



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 19

GUIDELINES ON LISTS OF REGULATED PESTS

(2003)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2003.

INTRODUCTION

SCOPE

This standard describes the procedures to prepare, maintain and make available lists of regulated pests.

REFERENCES

Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.

Glossary of phytosanitary terms, 2003. ISPM No. 5, FAO, Rome.

Guidelines for Pest Risk Analysis, 1996. ISPM No. 2, FAO, Rome.

Guidelines for Phytosanitary Certificates, 2001. ISPM No. 12, FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest Risk Analysis for quarantine pests including analysis of environmental risks, 2003. ISPM No. 11 Rev. 1, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

The International Plant Protection Convention (IPPC) requires contracting parties to the best of their abilities to establish, update and make available lists of regulated pests.

Lists of regulated pests are established by an importing contracting party to specify all currently regulated pests for which phytosanitary measures may be taken. Specific lists of regulated pests by commodity are a subset of these lists. Specific lists are provided on request to the NPPOs of exporting contracting parties as the means to specify the regulated pests for the certification of particular commodities.

Quarantine pests, including those subject to provisional or emergency measures, and regulated non-quarantine pests should be listed. Required information associated with the listing includes the pest's scientific name, the pest category and commodities or other articles that are regulated for the pest. Supplementary information may be provided such as synonyms and references to data sheets and pertinent legislation. Updating of the lists is required when pests are added or deleted or when required information or supplementary information changes.

Lists should be made available to the IPPC Secretariat, to Regional Plant Protection Organizations (RPPOs) of which the contracting party is a member and, on request, to other contracting parties. This may be done electronically and should be in an FAO language. Requests should be as specific as possible.

REQUIREMENTS

1. Basis for Lists of Regulated Pests

Article VII.2i of the IPPC (1997) states:

Contracting parties shall, to the best of their ability, establish and update lists of regulated pests, using scientific names, and make such lists available to the Secretary, to regional plant protection organizations of which they are members and, on request, to other contracting parties.

Therefore, contracting parties to the IPPC have the explicit obligation to prepare and make available, to the best of their abilities, lists of regulated pests. This is closely associated with other provisions of Article VII regarding the provision of phytosanitary requirements, restrictions and prohibitions (VII.2b) and the provision of the rationale for phytosanitary requirements (VII.2c).

In addition, the certifying statement of the Model Phytosanitary Certificate annexed to the Convention implies that lists of regulated pests are necessary by referring to:

- quarantine pests specified by the importing contracting party;
- phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests.

The availability of lists of regulated pests assists exporting contracting parties to issue Phytosanitary Certificates correctly. In instances where a list of regulated pests is not supplied by the importing contracting party, the exporting contracting party can only certify for pests it believes to be of regulatory concern (see ISPM No. 12: *Guidelines for Phytosanitary Certificates*, section 2.1).

The justification for regulating pests corresponds to the provisions of the IPPC requiring that:

- pests meet the defining criteria for quarantine or regulated non-quarantine pests to be regulated (Article II—“regulated pest”);
- only regulated pests are eligible for phytosanitary measures, (Article VI.2);
- phytosanitary measures are technically justified, (Article VI.1b); and
- PRA provides the basis for technical justification, (Article II—“technically justified”).

2. Purpose of Lists of Regulated Pests

The importing contracting party establishes and updates lists of regulated pests in order to assist it in preventing the introduction and/or spread of pests and to facilitate safe trade by enhancing transparency. These lists identify those pests that have been determined by the contracting party to be quarantine pests or regulated non-quarantine pests.

A specific list of regulated pests, which should be a subset of those lists, may be provided by the importing contracting party to the exporting contracting party as the means to make known to the exporting contracting party those pests for which inspection, testing or other specific procedures are required for particular imported commodities, including phytosanitary certification.

Lists of regulated pests may also be useful as the basis for harmonization of phytosanitary measures where several contracting parties with similar and shared phytosanitary concerns agree on pests that should be regulated by a group of countries or a region. This may be done through Regional Plant Protection Organizations (RPPOs).

In developing lists of regulated pests, some contracting parties identify non-regulated pests. There is no obligation for listing such pests. Contracting parties shall not require phytosanitary measures for non-regulated pests (Article VI.2 of the IPPC, 1997). The provision, however, of this information may be useful, for example for facilitating inspection.

3. Preparation of Lists of Regulated Pests

Lists of regulated pests are established and maintained by the importing contracting party. The pests to be listed are those that have been determined by the NPPO to require phytosanitary measures:

- quarantine pests, including pests which are the subject of provisional or emergency measures; or
- regulated non-quarantine pests.

A list of regulated pests may include pests for which measures are required only in certain circumstances.

4. Information on Listed Pests

4.1 Required information

The required information to be associated with listed pests includes:

Name of pest – The scientific name of the pest is used for listing purposes, at the taxonomic level which has been justified by PRA (see also ISPM No. 11 Rev. 1: *Pest Risk Analysis for quarantine pests including analysis of environmental risks*). The scientific name should include the authority (where appropriate) and be complemented by a common term for the relevant taxonomic group (e.g. insect, mollusc, virus, fungus, nematode, etc.).

Categories of regulated pests – These are quarantine pest, not present; quarantine pest, present but not widely distributed and under official control; or regulated non-quarantine pest. Pest lists may be organized using these categories.

Association with regulated article(s) – The host commodities or other articles that are specified as regulated for the listed pest(s).

Where codes are used for any of the above, the contracting party responsible for the list should also make available appropriate information for its proper understanding and use.

4.2 Supplementary information

Information that may be provided where appropriate includes:

- synonyms;
- reference to pertinent legislation, regulations, or requirements;
- reference to a pest data sheet or PRA;
- reference to provisional or emergency measures.

4.3 NPPO responsibilities

The NPPO is responsible for procedures to establish lists of regulated pests and to produce specific lists of regulated pests. Information used for necessary PRA and subsequent listing may come from various sources within or outside the NPPO including other agencies of the contracting party, other NPPOs (in particular where the NPPO of the exporting contracting party requests specific lists for certification purposes), RPPOs, scientific academia, scientific researchers and other sources.

5. Maintenance of Lists of Regulated Pests

The contracting party is responsible for the maintenance of pest lists. This involves updating lists and appropriate recordkeeping.

Lists of regulated pests require updating when pests are added or deleted, or the category of listed pests changes, or when information is added or changed for listed pests. The following are some of the more common reasons for updating these lists:

- changes to prohibitions, restrictions or requirements;
- change in pest status (see ISPM No. 8: *Determination of pest status in an area*);
- result of a new or revised PRA;
- change in taxonomy.

The updating of pest lists should be done as soon as the need for modifications is identified. Formal changes in legal instruments, where appropriate, should be adopted as quickly as possible.

It is desirable for NPPOs to keep appropriate records of changes in pest lists over time (e.g. rationale for change, date of change) for reference and to facilitate response to inquiries that may be related to disputes.

6. Availability of Lists of Regulated Pests

Lists may be included in legislation, regulations, requirements or administrative decisions. Contracting parties should create operational mechanisms for establishing, maintaining and making available lists in a responsive manner.

The IPPC makes provision for the official availability of lists and languages to be used.

6.1 Official availability

The IPPC requires that contracting parties make lists of regulated pests available to the IPPC Secretariat and RPPOs to which they are members. They are further obliged to provide such lists to other contracting parties upon request (Article VII.2i of the IPPC, 1997).

Lists of regulated pests should be made available officially to the IPPC Secretariat. This may be done in written or electronic form, including the Internet.

The means for making pest lists available to RPPOs is decided within each organization.

6.2 Requests for lists of regulated pests

NPPOs may request lists of regulated pests or specific lists of regulated pests from other NPPOs. In general, requests should be as specific as possible to the pests, commodities, and circumstances of concern to the contracting party.

Requests may be for:

- clarification of the regulatory status for particular pests;
- specification of quarantine pests for certification purposes;
- obtaining regulated pest lists for particular commodities;
- information concerning regulated pests not associated with any particular commodity;
- updating previously provided pest list(s).

Pest lists should be provided by NPPOs in a timely manner, with highest priority given to requests for lists necessary for phytosanitary certification or to facilitate the movement of commodities in trade. Copies of regulations may be provided where pest lists included in these regulations are considered adequate.

Both requests and responses for pest lists should be through official contact points. Pest lists may be provided by the IPPC Secretariat when available, but such provision is unofficial.

6.3 Format and language

Lists of regulated pests made available to the IPPC Secretariat, and in response to requests from contracting parties, should be provided in one of the five official languages of FAO (required under Article XIX.3c of the IPPC, 1997).

Pest lists may be provided electronically or by access to an appropriately structured Internet website where contracting parties have indicated this is possible and the corresponding organizations have the capability for such access and have indicated willingness to use this form of transmission.



INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 20

GUIDELINES FOR A PHYTOSANITARY IMPORT REGULATORY SYSTEM

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ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2004.

INTRODUCTION

SCOPE

This standard describes the structure and operation of a phytosanitary import regulatory system and the rights, obligations and responsibilities which should be considered in establishing, operating and revising the system. In this standard any reference to legislation, regulation, procedure, measure or action is a reference to phytosanitary legislation, regulation etc. unless otherwise specified.

REFERENCES

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

Code of conduct for the import and release of exotic biological control agents, 1996. ISPM No. 3, FAO, Rome.

Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.

Export certification system, 1997. ISPM No. 7, FAO, Rome.

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

Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

Guidelines for surveillance, 1998. ISPM No. 6, FAO, Rome.

Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.

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

Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.

Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.

Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

The objective of a phytosanitary import regulatory system is to prevent the introduction of quarantine pests or limit the entry of regulated non-quarantine pests with imported commodities and other regulated articles. An import regulatory system should consist of two components: a regulatory framework of phytosanitary legislation, regulations and procedures; and an official service, the NPPO, responsible for operation or oversight of the system. The legal framework should include: legal authority for the NPPO to carry out its duties; measures with which imported commodities should comply; other measures (including prohibitions) concerning imported commodities and other regulated articles; and actions that may be taken when incidents of non-compliance or incidents requiring emergency action are detected. It may include measures concerning consignments in transit.

In operating an import regulatory system, the NPPO has a number of responsibilities. These include the responsibilities identified in Article IV.2 of the IPPC (1997) relating to import including surveillance, inspection, disinfection or disinfection, the conduct of pest risk analysis, and training and development of staff. These responsibilities involve related functions in areas such as: administration; audit and compliance checking; action taken on non-compliance; emergency action; authorization of personnel; and settlement of disputes. In addition, contracting parties may assign to NPPOs other responsibilities, such as regulatory development and modification. NPPO resources are needed to carry out these responsibilities and functions. There are also requirements for international and national liaison, documentation, communication and review.

REQUIREMENTS

1. Objective

The objective of a phytosanitary import regulatory system is to prevent the introduction of quarantine pests or limit the entry of regulated non-quarantine pests (RNQPs) with imported commodities and other regulated articles.

2. Structure

The components of an import regulatory system are:

- a regulatory framework of phytosanitary legislation, regulations and procedures
- an NPPO that is responsible for the operation of the system.

Legal and administrative systems and structures differ among contracting parties. In particular, some legal systems require every aspect of the work of its officials to be detailed within a legal text whilst others provide a broad framework within which officials have the delegated authority to perform their functions through a largely administrative procedure. This standard accordingly provides general guidelines for the regulatory framework of an import regulatory system. This regulatory framework is further described in Section 4.

The NPPO is the official service responsible for the operation and/or oversight (organization and management) of the import regulatory system. Other government services, such as the Customs service, may have a role (with defined separation of responsibilities and functions) in the control of imported commodities and liaison should be maintained. The NPPO often utilizes its own officers to operate the import regulatory system, but may authorize other appropriate government services, or non-governmental organizations, or persons to act on its behalf and under its control for defined functions. The operation of the system is described in Section 5.

3. Rights, Obligations and Responsibilities

In establishing and operating its import regulatory system, the NPPO should take into account:

- rights, obligations and responsibilities arising from relevant international treaties, conventions or agreements
- rights, obligations and responsibilities arising from relevant international standards
- national legislation and policies
- administrative policies of the government, ministry or department, or NPPO.

3.1 International agreements, principles and standards

National governments have the sovereign right to regulate imports to achieve their appropriate level of protection, taking into account their international obligations. Rights, obligations and responsibilities associated with international agreements as well as the principles and standards resulting from international agreements, in particular the IPPC (1997) and the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO-SPS Agreement), affect the structure and implementation of import regulatory systems. These include effects on the drafting and adoption of import regulations, the application of regulations, and the operational activities arising from regulations.

The drafting, adoption and application of regulations require recognition of certain principles and concepts such as in ISPM No. 1 (*Principles of plant quarantine as related to international trade*), including:

- transparency
- sovereignty
- necessity
- non-discrimination
- minimal impact
- harmonization
- technical justification (such as through pest risk analysis)
- consistency
- managed risk
- modification
- emergency action and provisional measures
- equivalence
- pest free areas and areas of low pest prevalence.

In particular, the phytosanitary procedures and regulations should take into consideration the concept of minimal impact and issues of economic and operational feasibility in order to avoid unnecessary trade disruption.

3.2 Regional cooperation

Regional organizations, such as Regional Plant Protection Organizations (RPPOs) and regional agricultural development organizations, may encourage the harmonization of their members' import regulatory systems and may cooperate in the exchange of information for the benefit of members.

A regional economic integration organization recognized by the FAO may have rules that apply to its members and may also have the authority to enact and enforce certain regulations on behalf of members of that organization.

4. Regulatory Framework

The issuing of regulations is a government (contracting party) responsibility (Article IV.3c of the IPPC, 1997). Consistent with this responsibility, contracting parties may provide the NPPO with the authority for the formulation of phytosanitary import regulations and the implementation of the import regulatory system. Contracting parties should have a regulatory framework to provide the following:

- the specification of the responsibilities and functions of the NPPO in relation to the import regulatory system
- legal authority to enable the NPPO to carry out its responsibilities and functions with respect to the import regulatory system
- authority and procedures, such as through PRA, to determine import phytosanitary measures
- phytosanitary measures that apply to imported commodities and other regulated articles
- import prohibitions that apply to imported commodities and other regulated articles
- legal authority for action with respect to non-compliance and for emergency action
- the specification of interactions between the NPPO and other government bodies
- transparent and defined procedures and time frames for implementation of regulations, including their entry into force.

Contracting parties have obligations to make their regulations available according to Article VII.2b of the IPPC, 1997; these procedures may require a regulatory basis.

4.1 Regulated articles

Imported commodities that may be regulated include articles that may be infested or contaminated with regulated pests. Regulated pests are either quarantine pests or regulated non-quarantine pests. All commodities can be regulated for quarantine pests. Products for consumption or processing cannot be regulated for regulated non-quarantine pests. Regulated non-quarantine pests can only be regulated with respect to plants for planting. The following are examples of regulated articles:

- plants and plant products used for planting, consumption, processing, or any other purpose
- storage facilities
- packaging materials including dunnage
- conveyances and transport facilities
- soil, organic fertilizers and related materials
- organisms capable of harboring or spreading pests
- potentially contaminated equipment (such as used agricultural, military and earthmoving equipment)
- research and other scientific materials
- travellers' personal effects moving internationally
- international mail including international courier services
- pests and biological control agents¹.

Lists of regulated articles should be made publically available.

4.2 Phytosanitary measures for regulated articles

Contracting parties should not apply phytosanitary measures to the entry of regulated articles such as prohibitions, restrictions or other import requirements unless such measures are made necessary by phytosanitary considerations and are technically justified. Contracting parties should take into account, as appropriate, international standards and other relevant requirements and considerations of the IPPC when applying phytosanitary measures.

¹ Pests *per se* and biological control agents do not fall within the definition of 'regulated articles' (Article II.1 of the IPPC, 1997). However, where there is technical justification, they may be subjected to phytosanitary measures (IPPC, 1997; Article VI with respect to regulated pests, and Article VII.1c and VII.1d) and for the purposes of this standard may be considered as regulated articles.

4.2.1 Measures for consignments to be imported

The regulations should specify the measures with which imported consignments² of plants, plant products and other regulated articles should comply. These measures may be general, applying to all types of commodities, or the measures may be specific, applying to specified commodities from a particular origin. Measures may be required prior to entry, at entry or post entry. Systems approaches may also be used when appropriate.

Measures required in the exporting country, which the NPPO of the exporting country may be required to certify (in accordance with ISPM No. 7: *Export certification system*) include:

- inspection prior to export
- testing prior to export
- treatment prior to export
- produced from plants of specified phytosanitary status (for example grown from virus-tested plants or under specified conditions)
- inspection or testing in the growing season(s) prior to export
- origin of the consignment to be a pest free place of production or pest free production site, area of low pest prevalence or pest free area
- accreditation procedures
- maintenance of consignment integrity.

Measures that may be required during shipment include:

- treatment (for example appropriate physical or chemical treatments)
- maintenance of consignment integrity.

Measures that may be required at the point of entry include:

- documentation checks
- verification of consignment integrity
- verification of treatment during shipment
- phytosanitary inspection
- testing
- treatment
- detention of consignments pending the results of testing or verification of the efficacy of treatment.

Measures that may be required after entry include:

- detention in quarantine (such as in a post entry quarantine station) for inspection, testing or treatment
- detention at a designated place pending specified measures
- restrictions on the distribution or use of the consignment (for example for specified processing).

Other measures that may be required include:

- requirements for licences or permits
- limitations on the points of entry for specified commodities
- the requirement that importers notify in advance the arrival of specified consignments
- audit of procedures in the exporting country
- pre-clearance.

The import regulatory system should make provision for the evaluation and possible acceptance of alternative measures proposed by exporting contracting parties as being equivalent.

4.2.1.1 Provision for special imports

Contracting parties may make special provision for the import of pests, biological control agents (see also ISPM No. 3: *Code of conduct for the import and release of exotic biological control agents*) or other regulated articles for scientific research, education or other purposes. Such imports may be authorized subject to the provision of adequate safeguards.

² For the purpose of this standard, import is considered to cover all consignments moving into the country (except in transit), including movement into free trade zones (including duty free areas and consignments in bond) and illegal consignments detained by other services.

4.2.1.2 Pest free areas, pest free places of production, pest free production sites, areas of low pest prevalence and official control programmes

Importing contracting parties may designate pest free areas (according to ISPM No. 4: *Requirements for the establishment of pest free areas*), areas of low pest prevalence and official control programmes within their country. Import regulations may be required to protect or sustain such designations within the importing country. However such measures should respect the principle of non-discrimination.

Import regulations should recognize the existence of such designations and those related to other official procedures (such as pest free places of production and pest free production sites) within the countries of exporting contracting parties including the facility to recognize these measures as equivalent where appropriate. It may be necessary to make provision within regulatory systems to evaluate and accept the designations by other NPPOs and to respond accordingly.

4.2.2 Import authorization

The authority to import may be provided as a general authorization or through specific authorization on a case-by-case basis.

General authorization

General authorizations may be used:

- when there are no specific requirements relating to import
- where specific requirements have been established permitting entry as set out in the regulations for a range of commodities.

General authorizations should not require a licence or a permit but may be subject to checking at import.

Specific authorization

Specific authorizations, e.g. in the form of a licence or permit, may be required where official consent for import is necessary. These may be required for individual consignments or a series of consignments of a particular origin. Cases where this type of authorization may be required include:

- emergency or exceptional imports
- imports with specific, individual requirements such as those with post-entry quarantine requirements or designated end use or research purposes
- imports where the NPPO requires the ability to trace the material over a period of time after entry.

It is noted that some countries may use permits to specify general import conditions. However, the development of general authorizations is encouraged wherever similar specific authorizations become routine.

4.2.3 Prohibitions

The prohibition of import may apply to specified commodities or other regulated articles of all origins or specifically to a particular commodity or other regulated article of a specified origin. The prohibition of import should be used when no other alternatives for pest risk management exist. Prohibitions should be technically justified. NPPOs should make provision to assess equivalent, but less trade restrictive measures. Contracting parties, through their NPPOs where authorized, should modify their import regulations if such measures meet their appropriate level of protection. Prohibition applies to quarantine pests. Regulated non-quarantine pests should not be subject to prohibition but are subject to established pest tolerance levels.

Prohibited articles may be required for research or other purpose and provision may be required for their import under controlled conditions including appropriate safeguards through a system of licence or permit.

4.3 Consignments in transit

According to ISPM No. 5 (*Glossary of phytosanitary terms*), consignments in transit are not imported. However, the import regulatory system may be extended to cover consignments in transit and to establish technically justified measures to prevent the introduction and/or spread of pests (Article VII.4 of the IPPC, 1997). Measures may be required to track consignments, to verify their integrity and/or to confirm that they leave the country of transit. Countries may establish points of entry, routes within the country, conditions for transportation and time spans permitted within their territories.

4.4 Measures concerning non-compliance and emergency action

The import regulatory system should include provisions for action to be taken in the case of non-compliance or for emergency action (Article VII.2f of the IPPC, 1997; detailed information is contained in ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*), taking into consideration the principle of minimal impact.

Actions which may be taken when an imported consignment or other regulated articles does not comply with regulations and is initially refused entry include:

- treatment
- sorting or reconditioning
- disinfection of regulated articles (including equipment, premises, storage areas, means of transportation)
- direction to a particular end use such as processing
- reshipment
- destruction (such as incineration).

Detection of a non-compliance or an incident requiring emergency action may result in a revision of the regulations, or in revocation or suspension of authorization to import.

4.5 Other elements that may require a regulatory framework

International agreements give rise to obligations which may require a legal base or may be implemented through administrative procedures. Arrangements that may require such procedures include:

- notification of non-compliance
- pest reporting
- designation of an official contact point
- publication and dissemination of regulatory information
- international cooperation
- revision of regulations and documentation
- recognition of equivalence
- specification of points of entry
- notification of official documentation.

4.6 Legal authority for the NPPO

In order that the NPPO can discharge its responsibilities (Article IV of the IPPC, 1997), legal authority (powers) should be provided to enable the officers of the NPPO and other authorized persons to:

- enter premises, conveyances, and other places where imported commodities, regulated pests or other regulated articles may be present
- inspect or test imported commodities and other regulated articles
- take and remove samples from imported commodities or other regulated articles, or from places where regulated pests may be present (including for analysis which may result in the destruction of the sample)
- detain imported consignments or other regulated articles
- treat or require treatment of imported consignments, or other regulated articles including conveyances, or places or commodities in which a regulated pest may be present
- refuse entry of consignments, order their reshipment or destruction
- take emergency action
- set and collect fees for import-related activities or associated with penalties (optional).

5. Operation of an Import Regulatory System

The NPPO is responsible for the operation and/or oversight (organization and management) of the import regulatory system (see also Section 2, third paragraph). This responsibility arises in particular from Article IV.2 of the IPPC, 1997.

5.1 Management and operational responsibilities of the NPPO

The NPPO should have a management system and resources adequate to carry out its functions.

5.1.1 Administration

The administration of the import regulatory system by the NPPO should ensure the effective and consistent application of phytosanitary legislation and regulations and compliance with international obligations. This may require operational coordination with other government services or government agencies involved with imports, e.g. Customs. Administration of the import regulatory system should be coordinated at national level but may be organized on a functional, regional or other structural basis.

5.1.2 Regulatory development and revision

The issuing of phytosanitary regulations is a government (contracting party) responsibility (Article IV.3c of the IPPC, 1997). Consistent with this responsibility, governments may make the development and/or revision of phytosanitary regulations the responsibility of their NPPO. This action may be under the initiative of the NPPO in consultation or cooperation with other authorities as appropriate. Appropriate regulations should be developed, maintained and reviewed as necessary and in compliance with applicable international agreements, through the normal legal and consultative processes of the country. Consultation and collaboration with relevant agencies as well as affected industries and appropriate private sector groups can be helpful in increasing the understanding and acceptance of regulatory decisions by the private sector and is often useful for the improvement of regulations.

5.1.3 Surveillance

The technical justification of phytosanitary measures is determined in part by the pest status of regulated pests within the regulating country. Pest status may change and this may necessitate revision of import regulations. Surveillance of cultivated and non-cultivated plants in the importing country is required to maintain adequate information on pest status (according to ISPM No. 6: *Guidelines for surveillance*), and may be required to support PRA and pest listing.

5.1.4 Pest risk analysis and pest listing

Technical justification such as through pest risk analysis (PRA) is required to determine if pests should be regulated and the strength of phytosanitary measures to be taken against them (ISPM No. 11: *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004; ISPM No. 21: *Pest risk analysis for regulated non-quarantine pests*). PRA may be done on a specific pest or on all the pests associated with a particular pathway (e.g. a commodity). A commodity may be classified by its level of processing and/or its intended use. Regulated pests should be listed (according to ISPM No. 19: *Guidelines on lists of regulated pests*) and lists of regulated pests should be made available (Article VII.2i of the IPPC, 1997). If appropriate international standards are available, measures should take account of such standards and should not be more stringent unless technically justified.

The administrative framework of the PRA process should be clearly documented, if possible with a time frame for the completion of individual PRAs and with clear guidance on prioritization.

5.1.5 Audit and compliance checking

5.1.5.1 Audit of procedures in the exporting country

Import regulations often include specific requirements that should be done in the country of export, such as production procedures (usually during the growing period of the crop concerned) or specialized treatment procedures. In certain circumstances, such as in the development of a new trade, the requirements may include, in cooperation with the NPPO of the exporting country, an audit in the exporting country by the NPPO of the importing country of elements such as:

- production systems
- treatments
- inspection procedures
- phytosanitary management
- accreditation procedures
- testing procedures
- surveillance.

An importing country should make known the scope of any audit. The arrangements for such audits are normally written into a bilateral agreement, arrangement or work programme associated with import facilitation. Such arrangements may extend to clearance of consignments within the exporting country for entry into the importing country which usually facilitates a minimum of procedures at entry to the importing country. These types of audit procedure should not be applied as a permanent measure and should be considered satisfied as soon as the procedures in the exporting country have been validated. This approach, in its limitation on the length of its application, may differ from ongoing pre-clearance inspections mentioned in section 5.1.5.2.1. The results of audits should be made available to the NPPO of the exporting country.

5.1.5.2 Compliance checking at import

There are three basic elements to compliance checking:

- documentary checks
- consignment integrity checks
- phytosanitary inspection, testing etc.

Compliance checking of imported consignments and other regulated articles may be required:

- to determine their compliance with phytosanitary regulations
- to check that phytosanitary measures are effective in preventing the introduction of quarantine pests and limiting the entry of RNQPs
- to detect potential quarantine pests or quarantine pests whose entry with that commodity was not predicted.

Phytosanitary inspections should be carried out by, or under the authority of, the NPPO.

Compliance checks should be done promptly (Article VII.2d and VII.2e of the IPPC, 1997). Where possible, checks should be done in cooperation with other agencies involved with the regulation of imports, such as Customs, so as to minimise interference with the flow of trade and the impact on perishable products.

5.1.5.2.1 Inspection

Inspections may be done at the point of entry, at points of transhipment, at the point of destination or at other places where imported consignments can be identified, such as major markets, provided that their phytosanitary integrity is maintained and that appropriate phytosanitary procedures can be carried out. By bilateral agreement or arrangement, they may also be done in the country of origin as a part of a pre-clearance programme in cooperation with the NPPO of the exporting country.

Phytosanitary inspections, which should be technically justified, may be applied:

- to all consignments as a condition of entry
- as a part of an import monitoring programme where the level of monitoring (i.e. the number of consignments inspected) is established on the basis of predicted risk.

Inspection and sampling procedures may be based on general procedures or on specific procedures to achieve pre-determined objectives.

5.1.5.2.2 Sampling

Samples may be taken from consignments for the purposes of phytosanitary inspection, or for subsequent laboratory testing, or for reference purposes.

5.1.5.2.3 Testing including laboratory testing

Testing may be required for:

- identification of a visually detected pest
- confirmation of a visually identified pest
- checking of compliance with requirements concerning infestations not detectable by inspection
- checking for latent infections
- audit or monitoring
- reference purposes particularly in cases of non-compliance
- verification of the declared product.

Testing should be performed by persons experienced in the appropriate procedures and, if possible, following internationally agreed protocols. Cooperation with appropriate academic and international experts or institutes is recommended when validation of test results is needed.

5.1.6 Non-compliance and emergency action

Detailed information about non-compliance and emergency action is contained in ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*.

5.1.6.1 Action in case of non-compliance

Examples where phytosanitary action may be justified regarding non-compliance with import regulations include:

- the detection of a listed quarantine pest associated with consignments for which it is regulated
- the detection of a listed RNQP present in an imported consignment of plants for planting at a level which exceeds the required tolerance for those plants
- evidence of failure to meet prescribed requirements (including bilateral agreements or arrangements, or import permit conditions) such as field inspection, laboratory tests, registration of producers and/or facilities, lack of pest monitoring or surveillance

- the interception of a consignment which does not otherwise comply with the import regulations, such as because of the detected presence of undeclared commodities, soil or some other prohibited article or evidence of failure of specified treatments
- Phytosanitary Certificate or other required documentation invalid or missing
- prohibited consignments or articles
- failure to meet 'in-transit' measures.

The type of action will vary with the circumstances and should be the minimum necessary to counter the risk identified. Administrative errors such as incomplete Phytosanitary Certificates may be resolved through liaison with the exporting NPPO. Other infringements may require action such as:

Detention - This may be used if further information is required, taking into account the need to avoid consignment damage as far as possible.

Sorting and reconfiguring - The affected products may be removed by sorting and reconfiguring the consignment including repackaging if appropriate.

Treatment - Used by the NPPO when an efficacious treatment is available.

Destruction - The consignment may be destroyed in cases where the NPPO considers the consignment cannot be otherwise handled.

Reshipment - The non-complying consignment may be removed from the country by reshipping.

In the case of non-compliance for a RNQP, action should be consistent with domestic measures and limited to bringing the pest level in the consignment, where feasible, into compliance with the required tolerance, e.g. through treatment or by downgrading or reclassification where this is permitted for equivalent material produced or regulated domestically.

The NPPO is responsible for issuing the necessary instructions and for verifying their application. Enforcement is normally considered to be a function of the NPPO but other agencies may be authorized to assist.

An NPPO may decide not to apply phytosanitary action against a regulated pest or in other instances of non-compliance where actions are not technically justified in a particular situation, such as if there is no risk of establishment or spread (e.g. a change of intended use such as from consumption to processing or when a pest is in a stage of its life cycle which will not enable establishment or spread), or for some other reason.

5.1.6.2 Emergency action

Emergency action may be required in a new or unexpected phytosanitary situation, such as the detection of quarantine pests or potential quarantine pests:

- in consignments for which phytosanitary measures are not specified.
- in regulated consignments or other regulated articles in which their presence is not anticipated and for which no measures have been specified.
- as contaminants of conveyances, storage places or other places involved with imported commodities.

Action similar to that required in cases of non-compliance may be appropriate. Such actions may lead to the modification of existing phytosanitary measures, or the adoption of provisional measures pending review and full technical justification.

Commonly encountered situations requiring emergency action include:

Pests not previously assessed. Non-listed organisms may require emergency phytosanitary actions because they may not have been previously assessed. At the time of interception, they may be categorized as regulated pests on a preliminary basis because the NPPO has a cause to believe they pose a phytosanitary threat. In such instances, it is the responsibility of the NPPO to be able to provide a sound technical basis. If provisional measures are established, the NPPO should actively pursue additional information, if appropriate with the participation of the NPPO of the exporting country, and complete a PRA to establish in a timely manner the regulated or non-regulated status of the pest.

Pests not regulated for a particular pathway. Emergency phytosanitary actions may be applied for pests that are not regulated with respect to particular pathways. Although regulated, these pests may not have been listed or otherwise specified because they were not anticipated for the origin, commodity, or circumstances for which the list or measure was developed. Such pests should be included on the appropriate list(s) or other measure(s) if it is determined that the occurrence of the pest in the same and similar circumstances may be anticipated in the future.

Lack of adequate identification. In some instances, a pest may justify phytosanitary action because the pest cannot be adequately identified or is inadequately described taxonomically. This may be because the specimen has not been described (is taxonomically unknown), is in a condition which does not allow its identification, or the life stage being examined cannot be identified to the required taxonomic level. Where identification is not feasible, the NPPO should have a sound technical basis for the phytosanitary actions taken.

Where pests are routinely detected in a form that does not allow for adequate identification (e.g. eggs, early instar larvae, imperfect forms, etc.), every effort should be made to raise sufficient specimens to allow identification. Contact with the exporting country may assist with the identification or provide a presumed identification. Such pests in this state may be deemed temporarily to require phytosanitary measures. Once identification is achieved and if, on the basis of PRA, it is confirmed that such pests justify phytosanitary actions, NPPOs should add such pests to the relevant list(s) of regulated pests, noting the identification problem and the basis for requiring actions. Interested contracting parties should be informed that future action will be based on a presumed identification if such forms are detected. However, such future action should only be taken with respect to origins where there is an identified pest risk and the possibility of the presence of quarantine pests in imported consignments cannot be excluded.

5.1.6.3 Reporting of non-compliance and emergency action

The reporting of interceptions, instances of non-compliance and emergency action is an obligation for contracting parties to the IPPC so that exporting countries understand the basis for phytosanitary actions taken against their products on import and to facilitate corrections in export systems. Systems are needed for the collection and transmission of such information.

5.1.6.4 Withdrawal or modification of regulation

In the case of repeated non-compliance, or where a significant non-compliance or interception warranting emergency action occurs, the NPPO of the importing contracting party may withdraw the authorization (e.g. permit) allowing import, modify the regulation, or institute an emergency or provisional measure with modified entry procedures or a prohibition. The exporting country should be notified promptly of the change and rationale for this change.

5.1.7 Systems for authorization of non-NPPO personnel

NPPOs may authorize, under their control and responsibility, other government services, non-governmental organizations, agencies or persons, to act on their behalf for certain defined functions. In order to ensure that the requirements of the NPPO are met, operational procedures are required. In addition, procedures should be developed for the demonstration of competency and for audits, corrective actions, system review and withdrawal of authorization.

5.1.8 International liaison

Contracting parties have international obligations (Articles VII and VIII of the IPPC, 1997) including the:

- provision of an official contact point
- notification of specified points of entry
- publication and transmission of lists of regulated pests, phytosanitary requirements, restrictions and prohibitions
- notification of non-compliance and emergency action (ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*)
- provision of the rationale for phytosanitary measures, on request
- provision of relevant information.

Administrative arrangements are required to ensure that these obligations are discharged efficiently and promptly.

5.1.9 Notification and dissemination of regulatory information

5.1.9.1 New or revised regulations

Proposals for new or revised regulations should be published and provided to interested parties on request, allowing reasonable time for comment and implementation.

5.1.9.2 Dissemination of established regulations

Established import regulations, or relevant sections of them, should be made available to interested and affected contracting parties as appropriate, to the IPPC Secretariat and to the RPPO(s) of which they are a member. Through appropriate procedures, they may also be made available to other interested parties (such as import and export industry organizations and their representatives). NPPOs are encouraged to make import regulatory information available by publication, whenever possible using electronic means including Internet websites and linkage to these via the IPPC International Phytosanitary Portal (IPP) (<http://www.ippc.int>).

5.1.10 National liaison

Procedures that facilitate cooperative action, information-sharing and joint clearance activities within the country should be established with relevant government agencies or services as appropriate.

5.1.11 Settlement of disputes

The implementation of an import regulatory system may give rise to disputes with the authorities of other countries. The NPPO should establish procedures for consultation and exchange of information with other NPPOs, and for settlement of such disputes “shall consult among themselves as soon as possible” prior to considering calling on formal international dispute-settlement procedures (Article XIII.1 of the IPPC, 1997).

5.2 Resources of the NPPO

Contracting parties should provide to their NPPO appropriate resources to carry out its functions (Article IV.1 of the IPPC, 1997).

5.2.1 Staff, including training

The NPPO should:

- employ or authorize personnel who have appropriate qualifications and skills
- ensure that adequate and sustained training is provided to all personnel to ensure competency in the areas for which they have responsibility.

5.2.2 Information

The NPPO should, as far as possible, ensure that adequate information is available to personnel, in particular:

- guidance documents, procedures and work instructions as appropriate covering relevant aspects of the operation of the import regulatory system
- the import regulations of its country
- information on its regulated pests including biology, host range, pathways, global distribution, detection and identification methods, treatment methods.

The NPPO should have access to information on the presence of pests in its country (preferably as pest lists), to facilitate the categorization of pests during pest risk analysis. The NPPO should also maintain lists of all its regulated pests. Detailed information on lists of regulated pests is contained in ISPM No. 19: *Guidelines on lists of regulated pests*.

Where a regulated pest is present in the country, information should be maintained on its distribution, pest free areas, official control and, in the case of an RNQP, official programmes for plants for planting. Contracting parties should distribute information within their territory regarding regulated pests and the means of their prevention and control, and may assign this responsibility to their NPPOs.

5.2.3 Equipment and facilities

The NPPO should ensure that adequate equipment and facilities are available for:

- inspection, sampling, testing, surveillance and consignment verification procedures
- communication and access to information (by electronic means as far as possible).

DOCUMENTATION, COMMUNICATION AND REVIEW

6. Documentation

6.1 Procedures

The NPPO should maintain guidance documents, procedures and work instructions covering all aspects of the operation of the import regulatory system. Procedures to be documented include:

- preparation of pest lists
- pest risk analysis
- where appropriate, establishment of pest free areas, areas of low pest prevalence, pest free places of production or production sites, and official control programmes
- inspection, sampling and testing methodology (including methods for maintaining sample integrity)
- action on non-compliance, including treatment
- notification of non-compliance
- notification of emergency action.

6.2 Records

Records should be kept of all actions, results and decisions concerning the regulation of imports, following the relevant sections of ISPMs where appropriate, including:

- documentation of pest risk analyses (in accordance with ISPM No. 11: *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004, and other relevant ISPMs)
- where established, documentation of pest free areas, areas of low pest prevalence, and official control programmes (including information on the distribution of the pests and the measures used to maintain the PFA or area of low pest prevalence)
- records of inspection, sampling and testing
- non-compliance and emergency action (in accordance with ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*).

If appropriate, records may be kept of imported consignments:

- with specified end-uses
- subject to post-entry quarantine or treatment procedures
- requiring follow up action (including traceback), according to pest risk, or
- as necessary to manage the import regulatory system.

7. Communication

The NPPO should ensure that it has communication procedures to contact:

- importers and appropriate industry representatives
- NPPOs of exporting countries
- the Secretariat of the IPPC
- the Secretariats of the RPPO(s) of which it is a member.

8. Review Mechanism

8.1 System review

The contracting party should periodically review its import regulatory system. This may involve monitoring the effectiveness of phytosanitary measures, auditing the activities of the NPPO and authorized organizations or persons, and modifying the phytosanitary legislation, regulations and procedures as required.

8.2 Incident review

The NPPO should have procedures in place to review cases of non-compliance and emergency action. Such a review may lead to the adoption or modification of phytosanitary measures.



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 21

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

(2004)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2004.

INTRODUCTION

SCOPE

This standard provides guidelines for conducting pest risk analysis (PRA) for regulated non-quarantine pests (RNQPs). 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

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

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

Glossary supplement No. 1: *Guidelines on the interpretation and application of the concept of official control for regulated pests*, 2002. ISPM No. 5, FAO, Rome.

Glossary supplement No. 2: *Guidelines on the interpretation and application of potential economic importance and related terms including reference to environmental considerations*, 2003. ISPM No. 5, FAO, Rome.

Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.

Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

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

Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.

Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.

Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.

Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10, FAO, Rome.

The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

The 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 (RNQPs), 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 No. 5 Glossary of phytosanitary terms, Supplement No. 1 (*Guidelines on the interpretation and application of the concept of official control for regulated pests*), and the defining criteria of RNQPs are set out in ISPM No. 16 (*Regulated non-quarantine pests: concept and application*); 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 No. 16: *Regulated non-quarantine pests: concept and application*).

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 No. 5 Glossary of phytosanitary terms, Supplement No. 1: *Guidelines on the interpretation and application of the concept of official control for regulated pests*).

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 No 1: *Principles of plant quarantine as related to international trade* as well as the interpretation and application of official control (see ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1: *Guidelines on the interpretation and application of the concept of official control for regulated pests*).

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.1c) 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 No. 5 Glossary of phytosanitary terms, Supplement No. 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 No. 11: *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 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 No. 16: *Regulated non-quarantine pests: concept and application*).

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 be comprised of:

- reasons for initiating the process
- importance of the plants for planting as a source of the RNQP
- evaluation of the economic consequences in the PRA area.

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 No. 1: *Principles of plant quarantine as related to international trade*):

- *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 No. 5 Glossary of phytosanitary terms, Supplement No. 1: *Guidelines on the interpretation and application of the concept of official control for regulated pests*):

- import requirements should not be more stringent than domestic requirements
- domestic requirements should enter into force before or at the same time as import requirements
- domestic and import requirements should be the same or have an equivalent effect
- mandatory elements of domestic and import requirements should be the same
- the intensity of inspection of imported consignments should be the same as equivalent processes in domestic control 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 No. 10 (*Requirements for the establishment of pest free places of production and pest-free production sites*).

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 No. 16: *Regulated non-quarantine pests: concept and application*).

Management options may consist of a combination of two or more options (see ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*). Sampling, testing and inspection for the required tolerance may be relevant for all the management options.

These options may be applied to:

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

Section 3.4 of ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 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 No. 10: *Requirements for the establishment of pest free places of production and pest free production sites*)
- 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 No. 1: *Principles of plant quarantine as related to international trade*).

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, 1997 (Article VII.2c) and the principle of “transparency” (ISPM No. 1: *Principles of plant quarantine as related to international trade*) 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.



INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 22

REQUIREMENTS FOR THE ESTABLISHMENT OF AREAS OF LOW PEST PREVALENCE

(2005)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2005

INTRODUCTION**SCOPE**

This standard describes the requirements and procedures for the establishment of areas of low pest prevalence (ALPP) for regulated pests in an area and, to facilitate export, for pests regulated by an importing country only. This includes the identification, verification, maintenance and use of those ALPPs.

REFERENCES

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

Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.

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

Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.

Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

International Plant Protection Convention, 1997, FAO, Rome.

Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.

Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.

Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.

Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10, FAO, Rome.

The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

The establishment of an area of low pest prevalence (ALPP) is a pest management option used to maintain or reduce a pest population below a specified level in an area. An ALPP may be used to facilitate exports or to limit pest impact in the area.

A specified low pest level should be determined taking into consideration the overall operational and economic feasibility of establishing a programme to meet or maintain this level, and the objective for which an ALPP is to be established.

In determining an ALPP, a National Plant Protection Organization (NPPO) should describe the area involved. ALPPs may be established and maintained for regulated pests or for pests regulated by an importing country only.

Surveillance of the relevant pest should be conducted according to appropriate protocols. Additional phytosanitary procedures may be required to establish and maintain an ALPP.

Once established, the ALPP should be maintained by the continuation of the measures used for its establishment and the necessary documentation and verification procedures. In most cases an official operational plan which specifies the required phytosanitary procedures is needed. If there is a change in the status of the ALPP, a corrective action plan should be initiated.

BACKGROUND

1. General Considerations

1.1 Concept of areas of low pest prevalence

The concept of areas of low pest prevalence (ALPP) is referred to in the IPPC and the Agreement on Sanitary and Phytosanitary Measures of the World Trade Organization (WTO-SPS Agreement).

The IPPC (1997) defines an ALPP as “an area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures” (Article II). Furthermore, Article IV.2e states that the responsibilities of the National Plant Protection Organization (NPPO) includes the protection of endangered areas and the designation, maintenance and surveillance of pest free areas (PFAs) and ALPPs.

Article 6 of the WTO-SPS Agreement is entitled “Adaptation to regional conditions, including pest or disease-free areas and areas of low pest or disease prevalence”. It further elaborates on the responsibilities of member countries for ALPPs.

1.2 Advantages in using areas of low pest prevalence

Advantages in using ALPPs include:

- removal of the need for post-harvest treatment(s) when the specified pest level is not exceeded;
- for some pests, biological control methods that rely on low pest populations being present may reduce pesticide use;
- facilitation of market access for products from areas that were previously excluded;
- less restrictive movement controls including movement of commodities may be permitted from:
 - an ALPP to or through a pest free area (PFA), if the commodity is pest free;
 - one ALPP to or through another ALPP, if the commodity has equivalent pest risk.

1.3 Distinction between an area of low pest prevalence and a pest free area

The main difference between an ALPP and a PFA is that the presence of the pest below a specified population level is accepted in an ALPP, whereas the pest is absent from a PFA. When the pest is present in an area, the choice of establishing an ALPP or attempting to establish a PFA as a pest management option will depend on the characteristics of the pest, its distribution in the area of concern and the factors that determine this distribution, the overall operational and economic feasibility of the programme, and the objective for the establishment of a specific ALPP or PFA.

REQUIREMENTS

2. General Requirements

2.1 Determination of an area of low pest prevalence

The establishment of an ALPP is a pest management option used to maintain or reduce the pest population below a specified level in an area. It may be used to facilitate the movement of commodities out of areas where the pest is present, such as for domestic movement or for exports, and reduces or limits pest impact in the area. An ALPP can be established for pests across a broad range of environmental conditions and hosts, and should also take into account the biology of the pest and the characteristics of the area. Since ALPPs may be established for different purposes, the size and description of the ALPP will depend on the purpose.

Examples of where an ALPP may be established by an NPPO according to this standard are:

- an area of production where products are intended for export
- an area under an eradication or suppression programme
- an area acting as a buffer zone to protect a PFA
- an area within a PFA which has lost its status and is under an emergency action plan
- as part of official control in relation to regulated non-quarantine pests (see ISPM No. 16: *Regulated non-quarantine pests: concept and application*)
- an area of production in an infested area of a country from which products are intended to be moved to another ALPP in that country.

Where an ALPP is established and host materials are intended to be exported, they may be subject to additional phytosanitary measures. In this way, an ALPP would be part of a systems approach. Systems approaches are detailed in ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*. Such systems may be very efficient in mitigating the pest risk down to a level acceptable for the importing country and thus, in some cases, the pest risk may be reduced to that of host material originating from a PFA.

2.2 Operational plans

In most cases an official operational plan is needed which specifies the required phytosanitary procedures that a country is applying. If it is intended to use an ALPP to facilitate trade with another country, such plan may have the form of a specific work plan as part of a bilateral arrangement between the NPPOs of both importing and exporting contracting parties, or may be a general requirement of an importing country, which should be made available to it on request. It is recommended that the exporting country consults with the importing country in the early stages of the process in order to ensure that importing country requirements are met.

3. Specific Requirements

3.1 Establishment of an ALPP

Low pest prevalence can occur naturally or be established through the development and application of phytosanitary measures aimed at controlling the pest(s).

3.1.1 Determination of specified pest levels

Specified levels for the relevant pests should be established by the NPPO of the country where the ALPP is located, with sufficient precision to allow assessment of whether surveillance data and protocols are adequate to determine that pest prevalence is below these levels. Specified pest levels may be established through PRA, for example as described in ISPMs No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*) and No. 21 (*Pest risk analysis for regulated non-quarantine pests*). If the ALPP is intended to facilitate exports, the specified levels should be established in conjunction with the importing country.

3.1.2 Geographic description

The NPPO should describe the ALPP with supporting maps demonstrating the boundaries of the area. Where appropriate, the description may also include the places of production, the host plants in proximity to commercial production areas, as well as the natural barriers and/or buffer zones which may isolate the area.

It may be useful to indicate how the size and configuration of the natural barriers and buffer zones contribute to the exclusion or management of the pest, or why they serve as a barrier to the pest.

3.1.3 Documentation and verification

The NPPO should verify and document that all procedures are implemented. The elements of this process should include:

- documented procedures to be followed (i.e. procedural manual)
- implemented procedures and record keeping of these procedures
- audit of procedures
- developed and implemented corrective actions.

3.1.4 Phytosanitary procedures

3.1.4.1 Surveillance activities

The status of the relevant pest situation in the area, and when appropriate of the buffer zone, should be determined by surveillance (as described in ISPM No. 6: *Guidelines for surveillance*) during appropriate periods of time and at a level of sensitivity that will detect the specified pest at the specified level with an appropriate level of confidence. Surveillance should be conducted according to protocols for the specified pest(s). These protocols should include how to measure if the specified pest level has been maintained, e.g. type of trap, number of traps per hectare, acceptable number of pest individuals per trap per day or week, number of samples per hectare that need to be tested or inspected, part of the plant to be tested or inspected, etc.

Surveillance data should be collected and documented to demonstrate that the populations of the specified pests do not exceed the specified pest levels in any areas of the proposed ALPP, and any associated buffer zones, and include, where relevant, surveys of cultivated and uncultivated hosts, or habitats in particular in the case where the pest is a plant. The surveillance data should be relevant to the life cycles of the specified pests and should be statistically validated to detect and characterize the population levels of the pests.

When establishing an ALPP, technical reports of the specified pest(s) detections, and results of the surveillance activities should be recorded and maintained for a sufficient number of years, depending on the biology, reproductive potential and host range of the specified pests. However to supplement this information, data should be provided for as many years as possible, prior to the establishment of the ALPP.

3.1.4.2 Reducing pest levels and maintaining low prevalence

In the proposed ALPP, phytosanitary procedures should be documented and applied to meet pest(s) levels in cultivated hosts, uncultivated hosts, or habitats in particular in the case where the pest is a plant. Phytosanitary procedures should be relevant to the biology and behaviour of the specified pests. Examples of procedures used to meet a specified pest level are: removing alternative and/or alternate hosts; applying pesticides; releasing biological control agents; using high density trapping techniques to capture the pest.

When establishing an ALPP, control activities should be recorded for a sufficient number of years, depending on the biology, reproductive potential and host range of the specified pest(s). However to supplement this information, data should be provided for as many years as possible, prior to the establishment of the ALPP.

3.1.4.3 Reducing the risk of entry of specified pest(s)

In cases where an ALPP is established for a regulated pest, phytosanitary measures may be required to reduce the risk of entry of the specified pests into the ALPP (ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*). These may include:

- regulation of the pathways and of the articles that require control to maintain the ALPP. All pathways into and out of the ALPP should be identified. This may include the designation of points of entry, and requirements for documentation, treatment, inspection or sampling before or at entry into the area.
- verification of documents and of the phytosanitary status of consignments including identification of intercepted specimens of specified pest and maintenance of sampling records
- confirmation of the application and effectiveness of required treatments
- documentation of any other phytosanitary procedures.

An ALPP may be established for pests regulated domestically or to facilitate exports for pests regulated in an importing country. When an ALPP is established for a pest that is not a regulated pest for that area, measures to reduce the risk of entry may also be applied. However, such measures should not restrict trade of plant and plant products into the country, or discriminate between imported and nationally-produced commodities.

3.1.4.4 Corrective action plan

The NPPO should have a documented plan to be implemented if a specified pest level is exceeded in the ALPP, or when appropriate in the buffer zones (section 3.3 describes other situations where the status of an ALPP may change). The plan may include a delimiting survey to determine the area in which the specified pest level has been exceeded, commodity sampling, pesticide applications and/or other suppression activities. Corrective actions should also address all of the pathways.

3.1.5 Verification of an area of low pest prevalence

The NPPO of the country where the ALPP is to be established should verify that the measures necessary to meet the requirements of the ALPP are in place. This includes verification that all aspects of the documentation and verification procedures described in section 3.1.3 are implemented. If the area is being used for exports, the NPPO of the importing country may also want to verify compliance.

3.2 Maintenance of an area of low pest prevalence

Once an ALPP is established, the NPPO should maintain the established documentation and verification procedures, and continue following phytosanitary procedures and movement controls and keeping records. Records should be retained for at least the two previous years or as long as necessary to support the programme. If the ALPP is being used for export purposes, records should be made available to the importing country upon request. In addition, established procedures should be routinely audited, at least once a year.

3.3 Change in the status of an area of low pest prevalence

The main cause leading to a change in the status of an ALPP is the detection of the specified pest(s) at a level exceeding the specified pest level(s) within the ALPP.

Other examples that may cause a change in status of an ALPP and lead to the need to take action are:

- repeated failure of regulatory procedures
- incomplete documentation that jeopardises the integrity of the ALPP.

The change of status should result in the implementation of the corrective action plan as specified in Section 3.1.4.4 of this standard. The corrective actions should be initiated as soon as possible after confirmation that the specified pest level has been exceeded in the ALPP.

Depending on the outcome of the actions taken, the ALPP may be:

- continued (status not lost), if the phytosanitary actions taken (as part of the corrective action plan in the case of detection of specified pests above a specified pest levels) have been successful
- continued, if a failure of regulatory actions or other deficiencies has been rectified
- redefined to exclude a certain area, if the specified pest level of a pest is exceeded in a limited area that can be identified and isolated
- suspended (status lost).

If the ALPP is being used for export purposes, the importing country may require that such situations and associated activities are reported to it. Additional guidance is provided by ISPM No. 17: *Pest reporting*. Furthermore, a corrective action plan may be agreed to between the importing and exporting countries.

3.4 Suspension and reinstatement of the status of an area of low pest prevalence

If an ALPP is suspended, an investigation should be initiated to determine the cause of the failure. Corrective actions, and if necessary additional safeguards, should be implemented to prevent recurrence of the failure. The suspension of the ALPP will remain in effect until it is demonstrated that populations of the pest are below the specified pest level for an appropriate period of time, or that the other deficiencies have been corrected. As with the initial establishment of an ALPP, the minimum period of time below the specified pest level(s) for reinstatement of ALPP status will depend on the biology of the specified pest(s). Once the cause of the failure has been corrected and the integrity of the system is verified, the ALPP can be reinstated.



INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 23

GUIDELINES FOR INSPECTION

(2005)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2005

INTRODUCTION

SCOPE

This standard describes procedures for the inspection of consignments of plants, plant products and other regulated articles at import and export. It is focused on the determination of compliance with phytosanitary requirements, based on visual examination, documentary checks, and identity and integrity checks.

REFERENCES

Export certification system, 1997. ISPM No. 7, FAO, Rome.

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

Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.

Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.

Guidelines on phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

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

Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.

Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.

Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.

The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

National Plant Protection Organizations (NPPOs) have the responsibility for “*the inspection of consignments of plants and plant products moving in international traffic and, where appropriate, the inspection of other regulated articles, particularly with the object of preventing the introduction and/or spread of pests.*” (Article IV.2c of the IPPC, 1997).

Inspectors determine compliance of consignments with phytosanitary requirements, based on visual examination for detection of pests and regulated articles, and documentary checks, and identity and integrity checks. The result of inspection should allow an inspector to decide whether to accept, detain or reject the consignment, or whether further analysis is required.

NPPOs may determine that consignments should be sampled during inspection. The sampling methodology used should depend on the specific inspection objectives.

REQUIREMENTS

1. General Requirements

The responsibilities of a National Plant Protection Organization (NPPO) include "*the inspection of consignments of plants and plant products moving in international traffic and, where appropriate, the inspection of other regulated articles, particularly with the object of preventing the introduction and/or spread of pests*" (Article IV.2c of the IPPC, 1997).

Consignments may consist of one or more commodities or lots. Where a consignment is comprised of more than one commodity or lot, the inspection to determine compliance may have to consist of several separate visual examinations. Throughout this standard, the term "consignment" is used, but it should be recognized that the guidance provided for consignments may apply equally to individual lots within a consignment.

1.1 Inspection objectives

The objective of inspection of consignments is to confirm compliance with import or export requirements relating to quarantine pests or regulated non-quarantine pests. It often serves to verify the effectiveness of other phytosanitary measures taken at a previous stage in time.

An export inspection is used to ensure that the consignment meets specified phytosanitary requirements of the importing country at the time of inspection. An export inspection of a consignment may result in the issuance of a phytosanitary certificate for the consignment in question.

Inspection at import is used to verify compliance with phytosanitary import requirements. Inspection may also be carried out generally for the detection of organisms for which the phytosanitary risk has not yet been determined.

The collection of samples for laboratory testing or the verification of pest identity may be combined with the inspection procedure.

Inspection can be used as a risk management procedure.

1.2 Assumptions involved in the application of inspections

As inspection of entire consignments is often not feasible, phytosanitary inspection is consequently often based on sampling¹.

The use of inspection as a means to detect the presence of pests in, or to determine or verify the pest level of, a consignment is based on the following assumptions:

- the pests of concern, or the signs or symptoms they cause, are visually detectable
- inspection is operationally practical
- some probability of pests being undetected is recognized.

There is some probability of pests being undetected when inspection is used. This is because inspection is usually based on sampling, which may not involve visual examination of 100% of the lot or consignment, and also because inspection is not 100% effective for detecting a specified pest on the consignment or samples examined. When inspection is used as a risk management procedure, there is also a certain probability that a pest which is present in a consignment or lot may not be detected.

The size of a sample for inspection purposes is normally determined on the basis of a specified regulated pest associated with a specific commodity. It may be more difficult to determine the sample size in cases where inspection of consignments is targeted at several or all regulated pests.

1.3 Responsibility for inspection

NPPOs have the responsibility for inspection. Inspections are carried out by NPPOs or under their authority (see also section 3.1 of ISPM No. 7: *Export certification system*; and section 5.1.5.2 of ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*; Articles IV.2a, IV.2c and V.2a of the IPPC, 1997).

¹ Guidance on sampling will be provided in the ISPM under development.

1.4 Requirements for inspectors

As authorized officers or agents by the NPPO, inspectors should have:

- authority to discharge their duties and accountability for their actions
- technical qualifications and competencies, especially in pest detection
- knowledge of, or access to capability in, identification of pests, plants and plant products and other regulated articles
- access to appropriate inspection facilities, tools and equipment
- written guidelines (such as regulations, manuals, pest data sheets)
- knowledge of the operation of other regulatory agencies where appropriate
- objectivity and impartiality.

The inspector may be required to inspect consignments for:

- compliance with specified import or export requirements
- specified regulated pests
- organisms for which the phytosanitary risk has not yet been determined.

1.5 Other considerations for inspection

The decision to use inspection as a phytosanitary measure involves consideration of many factors, including in particular the phytosanitary requirements of the importing country and the pests of concern. Other factors that require consideration may include:

- the mitigation measures taken by the exporting country
- whether inspection is the only measure or combined with other measures
- commodity type and intended use
- place/area of production
- consignment size and configuration
- volume, frequency and timing of shipments
- experience with origin/shipper
- means of conveyance and packaging
- available financial and technical resources (including pest diagnostic capabilities)
- previous handling and processing
- sampling design characteristics necessary to achieve the inspection objectives
- difficulty of pest detection on a specific commodity
- experience and the results of previous inspections
- perishability of the commodity (see also Article VII.2e of the IPPC, 1997)
- effectiveness of the inspection procedure.

1.6 Inspection in relation to pest risk analysis

Pest risk analysis (PRA) provides the basis for technical justification for phytosanitary import requirements. PRA also provides the means for developing lists of regulated pests requiring phytosanitary measures, and identifies those for which inspection is appropriate and/or identifies commodities that are subject to inspection. If new pests are reported during inspection, emergency actions may be undertaken, as appropriate. Where emergency actions are taken, a PRA should be used for evaluating these pests and developing recommendations for appropriate further actions when necessary.

When considering inspection as an option for risk management and the basis for phytosanitary decision making, it is important to consider both technical and operational factors associated with a particular type and level of inspection. Such an inspection may be required to detect specified regulated pests at the desired level and confidence depending on the risk associated with them (see also ISPM No. 11: *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004, and ISPM No. 21: *Pest risk analysis for regulated non-quarantine pests*).

2. Specific Requirements

The technical requirements for inspection involve three distinct procedures that should be designed with a view to ensuring technical correctness while also considering operational practicality. These procedures are:

- examination of documents associated with a consignment
- verification of consignment identity and integrity
- visual examination for pests and other phytosanitary requirements (such as freedom from soil).

Certain aspects of inspection may differ depending on the purpose, such as for import/export purposes, or verification/risk management purposes.

2.1 Examination of documents associated with a consignment

Import and export documents are examined to ensure that they are:

- complete
- consistent
- accurate
- valid and not fraudulent (see section 1.4 of ISPM No. 12: *Guidelines for phytosanitary certificates*).

Examples of documents that may be associated with import and/or export certification include:

- phytosanitary certificate/re-export phytosanitary certificates
- manifest (including bills of lading, invoice)
- import permit
- treatment documents/certificates, marks (such as provided for in ISPM No. 15: *Guidelines on regulating wood packaging material in international trade*) or other indicators of treatment
- certificate of origin
- field inspection certificates/reports
- producer/packing records
- certification programme documents (e.g. seed potato certification programmes, pest free area documentation)
- inspection reports
- commercial invoices
- laboratory reports.

Problems encountered with either import or export documents should, where appropriate, be investigated first with the parties providing the documents before further action is taken.

2.2 Verification of consignment identity and integrity

The inspection for identity and integrity involves checking to ensure that the consignment is accurately described by its documents. The identity check verifies whether the type of plant or plant product or species is in accordance with the phytosanitary certificate received or to be issued. The integrity check verifies if the consignment is clearly identifiable and the quantity and status is as declared in the phytosanitary certificate received or to be issued. This may require a physical examination of the consignment to confirm the identity and integrity, including checking for seals, safety conditions and other relevant physical aspects of the shipment that may be of phytosanitary concern. Actions taken based on the result will depend on the extent and nature of the problem encountered.

2.3 Visual examination

Related aspects of visual examination include its use for pest detection and for verifying compliance with phytosanitary requirements.

2.3.1 Pests

A sample is taken from consignments/lots to determine if a pest is present, or if it exceeds a specified level. The ability to detect in a consistent manner the presence of a regulated pest with the desired confidence level requires practical and statistical considerations, such as the probability of detecting the pest, the size of the lot, the desired level of confidence, the sample size and the intensity of the inspection (see ISPM on sampling -under development).

If the objective of inspection is the detection of specified regulated pests to meet phytosanitary import requirements, then the sampling method should be based on a probability of detecting the pest that satisfies the corresponding phytosanitary requirements.

If the objective of the inspection is the verification of the general phytosanitary condition of a consignment/lot, such as when:

- no specified regulated pests have been identified
- no specified pest level has been identified for regulated pests
- the aim is to detect pests when there has been a failure of a phytosanitary measure,

then sampling methodology should reflect this.

The sampling method adopted should be based on transparent technical and operational criteria, and should be consistently applied (see also ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*).

2.3.2 Compliance of phytosanitary requirements

Inspection can be used to verify the compliance with some phytosanitary requirements. Examples include:

- treatment
- degree of processing
- freedom from contaminants (e.g. leaves, soil)
- required growth stage, variety, colour, age, degree of maturity etc.
- absence of unauthorized plants, plant products or other regulated articles
- consignment packaging and shipping requirements
- origin of consignment/ lots
- point of entry.

2.4 Inspection methods

The inspection method should be designed either to detect the specified regulated pests on or in the commodity being examined, or to be used for a general inspection for organisms for which the phytosanitary risk has not yet been determined. The inspector visually examines units in the sample until the target or other pest has been detected or all sample units have been examined. At that point, the inspection may cease. However, additional sample units may be examined if the NPPO needs to gather additional information concerning the pest and the commodity, for example if the pest is not observed, but signs or symptoms are. The inspector may also have access to other non visual tools that may be used in conjunction with the inspection process.

It is important that:

- examination of the sample be undertaken as soon as reasonably possible after the sample has been drawn and that the sample is as representative of the consignment/lot as possible.
- techniques are reviewed to take account of experience gained with the technique and of new technical developments.
- procedures are put in place to ensure the independence, integrity, traceability and security of samples for each consignment/lot.
- results of the inspection are documented.

Inspection procedures should be in accordance with the PRA where appropriate, and should be consistently applied.

2.5 Inspection outcome

The result of the inspection contributes to the decision to be made as to whether the consignment meets phytosanitary requirements. If phytosanitary requirements are met, consignments for exports may be provided with appropriate certification, e.g. phytosanitary certificates, and consignments for import will be released.

If phytosanitary requirements are not met, further actions can be taken. These actions may be determined by the nature of the findings, considering the regulated pest or other inspection objectives, and the circumstances. Actions for non-compliance are described in detail in ISPM No. 20 (*Guidelines for a phytosanitary import regulatory system*), section 5.1.6.

In many cases, pests or signs of pests that have been detected may require identification or a specialized analysis in a laboratory or by a specialist before a determination can be made on the phytosanitary status of the consignment. It may be decided that emergency measures are needed where new or previously unknown pests are found. A system for properly documenting and maintaining samples and/or specimens should be in place to ensure trace-back to the relevant consignment and to facilitate later review of the results if necessary.

In cases of repeated non-compliance, amongst other actions, the intensity and frequency of inspections for certain consignments may be increased.

Where a pest is detected in an import, the inspection report should be sufficiently detailed to allow for notifications of non-compliance (in accordance with ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*). Certain other record-keeping requirements may also rely on the availability of adequately completed inspection reports (e.g. as described in Articles VII and VIII of the IPPC, ISPM No. 8: *Determination of pest status in an area*, and ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*).

2.6 Review of inspection systems

NPPOs should conduct periodic reviews of import and export inspection systems to validate the appropriateness of their design and to determine any course of adjustments needed to ensure that they are technically sound.

Audits should be conducted in order to review the validity of the inspection systems. An additional inspection may be a component of the audit.

2.7 Transparency

As part of the inspection process, information concerning inspection procedures for a commodity should be documented and made available on request to the parties concerned in application of the transparency principle (ISPM No. 1: *Principles of plant quarantine as related to international trade*). This information may be part of bilateral arrangements covering the phytosanitary aspects of a commodity trade.



INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 24

GUIDELINES FOR THE DETERMINATION AND RECOGNITION OF EQUIVALENCE OF PHYTOSANITARY MEASURES

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ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2005

INTRODUCTION

SCOPE

This standard describes the principles and requirements that apply for the determination and recognition of equivalence of phytosanitary measures. It also describes a procedure for equivalence determinations in international trade.

REFERENCES

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

Export certification system, 1997. ISPM No. 7, FAO Rome.

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

Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.

Guidelines for regulating wood packaging material in international trade, 2002. ISPM No. 15. FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

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

Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.

The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

Equivalence is one of the IPPC general principles (ISPM No. 1: *Principles of plant quarantine as related to international trade*).

Equivalence generally applies to cases where phytosanitary measures already exist for a specific pest associated with trade in a commodity or commodity class. Equivalence determinations are based on the specified pest risk and equivalence may apply to individual measures, a combination of measures, or integrated measures in a systems approach.

A determination of equivalence requires an assessment of phytosanitary measures to determine their effectiveness in mitigating a specified pest risk. The determination of equivalence of measures may also include an evaluation of the exporting contracting party's phytosanitary systems or programs that support implementation of those measures. Normally, the determination involves a sequential process of information exchange and evaluation, and is generally an agreed procedure between importing and exporting contracting parties. Information is provided in a form that allows the evaluation of existing and proposed measures for their ability to meet the importing contracting party's appropriate level of protection¹.

The exporting contracting party may request information from the importing contracting party on the contribution that its existing measures make to meeting its appropriate level of protection. The exporting contracting party may propose an alternative measure, indicating how this measure achieves the required level of protection, and this is evaluated by the importing contracting party. In some cases, such as where technical assistance is provided, importing contracting parties may make proposals for alternative phytosanitary measures. Contracting parties should endeavour to undertake equivalence determinations and to resolve any differences without undue delays.

¹ This term is defined in the *Agreement on the Application of Sanitary and Phytosanitary Measures* of the World Trade Organization (WTO-SPS Agreement). Many WTO members otherwise refer to this concept as the "acceptable level of risk".

REQUIREMENTS

1. General Considerations

Equivalence is described as general principle No. 7 in ISPM No. 1 (*Principles of plant quarantine as related to international trade*, 1993): "*Equivalence: Countries shall recognize as being equivalent those phytosanitary measures that are not identical but which have the same effect*". Furthermore, the concept of equivalence and the obligation of contracting parties to observe the principle of equivalence is an integral element in other existing ISPMs. In addition, equivalence is described in Article 4 of the WTO-SPS Agreement.

The process of recognizing equivalence is the objective examination of alternative phytosanitary measures proposed to determine if they achieve the appropriate level of protection of an importing country as indicated by existing measures of that country.

Contracting parties recognize that alternative phytosanitary measures can achieve their appropriate level of protection. Therefore, while not formalized under the title of "equivalence", there is widespread application of equivalence in current phytosanitary practices.

To manage a specified pest risk and achieve a contracting party's appropriate level of protection, equivalence may be applied to:

- an individual measure,
- a combination of measures, or
- integrated measures in a systems approach.

In the case of a systems approach, alternative measures may be proposed as equivalent to one or more of the integrated measures, rather than changing the entire systems approach. Equivalence arrangements are applicable for commodities rather than for individual consignments.

The evaluation for equivalence of phytosanitary measures may not be limited to an assessment of the measures alone, but may also involve consideration of aspects of the export certification system or other factors associated with the implementation of pest risk management measures.

This standard provides guidelines for situations where an importing contracting party has a phytosanitary measure in place, or is proposing a new measure, and an exporting contracting party proposes an alternative measure to achieve the importing contracting party's appropriate level of protection. The alternative measure is then evaluated for equivalence.

In some cases importing contracting parties list a number of phytosanitary measures that are considered to achieve their appropriate level of protection. Contracting parties are encouraged to include two or more equivalent measures for regulated articles as part of their import regulations. This allows for taking into account different or changing phytosanitary situations in exporting countries. These measures may differ in the extent to which they achieve or exceed the contracting party's appropriate level of protection. The evaluation of the equivalence of such measures listed by an importing contracting party is not the primary subject of this standard.

Although equivalence is generally a bilateral process between importing and exporting contracting parties, multilateral arrangements for comparing alternative measures take place as part of the standard setting process of the IPPC. For example, there are alternative measures approved in ISPM No 15: *Guidelines for regulating wood packaging material in international trade*.

2. General Principles and Requirements

2.1 Sovereign authority

Contracting parties have sovereign authority, in accordance with applicable international agreements, to apply phytosanitary measures to protect plant health within their territories and to determine their appropriate level of protection to plant health. A contracting party has sovereign authority to regulate the entry of plants, plant products and other regulated articles (Article VII.1 of the IPPC, 1997). Therefore a contracting party has the right to make decisions relating to determinations of equivalence. In order to promote cooperation, an importing contracting party evaluates the equivalence of phytosanitary measures.

2.2 Other relevant principles of the IPPC

In equivalence evaluations, contracting parties should take into account the following principles:

- minimal impact (Article VII.2g of the IPPC, 1997)
- modification (Article VII.2h of the IPPC, 1997)
- transparency (Articles VII.2b, 2c, 2i and VIII.1a of the IPPC, 1997)
- harmonization (Article X.4 of the IPPC, 1997)
- risk analysis (Articles II and VI.1b of the IPPC, 1997)
- managed risk (Article VII.2a and 2g of the IPPC, 1997)
- non-discrimination (Article VI.1a of the IPPC, 1997).

2.3 Technical justification for equivalence

Assessments of equivalence should be risk-based, using an evaluation of available scientific information, either through PRA or by evaluation of the existing measures and the proposed measures. The exporting contracting party has the responsibility for providing the technical information to demonstrate that the alternative measures reduce the specified pest risk and that they achieve the appropriate level of protection of the importing contracting party. In some cases (e.g. as described in section 3.2), however, importing contracting parties may propose alternative measures for the exporting contracting party to consider. This information may be qualitative and/or quantitative as long as comparison is possible.

Although the alternative measures need to be examined, a new complete pest risk assessment may not necessarily be required since, as trade in the commodity or commodity class is already regulated, the importing country should have at least some PRA-related data.

2.4 Non-discrimination in the application of the equivalence of phytosanitary measures

The principle of non-discrimination requires that when equivalence of phytosanitary measures is granted for one exporting contracting party, this should also apply to contracting parties with the same phytosanitary status and similar conditions for the same commodity or commodity class and/or pest. Therefore, an importing contracting party which recognizes the equivalence of alternative phytosanitary measures of an exporting contracting party should ensure that it acts in a non-discriminatory manner. This applies both to applications from third countries for recognition of the equivalence of the same or similar measures, and to the equivalence of any domestic measures.

It should be recognized that equivalence of phytosanitary measures does not, however, mean that when a specific measure is granted equivalence for one exporting contracting party, this applies automatically to another contracting party for the same commodity or commodity class or pest. Phytosanitary measures should always be considered in the context of the pest status and phytosanitary regulatory system of the exporting contracting party, including the policies and procedures.

2.5 Information exchange

Contracting parties have obligations under the IPPC to provide and exchange information, which should be made available for equivalence determinations. This includes making available, on request, the rationale for phytosanitary requirements (Article VII.2c of the IPPC, 1997) and cooperating to the extent practicable in providing technical and biological information necessary for pest risk analysis (Article VIII of the IPPC, 1997). Contracting parties should aim to limit any data requests associated with an evaluation of equivalence to those which are necessary for this evaluation.

To facilitate discussions on equivalence the importing contracting party should, on request, provide information describing how its existing measures reduce the risk of the specified pest and how they achieve its appropriate level of protection. This information may be provided in either quantitative or qualitative terms. Such information should assist the exporting contracting party in understanding the existing measures. It may also help the exporting contracting party to explain how its proposed alternative measures reduce the pest risk and achieve the importing contracting party's appropriate level of protection.

2.6 Technical assistance

In accordance with Article XX of the IPPC (1997), contracting parties are encouraged to consider providing technical assistance for the development of measures based on equivalence if requested by another contracting party.

2.7 Timeliness

Contracting parties should endeavour to determine the equivalence of phytosanitary measures and to resolve any differences without undue delays.

3. Specific Requirements for the Application of Equivalence

3.1 Specific pests and commodities

The process of comparing alternative phytosanitary measures for the purpose of determining their equivalence usually relates to a specified export commodity and specified regulated pests identified through pest risk analysis.

3.2 Existing measures

Equivalence generally applies to cases where the importing contracting party has already existing measures for the current trade concerned. However, it may also apply where new measures are proposed by the importing contracting party. Usually an exporting contracting party presents an alternative measure that is intended to achieve the importing contracting party's appropriate level of protection. In some cases, such as where technical assistance is being provided, contracting parties may propose alternative measures for the consideration of other contracting parties.

Where new commodities or commodity classes are presented for importation and no measures exist, contracting parties should refer to ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) and ISPM No. 21 (*Pest risk analysis for regulated non-quarantine pests*) for the normal PRA procedure.

3.3 Entry into consultation

When requested, contracting parties are encouraged to enter into consultations with the aim of facilitating a determination of equivalence.

3.4 Agreed procedure

Contracting parties should agree on a procedure to determine equivalence. This may be based on the procedure recommended in Annex 1 of this standard or another bilaterally agreed procedure.

3.5 Factors considered in determining equivalence

The determination of the equivalence of phytosanitary measures depends on a number of factors. These may include:

- the effect of the measure as demonstrated in laboratory or field conditions
- the examination of relevant literature on the effect of the measure
- the results of experience in the practical application of the measure
- the factors affecting the implementation of the measure (e.g. the policies and procedures of the contracting party).

The effect of phytosanitary measures implemented in a third country may be considered as reference. Information on the measure is used by the importing contracting party to assess the contribution of the alternative measure in reducing the pest risk to a level that provides the appropriate level of protection.

When comparing existing measures and measures proposed as equivalent, importing and exporting contracting parties should assess the ability of the measures to reduce a specified pest risk. The proposed measures should be assessed for their ability to achieve the importing contracting party's appropriate level of protection. In cases where the effects of both the existing measures and the proposed measures are expressed in the same way (i.e. the same type of required response), the effects may be compared directly for their ability to reduce the pest risk. For example, a fumigation treatment and a cold treatment may be compared for their effects based on mortality.

Where measures are expressed differently, they may be difficult to compare directly. In such cases, the proposed measures should be assessed for their ability to achieve the importing contracting party's appropriate level of protection. This may require data to be converted or extrapolated so that common units are used before comparison is possible. For example, effects such as mortality and an area of low pest prevalence may be compared if considered in relation to pest freedom at an agreed level of confidence (for example per consignment or per year).

When determining equivalence, a comparison of specific technical requirements of the existing and proposed measures may suffice. In some circumstances, however, the determination of whether a proposed measure achieves the appropriate level of protection may need to be considered in relation to the capacity of the exporting country to apply this measure. In the cases where trade is already established between contracting parties, this provides knowledge about and experience with the exporting contracting party's phytosanitary regulatory systems (e.g. legal, surveillance, inspection, certification, etc.) This knowledge and experience should strengthen confidence between parties and assist, if

necessary, with the evaluation of an equivalence proposal. In relation to such information, an importing contracting party may require updated information, when technically justified, of procedures of the exporting contracting party related specifically to the implementation of the phytosanitary measures proposed as equivalent.

The final acceptance of a proposed measure may depend on practical considerations such as availability/approval of the technology, unintended effects of the proposed measure (e.g. phytotoxicity), and operational and economic feasibility.

3.6 Non-disruption of trade

A submission of a request for recognition of equivalence should not in itself alter the way in which trade occurs; it is not a justification for disruption or suspension of existing trade or existing phytosanitary import requirements.

3.7 Provision of access

In order to support an importing contracting party's consideration of an equivalence request, the exporting contracting party should facilitate access by the importing contracting party to relevant sites to conduct any reviews, inspections or verifications for an equivalence determination when technically justified.

3.8 Review and monitoring

After the recognition of equivalence, and to provide continued confidence in the equivalence arrangements, contracting parties should implement the same review and monitoring procedures as for similar phytosanitary measures. These may include assurance procedures such as audits, periodic checks, reporting of non-compliances (see also ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*) or other forms of verification.

3.9 Implementation and transparency

To achieve the required transparency, amendment of regulations and related procedures should also be made available to other interested contracting parties.

PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

The interactive procedure described below is recommended for assessing phytosanitary measures in order to make a determination as to their equivalence. However, the procedure that trading partners utilise to determine equivalence may vary depending on the circumstances.

Recommended steps are:

1. The exporting contracting party communicates its interest in an equivalence determination to its trading partner, indicating the specified commodity, the regulated pest of concern and the existing and proposed alternative measures, including relevant data. At the same time it may request from the importing contracting party the technical justification for the existing measures. In discussions on the determination of equivalence, an agreement including an outline of the steps involved, an agenda and a possible timetable may be established.

2. The importing contracting party describes its existing measures in terms that will help to facilitate a comparison with alternative phytosanitary measures. To the best of its ability, the information provided by the importing contracting party should include the following:

- a) the purpose of the phytosanitary measures, including identification of the specific pest risk that these measures are being used to mitigate
- b) to the extent possible, how the existing phytosanitary measures achieve the importing contracting party's appropriate level of protection
- c) the technical justification for the existing phytosanitary measures, including the PRA where appropriate
- d) any additional information that may assist the exporting contracting party in demonstrating that the proposed measures achieve the importing contracting party's appropriate level of protection.

3. The exporting contracting party provides the technical information that it believes demonstrates equivalence of phytosanitary measures, and makes a request for equivalence. This information should be in a form suitable for comparison with the information provided by the importing contracting party and which therefore facilitates the necessary evaluation by the importing contracting party. This should include the following elements:

- a) the description of the proposed alternative measures
- b) the effectiveness of the measures
- c) to the extent possible, the contribution of the proposed alternative measures in achieving the importing contracting party's appropriate level of protection
- d) information on how the measures were evaluated (e.g. laboratory testing, statistical analysis, practical operational experience), and the performance of the measures in practice
- e) a comparison between the proposed alternative measures and the importing contracting party's existing measures for same pest risk
- f) information on technical and operational feasibility of the proposed alternative measures.

4. The importing contracting party receives and evaluates the proposed alternative phytosanitary measures, taking into account, but not being limited to the following:

- a) the submission from the exporting contracting party, including supporting information regarding the effectiveness of the proposed alternative measures
- b) the degree to which the alternative phytosanitary measures achieve the appropriate level of protection, either on the basis of qualitative or quantitative information
- c) information regarding the method, action and operation of the proposed alternative phytosanitary measures in preventing or reducing the specified pest risk
- d) the operational and economic feasibility of adopting the proposed alternative phytosanitary measures.

During the evaluation further clarification may be required. Additional information and/or access to operational procedures may be requested by the importing contracting party in order to complete the assessment. The exporting contracting party should respond to any technical concerns raised by the importing contracting party by providing relevant information and/or providing access to relevant information or sites to facilitate reviews, inspections or other verifications necessary for making an equivalence determination.

5. The importing contracting party notifies the exporting contracting party of its decision and provides, upon request, an explanation and technical justification for its determination as quickly as possible.

6. In the event of a rejection of the request for equivalence, efforts should be made to resolve differences of opinion through bilateral dialogue.
7. If equivalence is recognized by the importing contracting party, implementation should be achieved by the prompt amendment of the import regulations and any associated procedures of the importing contracting party. The amendments should be communicated in accordance with Article VII.2b of the IPPC (1997).
8. An audit and monitoring procedure may be established and included in the plan or arrangement which implements any recognized equivalence measures or programmes.

