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NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM 40

Principles of Pest Risk Management for the Import of Commodities

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Review

NAPPO Regional Standards for Phytosanitary Measures are subject to periodic review and amendment. The next review date for this NAPPO standard is 2019. A review of any NAPPO Standard may be initiated at any time upon the request of a NAPPO member country.

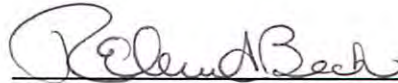
Approval

The Specifications for this standard were approved by the North American Plant Protection Organization (NAPPO) Executive Committee on February 28, 2012. This Standard was approved by the North American Plant Protection Organization (NAPPO) Executive Committee on July 28, 2014 and is effective immediately.

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Implementation

See the attached implementation plans for implementation dates in each NAPPO member country.

Amendment Record

Amendments to this Standard will be dated and filed with the NAPPO Secretariat.

Distribution

This Standard is distributed by the NAPPO Secretariat, to the Industry Advisory Group and Sustaining Associate Members, the International Plant Protection Convention (IPPC) Secretariat, and to other Regional Plant Protection Organizations (RPPOs).

Introduction

Scope

This document outlines the analytical process of risk management for identifying, evaluating, and recommending pest risk management options in the context of pest risk analysis. This standard provides detailed guidance on how to complete Stage 3 of pest risk analysis (PRA): 'pest risk management' (ISPM 2: 2007). The Standard assists National Plant Protection Organizations (NPPOs) of NAPPO member countries in identifying, evaluating and selecting appropriate risk management measures following the completion of the pest risk assessment stage (Stage 2) of a PRA. This standard focuses on managing the risk of introduction of plant pests associated with imported consignments of plants and plant products while acknowledging the risk of introduction associated with other types of pathways (e.g. packing materials, conveyances, travelers and their luggage, and the natural spread of a pest).

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Definitions

Definitions of phytosanitary terms used in the present standard can be found in NAPPO RSPM 5 and in ISPM 5.

Background

NAPPO's mission is to protect agricultural, forest and other plant resources against regulated plant pests while facilitating trade. The principles of necessity, managed risk, minimal impact, harmonization, non-discrimination, technical justification, cooperation, and equivalence as described in ISPM 1:2006 and the SPS Agreement of the WTO are all essential considerations in pest risk management. Trade disruption and disputes are often linked to perceived violations of these principles in the selection and application of phytosanitary measures.

A number of RSPMs and ISPMs provide guidance for specific risk management measures (e.g., ISPM 10: 1999; ISPM 18: 2003) or for commodity specific measures (e.g., RSPM 3: 2011; RSPM 24: 2013). This document provides guidance that is not provided in other standards on the fundamental concepts and approaches to the management of pest risks associated with the routine import of plant commodities.

Outline of Requirements

ISPM 2 was revised in 2007 to focus on Stage 1 of PRA, initiation, and ISPM 11: 2013 focuses primarily on Stage 2, pest risk assessment. The purpose of this standard is to provide guidance to assist NPPOs in identifying, evaluating and selecting appropriate risk management measures following the completion of the pest risk assessment stage of a PRA. The standard includes six components of this process; (1) sources of information, (2) identification of measures, (3) evaluation of measures, (4) selection of measures, (5) documentation and (6) monitoring and feedback.

1. General Requirements

1.1 Basis for regulating

Phytosanitary measures such as inspection, certification, treatments, systems approaches and post-entry quarantine can reduce the risk posed by the introduction and spread of pests associated with imported commodities. Increasing trade, globalization and consumer markets heighten the risk of introducing pests associated with these commodities. As a result, management of these pest risks becomes increasingly important.

1.2 Pest risk management

Pest risk management as described in ISPM 11: 2013 uses the conclusions from pest risk assessment to decide whether risk management is required and the subsequent strength of measures. According to ISPM 11: 2013, “the guiding principle for risk management should be to manage risk to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources”.

ISPM 1: 2006 states that countries shall agree to a policy based on the basic principle of “managed risk”. In implementing this principle, countries should decide what level of risk is acceptable to them. Risk management is a shared responsibility between the exporting and importing countries. Acceptable levels of risk are expressed in various ways:

- Reference to existing phytosanitary requirements for situations that pose similar risks.
- Indexed to estimated economic losses.
- Expressed on a scale of risk tolerance.

Overall risk is characterized as a combination of the probability of pest introduction and the consequences (economic or environmental) of pest introduction while also taking into account any uncertainty. If the risk is considered unacceptable, then the analytical process of risk management first identifies potential phytosanitary measures to reduce the risk to, or below an acceptable level. Measures are then evaluated for their efficacy and feasibility, and appropriate measures are selected.

The following principles should guide the selection process:

- Managed risk does not equal zero risk.
- Phytosanitary measures are shown to be cost-effective and feasible.
- According to IPPC Art. VII, 2 (g), “Contracting parties shall institute only phytosanitary measures that are technically justified, consistent with the pest risk involved and represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances”.
- Reassessment of previous 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” - if the pest under consideration is established in the PRA area but of limited distribution and under official control, the phytosanitary measures required of imports should not be more stringent than those applied within the PRA area; likewise, phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

Measures are not justified if the risk is already acceptable or must be accepted because it is not manageable (as may be the case with natural spread).

The measures that are most commonly applied to traded commodities can be classified into broad categories which relate to the pest status of the pathway in the country of origin.

These include measures:

- Applied to the consignment.
- Applied to prevent or reduce original infestation in the plant product.
- To ensure the area or place of production is free from the pest.
- Concerning the prohibition of commodities.
- Applied in the PRA area (e.g., restrictions on the use of a commodity, treatments).
- During pre and post-harvest handling

The pest risk management process concludes with the determination that there are no appropriate phytosanitary measures or with the selection of one or more pest risk management options that lower the pest risk to a level deemed acceptable level. The selected pest risk management options form the basis of phytosanitary regulations or requirements. The determinations and the process used to derive them must be clearly and thoroughly documented and communicated.

ISPM 1: 2006 notes that as phytosanitary conditions change and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of additional or different measures necessary for their success, or by removal of those found to be unnecessary. In order to fulfill this principle, the need for and efficacy of phytosanitary measures should be monitored.

2. Specific Requirements

2.1 Sources of information

A variety of sources can inform processes to identify, forecast, and assess risks associated with the import of commodities, as well as provide information on potential risk management measures. Historical records often capture precedence in cases where pests have been successfully managed in similar commodity/origin combinations. Access to historical information can be invaluable in such cases, and reinforces the importance of effective record-keeping and maintenance.

2.1.1 Pest risk assessment

Pest risk assessments provide a source, as well as record, of the relevant information necessary to develop risk management measures. Most pest risk assessments include a general overview of the pest or pathway, including basic biology, epidemiology, as well as probabilities of introduction, establishment, and natural spread. Specific mention of endangered areas (e.g., if the pest prefers a particular habitat) can suggest where to focus risk management efforts. Information on the availability of suitable or alternate hosts and vectors is useful in determining potential pest impact and spread. A cost-benefit analysis to compare potential economic consequences and costs of control methods with the benefits of managing the pest risk may be useful. Information from pest risk assessments should be cross-referenced with existing domestic and international standards.

2.1.2 Forecast/foresight

Forecasting pest threats through literature search and sharing of interception data permit effective preparation and rapid deployment of risk management measures. Given economic, resource, and trade pattern issues, this is not always feasible. Having a

proactive general risk management framework in place allows for a rapid response when new pest threats are detected. Additional inputs for effective forecasting of potential threats include pest-range modeling (including climate change where evidence exists), identification of pests associated with high-risk pathways, the specific pest's colonization and spread potential at origin, historical data of pest interceptions, etc. New trade patterns (e.g., new commodities or changed processing techniques) could also lead to possible pest introductions.

2.1.3 Non-commercial and environmental sources

An analysis of pest interceptions, including an assessment of uncertainty, provides information useful in assessing detection and control methods. Records of the extent of the infested area, the life-stage and seasonality of the pest, as well as its size and estimated age of population are all important in management of the pest.

2.1.4 Stakeholder engagement

Stakeholders affected by the pest(s) of concern should be consulted, where feasible, when developing risk management measures. Knowing stakeholder expectations in terms of pest or damage tolerance allows for the design of specific risk management measures. Consultation is also useful to identify stakeholders who should be included as part of risk communication or for information sharing purposes.

2.2 Identification of measures

The measures identified should be appropriate to the consignment type (hosts, parts of plants) and origin. In some instances, combinations of two or more measures (e.g., systems approaches) may be required to achieve an acceptable level of phytosanitary security. The measures described below include examples of those most commonly applied to traded commodities. They represent a continuum of options that may be applied throughout the production and international movement of plant products, and can be classified into broad categories:

- inspection / examination
- certification
- treatment
- surveillance and monitoring
- sanitation
- pest-free concepts
- post-entry measures
- systems approaches
- prohibition

2.2.1 Inspection/examination

Inspection is a visual examination of plants, plant products or other regulated articles (ISPM 5). Historically, inspection is the most widely used phytosanitary procedure for imported and exported commodities. Inspection as a risk management measure is most appropriate in situations where the target pest(s) are easily detected, produce characteristic signs or symptoms and present a low risk of introduction. Conversely, inspection may not be suitable for pests when several individuals are likely to be in or on one fruit, are difficult to detect, or are likely to survive in the commodity and mobile enough

to leave, find suitable hosts and mate. Guidance on the requirements and factors considered in implementing phytosanitary inspections are given in ISPM 23: 2005.

Examples of typical uses for inspections include:

- post-harvest inspection
- packinghouse inspection
- preshipment inspection
- fruit cutting (in orchard, post-harvest, or point of entry)
- point of entry inspection

2.2.1.1 Sampling

Because it is rarely feasible to inspect every article of an entire consignment, inspection for the detection of pests is based on some type of sampling. Sampling for inspection may be statistically based or dictated by operational feasibility. Sampling implies a threshold for the level of detection of infestation, infection or contamination (i.e., tolerance).

Statistically based inspections are conducted at levels corresponding to pest risk. The level of risk (i.e., threshold level of infection, infestation or contamination; tolerance) is fixed while the sample size varies according to the size of the consignment. Statistically based inspection is also referred to as biometric sampling or risk based inspection.

At times, operational feasibility may require setting a fixed inspection sample size (e.g., a percentage of each consignment). A fixed inspection rate results in variable risk as a function of variable lot size.

A fixed lot size allows both the sampling rate and the risk to be stabilized at a specific level. Guidance on sampling of consignments for inspection is given in ISPM 31: 2008.

2.2.1.2 Special examinations

In certain cases, inspection is not effective and other forms of examination are appropriate:

- Destructive sampling: For certain pests (e.g., fruit fly larvae), visual inspection may not be adequate to detect the pest. In such cases, destructive sampling methods like fruit cutting may be required.
- Laboratory examination (e.g., microscopic): Certain minute pests are not detectable by simple visual inspection and may require a more specialized laboratory examination (e.g., nematodes).
- Laboratory testing: Pests such as viruses may infect a plant without producing symptoms, or symptoms may be masked. In some cases the symptoms may not provide sufficient information to identify the pest.

2.2.2 Certification

A number of certification procedures may be considered in developing risk management protocols, including export certification (see ISPM 7: 2011). The issuance of phytosanitary certificates (see ISPM 12: 2011) confirms that the specified risk management options have been followed. An additional declaration may be required to indicate that a particular measure has been carried out. Other examples of certification measures include:

- oversight by the NPPO of the importing country
- registered or approved packinghouses

- label requirements for limited distribution
- compliance agreements with packinghouses
- bilateral work plans
- production of plants or plant parts in a certification program

2.2.3 Treatments

Treatments may be applied to the crop, field, or place of production pre-harvest for suppression, containment or eradication of pests. Treatments also may be applied to the consignment post-harvest for a number of desired effects including killing, inactivating or removing pests, or rendering pests infertile or for devitalization of a regulated article (ISPM 28: 2007).

Specified treatments could include chemical, thermal, irradiation or other physical methods and may be applied prior to export in the country of origin or upon import at the point of entry or destination. Examples of treatments may include:

- Chemical (e.g., fumigants, aerosols, mists, fogs, dusts, dips, granules, sprays)
- Thermal (e.g., hot water dip, hot air, vapor heat, cold)
- Drying
- Controlled atmospheres
- Physical methods; culling and grading (e.g., at harvest or during packing), or bagging (e.g., fruit bagged on the tree to prevent infection/infestation)
- Brushing and washing
- Irradiation (e.g., gamma, X-ray, microwave)

Irradiation is a critical option for commodities that otherwise have no treatment (as a phytosanitary treatment, irradiation need not have pest mortality as the endpoint for phytosanitary security. Treatment response options include mortality, sterilization, inactivity or devitalization. Specific guidance on the application of irradiation as a phytosanitary measure is given in ISPM 18: 2003.)

A combination of treatments may also be used.

2.2.4 Surveillance and monitoring

Surveillance and monitoring may be required during the production phase of a commodity to detect or delimit pest populations, or, for example to determine if specified pest populations levels are exceeded and require additional control measures. Surveillance and monitoring are also important components of pest risk management for measures such as pest freedom or areas of low pest prevalence. The different types and applications of surveillance and monitoring are described in ISPM 6: 1997.

2.2.5 Sanitation

Sanitation is an important component of pest risk management. In the field, sanitation might include removing fallen fruit from orchards, destroying or plowing under crop residues, or other similar activities that are designed to remove materials that may attract or harbour regulated pests. Sanitation may also be applied during or after harvest, in packing houses or before shipping, and can include removing damaged fruit or contaminants such as leaves or soil, and ensuring facilities are properly maintained and cleaned (e.g. removing residues and trash that may attract regulated pests).

2.2.6 Pest-free concepts

Pest-free concepts are described in several ISPMs (e.g., ISPM 4: 1995; ISPM 10: 1999; ISPM 26; 2006). Pest-free concepts are based on pest exclusion as a result of any combination of factors including pest management measures, cultural practices, climate, pest biology, physical geography and others. Some such concepts include:

- Pest-free area. Requirements for pest-free area status are described in ISPM 4: 1995. Pest free areas (PFA) recognize biological, physical or other natural limiting factors and effectively regulate human-assisted means for compromising the area. To do so requires routine monitoring and surveillance to establish, maintain and verify pest freedom.
- Pest-free place of production or pest-free production site. Requirements are described in ISPM 10: 1999.
- Pest-free growing period. This measure is based on the life cycle of the pest and the host. Pest-free growing periods require repeated monitoring and sometimes are linked to a pest control program. They may also require specific plant varieties and conditions.
- Harvest and shipping windows. This measure can allow for pest presence at times other than free periods when harvest and shipping are permitted. Success of the measure frequently relies on lack of colonization potential as when based on pest/host asynchrony.
- Shipment free from pests.

2.2.7 Post-harvest processing and handling

In some cases, a commodity may be handled after harvest in such a way as to reduce risk associated with certain pests. While these procedures may not be applied specifically to manage phytosanitary risk, they may nonetheless be considered in determining the need for additional phytosanitary measures. Such handling may include:

- Peeling
- Dicing, slicing or chopping

Other activities that may effectively remove pests from a commodity (e.g., washing). Further information about processing and handling of commodities is described in ISPM 32:2009.

2.2.8 Post-entry measures

Post-entry measures applied to the commodity by the importing country may be stand-alone measures or used as a component of a systems approach (see below). Examples of post-entry measures include:

- Post-entry quarantine: used for plants for planting and may be the only option for certain pests not detectable on entry.
- Limits on the end use of commodity; examples include allowing grain imports only for milling.
- Limited distribution: effectively removes portions of the PRA area from the area at risk. Use of this measure requires strict enforcement.

2.2.9 A systems approach is a pest risk management option that integrates different official measures, at least two of which act independently with cumulative effect (ISPM 5). Systems approaches provide the ability to address variability and uncertainty by adding redundant measures to meet the appropriate level of phytosanitary protection required.

Important concepts regarding systems approaches include:

- Two or more of the measures act independently.
- Safeguards; measures that do not kill pests or reduce their prevalence but reduce the potential for their entry and establishment, may be included.
- The combined effect of different measures, conditions and procedures are considered.
- Uncertainty is addressed by varying the number and strength of measures.
- The “chain” of events from field to distribution in the importing country is considered.
- Systems approaches provide an alternative to single and other less practical measures.

ISPM 14: 2002 provides guidance on the development and evaluation of systems approaches.

ISPM 36: 2012 provides specific guidance on the use of integrated measures to manage the risk of plants for planting in international trade.

Some of the risk management options used in systems approaches may include:

- Pre-harvest field or production measures
 - field monitoring and detection (e.g., to establish areas of low pest prevalence or pest-free area/place of production or site)
 - field treatments including biocontrol activities
 - other field or production measures
 - pest free growing structure (e.g., protected environments like a glasshouse)
 - limited altitude for growers and packing area to certain levels
 - quarantine road stations /signs
 - fruit bagging
 - registered or approved production sites
 - resistant cultivars / limit composition of a consignment so that it is composed of plants belonging to resistant or less susceptible species
 - use of certified planting material
 - specific planting time
 - regulation of movement of host material into production area
 - elimination of mature or over ripe host fruits from production area
 - removal of alternate hosts within a buffer / production area
 - allowing only certain plant parts to be exported
- Harvest measures
 - culling
 - sanitation
 - limit commodity to specific level of ripeness
 - specific harvest window (limit harvest to a specific season or plant age)
 - handling to prevent infestation/re-infestation
- Post-harvest measures
 - treatments and other packhouse procedures

- fungicidal/viricidal/antimicrobial dip
- structural features to keep packinghouses pest-free (e.g., screens)
- quality control measures, including culling, washing, brushing, dips, and waxing
- safeguarding of fruit from harvest to packinghouse to export
- prevention of infestation/reinfestation (e.g., limit packinghouse activities to daylight hours)
- requirement of absence of specific defects in the fruit (e.g., no fruit with cuts or blemishes that might attract fruit flies)
- inspection
- culling
- sanitation
- certification
- Shipping /transport
 - treatment (e.g., in transit cold treatments for arthropods)
 - sanitation / safeguarding to prevent infestation or re-infestation
 - type of transport (e.g., limit shipments to refrigerated sea or land transporting containers)
 - limited shipping season
 - limit consignment size
- Distribution / end use
 - restrict distribution within the importing country
 - restrict end use
 - post-entry quarantine

2.2.10 Prohibition

Prohibition should be used only when no other alternative measure is available as it is the most trade restrictive risk management option. Other, less trade-restrictive official measures providing an appropriate level of phytosanitary security should be considered before adopting prohibition as an import requirement (See ISPM 11: 2004; ISPM 20: 2004). The efficacy of prohibition should be considered before it is applied as a measure. In some instances, prohibition may actually increase risk if significant incentives for illegal importation are created.

Import prohibitions may apply to specific commodities or specific origins. Prohibition applies only to quarantine pests and not to regulated non-quarantine pests.

Provision may be made to allow import, under controlled conditions, of prohibited articles for research or other purposes.

2.3 Evaluating measures

2.3.1 Efficacy

The determination of efficacy evaluates the extent to which a given risk management measure reduces pest risk. A description of efficacy includes the specification of a desired response or endpoint and a measurement of that response or endpoint (e.g., mortality). When appropriate, efficacy should be expressed in quantitative terms including the usual statistical parameters (e.g., a confidence interval). When such calculation is not possible or

not feasible, efficacy may be expressed in qualitative terms of high, medium and low. Quantitative methods may be appropriate when relevant data are available (e.g., those related to determination of treatment efficacy). A qualitative evaluation may be more appropriate, when, for example, the evaluation of efficacy is based on an expert opinion.

Several factors should be considered in determining the required efficacy of a measure. These include:

- the level of phytosanitary risk presented by a given situation
- the appropriate level of protection
- the nature of the phytosanitary risk being addressed
- the biology of the organism(s) being managed
- the tolerance of the commodity to the applied risk management measure
- operational and technical considerations (e.g. practicality, cost, timing, available technologies, infrastructure, etc.)

2.3.1.1 Treatment efficacy

Mortality may not always be the most appropriate endpoint specified for evaluating treatment efficacy. High mortality treatments may not be technically justified or effective, for example, in cases of low risk pests, low infestation rates, or where a given pathway may preclude establishment of a pest. The pest risk assessment should determine the level of pest risk and inform the strength of measures considered (ISPM 11: 2013). Responses or endpoints for treatments may include:

- mortality
- sterility (including sterility of F1 generation)
- inactivation
- altered behaviour

Metrics used to measure treatment efficacy for various specified responses or endpoints may include:

- prevalence of pests in a consignment or proportion of pests removed
- pest approach rates (i.e., number of pests entering per unit time)
- probability of entry (e.g., probability of pest entry per unit of commodity imported)
- frequency or probability of establishment
- frequency or probability of pest outbreaks
- percent mortality (e.g., dose-response curves)
- probit analysis (a type of statistical analysis for dose-response curves)
- population counts

If a treatment is used as a phytosanitary measure, the required response or endpoint should be specified, along with the required level of efficacy. Where possible, the pest risk assessment should inform the pest risk management stage to determine what required response or endpoint is most appropriate.

Guidance for evaluating the efficacy of phytosanitary treatments is provided in ISPM 28: 2007.

2.3.1.2 Treatment efficacy: Probit analysis and high mortality treatments

Probit analysis is one of the most widely applied measures of efficacy for phytosanitary treatments where mortality is the desired response. Historically, different levels of efficacy,

expressed as probit levels, have been used for different types of pests. Very high probit levels have been used for certain types of arthropods (e.g., Tephritid fruit flies). However, this type of analysis is not suitable for measuring efficacy of a treatment for plant pathogens.

High mortality treatments are typically applied to commodity/pest combinations that meet the following criteria:

- high risk pests with variable or normally high infestation rates
- the host is easily infested
- distribution of the pest is highly clumped (e.g., more than one larva per fruit)
- treatment efficacy is easily established (tolerance of the pest to the treatment)
- the host is suitable (the treatment is not substantially phytotoxic)
- the pest is an internal feeder or difficult to detect

Several factors may compromise the level of phytosanitary security achieved with high mortality treatments. In cases where very high infestations are seen in the field, where survivors may easily establish and quickly reproduce in large numbers, or other factors that facilitate the establishment of a pest (e.g., commodity distributed to warm climates or during warm seasons), or if the commodity is not adequately safeguarded after treatment, even high mortality treatments may be overcome by the pest population. These factors include, but are not limited to:

- pre-shipment cultural practices
- the size of the shipment
- survival and reproductive capacity of the pest
- packaging and shipping conditions
- seasonality of shipments
- distribution of the commodity

2.3.1.3 Alternative treatment efficacies

In some cases, alternative treatment efficacies (e.g., lower mortality treatments) should be considered because high mortality treatments are either not feasible or not technically justified. A combination of low mortality treatments may be as effective as a single high mortality treatment. Acceptance and use of alternative treatment efficacies may provide NPPOs with viable and important options for pest risk management when few or no other options exist.

Alternative treatment efficacy may be a useful option when high mortality treatments are not feasible because:

- The required testing to establish high mortality efficacy rates is not possible based on the pest biology (e.g., wood boring insects that are difficult to rear in large enough numbers to establish the required statistical measures) but lower mortality rates can be established or lower statistical confidence can be achieved.
- The commodity is only tolerant of the treatment at lower rates of efficacy (e.g., a commodity may tolerate a cold treatment at a slightly higher temperature or shorter duration, but achieve a lower mortality rate compared to a cold treatment at a lower temperature or longer duration).

Alternative treatment efficacy can also be considered when:

- A commodity shows low infestation rates, such as with areas of low pest prevalence.
- A pest is considered to be low risk.
- A combination of measures is applied (e.g., some systems approaches).

2.3.1.4 Other measures of efficacy

Since phytosanitary measures may not directly affect mortality of the pest, other metrics of efficacy become necessary. Examples of less than high mortality phytosanitary measures include:

- the establishment or maintenance of pest free areas or areas of low pest prevalence
- exclusion measures (e.g., safeguarding measures)
- measures to verify requirements are met (e.g., program oversight, inspection, etc.)

The metrics used to determine efficacy in these cases may include:

- measurements of an activity (e.g., packinghouse culls)
- field data (e.g., trapping counts)
- inspection and audit results

2.3.2 Feasibility

In addition to being technically justified and effective, phytosanitary measures must also be feasible. Several ISPMs (e.g., ISPM 14:2002, ISPM 11:2013, ISPM 2: 2007, ISPM 28:2007) provide guidance on feasibility. In determining feasibility, the following factors should be considered, particularly for phytosanitary treatments:

- negative effects of treatments on the commodity (e.g., phytotoxicity, physical damage, shelf life)
- cost
- availability of facilities/equipment
- use labeling (pesticides)
- practicality

2.3.3 Impacts

The economic, social, and environmental impacts of phytosanitary measures should be identified and considered prior to selection and implementation. In certain circumstances, a formal assessment of impacts may be desirable.

In general, a formal assessment of impacts may be warranted when:

- There may be significant unintended social or environmental impacts of a risk management approach, e.g.,
 - the scope and magnitude of environmental impacts are unclear (i.e., release of biocontrol agents into the environment);
 - there may be public health sensitivities about certain control technologies (e.g., aerial spraying of urban areas).
- There may be different economic impacts on different groups in society:
 - producers in some states may benefit, but producers in other states are likely to be harmed by a specific risk management option.
- Implementation of risk management options pose unique challenges that may be subject to public scrutiny:

- substantial up-front capital investment of public funds, as for construction of irradiation facilities,
- establishment of pre-clearance programs in conflict or post-conflict areas.

2.3.3.1 Economic impacts

The evaluation of risk management measures should consider not only the potential reduction in the risk of pest introduction, but also the direct and indirect economic impacts of the risk management options themselves (ISPM 5 and ISPM 11: 2013). Direct and indirect effects of mitigation options should be considered, as relevant. Indirect effects may include impacts on the environment or social effects.

Examples of potential impact to consider include:

- Costs of phytosanitary measures (e.g., cost of materials, facility costs (where applicable), cost of domestic staff, and cost of oversight from foreign NPPO staff where applicable)
- Loss of quality and other impacts affecting marketability of commodity resulting from application of measure
- Cost of research where needed for specific toxicity studies or specific treatment schedules
- Effects of measure on market prices and on quantities supplied and demanded
- Increased incentives for non-compliance (e.g., smuggling or emergence of black markets)
- Negative environmental impacts, impacts on non-targeted organisms.

2.3.3.2 Impact on existing regulations

Impacts on existing regulations may need to be considered. This could include comparing proposed mitigations against existing requirements where similar conditions exist.

2.3.3.3 Efficacy against other quarantine pests

Efficacy for multiple pests should be considered in the development of the overall pest risk management strategy. For example, irradiation may be used to treat internal feeding pests (such as fruit flies) and may also be effective for managing external feeders (such as scale insects).

2.4 Selecting measures

Once potential measures have been identified based on efficacy, feasibility and impacts, specific measures may be selected. Selected phytosanitary measures should be appropriate to the pest risk and technically justified. For example, where a phytosanitary treatment is combined with other measures (e.g., areas of low pest prevalence), or for pest-host complexes, for which high mortality is difficult to establish (e.g. wood boring insects, or species where low levels of pests infest the commodity), less than high mortality treatments may be more appropriate and technically justified. Depending on the efficacy of the potential measures, and the appropriate level of protection, one or more measures may be selected.

2.4.1 Comparing risk management measures

The first step in selecting risk management measures is to compare identified options against criteria such as efficacy and cost. This may involve simply listing options with expected efficacy, the predicted effect(s) on pest risk and the potential costs and impacts of each measure. Options may also be compared against each other to determine which measures are most cost-effective while managing pest risk sufficiently to reach the appropriate level of protection.

2.4.1.1 Cost effectiveness

The relative cost effectiveness of proposed measures is determined by comparing their relative costs to achieve a desired response. Cost-effectiveness analysis can be useful in selecting measures when comparison of measures as described in Section 2.4.1 does not yield a definitive answer. Analyzing cost-effectiveness is only appropriate when comparing risk management options that achieve similar endpoints (e.g., mortality).

$$\text{Cost Effectiveness} = \frac{\text{Cost}}{\text{Efficacy}}$$

2.4.1.2 Cost-benefit analysis

Cost - benefit analysis measures economic efficiency by comparing the costs of risk management measure with the benefits of implementing those measures (usually losses averted). The phytosanitary measure with the greatest economic efficiency will be the one that provides the greatest benefits relative to its costs. Formal cost-benefit analyses can be complex and time-consuming and are usually undertaken only for measures that meet established monetary thresholds or are of political interest.

Cost-benefit analysis is the most common method for measuring economic efficiency. It is a systematic procedure for identifying, calculating, and comparing the costs and benefits associated with options for risk management measures.

Factors that could be considered in a cost-benefit analysis of measures include:

- a monetary estimate of the impact each proposed risk management measure has on existing regulations.
- direct and indirect commercial, environmental, and social costs that would result from each proposed option (see Section 2.3.3)
- benefits (losses averted) associated with each option (some options may be valid for a number of pests and others for a single pest.)
- the time periods in which costs and benefits accrue (i.e., with irradiation facilities, costs may all occur initially while benefits may occur in a stream over 20-30 years) and appropriate discounting factors
- the benefit of each measure's efficacy against other quarantine pests.

2.4.2 Rational relationship of measures to risk

Measures selected for pest risk management should demonstrate a rational relationship to the phytosanitary risk presented by a proposed commodity import. Rational relationship is composed of two elements:

- The measure has an effect on mitigating pest risk.
- The strength of measures is proportional to the pest risk.

This is consistent with the principles of managed risk and minimal impact (ISPM 1:2006). It also requires that pest risk management is directly linked to the pest risk assessment in identifying the hazards and the level of pest risk presented by those hazards. Hazards that present lower pest risks should be managed proportionately less than hazards that present higher pest risks.

2.4.3 Consistency and non-discrimination

In addition to considering the impact of official measures in terms of economic impact, NPPOs must consider the adoption of any official measures in terms of the basic principle of non-discrimination (ISPM 1: 2006). Selected pest risk management measures should be consistent among countries with the same phytosanitary status and comparable domestic phytosanitary situations.

2.4.4 Equivalence of phytosanitary measures

Equivalence of phytosanitary measures is one of the basic principles contained in ISPM 1:2006. Existing regulations of an importing country may indicate appropriate equivalent phytosanitary measures. Alternatively, equivalency may be determined through the exchange of information and evaluation of the measures by the NPPOs of the importing and exporting countries. In the latter case, guidance for recognizing equivalence is provided in ISPM 24: 2005. The determination of equivalence should be based on the pest risk as determined in a pest risk analysis.

2.4.5 Emergency measures and provisional measures

In some cases, pest risk management measures may be applied in the absence of a pest risk assessment. Emergency measures are phytosanitary regulations or procedures established as a matter of urgency in a new or unexpected phytosanitary situation (ISPM 5). An emergency measure may or may not be a provisional measure, a phytosanitary regulation or procedure established without full technical justification owing to current lack of adequate information (ISPM 5). A provisional measure is subjected to review and full justification as soon as possible. The country imposing the provisional measures is obligated to seek out information to technically justify either the maintenance or removal of the measures.

ISPM 1: 2006 (Section 2.11) refers to emergency actions for new or unexpected phytosanitary situations based on a preliminary PRA and indicating that such measures are temporary and the subject of a detailed PRA as soon as possible.

2.4.6 Uncertainty

Uncertainty is an inherent part of pest risk analysis. It may arise from insufficient information, variability (including natural variation), and imprecision (such as model errors). Uncertainty due to variability among individuals is inherent in biological systems and should be measured or described. New or additional information will not usually reduce uncertainty arising from variability. Uncertainty due to lack of knowledge may be reduced by further study and data collection.

Common sources of uncertainty include:

- old/dated information
- conflicting information
- absence of information
- extrapolation of information available for congeneric organisms
- reliance on expert judgment and conflicting or vague opinions from experts
- incorrect assumptions or models

Uncertainty in both the pest risk assessment and the pest risk management stages of pest risk analysis should be described. This includes descriptions of the source(s) and degree(s) of uncertainty in the assessment and management components. In some cases, it may be possible to quantify uncertainty through the application of specific methods (e.g., probabilistic scenario analysis). Options for reducing uncertainty may also be described, particularly in the risk management part of the analysis.

2.4.7 Redundancy

Adding measures or extra strength to measures as a means to compensate for uncertainty is sometimes referred to as redundancy. Redundancy may be a type of provisional measure and therefore requires technical justification to be maintained.

Redundancy may be used:

- to compensate for uncertainty
- as a safeguard for lack of experience
- when no less stringent measure is available
- when no single measure is available, or as an alternative to a single more stringent measure (as in systems approaches)

2.5 Documentation

The transparency principle (ISPM 1: 2006) requires that contracting parties provide technical justification, if requested, of phytosanitary measures implemented as a result of the pest risk management stage of pest risk analysis.

The main documentation elements in the risk management may include:

- reference to the findings of the pest risk assessment stage
- identified potential measures for pest risk management
- selected measures for pest risk management
- justification for selecting measures (and not selecting measures)

Technical justification of the identified or selected risk management measures must be documented using the best available and reliable scientific information (e.g., peer-reviewed research published in scientific journals). Guidance for evaluating the reliability of evidence is provided in Appendix 1.

Where it is appropriate and resources permit, quantitative analysis (e.g., probabilistic analysis) may be useful to provide technical justification of official measures for pest risk management.

Documentation of the pest risk management stage should include a discussion of all uncertainties considered in conducting the analysis to identify and select the official pest risk management measures.

It is important that risk management documentation clearly informs decision makers of the level of uncertainty regarding the scientific evidence forming the basis for the selection of risk management options.

2.6 Monitoring and feedback

2.6.1 Validation of efficacy, feasibility and impact of measures

At the request of the NPPO of the importing country, the NPPO of the exporting country should describe verification methods, including laboratory or diagnostic tests to determine if the pest risk management measure has achieved the required response. The efficacy of measures may also be verified through monitoring the implementation of the phytosanitary measures. This could include conducting point of entry inspections, reviewing internal and external audit reports provided by the NPPO of the exporting country or by conducting audits in the exporting country (ISPM 36: 2012). Both NPPOs must notify one another of detected non-compliances (ISPM 13: 2001; ISPM 36: 2012).

2.6.2 Using information gathered during monitoring of phytosanitary measures

Monitoring risk management measures may generate evidence that may be useful for several activities including:

- identifying strengths and weaknesses of the risk management measures
- suggesting a need to modify measures (could be increasing or decreasing requirements)
- Identifying research needs.

2.6.3 Monitoring as an indicator of system integrity

Information derived from monitoring the performance of risk management measures may serve as an indicator of the integrity of those measures. This may be especially true for complex or difficult to quantify phytosanitary measures (e.g., systems approaches, inspection) where it may be more difficult to establish a single metric for efficacy. In some cases (e.g., the use of integrated measures to produce pest-free plants for planting), even the detection of non-regulated pests through monitoring may indicate a failure in the system's integrity.

2.6.4 Maintaining a technical dialogue among trading partners (NPPOs)

For any given risk management program, monitoring the efficacy of official measures provides technical feedback (e.g., percentage of efficacy of each measure, accumulated total for risk mitigation supporting the analysis for improvement, equivalence or, reduction of phytosanitary measures) that can inform a continuing dialogue between NPPOs for improvement of the pest risk management program.

2.7 Conclusion of pest risk management

Pest risk management involves identifying suitable measures, determining the required efficacy of pest risk management and selecting appropriate measures. Once measures are selected, they should be documented, communicated and implemented. Those measures should be monitored and adjusted where appropriate. New information or changes in pest risk (either positively or negatively) in either the importing or exporting country may necessitate adjustments to a pest risk management program.

This appendix was adopted by the NAPPO Executive Committee on July 28, 2014.
The appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 1: Information sources and uncertainty

Understanding and describing uncertainty arising from the lack of knowledge, or from conflicting information, is important. Pest risk assessments and pest risk management decisions should be based on the available evidence, while uncertainty may be addressed by the strength or redundancy of measures. Uncertainty in pest risk management analyses may arise from a variety of sources. While measures should be appropriate to the pest risk, it may be technically justifiable to require additional measures to compensate for uncertainty. In those cases, the uncertainty should be identified (source of uncertainty, degree of uncertainty) and, if possible, addressed. Measures should be adjusted when uncertainty can be reduced.

The uncertainty associated with the available evidence can be evaluated in terms of both its reliability and its applicability (Table 1 and Table 2).

Reliability is defined in terms of the quality of the source, year of publication, the methodology used, and the degree of consensus (i.e. the extent to which methods or interpretation of results are generally accepted and agreed upon by experts). The quantity of information available can also be used in evaluating resources. For example, many resources from lower quality sources that have the same conclusion may be more powerful in terms of certainty than a single reference from a higher quality publication source.

Applicability refers to how applicable the information is to your situation. When possible, the risk assessment findings should be based on evidence of the pest's current behavior under conditions corresponding to the PRA area.

Together, the applicability and the reliability of information can be considered to provide an estimation of the level of certainty (or uncertainty) about the information available. Information that is both highly applicable and highly reliable lead to a greater degree of certainty; contrastingly, information that is low in reliability and low in applicability would lead to a higher degree of uncertainty.

This information is reflected in Figure 1.

Table 1: Reliability of sources of information from low to high

	Publication source	Reliability	Examples
1	Well-known peer-reviewed journal	Low	No peer reviewed literature
		Moderately low	Only one or a few; any found do not describe methodology OR methodology used is not widely accepted.
		Moderately high	At least one original research paper with detailed description of methodological approach. Several original research papers without specified methodology. Multiple published review articles; articles cite independent (separate) sources of information.
		High	Multiple original research papers with detailed description of the methodological approach(es) used; approaches are widely accepted.
2	Obscure or less-known peer-reviewed journals	Low	No original research. Few or no review or summary articles.
		Moderately low	Few or no original research papers; methodology may or may not be described. Multiple published review articles which may or may not cite independent (separate) sources of information.
		Moderately high	Multiple original research papers (with specified methodology).
		High	Many original research papers (by multiple authors) that include a detailed description of the methodological approach(es) used; approaches are widely accepted; supported by other evidence.

	Publication source	Reliability	Examples
3	Other expert sources that are not peer-reviewed (e.g., universities, subject matter experts, scientific societies) –may include extension reports, non-journal articles, bulletins, etc.	Low	Single reports; if more than one report, those that are found may or may not be based on independent (different) information sources. No supporting evidence found.
		Moderately low	A few articles and reports that may or may not have each been based on independent (different) information sources.
		Moderately high	Several independent article/reports based on independent information; methodology is described.
		High	Many reports from independent sources; well understood methodology; general consensus between information sources
4	Information from trading partner or developed by NPPO itself	Low	Evidence not well-documented or inconsistent with other sources; methodology not verified, not reported, or is not widely accepted.
		Moderately low	Evidence is well-documented and consistent with other sources; methodology has either not been verified or it is not widely accepted.
		Moderately high	Well-documented evidence that is generally consistent with other information; methodology verified and widely accepted.
		High	Well-documented evidence; methodology verified and widely accepted; supported several other sources.

	Publication source	Reliability	Examples
5	Scientific consensus – for instance, the degree to which there is agreement in the literature or among experts on methods or interpretation of results, despite some contradictory views or reports	Low	May or may not have scientific consensus. Methodology may or may not be generally accepted. NPPO may or may not have experience with pest; if so, the evidence may or may not be consistent with NPPO experience.
		Moderately low	May or may not have scientific consensus. Any methodology described may or may not be generally accepted. NPPO may or may not have experience with pest; if so, the evidence is generally consistent with NPPO experience.
		Moderately high	General consensus in scientific literature and other sources (but may include a few contradictory reports). Methodological approaches used are generally accepted. Evidence consistent with NPPO experience w/ pest.
		High	High consensus in scientific literature and other sources (no or practically no contradictory evidence found). Methodological approaches are widely accepted. Evidence generally consistent with NPPO experience w/ pest.

Table 2: Applicability of sources of information from low to high

	Publication information	Applicability	Examples
1	Species-specific data	Low	Species-specific data were limited; most of the species data were approximated or extrapolated from congeneric species, or other similar species.
		Moderately low	Species-specific data were used; some of the species data were approximated or extrapolated from congeneric (or other) species known to behave similarly.
		Moderately high	Species-specific data were used.
		High	Data for both pest and host(s) species were used.
2	Environment-specific data	Low	Environment-specific data were limited; no close proxy data was available; extrapolations were based on situations that may or may not be applicable.
		Moderately low	Some environmental-specific data were used, but most were approximated or extrapolated from similar situations (i.e., research conducted in the areas of comparable climate, on a closely related host).
		Moderately high	Some environment-specific data were used, but at least some data were approximated or extrapolated from similar situations (i.e., research conducted in the areas of comparable climate, on a closely related host).
		High	Environment-specific data were used.

Figure 1: Matrix for estimating an information uncertainty rating.

The “reliability” and “applicability” ratings can be combined to estimate the degree of uncertainty for the information used in the analysis.

		Reliability			
		Low	Moderately Low	Moderately High	High
Applicability	High	Moderately Uncertain	Moderately Certain	CERTAIN	CERTAIN
	Mod. High	Moderately Uncertain	Moderately Certain	Moderately Certain	CERTAIN
	Mod. Low	UNCERTAIN	Moderately Uncertain	Moderately Certain	Moderately Certain
	Low	UNCERTAIN	UNCERTAIN	Moderately Uncertain	Moderately Uncertain