NATIONAL STANDARDS FOR PHYTO SANITARY MEASURES

NSPM: 21

Pest risk analysis for regulated non-quarantine pests

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)
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1. Introduction

1.1 Scope

Pests that are not of quarantine value but require phytosanitary measures because of their ability to cause economically unacceptable damage are known as regulated non-quarantine pests (RNQPs). This standard describes procedures for evaluating biological and other relevant scientific and economic features for RNQPS, so as to determine whether the pest under observation should be regulated. Based on the result of this initiation, evaluation of appropriateness of available integrated phytosanitary measure for the selection of appropriate risk management options for RNQPs should be done. NSPM preparation 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

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994 World Trade Organization, Geneva

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome


Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.


1.3 Definitions
Definitions of phytosanitary terms used in this standard are as defined in ISPM No. 5 (Glossary of phytosanitary terms)

1.4 Outline of requirements
The PRA for RNQP will not be same as in quarantine pest. PRA for regulated non-quarantine pests (RNQPs) should be done either on specified area or specified pest. The PRA design should especially focus on, identification of pests associated with plants for planting, followed by risk assessment and identification of appropriate risk management options (Ref ISPM 16 and NSPM: pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms) and process need to be applied along with the Identification and categorization of individual pests to find out if the pest infestation is above the economically acceptable level.

2. Background
In general, studies done in the past show that the loss due to pest and diseases in agriculture both in pre and post harvest operations is in the range of 25-30 percentages in Nepal. Certain pests though are not of quarantine value but their presence in plants for planting can results in economically unacceptable impacts on those plants and often are widespread in the country, and so their economic impact need to be assessed.

The objectives of PRA for RNQPs are, to identify pests associated with plants for planting, to evaluate their risk and, identify appropriate, risk management options to achieve a tolerance level. Phytosanitary measures for RNQPs should be technically justified (IPPC 1997). The classification of a pest as an RNQP and any restrictions placed on the import of the plant species with which it is associated should be justified by PRA.

In this context, it is necessary to clarify that plants for planting are a pathway for the pest and also the main source of infestation (transmission pathway) of the pest that results in an economically unacceptable impact. It is not necessary to evaluate the
probability of establishment or the long-term economic impact of an RNQP. ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1 (Guidelines on the interpretation and application of the concept of official control for regulated pests), and the ISPM No. 16 (Regulated non-quarantine pests: concept and application); should be taken into account while carrying out PRA. Market access (i.e. access to export markets) and environmental effects are not considered relevant for RNQPs, since RNQPs are already present.

Further understanding of certain terms in the definition of RNQP may be important for the application of this standard.

2.1 Intended use and official control

2.1.1 Intended use
The intended use of plants for planting may be:

- growing for direct production (e.g. fruits, cut flowers, wood, grain)
- multiplication of plants for planting (e.g. tubers, cuttings, seeds, rhizomes)
- plants planted for amenity, aesthetic or other use (e.g. ornamentals);

Multiplication of plants for planting may include the production of different classes of plants for planting within a certification scheme, (e.g. plant breeding or for further propagation). In PRA for RNQPs, such a differentiation may be especially relevant in determining damage thresholds and pest risk management options.

2.2 Official control
In case of RNQP the word “Regulated” refers to official control. RNQPs are subject to official control in the form of phytosanitary measures for their suppression in the specified plants for planting. Principles and criteria of official control for regulated pests include:

- non-discrimination
- transparence
- technical justification
- enforcement
- Mandatory nature
- area of application
- NPPO authority and involvement.
3. Requirements

3.1 Pest risk analysis for regulated non-quarantine pests
Pest risk assessment in case of RNQPS needs to be made as simple as is technically justified by the circumstances adopting the principles of necessity, minimal impact, transparency, equivalence, risk analysis, managed risk and non-discrimination (ISPM No 1).

Stage-1

4. Initiation
Initiation stage is to identify the pests of specified plants that need to be regulated and that should be considered for risk analysis in relation to the intended use of the plants for planting in the identified PRA area.

4.1 Initiation point
The PRA process for RNQPs may be initiated when the following situation occurs:

- identification of plants for planting that could act as a pathway for potential RNQPs
- the identification of a pest that could qualify as an RNQP
- the review or revision of phytosanitary policies and priorities, including phytosanitary elements of official certification schemes

4.1.1 PRA of plants for planting that could act as a pathway for RNQPs
A new or revised PRA for plants for planting may be done when:

- new species of plants for planting are considered for regulation
- a change in susceptibility or resistance of plants for planting to a pest is identified

Pests list should be prepared using information from official sources, databases, scientific and other literature or expert consultation. It may be preferable to prioritize the list based on expert judgment. If no potential RNQPs are identified as likely to be associated with the plants for planting, the PRA may stop at this point.

4.1.2 PRA initiated by a pest
A new or revised PRA on a pest associated with plants for planting may arise when:

- Identification, through scientific research, of a new risk posed by a pest (e.g. there is a change in pest virulence, or an organism is demonstrated to be a pest vector)
- change in the prevalence or incidence of a pest
• change in pest status (e.g. a quarantine pest has become widely distributed, or is no longer regulated as a quarantine pest)
• presence of a new pest, not appropriate for regulation as a quarantine pest

4.1.3 PRA initiated when Phytosanitary policy is revised
A new or revised PRA should be carried out when:

• official control program (e.g. certification scheme, governments directives in import /export process ) to avoid unacceptable economic impact of specified RNQP(s) in plants for planting in the specified area is changed
• phytosanitary requirements to import of plants for planting that are already regulated in the PRA area is amended
• there is the availability of a new system, process, plant protection procedure, or new information that could influence a previous decision (e.g. a new treatment or loss of a treatment, or a new diagnostic method)
• a decision is taken to review phytosanitary regulations, requirements or operations (e.g. a decision is made to reclassify a quarantine pest as an RNQP)
• a proposal made by another country, by a regional organization (RPPO) or by an international organization (FAO) is assessed
• a dispute arises on phytosanitary measures.

4.2 Identification of the PRA area
The PRA area should be identified in order to define the area to which official control is or is intended to be applied.

4.3 Information
Information on the identity of the pest, its distribution, economic impact and association with the plants for planting including information as required to reach necessary decisions in PRA process should be collected. The information sources can be (Annual reports/ journals/ proceedings of seminars, individual reporting / IPM farmers’ group Agro Eco System Analysis (AESA) report and reports of various relevant institutions in plant Protection)

4.4 Review of previous PRAs
If there is a previous PRA for an RNQP, its validity should be verified taking into account that the circumstances may have changed.

4.5 Conclusion of initiation
At the end of the initiation phase recommendation for next phase of the PRA process should be made if the Pest identified are defined as potential RNQPs.
Stage- II

5. Pest risk assessments
The three interrelated steps include:

- pest categorization
- assessment of the plants for planting as the main source of pest infestation
- assessment of economic impacts associated with the intended use of the plants for planting

5.1 Pest categorization
After the identification of the pest, individual pest categorization as RNQPs should be done adopting the categorization process for PRA. Pest categorization helps to eliminate pest not requiring PRA. An advantage of pest categorization is that it can be done with little evidence. However, the evidence should be sufficient to carry out the categorization adequately.

5.1.1 Elements for categorization
The elements for categorization of a pest include the following:

- identity of the pest, host plant, part of plant under consideration and the intended use
- association of the pest with the plants for planting and the effect on their intended use
- pest presence and regulatory status
- Indication of economic impact(s) of the pest on the intended use of the plants for planting.

5.1.1.1 Identity of the pest, host plant, part of plant under consideration and the intended use
The following should be clearly defined:

- the identity of the pest
- the host plant that is regulated or potentially to be regulated
- the plant part(s) under consideration (cuttings, bulbs, seeds, plants in tissue culture, rhizomes etc.)
- the intended use

For the pest as well as for the host, the taxonomic unit is generally the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In the case of levels below the species (e.g. race), this should include evidence demonstrating that factors such as difference in virulence, host range or
vector relationships are significant enough to affect the phytosanitary status. Similarly, in the case of levels below the species e.g. variety, there should be evidence demonstrating that factors such as difference in host susceptibility or resistance are significant enough to affect the phytosanitary status. Taxa for plants for planting above the species level (genera) or unidentified species of known genera should not be used unless all species in the genus are being evaluated for the same intended use.

5.1.1.2 Association of the pest with the plants for planting and the effect on their intended use
Pest should be categorized taking into account its association with the plants for planting and the effect on the intended use. Where a PRA is initiated by a pest, more than one host may have been identified. Each host species and the plant part under consideration for official control should be assessed separately.

If from the categorization it is found that the pest is not associated with the plants for planting or the plant part under consideration or does not affect the intended use of those plants, the PRA may stop at this point.

5.1.1.3 Pest presence and regulatory status
If the pest is present and if it is under official control (or being considered for official control) in the PRA area, the pest may meet the criteria for an RNQP and the PRA process may continue.

If the pest is not present in the PRA area or is not under official control in the PRA area or not expected to be under official control in the near future, the PRA process may stop at this point including if there is Indication of economic impact(s) of the pest on the intended use of the plants for planting.

5.1.2 Conclusion of pest categorization
If the pest has the potential to be an RNQP, and meets all the criteria to be RNQPS causing unacceptable economic impact and also plants for planting are a pathway, and it is present in the PRA area. Further, it is expected to be under official control with respect to the specified plants for planting the PRA process should continue. If a pest does not fulfill all the criteria for an RNQP, the PRA process may stop.

5.2 Assessment of the plants for planting
Because the potential RNQP is present in the PRA area, it is necessary to determine if plants for planting are the main source of pest infestation of those plants. In order to do this, all sources of infestation should be evaluated and the results presented in the PRA.

The evaluation of all the sources of infestation is based on the:

- life cycle of the pest and host, pest epidemiology and sources of pest infestation
- determination of the relative economic impact of the sources of pest infestation
5.2.1 Life cycle of the pest and the host, pest epidemiology and sources of pest infestation

The identification of all the other sources of infestation is performed through the analysis of the pest and host life cycles. Different sources or pathways of pest infestation may include:

- soil
- water
- air
- other plants or plant products
- vectors of the pest
- Contaminated machinery or modes of transport
- By-products or waste.

Pest infestation and spread may occur as a result of natural movement (including wind, vectors and waterways), human action or other means from these sources of infestation. The characteristics of the pathways should be examined.

5.2.2 Determination of the relative economic impact of the sources of pest infestation

The evaluation process should address the importance of the pest infestation in the plants for planting on the epidemiology of the pest. The evaluation also should address the contribution of other sources of infestation to the development of the pest and its effect on the intended use as the importance of all these sources may be influenced by factors such as:

- the number of pest life cycles on the plants for planting (e.g. monocyclic or polycyclic pests)
- reproductive biology of the pest
- pathway efficiency, including mechanisms of dispersal and dispersal rate
- secondary infestation and transmission from the plants for planting to other plants
- climatological factors
- cultural practices, pre- and post-harvest
- soil types
- the susceptibility of the plants (e.g. young plant stages could be more or less susceptible to different pests; host resistance/susceptibility)
- presence of vectors
- presence of natural enemies and/or antagonists
- presence of other susceptible hosts
- pest prevalence in the PRA area
- impact or potential impact of the official control applied in the PRA area.
The different types and rates of pest transmission from the initial infestation in the plants for planting (seed to seed, seed to plant, plant to plant, within plant) may be important factors to consider. Their importance may depend on the intended use of the plants for planting and should be assessed accordingly. For example, the same initial pest infestation may have significantly different impacts in/on seed for further propagation or plants for planting intended to remain planted. Other factors include pest survival and controls during production, transport or storage of the plants.

5.2.3 Conclusion of the assessment of the plants for planting as the main source of pest infestation

Pests that are mainly transmitted by the plants for planting and which affect the intended use of those plants are subjected to the next stage of the risk assessment to establish when there is unacceptable economic impacts. Where plants for planting are found not to be the main source of infestation, the PRA may stop at this point.

5.3 Assessment of economic impacts on the intended use of the plants for planting

The information required to conduct an analysis is to determine if there are unacceptable economic impacts. Economic impacts may have previously been analyzed for the development of official control programs for the pest on plants for planting with the same intended use. The validity of any data should be checked as per the circumstances and available information existing scenario.

Wherever appropriate, quantitative data that will provide monetary values should be obtained. Qualitative data such as relative production or quality levels before and after infestation by the pest may also be used. The economic impact resulting from the pest may vary depending on the intended use of the plants for planting and this should therefore be taken into account. In cases where there is more than one source of infestation, the economic impact resulting from the pest on the plants for planting should be demonstrated to be the main source of the unacceptable economic impact.

5.3.1 Pest effects

Detailed information on scientific data, regulatory and other information from the national and international literature should be consulted and documented as appropriate. Most of the effects considered during the economic analysis will be direct effects on the plants for planting and their intended use.

Relevant factors in determining economic impacts include:

- reduction of quantity of marketable yield (e.g. reduction in yield)
- reduction of quality (e.g. reduced sugar content in grapes for wine, downgrading of marketed product)
- extra costs of pest control (e.g. roguing, pesticide application)
- extra costs of harvesting and grading (e.g. culling)
- costs of replanting (e.g. due to loss of longevity of plants)
- loss due to the necessity of growing substitute crops (e.g. due to need to plant lower yielding resistant varieties of the same crop or different crops)

5.3.2 Infestation and damage thresholds in relation to the intended use
Both quantitative and qualitative data should be gathered regarding the level of damage of the pest on the intended use of the plants for planting for all relevant sources of infestation in the PRA area. Determination of infestation thresholds will assist in the identification of appropriate tolerance levels at the pest risk management stage.

In cases where there is a lack of quantitative information on pest damage caused by the initial level of pest infestation in the plants for planting, expert judgment could be used on the basis of information obtained.

5.3.3 Analysis of economic consequences
Most of the effects of a pest, e.g. damage, will be of a commercial nature within the country. These effects should be identified and quantified. It may be useful to consider the negative effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices.

5.3.3.1 Analytical techniques
There are analytical techniques that can be used in consultation with expert economist to make a more detailed analysis of the economic effects of an RNQP. These should incorporate all of the effects that have been identified. (See, NSPM on Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms).

Data on the economic impact of the pest on the intended use of the plants for planting should be available and an economic analysis should be done. For some effects of the pests there may be uncertainties or variability in the data and/or only qualitative information may be available. Areas of uncertainty and variability should be explained in the PRA.

5.3.4 Conclusion of the assessment of economic consequences
The output of the assessment of economic consequences described in this step should normally be expressed in monetary value. The economic consequences can also be expressed qualitatively (such as relative profit before and after infestation) or using quantitative measures without monetary terms (such as productivity). Sources of information, assumptions and methods of analysis should be clearly specified. An assessment will need to be made as to whether the economic consequences are acceptable or unacceptable. If the economic consequences are considered acceptable then the PRA may stop.
5.4 Degree of uncertainty
Estimation of economic impact and the relative importance of sources of infestation may involve uncertainties. It is important to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where an expert judgment has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs. (Referred NSPM Frame work for PRA unpublished)

5.5 Conclusion of the pest risk assessment stage
As a result of the pest risk assessment, a quantitative or qualitative evaluation of the plants for planting being the main source of infestation of the pest and a corresponding quantitative or qualitative estimate of the economic consequences should be obtained and documented.

Measures are not justified if the risk is considered acceptable or should be accepted because it is not manageable through official control (for example, natural spread from other sources of infestation). An appropriate level of monitoring or audit is needed to maintain to ensure that future changes in the pest risk.

Where plants for planting have been identified as the main source of infestation for a pest and an unacceptable economic impact on the intended use of these plants has been demonstrated, pest risk management may be considered as appropriate (stage 3). These evaluations, together with associated uncertainties, are utilized in the pest risk management stage.

Stage 3

6. Pest Risk Management
The conclusions from pest risk assessment should be used to decide whether risk management is required or not. If the plants for planting are assessed as being the main source of infestation of the pests and the economic impact on the intended use of those plants is found to be unacceptable (stage 2), then risk management (stage 3) is used to identify possible phytosanitary measures with the aim of suppression or reduce the risk below, an acceptable level.

The most commonly used option for pest risk management for an RNQP is the establishment of measures to achieve an appropriate pest tolerance level. The same tolerance level should be applied for domestic production and import requirements (see section 6.3 of ISPM No. 16: Regulated non-quarantine pests: concept and application)

6.1 Technical information required
The decisions to be made in the pest risk management process will be based on the information particularly the biological information. This information will be comprised of:
• reasons for initiating the process
• importance of the plants for planting as a source of the RNQP
• evaluation of the economic consequences in the PRA area

6.2 Level and acceptability of risk
In implementing the principle of managed risk, the acceptable level of risk may be expressed as:

• reference to the existing acceptable level of risk for domestic production
• indexed to estimated economic losses
• expressed on a scale of risk tolerance
• compared with the level of risk accepted by other countries.

6.3 Factors to be considered in the identification and selection of appropriate risk management options
Appropriate measures should be chosen based on their effectiveness in limiting the economic impact of the pest on the intended use of the plants for planting. The choice should be based on the following considerations, which are related to international trade:

• Phytosanitary measures shown to be cost-effective and feasible and so the measure should not be more costly than the economic impact.
• Principle of "minimal impact" i.e. the measures should not be more trade restrictive than necessary.
• Assessment of existing phytosanitary requirements and so no additional measures should be imposed if existing measures are effective.
• Principle of "equivalence" i.e. If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
• Principle of "non-discrimination" and so phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area and also the phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

6.3.1 Non-discrimination
There should be consistency between import and domestic requirements for a defined pest (see ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1: Guidelines on the interpretation and application of the concept of official control for regulated pests):

• import requirements should not be more stringent than domestic requirements
• domestic requirements should enter into force before or at the same time as import requirements
• domestic and import requirements should be the same or have an equivalent effect
• mandatory elements of domestic and import requirements should be the same
• the intensity of inspection of imported consignments should be the same as equivalent processes in domestic control program
• in the case of non-compliance, the same or equivalent actions should be taken on imported consignments as are taken domestically
• tolerance level applied within a national program, and the level applied to equivalent imported material should be same. At entry point, compliance with import tolerance may be determined by inspection or testing

6.4 Tolerances
For RNQPs, the establishment of appropriate tolerances can be used to reduce the risk to an acceptable level. These tolerances should be based on the level of pest infestation (the infestation threshold) in plants for planting that result in an unacceptable economic impact. If infestation thresholds have been determined during the risk assessment stage, these should be considered in establishing appropriate tolerances. Tolerance levels should take into account appropriate scientific information including:

• intended use of the plants for planting
• biology, in particular epidemiological characteristics, of the pest
• susceptibility of the host
• sampling procedures (including confidence intervals), detection methods (with estimates of the precision), reliability of identification
• relationship between the pest level and the economic losses
• climate and cultural practices in PRA area.

The above information may be derived through reliable research and also through the following:

• experience with official control programs within the country
• experience from certification schemes
• history of imports
• data regarding interactions between the plant, the pest and the growing conditions.
6.4.1 Zero tolerance
Tolerances are indicators that, if exceeded, are likely to result in unacceptable impacts on plants for planting. Zero tolerance is not likely to be a general requirement. A zero tolerance may be technically justified in situations or combination of situations such as:

- where plants for planting are the only source of pest infestation in relation to the intended use of those plants and any level of pest infestation would result in an unacceptable economic impact (e.g. nuclear stock for further propagation, or a virulent degenerative disease where the intended use is further propagation)
- if the pest fulfils the defined criteria of an RNQP and an official control program is in place requiring zero tolerance for the same intended use for all domestic places of production or production sites. Similar requirements could be used as described in ISPM No.10 *(Requirements for the establishment of pest free places of production and pest-free production sites)*.

6.4.2 Selection of an appropriate tolerance level
Based on the above analysis, a tolerance level should be selected to avoid the unacceptable economical impact.

6.5 Options to achieve the required tolerance levels
There are a number of options that may achieve the required tolerance. Certification schemes are often useful for attaining the required tolerance and may include elements that may be relevant for all of the management options. Mutual recognition of certification schemes may facilitate trade of healthy plant material. However some aspects of certification schemes (e.g. varietal purity) are not relevant (see ISPM No. 16: *Regulated non-quarantine pests: concept and application*).

Management options may consist of a combination of two or more options (see NSPM on *The use of integrated measures in a systems approach for pest risk management*). Sampling, testing and inspection for the required tolerance may be relevant for all the management options. These options may be applied to:

- area of production
- place of production
- parent stock
- consignment of plants for planting.

6.5.1 Area of production
The following options may be applied to the area of production of the plants for planting:

- treatment
• area of low pest prevalence
• area where the pest is absent
• buffer zones (e.g. rivers, mountain ranges, urban areas)
• monitoring survey.

6.5.2 Place of production
The following options may be considered:

• isolation (place or time)
• pest free place of production or pest free production site.
• integrated pest management
• cultural practices (e.g. roguing, pest and vector control, hygiene, preceding crop, previous treatment)
• treatments.

6.5.3 Parent stock
The following options may be considered:

• treatment
• use of resistant varieties
• use of healthy planting material
• sorting and roguing
• selection of propagating material.

6.5.4 Consignment of plants for planting
The following options may be applied:

• treatment
• conditions of preparation and handling (e.g. storage, packaging and transport conditions)
• sorting, roguing, reclassification.

6.6 Verification of the tolerance levels
Maybe inspection, sampling and testing ought to be done to confirm that the plants for planting meet the tolerance level.

6.7 Conclusion of pest risk management
The conclusion of the risk management stage should be the identification of an appropriate tolerance level and Management options to achieve that tolerance level. If there are risk management options that are acceptable, these options form the basis of phytosanitary regulations or requirements.
7. Monitoring and review of phytosanitary measures
The principle of “modification” states: “As conditions change, and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of prohibitions, restrictions or requirements necessary for their success, or by removal of those found to be unnecessary.

The implementation of particular phytosanitary measures should not be considered to be permanent. The information supporting the pest risk analysis should be periodically reviewed to ensure that any new information that becomes available does not invalidate the decision taken.

8. Documentation of pest risk analysis
The whole process from initiation to pest risk management should be sufficiently documented so that when a request for the rationale for measures is received, or a dispute arises, or when measures are reviewed, the sources of information and rationale used in reaching the management decision can be clearly demonstrated.

The main elements of documentation are:

- purpose for the PRA
- pest, host, plants and/or parts or class of plants under consideration, pest list (if appropriate), sources of infestation, the intended use, PRA area
- sources of information
- categorized pest list
- conclusions of risk assessment
- risk management
- options identified