INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 12

GUIDELINES FOR PHYTOSANITARY CERTIFICATES

(2001)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2001.

INTRODUCTION

SCOPE

This standard describes principles and guidelines for the preparation and issue of phytosanitary certificates and phytosanitary certificates for re-export.

REFERENCES

Export certification system, 1997. ISPM No. 7, FAO, Rome.
Glossary of phytosanitary terms, 1999. ISPM No. 5, FAO, Rome.
New Revised Text of the International Plant Protection Convention, 1997. 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

This standard describes principles and guidelines to assist National Plant Protection Organizations (NPPOs) with the preparation and issue of phytosanitary certificates and phytosanitary certificates for re-export. Model certificates are provided in the Annex of the International Plant Protection Convention (IPPC) adopted in 1997 and are appended to this standard for reference. Explanations are given on the various components of the model certificates indicating the information needed for their appropriate completion.

REQUIREMENTS FOR PHYTOSANITARY CERTIFICATES

1. General Considerations

Article V.2a of the IPPC (1997) states that: "*Inspection and other related activities leading to issuance of phytosanitary certificates shall be carried out only by or under the authority of the official national plant protection organization. The issuance of phytosanitary certificates shall be carried out by public officers who are technically qualified and duly authorized by the official national plant protection organization to act on its behalf and under its control with such knowledge and information available to those officers that the authorities of importing contracting parties may accept the phytosanitary certificates with confidence as dependable documents.*" (See also ISPM No. 7: *Export certification system*).

Article V.3 states: "*Each contracting party undertakes not to require consignments of plants or plant products or other regulated articles imported into its territories to be accompanied by phytosanitary certificates inconsistent with the models set out in the Annex to this Convention. Any requirements for additional declarations shall be limited to those technically justified*."

As clarified at the time of the adoption of the IPPC (1997), it is understood that 'public officers who are technically qualified and duly authorized by the national plant protection organization' include officers from the national plant protection organization. 'Public' in this context means employed by a level of government, not by a private company. 'Include officers from the national plant protection organization' means that the officer may be directly employed by the NPPO, but does not have to be directly employed by the NPPO.

1.1 Purpose of phytosanitary certificates

Phytosanitary certificates are issued to indicate that consignments of plants, plant products or other regulated articles meet specified phytosanitary import requirements and are in conformity with the certifying statement of the appropriate model certificate. Phytosanitary certificates should only be issued for this purpose.

Model certificates provide a standard wording and format that should be followed for the preparation of official phytosanitary certificates. This is necessary to ensure the validity of the documents, that they are easily recognized, and that essential information is reported.

Importing countries should only require phytosanitary certificates for regulated articles. These include commodities such as plants, bulbs and tubers, or seeds for propagation, fruits and vegetables, cut flowers and branches, grain, and growing medium. Phytosanitary certificates may also be used for certain plant products that have been processed where such products, by their nature or that of their processing, have a potential for introducing regulated pests (e.g. wood, cotton). A phytosanitary certificate may also be required for other regulated articles where phytosanitary measures are technically justified (e.g. empty containers, vehicles, and organisms).

Importing countries should not require phytosanitary certificates for plant products that have been processed in such a way that they have no potential for introducing regulated pests, or for other articles that do not require phytosanitary measures.

NPPOs should agree bilaterally when there are differences between the views of the importing country and exporting country regarding the justification for requiring a phytosanitary certificate. Changes regarding the requirement for a phytosanitary certificate should respect the principles of transparency and non-discrimination.

1.2 Mode of issue

The phytosanitary certificate is an original document, or under specific circumstances is a certified copy issued by the NPPO, that accompanies the consignment and is presented to the relevant officials upon arrival in the importing country.

Alternatively, electronic certification may be used provided that:

- the mode of issue and security is acceptable by the importing countries
- the information provided is consistent with the appropriate model(s)
- the intent of certification under the IPPC is realized
- the identity of the issuing authority can be adequately established.

1.3 Attachments

Official attachments to the phytosanitary certificate should be limited to those instances where the information required to complete the certificate exceeds the available space on the certificate (see also point 2). Any attachments containing phytosanitary information should bear the phytosanitary certificate number, and should be dated, signed and stamped the

same as the phytosanitary certificate. The phytosanitary certificate should indicate, in the appropriate section, that the information belonging in that section is contained in the attachment. The attachment should not contain any information that would not be put on the phytosanitary certificate itself, had there been enough space.

1.4 Unacceptable certificates

Importing countries should not accept certificates that they determine to be invalid or fraudulent. The issuing authorities should be notified as soon as possible regarding unacceptable or suspect documents (see ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*). The NPPO of the exporting country should take corrective action when necessary and maintain systems for vigilance and security to ensure that a high level of confidence is associated with phytosanitary certificates issued by that authority.

1.4.1 Invalid phytosanitary certificates

Reasons for rejecting a phytosanitary certificate and/or for requesting additional information include:

- illegible
- incomplete
- period of validity expired or not complied with
- inclusion of unauthorized alterations or erasures
- inclusion of conflicting or inconsistent information
- use of wording that is inconsistent with the model certificates herein
- certification of prohibited products
- non-certified copies.

1.4.2 Fraudulent certificates

Fraudulent certificates include those:

- not authorized by the NPPO
- issued on forms not authorized by the issuing NPPO
- issued by persons or organizations or other entities that are not authorized by NPPO
- containing false or misleading information.

1.5 Requirements made by importing countries with respect to preparation and issue of phytosanitary certificates

Importing countries frequently specify requirements that should be observed with respect to the preparation and issue of phytosanitary certificates. They commonly include:

- language (countries may require that certificates be completed in a specific language or one of a list of languages - countries are encouraged to include one of the official languages of FAO)
- period of validity (importing countries may specify the period of time allowed for issue following inspection and/or treatment, dispatch of the consignment from the country of origin following issue, and validity of certificate)
- completion (countries may require that the certificate is completed by typing, or in handwritten legible capital letters)
- units (countries may require that the description of the consignment and quantities declared should be done in specified units).

2. Specific Principles and Guidelines for Preparation and Issue of Phytosanitary Certificates

Phytosanitary certificates and phytosanitary certificates for re-export should include only information related to phytosanitary matters. They should not include statements that requirements have been met and should not include references to animal or human health matters, pesticide residues or radioactivity, or commercial information such as letters of credit.

To facilitate cross-referencing between the phytosanitary certificates and documents not related to phytosanitary certification (e.g. letters of credit, bills of lading, CITES certificates), a note may be attached to the phytosanitary certificate which associates the phytosanitary certificate with the identification code, symbol or number(s) of the relevant document(s) which require cross-referencing. Such a note should only be attached when necessary and should not be considered an official part of the phytosanitary certificate.

All components of the phytosanitary certificates and phytosanitary certificates for re-export should normally be completed. Where no entry is made, the term “None” should be entered or the line should be blocked out (to prevent falsification).

2.1 Requirements for completing the phytosanitary certificate

(Headings in bold refer to the components of the model certificate)
The specific components of the phytosanitary certificate are explained as follows:

No. _____
This is the certificate identification number. It should be a unique serial number associated with an identification system that allows "trace-back", facilitates audits and serves for record keeping.

Plant Protection Organization of _____
This component requires the name of the official organization and the name of the country that is issuing the certificate. The name of the NPPO may be added here if it is not part of the printed form.

TO: Plant Protection Organization(s) of _____
The name of the importing country should be inserted here. In cases where the shipment transits through a country which has specific transit requirements, including the need for phytosanitary certificates, the names of both importing country and country of transit may be inserted. Care should be taken to ensure that the import and/or transit regulations of each country are met and appropriately indicated. In cases where the shipment is imported and re-exported to another country, the names of both importing countries may be inserted, provided the import regulations of both countries have been met.

Section I. Description of Consignment

Name and address of exporter: _____
This information identifies the source of the consignment to facilitate "trace back" and audit by the exporting NPPO. The name and address should be located in the exporting country. The name and address of a local exporter's agent or shipper should be used, where an international company with a foreign address is the exporter.

Declared name and address of consignee: _____
The name and address should be inserted here and should be in sufficient detail to enable the importing NPPO to confirm the identity of the consignee. The importing country may require that the address be a location in the importing country.

Number and description of packages: _____
Sufficient detail should be included in this section to enable the NPPO of the importing country to identify the consignment and its component parts, and verify their size if necessary. Container numbers and/or railcar numbers are a valid addition to the description of the packages and may be included here, if known.

Distinguishing marks: _____
Distinguishing marks may be indicated at this point on the phytosanitary certificate, or else on a stamped and signed attachment to the certificate. Distinguishing marks on bags, cartons or other containers should be included only where they assist in identifying the consignment. Where no entry is made, the term "None" should be entered or the line should be blocked out (to prevent falsification).

Place of origin: _____
This refers to place(s) from which a consignment gains its phytosanitary status, i.e. where it was possibly exposed to possible infestation or contamination by pests. Normally, this will be the place where the commodity was grown. If a commodity is stored or moved, its phytosanitary status may change over a period of time as a result of its new location. In such cases the new location may be considered as the place of origin. In specific circumstances, a commodity may gain its phytosanitary status from more than one place. In these cases where pests from one or more place may be involved, NPPOs should decide which place or places of origin most accurately describe the situation which has given the commodity its phytosanitary status. In such cases, each place should be declared. It is noted that in exceptional cases, such as with mixed seed lots that have more than one country of origin it is necessary to indicate all possible origins.

Countries may require that "pest free area," "pest free place of production," or "pest free production site" be identified in sufficient detail in this section. In any case, at least the country of origin should be indicated.

Declared means of conveyance: _____
Terms such as "sea, air, road, rail, mail, and passenger" should be used. The ship's name and voyage number or the aircraft's flight number should be included if known.

Declared point of entry: _____
This should be the first point of arrival in the country of final destination, or if not known, the country name. The point of entry of the first country of importation should be listed where more than one country is listed in the "TO:" section. The point of entry for the country of final destination should be listed in cases where the consignment only transits through another country. If the country of transit is also listed in the "TO:" section, the points of entry into the transit country as well as the final destination country may be listed (e.g. point A via point B).

Name of produce and quantity declared: _____
The information provided here should be sufficiently descriptive of the commodity (which should include the commodity class, i.e. fruit, plants for planting, etc.) and the quantity expressed as accurately as possible to enable officials in the importing country to adequately verify the contents of the consignment. International codes may be used to facilitate identification (e.g. customs codes) and internationally recognized units and terms should be used where appropriate. Different phytosanitary requirements may apply to the different end uses (for example, consumption as compared to propagation) or state of a product (e.g. fresh compared to dried); the intended end use or state of the product should be specified. Entries should not refer to trade names, sizes, or other commercial terms.

Botanical name of plants: _____
The information inserted here should identify plants and plant products using accepted scientific names, at least to genus level but preferably to species level.

It may not be feasible to provide a botanical description for certain regulated articles and products of complex composition such as stock feeds. In these cases, NPPOs should agree bilaterally on a suitable common name descriptor, or the words "Not applicable" or "N/A" may be entered.

Certifying statement
This is to certify that the plants, plant products or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests.

They are deemed to be practically free from other pests. (Optional clause)

In instances where specific import requirements exist and/or quarantine pests are specified, the certificate is used to certify conformity with the regulations or requirements of the importing country.

In instances where import requirements are not specific and/or quarantine pests are not specified, the exporting country can certify for any pests believed by it to be of regulatory concern.

The exporting countries may include the optional clause on their phytosanitary certificates or not.

"… *appropriate official procedures* …" refers to procedures carried out by the NPPO or persons authorized by the NPPO for purposes of phytosanitary certification. Such procedures should be in conformity with ISPMs where appropriate. Where ISPMs are not relevant or do not exist, the procedures may be specified by the NPPO of the importing country.

"… *considered to be free from quarantine pests* …" refers to freedom from pests in numbers or quantities that can be detected by the application of phytosanitary procedures. It should not be interpreted to mean absolute freedom in all cases but rather that quarantine pests are not believed to be present based on the procedures used for their detection or elimination. It should be recognized that phytosanitary procedures have inherent uncertainty and variability, and involve some probability that pests will not be detected or eliminated. This uncertainty and probability should be taken into account in the specification of appropriate procedures.

"… *phytosanitary requirements* …" are officially prescribed conditions to be met in order to prevent the introduction and/or spread of pests. Phytosanitary requirements should be specified in advance by the NPPO of the importing country in legislation, regulations, or elsewhere (e.g. import permits and bilateral agreements and arrangements).

"… *importing contracting party* …" refers to governments that have adhered to the IPPC including Members of the Interim Commission on Phytosanitary Measures until the amendments of 1997 come into force.

Section II. Additional Declaration
Additional declarations should be only those containing information required by the importing country and not otherwise noted on the certificate. Additional declarations should be kept to a minimum and be concise. The text of additional declarations may be specified in, for example, phytosanitary regulations, import permits or bilateral agreements. Treatment(s) should be indicated in Section III.

Section III. Disinfestation and/or Disinfection Treatment
Treatments indicated should only be those which are acceptable to the importing country and are performed in the exporting country or in transit to meet the phytosanitary requirements of the importing country. These can include devitalization and seed treatments.

Stamp of organization
This is the official seal, stamp or mark identifying the issuing NPPO. It may be printed on the certificate or added by the issuing official upon completion of the form. Care should be taken to ensure that the mark does not obscure essential information.

Name of authorized officer, date and signature
The name of the issuing official is typed or hand-written in legible capital letters (where applicable). The date is also to be typed or hand-written in legible capital letters (where applicable). Only abbreviations may be used to identify months, so that the month, day and year are not confused.

Although portions of the certificate may be completed in advance, the date should correspond to the date of signature. Certificates should not be post- or pre-dated, or issued after dispatch of the consignment unless bilaterally agreed. The NPPO of the exporting country should be able to verify the authenticity of signatures of authorized officers upon request.

Financial liability statement
The inclusion of a financial liability statement in a phytosanitary certificate is optional.

3. Specific Principles and Guidelines for Preparation and Issue of Phytosanitary Certificates for Re-export

The components of the phytosanitary certificate for re-export are the same as for the phytosanitary certificate (see section 2.1) except for the section covering certification. In this section, the NPPO indicates by inserting ticks in the appropriate boxes whether the certificate is accompanied by the original phytosanitary certificate or its certified copy, whether the consignment has been repacked or not, whether the containers are original or new, and whether an additional inspection has been done. ISPM No. 7 (*Export Certification Systems*) provides guidance on the need for additional inspection.

If the consignment is split up and the resulting consignments are exported separately, then phytosanitary certificates for re-export and certified copies of the original phytosanitary certificate will be required to accompany any such consignments.

3.1 Conditions for issuing a phytosanitary certificate for re-export

When a consignment is imported into a country, then exported to another, the NPPO should issue a phytosanitary certificate for re-export (see model). The NPPO should only issue a certificate for the export of an imported consignment if the NPPO is confident that the importing country's regulations are met. Re-export certification may still be done if the consignment has been stored, split up, combined with other consignments or re-packaged, provided that it has not been exposed to infestation or contamination by pests. The original phytosanitary certificate or its certified copy should also accompany the consignment.

3.2 Conditions for issuing a phytosanitary certificate for an imported consignment

If the consignment has been exposed to infestation or contamination by pests, or has lost its integrity or identity, or has been processed to change its nature, the NPPO should issue a phytosanitary certificate and not the phytosanitary certificate for re-export. The country of origin should still be indicated on the phytosanitary certificate. The NPPO must be confident that the importing country’s regulations are met.

If the consignment has been grown for a specific time (depending on the commodity concerned, but usually one growing season or more) the consignment can be considered to have changed its country of origin.

3.3 Transit

If a consignment is not imported, but is in transit through a country without being exposed to infestation or contamination by pests, the NPPO does not need to issue either a phytosanitary certificate or a phytosanitary certificate for re-export. If however, the consignment is exposed to infestation or contamination by pests, the NPPO should issue a phytosanitary certificate. If the consignment is split up, combined with other consignments or repackaged, the NPPO should issue a phytosanitary certificate for re-export.

APPENDIX

Model Phytosanitary Certificate

No. _____

Plant Protection Organization of _____
TO: Plant Protection Organization(s) of _____

I. Description of Consignment

Name and address of exporter: _____
Declared name and address of consignee: _____
Number and description of packages: _____
Distinguishing marks: _____
Place of origin: _____
Declared means of conveyance: _____
Declared point of entry: _____
Name of produce and quantity declared: _____
Botanical name of plants: _____

This is to certify that the plants, plant products or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests.

They are deemed to be practically free from other pests.*

II. Additional Declaration

III. Disinfestation and/or Disinfection Treatment

Date _____ Treatment _____ Chemical (active ingredient) _____
Duration and temperature _____
Concentration _____
Additional information _____
_____

Place of issue _____

(Stamp of Organization) Name of authorized officer _____

Date _____ (Signature) _____

No financial liability with respect to this certificate shall attach to (name of Plant Protection Organization) or to any of its officers or representatives.*

* Optional clause

Model Phytosanitary Certificate for Re-Export

No. _____

Plant Protection Organization of _____ (contracting party of re-export)
TO: Plant Protection Organization(s) of _____ (contracting party(ies) of import)

I. Description of Consignment

Name and address of exporter: _____
Declared name and address of consignee: _____
Number and description of packages: _____
Distinguishing marks: _____
Place of origin: _____
Declared means of conveyance: _____
Declared point of entry: _____
Name of produce and quantity declared: _____
Botanical name of plants: _____

This is to certify that the plants, plant products or other regulated articles described above _____ were imported into (contracting party of re-export) _____ from _____ (contracting party of origin) covered by Phytosanitary certificate No. _____, *original ☐ certified true copy ☐ of which is attached to this certificate; that they are packed ☐ repacked ☐ in original ☐ *new ☐ containers, that based on the original phytosanitary certificate ☐ and additional inspection ☐, they are considered to conform with the current phytosanitary requirements of the importing contracting party, and that during storage in _____ (contracting party of re-export), the consignment has not been subjected to the risk of infestation or infection.

* Insert tick in appropriate ☐ boxes

II. Additional Declaration

III. Disinfestation and/or Disinfection Treatment

Date _____ Treatment _____ Chemical (active ingredient) _____
Duration and temperature _____
Concentration _____
Additional information _____
_____

Place of issue _____

(Stamp of Organization) Name of authorized officer _____

Date _____ (Signature)_____

No financial liability with respect to this certificate shall attach to _____ (name of Plant Protection Organization) or to any of its officers or representatives.**

** Optional clause

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 13

GUIDELINES FOR THE NOTIFICATION OF NON-COMPLIANCE AND EMERGENCY ACTION

(2001)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2001.

INTRODUCTION

SCOPE

This standard describes the actions to be taken by countries regarding the notification of:

- a significant instance of failure of an imported consignment to comply with specified phytosanitary requirements, including the detection of specified regulated pests
- a significant instance of failure of an imported consignment to comply with documentary requirements for phytosanitary certification
- an emergency action taken on the detection in an imported consignment of a regulated pest not listed as being associated with the commodity from the exporting country
- an emergency action taken on the detection in an imported consignment of organisms posing a potential phytosanitary threat.

REFERENCES

Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.
Export certification systems, 1997. ISPM No. 7, FAO, Rome.
Glossary of phytosanitary terms, 1999. ISPM No. 5, FAO, Rome.
Guidelines for phytosanitary certificates, ISPM No. 12, FAO, Rome.
New Revised Text of the International Plant Protection Convention, 1997. 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, 1997) makes provision for contracting parties to report significant instances of non-compliance of imported consignments with phytosanitary requirements, including those related to documentation or to report appropriate emergency action, which is taken on the detection in the imported consignment of an organism posing a potential phytosanitary threat. The importing contracting party is required to notify the exporting contracting party as soon as possible regarding significant instances of non-compliance and emergency actions applied to imported consignments. The notification should identify the nature of non-compliance in such a way that the exporting contracting party may investigate and make the necessary corrections. Importing contracting parties may request a report of the results of such investigations.

Required information for notification includes the reference number, the date of notification, the identity of the NPPOs of the importing and exporting countries, the identity of the consignment and date of first action, the reasons for the action taken, information regarding the nature of non-compliance or emergency action, and the phytosanitary measures applied. Notification should be timely and follow a consistent format.

An importing country should investigate any new or unexpected phytosanitary situation where emergency action is taken in order to determine if actions are justified and if changes in phytosanitary requirements are needed. Exporting countries should investigate significant instances of non-compliance to determine the possible cause. Notifications for significant instances of non-compliance or emergency action associated with re-export are directed to the re-export country. Those associated with transit consignments are directed to the exporting country.

REQUIREMENTS

1. Purpose of Notifications

Notifications are provided by the importing country to the exporting country to identify significant failures of imported consignments to comply with specified phytosanitary requirements or to report emergency action that is taken on the detection of a pest posing a potential threat. The use of notification for other purposes is voluntary, but in all instances should only be undertaken with the aim of international cooperation to prevent the introduction and/or spread of regulated pests (IPPC Articles I and VIII). In the case of non-compliance the notification is intended to help in investigating the cause of the non-compliance, and to facilitate steps to avoid recurrence.

2. The Use of Notification Information

Notification is normally bilateral. Notifications and information used for notification are valuable for official purposes but may also be easily misunderstood or misused if taken out of context or used imprudently. To minimize the potential for misunderstandings or abuse, countries should be careful to ensure that notifications and information about notifications are distributed in the first instance only to the exporting country. In particular, the importing country may consult with the exporting country and provide the opportunity for the exporting country to investigate instances of apparent non-compliance, and correct as necessary. This should be done before changes in the phytosanitary status of a commodity or area, or other failures of phytosanitary systems in the exporting country are confirmed or reported more widely (see also good reporting practices for interceptions in ISPM No. 8: *Determination of pest status in an area*).

3. Provisions of the IPPC Related to Notification

The establishment of systems for the routine practice of notification is based on several provisions of the IPPC, summarized as follows:

- Art VII.2f states, "*Importing contracting parties shall, as soon as possible, inform the exporting contracting party concerned or, where appropriate, the re-exporting contracting party concerned, of significant instances of non-compliance with phytosanitary certification. The exporting contracting party or, where appropriate, the re-exporting contracting party concerned, should investigate and, on request, report the result of its investigation to the importing contracting party concerned*."
- Art VII.6 states contracting parties may take "*appropriate emergency action on the detection of a pest posing a potential threat to its territories or the report of such a detection. Any such action shall be evaluated as soon as possible to ensure that its continuance is justified. The action taken shall be immediately reported to contracting parties concerned, the Secretary, and any regional plant protection organization of which the contracting party is a member*."
- Art VIII.1 states that contracting parties shall cooperate in achieving the aims of the Convention.
- Art VIII.2 states that contracting parties shall designate a contact point for the exchange of information.

Countries that are not contracting parties to the IPPC are encouraged to use notification systems described in this standard (IPPC Article XVIII).

4. Basis for Notification

In most instances, notification is provided as the result of the detection of regulated pests in imported consignments. There are also other significant instances of non-compliance that require phytosanitary action and notification. In new or unexpected phytosanitary situations, emergency actions may be taken which should also be notified to the exporting country.

4.1 Significant instances of non-compliance

Countries may agree bilaterally on what instances of non-compliance are considered significant for notification purposes. In the absence of such agreements, the importing country may consider the following to be significant:

- failure to comply with phytosanitary requirements
- detection of regulated pests
- failure to comply with documentary requirements, including:
  - absence of phytosanitary certificates
  - uncertified alterations or erasures to phytosanitary certificates
  - serious deficiencies in information on phytosanitary certificates
  - fraudulent phytosanitary certificates
- prohibited consignments
- prohibited articles in consignments (e.g. soil)
- evidence of failure of specified treatments
- repeated instances of prohibited articles in small, non-commercial quantities carried by passengers or sent by mail.

Significant instances of non-compliance of an imported consignment with phytosanitary requirements should be notified to the exporting country whether or not the consignment requires a phytosanitary certificate.

4.2 Emergency action

Emergency actions are taken on the detection in an imported consignment of:

- regulated pests not listed as being associated with the commodity from the exporting country
- organisms posing a potential phytosanitary threat.

5. Timing of Notification

Notifications should be provided promptly once non-compliance or the need for emergency action has been confirmed and phytosanitary actions taken. Where there is a significant delay in confirming the reason for the notification (e.g. identification of an organism), a preliminary notification may be provided.

6. Information Included in a Notification

Notifications should use a consistent format and include certain minimum information. NPPOs are encouraged to provide additional information where such information is considered relevant and important or has been specifically requested by the exporting country.

6.1 Required information

Notifications should include the following information:

- Reference number - the reporting country should have a means of tracing the communication sent to an exporting country. This could be a unique reference number or the number of the phytosanitary certificate associated with the consignment
- Date - the date on which notification is sent should be noted
- Identity of the NPPO of the importing country
- Identity of the NPPO of the exporting country
- Identity of consignment - consignments should be identified by the phytosanitary certificate number if appropriate or by references to other documentation and including commodity class and scientific name (at least plant genus) for plants or plant products
- Identity of consignee and consignor
- Date of first action on the consignment
- Specific information regarding the nature of the non-compliance and emergency action including:
  - identity of pest (see also section 8 below)
  - where appropriate, whether part or all of the consignment is affected
  - problems with documentation
  - phytosanitary requirements to which the non-compliance applies
- *Phytosanitary actions taken* - the phytosanitary actions should be specifically described and the parts of the consignment affected by the actions identified
- *Authentication marks* - the notifying authority should have a means for authenticating valid notifications (e.g. stamp, seal, letterhead, authorized signature).

6.2 Supporting information

Upon request, supporting information should be made available to the exporting country and may include as appropriate:

- copy of the phytosanitary certificate or other relevant documents
- diagnostic results
- pest association, i.e. in which part of the consignment the pest was found or how it affects the consignment
- other information deemed to be useful for the exporting country to be able to identify and correct non-compliance.

6.3 Forms, codes, abbreviations or acronyms

Where forms, codes, abbreviations or acronyms are used in notification or supporting information, countries should make appropriate explanatory material available on request.

6.4 Language

The language(s) used for notification and supporting information will be the language(s) preferred by the notifying country except where bilaterally agreed otherwise. Where information is requested through contact points, information should be supplied in one of the FAO languages (IPPC Article XIX.3e).

7. Documentation and Means of Communication

The notifying country should keep notification documents, supporting information and associated records for at least one year after the date of notification. Electronic notifications should be used for efficiency and expediency whenever possible.

Notification should be sent to the IPPC contact point or, where a contact point has not been identified, to the NPPO of the exporting country unless bilateral arrangements exist which specify to whom the notification should be sent. Communication from official contact points is considered to be authentic unless the NPPO of the importing country indicates other official sources.

8. Pest Identification

The identification of organisms detected in imported consignments is required to determine if they are, or should be, regulated pests and to thereby justify phytosanitary or emergency action. Appropriate identification may not be possible where:

- the specimen(s) are of a life stage or condition that makes them difficult to identify
- appropriate taxonomic expertise is not available.

Where identifications are not possible the reason should be stated on the notification.

When identifying pests, importing countries should:

- be able to describe, on request, the procedures used for diagnosis and sampling, including the identity of the diagnostician and/or laboratory, and should retain, for an appropriate period (one year following the notification or until necessary investigation has been carried out), evidence such as appropriate specimens or material to allow validation of potentially controversial determinations
- indicate the life-stage of the pest and its viability where appropriate
- provide identification to species level where possible or to a taxonomic level that justifies the official actions taken.

9. Investigation of Non-compliance and Emergency Action

9.1 Non-compliance

The exporting country should investigate significant instances of non-compliance to determine the possible cause with a view to avoid recurrence. Upon request, the results of the investigation should be reported to the importing country. Where the results of the investigation indicate a change of pest status, this information should be communicated according to the good practices noted in ISPM No. 8: *Determination of pest status in an area*.

9.2 Emergency action

The importing country should investigate the new or unexpected phytosanitary situation to justify the emergency actions taken. Any such action should be evaluated as soon as possible to ensure that its continuance is technically justified. If continuance of actions is justified, phytosanitary measures of the importing country should be adjusted, published and transmitted to the exporting country.

10. Transit

For a consignment in transit, any instance of non-compliance with the requirements of the transit country or any emergency action taken should be notified to the exporting country. Where the transit country has reason to believe that the non-compliance or new or unexpected phytosanitary situation may be a problem for the country of final destination, the transit country may provide a notification to the country of final destination. The country of final destination may copy its notifications to any transit country involved.

11. Re-export

In cases associated with a phytosanitary certificate for re-export, the obligation and other provisions pertaining to the exporting country apply to the re-exporting country.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 14

THE USE OF INTEGRATED MEASURES IN A SYSTEMS APPROACH FOR PEST RISK MANAGEMENT

(2002)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in March 2002.

INTRODUCTION

SCOPE

This standard provides guidelines for the development and evaluation of integrated measures in a systems approach as an option for pest risk management under the relevant international standards for pest risk analysis designed to meet phytosanitary requirements for the import of plants, plant products and other regulated articles.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Glossary of phytosanitary terms, 2001. ISPM No. 5, FAO, Rome.
Guidelines for an integrated system of measures to mitigate pest risk (systems approach), 1998. V 1.2. COSAVE, Asuncion, Paraguay.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Hazard analysis and critical control point system and guidelines for its application, annex to the recommended international code of practice - general principles of food hygiene, 1969 (Revised 1997). Codex Alimentarius, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests, 2001. 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.

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 appropriate international PRA standards provide general guidance on measures for pest risk management. Systems approaches, which integrate measures for pest risk management in a defined manner, could provide an alternative to single measures to meet the appropriate level of phytosanitary protection of an importing country. They can also be developed to provide phytosanitary protection in situations where no single measure is available. A systems approach requires the integration of different measures, at least two of which act independently, with a cumulative effect.

Systems approaches range in complexity. The application of critical control points system in a systems approach may be useful to identify and evaluate points in a pathway where specified pest risks can be reduced and monitored. The development and evaluation of a systems approach may use quantitative or qualitative methods. Exporting and importing countries may consult and cooperate in the development and implementation of a systems approach. The decision regarding the acceptability of a systems approach lies with the importing country, subject to consideration of technical justification, minimal impact, transparency, non-discrimination, equivalence, and operational feasibility. A systems approach is usually designed as an option that is equivalent to but less restrictive than other measures.

REQUIREMENTS

1. Purpose of Systems Approaches

Many of the elements and individual components of pest risk management are described in appropriate international PRA standards. All pest risk management measures must be technically justified according to ArticleVII.2a IPPC (1997). A systems approach integrates pest risk management measures to meet the appropriate level of phytosanitary protection of the importing country. Systems approaches provide, where appropriate, an equivalent alternative to procedures such as disinfestation treatments or replace more restrictive measures like prohibition. This is achieved by considering the combined effect of different conditions and procedures. Systems approaches provide the opportunity to consider both pre- and post harvest procedures that may contribute to the effective management of pest risk. It is important to consider systems approaches among risk management options because the integration of measures may be less trade restrictive than other risk management options (particularly where the alternative is prohibition).

2. Characteristics of Systems Approaches

A systems approach requires two or more measures that are independent of each other, and may include any number of measures that are dependent on each other. An advantage of the systems approach is the ability to address variability and uncertainty by modifying the number and strength of measures to meet the appropriate level of phytosanitary protection and confidence.

Measures used in a systems approach may be applied pre- and/or post harvest wherever NPPOs have the ability to oversee and ensure compliance with official phytosanitary procedures. Thus a systems approach may include measures applied in the place of production, during the post harvest period, at the packinghouse, or during shipment and distribution of the commodity.

Cultural practices, field treatment, post harvest disinfestation, inspection and other procedures may be integrated in a systems approach. Risk management measures designed to prevent contamination or re-infestation are generally included in a systems approach (e.g. maintaining the integrity of lots, requiring pest-proof packaging, screening packing areas, etc.). Likewise, procedures such as pest surveillance, trapping and sampling can also be components of a systems approach.

Measures that do not kill pests or reduce their prevalence but reduce their potential for entry or establishment (safeguards) can be included in a systems approach. Examples include designated harvest or shipping periods, restrictions on the maturity, color, hardness, or other condition of the commodity, the use of resistant hosts, and limited distribution or restricted use at the destination.

3. Relationship with PRA and Available Risk Management Options

The conclusions from pest risk assessment are used to decide whether risk management is required and the strength of measures to be used (Stage 2 of PRA). Pest risk management, (Stage 3 of PRA), is the process of identifying ways to react to a perceived risk, evaluating the efficacy of these procedures, and recommending the most appropriate options.

A combination of pest risk management measures in a systems approach is one of the options which may be selected as the basis for import requirements to meet the appropriate level of phytosanitary protection of the importing country. As in the development of all pest risk management measures, these should take into account uncertainty of the risk. (see ISPM No. 11: *Pest risk analysis for quarantine pests*)

In principle, systems approaches should be composed of the combination of phytosanitary measures that are possible to implement within the exporting country. However, where the exporting country proposes measures that should be implemented within the territory of importing country and the importing country agrees, measures within the importing country may be combined in systems approaches.

The following summarizes many of the options commonly used:

Pre-planting

- healthy planting material
- resistant or less susceptible cultivars
- pest free areas, places or sites of production
- producer registration and training.

Pre-harvest

- field certification/management (e.g. inspection, pre-harvest treatments, pesticides, biocontrol, etc.)
- protected conditions (e.g. glasshouse, fruit bagging, etc.)
- pest mating disruption
- cultural controls (e.g. sanitation/weed control)
- low pest prevalence (continuous or at specific times)
- testing.

Harvest

- harvesting plants at a specific stage of development or time of year
- removal of infested products, inspection for selection
- stage of ripeness/maturity
- sanitation (e.g. removal of contaminants, "trash")
- harvest technique (e.g. handling).

Post harvest treatment and handling

- treatment to kill, sterilize or remove pests (e.g. fumigation, irradiation, cold storage, controlled atmosphere, washing, brushing, waxing, dipping, heat, etc.)
- inspection and grading (including selection for certain maturity stages)
- sanitation (including removal of parts of the host plant)
- certification of packing facilities
- sampling
- testing
- method of packing
- screening of storage areas.

Transportation and distribution

- treatment or processing during transport
- treatment or processing on arrival
- restrictions on end use, distribution and ports of entry
- restrictions on the period of import due to difference in seasons between origin and destination
- method of packing
- post entry quarantine
- inspection and/or testing
- speed and type of transport
- sanitation (freedom from contamination of conveyances).

4. Independent and Dependent Measures

A systems approach may be composed of independent and dependent measures (including safeguards). By definition, a systems approach must have at least two independent measures. An independent measure may be composed of several dependent measures.

With dependent measures the probability of failure is approximately additive. All dependent measures are needed for the system to be effective.

Example:
A pest-free glasshouse where both double-door and screening of all openings is required is an example where dependent measures are combined to form an independent measure. If the probability that the screening fails is 0.1 and the probability that the double doors fail is 0.1, then the probability that the glasshouse will be infested is the approximate sum of the two values. Therefore the probability that at least one of the measures fails is the sum of both probabilities minus the probability that both fail at the same time. In this example the probability is 0.19 (0.1 + 0.1 - 0.01), since both the measures could fail at the same time.

Where measures are independent of each other, both measures must fail for the system to fail. With independent measures, the probability of failure is the product of all the independent measures.

Example:
If the inspection of a shipment has a 0.05 probability of failure and the limiting of movement to certain areas has a 0.05 probability of failure, then the probability of the system failing would be 0.0025 (0.05 x 0.05).

5. Circumstances for Use

Systems approaches may be considered when one or more of the following circumstances apply:

- a particular measure is:
  - not adequate to meet the appropriate level of phytosanitary protection of the importing country
  - not available (or likely to become unavailable)
  - detrimental (to commodity, human health, environment)
  - not cost effective
  - overly trade restrictive
  - not feasible
- the pest and pest-host relationship is well known
- a systems approach has been demonstrated to be effective for a similar pest/commodity situation
- there is the possibility to assess the effectiveness of individual measures either qualitatively or quantitatively
- relevant growing, harvesting, packing, transportation and distribution practices are well-known and standardized
- individual measures can be monitored and corrected
- prevalence of the pest(s) is known and can be monitored
- a systems approach is cost effective (e.g. considering the value and/or volume of commodity).

6. Types of Systems Approaches

Systems approaches range in complexity and rigor from systems that simply combine independent measures known to be effective to more complex and precise systems such as critical control point systems (see Appendix I).

Other systems based on a combination of measures that do not meet the requirements for a critical control point system may be considered effective. However, the application of the critical control point concept may be generally useful for the development of other systems approaches. For example, non-phytosanitary certification programmes may have elements that are also valuable as risk management measures and may be included in a systems approach provided the phytosanitary elements of the process are made mandatory and can be overseen and controlled by the NPPO.

The minimum requirements for a measure to be considered a required component for a systems approach are that the measure:

- is clearly defined
- is efficacious
- is officially required (mandatory)
- can be monitored and controlled by the responsible NPPO.

7. Efficacy of Measures

Systems approaches may be developed or evaluated in either a quantitative or qualitative manner or a combination of both. A quantitative approach may be more appropriate where suitable data are available, such as those usually associated with measuring the efficacy of treatments. A qualitative approach should be considered more appropriate where efficacy is estimated by expert judgement.

The efficacy of independent measures that may be used to reduce pest risk can be expressed in different ways (e.g. mortality, reduction in prevalence, host susceptibility). The overall efficacy of a systems approach is based on the combination of the efficacy of required independent measures. Wherever possible this should be expressed in quantitative terms with a confidence interval. For example, efficacy for a particular situation may be determined to be no more than five infested fruit from a total population of one million fruit with 95% confidence. Where such calculations are not possible or are not done, the efficacy may be expressed in qualitative terms such as high, medium, and low.

8. Developing Systems Approaches

The development of a systems approach may be undertaken by the importing country, or by the exporting country, or ideally through the cooperation of both countries. The process of developing systems approaches may include consultation with industry, the scientific community, and trading partner(s). However, the NPPO of the importing country decides the suitability of the systems approach in meeting its requirements, subject to consideration of technical justification, minimal impact, transparency, non-discrimination, equivalence and operational feasibility.

A systems approach may include measures that are added or strengthened to compensate for uncertainty due to data gaps, variability, or lack of experience is the application of procedures. The level of such compensation included in a systems approach should be commensurate with the level of uncertainty.

Experience and the provision of additional information may provide the basis for renewed consideration of the number and strength of measures with a view to modifying the systems approach accordingly.

The development of a systems approach involves:

- obtaining from a PRA the identity of the pest risk and the description of the pathway
- identifying where and when management measures occur or can be applied (control points)
- distinguishing between measures that are essential to the system and other factors or conditions
- identifying independent and dependent measures and options for the compensation for uncertainty
- assessing the individual and integrated efficacy of measures that are essential to the system
- assessing feasibility and trade restrictiveness
- consultation
- implementation with documentation and reporting
- review and modification as necessary.

9. Evaluating Systems Approaches

In the evaluation of systems approaches, to meet the appropriate level of phytosanitary protection for the importing country, the evaluation of whether the requirement is met or not should consider the following:

- considering the relevance of existing systems approaches for similar or the same pest(s) on other commodities
- considering the relevance of systems approaches for other pest(s) on the same commodity
- evaluating information provided on:
  - efficacy of measures
  - surveillance and interception, sampling data (prevalence of pest)
  - pest host relationship
  - crop management practices
  - verification procedures
  - trade impacts and costs, including the time factor
- considering data against desired confidence levels and taking into account options for the compensation for uncertainty where appropriate.

9.1 Possible outcomes of evaluation

These may include determination that the systems approach is:

- acceptable
- unacceptable:
  - efficacious but not feasible
  - not sufficiently effective (requires an increase in the number or strength of measures)
  - unnecessarily restrictive (requires a reduction of the number or strength of measures)
  - not possible to evaluate due to insufficient data or unacceptably high uncertainty.

Where the systems approach has been found unacceptable, the rationale for this decision should be described in detail and made available to trading partners to facilitate the identification of possible improvements.

10. Responsibilities

Countries share the obligation to observe the principle of equivalence by considering risk management alternatives that will facilitate safe trade. Systems approaches provide significant opportunities to develop new and alternative risk management strategies, but their development and implementation requires consultation and cooperation. Depending on the number and nature of measures included in a systems approach, a significant amount of data may be required. Both exporting countries and importing countries should cooperate in the provision of sufficient data and the timely exchange of relevant information in all aspects of the development and implementation pest risk management measures, including systems approaches.

10.1 Importing country responsibilities

The importing country should provide specific information regarding its requirements. This includes specification of information and system requirements:

- identify pests of concern
- specify the appropriate level of phytosanitary protection
- describe types and level of assurance required (e.g. certification)
- identify points requiring verification.

Importing countries, in consultation with the exporting country where appropriate should select least trade restrictive measures where there are options.

Other responsibilities of the importing country may include to:

- propose improvements or alternative options
- audit (planned evaluation and verification of the systems approach)
- specify actions for non-compliance
- review and give feedback.

Where importing countries agree to accept the implementation of certain measures in their territories, importing countries are responsible for the implementation of those measures.

Agreed phytosanitary measures should be published (Article VII.2b, IPPC, 1997).

10.2 Exporting country responsibilities

The exporting country should provide sufficient information to support evaluation and acceptance of the systems approach. This may include:

- commodity, place of production and expected volume and frequency of shipments
- relevant production, harvest, packing/handling, transport details
- pest-host relationship
- risk management measures proposed for a systems approach, and relevant efficacy data
- relevant references.

Other responsibilities of the exporting country include:

- monitoring/auditing and reporting on system effectiveness
- taking appropriate corrective actions
- maintaining appropriate records
- providing phytosanitary certification in accordance with requirements of the system.

APPENDIX

CRITICAL CONTROL POINT SYSTEM

A critical control point system would involve the following procedures:

1. determine the hazards and the objectives for measures within a defined system
2. identify independent procedures that can be monitored and controlled
3. establish criteria or limits for the acceptance/failure of each independent procedure
4. implement the system with monitoring as required for the desired level of confidence
5. take corrective action when monitoring results indicate that criteria are not met
6. review or test to validate system efficacy and confidence
7. maintain adequate records and documentation.

An example of this type of system is practiced in food safety and is termed a Hazard Analysis Critical Control Point (HACCP) system.

The application of a critical control point system for phytosanitary purposes may be useful to identify and evaluate hazards as well as the points in a pathway where risks can be reduced and monitored and adjustments made where necessary. The use of a critical control point system for phytosanitary purposes does not imply or prescribe that application of controls is necessary to all control points. However, critical control point systems only rely on specific independent procedures known as control points. These are addressed by risk management procedures whose contribution to the efficacy of the system can be measured and controlled.

Therefore, systems approaches for phytosanitary purposes may include components that do not need to be entirely consistent with critical control point concept because they are considered to be important elements in a systems approach for phytosanitary purposes. For example, certain measures or conditions exist or are included to compensate for uncertainty. These may not be monitored as independent procedures (e.g. packhouse sorting), or may be monitored but not controlled (e.g. host preference/susceptibility).

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 15

GUIDELINES FOR REGULATING WOOD PACKAGING MATERIAL IN INTERNATIONAL TRADE

(2002)

with modifications to Annex I (2006)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in March 2002. Modifications to Annex I were endorsed by the Commission on Phytosanitary Measures in April 2006.

INTRODUCTION

SCOPE

This standard describes phytosanitary measures to reduce the risk of introduction and/or spread of quarantine pests associated with wood packaging material (including dunnage), made of coniferous and non-coniferous raw wood, in use 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, 2001. ISPM No. 5, FAO, Rome.
Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.
Guidelines on notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
ISO 3166-1-ALPHA-2 CODE ELEMENTS (http://www.din.de/gremien/nas/nabd/iso3166ma/codlstp1/en_listp1.html)
International Plant Protection Convention, 1997. FAO, Rome.
Principles of plant quarantine as related to international trade, 1995. ISPM No. 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

Wood packaging material made of unprocessed raw wood is a pathway for the introduction and spread of pests. Because the origin of wood packaging material is often difficult to determine, globally approved measures that significantly reduce the risk of pest spread are described. NPPOs are encouraged to accept wood packaging material that has been subjected to an approved measure without further requirements. Such wood packaging material includes dunnage, but excludes processed wood packaging material.

Procedures to verify that an approved measure, including the application of a globally recognized mark, has been applied should be in place in both exporting and importing countries. Other measures agreed to under a bilateral arrangement are also considered in this standard. Wood packaging material that does not comply with the requirements of this standard should be disposed of in an approved manner.

REGULATORY REQUIREMENTS

1. Basis for Regulating

Wood packaging material is frequently made of raw wood that may not have undergone sufficient processing or treatment to remove or kill pests and therefore becomes a pathway for the introduction and spread of pests. Furthermore, wood packaging material is very often re-used, recycled or re-manufactured (in that packaging received with an imported consignment may be re-used to accompany another consignment for export). The true origin of any piece of wood packaging material is difficult to determine and thus its phytosanitary status cannot be ascertained. Therefore the normal process of undertaking risk analysis to determine if measures are necessary and the strength of such measures is frequently not possible for wood packaging material because its origin and phytosanitary status may not be known. For this reason, this standard describes globally accepted measures that are approved and that may be applied to wood packaging material by all countries to practically eliminate the risk for most quarantine pests and significantly reduce the risk from a number of other pests that may be associated with that material.

Countries should have technical justification for requiring the application of the approved measures as described in this standard for imported wood packaging material. Requiring phytosanitary measures beyond an approved measure as described in this standard also requires technical justification.

2. Regulated Wood Packaging Material

These guidelines are for coniferous and non-coniferous raw wood packaging material that may serve as a pathway for plant pests posing a threat mainly to living trees. They cover wood packaging material such as pallets, dunnage, crating, packing blocks, drums, cases, load boards, pallet collars, and skids which can be present in almost any imported consignment, including consignments which would not normally be the target of phytosanitary inspection.

Wood packaging made wholly of wood-based products such as plywood, particle board, oriented strand board or veneer that have been created using glue, heat and pressure or a combination thereof should be considered sufficiently processed to have eliminated the risk associated with the raw wood. It is unlikely to be infested by raw wood pests during its use and therefore should not be regulated for these pests.

Wood packaging material such as veneer peeler cores[1], sawdust, wood wool, and shavings, and raw wood cut into thin[2] pieces may not be pathways for introduction of quarantine pests and should not be regulated unless technically justified.

3. Measures for Wood Packaging Material

3.1 Approved measures

Any treatment, process, or a combination of these that is significantly effective against most pests should be considered effective in mitigating pest risks associated with wood packaging material used in transport. The choice of a measure for wood packaging material is based on consideration of:

- the range of pests that may be affected
- the efficacy of the measure
- the technical and/or commercial feasibility.

Approved measures should be accepted by all NPPOs as the basis for authorizing the entry of wood packaging material without further requirements except where it is determined through interceptions and/or PRA that specific quarantine pests associated with certain types of wood packaging material from specific sources require more rigorous measures.

Approved measures are specified in Annex I.

Wood packaging material subjected to these approved measures should display a specified mark shown in Annex II.

The use of marks addresses the operational difficulties associated with the verification of compliance with treatment for wood packaging material. A universally recognized, non-language specific mark facilitates verification during inspection at the point of export, at the point of entry or elsewhere.

References for supporting documentation on approved measures are available from the IPPC Secretariat.

[1] Veneer peeler cores are a by-product of veneer production involving high temperatures and comprising the center of a log remaining after the peeling process.

[2] Thin wood is considered to be 6mm thickness or less according to the Customs Harmonized Commodity Description and Coding System (the Harmonized System or HS).

3.2 Measures pending approval

Other treatments or processes for wood packaging material will be approved when it can be demonstrated that they provide an appropriate level of phytosanitary protection (Annex III). The currently measures identified in Annex I continue to be under review, and new research may point, for example, to other temperature/time combinations. New measures may also reduce risk by changing the character of the wood packaging material. NPPOs should be aware that measures may be added or changed and should have sufficiently flexible import requirements for wood packaging to accommodate changes as they are approved.

3.3 Other measures

NPPOs may accept any measures other than those listed in Annex I by arrangement with their trading partners, especially in cases where the measures listed in Annex I cannot be applied or verified in the exporting country. Such measures should be technically justified and respect the principles of transparency, non-discrimination and equivalence.

The NPPOs of importing countries should consider other arrangements for wood packaging material associated with exports from any country (or particular source) where evidence is provided which demonstrates that the pest risk is adequately managed or absent (e.g. areas with similar phytosanitary situations or pest free areas).

Certain movements of wood packaging material (e.g. tropical hardwoods associated with exports to temperate countries) may be considered by the importing NPPO not to carry a phytosanitary risk and thus can be exempted from measures.

Subject to technical justification, countries may require that imported wood packaging material subjected to an approved measure be made from debarked wood and display a mark as shown in Annex II.

3.4 Review of measures

The approved measures specified in Annex I and the list of measures under consideration in Annex III should be reviewed based on new information provided to the Secretariat by NPPOs. This standard should be amended appropriately by the ICPM.

OPERATIONAL REQUIREMENTS

To meet the objective of preventing the spread of pests, both exporting and importing countries should verify that the requirements of this standard have been met.

4. Dunnage

Ideally, dunnage should also be marked in accordance with Annex II of this standard as having been subjected to an approved measure. If not, it requires special consideration and should, as a minimum, be made from bark-free wood that is free from pests and signs of live pests. Otherwise it should be refused entry or immediately disposed of in authorized manner (see section 6).

5. Procedures Used Prior to Export

5.1 Compliance checks on procedures applied prior to export

The NPPO of the exporting country has responsibility for ensuring that systems for exports meet the requirements set out in this standard. It includes monitoring certification and marking systems that verify compliance, and establishing inspection procedures (see also ISPM No. 7: *Export certification system), registration or accreditation and auditing of commercial companies that apply the measures*, etc.

5.2 Transit arrangements

Where consignments moving in transit have exposed wood packaging material that has not met the requirements for approved measures, the NPPOs of the transit countries may require measures in addition to those of the importing country to ensure that wood packaging material does not present an unacceptable risk.

6. Procedures upon Import

The regulation of wood packaging material requires that NPPOs have policies and procedures for other aspects of their responsibilities related to wood packaging material.

Since wood packaging materials are associated with almost all shipments, including those not normally the target of phytosanitary inspections, cooperation with agencies, organizations, etc. not normally involved with meeting phytosanitary export conditions or import requirements is important. For example, cooperation with Customs

organizations should be reviewed to ensure effectiveness in detecting potential non-compliance of wood packaging material. Cooperation with the producers of wood packaging material also needs to be developed.

6.1 Measures for non-compliance at point of entry

Where wood packaging material does not carry the required mark, action may be taken unless other bilateral arrangements are in place. This action may take the form of treatment, disposal or refused entry. The NPPO of the exporting country may be notified (see ISPM No. 13: *Guidelines on notification of non-compliance and emergency action*). Where the wood packaging material does carry the required mark, and evidence of live pests is found, action can be taken. These actions may take the form of treatment, disposal or refused entry. The NPPO of the exporting country should be notified in cases where live pests are found, and may be notified in other cases (see ISPM No. 13: *Guidelines on notification of non-compliance and emergency action*).

6.2 Disposal

Disposal of wood packaging material is a risk management option that may be used by the NPPO of the importing country upon arrival of the wood packaging material where treatment is not available or desirable. The following methods are recommended for the disposal of wood packaging material where this is required. Wood packaging material that requires emergency action should be appropriately safeguarded prior to treatment or disposal to prevent escape of any pest between the time of the detection of the pest posing the threat and the time of treatment or disposal.

Incineration

Complete burning

Burial

Deep burial in sites approved by appropriate authorities. (Note: not a suitable disposal option for wood infested with termites). The depth of the burial may depend on climatic conditions and the pest, but is recommended to be at least 1 metre. The material should be covered immediately after burial and should remain buried.

Processing

Chipping and further processing in a manner approved by the NPPO of the importing country for the elimination of pests of concern (e.g. manufacture of oriented strand board).

Other methods

Procedures endorsed by the NPPO as effective for the pests of concern.

The methods should be applied with the least possible delay.

ANNEX I (modified in 2006)

APPROVED MEASURES ASSOCIATED WITH WOOD PACKAGING MATERIAL

Heat treatment (HT)

Wood packaging material should be heated in accordance with a specific time-temperature schedule that achieves a minimum wood core temperature of 56°C for a minimum of 30 minutes[3].

Kiln-drying (KD), chemical pressure impregnation (CPI), or other treatments may be considered HT treatments to the extent that these meet the HT specifications. For example, CPI may meet the HT specification through the use of steam, hot water, or dry heat.

Heat treatment is indicated by the mark HT. (see Annex II)

Methyl bromide (MB) fumigation for wood packaging material (modified in 2006[4])

The wood packaging material should be fumigated with methyl bromide. The treatment is indicated by the mark MB. The minimum standard for methyl bromide fumigation treatment for wood packaging material is as follows:

Temperature	Dosage (g/m^3)	Minimum concentration (g/m^3) at:			
		2hrs.	4hrs.	12hrs.	24hrs.
21°C or above	48	36	31	28	24
16°C or above	56	42	36	32	28
10°C or above	64	48	42	36	32

The minimum temperature should not be less than 10°C and the minimum exposure time should be 24 hours. Monitoring of concentrations should be carried out at a minimum at 2, 4 and 24 hrs.

List of most significant pests targeted by HT and MB

Members of the following pest groups associated with wood packaging material are practically eliminated by HT and MB treatment in accordance with the specifications listed above:

Pest group
Insects
Anobiidae
Bostrichidae
Buprestidae
Cerambycidae
Curculionidae
Isoptera
Lyctidae (with some exceptions for HT)
Oedemeridae
Scolytidae
Siricidae
Nematodes
Bursaphelenchus xylophilus

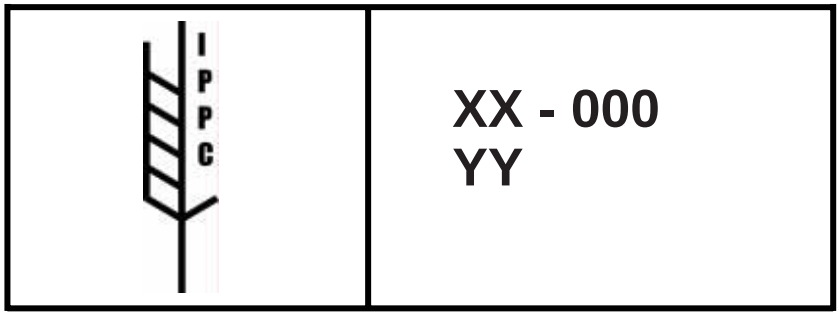
[3] A minimum core temperature of 56° C for a minimum of 30 min. is chosen in consideration of the wide range of pests for which this combination is documented to be lethal and a commercially feasible treatment. Although it is recognized that some pests are known to have a higher thermal tolerance, quarantine pests in this category are managed by NPPOs on a case by case basis.

[4] When a revised schedule is adopted for treatment of wood packaging, material treated under the previous treatment schedule does not need to be retreated, remarked or recertified.

ANNEX II

MARKING FOR APPROVED MEASURES

The mark shown below is to certify that the wood packaging material that bears the mark has been subjected to an approved measure.



The mark should at minimum include the:

- symbol
- ISO two letter country code followed by a unique number assigned by the NPPO to the producer of the wood packaging material, who is responsible for ensuring appropriate wood is used and properly marked
- IPPC abbreviation according to Annex I for the approved measure used (e.g. HT, MB).

NPPOs, producers or suppliers may at their discretion add control numbers or other information used for identifying specific lots. Where debarking is required the letters DB should be added to the abbreviation of the approved measure. Other information may also be included provided it is not confusing, misleading, or deceptive.

Markings should be:

- according to the model shown here
- legible
- permanent and not transferable
- placed in a visible location, preferably on at least two opposite sides of the article being certified.

The use of red or orange should be avoided since these colors are used in the labeling of dangerous goods.

Recycled, remanufactured or repaired wood packaging material should be re-certified and re-marked. All components of such material should have been treated.

Shippers should be encouraged to use appropriately marked wood for dunnage.

ANNEX III

MEASURES BEING CONSIDERED FOR APPROVAL UNDER THIS STANDARD

Treatments[5] being considered and which may be approved when appropriate data becomes available, include but are not limited to:

Fumigation

Phosphine
Sulfuryl fluoride
Carbonyl sulphide

CPI

High-pressure/vacuum process
Double vacuum process
Hot and cold open tank process
Sap displacement method

Irradiation

Gamma radiation
X-rays
Microwaves
Infra red
Electron beam treatment

Controlled atmosphere

[5] Certain treatments such as phosphine fumigation and some CPI treatments are generally believed to be very effective but at present lack experimental data concerning efficacy which would allow them to be approved measures. This present lack of data is specifically in relation to the elimination of raw wood pests present at the time of application of the treatment.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 16

REGULATED NON-QUARANTINE PESTS: CONCEPT AND APPLICATION

(2002)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in March 2002.

INTRODUCTION

SCOPE

This standard describes the concept of regulated non-quarantine pests and identifies their characteristics. It describes the application of the concept in practice and the relevant elements for regulatory systems.

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.
FAO. 1967. Types of losses caused by plant diseases, by J.C. Zadoks. FAO Symposium on crop losses. Rome, 2-6 October 1967, pp. 149-158.
Glossary of phytosanitary terms, 2001. ISPM No. 5, FAO, Rome.
Glossary supplement no. 1: Guidelines on the interpretation and application of the concept of official control for regulated pests, 2001. ISPM No. 5, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for surveillance, 1998. ISPM No. 6, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Principles of plant quarantine as related to international trade, 1995. ISPM No. 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

Pests that are not quarantine pests may be subject to phytosanitary measures because their presence in plants for planting results in economically unacceptable impacts. They are defined in the IPPC (1997) as regulated non-quarantine pests (RNQPs). Several provisions of the IPPC (1997) deal with RNQPs.

The distinction between RNQPs and quarantine pests, both of which are regulated pests, can be described in terms of the pest status, presence, pathway/commodity, economic impacts, and type of official control. In accordance with Article VI.2, "*contracting parties shall not require phytosanitary measures for non-regulated pests*." (IPPC, 1997)

The application of the concept of RNQPs follows the principles of technical justification, risk analysis, managed risk, minimal impact, equivalence, non-discrimination, and transparency. Each element of the definition of RNQPs has a specific meaning, and as a consequence, host-pest interactions, non-phytosanitary certification programmes that contain elements suitable for phytosanitary certification, tolerances, and non-compliance actions all need to be considered when defining the requirements for the application of measures for RNQPs.

GENERAL REQUIREMENTS

1. 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 the plants. Such pests are known as regulated non-quarantine pests (RNQPs) and are present and often widespread in the importing country. Where official control is applied to plants for planting produced within countries to protect them from such pests, then the same or equivalent phytosanitary measures may be applied to those pests on imported plants for planting of the same species for the same intended use.

2. Provisions of the IPPC Regarding Regulated Non-Quarantine Pests

In addition to definitions found in Article II, as well as other references to regulated pests in the IPPC (1997), the following provisions of the IPPC (1997) are relevant to regulated non-quarantine pests.

Article VII.1
With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:
a) prescribe and adopt phytosanitary measures…
b) refuse entry or detain, or require treatment, destruction or removal …
c) prohibit or restrict the movement of regulated pests….

Article VI.1
Contracting parties may require phytosanitary measures for quarantine pests and regulated non-quarantine pests, provided that such measures are:
a) no more stringent than measures applied to the same pests, if present within the territory of the importing contacting party; and
b) limited to what is necessary to protect plant health and/or safeguard the intended use and can be technically justified by the contracting party concerned.

Article VI.2
Contracting parties shall not require phytosanitary measures for non-regulated pests.

Article IV.3
Each contracting party shall make provision, to the best of its ability, for the following:
a) the distribution of information within the territory of the contracting party regarding regulated pests and the means of their prevention and control ...

Article VII.2i
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 (of the Commission on Phytosanitary Measures), to regional plant protection organizations of which they are members and, on request, to other contracting parties.

ANNEX:
Text of the Model Phytosanitary Certificate:
This is to certify that the plants, plant products or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests.

*They are deemed to be practically free from other pests.**

**Optional clause*

3. Comparison between RNQPs and Other Pests

3.1 Comparison with quarantine pests

Quarantine pests and RNQPs can be compared on the basis of four elements of their defining criteria: pest status in the importing country, pathway/commodity, economic impacts associated with the pest, and the application of official control.

The table below provides a summary of the distinctions.

Comparison of Quarantine Pests and RNQPs

Defining criteria	Quarantine pest	RNQP
Pest status	Absent or of limited distribution	Present and may be widely distributed
Pathway	Phytosanitary measures for any pathway	Phytosanitary measures only on plants for planting
Economic impact	Impact is predicted	Impact is known
Official control	Under official control if present with the aim of eradication or containment	Under official control with respect to the specified plants for planting with the aim of suppression

3.1.1 Pest status

In the case of quarantine pests, phytosanitary measures focus on reducing the likelihood of introduction, or if the pest is present, reducing the likelihood of spread. This means that, in the case of a quarantine pest, the pest is absent or is being prevented from invading new areas and is being officially controlled where it occurs. In the case of an RNQP, the likelihood of introduction is not relevant as a criterion, because the pest is present and quite possibly widespread.

3.1.2 Pathway

Phytosanitary regulations and procedures may be applied for quarantine pests associated with any host or pathway. For RNQPs, the only pathway that may be regulated is plants for planting of specified host(s) for a particular intended use.

3.1.3 Economic impacts

The main difference between the definitions of a quarantine pest and an RNQP with respect to economic impact is the distinction between potential economic importance for quarantine pests and known economically unacceptable impacts for regulated non-quarantine pests. Since the RNQP is present in the country, detailed first-hand information should be available about its impact, which is therefore known rather than predicted as for quarantine pests that are not yet present in that country. Furthermore, the potential economic importance associated with quarantine pests may include consideration of factors such as market access into other countries and environmental effects that are not relevant for RNQPs, because the pests are established.

3.1.4 Official control

All regulated pests are subject to official control. If present in an area, quarantine pests are subject to official control, in the form of phytosanitary measures for their eradication and/or containment. RNQPs are subject to official control in the form of phytosanitary measures for their suppression in the specified plants for planting.

3.2 Comparison with non-regulated pests

Some pests, which are neither quarantine pests nor RNQPs, may cause unacceptable impacts (i.e. damage) of a non-phytosanitary nature (e.g. commercial or food safety). Measures applied to plants damaged in this way are not phytosanitary measures. In accordance with Article VI.2, “contracting parties shall not require phytosanitary measures for non-regulated pests.” (IPPC, 1997)

4. Criteria that Define RNQPs

The definition of RNQPs provides criteria to distinguish this category of pests from quarantine pests. Further understanding of certain words in the definition is important for the proper interpretation and application of the concept.

4.1 “Plants for planting”

The concept of RNQPs is specifically limited in application to "plants for planting". Plants are defined as "living plants and parts thereof, including seeds". Therefore, "plants for planting" includes seeds, bulbs and tubers, and various kinds of vegetative propagating material, which may be whole plants or parts of plants (such as cuttings).

Since "plants for planting" includes "plants intended to remain planted", potted plants (including bonsai) are included. Risks associated with plants that are intended to remain planted may be less than for plants intended for multiplication.

4.2 "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, etc.)
- to remain planted (e.g. ornamentals)
- increasing the number of the same plants for planting (e.g. tubers, cuttings, seeds).

Risk of economically unacceptable impact varies with different pests, commodities, and intended use. Distinctions may 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.

4.3 "Those plants"

"Those plants" refers to the specific plants (species, varieties, etc.) for planting, either imported or domestically produced for the intended use, that are regulated by the importing country with respect to RNQPs.

4.4 "Economically unacceptable impact"

The definition for a regulated non-quarantine pest refers to an "economically unacceptable impact." This means that losses are measured in terms of economic impacts, and judged to be acceptable or unacceptable.

For quarantine pests, economic impacts include effects on market access as well as those impacts that may be less easily quantified in direct economic terms, such as certain effects on the environment as related to plant health. Because RNQPs are already present, there are not new or additional impacts related to market access or environmental health. Therefore these impacts are not considered relevant factors in determining economic impacts for RNQPs.

Relevant factors in determining economically unacceptable 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.

4.5 "Regulated"

"Regulated" in the definition of RNQP refers to official control. An official control programme for RNQPs can be applied on a national, sub-national, or local area basis. (see Glossary supplement no. 1: Guidelines on the interpretation and application of the concept of official control for regulated pests, 2001)

5. Relevant Principles and Obligations

The application of the concept of RNQPs follows in particular the principles and obligations of technical justification, risk analysis, managed risk, minimal impact, equivalence, non-discrimination, and transparency.

5.1 Technical justification

Phytosanitary measures covering 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 pest risk analysis.

5.2 Risk assessment

Pest risk assessment for RNQPs is not the same as pest risk assessment performed for a potential quarantine pest because it is not necessary to evaluate the probability of establishment, nor the long-term economic impact of an RNQP. It is, however, necessary to demonstrate that plants for planting are a pathway for the pest, and the plants for planting are the main source of infestation that result in economically unacceptable impacts.

5.3 Managed risk, minimal impact and equivalence

Risk management for RNQPs requires a decision regarding whether the economic impact determined through risk assessment represents an "unacceptable level of risk." Decisions regarding the strength of the measures to be used for risk management should be in accordance with the principles of non-discrimination, managed risk, and minimal impact, and should allow for the acceptance of equivalent measures where appropriate.

5.4 Non-discrimination

Phytosanitary measures for RNQPs should respect the principle of non-discrimination both between countries and between domestic and imported consignments. A pest can only qualify as an RNQP if there is official control within the territory of the contracting party requiring that no plants for planting with the same intended use (of the same or similar species of host plants), irrespective of their origin, be sold or planted if containing the pest, or containing the pest above a specified tolerance. A pest on an imported consignment can only be regulated as an RNQP if the plants are to be sold or planted within the territory of the importing country, or within that part of its territory, where the official control for the pest applies.

5.5 Transparency

National regulations and requirements for RNQPs, including details of official control programmes should be published and transmitted to any contracting party that may be directly affected (Article VII.2b). The technical justification for categorizing a pest as an RNQP and the justification for the strength of the measures applied for RNQPs should be made available by the importing contracting party upon request of another contracting party (Article VII.2c).

6. Application

When an NPPO wants to designate certain pests as RNQPs, the NPPO needs to consider the elements described above. In addition, some specific issues, such as host-pest interactions, and the existence of certification programmes (e.g. seed certification) for plants for planting may be considered.

6.1 Host-pest interaction

RNQPs should be defined in relation to a specified host or hosts because the same pest might not be regulated as an RNQP on other hosts. For example, a virus may cause economically unacceptable impact in one species of plants for planting, but not in another. Distinctions should be made regarding the specified taxonomic level of the host plants for the application of phytosanitary requirements for RNQPs where information available on host-pest interaction supports such distinctions (e.g. varietal resistance/susceptibility, pest virulence).

6.2 Certification programmes[1]

Programmes for the certification of plants for planting (sometimes known as “certification schemes”) frequently include specific requirements for pests, in addition to non-phytosanitary elements such as requirements for varietal purity, color, size of the product, etc. The pests concerned may be RNQPs if this can be technically justified and if the certification programme is mandatory, and thus can be considered to be official control, i.e. established or recognized by the national government or NPPO under appropriate legislative authority. In general, the pests for which certification programmes are intended are those which cause economically unacceptable impact for the crop concerned and are mainly transmitted in plants for planting, thereby qualifying as RNQPs. However, not all pests mentioned in certification programmes are necessarily RNQPs. Some existing programmes may include tolerances for pests or pest damage whose technical justification has not been demonstrated.

6.3 Tolerances

The application of the concept of RNQPs requires acceptance and establishment of appropriate tolerances for RNQP levels in official control programmes and corresponding requirements at import. The level of tolerance depends on the technical justification and follows in particular the principles of managed risk, non-discrimination, and minimal impact. In some cases, if technically justified, this tolerance may be zero, based on specified sampling and testing procedures.

6.4 Non-compliance

Phytosanitary action taken for non-compliance with phytosanitary requirements for RNQPs should be in accordance with the principles of non-discrimination and minimal impact.

Options include:

- downgrading (change commodity class or intended use)
- treatment
- redirection for another purpose (e.g. processing)
- redirection to origin or another country
- destruction.

[1] This certification is not to be confused with phytosanitary certification.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 17

PEST REPORTING

(2002)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in March 2002.

INTRODUCTION

SCOPE

This standard describes the responsibilities of and requirements for contracting parties in reporting the occurrence, outbreak and spread of pests in areas for which they are responsible. It also provides guidance on reporting successful eradication of pests and establishment of Pest Free Areas.

REFERENCES

Determination of pests status in an area, 1998. ISPM No. 8, FAO, Rome.
Glossary of phytosanitary terms, 2001. ISPM No. 5, FAO, Rome.
Guidelines for pest eradication programmes, 1999. ISPM No.9, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for surveillance, 1998. 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 quarantine pests, 2001. ISPM No. 11, FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM No. 4, 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 (1997) requires countries to report on the occurrence outbreak, and spread of pests with the purpose of communicating immediate or potential danger. National Plant Protection Organizations (NPPOs) have the responsibility to collect pest information by surveillance and to verify the pest records thus collected. Occurrence, outbreak or spread of pests that are known (on the basis of observation, previous experience, or Pest Risk Analysis [PRA]) to be of immediate or potential danger should be reported to other countries, in particular to neighbouring countries and trading partners.

Pest reports should contain information on the identity of the pest, location, pest status, and nature of the immediate or potential danger. They should be provided without undue delay, preferably through electronic means, through direct communication, openly available publication and/or the International Phytosanitary Portal (IPP)[1].

Reports of successful eradication, the establishment of Pest Free Areas and other information may also be provided utilizing the same reporting procedure.

[1] The IPP is the electronic mechanism provided by the IPPC Secretariat to facilitate the exchange of official phytosanitary information (including pest reporting) between NPPOs, RPPOs, and/or the IPPC Secretariat.

REQUIREMENTS

1. Provisions of the IPPC Regarding Pest Reporting

The IPPC (1997), in relation to its main purpose of "*securing common and effective action to prevent the spread and introduction of pests of plants and plant products,* (Article I.1) *requires countries to make provision, to the best of their ability, for an official national plant protection organization,*" (Article IV.1) whose responsibilities include the following:

"*…the surveillance of growing plants, including both areas under cultivation (inter alia fields, plantations, nurseries, gardens, greenhouses and laboratories) and wild flora, and of plants and plant products in storage or in transportation, particularly with the object of reporting the occurrence, outbreak and spread of pests, and of controlling those pests, including the reporting referred to under Article VIII paragraph 1(a)...*" (Article IV.2b).

Countries are responsible for the distribution of information within their territories regarding regulated pests (Article IV.3a), and they are required, "*to the best of their ability, to conduct surveillance for pests and develop and maintain adequate information on pest status in order to support categorization of pests, and for the development of appropriate phytosanitary measures. This information shall be made available to contracting parties, on request.*"(Article VII.2j). They are required to "*designate a contact point for the exchange of information connected with the implementation*" of the IPPC (Article VIII.2).

With these systems in operation, countries are able to fulfil the requirement under the IPPC:
"*…to cooperate with one another to the fullest practicable extent in achieving the aims of this Convention* (Article VIII.1)*, and in particular to cooperate in the exchange of information on plant pests, particularly the reporting of the occurrence, outbreak or spread of pests that may be of immediate or potential danger, in accordance with such procedures as may be established by the Commission* ...(Article VIII.1a).

2. Purpose of Pest Reporting

The main purpose of pest reporting is to communicate immediate or potential danger. Immediate or potential danger normally arises from the occurrence, outbreak or spread of a pest that is a quarantine pest in the country in which it is detected, or a quarantine pest for neighbouring countries and trading partners.

The provision of reliable and prompt pest reports confirms the operation of effective surveillance and reporting systems within countries.

Pest reporting allows countries to adjust as necessary their phytosanitary requirements and actions to take into account any changes in risk. It provides useful current and historical information for operation of phytosanitary systems. Accurate information on pest status facilitates technical justification of measures and helps to minimize unjustified interference with trade. Every country needs pest reports for these purposes, and can only obtain them by the cooperation of other countries. Phytosanitary actions taken by importing countries based on pest reports should be commensurate with the risk and technically justified.

3. National Responsibilities

NPPOs should make provision to ensure the collection, verification, and analysis of domestic pest reports.

3.1 Surveillance

Pest reporting depends on the establishment, within countries, of national systems for surveillance, as required by the IPPC (1997) (Article IV.2b). Information for pest reporting may be derived from either of the two types of pest surveillance systems defined in ISPM No. 6 (*Guidelines for surveillance*), general surveillance or specific surveys. Systems should be put in place to ensure that such information is sent to and collected by the NPPO. The surveillance and collection systems should operate on an ongoing and timely basis. Surveillance should be conducted in accordance with ISPM No. 6.

3.2 Sources of information

Information for pest reporting may be obtained directly by the NPPO or may be available to the NPPO from a variety of other sources (research institutions and journals, websites, growers and their journals, other NPPOs, etc). General surveillance by the NPPO includes the review of information from other sources.

3.3 Verification and analysis

NPPOs should put in place systems for verification of domestic pest reports from official and other sources (including those brought to their attention by other countries). This should be done by confirming the identification of the pest concerned and making a preliminary determination of its geographical distribution– and thus establishing its "pest status" in the country, according to ISPM No. 8 (*Determination of pest status in an area*). NPPOs should also put in place systems of Pest Risk Analysis (PRA) to determine whether new or unexpected pest situations constitute an immediate or potential danger to their country (i.e. the reporting country), requiring phytosanitary action. PRA may also be used to identify, as appropriate, whether the situations that have been reported may be of concern to other countries.

3.4 Motivation for domestic reporting

Where possible, countries should provide incentives for domestic reporting. Growers and others may be required officially to report on new or unexpected pest situations and may be encouraged in this, for example, by publicity, community action, rewards, or penalties.

4. Reporting Obligations

The obligation identified under the IPPC (1997, Article VIII.1a) is to report the occurrence, outbreak and spread of pests that may be of immediate or potential danger. Countries may optionally make other pest reports. Such reporting satisfies the general recommendation under the IPPC to cooperate in achieving the objectives of the Convention but is not a specific obligation. This standard also considers such other cases of pest reporting.

4.1 Reporting of immediate or potential danger

An immediate danger is considered to be one that has already been identified (pest already regulated) or is obvious on the basis of observation or previous experience. A potential danger is one that is identified as the result of a PRA.

Immediate and potential danger of a pest found in the reporting country normally lead to phytosanitary or emergency action in that country.

The occurrence, outbreak and spread of pests which is of immediate or potential danger to the reporting country may be of immediate or potential danger to other countries. There is an obligation to report it to other countries.

Countries have an obligation to report occurrence, outbreak or spread of pests that are not of danger to them but are known to be regulated by or of immediate danger to other countries. This will concern trading partners (for relevant pathways) and neighbouring countries to which the pest could spread without trade.

4.2 Other pest reports

Countries may also, as appropriate, use the same reporting systems to provide pest reports on other pests, or to report to other countries, if this contributes usefully to the exchange of information on plant pests foreseen under Article VIII of the IPPC. They may also enter into bilateral or multilateral agreements on pest reporting, e.g. through RPPOs.

4.3 Reporting of changed status, absence or correction of earlier reports

Countries may also report cases where immediate or potential danger has changed or is absent (including in particular pest absence). Where there has been an earlier report indicating immediate or potential danger and it later appears that the report was incorrect or circumstances change so that the risk changes or disappears, countries should report the change. Countries may also report that all or part of their territory has been categorized as a pest free area, according to ISPM No. 4 (*Requirements for the establishment of pest free areas*), or report successful eradication according to ISPM No. 9 (*Guidelines for pest eradication programmes*), or changes in host range or in the pest status of a pest according to one of the descriptions in ISPM No. 8 (*Determination of pest status in an area*).

4.4 Reporting of pests in imported consignments

Reporting the pests detected in imported consignments is covered by the ISPM No. 13 (*Guidelines for the notification of non-compliance and emergency action*) and not by this standard.

5. Initiation of Reports

Pest reports are initiated by the occurrence, outbreak, spread, or successful eradication of pests, or any other new or unexpected pest situation.

5.1 Occurrence

Occurrence should normally be reported where the presence of a pest is newly determined, which is known to be a regulated pest by neighbouring countries or trading partners (for relevant pathways).

5.2 Outbreak

An outbreak refers to a recently detected pest population. An outbreak should be reported when its presence corresponds at least to the status of **Transient: actionable** in ISPM No. 8 (*Determination of pest status in an area*). This means that it should be reported even when the pest may survive in the immediate future, but is not expected to establish.

The term outbreak also applies to an unexpected situation associated with an established pest which results in a significant increase in phytosanitary risk to the reporting country, neighbouring countries or trading partners, particularly if it is known that the pest is a regulated pest. Such unexpected situations could include a rapid increase in the pest population, changes in host range the development of a new, more vigorous strain or biotype, or the detection of a new pathway.

5.3 Spread

Spread concerns an established pest that expands its geographical distribution, resulting in a significant increase in risk to the reporting country, neighbouring countries or trading partners, particularly if it is known that the pest is regulated.

5.4 Successful eradication

Eradication may be reported when it is successful, that is when an established or transient pest is eliminated from an area and the absence of that pest is verified. (see ISPM No. 9: *Guidelines for pest eradication programmes*)

5.5 Establishment of Pest Free Area

The establishment of a Pest Free Area may be reported where this constitutes a change in the pest status in that area. (see ISPM No. 4: *Requirements for the establishment of Pest Free Areas*)

6. Pest Reporting

6.1 Content of reports

A pest report should clearly indicate:

- the identity of the pest with scientific name (where possible, to the species level, and below species level, if known and relevant)
- the date of the report
- host(s) or articles concerned (as appropriate)
- the status of the pest under ISPM No. 8
- geographical distribution of the pest (including a map, if appropriate)
- the nature of the immediate or potential danger, or other reason for reporting.

It may also indicate the phytosanitary measures applied or required, their purpose, and any other information as indicated for pest records in ISPM No. 8 (*Determination of pest status in an area*).

If all the information is not available on the pest situation then a preliminary report should be made and updates made, as further information becomes available.

6.2 Timing of reporting

Reports on occurrence, outbreak and spread should be provided without undue delay. This is especially important when the risk of immediate spread is high. It is recognized that the operation of the national systems for surveillance and reporting (see section 3), and in particular the processes of verification and analysis, require a certain time, but this should be kept to a minimum.

Reports should be updated, as new and more complete information becomes available.

6.3 Mechanism of reporting and destination of reports

Pest reports which are obligations under the IPPC should be made by NPPOs using at least one of the following three systems:

- direct communication to official contact points (mail, facsimile, or e-mail)–countries are encouraged to use electronic means of pest reporting to facilitate wide and prompt distribution of information
- publication on an openly available, official national website (such a website may be designated as part of an official contact point)–precise information on the website access address to the pest reports should be made available to other countries, or at least to the Secretariat
- the International Phytosanitary Portal (IPP).

In addition, for pests of known and immediate danger to other countries, direct communication to those countries, by mail or e–mail, is recommended in any case.

Countries may also address pest reports to RPPOs, to privately contracted reporting systems, through bilaterally agreed reporting systems, or in any other manner acceptable to the countries involved. Whatever reporting system is used, the NPPO should retain responsibility for the reports.

Publication of pest reports in a scientific journal, or in an official journal or gazette that typically has limited distribution, does not meet the requirements of this standard.

6.4 Good reporting practices

Countries should follow the "good reporting practices" set out in ISPM No. 8 (*Determination of pest status in an area*).

If the status of a pest in a country is questioned by another country, then an attempt should be made to resolve the matter bilaterally, in the first instance.

6.5 Confidentiality

Pest reports should not be confidential. However, national systems for surveillance, domestic reporting, verification, and analysis may contain confidential information.

Countries may have in place requirements regarding confidentiality of certain information, e.g. identity of growers. National requirements should not affect basic reporting obligations (content of reports, timeliness).

Confidentiality in bilateral arrangements should not conflict with international reporting obligations.

6.6 Language

There are no IPPC obligations in relation to the language used for pest reporting, except where countries request information under Article VII.2j (IPPC, 1997), when one of the five official languages of FAO should be used for the reply. Countries are encouraged to provide pest reports also in English, in particular for purposes of global electronic reporting.

7. Additional Information

On the basis of pest reports, countries may request additional information through official contact points. The reporting country, to the best of its ability, should report information required under Article VII.2j (IPPC, 1997).

8. Review

NPPOs should undertake periodic review of their pest surveillance and reporting systems to ensure that they are meeting their reporting obligations and to identify possibilities for improving reliability and timeliness. They should make adjustments as appropriate.

9. Documentation

National pest surveillance and reporting systems should be adequately described and documented and this information should be made available to other countries on request (see ISPM No. 6: *Guidelines for surveillance*).

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 18

GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY MEASURE

(2003)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

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

INTRODUCTION

SCOPE

This standard[1] provides technical guidance on the specific procedures for the application of ionizing radiation as a phytosanitary treatment for regulated pests or articles. This does not include treatments used for:

- the production of sterile organisms for pest control;
- sanitary treatments (food safety and animal health);
- the preservation or improvement of commodity quality (e.g. shelf life extension); or
- inducing mutagenesis.

REFERENCES

Export certification system, 1997. ISPM No. 7, FAO, Rome.
Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.
Glossary of phytosanitary terms, 2003. ISPM No. 5, FAO, Rome.
Guidelines for Pest Risk Analysis, 1996. ISPM No. 2, 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.
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

Treatment with ionizing radiation (irradiation) may be used for pest risk management. NPPOs should be assured that the efficacy of the treatment is scientifically demonstrated for the regulated pest(s) of concern and the required response. Application of the treatment requires dosimetry and dose mapping to ensure that the treatment is effective in particular facilities and with specific commodity configurations. The NPPO is responsible for ensuring that facilities are appropriately designed for phytosanitary treatments. Procedures should be in place to ensure that the treatment can be conducted properly and commodity lots are handled, stored and identified to ensure that phytosanitary security is maintained. Recordkeeping by the treatment facility and documentation requirements for the facility and NPPO are required, and should include a compliance agreement between facility operator and the NPPO stipulating in particular the specific requirements for phytosanitary measures.

[1] Nothing in this standard shall affect the rights or obligations of contracting parties under other international agreements or national legislation, including those applicable to irradiation of food.

GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY MEASURE

1. Authority

The NPPO is responsible for the phytosanitary aspects of evaluation, adoption and use of irradiation as a phytosanitary measure. To the extent necessary, it is the NPPO's responsibility to cooperate with other national and international regulatory agencies concerned with the development, approval, safety and application of irradiation, or the distribution, use or consumption of irradiated products. Their respective responsibilities should be identified to avoid overlapping, conflicting, inconsistent or unjustified requirements.

2. Treatment Objective

The objective of using irradiation as a phytosanitary measure is to prevent the introduction or spread of regulated pests. This may be realized by achieving certain responses in the targeted pest(s) such as:

- mortality;
- preventing successful development (e.g. non-emergence of adults);
- inability to reproduce (e.g. sterility); or
- inactivation.

Phytosanitary uses of irradiation also include the devitalization of plants (e.g. seeds may germinate but seedlings do not grow; or tubers, bulbs or cuttings do not sprout).

2.1 Efficacy

The required treatment efficacy should be specifically defined by the NPPO of the importing country. It consists of two distinct components:

- a precise description of required response;
- the statistical level of response required.

It is not sufficient to only specify a response without also describing how this is to be measured.

The choice of a required response is based on the risk as assessed through PRA, considering in particular the biological factors leading to establishment and taking into account the principle of minimal impact. A response such as mortality may be appropriate where the treatment is for the vector of a pathogen, whereas sterility may be an appropriate response for pest(s) that are not vectors and remain on or in the commodity.

If the required response is mortality, time limits for the effect of the treatment should be established.

A range of specific options may be specified where the required response is the inability of the pest to reproduce. These may include:

- complete sterility;
- limited fertility of only one sex;
- egg laying and/or hatching without further development;
- altered behaviour; and
- sterility of F_1 generation.

3. Treatment

Ionizing radiation may be provided by radioactive isotopes (gamma rays from cobalt-60 or cesium-137), electrons generated from machine sources (up to 10 MeV), or by x-rays (up to 5 MeV) (limits set by Codex Alimentarius[2]). The unit of measurement for absorbed dose should be gray (Gy).

Variables to consider when implementing treatments include the dose rate, treatment time, temperature, humidity, ventilation, and modified atmospheres; these should be compatible with treatment effectiveness. Modified atmospheres may reduce treatment efficacy at a prescribed dose.

Treatment procedures should also ensure that the minimum absorbed dose (Dmin) is fully attained throughout the commodity to provide the prescribed level of efficacy. Owing to the differences in the configuration of treatment lots, higher doses than the Dmin may be required to ensure that the Dmin is achieved throughout the configured consignment or lot. The intended end use of the product should be considered when conducting irradiation treatments.

[2] *Codex general standard for irradiated food*: *Codex Stand.* 106-1983. Codex Alimentarius, Section 7.1, Col. 1A (currently under revision).

Because mortality will rarely be technically justified as the required response, live target pests may be found. Therefore it is essential that the irradiation treatment ensures they are unable to reproduce. In addition, it is preferable that such pest(s) are unable to emerge or escape from the commodity unless they can be practically distinguished from non-irradiated pest(s).

3.1 Application

Irradiation can be applied:

- as an integral part of packing operations;
- to bulk unpackaged commodities (such as grain moving over a belt);
- at centralized locations such as the port of embarkation.

When safeguards are adequate and transit movement of the untreated commodity is operationally feasible, treatment may also be performed at:

- the point of entry;
- a designated location in a third country;
- a designated location within the country of final destination.

Treated commodities should be certified and released only after dosimetry measurements confirm that the Dmin was met. Where appropriate, re-treatment of consignments may be allowed, provided that the maximum absorbed dose is within the limits allowed by the importing country.

The purpose of Annex 1 [to be completed] is to list the doses for specific approved treatments as part of this ISPM. Appendix 1, which is attached for information only, provides some published information on absorbed dose ranges for certain pest groups.

According to the pest risks to be addressed and the available options for pest risk management, irradiation can be used as a single treatment or combined with other treatments as part of a systems approach to meet the level of efficacy required (see ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*).

4. Dosimetry

Dosimetry ensures that the required Dmin for a particular commodity was delivered to all parts of the consignment. The selection of the dosimetry system should be such that the dosimeter response covers the entire range of doses likely to be received by the product. In addition, the dosimetry system should be calibrated in accordance with international standards or appropriate national standards (e.g. Standard ISO/ASTM 51261 *Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing*).

Dosimeters should be appropriate for the treatment conditions. Dosimeters should be evaluated for stability against the effects of variables such as light, temperature, humidity, storage time, and the type and timing of analyses required.

Dosimetry should consider variations due to density and composition of the material treated, variations in shape and size, variations in orientation of the product, stacking, volume and packaging. Dose mapping of the product in each geometric packing configuration, arrangement and product density that will be used during routine treatments should be required by the NPPO prior to the approval of a facility for the treatment application. Only the configurations approved by the NPPO should be used for actual treatments.

4.1 Calibration of components of the dosimetry system

All components of the dosimetry system should be calibrated according to documented standard operating procedures. An independent organization recognized by the NPPO should assess performance of the dosimetry system.

4.2 Dose mapping

Dose mapping studies should be conducted to fully characterize the dose distribution within the irradiation chambers and commodity, and demonstrate that the treatment consistently meets the prescribed requirements under defined and controlled conditions. Dose mapping should be done in accordance with documented standard operating procedures. The information from the dose mapping studies is used in the selection of locations for dosimeters during routine processing.

Independent dose mapping for incomplete (partially-filled) as well as first and last process loads is required to determine if the absorbed-dose distribution is significantly different from a routine load and to adjust the treatment accordingly.

4.3 Routine dosimetry

An accurate measurement of absorbed dose in a consignment is critical for determining and monitoring efficacy and is part of the verification process. The required number, location and frequency of these measurements should be prescribed based on the specific equipment, processes, commodities, relevant standards and phytosanitary requirements.

5. Approval of Facilities

Treatment facilities should be approved by relevant nuclear regulatory authorities where appropriate. Treatment facilities should also be subject to approval (qualification, certification or accreditation) by the NPPO in the country where the facility is located prior to applying phytosanitary treatments. Phytosanitary approval should be based on a common set of criteria plus those specific to the site and commodity programmes (see Annex 2).

Phytosanitary re-approval should be done on an appropriate regular basis. Documented dose mapping should be done following repairs, modifications or adjustments in equipment or processes that affect the absorbed dose.

6. Phytosanitary System Integrity

Confidence in the adequacy of an irradiation treatment is primarily based on assurance that the treatment is effective against the pest(s) of concern under specific conditions and the treatment has been properly applied and the commodity adequately safeguarded. The NPPO of the country where the facility is located is responsible for ensuring system integrity, so that treatments meet the phytosanitary requirements of the importing country.

Efficacy research and dosimetry provide assurance that only effective treatments are used. Well-designed and closely monitored systems for treatment delivery and safeguarding assure that treatments are properly conducted and consignments protected from infestation, reinfestation or loss of integrity.

6.1 Phytosanitary security measures at the treatment facility

Because it is not usually possible to visually distinguish irradiated from non-irradiated products, treated commodities should be adequately segregated, clearly identified, and handled under conditions that will safeguard against contamination and/or infestation, or misidentification.

A secure means of moving the commodity from receiving areas to treatment areas without misidentification or risk of cross-contamination and/or infestation is essential. Appropriate procedures specific to each facility and commodity treatment programme should be agreed upon in advance. Commodities that are unpackaged or exposed in packaging require safeguarding immediately following treatment to ensure that they are not subject to infestation, reinfestation or contamination afterwards.

Packaging prior to irradiation may be useful to prevent reinfestation if irradiation is done prior to export, or to prevent the accidental escape of target pest(s) if treatment is done at the destination.

6.2 Labelling

Packages should be labelled with treatment lot numbers and other identifying features allowing the identification of treatment lots and trace-back (i.e. packing and treatment facility identification and location, dates of packing and treatment).

6.3 Verification

The adequacy of treatment facilities and processes should be verified through monitoring and audit of facility treatment records that include, as necessary, direct treatment oversight. Direct, continuous supervision of treatments should not be necessary provided treatment programmes are properly designed to ensure a high degree of system integrity for the facility, process and commodity in question. The level of oversight should be sufficient to detect and correct deficiencies promptly.

A compliance agreement should be concluded between the facility and the NPPO of the country where the facility is located. Such an agreement may include the following elements:

- approval of the facility by the NPPO of the country where the facility is located;
- the monitoring programme as administered by the NPPO of the country where treatments are conducted;
- audit provisions including unannounced visits;
- free access to documentation and records of the treatment facility; and
- corrective action to be taken in cases of non-compliance.

7. Documentation by the Treatment Facility

The NPPO of the country where the facility is located is responsible for monitoring recordkeeping and documentation

by the treatment facility and ensuring that records are available to concerned parties. As in the case of any phytosanitary treatment, trace-back capability is essential.

7.1 Documentation of procedures

Documented procedures help to ensure that commodities are consistently treated as required. Process controls and operational parameters are usually established to provide the operational details necessary for a specific authorization and/or facility. Calibration and quality control programmes should be documented by the facility operator. At a minimum, an agreed written procedure should address the following:

- consignment handling procedures before, during and after treatment;
- orientation and configuration of the commodity during treatment;
- critical process parameters and the means for their monitoring;
- dosimetry;
- contingency plans and corrective actions to be taken in the event of treatment failure or problems with critical treatment processes;
- procedures for handling rejected lots;
- labelling, recordkeeping, and documentation requirements.

7.2 Facility records and traceability

Packers and treatment facility operators should be required to keep records. These records should be available to the NPPO for review, e.g. when a trace-back is necessary.

Appropriate treatment records for phytosanitary purposes should be kept by the irradiation facility for at least one year to ensure traceability of treated lots. The facility operator should keep all records for every treatment. Dosimetry records should be kept by the treatment facility for at least one full year after treatment. In most cases, these records are required under other authorities, but these records should also be available to the NPPO for review. Other information that may be required to be recorded includes:

- identification of facility and responsible parties;
- identity of commodities treated;
- purpose of treatment;
- target regulated pest(s);
- packer, grower and identification of the place of production of the commodity;
- lot size, volume and identification, including number of articles or packages;
- identifying markings or characteristics;
- quantity in lot;
- absorbed doses (target and measured);
- date of treatment;
- any observed deviation from treatment specification.

8. Inspection and Phytosanitary Certification by the NPPO

8.1 Export inspection

Inspection to ensure the consignment meets the phytosanitary requirements of the importing country should include:

- documentation verification; and
- examination for non-target pests.

Documentation is checked for completeness and accuracy as the basis for certifying the treatment. Inspection is done to detect any non-target pests. This inspection may be done before or after the treatment. Where non-target pests are found, the NPPO should verify whether these are regulated by the importing country.

Live target pests may be found after treatment but should not result in the certification being refused except when mortality is the required response. Where mortality is required, live target pests may be found during the period immediately following the treatment application depending on the specification for efficacy (see section 2.1). If live pests are found, certification could be based on audit checks which confirm that mortality will be attained. When mortality is not the required response, it is more likely that live target pests may persist in the treated consignment. This should also not result in the certification being refused. Audit checks, including laboratory analyses, may be undertaken to ensure that the required response is achieved. Such checks may be part of the normal verification programme.

8.2 Phytosanitary certification

Certification in accordance with the IPPC validates the successful completion of a treatment when required by the importing country. The Phytosanitary Certificate or its associated documentation should at least specifically identify the

treated lot(s), date of treatment, the target minimum dose and the verified Dmin.

The NPPO may issue Phytosanitary Certificates based on treatment information provided to it by an entity approved by the NPPO. It should be recognized that the Phytosanitary Certificate may require other information supplied to verify that additional phytosanitary requirements have also been met (see ISPM No. 7: *Export certification system* and ISPM No.12: *Guidelines for Phytosanitary Certificates*).

8.3 Import inspection

When mortality is not the required response, the detection of live stages of target pests in import inspection should not be considered to represent treatment failure resulting in non-compliance unless evidence exists to indicate that the integrity of the treatment system was inadequate. Laboratory or other analyses may be performed on surviving target pest(s) to verify treatment efficacy. Such analyses should only be required infrequently as part of monitoring unless there is evidence to indicate problems in the treatment process. Where mortality is the required response, this may be confirmed. Where mortality is required, live target pests may be found when transport times are short, but should not normally result in the consignment being refused, unless the established mortality time has been exceeded.

The detection of pests other than target pest(s) on import should be assessed for the risk posed and appropriate measures taken, considering in particular the effect the treatment may have had on the non-target pest(s). The consignment may be detained and any other appropriate action may be taken by the NPPO of the importing country. NPPOs should clearly identify the contingency actions to be taken if live pests are found:

- target pests—no action to be taken unless the required response was not achieved;
- non-target regulated pests:
  - no action if the treatment is believed to have been effective;
  - action if there is insufficient data on efficacy or the treatment is not known to be effective;
- non-target non-regulated pests—no action, or emergency action for new pests.

In case of non-compliance or emergency action, the NPPO of the importing country should notify the NPPO of the exporting country as soon as possible (see ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*).

8.4 Verification methods for treatment efficacy in export and import inspection

Verification methods, including laboratory tests or analysis to determine if the required response has been achieved should be described by the exporting country at the request of the importing country.

8.5 Administration and documentation by the NPPO

The NPPO should have the ability and resources to evaluate, monitor, and authorize irradiation undertaken for phytosanitary purposes. Policies, procedures and requirements developed for irradiation should be consistent with those associated with other phytosanitary measures, except where the use of irradiation requires a different approach because of unique circumstances.

The monitoring, certification, accreditation and approval of facilities for phytosanitary treatments is normally undertaken by the NPPO where the facility is located, but by cooperative agreement may be undertaken by:

- the NPPO of the importing country;
- the NPPO of the exporting country; or
- other national authorities.

Memoranda of Understanding (MOUs), compliance agreements, or similar documented agreements between the NPPO and the treatment applicator/facility should be used to specify process requirements and to assure that responsibilities, liabilities and the consequences of non-compliance are clearly understood. Such documents also strengthen the enforcement capability of the NPPO if corrective action may be necessary. The NPPO of the importing country may establish cooperative approval and audit procedures with the NPPO of the exporting country to verify requirements.

All NPPO procedures should be appropriately documented and records, including those of monitoring inspections made and Phytosanitary Certificates issued, should be maintained for at least one year. In cases of non-compliance or new or unexpected phytosanitary situations, documentation should be made available as described in ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action.*

9. Research

Appendix 2 provides guidance on undertaking research for the irradiation of regulated pests.

ANNEX 1

SPECIFIC APPROVED TREATMENTS

This annex is a prescriptive part of the standard. Its purpose is to list irradiation treatments that may be approved for specified applications. Treatment schedules to be added as agreed by the ICPM in future.

ANNEX 2

CHECKLIST FOR FACILITY APPROVAL

This annex is a prescriptive part of the standard. The following checklist is intended to assist persons inspecting or monitoring facilities seeking to establish/maintain facility approval and certification of irradiated commodities for international trade. The failure to receive an affirmative response to any item should result in the refusal to establish, or the termination of, an approval or certification.

Criteria	**Yes**	**No**
1. Premises		
Irradiation facility meets the approval of the NPPO as regards phytosanitary requirements. The NPPO has reasonable access to the facility and appropriate records as necessary to validate phytosanitary treatments		
Facility buildings are designed and built to be suitable in size, materials, and placement of equipment to facilitate proper maintenance and operations for the lots to be treated		
Appropriate means, integral to the facility design, are available to maintain non-irradiated consignments and/or lots separate from treated consignments and/or lots		
Appropriate facilities are available for perishable commodities before and after treatment		
Buildings, equipment, and other physical facilities are maintained in a sanitary condition and in repair sufficient to prevent contamination of the consignments and/or lots being treated		
Effective measures are in place to prevent pests from being introduced into processing areas and to protect against the contamination or infestation of consignments and/or lots being stored or processed		
Adequate measures are in place to handle breakage, spills, or the loss of lot integrity		
Adequate systems are in place to dispose of commodities or consignments that are improperly treated or unsuitable for treatment		
Adequate systems are in place to control non-compliant consignments and/or lots and when necessary to suspend facility approval		
2. Personnel		
The facility is adequately staffed with trained, competent personnel		
Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes		
3. Product handling, storage and segregation		
Commodities are inspected upon receipt to ensure that they are suitable for irradiation treatment		
Commodities are handled in an environment that does not increase the risk of contamination from physical, chemical or biological hazards		
Commodities are appropriately stored and adequately identified. Procedures and facilities are in place to ensure the segregation of treated and untreated consignments and/or lots. There is a physical separation between incoming and outgoing holding areas where required		
4. Irradiation treatment		
Facility is able to perform required treatments in conformity with a scheduled process. A process control system is in place providing criteria to assess irradiation efficacy		
Proper process parameters are established for each type of commodity or consignment to be treated. Written procedures have been submitted to the NPPO and are well known to appropriate treatment facility personnel		
Absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices using calibrated dosimetry. Dosimetry records are kept and made available to the NPPO as needed		
5. Packaging and labeling		
Commodity is packaged (if necessary) using materials suitable to the product and process		
Treated consignments and/or lots are adequately identified or labelled (if required) and adequately documented		
Each consignments and/or lot carries an identification number or other code to distinguish it from all other consignments and/or lots		

Criteria	**Yes**	**No**
6. Documentation		
All records about each consignment and/or lot irradiated are retained at the facility for the period of time specified by relevant authorities and are available for inspection by the NPPO as needed		
The NPPO has a written compliance agreement with the facility		

APPENDIX 1

This appendix is for reference purposes only and is not a prescriptive part of the standard. The list is not exhaustive and should be adapted to specific circumstances. The references here are widely available, easily accessible and generally recognized as authoritative. The list is not comprehensive or static; nor is it endorsed as a standard under this ISPM.

ESTIMATED MINIMUM ABSORBED DOSES FOR CERTAIN RESPONSES FOR SELECTED PEST GROUPS[3]

The following table identifies ranges of minimum absorbed dose for pest groups based on treatment research reported in the scientific literature. Minimum doses are taken from many publications that are in the references listed below. Confirmatory testing should be done before adopting the minimum dose for a specific pest treatment.

To ensure the minimum absorbed dose is achieved for phytosanitary purposes, it is recommended to seek information about the Dmin for a particular target species and also to take into consideration the note in Appendix 2.

Pest group	Required response	Minimum dose range (Gy)
Aphids and whiteflies (Homoptera)	Sterilize actively reproducing adult	50-100
Seed weevils (Bruchidae)	Sterilize actively reproducing adult	70-300
Scarab beetles (Scarabidae)	Sterilize actively reproducing adult	50-150
Fruit flies (Tephritidae)	Prevent adult emergence from 3rd instar	50-250
Weevils (Curculionidae)	Sterilize actively reproducing adult	80-165
Borers (Lepidoptera)	Prevent adult development from late larva	100-280
Thrips (Thysanoptera)	Sterilize actively reproducing adult	150-250
Borers (Lepidoptera)	Sterilize late pupa	200-350
Spider mites (Acaridae)	Sterilize actively reproducing adult	200-350
Stored product beetles (Coleoptera)	Sterilize actively reproducing adult	50-400
Stored product moths (Lepidoptera)	Sterilize actively reproducing adult	100-1,000
Nematodes (Nematoda)	Sterilize actively reproducing adult	~4,000

REFERENCES

International Atomic Energy Agency. 2002. International Database on Insect Disinfestation and Sterilization. (available at http://www-ididas.iaea.org).

Hallman, G. J. 2001. Irradiation as a quarantine treatment. *In*: Molins, R.A. (ed.) *Food Irradiation Principles and Applications*. New York: J. Wiley & Sons. p. 113-130.

Hallman, G. J. 2000. Expanding radiation quarantine treatments beyond fruit flies. *Agricultural and Forest Entomology*. 2:85-95.

http://www.iaea.org/icgfi is also a useful website for technical information on food irradiation.

[3] Not conclusively demonstrated with large scale testing. Based on literature review by Hallman, 2001.

APPENDIX 2

This appendix is for reference purposes only and is not a prescriptive part of the standard.

RESEARCH PROTOCOL[4]

Research materials

It is recommended to archive samples of the different developmental stages of the pests studied in order to, among other reasons, resolve possible future disputes on identification. The commodity to be used should be of normal commercial condition.

To perform treatment research to control quarantine pests it is necessary to know its basic biology as well as define how the pests used in the research will be obtained. The experiments with irradiation should be carried out on the commodity infested naturally in the field and/or with laboratory-reared pests that are used to infest the commodity preferably in a natural form. The method of rearing and feeding should be carefully detailed.

Note: Studies done with pests *in vitro* are not recommended because the results could be different from those obtained when irradiating the pests in commodities unless preliminary testing indicates that results from *in vitro* treatments are no different than *in situ*.

Dosimetry

The dosimetry system should be calibrated, certified and used according to recognized international standards. The minimum and maximum doses absorbed by the irradiated product should be determined striving for dose uniformity. Routine dosimetry should be conducted periodically.

International ISO Guidelines are available for conducting dosimetry research on food and agricultural products (see Standard ISO/ASTM 51261 *Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing*).

Estimation and confirmation of minimum absorbed dose for treatment

Preliminary Tests

The following steps should be carried out to estimate the dose required to ensure quarantine security:

- Radiosensitivity of the different stages of development of the pest in question that may be present in the commodity that is marketed must be established with the purpose of determining the most resistant stage. The most resistant stage, even if it is not the most common one occurring in the commodity, is the stage for which the quarantine treatment dose is established.
- The minimum absorbed dose will be determined experimentally. If pertinent data do not already exist, it is recommended to use at least five (5) dose levels and a control for each developmental stage, with a minimum of 50 individuals where possible for each of the doses and a minimum of three (3) replicates. The relationship between dose and response for each stage will be determined to identify the most resistant stage. The optimum dose to interrupt the development of the most resistant stage and/or to avoid the reproduction of the pests needs to be determined. The remainder of the research will be conducted on the most radiotolerant stage.
- During the period of post-treatment observation of the commodities and associated pests, both treated and control, must remain under favorable conditions for survival, development, and reproduction of the pests so that these parameters can be measured. The untreated controls must develop and/or reproduce normally for a given replicate for the experiment to be valid. Any study where the control or check mortalities are high indicates that the organisms were held and handled under sub-optimal conditions. These organisms may give misleading results if their treatment mortality is used to predict an optimum treatment dose. In general, mortality in the control or check should not exceed 10%.

Large Scale (Confirmatory) Tests

- To confirm if the estimated minimum dose to provide quarantine security is valid, it is necessary to treat a large number of individuals of the most resistant stage of the organism while achieving the desired result, be it prevention of pest development or sterility. The number treated will depend on the required level of confidence. The level of efficacy of the treatment should be established between the exporting and importing countries and be technically justifiable.

[4] Based primarily on insect pest treatment research.

- Because the maximum dose measured during the confirmatory part of the research will be the minimum dose required for the approved treatment, it is recommended to keep the maximum-minimum dose ratio as low as possible.

Recordkeeping

Test records and data need to be kept to validate the data requirements and should upon request be presented to interested parties, for example the NPPO of the importing country, for consideration in establishing an agreed commodity treatment.

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

CONTENTS

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

(2004)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

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, disinfestation 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 agents[1].

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 consignments[2] 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

CONTENTS

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

CONTENTS

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

CONTENTS

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 sampling[1].

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

(2005)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

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 protection[1].

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.

ANNEX 1

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.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 25

CONSIGNMENTS IN TRANSIT

(2006)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in April 2006.

INTRODUCTION

SCOPE

This standard describes procedures to identify, assess and manage phytosanitary risks associated with consignments of regulated articles which pass through a country without being imported, in such a manner that any phytosanitary measures applied in the country of transit are technically justified and necessary to prevent the introduction into and/or spread of pests within that country.

REFERENCES

Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines for inspection, 2005. ISPM No. 23, 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 reporting, 2002. ISPM No. 17, FAO, Rome.
Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, 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

International trade may involve the movement of consignments of regulated articles which pass through a country without being imported, under Customs[1] control. Such movements may present a phytosanitary risk to the country of transit. Contracting parties to the IPPC may apply measures to consignments in transit through their territories (Articles VII.1c and VII.2g of the IPPC, 1997), provided that the measures are technically justified and necessary to prevent the introduction and/or spread of pests (Article VII.4 of the IPPC, 1997).

This standard provides guidelines by which the National Plant Protection Organization (NPPO) of the country of transit may decide which movements require intervention of the NPPO and are subject to the application of phytosanitary measures, and if so, the type of phytosanitary measures to be applied. In such cases the responsibilities and elements of the transit system are described, together with the need for cooperation and communication, non-discrimination, review and documentation.

[1] Customs techniques which cover all aspects of Customs legislation, including annex E1 concerning customs transit and annex E2 concerning transhipment, are harmonized by the "International Convention on the simplification and harmonization of Customs procedures", also known as the Kyoto Convention, 1973.

BACKGROUND

Consignments in transit and their conveyances are included within the scope of the IPPC in Article VII and in Article I.

Article VII.1c states:

"*With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate . . . and, to this end, may . . . prohibit or restrict the movement of regulated pests into their territories*".

Article VII.4 states:

"*Contracting parties may apply measures specified in this Article to consignments in transit through their territories only where such measures are technically justified and necessary to prevent the introduction and/or spread of pests*".

Article I.4 states:

"*Where appropriate, the provisions of this Convention may be deemed by contracting parties to extend, in addition to plants and plant products, to storage places, packaging, conveyances, containers, soil and any other organism, object or material capable of harbouring or spreading plant pests, particularly where international transportation is involved*".

Transit involves the movement of consignments of regulated articles which pass through a country (further referred to as country of transit) without being imported. Consignments in transit constitute a potential pathway for the introduction and/or spread of pests to the country of transit.

Consignments in transit may pass through the country of transit remaining enclosed and sealed if necessary, without being split up or combined with other consignments, and without having their packaging changed. Under such conditions, the movement of consignments will, in many cases, not present a phytosanitary risk and will not require phytosanitary measures, especially if the consignments are transported in sealed containers[2]. However, even under such conditions, contingency plans may be required to address unexpected situations, such as an accident during transit.

Consignments and their conveyances passing through a country may, however, also be transported or handled in such a manner that they do present a phytosanitary risk to that country. This may, for example, be the case when consignments are transported open rather than enclosed, or when they do not pass directly through the country but are held for a period of storage, or are split up, combined or repackaged, or if the means of transport changes (e.g. from ship to railway). In such cases, phytosanitary measures may be applied in the country of transit to prevent the introduction of pests into, and/or their spread within, that country.

It should be noted that the term 'transit' is not only used for phytosanitary purposes but is also the accepted name for the standard procedure for moving goods under Customs control. Customs control may include document verification, tracking (e.g. electronic), sealing, control of carrier and entry/exit control. Customs control by itself is not intended to guarantee phytosanitary integrity and security of consignments and thus will not necessarily offer protection against the introduction and/or spread of pests.

Transhipment is a particular aspect of transport of consignments between countries. It refers to the transfer of consignments from one conveyance (means of transport) to another (e.g. ship to ship at a seaport) during the transportation process. Usually transhipment takes place under Customs control within an area specified by Customs. Transhipment may occur in a transit country and is thus covered by this standard.

REQUIREMENTS

1. Risk Analysis for the Country of Transit

Risk analysis related to consignments in transit would be facilitated by the sharing of relevant pest risk analysis (PRA) information already obtained and/or developed by one or both of the NPPOs of the importing and exporting contracting parties.

1.1 Risk identification

In order to identify potential phytosanitary risks related to consignments in transit, the NPPO of the country of transit (from this point onwards, "the NPPO") should collect and review relevant information.

[2] A standard, fully enclosed and secure transport container as commonly used in ocean going trade.

Elements of such information may include:

- procedures applied by Customs and other relevant services
- classes of commodities or regulated articles in transit and their country of origin
- means and methods of transport for consignments in transit
- regulated pests associated with the consignments in transit
- host distribution in the country of transit
- knowledge of transit route in the country of transit
- possibilities that pests may escape from consignments
- existing phytosanitary measures for consignments of commodities in transit
- types of packaging
- conditions of transport (refrigeration, modified atmosphere, etc.).

The NPPO may decide that consignments in transit that pose no potential phytosanitary risk, for instance when no pests regulated by the country of transit are associated with the consignments in transit, may move or continue to move without phytosanitary procedures.

The NPPO may also decide that consignments in transit that pose negligible phytosanitary risks, for example conveyances or packaging which are fully enclosed, sealed and secure, or when pests are regulated by the country of transit and are unlikely to escape from the consignment in transit, may move or continue to move without phytosanitary procedures..

If potential phytosanitary risks are identified, risk assessment for particular pests or commodities in transit is needed in order to identify the necessity and technical justification of any phytosanitary measure.

Only those phytosanitary risks which concern regulated pests of the country of transit or those pests that are under emergency action in that country should be considered.

1.2 Risk assessment

An assessment of the phytosanitary risks associated with the transit pathway should normally focus only on evaluating the probability of pests being introduced or spread from consignments in transit. The associated potential economic consequences should have been evaluated previously in the case of an existing regulated pest and therefore should not need to be repeated.

Guidance for the assessment of the probability of introduction and spread of a pest is provided in ISPM No. 11 (2004, *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*), in particular section 2.2. For consignments in transit, the following information may also be relevant:

- pathways for introduction and/or spread of regulated pests from the consignments in transit
- dispersal mechanism and mobility of the relevant pests
- means of transport (e.g. truck, rail, airplane, ship, etc.)
- phytosanitary security of the conveyance (e.g. closed, sealed, etc.)
- existence and type of packaging
- changes of configuration (e.g. combined, split, repacked)
- duration of transit or storage, and storage conditions
- route taken by the consignment prior to and within the country of transit
- frequency, volume and season of transit.

In cases where the NPPO, through risk assessment, has identified phytosanitary risks, pest risk management options can be considered.

1.3 Risk management

Based on risk assessment, consignments in transit may be classified by the NPPO into two broad risk management categories:

- transit requiring no further phytosanitary measures, or
- transit requiring further phytosanitary measures.

Further details on risk management are provided in ISPM No. 11 (2004, *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*).

1.3.1 Transit requiring no further phytosanitary measures

The NPPO, through the assessment of phytosanitary risk, may determine that Customs control alone is adequate. If this is the case, the NPPO should not apply any phytosanitary measures in addition to Customs control.

1.3.2 Transit requiring further phytosanitary measures

The risk assessment for consignments in transit may conclude that specific phytosanitary measures are necessary. These may include the following:

- verification of consignment identity or integrity (further details provided in ISPM No. 23: *Guidelines for inspection*)
- phytosanitary movement document (e.g. transit permit)
- phytosanitary certificates (with transit requirements)
- designated entry and exit points
- verification of exit of the consignment
- mode of transport and designated transit routes
- regulation of the changes of configuration (e.g. combined, split, repacked)
- use of NPPO-prescribed equipment or facilities
- Customs facilities recognized by the NPPO
- phytosanitary treatments (e.g. pre-shipment treatments, treatments when consignment integrity is doubtful)
- consignment tracking while in transit
- physical conditions (e.g. refrigeration, pest-proof packaging and/or conveyance preventing spillage)
- use of NPPO-specific seals for conveyances or consignment
- specific carrier's emergency management plans
- transit time or season limits
- documentation in addition to that required by Customs
- inspection of consignment by NPPO
- packaging
- disposal of waste.

Such phytosanitary measures should only be applied for regulated pests of the country of transit or those pests that are under emergency action in that country.

1.3.3 Other phytosanitary measures

When appropriate phytosanitary measures for consignments in transit are not available or are impossible to apply, the NPPO may require that such consignments are subject to the same requirements as imports, which may include prohibition.

If consignments in transit are stored or repackaged in such a way that they present a phytosanitary risk, the NPPO may decide that the consignments should meet import requirements or subject them to other appropriate phytosanitary measures.

2. Establishment of a Transit System

The contracting party may develop a transit system for phytosanitary control of consignments in transit with the NPPO, Customs and other relevant authorities of their country as collaborators. The objective of such a transit system is to prevent the introduction into and/or spread within the country of transit of regulated pests associated with consignments in transit and their conveyances. Transit systems require a basis of a regulatory framework of phytosanitary legislation, regulations and procedures. The transit system is operated by the NPPO, Customs and other relevant authorities in cooperation as appropriate, and should ensure that prescribed phytosanitary measures are applied.

The NPPO has responsibility for the phytosanitary aspects of the transit system and establishes and implements phytosanitary measures necessary to manage phytosanitary risks, taking into account the transit procedures of Customs.

3. Measures for Non-compliance and Emergency Situations

The transit system may include measures, established by the NPPO, for non-compliance and emergency situations (for example, accidents in the country of transit which could lead to the unexpected escape of a regulated pest from a consignment moving in transit). ISPM No. 13 (*Guidelines for the notification of non-compliance and emergency action*) contains specific guidelines for the country of transit for issuing notices of non-compliance to the exporting country and, where appropriate, to the country of destination.

4. Cooperation and Domestic Communication

Cooperation between NPPOs and Customs and other authorities (for example, port authorities) is essential to establish and/or maintain an effective transit system and identify consignments of regulated articles in transit. Therefore specific agreement with Customs may be needed for the NPPO to be informed of, and have access to, consignments under Customs control.

The NPPO may also establish cooperation and maintain communication with all stakeholders involved in transit as appropriate.

5. Non-discrimination

Consignments in transit should not be subject to more restrictive phytosanitary measures than those applied to consignments of the same phytosanitary status imported into that country of transit.

6. Review

The NPPO should, as necessary, review and adjust the transit system, the types of consignments in transit and the associated phytosanitary risks, in cooperation with relevant authorities and stakeholders as appropriate.

7. Documentation

Any transit system should be adequately described and documented.

Phytosanitary requirements, restrictions and prohibitions for consignments in transit should be made available, upon request, to any contracting party or parties that may be directly affected by such measures.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 26

ESTABLISHMENT OF PEST FREE AREAS FOR FRUIT FLIES (TEPHRITIDAE)

(2006)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in April 2006.

INTRODUCTION

SCOPE

This standard provides guidelines for the establishment of pest free areas for fruit flies (Tephritidae) of economic importance, and for the maintenance of their pest free status.

REFERENCES

Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.
Glossary of phytosanitary terms, 2006. 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.
International Plant Protection Convention, 1997. FAO, Rome.
Pest reporting, 2002. ISPM No. 17, 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 general requirements for establishing a fruit fly-pest free area (FF-PFA) include:

- the preparation of a public awareness programme
- the management elements of the system (documentation and review systems, record keeping), and
- supervision activities.

The major elements of the FF-PFA are:

- the characterization of the FF-PFA
- the establishment and maintenance of the FF-PFA.

These elements include the surveillance activities of trapping and fruit sampling, and official control on the movement of regulated articles. Guidance on surveillance and fruit sampling activities is provided in Appendices 1 and 2.

Additional elements include: corrective action planning, suspension, loss of pest free status and reinstatement (if possible) of the FF-PFA. Corrective action planning is described in Annex 1.

BACKGROUND

Fruit flies are a very important group of pests for many countries due to their potential to cause damage in fruits and to their potential to restrict access to international markets for plant products that can host fruit flies. The high probability of introduction of fruit flies associated with a wide range of hosts results in restrictions imposed by many importing countries to accept fruits from areas in which these pests are established. For these reasons, there is a need for an ISPM that provides specific guidance for the establishment and maintenance of pest free areas for fruit flies.

A pest free area is "*an area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained*" (ISPM No. 5: *Glossary of phytosanitary terms*). Areas initially free from fruit flies may remain naturally free from fruit flies due to the presence of barriers or climate conditions, and/or maintained free through movement restrictions and related measures (though fruit flies have the potential to establish there) or may be made free by an eradication programme (ISPM No. 9: *Guidelines for pest eradication programmes*). ISPM No. 4 (*Requirements for the establishment of pest free areas*) describes different types of pest free areas and provides general guidance on the establishment of pest free areas. However, a need for additional guidance on establishment and maintenance of pest free areas specifically for fruit flies (fruit fly-pest free areas, FF-PFA) was recognized. This standard describes additional requirements for establishment and maintenance of FF-PFAs. The target pests for which this standard was developed include insects of the order Diptera, family Tephritidae, of the genera *Anastrepha, Bactrocera, Ceratitis, Dacus, Rhagoletis* and *Toxotrypana*.

The establishment and maintenance of a FF-PFA implies that no other phytosanitary measures specific for the target species are required for host commodities within the PFA.

REQUIREMENTS

1. General Requirements

The concepts and provisions of ISPM No. 4 (*Requirements for the establishment of pest free areas*) apply to the establishment and maintenance of pest free areas for all pests including fruit flies and therefore ISPM No. 4 should be referred to in conjunction with this standard.

Phytosanitary measures and specific procedures as further described in this standard may be required for the establishment and maintenance of FF-PFA. The decision to establish a formal FF-PFA may be made based on the technical factors provided in this standard. They include components such as: pest biology, size of the area, pest population levels and dispersal pathway, ecological conditions, geographical isolation and availability of methods for pest eradication.

FF-PFAs may be established in accordance with this ISPM under a variety of different situations. Some of them require the application of the full range of elements provided by this standard, others require only the application of some of these elements.

In areas where the fruit flies concerned are not capable of establishment because of climatic, geographical or other reasons, absence should be recognized according to the first paragraph of section 3.1.2 of ISPM No. 8 (*Determination of pest status in an area*). If, however, the fruit flies are detected and can cause economic damage during a season (Article VII.3 of the IPPC), corrective actions should be applied in order to allow the maintenance of a FF-PFA.

In areas where the fruit flies are capable of establishment and known to be absent, general surveillance in accordance with section 3.1.2 of ISPM No. 8 (*Determination of pest status in an area*), is normally sufficient for the purpose of delimiting and establishing a pest free area. Where appropriate, import requirements and/or domestic movement restrictions against the introduction of the relevant fruit fly species into the area may be required to maintain the area free from the pest.

1.1 Public awareness

A public awareness programme is most important in areas where the risk of introduction is higher. An important factor in the establishment and maintenance of FF-PFAs is the support and participation of the public (especially the local community) close to the FF-PFA and individuals that travel to or through the area, including parties with direct and indirect interests. The public and stakeholders should be informed through different forms of media (written, radio, TV) of the importance of establishing and maintaining the pest free status of the area, and of avoiding the introduction or re-introduction of potentially infested host material. This may contribute to and improve compliance with the phytosanitary measures for the FF-PFA. The public awareness and phytosanitary education programme should be ongoing and may include information on:

- permanent or random checkpoints
- posting signs at entry points and transit corridors
- disposal bins for host material
- leaflets or brochures with information on the pest and the pest free area
- publications (e.g. print, electronic media)
- systems to regulate fruit movement
- non-commercial hosts
- security of the traps
- penalties for non-compliance, where applicable.

1.2 Documentation and record keeping

The phytosanitary measures used for the establishment and maintenance of FF-PFA should be adequately documented as part of phytosanitary procedures. They should be reviewed and updated regularly, including corrective actions, if required (see also ISPM No. 4: *Requirements for the establishment of pest free areas*).

The records of surveys, detections, occurrences or outbreaks and results of other operational procedures should be retained for at least 24 months. Such records should be made available to the NPPO of the importing country on request.

1.3 Supervision activities

The FF-PFA programme, including regulatory control, surveillance procedures (for example trapping, fruit sampling) and corrective action planning should comply with officially approved procedures.

Such procedures should include official delegation of responsibility assigned to key personnel, for example:

- a person with defined authority and responsibility to ensure that the systems/procedures are implemented and maintained appropriately;
- entomologist(s) with responsibility for the authoritative identification of fruit flies to species level.

The effectiveness of the programme should be monitored periodically by the NPPO of the exporting country, through review of documentation and procedures.

2. Specific Requirements

2.1 Characterization of the FF-PFA

The determining characteristics of the FF-PFA include:

- the target fruit fly species and its distribution within or adjacent to the area
- commercial and non-commercial host species
- delimitation of the area (detailed maps or GPS coordinates showing the boundaries, natural barriers, entry points and host area locations, and, where necessary, buffer zones)
- climate, for example rainfall, relative humidity, temperature, prevailing wind speed and direction.

Further guidance on establishing and describing a PFA is provided in ISPM No. 4 (*Requirements for the establishment of pest free areas*).

2.2 Establishment of the FF-PFA

The following should be developed and implemented:

- surveillance activities for establishment of the FF-PFA
- delimitation of the FF-PFA
- phytosanitary measures related to movement of host material or regulated articles
- pest suppression and eradication techniques as appropriate.

The establishment of buffer zones may also be necessary (as described in Section 2.2.1) and it may be useful to collect additional technical information during the establishment of the FF-PFA.

2.2.1 Buffer zone

In areas where geographic isolation is not considered adequate to prevent introduction to or reinfestation of a PFA or where there are no other means of preventing fruit fly movement to the PFA, a buffer zone should be established. Factors that should be considered in the establishment and effectiveness of a buffer zone include:

- pest suppression techniques which may be used to reduce the fruit fly population, including:
  - use of selective insecticide-bait
  - spraying
  - sterile insect technique
  - male annihilation technique
  - biological control
  - mechanical control, etc.
- host availability, cropping systems, natural vegetation
- climatic conditions
- the geography of the area
- capacity for natural spread through identified pathways
- the ability to implement a system to monitor the effectiveness of buffer zone establishment (e.g. trapping network).

2.2.2 Surveillance activities prior to establishment

A regular survey programme should be established and implemented. Trapping is the preferred option to determine fruit fly absence or presence in an area for lure/bait responsive species. However, fruit sampling activities may sometimes be required to complement the trapping programme in cases where trapping is less effective, for example when species are less responsive to specific lures.

Prior to the establishment of a FF-PFA, surveillance should be undertaken for a period determined by the climatic characteristics of the area, and as technically appropriate for at least 12 consecutive months in the FF-PFA in all relevant areas of commercial and non-commercial host plants to demonstrate that the pest is not present in the area. There should be no populations detected during the surveillance activities prior to establishment. A single adult detection, depending on its status (in accordance with ISPM No. 8: *Determination of pest status in an area*), may not disqualify an area from subsequent designation as a FF-PFA. For qualifying the area as a pest free area, there should be no detection of an immature specimen, two or more fertile adults, or an inseminated female of the target species during the survey period. There are different trapping and fruit sampling regimes for different fruit fly species. Surveys should be conducted using the guidelines in Appendices 1 and 2. These guidelines may be revised as trap, lure and fruit sampling efficiencies improve.

2.2.2.1 Trapping procedures

This section contains general information on trapping procedures for target fruit fly species. Trapping conditions may vary depending on, for example, the target fruit fly and environmental conditions. More information is provided in Appendix 1. When planning for trapping, the following should be considered:

Trap type and lures

Several types of traps and lures have been developed over decades to survey fruit fly populations. Fly catches differ depending on the types of lure used. The type of trap chosen for a survey depends on the target fruit fly species and the nature of the attractant. The most widely used traps include Jackson, McPhail, Steiner, open bottom dry trap (OBDT), yellow panel traps, which may use specific attractants (para-pheromone or pheromone lures that are male specific), or food or host odours (liquid protein or dry synthetic). Liquid protein is used to catch a wide range of different fruit fly species and capture both females and males, with a slightly higher percentage of females captured. However identification of the fruit flies can be difficult due to decomposition within the liquid bait. In traps such as McPhail, ethylene glycol may be added to delay decomposition. Dry synthetic protein baits are female biased, capture less non-target organisms and, when used in dry traps, may prevent premature decomposition of captured specimens.

Trap density

Trap density (number of traps per unit area) is a critical factor for effective fruit fly surveys and it should be designed based on target fruit fly species, trap efficiency, cultivation practices, and other biotic and abiotic factors. Density may change depending on the programme phase, with different densities required during the establishment of FF-PFA and the maintenance phase. Trap density also depends on the risk associated with potential pathways for entry into the designated PFA.

Trap deployment (determination of the specific location of the traps)

In a FF-PFA programme, an extensive trapping network should be deployed over the entire area. The trapping network layout will depend on the characteristics of the area, host distribution and the biology of the fruit fly of concern. One of the most important features of trap placement is the selection of a proper location and trap site within the host plant. The application of global positioning systems (GPS) and geographic information systems (GIS) are useful tools for management of a trapping network.

Trap location should take into consideration the presence of the preferred hosts (primary, secondary and occasional hosts) of the target species. Because the pest is associated with maturing fruit, the location including rotation of traps should follow the sequence of fruit maturity in host plants. Consideration should be given to commercial management practices in the area where host trees are selected. For example, the regular application of insecticides (and/or other chemicals) to selected host trees may have a false-negative effect on the trapping programme.

Trap servicing

The frequency of trap servicing (maintaining and refreshing the traps) during the period of trapping should depend on the:

- longevity of baits (attractant persistency)
- retention capacity
- rate of catch
- season of fruit fly activity
- placement of the traps
- biology of the species
- environmental conditions.

Trap inspection (checking the traps for fruit flies)

The frequency of regular inspection during the period of trapping should depend on:

- expected fruit fly activity (biology of the species)
- response of the target fruit fly in relation to host status at different times of the year
- relative number of target and non-target fruit flies expected to be caught in a trap
- type of trap used
- physical condition of the flies in the trap (and whether they can be identified).

In certain traps, specimens may degrade quickly making identification difficult or impossible unless the traps are checked frequently.

Identification capability

NPPOs should have in place, or have ready access to, adequate infrastructure and trained personnel to identify detected specimens of the target species in an expeditious manner, preferably within 48 hours. Continuous access to expertise may be necessary during the establishment phase or when implementing corrective actions.

2.2.2.2 Fruit sampling procedures

Fruit sampling may be used as a surveillance method in combination with trapping where trapping is less effective. It should be noted that fruit sampling is particularly effective in small-scale delimiting surveys in an outbreak area. However, it is labour-intensive, time consuming and expensive due to the destruction of fruit. It is important that fruit samples should be held in suitable condition to maintain the viability of all immature stages of fruit fly in infested fruit for identification purpose.

Host preference

Fruit sampling should take into consideration the presence of primary, secondary and occasional hosts of the target species. Fruit sampling should also take into account the maturity of fruit, apparent signs of infestation in fruit, and commercial practices (e.g. application of insecticides) in the area.

Focusing on high risk areas

Fruit sampling should be targeted on areas likely to have presence of infested fruits such as:

- urban areas
- abandoned orchards
- rejected fruit at packing facilities
- fruit markets
- sites with a high concentration of primary hosts
- entrance points into the FF-PFA, where appropriate.

The sequence of hosts that are likely to be infested by the target fruit fly species in the area should be used as fruit sampling areas.

Sample size and selection

Factors to be considered include:

- the required level of confidence
- the availability of primary host material in the field
- fruits with symptoms on trees, fallen or rejected fruit (for example at packing facilities), where appropriate.

Procedures for processing sampled fruit for inspection

Fruit samples collected in the field should be brought to a facility for holding, fruit dissection, pest recovery and identification. Fruit should be labeled, transported and held in a secure manner to avoid mixing fruits from different samples.

Identification capability

NPPOs should have in place, or have ready access to, adequate infrastructure and trained personnel to identify fruit fly immature stages and emerged adults of the target species in an expeditious manner.

2.2.3 Controls on the movement of regulated articles

Movement controls of regulated articles should be implemented to prevent the entry of target pests into the FF-PFA. These controls depend on the assessed risks (after identification of likely pathways and regulated articles) and may include:

- listing of the target fruit fly species on a quarantine pest list
- regulation of the pathways and articles that require control to maintain the FF-PFA
- domestic restrictions to control the movement of regulated articles into the FF-PFA
- inspection of regulated articles, examination of relevant documentation as appropriate and, where necessary for cases of non-compliance, the application of appropriate phytosanitary measures (e.g. treatment, refusal or destruction).

2.2.4 Additional technical information for establishment of a FF-PFA

Additional information may be useful during the establishment phase of FF-PFAs. This includes:

- historical records of detection, biology and population dynamics of the target pest(s), and survey activities for the designated target pest(s) in the FF-PFA
- the results of phytosanitary measures taken as part of actions following detections of fruit flies in the FF-PFA
- records of the commercial production of host crops in the area, an estimate of non-commercial production and the presence of wild host material
- lists of the other fruit fly species of economic importance that may be present in the FF-PFA.

2.2.5 Domestic declaration of pest freedom

The NPPO should verify the fruit fly free status of the area (in accordance with ISPM No. 8: *Determination of pest status in an area*) specifically by confirming compliance with the procedures set up in accordance with this standard (surveillance and controls). The NPPO should declare and notify the establishment of the FF-PFA, as appropriate.

In order to be able to verify the fruit fly free status in the area and for purposes of internal management, the continuing FF-PFA status should be checked after the PFA has been established and any phytosanitary measures for the maintenance of the FF-PFA have been put in place.

2.3 Maintenance of the FF-PFA

In order to maintain the FF-PFA status, the NPPO should continue to monitor the operation of the surveillance and control activities, continuously verifying the pest free status.

2.3.1 Surveillance for maintenance of the FF-PFA

After verifying and declaring the FF-PFA, the official surveillance programme should be continued at a level assessed as being necessary for maintenance of the FF-PFA. Regular technical reports of the survey activities should be generated (for example monthly). Requirements for this are essentially the same as for establishment of the FF-PFA (see Section 2.2) but with differences in density and trap locations dependent upon the assessed level of risk of introduction of the target species.

2.3.2 Controls on the movement of regulated articles

These are the same as for establishment of the FF-PFA (provided in Section 2.2.3).

2.3.3 Corrective actions (including response to an outbreak)

The NPPO should have prepared plans for corrective actions that may be implemented if the target pest(s) is detected in the FF-PFA or in host material from that area (detailed guidelines are provided in Annex 1), or if faulty procedures are found. This plan should include components or systems to cover:

- outbreak declaration according to criteria in ISPM No. 8 (*Determination of pest status in an area*) and notification
- delimiting surveillance (trapping and fruit sampling) to determine the infested area under corrective actions
- implementation of control measures
- further surveillance
- criteria for the reinstatement of freedom of the area affected by the outbreak
- responses to interceptions.

A corrective action plan should be initiated as soon as possible and in any case within 72 hours of the detection (of an adult or immature stage of the target pest).

2.4 Suspension, reinstatement or loss of a FF-PFA status

2.4.1 Suspension

The status of the FF-PFA or the affected part within the FF-PFA should be suspended when an outbreak of the target fruit fly occurs or based on one of the following triggers: detection of an immature specimen of the target fruit fly, two or more fertile adults as demonstrated by scientific evidence, or an inseminated female within a defined period and distance. Suspension may also be applied if procedures are found to be faulty (for example inadequate trapping, host movement controls or treatments).

If the criteria for an outbreak are met, this should result in the implementation of the corrective action plan as specified in this standard and immediate notification to interested importing countries' NPPOs (see ISPM No. 17: *Pest reporting*). The whole or part of the FF-PFA may be suspended or revoked. In most cases a suspension radius will delimit the affected part of the FF-PFA. The radius will depend on the biology and ecology of the target fruit fly. The same radius will generally apply for all FF-PFAs for a given target species unless scientific evidence supports any proposed deviation. Where a suspension is put in place, the criteria for lifting the suspension should be made clear. Interested importing countries' NPPOs should be informed of any change in FF-PFA status.

2.4.2 Reinstatement

Reinstatement should be based on requirements for establishment with the following conditions:

- no further detection of the target pest species for a period determined by the biology of the species and the prevailing environmental conditions[1], as confirmed by surveillance or;
- in the case of a fault in the procedures, only when the fault has been corrected.

2.4.3 Loss of FF-PFA status

If the control measures are not effective and the pest becomes established in the whole area (the area recognized as pest free), the status of the FF-PFA should be lost. In order to achieve again the FF-PFA, the procedures of establishment and maintenance outlined in this standard should be followed.

[1] The period starts from the last detection. For some species, no further detection should occur for at least three life cycles, however the required period should be based on scientific information including that provided by the surveillance systems in place.

ANNEX 1

GUIDELINES ON CORRECTIVE ACTION PLANS

The detection of a single fruit fly (adult or immature) of the target species in the FF-PFA should trigger enforcement of a corrective action plan.

In case of an outbreak, the objective of the corrective action plan is to ensure eradication of the pest to enable reinstatement of pest status in the affected area into the FF-PFA.

The corrective action plan should be prepared taking into account the biology of the target fruit fly species, the geography of the FF-PFA area, climatic conditions and host distribution within the area.

The elements required for implementation of a corrective action plan include:

- legal framework under which the corrective action plan can be applied
- criteria for the declaration of an outbreak
- time scales for the initial response
- technical criteria for delimiting trapping, fruit sampling, application of the eradication actions and establishment of regulatory measures
- availability of sufficient operational resources
- identification capability
- effective communication within the NPPO and with the NPPO (s) of the importing country(s), including provision of contact details of all parties involved.

Actions to apply the corrective action plan

1. Determination of the phytosanitary status of the detection (actionable or non actionable)

1.1. If the detection is a transient non actionable occurrence (ISPM No. 8: *Determination of pests status in an area*), no further action is required.

1.2. If the detection of a target pest may be actionable, a delimiting survey, which includes additional traps, and usually fruit sampling as well as an increased trap inspection rate, should be implemented immediately after the detection to assess whether the detection represents an outbreak, which will determine necessary responsive actions. If a population is present, this action is also used to determine the size of the affected area.

2. Suspension of FF-PFA status

If after detection it is determined that an outbreak has occurred or any of the triggers specified in Section 2.4.1 is reached, the FF-PFA status in the affected area should be suspended. The affected area may be limited to parts of the FF-PFA or may be the whole FF-PFA.

3. Implementation of control measures in the affected area

As per ISPM No. 9 (*Guidelines for pest eradication programmes*), specific corrective or eradication actions should be implemented immediately in the affected area(s) and adequately communicated to the community. Eradication actions may include:

- selective insecticide-bait treatments
- sterile fly release
- total harvest of fruit in the trees
- male annihilation technique
- destruction of infested fruit
- soil treatment (chemical or physical)
- insecticide application.

Phytosanitary measures should be immediately enforced for control of movement of regulated articles that can host fruit flies. These measures may include cancellation of shipments of fruit commodities from the affected area and as appropriate, fruit disinfestation and the operation of road blocks to prevent the movement of infested fruit from the affected area to the rest of the pest free area. Other measures could be adopted if agreed by the importing country, for example treatment, increased surveys, supplementary trapping.

4. Criteria for reinstatement of a FF-PFA after an outbreak and actions to be taken

The criteria for determining that eradication has been successful are specified in section 2.4.2 and should be included in the corrective action plan for the target fruit fly. The time period will depend on the biology of the species and the prevailing environmental conditions. Once the criteria have been fulfilled the following actions should be taken:

- notification of NPPOs of importing countries
- reinstatement of normal surveillance levels
- reinstatement of the FF-PFA.

5. Notification of relevant agencies

Relevant NPPOs and other agencies should be kept informed of any change in FF-PFA status as appropriate, and IPPC pest reporting obligations observed (ISPM No. 17: *Pest reporting*).

APPENDIX 1

This appendix is for reference purposes only and is not a prescriptive part of the standard. The publication below is widely available, easily accessible and generally recognized as authoritative.

GUIDELINES ON TRAPPING PROCEDURES

Information about trapping is available in the following publication of the International Atomic Energy Agency (IAEA): *Trapping Guidelines for area-wide fruit fly programmes*, IAEA/FAO-TG/FFP, 2003. IAEA, Vienna.

APPENDIX 2

This appendix is for reference purposes only and is not a prescriptive part of the standard.

GUIDELINES FOR FRUIT SAMPLING

Information about sampling is available in the references listed below. The list is not exhaustive.

Enkerlin, W.R.; Lopez, L.; Celedonio, H. (1996) Increased accuracy in discrimination between captured wild unmarked and released dyed-marked adults in fruit fly (Diptera: Tephritidae) sterile release programs. *Journal of Economic Entomology* **89**(4), 946-949.

Enkerlin W.; Reyes, J. (1984) *Evaluacion de un sistema de muestreo de frutos para la deteccion de Ceratitis capitata (Wiedemann)*. 11 Congreso Nacional de Manejo Integrado de Plagas. Asociacion Guatemalteca de Manejo Integrado de Plagas (AGMIP). Ciudad Guatemala, Guatemala, Centro America.

Programa Moscamed (1990) Manual de Operaciones de Campo. Talleres Graficos de la Nacion. Gobierno de Mexico. SAGAR//DGSV.

Programa regional Moscamed (2003) Manual del sistema de detección por muestreo de la mosca del mediterráneo. 26 pp.

Shukla, R.P.; Prasad, U.G. (1985) Population fluctuations of the Oriental fruit fly, *Dacus dorsalis* (Hendel) in relation to hosts and abiotic factors. *Tropical Pest Management* **31**(4)273-275.

Tan, K.H.; Serit, M. (1994) Adult population dynamics of *Bactrocera dorsalis* (Diptera: Tephritidae) in relation to host phenology and weather in two villages of Penang Island, Malaysia. *Environmental Entomology* **23**(2), 267-275.

Wong, T.Y.; Nishimoto, J.I.; Mochizuki, N. (1983) Infestation patterns of Mediterranean fruit fly and the Oriental fruit fly (Diptera: Tephritidae) in the Kula area of Mavi, Hawaii. *Environmental Entomology* **12**(4): 1031-1039. IV Chemical control.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 27

DIAGNOSTIC PROTOCOLS FOR REGULATED PESTS

(2006)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in April 2006.

INTRODUCTION

SCOPE

This standard provides guidance on the structure and content of the International Plant Protection Convention (IPPC) diagnostic protocols for regulated pests. The protocols describe procedures and methods for the official diagnosis of regulated pests that are relevant for international trade. They provide at least the minimum requirements for reliable diagnosis of regulated pests.

REFERENCES

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, 2006. ISPM No. 5. FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20. FAO, Rome.
Guidelines for inspection, 2005. ISPM No. 23. 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 reporting, 2002. ISPM No. 17. FAO, Rome.
Requirements for the establishment of areas of low pest prevalence, 2005. ISPM No. 22. 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

This standard sets the framework for the content of diagnostic protocols, their purpose and use, their publication and their development. Diagnostic protocols for specific regulated pests are included as annexes to this standard.

Information relevant for diagnosis is provided in the diagnostic protocol on the specified regulated pest, its taxonomic position, and the methods to detect and identify it. Diagnostic protocols contain the minimum requirements for reliable diagnosis of the specified regulated pests and provide flexibility to ensure that methods are appropriate for use in the full range of circumstances. The methods included in diagnostic protocols are selected on the basis of their sensitivity, specificity and reproducibility, and information related to these factors is provided for each of these methods.

Detailed information and guidance for the detection of pests is provided on, for example, signs and/or symptoms associated with the pest, illustrations (where appropriate), developmental stages of the pest, and methods for detecting the pest in a commodity, as well as methods for extracting, recovering and collecting the pests from plants. Information and guidance for the identification of pests includes detailed information on morphological and morphometric methods, methods based on biological properties, and methods based on biochemical and molecular properties of the pest. Furthermore detailed guidance is provided on the records that should be kept.

Diagnostic protocols are intended to be used by laboratories performing pest diagnosis as part of phytosanitary measures. They are subject to review and amendment to take into account new developments in pest diagnosis. The standard also provides guidance on how these protocols will be initiated, developed, reviewed and published.

BACKGROUND

Proper pest detection and pest identification are crucial for the appropriate application of phytosanitary measures (see for example ISPM No. 4: *Requirements for the establishment of pest free areas*; ISPM No. 6: *Guidelines for surveillance*; ISPM No. 7: *Export certification system;* ISPM No. 9: *Guidelines for pest eradication programmes*; and ISPM No 20: *Guidelines for a phytosanitary import regulatory system*). In particular, contracting parties need proper diagnostic procedures for determination of pest status and pest reporting (ISPM No. 8: *Determination of pest status in an area;* ISPM No. 17: *Pest reporting*), and the diagnosis of pests in imported consignments (ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action).*

National Plant Protection Organizations (NPPOs) have produced diagnostic protocols for regulated pests in order to adequately fulfil responsibilities according to Article IV of the IPPC (1997), in particular regarding surveillance, import inspections and export certification. In response to the need for regional harmonization, several Regional Plant Protection Organizations (RPPOs) have developed a significant number of regional diagnostic standards. This underlines the need for international harmonization, and those national and regional standards may form the basis for international protocols. Subsequently, the ICPM, at its Sixth session in 2004, recognized that there was a need for international diagnostic protocols within the framework of the IPPC and approved the formation of a Technical Panel on Diagnostic Protocols (TPDP) for that purpose.

PURPOSE AND USE OF DIAGNOSTIC PROTOCOLS

The purpose of harmonized diagnostic protocols is to support efficient phytosanitary measures in a wide range of circumstances and to enhance the mutual recognition of diagnostic results by NPPOs, which may also facilitate trade. Furthermore these protocols should aid the development of expertise and technical cooperation, and they may also be relevant to the accreditation and/or approval of laboratories.

In addition to the methods included in the diagnostic protocols presented in the annexes to this standard, NPPOs may use other methods for diagnosing the same pests (for example based on bilateral agreements). The protocols and their components annexed to this ISPM are considered to have the status of an ISPM or part thereof (see section 3 of this ISPM and article X of the IPPC). Therefore, contracting parties should take into account, as appropriate, these diagnostic protocols when using or requiring the use of diagnostic methods in particular where other contracting parties may be affected.

Diagnostic protocols describe procedures and methods for the detection and identification of regulated pests that are relevant to international trade.

Diagnostic protocols may be used in different circumstances that may require methods with different characteristics. Examples of such circumstances grouped according to an increased need for high sensitivity, specificity and reliability are:

- routine diagnosis of a pest widely established in a country
- general surveillance for pest status
- testing of material for compliance with certification schemes
- surveillance for latent infection by pests
- surveillance as part of an official control or eradication programme
- pest diagnostic associated with phytosanitary certification
- routine diagnosis for pests found in imported consignments
- detection of a pest in an area where it is not known to occur
- cases where a pest is identified by a laboratory for the first time
- detection of a pest in a consignment originating in a country where the pest is declared to be absent.

For example, in the case of routine diagnosis, the speed and cost of a test method may be more relevant than sensitivity or specificity. However, the identification of a pest by a laboratory or in an area for the first time may require methods with a high level of specificity and reproducibility. The significance of the outcome of a diagnosis is often dependent on proper sampling procedures. Such procedures are addressed by other ISPMs (under preparation).

Diagnostic protocols provide the minimum requirements for reliable diagnosis of regulated pests. This may be achieved by a single method or a combination of methods. Diagnostic protocols also provide additional methods to cover the full range of circumstances for which a diagnostic protocol may be used. The level of sensitivity, specificity and reproducibility of each method is indicated where possible. NPPOs may use these criteria to determine the method or combination of methods that are appropriate for the relevant circumstances.

Diagnostic protocols are intended to be used by laboratories performing pest diagnosis. Such laboratories may be established under or may be authorized by the NPPO to perform these activities in such manner that the results of the pest diagnosis may be considered as part of a phytosanitary measure of the NPPO.

The main elements of the procedure for the development of diagnostic protocols are presented in Appendix 1.

REQUIREMENTS

1. General Requirements for Diagnostic Protocols[1]

Each protocol contains the methods and guidance necessary for the regulated pest(s) to be detected and positively identified by an expert (i.e. an entomologist, mycologist, virologist, bacteriologist, nematologist, weed-scientist, molecular biologist) or competent staff that are specifically trained.

The methods included in diagnostic protocols are selected on the basis of their sensitivity, specificity and reproducibility. In addition, the availability of equipment, the expertise required for these methods and their practicability (for example ease of use, speed and cost) are taken into account when selecting methods for inclusion in the diagnostic protocol. Usually these methods and their associated information should also be published. It may be necessary that some methods are validated before inclusion in the protocols. Such validation may include, for example, the use of a set of known samples, including controls, prepared to verify sensitivity, specificity and reproducibility.

Each diagnostic protocol usually describes more than one method to take into account the capabilities of laboratories and the situations for which the methods are applied. Such situations include diagnosis of different developmental stages of organisms, which require different methodologies, the need for an alternative diagnostic technique because of uncertainties of the initial diagnosis, as well as varying requirements for the level of sensitivity, specificity and reliability. For some purposes a single method may be sufficient, for other purposes a combination of methods may be necessary. Each protocol contains introductory information, information on the taxonomic position of the pest, methods for detection and identification of the pest, records to be kept, and references to appropriate scientific publications. In many cases a wide range of supplementary information is available which may support diagnosis, for example geographical distribution of the pest and host lists, but diagnostic protocols focus on the critical methods and procedures for pest diagnosis.

The aspects of quality assurance and in particular the reference materials that are required by diagnostic protocols (such as inclusion of positive and negative controls or collection of specimens) are specifically indicated in the corresponding section of the protocol.

2. Specific Requirements for a Diagnostic Protocol

Diagnostic protocols are arranged according to the following sections:

- Pest information
- Taxonomic information
- Detection
- Identification
- Records
- Contact points for further information
- Acknowledgements
- References.

2.1 Pest information

Brief information is provided on the pest, including, where appropriate, its life cycle, morphology, variation (morphological and/or biological), relationship with other organisms, host range (in general), effects on hosts, present and past geographical distribution (in general), mode of transmission and dissemination (vectors and pathways). When available, reference to a pest data sheet should also be provided.

[1] The following general provisions apply to all diagnostic protocols:
- Laboratory tests may involve the use of chemicals or equipment which present a certain hazard. In all cases, national safety procedures should be strictly followed;
- Use of names of chemicals or equipment in these diagnostic protocols implies no approval of them to the exclusion of others that may also be suitable;
- Laboratory procedures presented in the protocols may be adjusted to the standards of individual laboratories, provided that they are adequately validated.

2.2 Taxonomic information

This section provides information on the taxonomy of the pest involved and includes:

- name (current scientific name, author and year (for fungi, teleomorph name if known))
  - synonyms (including former names)
  - accepted common names, anamorph name of fungi (including synonyms)
  - acronym of viruses and viroids
- taxonomic position (including information on subspecies classifications where relevant).

2.3 Detection

This section of the diagnostic protocol provides information and guidance on:

- the plants, plant products or other articles capable of harbouring the pest
- the signs and/or symptoms associated with the pest (characteristic features, differences or similarities with signs and/or symptoms from other causes), including illustrations, where appropriate
- the part(s) of the plant, plant products or other articles on/in which the pest may be found
- the developmental stages of the pest that may be detected, together with their likely abundance and distribution on/in the plants/plant products or other articles
- the likely occurrence of the pest associated with developmental stages of the host(s), climatic conditions and seasonality
- methods for detecting the pest in the commodity (e.g. visual, hand lens)
- methods for extracting, recovering and collecting the pest from the plants, plant products or other articles, or for demonstrating the presence of the pest in the plants, plant products or other articles
- methods for indicating the presence of the pest in asymptomatic plant material or other materials (e.g. soil or water), such as ELISA[2] tests or culturing on selective media
- viability of the pest.

For all the methods included in this section, information is provided on their sensitivity, specificity and reproducibility, where relevant. Where appropriate, guidance is provided on positive and negative controls and reference material to be included in tests. Guidance is also provided on resolving possible confusion with similar signs and/or symptoms due to other causes.

2.4 Identification

This section provides information and guidance on methods that either used alone or in combination lead to the identification of the pest. When several methods are mentioned, their advantages/disadvantages are given as well as the extent to which the methods or combinations of methods are equivalent. A flow diagram may be presented if several methods are needed to identify the pest or many alternative methods are included.

Main types of methodologies used in diagnostic protocols include those based on morphological and morphometric characteristics, biological properties such as virulence or host range of a pest, and those based on biochemical and molecular properties. Morphological characteristics may be investigated directly or after culturing or isolation of the pest. Culturing and/ or isolation may also be required for biochemical and/or molecular assays. Details are provided when culturing or isolation procedures are necessary components of methods.

For morphological and morphometric identifications, details are provided, as appropriate, on:

- methods to prepare, mount and examine the pest (such as for light microscopy, electron microscopy and measurement techniques)
- identification keys (to family, genus, species)
- descriptions of the morphology of the pest or of its colonies, including illustrations of morphological diagnostic characteristics, and an indication of any difficulties in seeing particular structures
- comparison with similar or related species
- relevant reference specimens or cultures.

For biochemical or molecular identifications, each method (e.g. serological methods, electrophoresis, PCR[3], DNA barcoding, RFLP[4], DNA sequencing) is described separately in sufficient detail (including equipment, reagents and consumables) to perform the test. Where appropriate, reference may be made to methodology described in other diagnostic protocols annexed to this standard.

[2] Enzyme-Linked Immunosorbent Assay
[3] Polymerase Chain Reaction
[4] Restriction Fragment Length Polymorphism

In cases where more than one method can be used reliably, other appropriate methods may be presented as alternative or supplementary methods, e.g. where morphological methods can be used reliably and appropriate molecular methods are also available.

Where appropriate, methods for isolation of pests from asymptomatic plants or plant products (such as tests for latent infection) are given, as well as methods for extraction, recovery and collection of pests from plant or other material. In these cases, methods may also be provided for direct identification of pests using biochemical or molecular tests on asymptomatic material.

For all the methods included in this section, information is provided on their sensitivity, specificity and reproducibility, where relevant. Where appropriate, guidance is provided on positive and negative controls and reference material to be included in tests. Guidance is also provided on removing possible confusion with similar and related species or taxa.

Diagnostic protocols provide guidance on the criteria for the determination of a positive or negative result for each method or information necessary to determine if an alternative method be applied.

Those cases where the use of appropriate controls for a specific technique, including where relevant reference material, is essential are clearly indicated in the protocol. When appropriate controls are not available, other tests, preferably based on different identification principles, may increase the certainty of the identification. Alternatively, a sample, specimen or, where appropriate, an image should be sent to another laboratory with experience in diagnosis of the suspected pest and possessing the required control or reference materials. Specimen(s) or material for reference purposes should be properly preserved.

Methods for quick, preliminary indications of identity (which will later need to be confirmed) may also be included in diagnostic protocols.

2.5 Records

This section provides information on the records that should be kept:

- scientific name of pest identified
- code or reference number of the sample (for traceability)
- nature of the infested material including scientific name of host where applicable
- origin (including the geographic location if known) of the infested material, and location of interception or detection
- description of signs or symptoms (including photographs where relevant), or their absence
- methods, including controls, used in the diagnosis and the results obtained with each method
- for morphological or morphometric methods, measurements, drawings or photographs of the diagnostic features (where relevant) and, if applicable, an indication of the developmental stage(s)
- for biochemical and molecular methods, documentation of test results such as photographs of diagnostic gels or ELISA printouts of results on which the diagnosis was based
- where appropriate, the magnitude of any infestation (how many individual pests found, how much damaged tissue)
- the name of the laboratory and, where appropriate, the name of the person(s) responsible for and/or who performed the diagnosis
- dates of collection of the sample, and of detection and identification of the pest.
- where appropriate, state of the pest, alive or dead, or viability of its development stages.

Evidence such as culture(s) of the pest, nucleic acid of the pest, preserved/mounted specimens or test materials (e.g. photograph of gels, ELISA plate printout results) should be retained, in particular in cases of non-compliance (ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*) and where pests are found for the first time (ISPM No. 17: *Pest reporting*). Additional items may be required under other ISPMs such as ISPM No. 8 (*Determination of pest status in an area*).

The period for which records should be kept depends on the purpose for which a diagnosis is made. In cases where other contracting parties may be adversely affected by the results of the diagnosis, records and evidence of the results of the diagnosis should be retained for at least one year.

2.6 Contact points for further information

Contact details of organizations or individuals with particular expertise on the pest(s) are provided; they may be consulted regarding details on the diagnostic protocol.

2.7 Acknowledgements

The name and address of the experts who wrote the first draft of the diagnostic protocol are given, together with those of any others who made major contributions.

2.8 References

References to accessible scientific publications and/or published laboratory manuals are given that may provide further guidance on the methods and procedures contained in the diagnostic protocol.

3. Publication of Diagnostic Protocols

Diagnostic protocols are published as annexes to this ISPM and thus are individual publications under the IPPC framework with a specific publication and/or revision date. If appropriate, they may also form part of other ISPMs. The process of their adoption includes stringent review by internationally acknowledged scientists/experts for the relevant discipline.

An index to the annexes is provided as Appendix 2 [Appendix 2 will be added to the standard when protocols have been approved].

APPENDIX 1

MAIN ELEMENTS OF PROCEDURES FOR DIAGNOSTIC PROTOCOLS

1. Development of Diagnostic Protocols

The TPDP will commission an expert to lead the development of a diagnostic protocol by adapting, as appropriate, protocols that have already been approved by RPPOs, or other international or national organizations, or by developing a new diagnostic protocol. The diagnostic protocol will be developed further by a small group of experts selected by the TPDP and will then be submitted, in cooperation with the IPPC Secretariat, to the TPDP which, when satisfied with the content, will submit it to the Standards Committee.

2. Review of Existing Diagnostic Protocols

TPDP members will review the diagnostic protocols in their discipline on an annual basis or as determined by the TPDP. A request for a revision to a diagnostic protocol may also be submitted by NPPOs, RPPOs or CPM subsidiary bodies through the IPPC Secretariat (ippc@fao.org), which will in turn forward it to the TPDP.

The TPDP will evaluate the request, identify those diagnostic protocols that require revision and oversee their revision. New methods should be at least equivalent to existing methods or provide a significant advantage for their worldwide application such as costs, sensitivity or specificity. Appropriate evidence should be provided to support any claims.

3. Requests for New Diagnostic Protocols

Requests for new diagnostic protocols, in addition to those identified in the work programme of the TPDP, should be sent by NPPOs, RPPOs or CPM subsidiary bodies through the IPPC Secretariat using a form for topics and priorities for standards, by 31 July of each year.