRA Stage 1, summarizes PRA Stages 2 and 3, and addresses issues generic to the entire PRA process. For Stages 2 and 3 it refers to ISPMs No. 3, No. 11 and No. 21 dealing with the PRA process.

The PRA process is initiated in Stage 1 with the identification of an organism or pathway that may be considered for pest risk assessment, or as part of the review of existing phytosanitary measures, in relation to a defined PRA area. The first step is to determine or confirm whether or not the organism considered is a pest. If no pests are identified, the analysis need not continue. The analysis of pests identified in Stage 1 continues to Stages 2 and 3 using guidance provided in other standards. Information gathering, documentation and risk communication, as well as uncertainty and consistency, are issues common to all PRA stages.

BACKGROUND

Pest risk analysis (PRA) provides the rationale for phytosanitary measures for a specified PRA area. It evaluates scientific evidence to determine whether an organism is a pest. If so, the analysis evaluates the probability of introduction and spread of the pest and the magnitude of potential economic consequences in a defined area, using biological or other scientific and economic evidence. If the risk is deemed unacceptable, the analysis may continue by suggesting management options that can reduce the risk to an acceptable level. Subsequently, pest risk management options may be used to establish phytosanitary regulations.

For some organisms, it is known beforehand that they are pests, but for others, the question of whether or not they are pests should initially be resolved[1].

The pest risks posed by the introduction of organisms associated with a particular pathway, such as a commodity, should also be considered in a PRA. The commodity itself may not pose a pest risk but may harbour organisms that are pests. Lists of such organisms are compiled during the initiation stage. Specific organisms may then be analysed individually, or in groups where individual species share common biological characteristics.

Less commonly, the commodity itself may pose a pest risk. When deliberately introduced and established in intended habitats in new areas, organisms imported as commodities (such as plants for planting, biological control agents and other beneficial organisms, and living modified organisms (LMOs)) may pose a risk of accidentally spreading to unintended habitats causing injury to plants or plant products. Such risks may also be analysed using the PRA process.

The PRA process is applied to pests of cultivated plants and wild flora, in accordance with the scope of the IPPC. It does not cover the analysis of risks beyond the scope of the IPPC.

Provisions of other international agreements may address risk assessment (e.g. the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to that convention).

The PRA structure

The PRA process consists of three stages:

- Stage 1: Initiation
- Stage 2: Pest risk assessment
- Stage 3: Pest risk management.

Information gathering, documentation and risk communication are carried out throughout the PRA process. PRA is not necessarily a linear process because, in conducting the entire analysis, it may be necessary to go back and forth between various stages.

Revision of this standard

This revision of ISPM No. 2 particularly addresses the issues of:

- aligning the text with the 1997 revision of the IPPC
- aligning the text with further conceptual developments of the PRA scope and procedures as appearing in ISPMs No. 3, No. 11 and No. 21
- including regulated non-quarantine pests (RNQPs) in the description of the PRA process
- including organisms not known beforehand to be pests in the description of the PRA process
- including aspects common to all PRA stages in the description of the PRA.

Thus, this standard provides detailed guidance on PRA Stage 1 and issues generic to all PRA stages, and refers to other ISPMs (identified in Table 1) as appropriate for further analysis through PRA Stages 2 and 3. This standard is conceptual and is not a detailed operational or methodological guide for assessors. An overview of the full PRA process is illustrated in Appendix 1.

[1] The IPPC defines a pest as "*any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products*". The understanding of the term "pests" includes organisms that are pests because they directly affect cultivated/managed or uncultivated/unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms (c.f. Annex 1 of ISPM No. 11, 2004).

Provisions of the IPPC regarding pest risk analysis

The International Plant Protection Convention (IPPC, 1997, Article VII.2a) requires that: "*Contracting parties shall not ... take any of the measures specified in paragraph 1 of this Article* [i.e. phytosanitary measures] *unless such measures are made necessary by phytosanitary considerations and are technically justified*."

Article VI.1b requires that phytosanitary measures are: "*limited to what is necessary to protect plant health and/or safeguard the intended use and can be technically justified by the contracting party concerned.*"

"Technically justified" is defined in Article II.1 as: "*justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information.*"

Article IV.2f states that the responsibilities of the National Plant Protection Organization (NPPO) include "*the conduct of pest risk analyses*". The issuing of regulations is a responsibility of the contracting party to the IPPC (Article IV.3c), although contracting parties may delegate this responsibility to the NPPO.

In conducting a PRA, the obligations established in the IPPC should be taken into account. Those of particular relevance to the PRA process include:

- cooperation in the provision of information
- minimal impact
- non-discrimination
- harmonization
- transparency
- avoidance of undue delay.

REQUIREMENTS

1. PRA Stage 1: Initiation

Initiation is the identification of organisms and pathways that may be considered for pest risk assessment in relation to the identified PRA area.

A PRA process may be triggered in the following situations (initiation points, section 1.1):

- a request is made to consider a pathway that may require phytosanitary measures
- a pest is identified that may justify phytosanitary measures
- a decision is made to review or revise phytosanitary measures or policies
- a request is made to determine whether an organism is a pest.

The initiation stage involves four steps:

- determination whether the organism is a pest (section 1.2)
- defining the PRA area (section 1.3)
- evaluating any previous PRA (section 1.4)
- conclusion (section 1.5).

When the PRA process has been triggered by a request to consider a pathway, the above steps are preceded by assembling a list of organisms of possible regulatory concern because they are likely to be associated with a pathway.

At this stage, information is necessary to identify the organism and its potential economic impact, which includes environmental impact[2]. Other useful information on the organism may include its geographical distribution, host plants, habitats and association with commodities (or, for RNQP candidates, association with plants for planting). For pathways, information about the commodity, including modes of transport, and its intended end use, is essential.

1.1 Initiation points

1.1.1 Identification of a pathway

The need for a new or revised PRA for a specific pathway may arise in situations such as when

- import is proposed of a commodity not previously imported or a commodity from a new area of origin

[2] Further information on this aspect is provided in *Supplement no. 2 (Guidelines on the interpretation and application of potential economic importance and related terms including reference to environmental considerations)* to ISPM No. 5 (*Glossary of phytosanitary terms*).

- there is an intention to import for selection and/or scientific research a plant species or cultivar not yet introduced that could potentially be a host of pests
- a pathway other than commodity import is identified (natural spread, packing material, mail, garbage, compost, passenger baggage, etc.)
- a change in susceptibility of a plant to a pest is identified
- a change in virulence/aggressiveness or host range of a pest.

These are situations where the commodity itself is not a pest. When the commodity itself may be a pest, it should also be considered under section 1.1.4.

A list of organisms likely to be associated with the pathway should be assembled, including organisms that have not yet been clearly identified as pests. When a PRA is carried out for a commodity for which trade already exists, records of actual pest interceptions should be used as the basis for the listing of associated pests.

1.1.2 Identification of a pest

The need for a new or revised PRA on a specific recognized pest may arise in situations such as when

- an infestation or an outbreak of a new pest is discovered
- a new pest is identified by scientific research
- a pest is reported to be more injurious than previously known
- an organism is identified as a vector for other recognized pests
- there is a change in the status or incidence of a pest in the PRA area
- a new pest is intercepted on an imported commodity
- a pest is repeatedly intercepted at import
- a pest is proposed to be imported for research or other purposes.

In these situations, the fact that the organism is known to be a pest can be recorded in preparation for PRA Stage 2.

1.1.3 Review of phytosanitary policies

The need for a new or revised PRA may arise from situations such as when

- a national review of phytosanitary regulations, requirements or operations is undertaken
- an official control programme (e.g. a certification programme encompassing phytosanitary elements) is developed to avoid unacceptable economic impact of specified RNQPs in plants for planting
- an evaluation of a regulatory proposal of another country or international organization is undertaken
- a new system, process or procedure is introduced or new information made available that could influence a previous decision (e.g. results of monitoring; a new treatment or withdrawal of a treatment; new diagnostic methods)
- an international dispute on phytosanitary measures arises
- the phytosanitary situation in a country changes or political boundaries change.

In these situations, pests will already have been identified and this fact should be recorded in preparation for PRA Stage 2.

For existing trade, new measures should be applied until the revision or new PRA has been completed, unless this is warranted by new or unexpected phytosanitary situations which may necessitate emergency measures.

1.1.4 Identification of an organism not previously known to be a pest

An organism may be considered for PRA in situations such as when

- a proposal is made to import a new plant species or variety for cropping, amenity or environmental purposes
- a proposal is made to import or release a biological control agent or other beneficial organism
- an organism is found which has not yet been fully named or described or is difficult to identify
- a proposal is made to import an organism for research, analysis or other purpose
- a proposal is made to import or release an LMO.

In these situations it would be necessary to determine if the organism is a pest and thus subject to PRA Stage 2. Section 1.2 provides further guidance in this matter.

1.2 Determination of an organism as a pest

Pre-selection or screening are terms sometimes used to cover the early step of determining whether an organism is a pest or not.

The taxonomic identity of the organism should be specified because any biological and other information used should be relevant to the organism in question. If the organism has not yet been fully named or described, then, to be determined as a pest, it should at least have been shown to be identifiable, consistently to produce injury to plants or plant products (e.g. symptoms, reduced growth rate, yield loss or any other damage) and to be transmissible or able to disperse.

The taxonomic level for organisms considered in PRA is usually the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In cases where levels below the species level are being analysed, the rationale for this distinction should include evidence of reported significant variation in factors such as virulence, pesticide resistance, environmental adaptability, host range or its role as a vector.

Predictive indicators of an organism are characteristics that, if found, would suggest the organism may be a pest. The information on the organism should be checked against such indicators, and if none are found, it may be concluded that the organism is not a pest, and the analysis may be ended by recording the basis of that decision.

The following are examples of indicators to consider:

- previous history of successful establishment in new areas
- phytopathogenic characteristics
- phytophagous characteristics
- presence detected in connection with observations of injury to plants, beneficial organisms, etc. before any clear causal link has been established
- belonging to taxa (family or genus) commonly containing known pests
- capability of acting as a vector for known pests
- adverse effects on non-target organisms beneficial to plants (such as pollinators or predators of plant pests).

Particular cases for analysis include plant species, biological control agents and other beneficial organisms, organisms which have not yet been fully named or described, or are difficult to identify, intentional import of organisms and LMOs. The pest potential of LM-plants should be determined as outlined in section 1.2.4.

1.2.1 Plants as pests

Plants have deliberately been spread among countries and continents for millennia, and new species or varieties of plants for cropping, amenity or environmental purposes are continually imported. Some plant species or cultivars transferred to regions beyond their natural range may escape from where they were initially released and invade unintended habitats such as arable land, natural or semi-natural habitats to become pests.

Plants as pests may also be introduced unintentionally into a country, for example as contaminants of seeds for sowing, grain for consumption or fodder, wool, soil, machinery, equipment, vehicles, containers or ballast water.

Plants as pests may affect other plants by competing for water, light, minerals, etc. or through direct parasitism and thus suppressing or eliminating other plants. Imported plants may also affect, by hybridization, plant populations under cultivation or in the wild nearby and may become pests for that reason. Further information is provided in the supplementary text on environmental risks in ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004).

The primary indicator that a plant species may become a pest in the PRA area is the existence of reports that the plant species has been recorded as a pest elsewhere. Some intrinsic attributes that may indicate that a plant species could be a pest include:

- adaptability to a wide range of ecological conditions
- strong competitiveness in plant stands
- high rate of propagation
- ability to build up a persistent soil-seed bank
- high mobility of propagules
- allelopathy
- parasitic capacity
- capacity to hybridize.

However, it should be noted that plants without such attributes may nevertheless become pests and that long time lags have often been observed between the introduction of a new plant species and evidence that the plant is a pest.

1.2.2 Biological control agents and other beneficial organisms

Biological control agents and other beneficial organisms are intended to be beneficial to plants. Thus, when performing

a PRA, the main concern is to look for potential injury to non-target organisms[3]. Other concerns may include:

- contamination of cultures of beneficial organisms with other species, the culture thereby acting as a pathway for pests
- reliability of containment facilities when such are required.

1.2.3 Organisms not yet fully described or difficult to identify

Organisms that have not yet been fully named or described or are difficult to identify (e.g. damaged specimen or unidentifiable life stages) may be detected in imported consignments or during surveillance, in which case a decision as to whether phytosanitary action is justified and recommendations for phytosanitary measures may need to be made. These should be based on a PRA using the information available, even if very limited. It is recommended that, in such cases, specimens are deposited in an accessible reference collection for future further examination.

1.2.4 Living modified organisms

LMOs are organisms that possess a novel combination of genetic material, obtained through the use of modern biotechnology and are designed to express one or more new or altered traits. Types of LMOs for which a PRA may be conducted include:

- plants for use in agriculture, horticulture or silviculture, bioremediation of soil, for industrial purposes, or as therapeutic agents (e.g. LMO plants with an enhanced vitamin profile)
- biological control agents and other beneficial organisms modified to improve their performance
- pests modified to alter their pathogenic characteristics.

The modification may result in an organism with a new trait that may now present a pest risk beyond that posed by the non-modified recipient or donor organisms, or similar organisms. Risks may include:

- increased potential for establishment and spread
- those resulting from inserted gene sequences that may act independently of the organism with subsequent unintended consequences
- potential to act as a vector for the entering of genetic sequence into domesticated or wild relatives of that organism, resulting in an increase in the pest risk of that related organism
- in case of a modified plant species, the potential to act as a vector for the entering of an injurious genetic sequence into relatives of that species.

PRA is usually concerned with phenotypic rather than genotypic characteristics. However, genotypic characteristics should also be considered when assessing the pest risks of LMOs.

Predictive indicators more specific to LMOs include intrinsic attributes such as:

- phenotypic similarities or genetic relationships to known pest species
- introduced changes in adaptive characteristics that may increase the potential for introduction or spread
- phenotypic and genotypic instability.

For LMOs, identification requires information regarding the taxonomic status of the recipient and the donor organism, and description of the vector, the nature of the genetic modification, and the genetic sequence and its insertion site in the recipient genome.

Further potential risks of LMOs are outlined in Annex 3 to ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004). A PRA may be carried out to determine whether the LMO is a pest, and subsequently assess the pest risk.

1.2.5 Import of organisms for specific uses

When a request is made to import an organism that may be a pest for use in scientific research, education, industry or other purposes, the identity of the organism should be clearly defined. Information on the organism or closely related organisms may be assessed to identify indicators that it may be a pest. For organisms determined to be pests, pest risk assessment may be carried out.

[3] ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, 2005) recommends that NPPOs should conduct a PRA either before import or before release of biological control agents and other beneficial organisms.

1.3 Defining the PRA area

The area to which the PRA refers has to be clearly defined. It may be the whole or part of a country or several countries. Whereas information may be gathered from a wider geographical area, the analysis of establishment, spread and economic impact should relate only to the defined PRA area.

In PRA Stage 2, the *endangered* area is identified. In PRA Stage 3, the *regulated* area may, however, be designated as wider than the endangered area if technically justified and not in conflict with the principle of non-discrimination.

1.4 Previous pest risk analyses

Before performing a new PRA, a check should be made to determine if the organism, pest or pathway has ever been subjected to a previous PRA. The validity of any existing analysis should be verified because circumstances and information may have changed. Its relevance to the PRA area should be confirmed.

The possibility of using a PRA of a similar organism, pest or pathway may also be investigated, particularly when information on the specific organism is absent or incomplete. Information assembled for other purposes, such as environmental impact assessments of the same or a closely related organism, may be useful but cannot substitute for a PRA.

1.5 Conclusion of initiation

At the end of PRA Stage 1, pests and pathways of concern will have been identified and the PRA area defined. Relevant information will have been collected and pests identified as candidates for further assessment, either individually or in association with a pathway.

Organisms determined not to be pests and pathways not carrying pests need not be further assessed. The decision and rationale should be recorded and communicated, as appropriate.

Where an organism has been determined to be a pest the process may continue to PRA Stage 2. Where a list of pests has been identified for a pathway, pests may be assessed as groups, where biologically similar, or separately.

Where the PRA is specifically aimed at determining if the pest should be regulated as a quarantine pest, the process may proceed immediately to the pest categorization step of pest risk assessment (PRA Stage 2) of ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms,* 2004). That ISPM is relevant for organisms that appear to meet the following criteria:

- not present in the PRA area or, if present, of limited distribution and subject to official control or being considered for official control
- having the potential to cause injury to plants or plant products in the PRA area
- having the potential to establish and spread in the PRA area.

Where the PRA is specifically aimed at determining if the pest should be regulated as an RNQP, the process may proceed immediately to the pest categorization step of pest risk assessment (PRA Stage 2) of ISPM No. 21 (*Pest risk analysis for regulated non-quarantine pests*). That ISPM is relevant for organisms that appear to meet the following criteria:

- present in the PRA area and subject to official control or being considered for official control
- plants for planting are a pathway for the pest in the PRA area
- having the potential to affect the intended use of plants for planting with an economically unacceptable impact in the PRA area.

2. Summary of PRA Stages 2 and 3

2.1 Linked standards

The PRA process for different pest categories is described in separate ISPMs, as summarized in Table 1. As circumstances change and techniques evolve, new standards may be developed and others revised.

Table 1: Standards linked to ISPM No. 2

ISPM	Title	Coverage of PRA
ISPM No. 11 (2004)	*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*	Specific guidance on PRA of quarantine pests including: - Stage 1: Initiation[4] - Stage 2: Pest risk assessment including environmental risks and LMO assessment - Stage 3: Pest risk management
ISPM No. 21	*Pest risk analysis for regulated non-quarantine pests*	Specific guidance on PRA of regulated non-quarantine pests including: - Stage 1: Initiation[4] - Stage 2: Pest risk assessment especially of plants for planting as the main source of infestation and economic impact on their intended use - Stage 3: Pest risk management
ISPM No. 3 (2005)	*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*	Specific guidance on pest risk management for biological control agents and beneficial organisms[5]

2.2 Summary of PRA Stage 2: Pest risk assessment

Stage 2 involves several steps:

- pest categorization: the determination of whether the pest has the characteristics of a quarantine pest or RNQP, respectively
- assessment of introduction and spread
  - candidates for quarantine pests: the identification of the endangered area and assessment of the probability of introduction and spread
  - candidates for RNQPs: assessment of whether the plants for planting are or will be the main source of pest infestation, in comparison to other sources of infestation of the area
- assessment of economic impacts
  - candidates for quarantine pests: assessment of economic impacts, including environmental impacts
  - candidates for RNQPs: assessment of potential economic impacts associated with the intended use of plants for planting in the PRA area (including analysis of infestation threshold and tolerance level)
- conclusion, summarizing the overall pest risk on the basis of assessment results regarding introduction, spread and potential 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 (Stage 3) is required.

2.3 Summary of PRA Stage 3: Pest risk management

Stage 3 involves the identification of phytosanitary measures that (alone or in combination) reduce the risk to an acceptable level.

Phytosanitary measures are not justified if the pest risk is considered acceptable or if they are not feasible (e.g. as may be the case with natural spread). However, even in such cases contracting parties may decide to maintain a low level of monitoring or audit regarding the pest risk to ensure that future changes in that risk are identified.

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 available, cost-effective and feasible.

In addition to standards for PRA (Table 1), other standards provide specific technical guidance to pest risk management options.

[4] The present ISPMs No. 11 and No. 21, adopted before this revision of ISPM No. 2, include some guidance on PRA Stage 1 for quarantine pests and RNQPs, respectively.

[5] ISPM No. 3 provides more detailed guidance appropriate to PRA Stage 1, for example with respect to the provision of necessary information, documentation and communication to relevant parties.

3. Aspects Common to All PRA Stages

3.1 Uncertainty

Uncertainty is a component of risk and therefore important to recognize and document when performing PRAs. Sources of uncertainty with a particular PRA 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.

The nature and degree of uncertainty in the analysis should be documented and communicated, and the use of expert judgement indicated. If adding or strengthening of phytosanitary measures are recommended to compensate for uncertainty, this should be recorded. Documentation of uncertainty contributes to transparency and may also be used for identifying research needs or priorities.

As uncertainty is an inherent part of PRA, it is appropriate to monitor the phytosanitary situation resulting from the regulation based on any particular PRA and to re-evaluate previous decisions.

3.2 Information gathering

Throughout the process, information should be gathered and analysed as required to reach recommendations and conclusions. Scientific publications as well as technical information such as data from surveys and interceptions may be relevant. As the analysis progresses, information gaps may be identified necessitating further enquiries or research. Where information is insufficient or inconclusive, expert judgement may be used if appropriate.

Cooperation in the provision of information and responding to requests for information made via the official contact point are IPPC obligations (Articles VIII.1c and VIII.2). When requesting information from other contracting parties, requests should be as specific as possible and limited to information essential to the analysis. Other agencies may be approached for information appropriate to the analysis.

3.3 Documentation

The principle of transparency requires that contracting parties should, on request, make available the technical justification for phytosanitary requirements. Thus, the PRA should be sufficiently documented. Documenting PRA has two levels:

- documenting the general PRA process
- documenting each analysis made.

3.3.1 Documenting the general PRA process

The NPPO should preferably document procedures and criteria of its general PRA process.

3.3.2 Documenting each specific PRA

For each particular analysis the entire process from initiation to pest risk management should be sufficiently documented so that sources of information and rationale for management decisions can be clearly demonstrated. However, a PRA does not necessarily need to be long and complex. A short and concise PRA may be sufficient provided justifiable conclusions can be reached after completing only a limited number of steps in the PRA process.

The main elements to be documented are:

- purpose of the PRA
- identity of the organism
- PRA area
- biological attributes of the organism and evidence of ability to cause injury
- for quarantine pests: pest, pathways, endangered area
- for RNQPs: pest, host, plants and/or parts or class of plants under consideration, sources of infestation, intended use of the plants
- sources of information
- nature and degree of uncertainty and measures envisaged to compensate for uncertainty
- for pathway-initiated analysis: commodity description and categorized pest list
- evidence of economic impact, which includes environmental impact
- conclusions of pest risk assessment (probabilities and consequences)
- decisions and justifications to stop the PRA process
- pest risk management: phytosanitary measures identified, evaluated and recommended
- date of completion and the NPPO responsible for the analysis, including if appropriate names of authors, contributors and reviewers.

Other aspects to be documented may include[6]:

- particular need for monitoring the efficacy of proposed phytosanitary measures
- hazards identified outside the scope of the IPPC and to be communicated to other authorities.

3.4 Risk communication

Risk communication is generally recognized as an interactive process allowing exchange of information between the NPPO and stakeholders. It is not simply a one-way movement of information or about making stakeholders understand the risk situation, but is meant to reconcile the views of scientists, stakeholders, politicians, etc. in order to:

- achieve a common understanding of the pest risks
- develop credible pest risk management options
- develop credible and consistent regulations and policies to deal with pest risks
- promote awareness of the phytosanitary issues under consideration.

At the end of the PRA, evidence supporting the PRA, the proposed mitigations and uncertainties should preferably be communicated to stakeholders and other interested parties, including other contracting parties, RPPOs and NPPOs, as appropriate.

If, subsequent to the PRA, phytosanitary requirements, restrictions or prohibitions are adopted, the contracting party shall immediately publish and transmit those to contracting parties that it believes may be directly affected (according to IPPC Article VII.2b) and on request make the rationale available to any contracting party (according to IPPC Article VII.2c).

If, subsequent to the PRA, phytosanitary requirements, restrictions or prohibitions are not adopted, contracting parties are encouraged to make this information available.

NPPOs are encouraged to communicate evidence of hazards other than pest risks (such as to animals or human health) to the appropriate authorities.

3.5 Consistency in PRA

It is recommended that an NPPO strives for consistency in its conduct of PRAs. Consistency offers numerous benefits, including:

- facilitation of the principles of non-discrimination and transparency
- improved familiarity with the PRA process
- increased efficiency in completing PRAs and managing related data
- improved comparability between PRAs conducted on similar products or pests, which in turn aids in development and implementation of similar or equivalent management measures.

Consistency may be assured through, for example, the elaboration of generic decision criteria and procedural steps, training of individuals conducting PRAs and review of draft PRAs.

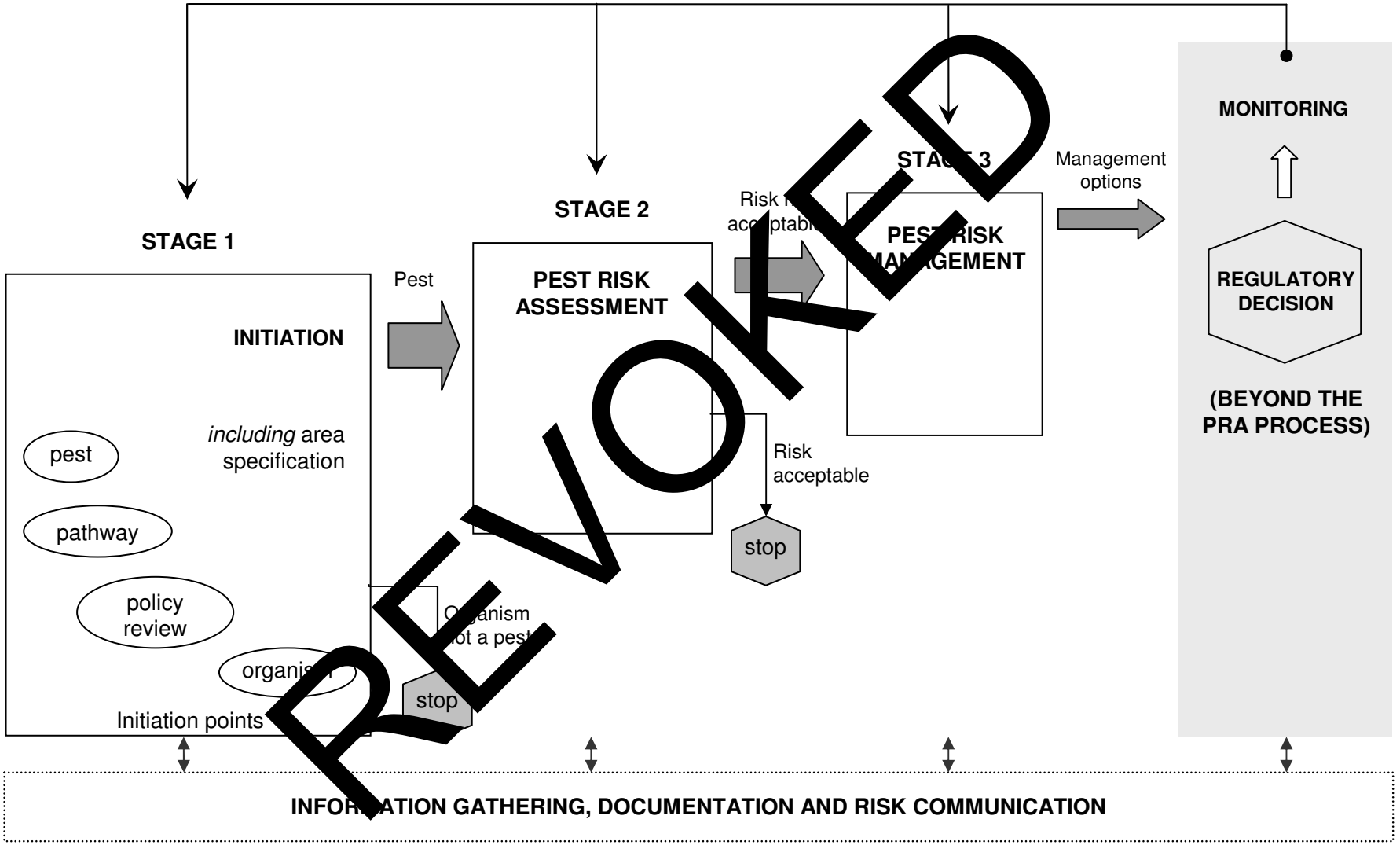
3.6 Avoidance of undue delay

Where other contracting parties are directly affected, the NPPO should, on request, supply information about the completion of individual analyses, and if possible the anticipated time frame, taking into account avoidance of undue delay (section 2.14 of ISPM No. 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006).

[6] ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, 2005) lists additional documentation requirements in relation to such organisms.

APPENDIX 1

PEST RISK ANALYSIS FLOW CHART[7]



[7] This appendix is not an official part of the standard. It is provided for information only.