

ISPM 21



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM 21

**PEST RISK ANALYSIS FOR REGULATED
NON-QUARANTINE PESTS**

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Adoption

This standard was adopted by the Sixth Session of the Interim Commission on Phytosanitary Measures in March–April 2004.

INTRODUCTION

Scope

This standard provides guidelines for conducting pest risk analysis for regulated non-quarantine pests. It describes the integrated processes to be used for risk assessment and the selection of risk management options to achieve a pest tolerance level.

References

- IPPC.** 1997. *International Plant Protection Convention*. Rome, IPPC, FAO.
- ISPM 1.** 1993. *Principles of plant quarantine as related to international trade*. Rome, IPPC, FAO. [published 1995] [revised; now ISPM 1: 2006]
- ISPM 2.** 1995. *Guidelines for pest risk analysis*. Rome, IPPC, FAO. [published 1996] [revised; now ISPM 2: 2007]
- ISPM 4.** 1995. *Requirements for the establishment of pest free areas*. Rome, IPPC, FAO. [published 1996]
- ISPM 5.** *Glossary of phytosanitary terms*. Rome, IPPC, FAO.
- ISPM 5 Supplement 1.** 2001. *Guidelines on the interpretation and application of the concept of official control for regulated pests*. 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 6.** 1997. *Guidelines for surveillance*. Rome, IPPC, FAO.
- ISPM 10.** 1999. *Requirements for the establishment of pest free places of production and pest free production sites*. 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 16.** 2002. *Regulated non-quarantine pests: concept and application*. Rome, IPPC, FAO.
- WTO.** 1994. *Agreement on the Application of Sanitary and Phytosanitary Measures*. Geneva, World Trade Organization.

Definitions

Definitions of phytosanitary terms used in the present standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

Outline of Requirements

The objectives of a pest risk analysis (PRA) for regulated non-quarantine pests (RNQPs) are, for a specified PRA area, to identify pests associated with plants for planting, to evaluate their risk and, if appropriate, to identify risk management options to achieve a tolerance level. PRA for RNQPs follows a process defined by three stages:

Stage 1 (initiating the process) involves identifying the pest(s) associated with the plants for planting that are not quarantine pests but which may be of regulatory concern and that should be considered for risk analysis in relation to the identified PRA area.

Stage 2 (risk assessment) begins with the categorization of individual pests associated with the plants for planting and their intended use to determine whether the criteria for an RNQP are satisfied. Risk assessment continues with an analysis to determine if the plants for planting are the main source of the pest infestation and if the economic impact(s) of the pest on the intended use of those plants for planting are unacceptable.

Stage 3 (risk management) involves identifying a pest tolerance level to avoid the unacceptable economic impact(s) identified at Stage 2 and management options to achieve that tolerance.

BACKGROUND

Certain pests that are not quarantine pests are subject to phytosanitary measures because their presence in plants for planting results in economically unacceptable impacts associated with the intended use of those plants. Such pests are known as regulated non-quarantine pests, are present and often widespread in the importing country, and their economic impact should be known.

The objectives of a PRA for RNQPs are, for a specified PRA area, to identify pests associated with plants for planting, to evaluate their risk and, if appropriate, to identify risk management options to achieve a tolerance level.

Phytosanitary measures for RNQPs should be technically justified as required by the 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.

It is necessary to demonstrate that plants for planting are a pathway for the pest and that the plants for planting are the main source of infestation (transmission pathway) of the pest that results in an economically unacceptable impact on the intended use of those plants. It is not necessary to evaluate the probability of establishment or the long-term economic impact of an RNQP. Market access (i.e. access to export markets) and environmental effects are not considered relevant for RNQPs, since RNQPs are already present.

Requirements for official control are set out in ISPM 5 Supplement 1 (*Guidelines on the interpretation and application of the concept of official control for regulated pests*), and the defining criteria of RNQPs are set out in ISPM 16:2002; these standards should be taken into account in PRA.

1. Intended Use and Official Control

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

1.1 Intended use

The intended use of plants for planting may be:

- growing for direct production of other commodity classes (e.g. fruits, cut flowers, wood, grain)
- increasing the number of the same plants for planting (e.g. tubers, cuttings, seeds, rhizomes)
- to remain planted (e.g. ornamentals); this includes plants that are intended to be used for amenity, aesthetic or other use.

Where the intended use is to increase the number of the same plants for planting, this may include the production of different classes of plants for planting within a certification scheme, such as for plant breeding or for further propagation. As part of a PRA for RNQPs, such a differentiation may be especially relevant in determining damage thresholds and pest risk management options. Distinctions based on these classes should be technically justified.

Distinctions may also be made between commercial use (involving a sale or intention to sell) and non-commercial use (not involving a sale and limited to a low number of plants for planting for private use), where such a distinction is technically justified.

1.2 Official control

“Regulated” in the definition of an RNQP 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 (see section 3.1.4 of ISPM 16:2002).

Principles and criteria relevant for the interpretation and application of the concept of official control for regulated pests are:

- non-discrimination
- transparency
- technical justification
- enforcement
- mandatory nature
- area of application
- NPPO authority and involvement.

An official control programme for RNQPs can be applied on a national, sub-national or local area basis (see ISPM 5 Supplement 1).

REQUIREMENTS

PEST RISK ANALYSIS FOR REGULATED NON-QUARANTINE PESTS

In most cases, the following steps will be applied sequentially in a PRA but it is not essential to follow a particular sequence. Pest risk assessment needs to be only as complex as is technically justified by the circumstances. This standard allows a specific PRA to be judged against the principles of necessity, minimal impact, transparency, equivalence, risk analysis, managed risk and non-discrimination set out in ISPM 1:1995 as well as the interpretation and application of official control (see ISPM 5 Supplement 1).

2. Stage 1: Initiation

The aim of the initiation stage is to identify the pests of specified plants for planting that may be regulated as RNQPs and that should be considered for risk analysis in relation to the intended use of the plants for planting in the identified PRA area.

2.1 Initiation points

The PRA process for RNQPs may be initiated as a result of:

- 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.

2.1.1 PRA initiated by the identification of plants for planting that could act as a pathway for RNQPs

A requirement for a new or revised PRA for plants for planting may arise in situations such as:

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

2.1.2 PRA initiated by a pest

A requirement for a new or revised PRA on a pest associated with plants for planting may arise in situations such as:

- 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)
- detection in the PRA area of the following situations:
 - . 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.

2.1.3 PRA initiated by the review or revision of a phytosanitary policy

A requirement for a new or revised PRA for RNQPs may occur due to policy concerns arising from situations such as:

- consideration of an official control programme (e.g. certification scheme) including the strength of measures to be applied to a pest to avoid unacceptable economic impact of specified RNQP(s) in plants for planting in the PRA area
- in order to extend phytosanitary requirements to import of plants for planting that are already regulated in the PRA area
- 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.

2.2 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 and for which information is needed.

2.3 Information

Information gathering is an essential element of all stages of PRA. It is important at the initiation stage in order to clarify the identity of the pest, its distribution, economic impact and association with the plants for planting. Other information will be gathered as required to reach necessary decisions as the PRA continues.

The information for the PRA can come from various sources. The provision of official information on the situation of a pest is an obligation according to the IPPC (Article VIII.1(c)) and facilitated by the official contact points (Article VIII.2).

2.4 Review of previous PRAs

Before performing a new PRA, a check should be made as to whether the plants for planting have, or the pest has, been subject to the PRA process. PRAs for other purposes, such as for quarantine pests, may provide useful information. If there is a previous PRA for an RNQP, its validity should be verified taking into account that circumstances may have changed.

2.5 Conclusion of initiation

At the end of the initiation phase the pests associated with the plants for planting that are identified as potential RNQPs are subjected to the next phase of the PRA process.

3. Stage 2: Pest Risk Assessment

The process for pest risk assessment can be divided into three interrelated steps:

- 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.

3.1 Pest categorization

At the outset, it may not be clear which pest(s) identified in Stage 1 require(s) a PRA. The categorization process examines for each pest individually whether the criteria in the definition for an RNQP are met.

During the initiation stage a pest or a list of pests has been identified for categorization and further risk assessment. The opportunity to eliminate an organism or organisms from consideration before in-depth examination is undertaken is a valuable characteristic of the categorization process.

An advantage of pest categorization is that it can be done with little evidence. However, the evidence should be sufficient to carry out the categorization adequately.

3.1.1 Elements for categorization

The categorization of a pest as a potential RNQP in specified plants for planting includes the following elements:

- 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.

3.1.1.1 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.

This is to make sure that the analysis is performed on distinct pests and hosts, and that the biological information used is relevant for the pest, the host plant and intended use under consideration.

For the pest, 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.

Also 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. 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.

3.1.1.2 Association of the pest with the plants for planting and the effect on their intended use

The 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 it is clear from the categorization 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.

3.1.1.3 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 with respect to the identified plants for planting with the same intended use, or not expected to be under official control in the near future, the PRA process may stop at this point.

3.1.1.4 Indication of economic impact(s) of the pest on the intended use of the plants for planting

There should be clear indications that the pest causes an economic impact on the intended use of the plants for planting (see ISPM 5 Supplement 2 *Guidelines on the understanding of potential economic importance and related terms*).

If the pest does not cause an economic impact, according to the information available, or there is no information on economic impacts, the PRA may stop at this point.

3.1.2 Conclusion of pest categorization

If it has been determined that the pest has the potential to be an RNQP, that is:

- plants for planting are a pathway, and
 - it may cause unacceptable economic impact, and
 - it is present in the PRA area, and
 - it is or 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 fulfil all the criteria for an RNQP, the PRA process may stop.

3.2 Assessment of the plants for planting as the main source of pest infestation

Because the potential RNQP is present in the PRA area, it is necessary to determine whether plants for planting are the main source of pest infestation of those plants or not. 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.

In the analysis of the main source of pest infestation, consideration should be given to conditions in the PRA area and the influence of official control.

3.2.1 Life cycle of the pest and the host, pest epidemiology and sources of pest infestation

The aim of this part of the assessment is to evaluate the relationship between the pest and the plants for planting, and to identify all the other 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.

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

The aim of this part of the assessment is to determine the importance of the pest infestation associated with the plants for planting relative to the other sources of infestation in the PRA area and the intended use of those plants. Information from section 3.2.1 should be used.

The evaluation will address the importance of the pest infestation in the plants for planting on the epidemiology of the pest. The evaluation will also address the contribution of other sources of infestation to the development of the pest and its effect on the intended use. 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 may influence the evaluation of the plants for planting as the main source of infestation as compared to other sources. These may include pest survival and controls during production, transport or storage of the plants.

3.2.3 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 whether there are unacceptable economic impacts.

Where plants for planting are found not to be the main source of infestation, the PRA may stop at this point. In cases where other sources of infestation are also relevant their contribution to the damage on the intended use of the plants for planting should be evaluated.

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

Requirements described in this step indicate the information required to conduct an analysis to determine if there are unacceptable economic impacts. Economic impacts may have previously been analysed for the development of official control programmes for the pest on plants for planting with the same intended use. The validity of any data should be checked as circumstances and information may have changed.

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.

3.3.1 Pest effects

As the pest is present in the PRA area, detailed information should be available about its economic impact in that area. 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).

In particular cases, pest effects on other host plants at the place of production may be considered relevant factors. For example, some varieties or species of host plants may not be seriously affected by

an infestation of the assessed pest. However, the planting of such an infested host plant may have a major effect on the more susceptible hosts at places of production in the PRA area. In such cases the assessment of the consequences of the intended use of those plants may include all relevant host plants grown at the place of production.

In some cases, economic consequences may only become apparent after a long period of time (e.g. a degenerative disease in a perennial crop, a pest with a long-lived resting stage). Furthermore, the infestation in the plants may result in contamination of places of production with a consequential impact on future crops. In such cases the consequences on intended use may extend beyond the first production cycle.

Pest consequences such as impacts on market access or environmental health are not considered relevant factors in determining economic impacts for RNQPs. The ability to act as a vector for other pests may nevertheless be a relevant factor.

3.3.2 Infestation and damage thresholds in relation to the intended use

Data, either quantitative or qualitative, should be available 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. In cases where plants for planting are the only source of infestation, these data provide the basis for determining infestation thresholds and the resultant damage thresholds in relation to the economic impact on the intended use.

Where other sources of infestation are also relevant, their relative contribution to the total damage should be assessed. The proportion of damage caused by the pest on the plants for planting should be compared with the proportion from other sources to determine their relative contribution to the damage thresholds in relation to the intended use of those plants.

Determination of infestation thresholds will assist in the identification of appropriate tolerance levels at the pest risk management stage (see section 4.4).

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 judgement could be used on the basis of information obtained in sections 3.2.1 and 3.2.2.

3.3.3 Analysis of economic consequences

As determined above, 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.

3.3.3.1 Analytical techniques

There are analytical techniques that can be used in consultation with experts in economics to make a more detailed analysis of the economic effects of an RNQP. These should incorporate all of the effects that have been identified. These techniques (see section 2.3.2.3 of ISPM 11:2004) may include:

- *Partial budgeting.* This will be adequate, if the economic effects induced by the action of the pest to producer profits are generally limited to producers and are considered to be relatively minor.
- *Partial equilibrium.* This is recommended if, under point 3.3.3, there is a significant change in producer profits, or if there is a significant change in consumer demand. Partial equilibrium analysis is necessary to measure welfare changes, or the net changes arising from the pest impacts on producers and consumers.

Data on the economic impact of the pest on the intended use of the plants for planting should be available for the PRA area and an economic analysis may be available. 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.

The use of certain analytical techniques is often limited by the lack of data, by uncertainties in the data, and by the fact that for certain effects only qualitative information can be obtained. If quantitative measurement of the economic consequences is not feasible, qualitative information about the consequences may be provided. An explanation of how this information has been incorporated into decisions should also be provided.

3.3.4 Conclusion of the assessment of economic consequences

The output of the assessment of economic consequences described in this step should normally be in terms of a 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 tonnes of yield). 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 (i.e. little damage or damage is largely from sources other than the plants for planting) then the PRA may stop.

3.4 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 expert judgement has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs.

3.5 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 have been obtained and documented, or an overall rating could have been assigned.

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). Countries may decide that an appropriate level of monitoring or audit is maintained to ensure that future changes in the pest risk are identified.

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 of the PRA.

4. Stage 3: Pest Risk Management

The conclusions from pest risk assessment are used to decide whether risk management is required and the strength of measures to be used.

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 and thereby will reduce the risk to, or 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 16:2002).

4.1 Technical information required

The decisions to be made in the pest risk management process will be based on the information collected during the preceding stages of PRA, particularly the biological information. This information will comprise:

- 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.

4.2 Level and acceptability of risk

In implementing the principle of managed risk, countries should decide what level of risk is acceptable for them.

The acceptable level of risk may be expressed in a number of ways, such 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.

4.3 Factors to be taken into account 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 include several of the principles of plant quarantine as related to international trade (ISPM 1:1993):

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

4.3.1 Non-discrimination

There should be consistency between import and domestic requirements for a defined pest (see ISPM 5 Supplement 1):

- 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 programmes.
- In the case of non-compliance, the same or equivalent actions should be taken on imported consignments as are taken domestically.
- If a tolerance is applied within a national programme, the same tolerance should be applied to equivalent imported material, e.g. same class within a certification scheme or same stage of development. In particular, if no action is taken in the national official control programme because the infestation level does not exceed a particular level, then no action should be taken for an imported consignment if its infestation level does not exceed that same level. At entry, compliance with import tolerance may be determined by inspection or testing. The tolerance for domestic consignments should be determined at the last or most appropriate point where official control is applied.
- If downgrading or reclassifying is permitted within a national official control programme, similar options should be available for imported consignments.

In cases where countries have, or are considering, import requirements for RNQPs in plants for planting that are not produced domestically, phytosanitary measures should be technically justified.

The measures should be as precise as possible concerning the species of plants for planting (including different classes, for example within a certification scheme) and their intended use to prevent barriers to trade such as by limiting the import of products where this is not justified.

4.4 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. Tolerances are indicators that, if exceeded, are likely to result in unacceptable impacts on plants for planting. 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 programmes within the country for the plants for planting concerned
- experience from certification schemes for the plants for planting
- history of imports of the plants for planting
- data regarding interactions between the plant, the pest and the growing conditions.

4.4.1 Zero tolerance

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)

- the pest fulfils the defining criteria of an RNQP and an official control programme is in place requiring pest freedom in plants for planting (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 10:1999.

4.4.2 Selection of an appropriate tolerance level

Based on the above analysis, a tolerance level should be selected which aims to avoid an unacceptable economic impact as assessed under 3.3.4.

4.5 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 section 6.2 of ISPM 16:2002).

Management options may consist of a combination of two or more options (see ISPM 14:2002). 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.

Section 3.4 of ISPM 11:2004 also provides information on the identification and selection of risk management options.

4.5.1 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.

4.5.2 Place of production

The following options may be applied to the place of production of the plants for planting to achieve a required tolerance:

- isolation (place or time)
- pest free place of production or pest free production site (see ISPM 10:1999)
- integrated pest management
- cultural practices (e.g. roguing, pest and vector control, hygiene, preceding crop, previous treatment)
- treatments.

4.5.3 Parent stock

The following options may be applied to the parent stock of the plants for planting to achieve a required tolerance:

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

4.5.4 Consignment of plants for planting

The following options may be applied to consignment of plants for planting to achieve a required tolerance:

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

4.6 Verification of the tolerance levels

Inspection, sampling and testing might be needed to confirm that the plants for planting meet the tolerance level.

4.7 Conclusion of pest risk management

The conclusion of the risk management stage is the identification of:

- an appropriate tolerance level
- management options to achieve that tolerance level.

The result of the process is a decision on whether to accept the economic impact that could be caused by the pest. If there are risk management options that are acceptable, these options form the basis of phytosanitary regulations or requirements

Measures for RNQPs should only concern the plants for planting. Therefore only management options relating to consignments of plants for planting can be selected and included in phytosanitary requirements. Other management options such as for the parent stock, place of production or area of production may be included in phytosanitary requirements, but should be related to the tolerance which is required to be achieved. Measures proposed as equivalent should be evaluated. The information related to the efficacy of options which are proposed as alternatives should be provided on request to assist interested parties (both domestic industry as well as other contracting parties) in complying with the requirements. Confirmation that the tolerance has been achieved does not imply testing of all consignments, but testing or inspection may be used as an audit, as appropriate.

5. 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” (ISPM 1:1993).

Thus, the implementation of particular phytosanitary measures should not be considered to be permanent. After application, the success of the measures in achieving their aim should be determined by monitoring. This may be achieved by monitoring the plants for planting at appropriate times and places and/or damage levels (economic impact). 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.

6. Documentation of Pest Risk Analysis

The IPPC (Article VII.2(c)) and the principle of “transparency” (ISPM 1:1993) require that contracting parties should, on request, make available the rationale for phytosanitary requirements. 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.