NATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

NSPM: 2

Framework for Pest Risk Analysis
2013

(This standard is approved by (the NPPO and) the Quarantine Committee of Nepal, chaired by the secretary of the Ministry of Agriculture Development on 1st December 2013 and, is submitted by National Plant Quarantine Program to the National Notification Authority to be notified to the WTO member states)

Table of Contents

Abbreviations (frequently used in the standard)

APPPC – Asia Pacific Plant Protection Commission
GMO – Genetically Modified Organism
IP – Import Permit
IPPC – International Plant Protection Convention
ISPM – International Standard for Phytosanitary Measures
LMO – Living Modified Organism
MoAD – Ministry of Agriculture Development
NSPM – National Standards for Phytosanitary Measures
NPPO – National Plant Protection Organization
NPQP – National Plant Quarantine Programme
PC – Phytosanitary certificate
PFA – Pest free area
PRA – Pest Risk Analysis
PP – Plant Protection
PPD – Plant Protection Directorate
RNQP – Regulated Non Quarantine Pest
RPPO – Regional Plant Protection Organization
RSPM – Regional Standard for Phytosanitary Measures
SPS – Sanitary and Phytosanitary
WTO – World trade organization

1. Introduction

1.1 Scope

This standard provides framework on pest risk analysis (PRA) and technical and administrative process to be used by the NPPO so as to justify their phytosanitary measures. It covers 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. NSPM preparation is based on guidelines and recommendations developed within the framework of the IPPC. This standard also adopted the principles, recommendations and format of ISPM to achieve international harmonization of phytosanitary measures with the aim to facilitate trade.

1.2 References

IPPC. 1997. *International Plant Protection Convention*. Rome, IPPC, FAO.

IPPC Procedural Manual, 2006. Website: www.ippc.int/id/159891?language=en

ISPM 1. 2006. *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*. Rome, IPPC, FAO.

ISPM 2. 2007. *Framework for Pest risk analysis.* Rome, IPPC, FAO.

ISPM 3. 2005. *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*. Rome, IPPC, FAO.

ISPM 5. *Glossary of phytosanitary terms*. Rome, IPPC, FAO.

ISPM 5 Supplement 2. 2003. *Guidelines on the understanding of* potential economic importance *and related terms including reference to environmental considerations*. Rome, IPPC, FAO.

ISPM 8: *Determination of pest status in an area.* Rome, IPPC, FAO.

ISPM 11. 2004. *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*. Rome, IPPC, FAO.

ISPM 14. 2002. *The use of integrated measures in a systems approach for pest risk management*. Rome, IPPC, FAO.

ISPM 21. 2004. *Pest risk analysis for regulated non-quarantine pests*. Rome, IPPC, FAO.

Plant Pest Risk Analysis Reference Manual (2004, November Edition) Compiled by Biosecurity Australia. 185 pp

Plant Protection Act, 2007, NPQP, PPD, Nepal

Plant Protection Regulation, 2010. NPQP, PPD, Nepal

WTO. 1994. *Agreement on the Application of Sanitary and Phytosanitary Measures*. Geneva,

World Trade Organization.

1.3 Definitions

Definition of phytosanitary terms used in the present standard can be found in ISPM 5 (*Glossary of phytosanitary terms*) and PP Act, 2007 and Regulation, 2010.

1.4 Outline of requirements

The PRA is the only mechanism by which NPPO can justify any regulatory actions taken against trading partners. PRA is a technical tool developed by the ISPM of IPPC and recognized by WTO/SPS Agreement as a decision-making process for analyzing the pest risk. Pest Risk Analysis (PRA) is done to protect the country's agriculture from damages that can be caused by harmful (quarantine) pests which can be brought in along with imported commodities.

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 administrative process and 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 NSPM: "Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms" and NSPM: "Pest risk analysis for regulated non-quarantine pests" 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 being 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 this standard.

2. Background

PRA is the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it. The unwanted pests may be introduced into the country through potential carriers such as people, commodities and conveyances. For excluding foreign pests, recognition of these risks measures should be reflected in quarantine legislation to control the movement of consignments as a way of protecting plant life and health. All these quarantine policy and risk management measures should be based on risk analysis to minimize the trade barrier.

NPPO and quarantine authorities have the mandate for protecting the plant resources, (both natural and cultivated) of their countries from invasive pests entering from outside their borders. Nepal being the contracting party of IPPC and member country of WTO/ SPS attempts to prevent the international spread of plant pests through the application of phytosanitary measures.

These measures should be based on pest risk analysis for technical justification and scientific evidence to determine whether an organism is a pest.

PRA can be regarded as a process to answer the following questions:

- Is the organism a pest?
- What is the likelihood of introduction, establishment and spread?
- How much economic (including environmental and social) damage (unacceptable impacts) does it cause?
- What can be done to mitigate unacceptable impacts?

PRA is conducted

- To evaluate and manage risk from specific pests and internationally traded commodities
- Identify and assess risks to agricultural and horticultural crops, forestry and the environment from plant pests
- To create lists of regulated pests
- To produce lists of prohibited plants and plant products
- To assist in identifying appropriate management options

NPPO may use PRA for a variety of reasons-

- Analyzing risks associated with specific organisms as a pest
- Analyzing risks associated pathways
- Analyzing risks associated 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
- Supporting new policies or changes to existing policies

The standard does not cover the analysis of risks beyond the scope of the IPPC.

This standard provides administrative process to be followed while preparing PRA report and detail guidance on PRA stage 1 and issues generic to all PRA stages, and refers to other ISPM / NSPMs (identified in Table 1) as appropriate for further analysis through PRA stages 2 and 3. This standard is conceptual and is not a detail operational or methodological guide for assessors. An

Overview of the full PRA process is illustrated in Appendix 1 and weed risk assessment in Appendix 2.

The standard recognizes three main technical stages in a PRA:

- Stage 1: Initiation of the analysis;

- Stage 2: Risk assessment -the scientific evaluation of the biological risk and potential consequences; and

- Stage 3: Risk management - a process of determining appropriate measures to reduce risk.

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.

Provisions of the IPPC regarding pest risk analysis
The International Plant Protection Convention (IPPC, Article VII.2(a)) requires that: "Contracting parties shall not , under their phytosanitary legislation, take any of the measures specified in paragraph 1 of this Article unless such measures are made necessary by phytosanitary considerations and are technically justified."
Article VI.1(b) 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.2(f) 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.3(c)), 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.

3. General requirements

3.1 Regulation/ Authority

The Plant Protection Act, 2007 in Article V. 17(1) refers to conduct PRA for determining the regulated pests. The PP Act also states the notifying the regulated pests in Gazette (Article V. 17(2)). The PP Regulation, 2010 in Article II 3(b) prescribes conducting PRA for LMO and GMO

for the application of import measures for such.

The NPPO shall be the sole authority to conduct and to forward the final PRA to Plant Quarantine Committee for the approval, publication of final PRA and enforcement of import phytosanitary regulation as per risk analysis

3.2 Administrative process

- **PRA Methodology**: For conducting PRA, the methodologies should be followed as instructed in the National Standard, that is in consistent with the relevant ISPM 5 and the requirements of WTO/ SPS Agreement.

- **Communication with stakeholders**: NPPO should maintain a register of stakeholders to assist effective consultation and communication. Stakeholders may be government organization, NPPO members, individual growers and commercial growers or industry groups.

3.2.1 Initiation

- **PRA request**: Requests for PRA seeking to export by the relevant government authorities or industry organization may arise or through application to NPPO for import permit for a new commodity or review of policy.

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 4.1):

- 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.

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.

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).

The initiation stage involves four steps:

- determination whether an organism is a pest (section 4.2)

- defining the PRA area (section 4.3)

- evaluating any previous PRA (section 4.4)

- conclusion (section 4.5).

3.2.2 Scheduling and scoping

- **PRA work program**: NPPO should examine proposals or request to determine which one requires PRA. Required PRA should be scheduled, taking into factors as qualified PRA experts, resources & availability of information necessary to support the analysis.

- NPPO should notify about PRA work program with status currently underway to stakeholders through mail, letter or website. Provision should be made for changing priorities, research needs and resource constraints.

3.2.3 Consultations with other agencies

- NPPO should closely work with relevant organization/ agencies on PRA work program & an arrangement for PRA that reflects MOU between agencies.

3.2.4 Formation of a PRA team

- PRA team members should be able to analyze with sound scientific judgment as per the objectives. A team of experts, including all disciplines (pathologist, entomologist, nematologist, weed scientist) should be formed for conducting PRA. Such expertise should understand PRA and may be drawn from variety of places as government agencies, industry, scientific research organization, academic, private consultant. Information source should be collected by PRA team so as to prepare the pest list for developing the draft PRA.

3.2.5 Stakeholders consultation

- When work on draft PRA is about to commence, NPPO should comment with variety of stakeholders for getting information & viewpoints.

3.2.6 Peer review

- Before finalizing either the draft or the final PRA report, the team may seek advice from independent peer reviewers

3.2.7 Notification of draft PRA to WTO

- The PRA draft should be notified to WTO for the comments

3.2.8 Preparation of final report

- PRA team identifies needs to make significant changes to analysis in finalizing report.

2.9 Approval of PRA report

- The PRA team submits the final report to NPPO along with the parameters for import and recommendations are forwarded to PQC (Plant Quarantine Committee) for the approval for a policy determination

3.2.10 Final publications of import regulations

- The import regulation are then published in Nepal gazette, notified to WTO and also placed on website for public

4. Technical Process

4.1 Development of resources

The PRA experts should be provided with National pest database, pest information and access to international databases to work with.

4. 2 Sources of information

It is important to ensure that the information used to support the PRA is both reliable and relevant. The information should be verifiable and retrievable at a later date. Information sources should be properly cited in the PRA. In addition to the information provided by the exporting country's NPPO (which can include official pest lists and pest reports) other sources of scientific information may include:

- published scientific literature, such as reference books and journals
- previous PRAs (national or international) and/or PRAs from similar pests or pathways
- official files, published and unpublished reports and other correspondence from plant health and quarantine authorities, information from RPPOs
- pest or commodity databases (e.g. CAB International Crop Protection Compendium, and CAB International Forestry Compendium), and other abstract compilation services
- climate data, maps, and models
- crop production data from the PRA area
- pest and disease interception databases from quarantine authorities
- data on control or mitigation measures
- pest records and pest reports
- the internet and online information sources and list servers

- reference collections of plants, insect pests and plant pathogens of agricultural importance
- trade data
- expert judgment (consultation with botanists, entomologists, nematologists, pathologists, plant health and quarantine officers and other experts)
- national IPPC contact points
- environmental impact assessments

4.3 Pest database

The pest database of commodities should be documented for the information in conducting risk assessment and to provide trading partners on request (see Table 4).

5. PRA Stage 1: Initiation

The PRA process begins with the initiation stage. Initiation is the identification of organisms and pathways that may be considered for pest risk assessment (Stage 2).

PRA may be initiated as a result of:

- identification of a pathway that presents a potential pest risk (i.e. is a means of pest introduction or spread)
- identification of a pest that may require phytosanitary measures (pest may have been detected or intercepted, a request made to import it, or it may have been reported elsewhere)
- review or revision of existing phytosanitary policies and priorities
- identification of an organism not previously known to be a pest (such as an ornamental plant, a biological control agent or LMO)

PRA's are most often initiated following a request for market access

5.1 Initiation points

5.1.1 Identification of a pathway

Any means that allow the entry or spread of a pest could be a pathway eg.

- An imported commodity (A commodity is a plant or plant product being moved for trade or other purposes)
- a means of transportation or storage

- packaging, or other articles associated with the commodity
- a natural means of spread (e.g., wind)

A requirement for a new or revised PRA originating from a specific pathway will most frequently arise in the following situations:

- A request to import something that has not previously been imported from the proposed country of origin
- New plant species are imported for selection and scientific research purposes.
- A pathway other than commodity import is identified (natural spread, mail, garbage, passenger's baggage etc.)
- A different end-use is proposed for a commodity that is already being imported

  Potato tubers for propagation vs. consumption
- A new treatment is proposed for a commodity that is already being imported
- An interception is made
- Live pests are found on a previously unidentified pathway or commodity

The pathway should be defined as precisely as possible. A list of pests likely to be associated with the pathway (e.g. carried by the commodity) may be generated. This is commonly referred to as a pest list. When a PRA is carried out for a commodity, records of actual pest interceptions should be used to form the basis of the pest list. Regulated pest lists are produced in order to inform other countries of the plant quarantine import requirements of the NPPO. In developing a pest list for a PRA, it may be helpful to examine regulated pest lists of the exporting country to determine if a pest is present or not, and if present is under official control. If no potential quarantine pests are identified as likely to follow the pathway, the PRA may stop at this point and the rationale should be recorded.

Compilation of commodity pests lists (bacteria, fungi, nematodes, viruses, mycoplasms, insects, mites, mollusks & weeds) needs to be developed as per the guidelines provided by ISPM No.8 " Determination of pest status in an area". -

5.1.2 Identification of a pest

A new or revised PRA may become necessary as a result of identification or a report of a specific pest, for example:

- An emergency arises on discovery of an established infestation or an outbreak of a new pest within the PRA area
- An emergency arises on interception of a new pest on an imported commodity
- A new pest is identified by scientific research

- A pest is reported to be more injurious than previously known.
- There is a change in the status or incidence of a pest in the PRA area.
- A pest is introduced into an area
- A pest is reported to be more damaging in an area other than in its area of origin
- A pest is repeatedly intercepted
- A request is made to import an organism for research or other purpose
- An organism is identified as a vector for other pests
- An organism is genetically altered in a way that impacts its potential to be a pest of plants.

5.1.3 Review of phytosanitary policies

A requirement for a new or revised PRA originating from policy reviews may arise in the following situations:

- an NPPO decides to review its phytosanitary regulations, requirements or operations.
- an official control program is developed to avoid unacceptable economic impact of specified regulated non-quarantine pests (RNQPs) in plants for planting.
- a proposal made by another country or by an international organization is reviewed.
- a new treatment is developed or proposed, an approved treatment process becomes unavailable due to regulatory, economic or technical reasons, or new treatment information on an existing treatment influences an earlier decision.
- a dispute arises over a phytosanitary measure.
- the phytosanitary situation in a country changes, a new country is created, or political boundaries are changed.

A request for a PRA may also arise if a country's policies differ from those of another country relative to a specific commodity which is proposed for trade.

5.1.4 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 that 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 4.2 provides further guidance in this matter.

5.2 Determination of an organism as a pest

Many kinds of organisms may come to the attention of an NPPO, either by way of their association or potential association, with plants and plant products, or as a result of a request to import or export a product. Before commencing the pest risk assessment stage of the PRA, it is necessary to determine if the organism is a pest according to the IPPC definition. The taxonomic identity of the organism should be specified so that 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 analyzed, 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 5.2.4.

5.2.1 Plants as pests

Plants as pests may also be introduced unintentionally into a country, for example as weeds, 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 flora, and may become pests for that reason. For further information details is provided in NSPM: pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms.
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.

5.2.2 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 organisms3. 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.

5.2.3 Organisms difficult to identify or new to science

During inspection of imported consignments or during surveillance, organisms may be detected that are difficult to identify (e.g., damaged specimens or unidentifiable life stages) or are new to science. Although in such cases the information available may be very limited, a decision may need to be made as to whether phytosanitary action is justified. When organisms have been detected that are difficult or impossible to identify, recommendations for phytosanitary measures may have to be made based on incomplete identification or information. 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.

5.2.4 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 a 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 NSPM: pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms. A PRA may be carried out to determine whether the LMO is a pest, and subsequently assess the pest risk.

5.2.5 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.

5.3 Defining the PRA area

The PRA may be a whole country, part of a country or several countries together. It is important that the PRA clearly define the area to which it applies, and that all considerations in the PRA (i.e., assessment of potential distribution or potential impacts, consideration of other influences, or evaluation of phytosanitary measures) apply to the same area.

5.4 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.

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.

5.5 Conclusion of the initiation stage

At the end of Stage 1, the pests and pathways of concern have been determined and the PRA area identified. Relevant information has been gathered, pathways and pests have been identified for further assessment either commodity wise (pathway) or individually (pest wise).. If the pests need to be regulated as an RNQP, the process may proceed immediately to the pest categorization step of pest risk assessment (PRA stage 2) of NSPM pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms
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Organisms that have been determined not to be pests, and pathways not carrying pests, do not need to be assessed further. The decision and rationale to stop the PRA at this point should be recorded and communicated, as appropriate.

6. Summary of PRA Stages 2 and 3

6.1 Linked standards

The PRA process for different pest categories is described separately in NSPMs and ISPM, as summarized in Table 1.

Table 1: Standards linked to NSPM 2

NSPMs	Title	Coverage of PRA
NSPM:	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: Initiation1 - Stage 2: Pest risk assessment including environmental risks and LMO assessment - Stage 3: Pest risk management
NSPM:	Pest risk analysis for regulated non-quarantine pests	Specific guidance on PRA of regulated non-quarantine pests including: - Stage 1: Initiation1 - 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 3:	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 organisms2

6.2 Summary of PRA Stage 2: Pest risk assessment

Stage 2 of PRA is the assessment of pest risk. There are three steps to this stage:

- Step 1: pest categorization
- Step 2: assessment of the probability of introduction (entry and establishment) and spread
- Step 3: assessment of potential impacts of introduction and spread
- 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..

6.3 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.

7. Aspects Common to all PRA stages

7.1 Uncertainty

Uncertainty is inherent to any PRA as complete information is seldom available. Most

analyses performed during pest risk assessment use historical data to predict the future, andthis can result in varying degrees of uncertainty. It is a component of risk and needs to recognize and document when performing PRA.

Uncertainty can be grouped into types of uncertainty and sources of uncertainty, as described in the following table.

Type of uncertainty	**Possible sources of uncertainty**	**Methods to cope with uncertainty**
Uncertainty in data value	Missing data, inaccurate data, non-representative data	Collect further data, analysis of statistical properties of datasheets, validate data with observation
Structural uncertainty	Some pathways not considered, pathways described inappropriately, inadequate epidemiological models	Define limits to the risk being examined, specify assumptions, compare contrasting models, compare model outputs using different inputs

Unpredictability	Random events in complex systems, pest behaviour, human behaviour	Specify all plausible scenarios, state assumptions and subjective judgments

7.2 Information gathering

Information gathering is essential to complete all stages of a PRA.. The risk analyst will

need to judge all of the information needed 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 judgment may be used if appropriate.

Cooperation in the provision of information and responding to requests for information should be made through the SPS enquiry point, DFTQC (Department of food technology and quality control)as per IPPC obligations (Articles VIII.1(c) 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.

7.3 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.

7.3.1 Documenting the general PRA process

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

7.3.2 Documenting each specific PRA

For each particular analysis, the entire process from initiation to pest risk management should be sufficiently documented so that the 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 include4:

- 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.

7.4 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.

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

7.5 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 PRA, and review of draft PRAs.

7.6 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 1:2006).

Appendix 1: Pest risk analysis flow chart

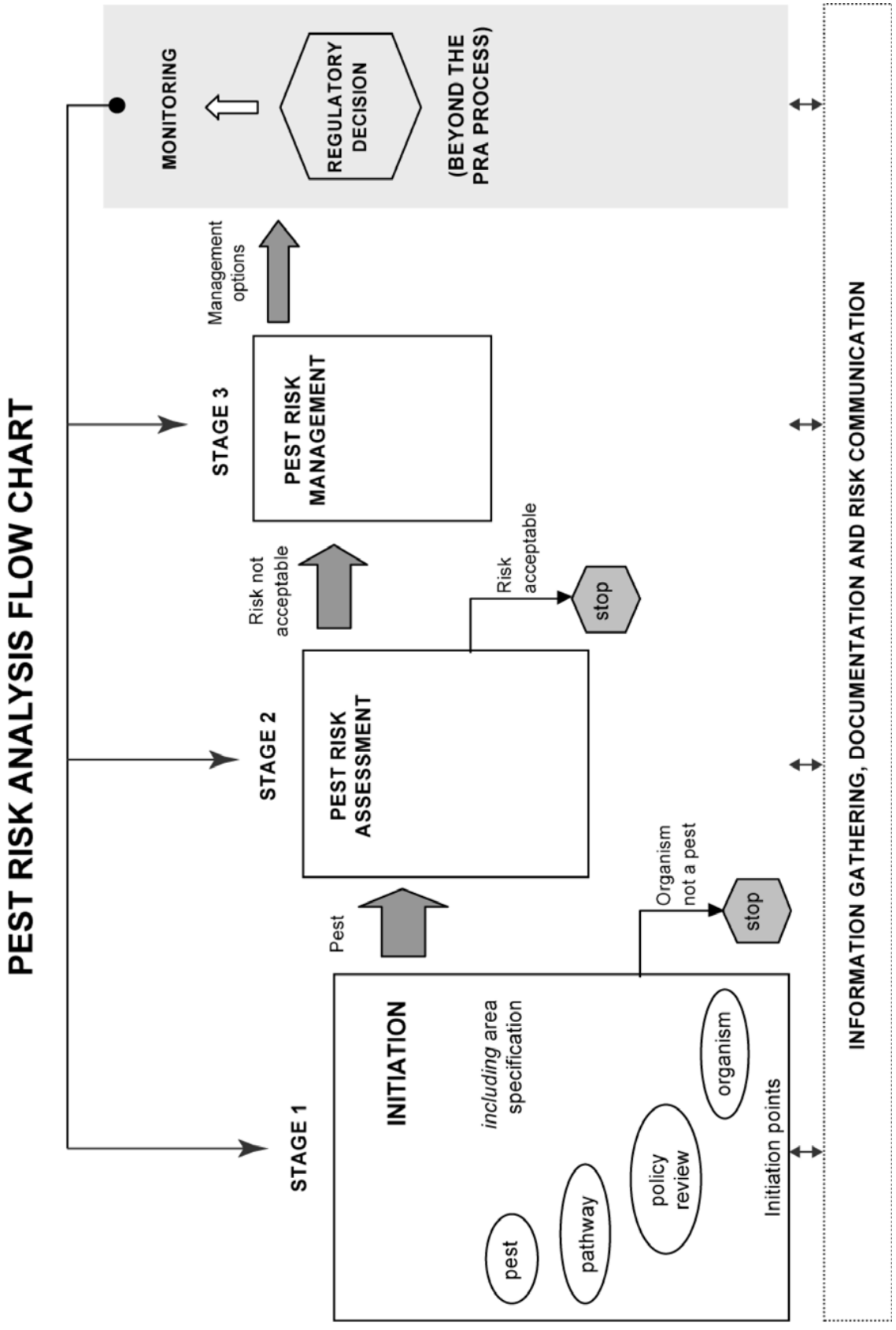
Appendix 2: Weed Risk Analysis Flowchart

Table 2: Example of Listing Potential Quarantine Pests of Ginger as carried out by Nepal PRA

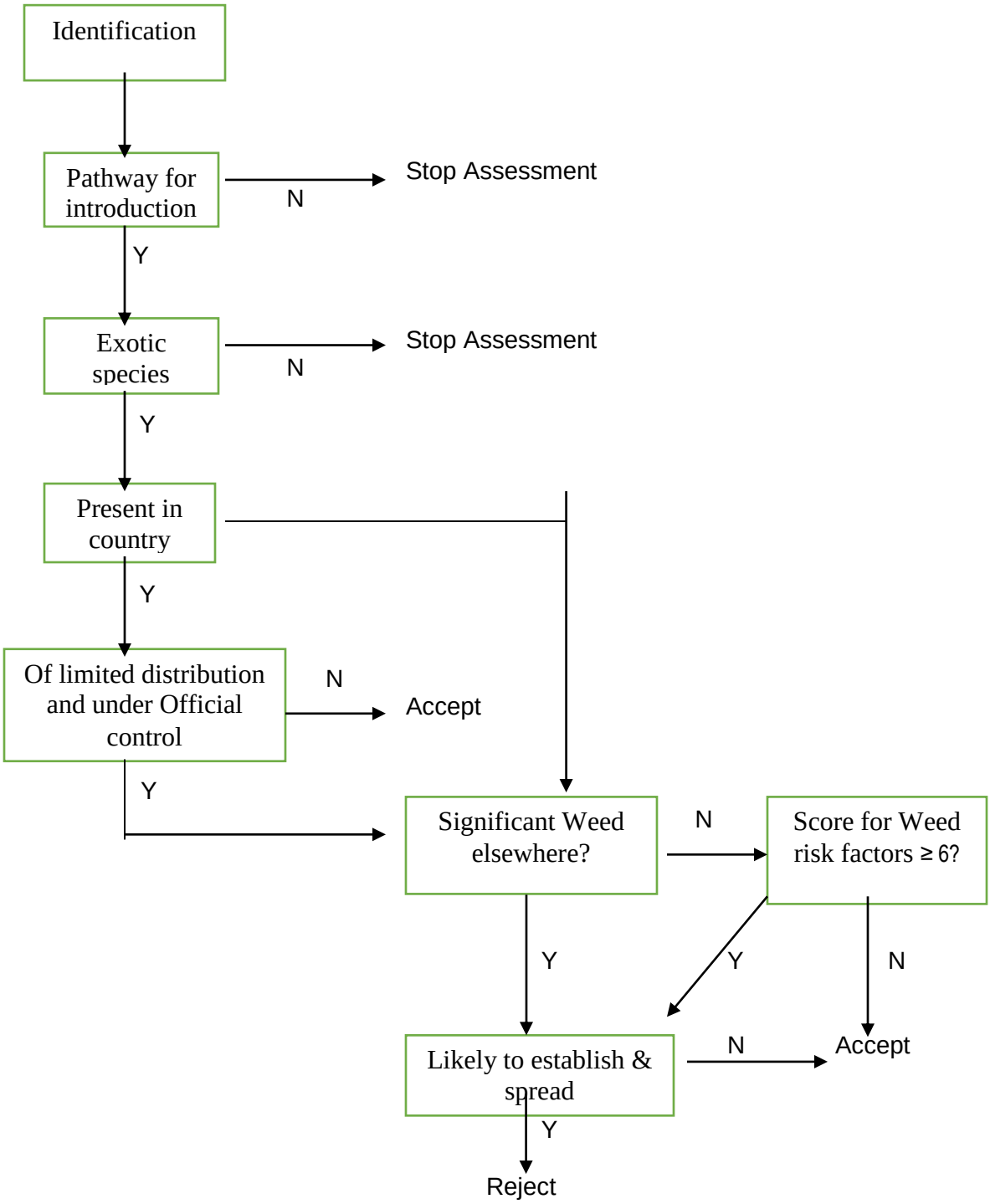
Table 3: Example of categorization of certain pest for a risk analysis for the importation of citrus

Table 4: Refers to a pest database of apple as documented by NPPO of Nepal.

Appendix 1: Pest risk analysis flow chart



Appendix 2: Weed risk analysis flowchart



Y= Yes
N= No

Table 2: Example of Listing Potential Quarantine Pests of Ginger as carried out by Nepal PRA

Global pests in CPC (A)	Nepal Pests in NPD (B)	Pests of Nepal in CPC (C)	Pests reported in literatures in Nepal (D)	Potential Quarantine pests for Nepal (A-(B+C+D)
Adoretus sinicus Burmeister (rose beetle) Coleoptera: Scarabaeidae	*Calobata* sp. Diptera: Micropezidae	*Aleurocanthus woglumi* Ashley (citrus blackfly) Hemiptera: Aleyrodidae	*Brahmina coriacea*(Hope) Coleoptera: Scarabaeidae	*Adoretus sinicus* Burmeister (rose beetle) Coleoptera: Scarabaeidae
Adoretus versutus Harold (rose beetle) Coleoptera: Scarabaeidae	*Conogethes punctiferalis* (Guenee) (castor capsule borer) Lepidoptera: Crambidae	*Aspidiotus destructor* Signoret (coconut scale) Hemiptera: Diaspididae	*Lasioderma serricorne* Fabricius (cigarette beetle) Coleoptera: Anobiidae	*Adoretus versutus* Harold (rose beetle) Coleoptera: Scarabaeidae
Aleurocanthus woglumi Ashley (citrus blackfly) Hemiptera: Aleyrodidae	*Dorylus orientalis*Westwood Hymenoptera: Formicidae	*Atherigona orientalis* Shiner (pepper fruit fly) Diptera: Muscidae	*Stegobium paniceum* (Linnaeus) (drugstore beetle) Coleoptera: Anobiidae	*Aspidiella hartii* (Cockerell) (yam scale) Hemiptera: Diaspididae

Table 3: Example of categorization of certain pest for a risk analysis for the importation of citrus

Scientific name	Common name	Present in exporting country (Yes/No)	Present in importing country (Yes/No)	Associated with commodity (pathway)	Consider further (Yes/No)
Elsinoe fawcetti	Citrus scab	Yes	No	Yes (infects fruit, leaves and twigs)	Yes
Bactocera dorsalis	Oriental fruitfly	Yes	Yes	Yes (infects fruits)	Yes
Candidatus liberibacter asiaticus	Huanglongbing	Yes	Yes	Yes (live host plants, stem ,leaves)	No

Table 4: Refers to a pest database of apple as documented by NPPO of Nepal.

Pest Category	Scientific Name of Pest	Common Name of Pest	Common Name of Host	Plant Parts Affected	Location	Symptom	Collector	Identifier	Verifier
Insecta	*Actias selene*	Luna moth	Apple	Stems, Leaves	Central Region, Kathmandu, Kathmandu	Leaf defoliation.	K.C. Sharma	Not Reported	Not Reported
Insecta	*Adoretus limbatus*		Apple	Not reported	Central Region, Kathmandu, Kakani	Not reported.	D.R. Sharma	Not Reported	Not Reported
Insecta	*Anomis mesogona*		Apple	Leaves	Central Region, Kathmandu, Kirtipur	Not reported.	K.C. Sharma	Not Reported	Not Reported
Insecta	*Aphis gossypii*		Apple	Stems, Leaves, Flowers & Inflorescence	Not known	Leaves: abnormal colours; abnormal forms; wilting; honeydew or sooty mould.	Not Reported	Not Reported	Not Reported