INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

1 to 27

(2006 edition)

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FAO

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Produced by the Secretariat of the International Plant Protection Convention

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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The designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations concerning the legal or development status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

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GENERAL INTRODUCTION

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES (ISPMs)

GENERAL INTRODUCTION

ENDORSEMENT

International Standards for Phytosanitary Measures are prepared by the Secretariat of the International Plant Protection Convention as part of the United Nations Food and Agriculture Organization's global programme of policy and technical assistance in plant quarantine. This programme makes available to FAO Members and other interested parties these standards, guidelines and recommendations to achieve international harmonization of phytosanitary measures, with the aim to facilitate trade and avoid the use of unjustifiable measures as barriers to trade.

The date of endorsement is given in each standard.

APPLICATION

International Standards for Phytosanitary Measures (ISPMs) are adopted by contracting parties to the IPPC through the Commission on Phytosanitary Measures. ISPMs are the standards, guidelines and recommendations recognized as the basis for phytosanitary measures applied by Members of the World Trade Organization under the Agreement on the Application of Sanitary and Phytosanitary Measures. Non-contracting parties to the IPPC are encouraged to observe these standards.

REVIEW AND AMENDMENT

International Standards for Phytosanitary Measures are subject to periodic review and amendment. The next review date for each standard is five years from their endorsement, or such other date as may be agreed upon by the Commission on Phytosanitary Measures.

Standards will be updated and republished as necessary. Standard holders should ensure that the current edition of standards is being used.

DISTRIBUTION

International Standards for Phytosanitary Measures are distributed by the Secretariat of the International Plant Protection Convention to IPPC contracting parties, plus the Executive/Technical Secretariats of the Regional Plant Protection Organizations:

- Asia and Pacific Plant Protection Commission
- Caribbean Plant Protection Commission
- Comité Regional de Sanidad Vegetal para el Cono Sur
- Comunidad Andina
- European and Mediterranean Plant Protection Organization
- Inter-African Phytosanitary Council
- North American Plant Protection Organization
- Organismo Internacional Regional de Sanidad Agropecuaria
- Pacific Plant Protection Organization.

NOTES ON THE PUBLICATION

International Standards for Phytosanitary Measures (ISPMs) were originally produced as separate booklets. The current book was produced by the IPPC Secretariat according to the decision made by the Interim Commission for Phytosanitary Measures at its Seventh session in 2005 (ICPM-7). It compiles all ISPMs without modification to their content, except in relation to the section Definitions, as decided by ICPM-7. The book is also available on line on the IPPC website at https://www.ippc.int. In addition, individual standards are available on the IPPC website as extracts from the book. To facilitate reference, the text of the International Plant Protection Convention is included at the beginning of this publication.

IPPC

INTERNATIONAL PLANT PROTECTION CONVENTION

(1997)

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NEW REVISED TEXT

INTERNATIONAL PLANT PROTECTION CONVENTION

PREAMBLE

The contracting parties,

- *recognizing* the necessity for international cooperation in controlling pests of plants and plant products and in preventing their international spread, and especially their introduction into endangered areas;
- *recognizing* that phytosanitary measures should be technically justified, transparent and should not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade;
- *desiring* to ensure close coordination of measures directed to these ends;
- *desiring* to provide a framework for the development and application of harmonized phytosanitary measures and the elaboration of international standards to that effect;
- *taking into account* internationally approved principles governing the protection of plant, human and animal health, and the environment; and
- *noting* the agreements concluded as a result of the Uruguay Round of Multilateral Trade Negotiations, including the Agreement on the Application of Sanitary and Phytosanitary Measures;

have agreed as follows:

ARTICLE I
Purpose and responsibility

1. With the purpose of securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control, the contracting parties undertake to adopt the legislative, technical and administrative measures specified in this Convention and in supplementary agreements pursuant to Article XVI.

2. Each contracting party shall assume responsibility, without prejudice to obligations assumed under other international agreements, for the fulfilment within its territories of all requirements under this Convention.

3. The division of responsibilities for the fulfilment of the requirements of this Convention between member organizations of FAO and their member states that are contracting parties shall be in accordance with their respective competencies.

4. 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.

ARTICLE II
Use of terms

1. For the purpose of this Convention, the following terms shall have the meanings hereunder assigned to them:

"Area of low pest prevalence" - 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;

"Commission" - the Commission on Phytosanitary Measures established under Article XI;

"Endangered area" - an area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss;

"Establishment" - perpetuation, for the foreseeable future, of a pest within an area after entry;

"Harmonized phytosanitary measures" - phytosanitary measures established by contracting parties based on international standards;

"International standards" - international standards established in accordance with Article X, paragraphs 1 and 2;

"Introduction" - the entry of a pest resulting in its establishment;

"Pest" - any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products;

"Pest risk analysis" - the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it;

"Phytosanitary measure" - any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of pests;

"Plant products" - unmanufactured material of plant origin (including grain) and those manufactured products that, by their nature or that of their processing, may create a risk for the introduction and spread of pests;

"Plants" - living plants and parts thereof, including seeds and germplasm;

"Quarantine pest" - a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled;

"Regional standards" - standards established by a regional plant protection organization for the guidance of the members of that organization;

"Regulated article" - any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved;

"Regulated non-quarantine pest" - a non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party;

"Regulated pest" - a quarantine pest or a regulated non-quarantine pest;

"Secretary" - Secretary of the Commission appointed pursuant to Article XII;

"Technically justified" - justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information.

2. The definitions set forth in this Article, being limited to the application of this Convention, shall not be deemed to affect definitions established under domestic laws or regulations of contracting parties.

ARTICLE III
Relationship with other international agreements

Nothing in this Convention shall affect the rights and obligations of the contracting parties under relevant international agreements.

ARTICLE IV
General provisions relating to the organizational arrangements for national plant protection

1. Each contracting party shall make provision, to the best of its ability, for an official national plant protection organization with the main responsibilities set out in this Article.

2. The responsibilities of an official national plant protection organization shall include the following:

(a) the issuance of certificates relating to the phytosanitary regulations of the importing contracting party for consignments of plants, plant products and other regulated articles;

(b) 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);

(c) 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;

(d) the disinfestation or disinfection of consignments of plants, plant products and other regulated articles moving in international traffic, to meet phytosanitary requirements;

(e) the protection of endangered areas and the designation, maintenance and surveillance of pest free areas and areas of low pest prevalence;

(f) the conduct of pest risk analyses;

(g) to ensure through appropriate procedures that the phytosanitary security of consignments after certification regarding composition, substitution and reinfestation is maintained prior to export; and

(h) training and development of staff.

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;

(b) research and investigation in the field of plant protection;

(c) the issuance of phytosanitary regulations; and

(d) the performance of such other functions as may be required for the implementation of this Convention.

4. Each contracting party shall submit a description of its official national plant protection organization and of changes in such organization to the Secretary. A contracting party shall provide a description of its organizational arrangements for plant protection to another contracting party, upon request.

ARTICLE V
Phytosanitary certification

1. Each contracting party shall make arrangements for phytosanitary certification, with the objective of ensuring that exported plants, plant products and other regulated articles and consignments thereof are in conformity with the certifying statement to be made pursuant to paragraph 2(b) of this Article.

2. Each contracting party shall make arrangements for the issuance of phytosanitary certificates in conformity with the following provisions:

(a) 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.

(b) Phytosanitary certificates, or their electronic equivalent where accepted by the importing contracting party concerned, shall be as worded in the models set out in the Annex to this Convention. These certificates should be completed and issued taking into account relevant international standards.

(c) Uncertified alterations or erasures shall invalidate the certificates.

3. 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.

ARTICLE VI
Regulated pests

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 contracting 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.

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

ARTICLE VII
Requirements in relation to imports

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 concerning the importation of plants, plant products and other regulated articles, including, for example, inspection, prohibition on importation, and treatment;

(b) refuse entry or detain, or require treatment, destruction or removal from the territory of the contracting party, of plants, plant products and other regulated articles or consignments thereof that do not comply with the phytosanitary measures prescribed or adopted under subparagraph (a);

(c) prohibit or restrict the movement of regulated pests into their territories;

(d) prohibit or restrict the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into their territories.

2. In order to minimize interference with international trade, each contracting party, in exercising its authority under paragraph 1 of this Article, undertakes to act in conformity with the following:

(a) Contracting parties shall not, under their phytosanitary legislation, take any of the measures specified in paragraph 1 of this Article unless such measures are made necessary by phytosanitary considerations and are technically justified.

(b) Contracting parties shall, immediately upon their adoption, publish and transmit phytosanitary requirements, restrictions and prohibitions to any contracting party or parties that they believe may be directly affected by such measures.

(c) Contracting parties shall, on request, make available to any contracting party the rationale for phytosanitary requirements, restrictions and prohibitions.

(d) If a contracting party requires consignments of particular plants or plant products to be imported only through specified points of entry, such points shall be so selected as not to unnecessarily impede international trade. The contracting party shall publish a list of such points of entry and communicate it to the Secretary, any regional plant protection organization of which the contracting party is a member, all contracting parties which the contracting party believes to be directly affected, and other contracting parties upon request. Such restrictions on points of entry shall not be made unless the plants, plant products or other regulated articles concerned are required to be accompanied by phytosanitary certificates or to be submitted to inspection or treatment.

(e) Any inspection or other phytosanitary procedure required by the plant protection organization of a contracting party for a consignment of plants, plant products or other regulated articles offered for importation, shall take place as promptly as possible with due regard to their perishability.

(f) 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.

(g) Contracting parties shall institute only phytosanitary measures that are technically justified, consistent with the pest risk involved and represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances.

(h) Contracting parties shall, as conditions change, and as new facts become available, ensure that phytosanitary measures are promptly modified or removed if found to be unnecessary.

(i) 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.

(j) Contracting parties shall, to the best of their ability, 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.

3. A contracting party may apply measures specified in this Article to pests which may not be capable of establishment in its territories but, if they gained entry, cause economic damage. Measures taken against these pests must be technically justified.

4. 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.

5. Nothing in this Article shall prevent importing contracting parties from making special provision, subject to adequate safeguards, for the importation, for the purpose of scientific research, education, or other specific use, of plants and plant products and other regulated articles, and of plant pests.

6. Nothing in this Article shall prevent any contracting party from taking 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.

ARTICLE VIII
International cooperation

1. The contracting parties shall cooperate with one another to the fullest practicable extent in achieving the aims of this Convention, and shall in particular:

   (a) 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;

   (b) participate, in so far as is practicable, in any special campaigns for combatting pests that may seriously threaten crop production and need international action to meet the emergencies; and

   (c) cooperate, to the extent practicable, in providing technical and biological information necessary for pest risk analysis.

2. Each contracting party shall designate a contact point for the exchange of information connected with the implementation of this Convention.

ARTICLE IX
Regional plant protection organizations

1. The contracting parties undertake to cooperate with one another in establishing regional plant protection organizations in appropriate areas.

2. The regional plant protection organizations shall function as the coordinating bodies in the areas covered, shall participate in various activities to achieve the objectives of this Convention and, where appropriate, shall gather and disseminate information.

3. The regional plant protection organizations shall cooperate with the Secretary in achieving the objectives of the Convention and, where appropriate, cooperate with the Secretary and the Commission in developing international standards.

4. The Secretary will convene regular Technical Consultations of representatives of regional plant protection organizations to:

   (a) promote the development and use of relevant international standards for phytosanitary measures; and

   (b) encourage inter-regional cooperation in promoting harmonized phytosanitary measures for controlling pests and in preventing their spread and/or introduction.

ARTICLE X
Standards

1. The contracting parties agree to cooperate in the development of international standards in accordance with the procedures adopted by the Commission.

2. International standards shall be adopted by the Commission.

3. Regional standards should be consistent with the principles of this Convention; such standards may be deposited with the Commission for consideration as candidates for international standards for phytosanitary measures if more broadly applicable.

4. Contracting parties should take into account, as appropriate, international standards when undertaking activities related to this Convention.

ARTICLE XI
Commission on Phytosanitary Measures

1. Contracting parties agree to establish the Commission on Phytosanitary Measures within the framework of the Food and Agriculture Organization of the United Nations (FAO).

2. The functions of the Commission shall be to promote the full implementation of the objectives of the Convention and, in particular, to:

   (a) review the state of plant protection in the world and the need for action to control the international spread of pests and their introduction into endangered areas;

(b) establish and keep under review the necessary institutional arrangements and procedures for the development and adoption of international standards, and to adopt international standards;

(c) establish rules and procedures for the resolution of disputes in accordance with Article XIII;

(d) establish such subsidiary bodies of the Commission as may be necessary for the proper implementation of its functions;

(e) adopt guidelines regarding the recognition of regional plant protection organizations;

(f) establish cooperation with other relevant international organizations on matters covered by this Convention;

(g) adopt such recommendations for the implementation of the Convention as necessary; and

(h) perform such other functions as may be necessary to the fulfilment of the objectives of this Convention.

3. Membership in the Commission shall be open to all contracting parties.

4. Each contracting party may be represented at sessions of the Commission by a single delegate who may be accompanied by an alternate, and by experts and advisers. Alternates, experts and advisers may take part in the proceedings of the Commission but may not vote, except in the case of an alternate who is duly authorized to substitute for the delegate.

5. The contracting parties shall make every effort to reach agreement on all matters by consensus. If all efforts to reach consensus have been exhausted and no agreement is reached, the decision shall, as a last resort, be taken by a two-thirds majority of the contracting parties present and voting.

6. A member organization of FAO that is a contracting party and the member states of that member organization that are contracting parties shall exercise their membership rights and fulfil their membership obligations in accordance, *mutatis mutandis*, with the Constitution and General Rules of FAO.

7. The Commission may adopt and amend, as required, its own Rules of Procedure, which shall not be inconsistent with this Convention or with the Constitution of FAO.

8. The Chairperson of the Commission shall convene an annual regular session of the Commission.

9. Special sessions of the Commission shall be convened by the Chairperson of the Commission at the request of at least one-third of its members.

10. The Commission shall elect its Chairperson and no more than two Vice-Chairpersons, each of whom shall serve for a term of two years.

ARTICLE XII
Secretariat

1. The Secretary of the Commission shall be appointed by the Director-General of FAO.

2. The Secretary shall be assisted by such secretariat staff as may be required.

3. The Secretary shall be responsible for implementing the policies and activities of the Commission and carrying out such other functions as may be assigned to the Secretary by this Convention and shall report thereon to the Commission.

4. The Secretary shall disseminate:

(a) international standards to all contracting parties within sixty days of adoption;

(b) to all contracting parties, lists of points of entry under Article VII paragraph 2(d) communicated by contracting parties;

(c) lists of regulated pests whose entry is prohibited or referred to in Article VII paragraph 2(i) to all contracting parties and regional plant protection organizations;

(d) information received from contracting parties on phytosanitary requirements, restrictions and prohibitions referred to in Article VII paragraph 2(b), and descriptions of official national plant protection organizations referred to in Article IV paragraph 4.

5. The Secretary shall provide translations in the official languages of FAO of documentation for meetings of the Commission and international standards.

6. The Secretary shall cooperate with regional plant protection organizations in achieving the aims of the Convention.

ARTICLE XIII
Settlement of disputes

1. If there is any dispute regarding the interpretation or application of this Convention, or if a contracting party considers that any action by another contracting party is in conflict with the obligations of the latter under Articles V and VII of this Convention, especially regarding the basis of prohibiting or restricting the imports of plants, plant products or other regulated articles coming from its territories, the contracting parties concerned shall consult among themselves as soon as possible with a view to resolving the dispute.

2. If the dispute cannot be resolved by the means referred to in paragraph 1, the contracting party or parties concerned may request the Director-General of FAO to appoint a committee of experts to consider the question in dispute, in accordance with rules and procedures that may be established by the Commission.

3. This Committee shall include representatives designated by each contracting party concerned. The Committee shall consider the question in dispute, taking into account all documents and other forms of evidence submitted by the contracting parties concerned. The Committee shall prepare a report on the technical aspects of the dispute for the purpose of seeking its resolution. The preparation of the report and its approval shall be according to rules and procedures established by the Commission, and it shall be transmitted by the Director-General to the contracting parties concerned. The report may also be submitted, upon its request, to the competent body of the international organization responsible for resolving trade disputes.

4. The contracting parties agree that the recommendations of such a committee, while not binding in character, will become the basis for renewed consideration by the contracting parties concerned of the matter out of which the disagreement arose.

5. The contracting parties concerned shall share the expenses of the experts.

6. The provisions of this Article shall be complementary to and not in derogation of the dispute settlement procedures provided for in other international agreements dealing with trade matters.

ARTICLE XIV
Substitution of prior agreements

This Convention shall terminate and replace, between contracting parties, the International Convention respecting measures to be taken against the *Phylloxera vastatrix* of 3 November 1881, the additional Convention signed at Berne on 15 April 1889 and the International Convention for the Protection of Plants signed at Rome on 16 April 1929.

ARTICLE XV
Territorial application

1. Any contracting party may at the time of ratification or adherence or at any time thereafter communicate to the Director-General of FAO a declaration that this Convention shall extend to all or any of the territories for the international relations of which it is responsible, and this Convention shall be applicable to all territories specified in the declaration as from the thirtieth day after the receipt of the declaration by the Director-General.

2. Any contracting party which has communicated to the Director-General of FAO a declaration in accordance with paragraph 1 of this Article may at any time communicate a further declaration modifying the scope of any former declaration or terminating the application of the provisions of the present Convention in respect of any territory. Such modification or termination shall take effect as from the thirtieth day after the receipt of the declaration by the Director-General.

3. The Director-General of FAO shall inform all contracting parties of any declaration received under this Article.

ARTICLE XVI
Supplementary agreements

1. The contracting parties may, for the purpose of meeting special problems of plant protection which need particular attention or action, enter into supplementary agreements. Such agreements may be applicable to specific regions, to specific pests, to specific plants and plant products, to specific methods of international transportation of plants and plant products, or otherwise supplement the provisions of this Convention.

2. Any such supplementary agreements shall come into force for each contracting party concerned after acceptance in accordance with the provisions of the supplementary agreements concerned.

3. Supplementary agreements shall promote the intent of this Convention and shall conform to the principles and provisions of this Convention, as well as to the principles of transparency, non-discrimination and the avoidance of disguised restrictions, particularly on international trade.

ARTICLE XVII
Ratification and adherence

1. This Convention shall be open for signature by all states until 1 May 1952 and shall be ratified at the earliest possible date. The instruments of ratification shall be deposited with the Director-General of FAO, who shall give notice of the date of deposit to each of the signatory states.

2. As soon as this Convention has come into force in accordance with Article XXII it shall be open for adherence by non-signatory states and member organizations of FAO. Adherence shall be effected by the deposit of an instrument of adherence with the Director-General of FAO, who shall notify all contracting parties.

3. When a member organization of FAO becomes a contracting party to this Convention, the member organization shall, in accordance with the provisions of Article II paragraph 7 of the FAO Constitution, as appropriate, notify at the time of its adherence such modifications or clarifications to its declaration of competence submitted under Article II paragraph 5 of the FAO Constitution as may be necessary in light of its acceptance of this Convention. Any contracting party to this Convention may, at any time, request a member organization of FAO that is a contracting party to this Convention to provide information as to which, as between the member organization and its member states, is responsible for the implementation of any particular matter covered by this Convention. The member organization shall provide this information within a reasonable time.

ARTICLE XVIII
Non-contracting parties

The contracting parties shall encourage any state or member organization of FAO, not a party to this Convention, to accept this Convention, and shall encourage any non-contracting party to apply phytosanitary measures consistent with the provisions of this Convention and any international standards adopted hereunder.

ARTICLE XIX
Languages

1. The authentic languages of this Convention shall be all official languages of FAO.

2. Nothing in this Convention shall be construed as requiring contracting parties to provide and to publish documents or to provide copies of them other than in the language(s) of the contracting party, except as stated in paragraph 3 below.

3. The following documents shall be in at least one of the official languages of FAO:

   (a) information provided according to Article IV paragraph 4;
   (b) cover notes giving bibliographical data on documents transmitted according to Article VII paragraph 2(b);
   (c) information provided according to Article VII paragraph 2(b), (d), (i) and (j);
   (d) notes giving bibliographical data and a short summary of relevant documents on information provided according to Article VIII paragraph 1(a);
   (e) requests for information from contact points as well as replies to such requests, but not including any attached documents;
   (f) any document made available by contracting parties for meetings of the Commission.

ARTICLE XX
Technical assistance

The contracting parties agree to promote the provision of technical assistance to contracting parties, especially those that are developing contracting parties, either bilaterally or through the appropriate international organizations, with the objective of facilitating the implementation of this Convention.

ARTICLE XXI
Amendment

1. Any proposal by a contracting party for the amendment of this Convention shall be communicated to the Director-General of FAO.

2. Any proposed amendment of this Convention received by the Director-General of FAO from a contracting party shall be presented to a regular or special session of the Commission for approval and, if the amendment involves important technical changes or imposes additional obligations on the contracting parties, it shall be considered by an advisory committee of specialists convened by FAO prior to the Commission.

3. Notice of any proposed amendment of this Convention, other than amendments to the Annex, shall be transmitted to the contracting parties by the Director-General of FAO not later than the time when the agenda of the session of the Commission at which the matter is to be considered is dispatched.

4. Any such proposed amendment of this Convention shall require the approval of the Commission and shall come into force as from the thirtieth day after acceptance by two-thirds of the contracting parties. For the purpose of this Article, an instrument deposited by a member organization of FAO shall not be counted as additional to those deposited by member states of such an organization.

5. Amendments involving new obligations for contracting parties, however, shall come into force in respect of each contracting party only on acceptance by it and as from the thirtieth day after such acceptance. The instruments of acceptance of amendments involving new obligations shall be deposited with the Director-General of FAO, who shall inform all contracting parties of the receipt of acceptance and the entry into force of amendments.

6. Proposals for amendments to the model phytosanitary certificates set out in the Annex to this Convention shall be sent to the Secretary and shall be considered for approval by the Commission. Approved amendments to the model phytosanitary certificates set out in the Annex to this Convention shall become effective ninety days after their notification to the contracting parties by the Secretary.

7. For a period of not more than twelve months from an amendment to the model phytosanitary certificates set out in the Annex to this Convention becoming effective, the previous version of the phytosanitary certificates shall also be legally valid for the purpose of this Convention.

ARTICLE XXII
Entry into force

As soon as this Convention has been ratified by three signatory states it shall come into force among them. It shall come into force for each state or member organization of FAO ratifying or adhering thereafter from the date of deposit of its instrument of ratification or adherence.

ARTICLE XXIII
Denunciation

1. Any contracting party may at any time give notice of denunciation of this Convention by notification addressed to the Director-General of FAO. The Director-General shall at once inform all contracting parties.

2. Denunciation shall take effect one year from the date of receipt of the notification by the Director-General of FAO.

ANNEX

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. 1

PHYTOSANITARY PRINCIPLES FOR THE PROTECTION OF PLANTS AND THE APPLICATION OF PHYTOSANITARY MEASURES IN INTERNATIONAL TRADE

(2006)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

ISPM No. 1 was first endorsed by the 27th Session of the FAO Conference in November 1993 as: *Principles of plant quarantine as related to international trade*. The first revision was endorsed by the Commission on Phytosanitary Measures in April 2006 as the present standard, ISPM No. 1 (2006).

INTRODUCTION

SCOPE

This standard describes phytosanitary principles for the protection of plants that are embodied in the International Plant Protection Convention (IPPC) and elaborated in its International Standards for Phytosanitary Measures. It covers principles related to the protection of plants, including cultivated and non-cultivated/unmanaged plants, wild flora and aquatic plants, those regarding the application of phytosanitary measures to the international movement of people, commodities and conveyances, as well as those inherent in the objectives of the IPPC. The standard does not alter the IPPC, extend existing obligations, or interpret any other agreement or body of law.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
All International Standards for Phytosanitary Measures.

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 the following basic principles under the IPPC: sovereignty, necessity, managed risk, minimal impact, transparency, harmonization, non-discrimination, technical justification, cooperation, equivalence of phytosanitary measures and modification. This standard also describes the operational principles under the IPPC, which are related to the establishment, implementation and monitoring of phytosanitary measures, and to the administration of official phytosanitary systems. The operational principles are: pest risk analysis, pest listing, recognition of pest free areas and areas of low pest prevalence, official control for regulated pests, systems approach, surveillance, pest reporting, phytosanitary certification, phytosanitary integrity and security of consignments, prompt action, emergency measures, provision of a National Plant Protection Organization, dispute settlement, avoidance of undue delays, notification of non-compliance, information exchange and technical assistance.

BACKGROUND

The original version of ISPM No. 1 (*Principles of plant quarantine as related to international trade*) was endorsed as a reference standard by the 27th Session of FAO Conference in 1993. It was developed at the time the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (SPS Agreement) was being negotiated. It helped to clarify some of the elements of the SPS Agreement which were under discussion at that time. The SPS Agreement was adopted in April 1994, and experience has been gained since then on its practical application in relation to phytosanitary measures.

The new revised text of the IPPC was adopted by FAO Conference in 1997. It includes many changes to the 1979 version of the Convention. The revision of the IPPC in 1997 has meant that ISPM No. 1 required revision.

In addition to the SPS Agreement, other international conventions exist which also directly or indirectly deal with the protection of plants.

This standard aims to aid in the understanding of the IPPC and provides guidance on the fundamental elements in phytosanitary systems. The principles described below reflect key elements of the IPPC. In some cases, additional guidance on these elements is provided. The standard should be interpreted in accordance with the full text of the IPPC. Quotations from the IPPC are indicated in quotation marks and italics.

PRINCIPLES

These principles are related to the rights and obligations of contracting parties to the IPPC. They should be considered collectively, in accordance with the full text of the IPPC, and not interpreted individually.

1. Basic principles

1.1 Sovereignty

Contracting parties have sovereign authority, in accordance with applicable international agreements, to prescribe and adopt phytosanitary measures to protect plant health within their territories and to determine their appropriate level of protection for plant health.

In relation to phytosanitary measures, the IPPC provides that:

"*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 concerning the importation of plants, plant products and other regulated articles, including, for example, inspection, prohibition on importation, and treatment;*

b) *refuse entry or detain, or require treatment, destruction or removal from the territory of the contracting party, of plants, plant products and other regulated articles or consignments thereof that do not comply with the phytosanitary measures prescribed or adopted under subparagraph (a);*

c) *prohibit or restrict the movement of regulated pests into their territories;*

d) *prohibit or restrict the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into their territories*." (Article VII.1)

In exercising this authority, and "*In order to minimize interference with international trade, ...*" (Article VII.2) each contracting party undertakes to act in conformity with the provisions of Article VII.2 of the IPPC.

1.2 Necessity

Contracting parties may apply phytosanitary measures only where such measures are necessary to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests. In this regard, the IPPC provides that: "*Contracting parties shall not, under their phytosanitary legislation, take any of the measures specified in ... unless such measures are made necessary by phytosanitary considerations* ..." (Article VII.2a). Article VI.1b states that "*Contracting parties may require phytosanitary measures for quarantine pests and regulated non-quarantine pests, provided that such measures are …limited to what is necessary to protect plant health…*". Article VI.2 states that "*Contracting parties shall not require phytosanitary measures for non-regulated pests*."

1.3 Managed risk

Contracting parties should apply phytosanitary measures based on a policy of managed risk, recognizing that risk of the spread and introduction of pests always exists when importing plants, plant products and other regulated articles. Contracting parties "*... shall institute only phytosanitary measures that are ... consistent with the pest risk involved ...*" (Article VII.2g).

1.4 Minimal impact

Contracting parties should apply phytosanitary measures with minimal impact. In this regard, the IPPC provides that they "*…shall institute only phytosanitary measures that ... represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances.*" (Article VII.2g).

1.5 Transparency

Contracting parties shall make relevant information available to other contracting parties as set forth in the IPPC. In this regard, the IPPC states that, for example:

- "*... contracting parties shall, immediately upon their adoption, publish and transmit phytosanitary requirements, restrictions and prohibitions to any contracting party or parties that they believe may be directly affected by such measures.*" (Article VII.2b)
- "*Contracting parties shall, on request, make available to any contracting party the rationale for phytosanitary requirements, restrictions and prohibitions.*" (Article VII.2c)
- "*The contracting parties shall ... cooperate in the exchange of information on plant pests ...*" (Article VIII.1 & 1a).
- "*Contracting parties shall, to the best of their ability, establish and update lists of regulated pest … and make such lists available …"* (Article VII.2i)
- *"Contracting parties shall, to the best of their ability … develop and maintain adequate information on pests status …. This information shall be made available …"* (Article VII.2j).

1.6 Harmonization

Contracting parties should cooperate in the development of harmonized standards for phytosanitary measures. In this regard, the IPPC provides that *"The contracting parties agree to cooperate in the development of international standards ...*" (Article X.1). Contracting parties should "*... take into account, as appropriate, international standards when undertaking activities related to this Convention.*" (Article X.4). *"The contracting parties shall encourage any state or member organization of FAO, not a party to this convention …to apply phytosanitary measures consistent with the provisions of this Convention and any international standards adopted hereunder."* (Article XVIII).

1.7 Non-discrimination

Contracting parties should, in accordance with the IPPC, apply phytosanitary measures without discrimination between contracting parties if contracting parties can demonstrate that they have the same phytosanitary status and apply identical or equivalent phytosanitary measures.

Contracting parties should also apply phytosanitary measures without discrimination between comparable domestic and international phytosanitary situations.

In these regards, the IPPC provides that:

- phytosanitary measures "*... should not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade.*" (Preamble)
- contracting parties may require phytosanitary measures, provided that such measures are "*... no more stringent than measures applied to the same pests, if present within the territory of the importing contracting party*." (Article VI.1a).

1.8 Technical justification

Contracting parties shall technically justify phytosanitary measures "*...on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information.*" (Article II.1). In this regard, the IPPC provides that "*Contracting parties shall not, under their phytosanitary legislation, take any of the measures specified in paragraph 1 of this Article* (VII) *unless such measures ... are technically justified.*" (Article VII.2a). Article VI.1b also refers to technical justification. Phytosanitary measures which conform to ISPMs are deemed to be technically justified.

1.9 Cooperation

Contracting parties should cooperate with one another to achieve the objectives of the IPPC. In particular, they "*...shall cooperate with one another to the fullest practicable extent in achieving the aims of* [the] *Convention ...*" (Article VIII). Contracting parties should also actively participate in bodies established under the IPPC.

1.10 Equivalence of phytosanitary measures

Importing contracting parties should recognize alternative phytosanitary measures proposed by exporting contracting parties as equivalent when those measures are demonstrated to achieve the appropriate level of protection determined by the importing contracting party.

Relevant ISPM: No. 24.

1.11 Modification

Modifications of phytosanitary measures should be determined on the basis of a new or updated pest risk analysis or relevant scientific information. Contracting parties should not arbitrarily modify phytosanitary measures. "*Contracting parties shall, as conditions change, and as new facts become available, ensure that phytosanitary measures are promptly modified or removed if found to be unnecessary*." (Article VII.2h).

2. Operational principles

Operational IPPC principles are related to the establishment, implementation and monitoring of phytosanitary measures, and to the administration of official phytosanitary systems.

2.1 Pest risk analysis

National Plant Protection Organizations (NPPOs) should, when performing pest risk analysis, base it on biological or other scientific and economic evidence, following the relevant ISPMs. In doing this, threats to biodiversity resulting from effects on plants should also be taken into account.

Relevant Articles in the IPPC: Preamble, Articles II, IV.2f and VII.2g.
Relevant ISPMs: No 2, No. 5 (including supplement No. 2), No. 11 and No. 21.

2.2 Pest listing

Contracting parties "*... shall, to the best of their ability, establish and update lists of regulated pests ...*" (Article VII.2i).

Relevant Articles in the IPPC: VII.2i.
Relevant ISPMs: No. 19.

2.3 Recognition of pest free areas and areas of low pest prevalence

Contracting parties should ensure that their phytosanitary measures concerning consignments moving into their territories take into account the status of areas, as designated by the NPPOs of the exporting countries. These may be areas where a regulated pest does not occur or occurs with low prevalence or they may be pest free production sites or pest free places of production.

Relevant articles in the IPPC: II.
Relevant ISPMs: No. 4, No. 8, No. 10 and No. 22.

2.4 Official control for regulated pests

When a pest which is present in a country is regulated as a quarantine pest or regulated non-quarantine pest, the contracting party should ensure that the pest is being officially controlled.

Relevant ISPM: ISPM No. 5 (including supplement No. 1).

2.5 Systems approach

Integrated measures for pest risk management, applied in a defined manner, may provide an alternative to single measures to meet the appropriate level of phytosanitary protection of an importing contracting party.

Relevant ISPM: No. 14.

2.6 Surveillance

Contracting parties should collect and record data on pest occurrence and absence to support phytosanitary certification and the technical justification of their phytosanitary measures. In this regard, the IPPC also provides that "*Contracting parties shall, to the best of their ability, 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*." (ArticleVII.2j).

Relevant Articles in the IPPC : IV.2b, IV.2e and VII.2j.
Relevant ISPMs: No. 6 and No. 8.

2.7 Pest reporting

Contracting parties "*... shall cooperate ... to the fullest practicable extent in ... the reporting of the occurrence, outbreak or spread of pests that may be of immediate or potential danger ...*" to other contracting parties (Article VIII.1a). In this respect, they should follow the procedures established in ISPM No. 17 and other relevant procedures.

Relevant Article in the IPPC: VIII.1a.
Relevant ISPM: No. 17.

2.8 Phytosanitary certification

Contracting parties should exercise due diligence in operating an export certification system and ensuring the accuracy of the information and additional declarations contained in phytosanitary certificates. "Each contracting party shall make arrangements for phytosanitary certification …" (Article V).

Relevant Articles in the IPPC: IV.2a and V.
Relevant ISPMs: No. 7 and No. 12.

2.9 Phytosanitary integrity and security of consignments

In order to maintain the integrity of consignments after certification, contracting parties, through their NPPO, shall "ensure through appropriate procedures that the phytosanitary security of consignments after certification regarding composition, substitution and reinfestation is maintained prior to export." (Article IV.2g).

Relevant Articles in the IPPC: IV.2g and V.
Relevant ISPMs: No. 7 and No. 12.

2.10 Prompt action

Contracting parties should ensure that inspection or other phytosanitary procedures required at import "*... shall take place as promptly as possible with due regard to ... perishability*" of the regulated article (Article VII.2e).

Relevant Article in the IPPC: VII.2e.

2.11 Emergency measures

Contracting parties may adopt and/or implement emergency actions, including emergency measures, when a new or unexpected phytosanitary risk is identified[1]. Emergency measures should be temporary in their application. The continuance of the measures should be evaluated by pest risk analysis or other comparable examination as soon as possible, to ensure that the continuance of the measure is technically justified.

Relevant Article in the IPPC: VII.6.
Relevant ISPM: No. 13.

2.12 Provision of a NPPO

"*Each contracting party shall make provision, to the best of its ability, for an official national plant protection organization with the main responsibilities set out in* [Article IV.1]." (Article IV.1).

Relevant Article in the IPPC: IV.

2.13 Dispute settlement

Contracting parties should be open to consultation regarding their phytosanitary measures, when requested by other contracting parties. If there is a dispute regarding the interpretation or application of the IPPC or its ISPMs, or if a contracting party considers that an action by another contracting party is in conflict with the obligations of the IPPC or guidance provided in its ISPMs, "*... the contracting parties concerned shall consult among themselves as soon as possible with a view to resolving the dispute*." (Article XIII.1). If the dispute cannot be resolved in this way, then the provisions of Article XIII relating to the settlement of disputes or other means of dispute settlement may be applied[2].

Relevant Article in the IPPC: XIII.

2.14 Avoidance of undue delays

When a contracting party requests another contracting party to establish, modify or remove phytosanitary measures, when conditions have changed or new facts have become available, this request should be considered without undue

[1] The term emergency actions in Article VII.6 of the IPPC is interpreted to include emergency measures as defined in ISPM No. 5.
[2] A non-binding dispute settlement procedure has been developed by the IPPC for use by the contracting parties.

delay. Associated procedures, which include, but are not limited to, pest risk analysis, recognition of pest free areas or recognition of equivalence, should also be performed promptly.

Relevant Article in the IPPC: VII.2h.
Relevant ISPM: No. 24 (section 2.7 and annex I, step 7).

2.15 Notification of non-compliance

Importing contracting parties "*… shall, as soon as possible, inform the exporting contracting party concerned…of significant instances of non-compliance with phytosanitary certification.*" (Article VII.2f).

Relevant Article in the IPPC: VII.2f.
Relevant ISPM: No. 13.

2.16 Information exchange

Contracting parties shall, as appropriate, provide information specified in the IPPC, as follows:

- Official contact points (Article VIII.2)
- Description of the NPPO and organizational arrangements of plant protection (Article IV.4)
- Phytosanitary requirements, restrictions and prohibitions (Article VII.2b) (including specified points of entry - Article VII.2d) and their rationale (Article VII.2c)
- List of regulated pests (Article VII.2i)
- Pest reporting, including occurrence, outbreak and spread of pests (Articles IV.2b and VIII.1a)
- Emergency actions (Article VII.6) and non-compliance (Article VII.2f)
- Pest status (Article VII.2j)
- Technical and biological information necessary for pest risk analysis (to the extent practicable) (Article VIII.1c).

2.17 Technical assistance

Contracting parties "*... agree to promote the provision of technical assistance to contracting parties, especially those that are developing contracting parties … with the objectives of facilitating the implementation of the Convention.*" (Article XX).

Relevant Article in the IPPC: XX.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 2

GUIDELINES FOR PEST RISK ANALYSIS

(1995)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

The following standard was endorsed by the 28th Session of the FAO Conference in November 1995.

INTRODUCTION

SCOPE

This standard describes the process of pest risk analysis for plant pests for the purpose of preparing phytosanitary regulations by National Plant Protection Organizations.

REFERENCES

FAO Glossary of Phytosanitary Terms, *FAO Plant Protection Bulletin* 38(1), 1990: 5-23.
International Plant Protection Convention, 1992. 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

Pest risk analysis (PRA) consists of three stages: initiating the process for analyzing risk, assessing pest risk, and managing pest risk (See Figures 1-3).

Initiating the process involves identification of pests or pathways for which the PRA is needed. Pest risk assessment determines whether each pest identified as such, or associated with a pathway, is a quarantine pest, characterized in terms of likelihood of entry, establishment, spread and economic importance. Pest risk management involves developing, evaluating, comparing and selecting options for reducing the risk.

PRA is only meaningful in relation to a defined "PRA area" considered to be at risk. This is usually a country, but can also be an area within a country, or an area covering all or parts of several countries [e.g. the area covered by a Regional Plant Protection Organization (RPPO)].

GENERAL REQUIREMENTS FOR PEST RISK ANALYSIS (PRA)

1. STAGE 1: INITIATING THE PRA PROCESS

There are generally two initiation points for a pest risk analysis (see Figure 1):

- the identification of a pathway, usually an imported commodity, that may allow the introduction and/or spread of quarantine pests
- the identification of a pest that may qualify as a quarantine pest.

Either can involve pests already present in the PRA area but not widely distributed and being officially controlled, as well as pests absent from the PRA area, since both are covered by the quarantine pest definition.

1.1 PRA Initiated by a Pathway

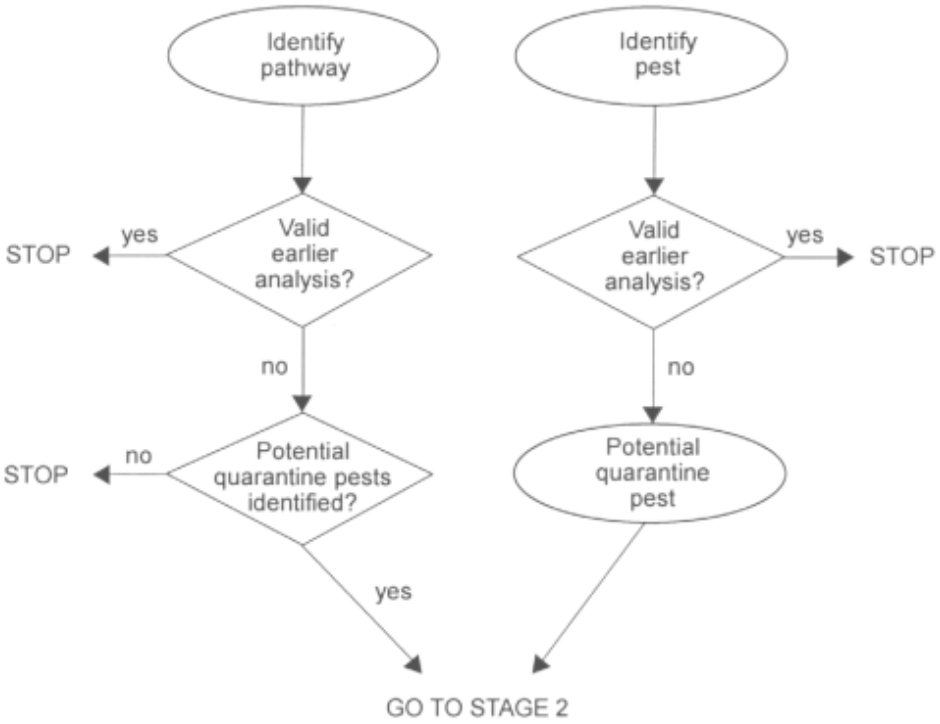
A requirement for a new or revised PRA originating from a specific pathway will most frequently arise in the following situations:

- International trade is initiated in a new commodity (usually a plant or plant product) or a commodity from a new origin. The PRA may be triggered by a request for import, or by the appearance in trade of consignments of a commodity. The pathway may concern a single area of origin or several.
- New plant species are imported for selection and scientific research purposes
- A pathway other than commodity import is identified (natural spread, mail, garbage, passenger's baggage etc.)
- A policy decision is taken to establish or revise phytosanitary regulations or requirements concerning specific commodities
- A new treatment, system or process, or new information impacts on an earlier decision.

FIGURE 1

PEST RISK ANALYSIS

Stage 1: Initiation



The pests which are likely to follow the pathway (e.g. be carried by the commodity) are then listed, and each is then subjected to Stage 2 in the PRA process[1]. If no potential quarantine pests are identified as likely to follow the pathway, the PRA stops at this point.

1.2 PRA Initiated by a Pest

A requirement for a new or revised PRA originating from a specific pest will most frequently arise in the following situations:

- An emergency arises on discovery of an established infestation or an outbreak of a new pest within a PRA area
- An emergency arises on interception of a new pest on an imported commodity
- A new pest risk is identified by scientific research
- A pest is introduced into a new area other than the PRA area
- A pest is reported to be more damaging in a new area other than the PRA area itself, than in its area of origin
- Audits reveal that a particular pest is repeatedly intercepted
- A request is made to import, as such, an organism, for example by researchers, educators, biological practitioners, businesses (pet store owners), the food industry (snails for consumption) or hobbyists (aquatic plants for aquaria)
- A policy decision is taken to revise phytosanitary regulations or requirements concerning specific pests
- A proposal is made by another country or by an international organization (RPPO, FAO)
- A new treatment system, process, or new information impacts on an earlier decision.

The specific pest identified is then subjected to Stage 2 in the PRA process.

1.3 Review of Earlier PRAs

Prior to proceeding with a new PRA, a check should be made as to whether the pathway or pest has already been subjected to the PRA process, either nationally or internationally. If a PRA exists, its validity should be checked as circumstances may have changed. The possibility of using a PRA from a similar pathway or pest, that may partly or entirely replace the need for this PRA, should also be investigated.

1.4 Conclusion for Stage 1

At the end of Stage 1, pests have been identified as potential quarantine pests, individually or in association with a pathway.

2. STAGE 2: PEST RISK ASSESSMENT

Stage 1 has identified a pest, or list of pests (in the case of initiation by a pathway), to be subjected to risk assessment. Stage 2 considers these pests individually (see Figure 2). It examines, for each, whether the criteria for quarantine pest status are satisfied:

> "a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled".

In this context, "area" should be understood to mean:

> "an officially defined country, part of a country, or all or part of several countries",

and "endangered area" should be understood to mean:

> "an area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss".

In doing so, the PRA considers all aspects of each pest and in particular actual information about its geographical distribution, biology and economic importance. Expert judgement is then used to assess the establishment, spread and economic importance potential in the PRA area. Finally, the potential for introduction into the PRA area is characterized.

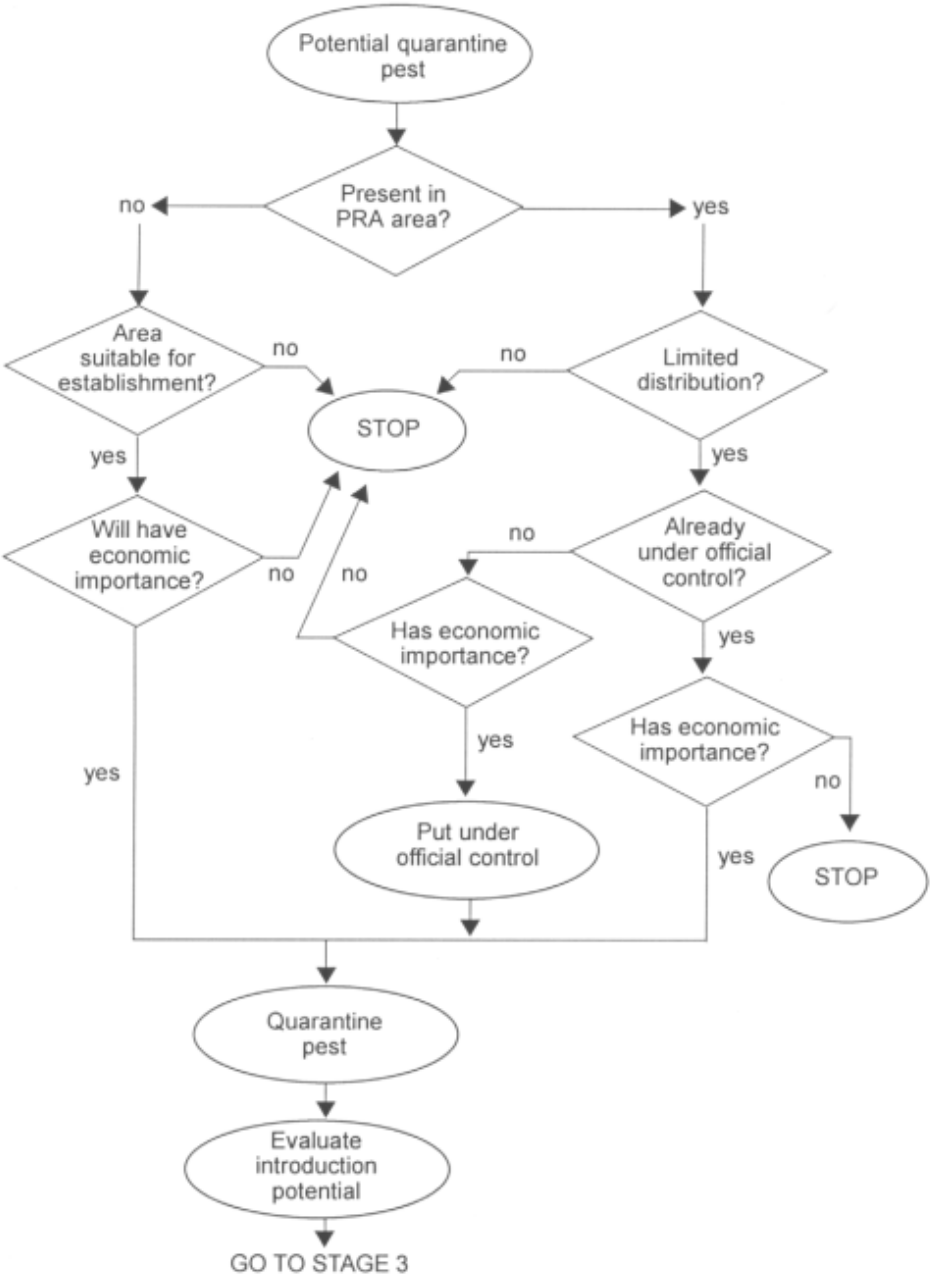
In characterizing the risk, the amount of information available will vary with each pest and the sophistication of the assessment will vary with available tools. For example, one country may have elaborate pest databases and geographical information systems, another may depend on books, printed soil maps, and climate maps. In some cases, virtually no information may be available, or research may be needed to obtain it. Assessments will be limited by the amount of information available on the biology of a particular pest. Countries where the pest is present may provide available information for the country conducting the PRA, on request.

[1] The list of pests may be generated by any combination of databases, literature sources, or expert consultation. Once the list of pests has been established, it is preferable to prioritize it by using expert judgement before the next step. According to the results obtained, it may or may not be necessary to conduct a risk assessment on all pests on the list.

FIGURE 2

PEST RISK ANALYSIS

Stage 2: Assessment



2.1 Geographical and Regulatory Criteria

For each pest subjected to the PRA process, the geographical and regulatory criteria in the quarantine pest definition should be considered:

- If the pest is present in the PRA area and has reached the limits of its ecological range (i.e. is widely distributed), then the pest does not satisfy the definition of a quarantine pest and the PRA for the pest stops at this point
- If the pest is present in the PRA area and has not reached the limits of its ecological range (i.e. not widely distributed), and the pest is subject to official control in the PRA area, then the pest satisfies this aspect of the definition of a quarantine pest
- If the pest is not widely distributed but is under consideration of future official control in the PRA area, then the PRA will determine whether the pest should be placed under official control. If the conclusion is reached that the pest should be subject to official control, then the pest satisfies this aspect of the definition of the definition of a quarantine pest.

- If the pest is not widely distributed but is not subject to official control or consideration of future official control in the PRA area, then the pest does not satisfy the definition of a quarantine pest and the PRA for the pest stops at this point
- If the pest is absent from the PRA area, then it satisfies this aspect of the definition of a quarantine pest.

2.2 Economic Importance Criteria

For potential economic importance to be expressed, a pest must become established and spread. Thus the risk of a pest, having entered, becoming established and spreading in the PRA area must be characterized. The factors to be considered are set out below[2].

2.2.1 Establishment potential

In order to estimate the establishment potential of a pest, reliable biological information (life cycle, host range, epidemiology, survival etc.) should be obtained from the areas where the pest currently occurs.

The situation in the PRA area can then be carefully compared with that in the areas where it currently occurs and expert judgement used to assess the establishment potential. Case histories concerning comparable pests can usefully be considered. Examples of the factors to consider are:

- availability, quantity and distribution of hosts in the PRA area
- environmental suitability in the PRA area
- potential for adaptation of the pest
- reproductive strategy of the pest
- method of pest survival.

If a pest has no potential for establishment in the PRA area, then it does not satisfy the definition of a quarantine pest and the PRA for the pest stops at this point.

2.2.2 Spread potential after establishment

In order to estimate spread potential of the pest, reliable, biological information should be obtained from areas where the pest currently occurs.

The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs and expert judgement used to assess the spread potential. Case histories concerning comparable pests can usefully be considered. Examples of the factors to consider are:

- suitability of the natural and/or managed environment for natural spread of the pest
- movement with commodities or conveyances
- intended use of the commodity
- potential vectors of the pest in the PRA area
- potential natural enemies of the pest in the PRA area.

The information on spread potential is used to estimate how rapidly a pest's potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area of low potential economic importance and then spread to an area of high potential economic importance. In addition it may be important in the risk management stage (see Figure 3) when considering the ease with which an introduced pest could be contained or eradicated.

2.2.3 Potential economic importance

The next step in the PRA process is to determine whether the pest is of potential economic importance in the PRA area.

In order to estimate the potential economic importance of the pest, information should be obtained from areas where the pest currently occurs. For each of these areas, note whether the pest causes major, minor or no damage. Note whether the pest causes damage frequently or infrequently. Relate this, if possible, to biotic and abiotic effects, particularly climate.

The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs. Case histories concerning comparable pests can usefully be considered. Expert judgement is then used to assess the potential for economic importance. Examples of the factors to consider are:

[2] Fuller checklists of information which can usefully be considered in assessing the potential for establishment, spread and economic importance, are available from national and international sources.

- type of damage
- crop losses
- loss of export markets
- increases in control costs
- effects on ongoing integrated pest management (IPM) programmes
- environmental damage
- capacity to act as a vector for other pests
- perceived social costs such as unemployment.

If a pest has no potential economic importance in the PRA area, then it does not satisfy the definition of a quarantine pest and the PRA for the pest stops at this point.

2.3 Introduction Potential

The final stage of assessment concerns the introduction potential which depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. Documented pathways for the pest to enter new areas should be noted. Potential pathways which may not currently exist should be assessed if known.

The following is a partial checklist that may be used to estimate the introduction potential divided into those factors which may affect the likelihood of entry and those factors which may affect the likelihood of establishment.

Entry:

- opportunity for contamination of commodities or conveyances by the pest
- survival of the pest under the environmental conditions of transport
- ease or difficulty of detecting the pest at entry inspection
- frequency and quantity of pest movement into the PRA area by natural means
- frequency and number of persons entering from another country at any given port of entry.

Establishment:

- number and frequency of consignments of the commodity
- number of individuals of a given pest associated with the means of conveyance
- intended use of the commodity
- environmental conditions and availability of hosts at the destination and during transport in the PRA area.

2.4 Conclusion for Stage 2

If the pest satisfies the definition of a quarantine pest, expert judgement should be used to review the information collected during Stage 2 to decide whether the pest has sufficient economic importance and introduction potential, i.e. sufficient risk, for phytosanitary measures to be justified. If so, proceed to Stage 3; if not, the PRA for the pest stops at this point[3].

3. STAGE 3: PEST RISK MANAGEMENT

Pest risk management (see Figure 3) to protect the endangered areas should be proportional to the risk identified in the pest risk assessment. In most respects it can be based on the information gathered in the pest risk assessment. Phytosanitary measures should be applied to the minimum area necessary for the effective protection of the endangered area.

3.1 Risk Management Options

A list of options for reducing risks to an acceptable level should be assembled. These options will primarily concern pathways and in particular the conditions for permitting entry of commodities. Examples of the options to consider are:

- inclusion in list of prohibited pests
- phytosanitary inspection and certification prior to export
- definition of requirements to be satisfied before export (e.g. treatment, origin from pest free area, growing season inspection, certification scheme)
- inspection at entry
- treatment at point of entry, inspection station or, if appropriate, at place of destination
- detention in post-entry quarantine
- post-entry measures (restrictions on use of commodity, control measures)
- prohibition of entry of specific commodities from specific origins.

[3] Decision-making schemes, or expert systems, may be useful at this stage to assist expert judgement.

They may also, however, concern ways of reducing the risk of damage, for example, introduction of a biological control agent, or ease of eradication or containment.

3.2 Efficacy and Impact of the Options

The efficacy and impact of the various options in reducing risk to an acceptable level should be evaluated, in terms of the following factors:

- biological effectiveness
- cost/benefit of implementation
- impact on existing regulations
- commercial impact
- social impact
- phytosanitary policy considerations
- time to implement a new regulation
- efficacy of option against other quarantine pests
- environmental impact.

The positive and negative aspects of the options should be specified. While it is recognized that countries according to the sovereignty principle may exercise their sovereign right to utilize phytosanitary measures, countries should also take particular note of the "Minimal impact" principle:

> *Phytosanitary measures shall be consistent with the pest risk involved, and shall represent the least restrictive measures available which result in the minimum impediment to the international movement of people, commodities and conveyances.*

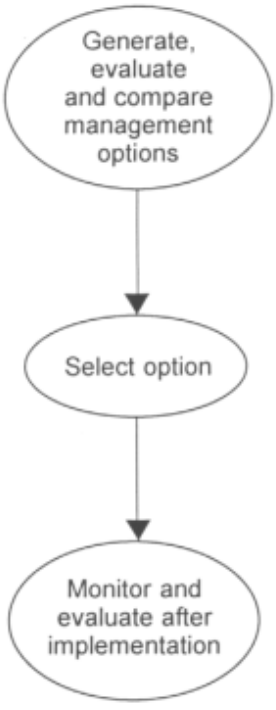
Article VI.2(f) of the International Plant Protection Convention makes a similar but less comprehensive provision. Phytosanitary measures recommended should be based on all of the above factors.

FIGURE 3

PEST RISK ANALYSIS

Stage 3: Management

from Stage 2



In order to determine which options are appropriate, it may be advisable to communicate with interested and affected groups within and outside the PRA area.

3.3 Conclusion for Stage 3

At the end of Stage 3, the appropriate phytosanitary measures concerning the pest or pathway have been decided. Completion of Stage 3 is essential; it is in particular not justified to complete only Stages 1 and 2 and then take phytosanitary measures without proper assessment of risk management options. After implementation of the phytosanitary measures, their effectiveness should be monitored and the risk management options should be reviewed, if necessary.

4. DOCUMENTING THE PRA PROCESS

A PRA should be sufficiently documented so that when a review or a dispute arises, the PRA will clearly state the sources of information and the rationales used in reaching a management decision regarding phytosanitary measures taken or to be taken.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 3

GUIDELINES FOR THE EXPORT, SHIPMENT, IMPORT AND RELEASE OF BIOLOGICAL CONTROL AGENTS AND OTHER BENEFICIAL ORGANISMS

(2005)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

ISPM No. 3 was first endorsed by the 28th Session of the FAO Conference in November 1995 as: *Code of conduct for the import and release of exotic biological control agents*. The first revision was endorsed by the Interim Commission on Phytosanitary Measures in April 2005 as the present standard, ISPM No. 3 (2005).

INTRODUCTION

SCOPE

This standard[1] provides guidelines for risk management related to the export, shipment, import and release of biological control agents and other beneficial organisms. It lists the related responsibilities of contracting parties to the IPPC ('contracting parties'), National Plant Protection Organizations (NPPOs) or other responsible authorities, importers and exporters (as described in the standard). The standard addresses biological control agents capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), as well as sterile insects and other beneficial organisms (such as mycorrhizae and pollinators), and includes those packaged or formulated as commercial products. Provisions are also included for import for research in quarantine facilities of non-indigenous biological control agents and other beneficial organisms.

The scope of this standard does not include living modified organisms, issues related to registration of biopesticides, or microbial agents intended for vertebrate pest control.

REFERENCES

Convention on Biological Diversity, 1992. CBD, Montreal.
Glossary of phytosanitary terms, 2004. 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 a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines on lists of regulated pests, 2003. ISPM No. 19, 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*).

[1] Nothing in this standard shall affect the rights or obligations of contracting parties under other international agreements. Provisions of other international agreements may be applicable, for example the Convention on Biological Diversity.

OUTLINE OF REQUIREMENTS

This standard is intended to facilitate the safe export, shipment, import and release of biological control agents and other beneficial organisms. Responsibilities relating to this are held by contracting parties, National Plant Protection Organizations (NPPOs) or other responsible authorities, and by importers and exporters.

Contracting parties, or their designated authorities, should consider and implement appropriate phytosanitary measures related to the export, shipment, import and release of biological control agents and other beneficial organisms and, when necessary, issue related import permits.

As described in this standard, NPPOs or other responsible authorities should:

- carry out pest risk analysis of biological control agents and other beneficial organisms prior to import or prior to release;
- ensure, when certifying exports, that the phytosanitary import requirements of importing contracting parties are complied with;
- obtain, provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biological control agents and other beneficial organisms;
- ensure that biological control agents and other beneficial organisms are taken either directly to designated quarantine facilities or mass-rearing facilities or, if appropriate, passed directly for release into the environment;
- encourage monitoring of release of biological control agents or beneficial organisms in order to assess impact on target and non target organisms.

Responsibilities of, and recommendations for, exporters include ensuring that consignments of biological control agents and other beneficial organisms comply with phytosanitary import requirements of importing countries and relevant international agreements, packaging consignments securely, and providing appropriate documentation relating to biological control agents or other beneficial organisms.

Responsibilities of, and recommendations for, importers include providing appropriate documentation relating to the target pest(s) and biological control agent or other beneficial organisms to the NPPO or other responsible authority of the importing country.

BACKGROUND

The International Plant Protection Convention (IPPC) is based on securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and the promotion of appropriate measures for their control (Article I of the IPPC, 1997). In this context, the provisions of the IPPC extend to any organism capable of harbouring or spreading plant pests, particularly where international transportation is involved (Article I of the IPPC, 1997).

The IPPC (1997) contains the following provision in relation to the regulation of biological control agents and other beneficial organisms. Article VII.1 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, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may: ...
c) prohibit or restrict the movement of regulated pests into their territories;
d) prohibit or restrict the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into their territories."

Section 4.1 of ISPM No. 20 (*Guidelines for a phytosanitary import regulatory system*), contains a reference to the regulation of biological control agents; it states:
"*Imported commodities that may be regulated include articles that may be infested or contaminated with regulated pests. ... The following are examples of regulated articles: ... pests and biological control agents.*"

This revision of ISPM No. 3 provides guidelines related to phytosanitary measures, as well as recommended guidelines for safe usage of biological control agents and other beneficial organisms. In some cases, the scope of these guidelines may be deemed to extend beyond the scope and provisions of the IPPC as described above. For example, although the primary context of this standard relates to phytosanitary concerns, "safe" usage as mentioned in the standard is intended to be interpreted in a broader sense, i.e. minimizing other non-phytosanitary negative effects. Phytosanitary concerns may include the possibility that newly introduced biological control agents may primarily affect other non-target organisms, but thereby result in harmful effects on plant species, or plant health in habitats or ecosystems. However, it is not intended that any aspects of this standard alter in any way the scope or obligations of the IPPC itself as contained in the New Revised Text of the IPPC (1997) or elaborated on in any of the other ISPMs.

The structure of this revised standard broadly follows the same structure of the original ISPM No. 3, and its content is based primarily on risk management relating to the use of biological control agents and other beneficial organisms. It is recognized that the existing standards on pest risk analysis (ISPM No. 2: *Guidelines for pest risk analysis* and ISPM No. 11: *Pest Risk Analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) provide the appropriate fundamental processes for carrying out pest risk assessments for biological control agents and other beneficial organisms. In particular, ISPM No. 11 includes provisions for pest risk assessment in relation to environmental risks, and this aspect covers environmental concerns related to the use of biological control agents.

The IPPC (1997) takes into account internationally approved principles governing the protection of the environment (Preamble). Its purpose includes promoting appropriate phytosanitary measures (Article I.1). When carrying out pest risk analysis in accordance with this and other appropriate ISPMs, and in developing and applying related phytosanitary measures, contracting parties should also consider the potential for broader environmental impacts resulting from releasing biological control agents and other beneficial organisms[2] (for example, impacts on non-target invertebrates).

Most of this standard is based on the premise that a biological control agent or other beneficial organism may be a potential pest itself, and in this sense Article VII.1c of the IPPC (1997) applies because contracting parties may prohibit or restrict the movement of regulated pests into their territories. In some situations, biological control agents and other beneficial organisms may act as a carrier or pathway for plant pests, hyperparasitoids, hyperparasites and entomopathogens. In this sense, biological control agents and other beneficial organisms may be considered to be regulated articles as described in Article VII.1 of the IPPC (1997) and ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*.

Purpose of the standard

The objectives of the standard are to:

- facilitate the safe export, shipment, import and release of biological control agents and other beneficial

[2] Available expertise, instruments and work in international fora with competence in the area of risks to the environment should be taken into account as appropriate.

organisms by providing guidelines for all public and private bodies involved, particularly through the development of national legislation where it does not exist.

- describe the need for cooperation between importing and exporting countries so that:
  - benefits to be derived from using biological control agents or other beneficial organisms are achieved with minimal adverse effects
  - practices which ensure efficient and safe use while minimizing environmental risks due to improper handling or use are promoted.

Guidelines in support of these objectives are described that:

- encourage responsible trade practices
- assist countries to design regulations to address the safe handling, assessment and use of biological control agents and other beneficial organisms
- provide risk management recommendations for the safe export, shipment, import and release of biological control agents and other beneficial organisms
- promote the safe use of biological control agents and other beneficial organisms.

REQUIREMENTS

1. Designation of Responsible Authority and Description of General Responsibilities

1.1 Contracting parties

Contracting parties should designate an authority with appropriate competencies (usually their NPPO) to be responsible for export certification and to regulate the import or release of biological control agents and other beneficial organisms, subject to relevant phytosanitary measures and procedures.

Contracting parties should have provisions for implementing appropriate phytosanitary measures for the export, shipment, import or release of biological control agents and other beneficial organisms.

1.2 General responsibilities

The NPPO or other responsible authority should establish procedures for the implementation of this standard, including for the assessment of relevant documentation specified in section 4.

The NPPO or other responsible authority should:

- carry out pest risk analysis prior to import or release of biological control agents and other beneficial organisms
- ensure, when certifying exports, that the regulations of importing countries are complied with
- provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biological control agents and other beneficial organisms
- ensure that biological control agents and other beneficial organisms are taken either directly to designated quarantine facilities or, if appropriate, passed to mass rearing facilities or directly for release into the environment
- ensure that importers and, where appropriate, exporters meet their responsibilities
- consider possible impacts on the environment, such as impacts on non-target invertebrates.

The NPPO or other responsible authority should maintain communication and, where appropriate, coordinate with relevant parties including other NPPOs or relevant authorities on:

- characteristics of biological control agent and other beneficial organisms
- assessment of risks including environmental risks
- labelling, packaging and storage during shipment
- dispatch and handling procedures
- distribution and trade
- release
- evaluation of performance
- information exchange
- occurrence of unexpected and/or harmful incidents, including remedial action taken.

2. Pest Risk Analysis

The NPPO of the importing country should determine whether an organism is required to be subjected to pest risk analysis (PRA). The NPPO or other responsible authority may also be responsible for ensuring that other national legislative requirements are met; however, these may not be IPPC obligations.

Pest risk assessment should be conducted in accordance with ISPM No. 2 (*Guidelines for pest risk analysis*) and/or stage 2 of ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified*

organisms, 2004) as appropriate, taking into account uncertainties, and potential environmental consequences, as provided for in those standards. In addition to conducting pest risk assessment, contracting parties should also consider possible impacts on the environment, such as impacts on non-target invertebrates.

Most contracting parties require PRA to be completed prior to import and technical justification, as described in ISPM No. 20 (*Guidelines for a phytosanitary import regulatory system*), such as through PRA, is required to determine if pests should be regulated and the strength of phytosanitary measures to be taken against them. Where applicable, if pest risk assessment of the proposed organism has not been undertaken or completed prior to import, it should be completed prior to release (see section 7). However, it is recognized that biological control agents and other beneficial organisms may need to be imported for research and evaluation in secure facilities prior to release. ISPM No. 20 also states that contracting parties may make special provision for the import of biological control agents and other beneficial organisms for scientific research, and that such imports may be authorized subject to the provision of adequate safeguards. The NPPO should be prepared for such imports with the expectation that, where necessary, a full PRA in accordance with ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) will be completed prior to release. When non-phytosanitary risks are identified, these may need to be referred to other appropriate authorities for possible action.

It may be important that further scientific investigations are carried out in the exporting country prior to importing the biological control agents or other beneficial organisms in order to verify the accuracy and reliability of the risk assessment. Among other options, and where appropriate, NPPOs or other responsible authorities may consider possibilities for such scientific investigations, in cooperation with the authorities of the exporting country and in accordance with relevant procedures and regulations.

3. Responsibilities of Contracting Parties prior to Import

3.1 Responsibilities of the importing contracting party

The importing contracting party or its NPPO or other responsible authority should:

3.1.1 Promote awareness of, and compliance with this standard and introduce necessary phytosanitary measures to regulate the import, shipment or release of biological control agents and other beneficial organisms in its country, and make provision for effective enforcement.

3.1.2 Evaluate the documentation on the target pest and on the biological control agent and beneficial organisms supplied by the importer (see section 4) in relation to the level of acceptable risk. The contracting party should establish appropriate phytosanitary measures for import, shipment, quarantine facilities (including approval of research facilities, and phytosanitary measures for containment and disposal) or release of biological control agents appropriate to the assessed risk. If the biological control agent or other beneficial organism is already present in the country, regulation may only be needed to ensure there is no contamination or infestation of this organism, or that interbreeding with local genotypes of the same species does not result in new phytosanitary risks. Inundative release may be restricted for these reasons.

3.1.3 Issue regulations stating requirements to be fulfilled by the exporting country, the exporter and the importer[3]. Where appropriate, these may include:

- the issuing of an accompanying authorising document (import permit or licence)
- phytosanitary certification, in accordance with ISPM No. 12: *Guidelines for phytosanitary certificates*
- a specific certification document
- authoritative identification of organisms during quarantine and provision of a reference specimen
- specification of the source of the biological control agent or other beneficial organism(s), including origin and/or point of production where relevant
- precautions to be taken against inclusion of natural enemies of the biological control agent or other beneficial organism and of contamination or infestation
- requirements regarding packaging for shipment during transport and storage
- procedures for the disposal of packaging
- means to validate documentation
- means to validate the contents of consignments
- conditions under which the package may be opened
- designation of point(s) of entry
- identification of the person or organization to receive the consignment
- requirements for the facilities in which the biological control agent or other beneficial organisms may be held.

[3] Provisions of other international agreements may address the import of biological control agents or other beneficial organisms (for example the Convention on Biological Diversity).

3.1.4 Ensure that procedures are in place for the documentation of:

- pest risk analysis
- the import (identity, origins, dates)
- nurturing, rearing or multiplication
- release (quantities released, dates, locations), and
- any other relevant data.

Such records may be made available to the scientific community and the public, as may be appropriate, while protecting any proprietary rights to the data.

3.1.5 If appropriate, ensure entry of consignments, and processing where required, through quarantine facilities. Where a country does not have secure quarantine facilities, import through a quarantine station in a third country, recognized by the importing contracting party, may be considered.

3.1.6 Consider, through pest risk analysis, the risk of introducing other organisms associated with the biological control agent or beneficial organism. Considerations (keeping in mind the principles of necessity and minimal impact) should include phytosanitary measures requiring the culturing of imported biological control agents and other beneficial organisms in quarantine before release. Culturing for at least one generation can help in ensuring purity of the culture and freedom from hyperparasites and pathogens or associated pests, as well as facilitating authoritative identification. This is particularly advisable when biological control agents and other beneficial organisms are collected from the wild.

3.1.7 Where possible, ensure the deposition in collections of authoritatively identified reference specimens of the imported biological control agent or other beneficial organism (and host(s) where appropriate). It is preferable to deposit a series of specimens, where available, to accommodate natural variation.

3.1.8 In the case of sterile insect technique, the sterile insect may be marked to differentiate it from the wild insect.

3.1.9 Consider, through pest risk analysis (consistent with the principles of necessity and minimal impact), if, after a first import or release, further imports of the same biological control agent or other beneficial organism may be exempted from some or all of the requirements for import. The publication of lists of approved and prohibited biological control agents and other beneficial organisms may also be considered. If appropriate, biological control agents that are prohibited should be included in lists of regulated pests (established and updated by contracting parties in accordance with the IPPC (1997) and ISPM No. 19: *Guidelines on lists of regulated pests*).

3.2 Responsibilities of the NPPO of an exporting country

The NPPO of an exporting country should ensure that the phytosanitary import requirements of the importing country are satisfied and that phytosanitary certificates are issued in accordance with ISPM No. 12: *Guidelines for phytosanitary certificates*, where required by the importing country for consignments of biological control agents or other beneficial organisms, if these are considered as potential pests or pathways for plant pests.

The NPPO is also encouraged to follow the appropriate elements of this standard where the importing country has no legislation concerning the import of biological control agents and other beneficial organisms.

4. Documentary responsibilities of importer prior to import

4.1 Documentary requirements related to the target organism

Prior to the first importation, the importer of biological control agents or other beneficial organisms should provide information as required by the NPPO or other responsible authority of the importing contracting party. For all biological control agents or other beneficial organisms, this information includes accurate identification of the target organism(s), generally at the species level. Where a biological control agent intended to control a pest is being imported, the information on the target pest may also include:

- its world distribution and probable origin
- its known biology and ecology
- available information on its economic importance and environmental impact
- possible benefits and any conflicting interests surrounding its use
- known natural enemies, antagonists and other biological control agents or competitors of the target pest already present or used in the proposed release area or in other parts of the world.

For all biological control agents or other beneficial organisms, other information relevant to a PRA may also be requested by the NPPO or other responsible authority of the importing contracting party.

4.2 Documentary requirements related to the biological control agent or other beneficial organism

Prior to first import, the importer of biological control agents or other beneficial organisms should coordinate with the exporter to provide documentation, accompanied by appropriate scientific references, to the NPPO or other responsible authority of the importing contracting party with information on the biological control agent or beneficial organism including:

- sufficient characterization of the biological control agent or other beneficial organism to allow for its accurate identification, in general to the species level at minimum
- a summary of all available information on its origin, world distribution, biology, natural enemies, hyperparasites, and impact in its area of distribution
- available information on host specificity (in particular, a list of confirmed hosts) of the biological control agent or beneficial organism and any potential hazards posed to non-target hosts
- description of natural enemies and contaminants of the agent and procedures required for their elimination from laboratory colonies. This includes, where appropriate, procedures to identify accurately and, if necessary, eliminate from the culture the host upon which the biological control agent or beneficial organism was cultured. Information on any phytosanitary measures taken prior to shipment should also be provided.

4.3 Documentary requirements related to potential hazards and emergency actions

Prior to first importation, the importer of biological control agents or other beneficial organisms is encouraged to provide documentation to the NPPO or other responsible authority that:

- identifies potential health hazards and analyzes the risks[4] posed to staff operatives exposed when handling biological control agents or other beneficial organisms under laboratory, production and application conditions.
- details emergency action plans or procedures already in existence, should the biological control agent or beneficial organism display unexpected adverse properties.

4.4 Documentary requirements related to research in quarantine

An importer of biological control agents or other beneficial organisms proposed for research in quarantine should provide as much information as possible as described in points 4.1–4.3. However, it is recognized that field collected organisms imported by researchers in initial shipments of potential biological control agents may not be described with regard to their exact taxonomic identity, host range, impact on non-target organisms, distribution, biology, impact in an area of distribution, etc. This information will be determined after candidate biological control agents are studied under quarantine security.

The researcher, in conjunction with the quarantine facility to be used, should also provide the following information:

- the nature of the material proposed for importation
- the type of the research to be carried out
- detailed description of containment facilities (including security and the competency and qualifications of the staff)
- an emergency plan that will be implemented in the case of an escape from the facility.

This information may be required by the NPPO or other responsible authority prior to approval of the research to be conducted. The NPPO or other responsible authority may verify the accuracy of the documentation provided and examine the facilities, and may require modifications as necessary.

5. Responsibilities of Exporter

The exporter of biological control agents or other beneficial organisms is encouraged to ensure that:

- all phytosanitary import requirements specified in the regulations of the importing country or on an import permit are complied with (see also section 3.2, which describes the related responsibilities of the NPPO)
- all appropriate documentation accompanies the consignment
- packaging is secure in order to prevent escape of the contents
- organisms for SIT have been treated to achieve the required sterility for SIT purposes (e.g. using irradiation with the required minimum absorbed dose). The treatment(s) used and an indication of the effectiveness of sterilization should also be provided.

5.1 Specific responsibilities regarding organisms intended for inundative release

Exporters of biological control agents or other beneficial organisms for inundative release should provide documentation on measures undertaken to ensure that levels of contamination acceptable to the importing NPPO or other responsible authority are not exceeded.

[4] Available expertise, instruments and work in international fora with competence in the area of risks to human health should be taken into account as appropriate.

6. Responsibilities of the NPPO or other responsible authority of the importing contracting party upon import

6.1 Inspection

Where required (see section 3.1.5) after checking the documentation, inspection should take place at an officially nominated quarantine facility.

6.2 Quarantine

The NPPO should ensure that biological control agents or other beneficial organisms are cultured or reared in quarantine, if appropriate (see section 3.1.6), for as long as considered necessary.

6.3 Release

The NPPO or other responsible authority may allow biological control agents or other beneficial organisms to be passed directly for release, provided that all conditions have been complied with (particularly as described in section 3) and required documentary evidence is made available (see section 4).

7. Responsibilities of the NPPO or other responsible authority before, upon and following release

Prior to release, NPPOs or other responsible authorities are encouraged to communicate details of the intended release that may affect neighbouring countries. To facilitate information sharing in this manner, details of intended releases may also be communicated to relevant RPPOs prior to release.

If pest risk analysis was not undertaken prior to import in accordance with ISPM No. 2 (*Guidelines for pest risk analysis*) and/or ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004), it should be undertaken prior to release, taking into account uncertainties, as provided for in those standards. In addition to conducting pest risk assessment, contracting parties should also consider possible impacts on the environment, such as impacts on non-target invertebrates.

The NPPO or other responsible authority may verify the effectiveness of sterilization treatment(s) prior to release of sterile insects.

7.1 Release

The NPPO or other responsible authority should authorize and audit official requirements related to the release of biological control agents or other beneficial organisms, e.g. requirements related to release only in specific areas. This audit may be used to alter the requirements related to import or release of the organism.

7.2 Documentation

Documentation sufficient to allow trace-back of released biological control agents or other beneficial organisms should be maintained by the NPPO or other responsible authority.

7.3 Monitoring and evaluation

The NPPO or other responsible authority may monitor the release of biological control agents or other beneficial organisms in order to evaluate and, as necessary, respond to the impact on the target and non-target organisms. Where appropriate, it should include a marking system to facilitate recognition of the biological control agent (e.g. sterile insects) or other beneficial organism in comparison with the organism in its natural state and environment.

7.4 Emergency measures

The NPPO or other responsible authority of the importing contracting party is responsible for developing or adopting emergency plans or procedures, as appropriate, for use within the importing country.

Where problems are identified (i.e. unexpected harmful incidents), the NPPO or other responsible authority should consider possible measures or corrective actions and, where appropriate, ensure that they are implemented and that all relevant parties are informed.

7.5 Communication

It is recommended that the NPPO or other responsible authority ensures that local users and suppliers of biological control agents or other beneficial organisms, and farmers, farmer organizations and other stakeholders, are kept sufficiently informed and educated on the appropriate measures for their use.

7.6 Reporting

The contracting party should abide by any reporting obligations under the IPPC, e.g. where an organism used as a biological control agent or beneficial organism has shown pest characteristics.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 4

REQUIREMENTS FOR THE ESTABLISHMENT OF PEST FREE AREAS

(1995)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the 28th Session of the FAO Conference in November 1995.

INTRODUCTION

SCOPE

This standard describes the requirements for the establishment and use of pest free areas (PFAs) as a risk management option for phytosanitary certification of plants and plant products and other regulated articles exported from the PFA or to support the scientific justification for phytosanitary measures taken by an importing country for protection of an endangered PFA.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
FAO Glossary of Phytosanitary Terms, *FAO Plant Protection Bulletin* 38(1), 1990: 5-23.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for surveillance, 1998. ISPM No. 6, FAO, Rome.
International Plant Protection Convention, 1992. 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

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".

The establishment and use of a PFA by an NPPO provides for the export of plants, plant products and other regulated articles from the country in which the area is situated (exporting country) to another country (importing country) without the need for application of additional phytosanitary measures when certain requirements are met. Thus, the pest free status of an area may be used as the basis for the phytosanitary certification of plants, plant products and other regulated articles with respect to the stated pest(s). It also provides, as an element in pest risk assessment, the confirmation on a scientific basis of the absence of a stated pest from an area. The PFA is then an element in the justification of phytosanitary measures taken by an importing country to protect an endangered area.

Although the term "pest free areas" encompasses a whole range of types (from an entire country which is pest free to a small area which is pest free but situated in a country where that pest is prevalent), it has been found to be convenient to discuss the requirements of PFAs by defining three types:

- an entire country
- an uninfested part of a country in which a limited infested area is present
- an uninfested part of a country situated within a generally infested area.

In each of these cases, the PFA may, as appropriate, concern all or part of several countries.

Three main components or stages are considered in the establishment and subsequent maintenance of a PFA:

- systems to establish freedom
- phytosanitary measures to maintain freedom
- checks to verify freedom has been maintained.

The nature of these components will vary according to the biology of the pest, the types and characteristics of the PFA and the level of phytosanitary security required, as based on pest risk analysis. The methods used to achieve these components may include:

- data assembly
- surveys (delimiting, detection, monitoring)
- regulatory controls
- audit (review and evaluation)
- documentation (reports, work plans).

1. GENERAL REQUIREMENTS FOR PEST FREE AREAS (PFAs)

1.1 Determination of a PFA

The delimitation of a PFA should be relevant to the biology of the pest concerned. This will affect the scale at which it is possible to define a PFA and the types of boundaries by which it can be delimited. In principle, PFAs should be delimited in close relation with the occurrence of the pest. In practice, however, PFAs are generally delimited by readily recognizable boundaries, considered to coincide acceptably with a pest's biological limits. These may be administrative (e.g. country, province or commune borders), physical features (e.g. rivers, seas, mountain ranges, roads) or property boundaries which are clear to all parties. For various practical reasons, it may also be decided to establish a PFA inside an area considered to be pest free, and thus avoid the necessity for exact delimitation of the true limits of the PFA.

1.2 Establishment and Maintenance of a PFA

There are three main components in establishing and maintaining a PFA. These are:

- systems to establish freedom
- phytosanitary measures to maintain freedom
- checks to verify freedom has been maintained.

The nature of these components will vary according to the:

- biology of the pest including:
  - its survival potential
  - its rate of reproduction
  - its means of dispersal
  - the availability of host plants etc
- relevant PFA characteristics including its:
  - size
  - degree of isolation
  - ecological conditions
  - homogeneity etc.
- level of phytosanitary security required as related to the assessed level of risk, according to the pest risk analysis conducted.

The international standards for phytosanitary measures: Guidelines for surveillance and Guidelines for pest risk analysis, provide further details on general surveillance and specific survey requirements.

1.2.1 Systems to establish freedom

Two general types of systems to provide data are recognized, though variations on, or combinations of the two can be used. These are:

- general surveillance
- specific surveys.

General surveillance

This involves utilizing all sources of data such as NPPOs, other national and local government agencies, research institutions, universities, scientific societies (including amateur specialists), producers, consultants, museums and the general public. Information may be obtained from:

- scientific and trade journals
- unpublished historical data
- contemporary observations.

Specific surveys

These may be detection or delimiting surveys. They are official surveys and should follow a plan which is approved by the NPPO concerned.

1.2.2 Phytosanitary measures to maintain freedom

Specific measures can be used to prevent the introduction and spread of a pest including:

- regulatory action such as the:
  - listing of a pest on a quarantine pest list
  - specification of import requirements into a country or area
  - restriction of the movement of certain products within areas of a country or countries including buffer zones
- routine monitoring
- extension advice to producers.

The application of phytosanitary measures to maintain pest freedom status is only justified in a PFA, or any portion of a PFA, in which ecological conditions are suitable for the pest to establish.

1.2.3 Checks to verify freedom has been maintained

In order to be able to verify the pest free status of a PFA and for purposes of internal management, the continuing pest free status should be checked after the PFA has been established and phytosanitary measures for maintenance have been put in place. The strength of the checking systems used should be related to the phytosanitary security required. These checks may include:

- *ad hoc* inspection of exported consignments
- requirement that researchers, advisers or inspectors notify the NPPO of any occurrences of the pest
- monitoring surveys.

1.3 Documentation and Review

The establishment and maintenance of a PFA should be adequately documented and periodically reviewed.

Whatever the type of PFA, documentation should be available, as appropriate, on the:

- data assembled to establish the PFA
- various administrative measures taken in support of the PFA
- delimitation of the PFA
- phytosanitary regulations applied
- technical details of surveillance, or survey and monitoring systems used.

It may be useful for an NPPO to send documentation about a PFA to a central information service (FAO or a Regional Plant Protection Organization), with all relevant details, so that the information can be communicated to all interested NPPOs at their request.

When a PFA requires complex measures for its establishment and maintenance to provide a high degree of phytosanitary security, an operational plan based on a bilateral agreement may be needed. Such a plan would list the specific details of activities required in the operation of the PFA including the role and responsibilities of the producers and traders of the country where the PFA is situated. The activities would be reviewed and evaluated regularly and the results could form part of the plan.

2. SPECIFIC REQUIREMENTS OF DIFFERENT TYPES OF PFA

The term "pest free area" encompasses the spectrum of all types of PFA. For convenience, the requirements of PFAs are discussed by dividing them into three arbitrary types of pest free areas:

- an entire country
- an uninfested part of a country in which a limited infested area is present
- an uninfested part of a country situated within a generally infested area.

In each of these cases, the PFA may, as appropriate, concern all or part of several countries. The specific requirements for the three types of pest free areas are discussed below.

2.1 Entire Country

In this instance, entire country freedom for a specific pest applies to a political entity for which an NPPO has responsibility.

Requirements may include:

2.1.1 Systems to establish freedom

Both data from general surveillance and from specific surveys are acceptable. They are different in that they may provide for different kinds or degrees of phytosanitary security.

2.1.2 Phytosanitary measures to maintain freedom

These may include those listed in section 1.2.2.

2.1.3 Checks to verify freedom has been maintained

These may include those listed in section 1.2.3.

2.1.4 Documentation and review

These may include those items listed in section 1.3.

2.2 Uninfested Part of a Country in Which a Limited Infested Area is Present

In this instance, the distribution of the pest is limited to part of a country as determined by the NPPO. Official controls are applied to contain a pest population. The PFA may be all or part of the uninfested area.

Requirements may include:

2.2.1 Systems to establish freedom

Normally PFA status is based on verification from specific surveys. An official delimiting survey may be used to determine the extent of the infestation and, in addition, an official detection survey may be required in the uninfested area to verify absence of the pest.

General surveillance (see 2.1.1 above) may also, if appropriate, be applied to the uninfested part of a country in which a limited infested area is present.

2.2.2 Phytosanitary measures to maintain freedom

These may include those listed in section 1.2.2. With this type of PFA, phytosanitary regulations may also be required on the movement of commodities out of the infested area to the uninfested area to prevent spread of the pest as noted in 1.2.2.

2.2.3 Checks to verify freedom has been maintained

These may include those listed in section 1.2.3. Monitoring surveys are of more significance in this type of PFA than for that involving an entire country.

2.2.4 Documentation and review

Documentation may include supporting evidence describing official controls such as survey results, phytosanitary regulations and information on the NPPO as noted in section 1.3.

2.3 Uninfested Part of a Country Situated Within a Generally Infested Area

This type of PFA is an area, within a generally infested area, which has been made (or shown to be) free from a specific pest. It is maintained pest free so that an exporting country can use this status as a basis for phytosanitary certification of plants and/or plant products.

In certain cases, a PFA may be established within an area whose infestation status has not been based on specific surveys.

The PFA should be adequately isolated in relation to the biology of the pest.

Requirements should include:

2.3.1 Systems to establish freedom

Delimiting and detection surveys would be required for this type of PFA.

2.3.2 Phytosanitary measures to maintain freedom

These may include those listed in section 1.2.2. With this type of PFA, phytosanitary regulations may also be required on the movement of host material out of the infested area to the uninfested area to prevent spread of the pest as noted in 1.2.2.

2.3.3 Checks to verify freedom has been maintained

These may include those listed in section 1.2.3. Ongoing monitoring surveys are a likely requirement with this type of PFA.

2.3.4 Documentation and review

Documentation may include supporting evidence describing official controls such as survey results, phytosanitary regulations and information on the NPPO as noted in section 1.3. As this type of PFA is likely to involve an agreement between trade partners, its implementation would need to be reviewed and evaluated by the NPPO of the importing country.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 5

GLOSSARY OF PHYTOSANITARY TERMS

(2006)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

INTRODUCTION

SCOPE

This reference standard is a listing of terms and definitions with specific meaning for phytosanitary systems worldwide. It has been developed to provide a harmonized internationally agreed vocabulary associated with the implementation of the International Plant Protection Convention (IPPC) and International Standards for Phytosanitary Measures (ISPMs).

PURPOSE

The purpose of this reference standard is to increase clarity and consistency in the use and understanding of terms and definitions which are used by contracting parties for official phytosanitary purposes, in phytosanitary legislation and regulations, as well as for official information exchange.

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OUTLINE OF REFERENCE

The purpose of this standard is to assist National Plant Protection Organizations and others in information exchange and the harmonization of vocabulary used in official communications and legislation pertaining to phytosanitary measures. The present version incorporates revisions agreed as a result of the approval of the International Plant Protection Convention (1997) and terms added through the adoption of additional International Standards for Phytosanitary Measures (ISPMs).

All elements of this Glossary have been established on the basis that the New Revised Text of the IPPC (1997) is approved. The Glossary contains all terms and definitions approved until the First session of the Commission on Phytosanitary Measures in 2006. References in square brackets refer to the approval of the term and definition, and not to subsequent adjustments in translation.

As in previous editions of the Glossary, terms in definitions are printed in bold to indicate their relation to other Glossary terms and to avoid unnecessary repetition of elements described elsewhere in the Glossary. Derived forms of words that appear in the Glossary, e.g. *inspected* from *inspection*, are also considered glossary terms.

PHYTOSANITARY TERMS AND DEFINITIONS

absorbed dose	Quantity of radiating energy (in **gray**) absorbed per unit of mass of a specified target [ISPM No. 18, 2003]
Additional Declaration	A statement that is required by an importing country to be entered on a **Phytosanitary Certificate** and which provides specific additional information on a **consignment** in relation to **regulated pests** [FAO, 1990; revised ICPM, 2005]
antagonist	An **organism** (usually pathogen) which does no significant damage to the host but its colonization of the host protects the host from significant subsequent damage by a **pest** [ISPM No. 3, 1996]
area	An **officially** defined country, part of a country or all or parts of several countries [FAO, 1990; revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]
area endangered	See **endangered area**
area of low pest prevalence	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 [IPPC, 1997]
authority	The **National Plant Protection Organization**, or other entity or person officially designated by the government to deal with matters arising from the responsibilities set forth in the Code [ISPM No. 3, 1996]
bark-free wood	**Wood** from which all bark excluding the vascular cambium, ingrown bark around knots, and bark pockets between rings of annual growth has been removed [ISPM No. 15, 2002]
beneficial organism	Any **organism** directly or indirectly advantageous to **plants** or **plant products**, including **biological control agents** [ISPM No. 3, 2005]
biological control	**Pest control** strategy making use of living **natural enemies**, **antagonists**, **competitors** or other **biological control agents** [ISPM No. 3, 1996; revised ISPM No. 3, 2005; formerly **biological control (biocontrol)**]
biological control agent	A **natural enemy**, **antagonist** or **competitor**, or other **organism**, used for **pest control** [ISPM No. 3, 1996; revised ISPM No. 3, 2005]
biological pesticide (biopesticide)	A generic term, not specifically definable, but generally applied to a biological control agent, usually a pathogen, formulated and applied in a manner similar to a chemical pesticide, and normally used for the rapid reduction of a **pest** population for short-term **pest control** [ISPM No. 3, 1996]
buffer zone	An **area** in which a specific **pest** does not occur or occurs at a low level and is **officially controlled**, that either encloses or is adjacent to an infested **area**, an infested **place of production**, an **area of low pest prevalence**, a **pest free area**, a **pest free place of production** or a **pest free production site**, and in which **phytosanitary measures** are taken to prevent **spread** of the **pest** [ISPM No. 10, 1999; revised ISPM No. 22, 2005]
bulbs and tubers	A **commodity class** for dormant underground parts of **plants** intended for **planting** (includes corms and rhizomes) [FAO, 1990; revised ICPM, 2001]
certificate	An **official** document which attests to the phytosanitary status of any **consignment** affected by **phytosanitary regulations** [FAO, 1990]
chemical pressure impregnation	**Treatment** of **wood** with a chemical preservative through a process of pressure in accordance with an official technical specification [ISPM No. 15, 2002; revised ICPM, 2005]
classical biological control	The intentional introduction and permanent **establishment** of an exotic biological agent for long-term **pest control** [ISPM No. 3, 1996]

clearance (of a **consignment**)	Verification of compliance with **phytosanitary regulations** [FAO, 1995]
Commission	The Commission on **phytosanitary measures** established under Article XI [IPPC, 1997]
commodity	A type of **plant**, **plant product**, or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
commodity class	A category of similar **commodities** that can be considered together in **phytosanitary regulations** [FAO, 1990]
commodity pest list	A list of **pests occurring** in an **area** which may be associated with a specific **commodity** [CEPM, 1996]
competitor	An **organism** which competes with **pests** for essential elements (e.g. food, shelter) in the environment [ISPM No. 3, 1996]
compliance procedure (for a **consignment**)	**Official procedure** used to verify that a **consignment** complies with stated phytosanitary requirements [CEPM, 1999]
consignment	A quantity of **plants**, **plant products** and/or other articles being moved from one country to another and covered, when required, by a single **phytosanitary certificate** (a **consignment** may be composed of one or more **commodities** or **lots**) [FAO, 1990; revised ICPM, 2001]
consignment in transit	A **consignment** which passes through a country without being imported, and that may be subject to **phytosanitary measures** [FAO, 1990; revised CEPM, 1996; CEPM 1999; ICPM, 2002; ISPM No. 25, 2006; formerly **country of transit**]
containment	Application of **phytosanitary measures** in and around an infested **area** to prevent **spread** of a **pest** [FAO, 1995]
contaminating pest	A **pest** that is carried by a **commodity** and, in the case of **plants** and **plant products**, does not infest those **plants** or **plant products** [CEPM, 1996; revised CEPM, 1999]
contamination	Presence in a **commodity**, storage place, conveyance or container, of **pests** or other **regulated articles**, not constituting an **infestation** (see **infestation**) [CEPM, 1997; revised CEPM, 1999]
control (of a **pest**)	**Suppression, containment** or **eradication** of a **pest** population [FAO, 1995]
control point	A step in a system where specific procedures can be applied to achieve a defined effect and can be measured, monitored, controlled and corrected [ISPM No. 14, 2002]
controlled area	A **regulated area** which an **NPPO** has determined to be the minimum **area** necessary to prevent spread of a pest from a **quarantine area** [CEPM, 1996]
country of origin (of a **consignment** of **plant products**)	Country where the **plants** from which the **plant products** are derived were grown [FAO, 1990; revised CEPM, 1996; CEPM, 1999]
country of origin (of a **consignment** of **plants**)	Country where the **plants** were grown [FAO, 1990; revised CEPM, 1996; CEPM, 1999]
country of origin (of **regulated articles** other than **plants** and **plant products**)	Country where the **regulated articles** were first exposed to **contamination** by **pests** [FAO, 1990; revised CEPM, 1996; CEPM, 1999]
cut flowers and branches	A **commodity class** for fresh parts of **plants** intended for decorative use and not for **planting** [FAO, 1990; revised ICPM, 2001]
debarking	Removal of bark from **round wood (debarking** does not necessarily make the **wood** bark-free) [FAO, 1990]
delimiting survey	**Survey** conducted to establish the boundaries of an **area** considered to be infested by or **free from** a **pest** [FAO, 1990]

detection survey	**Survey** conducted in an **area** to determine if **pests** are present [FAO, 1990, revised FAO, 1995]
detention	Keeping a **consignment** in **official** custody or confinement, as a phytosanitary measure (see **quarantine**) [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2005]
devitalization	A procedure rendering **plants** or **plant products** incapable of germination, growth or further reproduction [ICPM, 2001]
dose mapping	Measurement of the **absorbed dose** distribution within a **process load** through the use of **dosimeters** placed at specific locations within the **process load** [ISPM No. 18, 2003]
dosimeter	A device that, when irradiated, exhibits a quantifiable change in some property of the device which can be related to **absorbed dose** in a given material using appropriate analytical instrumentation and techniques [ISPM No. 18, 2003]
dosimetry	A system used for determining **absorbed dose**, consisting of **dosimeters**, measurement instruments and their associated reference standards, and procedures for the system's use [ISPM No. 18, 2003]
dunnage	**Wood packaging material** used to secure or support a **commodity** but which does not remain associated with the commodity [FAO, 1990; revised ISPM No. 15, 2002]
ecosystem	A dynamic complex of **plant**, animal and micro-organism communities and their abiotic environment interacting as a functional unit [ISPM No. 3, 1996; revised ICPM, 2005]
efficacy (treatment)	A defined, measurable, and reproducible effect by a prescribed **treatment** [ISPM No. 18, 2003]
emergency action	A prompt **phytosanitary action** undertaken in a new or unexpected phytosanitary situation [ICPM, 2001]
emergency measure	A **phytosanitary measure** established as a matter of urgency in a new or unexpected phytosanitary situation. An emergency measure may or may not be a **provisional measure** [ICPM, 2001; revised ICPM, 2005]
endangered area	An **area** where ecological factors favour the **establishment** of a **pest** whose presence in the **area** will result in economically important loss [FAO, 1995]
entry (of a **consignment**)	Movement through a **point of entry** into an **area** [FAO, 1995]
entry (of a **pest**)	Movement of a **pest** into an **area** where it is not yet present, or present but not widely distributed and being **officially controlled** [FAO, 1995]
equivalence (of phytosanitary measures)	The situation where, for a specified pest risk, different **phytosanitary measures** achieve a contracting party's appropriate level of protection [FAO, 1995; revised CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures; revised ISPM No. 24, 2005]
eradication	Application of **phytosanitary measures** to eliminate a **pest** from an **area** [FAO, 1990; revised FAO, 1995; formerly **eradicate**]
establishment	Perpetuation, for the foreseeable future, of a **pest** within an **area** after **entry** [FAO, 1990; revised FAO, 1995; IPPC, 1997; formerly **established**]
establishment (of a **biological control agent**)	The perpetuation, for the foreseeable future, of a **biological control agent** within an **area** after **entry** [ISPM No. 3, 1996]
exotic	Not native to a particular country, **ecosystem** or **ecoarea** (applied to **organisms** intentionally or accidentally introduced as a result of human activities). As the Code is directed at the **introduction** of **biological control agents** from one country to another, the term **"exotic"** is used for **organisms** not native to a country [ISPM No. 3, 1996]
field	A plot of land with defined boundaries within a **place of production** on which a **commodity** is grown [FAO, 1990]

find free	To **inspect** a **consignmen**t, **field** or **place of production** and consider it to be **free from** a specific **pest** [FAO, 1990]
free from (of a **consignmen**t, **field** or **place of production**)	Without **pests** (or a specific **pest**) in numbers or quantities that can be detected by the application of **phytosanitary procedures** [FAO, 1990; revised FAO, 1995; CEPM, 1999]
fresh	Living; not dried, deep-frozen or otherwise conserved [FAO, 1990]
fruits and vegetables	A **commodity class** for **fresh** parts of **plants** intended for consumption or processing and not for **planting** [FAO, 1990; revised ICPM, 2001]
fumigation	**Treatment** with a chemical agent that reaches the **commodity** wholly or primarily in a gaseous state [FAO, 1990; revised FAO, 1995]
germplasm	**Plants** intended for use in breeding or conservation programmes [FAO, 1990]
grain	A **commodity class** for **seeds** intended for processing or consumption and not for **planting** (see **seeds**) [FAO, 1990; revised ICPM, 2001]
gray (Gy)	Unit of **absorbed dose** where 1 Gy is equivalent to the absorption of 1 joule per kilogram (1 Gy = 1 J.kg -1) [ISPM No. 18, 2003]
growing medium	Any material in which **plant** roots are growing or intended for that purpose [FAO, 1990]
growing period (of a **plant** species)	Time period of active growth during a **growing season** [ICPM, 2003]
growing season	Period or periods of the year when **plants** actively grow in an **area, place of production** or production site [FAO, 1990; revised ICPM, 2003]
habitat	Part of an **ecosystem** with conditions in which an **organism** naturally occurs or can establish [ICPM, 2005]
harmonization	The establishment, recognition and application by different countries of **phytosanitary measures** based on common **standards** [FAO, 1995; revised CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]
harmonized phytosanitary measures	**Phytosanitary measures** established by contracting parties to the **IPPC**, based on **international standards** [IPPC, 1997]
heat treatment	The process in which a **commodity** is heated until it reaches a minimum temperature for a minimum period of time according to an **official** technical specification [ISPM No. 15, 2002; revised ICPM, 2005]
hitch-hiker pest	See **contaminating pest**
host pest list	A list of **pests** that infest a **plant** species, globally or in an **area** [CEPM, 1996; revised CEPM, 1999]
host range	Species capable, under natural conditions, of sustaining a specific **pest** or other **organism** [FAO, 1990; revised ISPM No. 3, 2005]
Import Permit	**Official** document authorizing importation of a **commodity** in accordance with specified phytosanitary import requirements [FAO, 1990; revised FAO, 1995; ICPM, 2005]
Import Permit (of a **biological control agent**)	An **official** document authorizing importation (of a **biological control agent**) in accordance with specified requirements [ISPM No. 3, 1996]
inactivation	Rendering micro-organisms incapable of development [ISPM No. 18, 2003]
incursion	An isolated population of a **pest** recently detected in an **area**, not known to be established, but expected to survive for the immediate future [ICPM, 2003]
infestation (of a **commodity**)	Presence in a **commodity** of a living **pest** of the **plant** or **plant product** concerned. **Infestation** includes infection [CEPM, 1997; revised CEPM, 1999]

inspection	**Official** visual examination of **plants, plant products** or other **regulated articles** to determine if **pests** are present and/or to determine compliance with **phytosanitary regulations** [FAO, 1990; revised FAO, 1995; formerly **inspect**]
inspector	Person authorized by a **National Plant Protection Organization** to discharge its functions [FAO, 1990]
intended use	Declared purpose for which **plants**, **plant product**s, or other **regulated articles** are imported, produced, or used [ISPM No. 16, 2002]
interception (of a **consignment**)	The **refusal** or controlled **entry** of an imported **consignment** due to failure to comply with **phytosanitary regulations** [FAO, 1990; revised FAO, 1995]
interception (of a **pest**)	The detection of a **pest** during **inspection** or **testing** of an imported **consignment** [FAO, 1990; revised CEPM, 1996]
intermediate quarantine	**Quarantine** in a country other than the **country of origin** or destination [CEPM, 1996]
International Plant Protection Convention	International Plant Protection Convention, as deposited with FAO in Rome in 1951 and as subsequently amended [FAO, 1990]
International Standard for Phytosanitary Measures	An **international standard** adopted by the Conference of FAO, the Interim Commission on **phytosanitary measures** or the Commission on **phytosanitary measures**, established under the **IPPC** [CEPM, 1996; revised CEPM, 1999]
international standards	International **standards** established in accordance with Article X paragraph 1 and 2 of the **IPPC** [IPPC, 1997]
introduction	The **entry** of a **pest** resulting in its **establishment** [FAO, 1990; revised FAO, 1995; IPPC, 1997]
introduction (of a **biological control agent**)	The release of a **biological control agent** into an **ecosystem** where it did not exist previously (see **establishment**) [ISPM No. 3, 1996]
inundative release	The release of large numbers of mass-produced **biological control agents** or **beneficial organisms** with the expectation of achieving a rapid effect [ISPM No. 3, 1996; revised ISPM No. 3, 2005]
ionizing radiation	Charged particles and electromagnetic waves that as a result of physical interaction create ions by either primary or secondary processes [ISPM No. 18, 2003]
IPPC	**International Plant Protection Convention**, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
irradiation	Treatment with any type of **ionizing radiation** [ISPM No. 18, 2003]
ISPM	**International Standard for Phytosanitary Measures** [CEPM, 1996; revised ICPM, 2001]
kiln-drying	A process in which **wood** is dried in a closed chamber using heat and/or humidity control to achieve a required moisture content [ISPM No. 15, 2002]
legislation	Any act, law, regulation, guideline or other administrative order promulgated by a government [ISPM No. 3, 1996]
living modified organism	Any living organism that possesses a novel combination of genetic material obtained through the use of **modern biotechnology** [*Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2000]
LMO	**living modified organism** [ISPM No. 11, 2004]
lot	A number of units of a single **commodity**, identifiable by its homogeneity of composition, origin etc., forming part of a **consignment** [FAO, 1990]
mark	An **official** stamp or brand, internationally recognized, applied to a **regulated article** to attest its phytosanitary status [ISPM No. 15, 2002]
micro-organism	A protozoan, fungus, bacterium, virus or other microscopic self-replicating biotic entity [ISPM No. 3, 1996]

minimum absorbed dose (Dmin)	The localized minimum **absorbed dose** within the **process load** [ISPM No. 18, 2003]
modern biotechnology	The application of: a. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or b. fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. [*Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2000]
monitoring	An **official** ongoing process to verify phytosanitary situations [CEPM, 1996]
monitoring survey	Ongoing **survey** to verify the characteristics of a **pest** population [FAO, 1995]
National Plant Protection Organization	**Official** service established by a government to discharge the functions specified by the **IPPC** [FAO, 1990; formerly **Plant Protection Organization (National)**]
natural enemy	An **organism** which lives at the expense of another **organism** in its area of origin and which may help to limit the population of that **organism**. This includes **parasitoids**, **parasites**, **predators**, phytophagous organisms and **pathogens** [ISPM No. 3, 1996; revised ISPM No. 3, 2005]
naturally occurring	A component of an **ecosystem** or a selection from a wild population, not altered by artificial means [ISPM No. 3, 1996]
non-quarantine pest	**Pest** that is not a **quarantine pest** for an **area** [FAO, 1995]
NPPO	**National Plant Protection Organization** [FAO, 1990; ICPM, 2001]
occurrence	The presence in an **area** of a **pest officially** recognized to be indigenous or **introduced** and/or not **officially** reported to have been **eradicated** [FAO, 1990; revised FAO, 1995; ISPM No. 17; formerly **occur**]
official	Established, authorized or performed by a **National Plant Protection Organization** [FAO, 1990]
official control	The active enforcement of mandatory **phytosanitary regulations** and the application of mandatory **phytosanitary procedures** with the objective of **eradication** or **containment** of **quarantine pests** or for the management of **regulated non-quarantine pests** (see Glossary Supplement No. 1) [ICPM, 2001]
organism	Any biotic entity capable of reproduction or replication in its naturally occurring state [ISPM No. 3, 1996; revised ISPM No. 3, 2005]
outbreak	A recently detected **pest** population, including an **incursion**, or a sudden significant increase of an established **pest** population in an **area** [FAO, 1995; revised ICPM, 2003]
packaging	Material used in supporting, protecting or carrying a **commodity** [ISPM No. 20, 2004]
parasite	An **organism** which lives on or in a larger **organism**, feeding upon it [ISPM No. 3, 1996]
parasitoid	An insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult [ISPM No. 3, 1996]
pathogen	**Micro-organism** causing disease [ISPM No. 3, 1996]
pathway	Any means that allows the **entry** or **spread** of a **pest** [FAO, 1990; revised FAO, 1995]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to **plants** or **plant products** [FAO, 1990; revised FAO, 1995; IPPC, 1997]
pest categorization	The process for determining whether a **pest** has or has not the characteristics of a **quarantine pest** or those of a **regulated non-quarantine pest** [ISPM No. 11, 2001]
pest diagnosis	The process of detection and identification of a **pest** [ISPM No. 27, 2006]

Pest Free Area	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 [FAO, 1995]
pest free place of production	**Place of production** in which a specific **pest** does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period [ISPM No. 10, 1999]
pest free production site	A defined portion of a **place of production** in which a specific **pest** does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period and that is managed as a separate unit in the same way as a **pest free place of production** [ISPM No. 10, 1999]
pest record	A document providing information concerning the presence or absence of a specific **pest** at a particular location at a certain time, within an **area** (usually a country) under described circumstances [CEPM, 1997]
Pest Risk Analysis	The process of evaluating biological or other scientific and economic evidence to determine whether a **pest** should be regulated and the strength of any **phytosanitary measures** to be taken against it [FAO, 1995; revised IPPC, 1997]
pest risk assessment (for **quarantine pests)**	Evaluation of the probability of the **introduction** and **spread** of a **pest** and of the associated potential economic consequences [FAO, 1995; revised ISPM No. 11, 2001]
pest risk assessment (for regulated non-quarantine pests)	Evaluation of the probability that a **pest** in **plants for planting** affects the **intended use** of those **plants** with an economically unacceptable impact [ICPM, 2005]
pest risk management (for **quarantine pests**)	Evaluation and selection of options to reduce the risk of **introduction** and **spread** of a **pest** [FAO, 1995; revised ISPM No. 11, 2001]
pest risk management (for regulated non-quarantine pests)	Evaluation and selection of options to reduce the risk that a **pest** in **plants for planting** causes an economically unacceptable impact on the **intended use** of those **plants** [ICPM, 2005]
pest status (in an **area**)	Presence or absence, at the present time, of a **pest** in an **area**, including where appropriate its distribution, as **officially** determined using expert judgement on the basis of current and historical **pest records** and other information [CEPM, 1997; revised ICPM, 1998]
PFA	**Pest Free Area** [FAO, 1995; revised ICPM, 2001]
phytosanitary action	An **official** operation, such as **inspection**, **testing**, **surveillance** or **treatment**, undertaken to implement **phytosanitary measures** [ICPM, 2001; revised ICPM, 2005]
Phytosanitary Certificate	**Certificate** patterned after the model **certificates** of the **IPPC** [FAO, 1990]
phytosanitary certification	Use of **phytosanitary procedures** leading to the issue of a **Phytosanitary Certificate** [FAO, 1990]
phytosanitary import requirements	Specific **phytosanitary measures** established by an importing country concerning **consignments** moving into that country [ICPM, 2005]
phytosanitary legislation	Basic laws granting legal authority to a **National Plant Protection Organization** from which **phytosanitary regulations** may be drafted [FAO, 1990; revised FAO, 1995]
phytosanitary measure (agreed interpretation)	Any **legislation**, **regulation** or **official** procedure having the purpose to prevent the **introduction** and/or **spread** of **quarantine pest**s, or to limit the economic impact of **regulated non-quarantine pests** [FAO, 1995; revised IPPC, 1997; ICPM, 2002]

The agreed interpretation of the term phytosanitary measure accounts for the relationship of phytosanitary measures to regulated non-quarantine pests. This relationship is not adequately reflected in the definition found in Article II of the IPPC (1997).

phytosanitary procedure	Any **official** method for implementing **phytosanitary measures** including the performance of **inspections**, **tests**, **surveillance** or **treatments** in connection with **regulated pests** [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001; ICPM, 2005]
phytosanitary regulation	**Official** rule to prevent the **introduction** and/or **spread** of **quarantine pests**, or to limit the economic impact of **regulated non-quarantine pests**, including establishment of **procedures** for **phytosanitary certification** [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
place of production	Any premises or collection of **fields** operated as a single production or farming unit. This may include production sites which are separately managed for phytosanitary purposes [FAO, 1990; revised CEPM, 1999]
plant pest	See **pest**
plant products	Unmanufactured material of **plant** origin (including **grain**) and those manufactured products that, by their nature or that of their processing, may create a risk for the **introduction** and **spread** of **pests** [FAO, 1990; revised IPPC, 1997; formerly **plant product**]
plant protection organization (national)	See **National Plant Protection Organization**
plant quarantine	All activities designed to prevent the **introduction** and/or **spread** of **quarantine pests** or to ensure their **official control** [FAO, 1990; revised FAO, 1995]
planting (including **replanting**)	Any operation for the placing of **plants** in a **growing medium**, or by grafting or similar operations, to ensure their subsequent growth, reproduction or propagation [FAO, 1990; revised CEPM,1999]
plants	Living plants and parts thereof, including **seeds** and **germplasm** [FAO, 1990; revised IPPC, 1997]
plants for planting	**Plants** intended to remain **planted**, to be **planted** or **replanted** [FAO, 1990]
plants *in vitro*	A **commodity class** for plants growing in an aseptic medium in a closed container [FAO, 1990; revised CEPM, 1999; ICPM, 2002; formerly **plants in tissue culture**]
point of entry	Airport, seaport or land border point **officially** designated for the importation of **consignments**, and/or entrance of passengers [FAO, 1995]
post-entry quarantine	**Quarantine** applied to a **consignment** after **entry** [FAO, 1995]
PRA	**Pest Risk Analysis** [FAO, 1995; revised ICPM, 2001]
PRA area	**Area** in relation to which a **Pest Risk Analysis** is conducted [FAO, 1995]
practically free	Of a **consignment**, **field**, or **place of production**, without **pests** (or a specific **pest**) in numbers or quantities in excess of those that can be expected to result from, and be consistent with good cultural and handling practices employed in the production and marketing of the **commodity** [FAO, 1990; revised FAO, 1995]
pre-clearance	**Phytosanitary certification** and/or **clearance** in the **country of origin**, performed by or under the regular supervision of the **National Plant Protection Organization** of the country of destination [FAO, 1990; revised FAO, 1995]
predator	A natural enemy that preys and feeds on other animal **organisms**, more than one of which are killed during its lifetime [ISPM No. 3, 1996]
process load	A volume of material with a specified loading configuration and treated as a single entity [ISPM No. 18, 2003]
processed wood material	Products that are a composite of **wood** constructed using glue, heat and pressure, or any combination thereof [ISPM No. 15, 2002]
prohibition	A **phytosanitary regulation** forbidding the importation or movement of specified **pests** or **commodities** [FAO, 1990; revised FAO, 1995]

protected area	A **regulated area** that an **NPPO** has determined to be the minimum **area** necessary for the effective protection of an **endangered area** [FAO, 1990; omitted from FAO, 1995; new concept from CEPM, 1996]
provisional measure	A **phytosanitary regulation** or procedure established without full **technical justification** owing to current lack of adequate information. A **provisional measure** is subjected to periodic review and full technical justification as soon as possible [ICPM, 2001]
quarantine	**Official** confinement of **regulated articles** for observation and research or for further **inspection**, **testing** and/or **treatment** [FAO, 1990; revised FAO, 1995; CEPM, 1999]
quarantine area	An **area** within which a **quarantine pest** is present and is being **officially controlled** [FAO, 1990; revised FAO, 1995]
quarantine pest	A **pest** of potential economic importance to the **area endangered** thereby and not yet present there, or present but not widely distributed and being **officially controlled** [FAO, 1990; revised FAO, 1995; IPPC 1997]
quarantine station	**Official** station for holding **plants** or **plant products** in **quarantine** [FAO, 1990; revised FAO, 1995; formerly **quarantine station or facility**]
raw wood	**Wood** which has not undergone processing or **treatment** [ISPM No. 15, 2002]
re-exported consignment	**Consignment** that has been imported into a country from which it is then exported. The consignment may be stored, split up, combined with other consignments or have its packaging changed (formerly **country of re-export**) [FAO, 1990; revised CEPM, 1996; CEPM, 1999; ICPM, 2001; ICPM, 2002]
reference specimen(s)	Individual specimen(s) from a specific population conserved in a reference culture collection and, where possible, in publicly available collection(s) [ISPM No. 3, 2005]
refusal	Forbidding **entry** of a **consignment** or other **regulated article** when it fails to comply with **phytosanitary regulations** [FAO, 1990; revised FAO, 1995]
Regional Plant Protection Organization	An intergovernmental organization with the functions laid down by Article IX of the **IPPC** [FAO, 1990; revised FAO, 1995; CEPM, 1999; formerly **plant protection organization (regional)**]
regional standards	**Standards** established by a **Regional Plant Protection Organization** for the guidance of the members of that organization [IPPC, 1997]
regulated area	An **area** into which, within which and/or from which **plants**, **plant products** and other **regulated articles** are subjected to **phytosanitary regulations** or **procedures** in order to prevent the **introduction** and/or **spread** of **quarantine pests** or to limit the economic impact of **regulated non-quarantine pests** [CEPM, 1996; revised CEPM, 1999; ICPM, 2001]
regulated article	Any **plant**, **plant product**, storage place, packaging, conveyance, container, soil and any other **organism**, object or material capable of harbouring or spreading **pests**, deemed to require **phytosanitary measures**, particularly where international transportation is involved [FAO, 1990; revised FAO, 1995; IPPC, 1997]
regulated non-quarantine pest	A **non-quarantine pest** whose presence in **plants for planting** affects the **intended use** of those **plants** with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party [IPPC, 1997]
regulated pest	A **quarantine pest** or a **regulated non-quarantine pest** [IPPC, 1997]
release (into the environment)	Intentional liberation of an **organism** into the environment (see **introduction** and **establishmen**t) [ISPM No. 3, 1996]
release (of a **consignmen**t)	Authorization for **entry** after **clearance** [FAO, 1995]
replanting	See **planting**
required response	A specified level of effect for a **treatment** [ISPM No. 18, 2003]

restriction	A **phytosanitary regulation** allowing the importation or movement of specified **commodities** subject to specific requirements [CEPM, 1996, revised CEPM, 1999]
RNQP	**Regulated non-quarantine pest** [ISPM No. 16, 2002]
round wood	**Wood** not sawn longitudinally, carrying its natural rounded surface, with or without bark [FAO, 1990]
RPPO	**Regional Plant Protection Organization** [FAO, 1990; revised ICPM, 2001]
sawn wood	**Wood** sawn longitudinally, with or without its natural rounded surface with or without bark [FAO, 1990]
Secretary	**Secretary** of the **Commission** appointed pursuant to Article XII [IPPC, 1997]
seeds	A **commodity class** for seeds for **planting** or intended for planting and not for consumption or processing (see **grain**) [FAO, 1990; revised ICPM, 2001]
SIT	**sterile insect technique** [ISPM No. 3, 2005]
specificity	A measure of the host range of a **biological control agent** on a scale ranging from an extreme specialist only able to complete development on a single species or strain of its host (monophagous) to a generalist with many hosts ranging over several groups of **organisms** (polyphagous) [ISPM No. 3, 1996]
spread	Expansion of the geographical distribution of a **pest** within an **area** [FAO, 1995]
standard	Document established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context [FAO, 1995; ISO/IEC GUIDE 2:1991 definition]
sterile insect	An insect that, as a result of a specific treatment, is unable to reproduce [ISPM No. 3, 2005]
sterile insect technique	Method of **pest control** using area-wide **inundative release** of **sterile insects** to reduce reproduction in a field population of the same species [ISPM No. 3, 2005]
stored product	Unmanufactured **plant product** intended for consumption or processing, stored in a dried form (this includes in particular **grain** and dried **fruits** and **vegetables**) [FAO, 1990]
suppression	The application of **phytosanitary measures** in an infested **area** to reduce **pest** populations [FAO, 1995; revised CEPM, 1999]
surveillance	An **official** process which collects and records data on **pest occurrence** or absence by **survey**, **monitoring** or other procedures [CEPM, 1996]
survey	An **official** procedure conducted over a defined period of time to determine the characteristics of a **pest** population or to determine which species **occur** in an **area** [FAO, 1990; revised CEPM, 1996]
systems approach(es)	The integration of different risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of protection against **regulated pests** [ISPM No. 14, 2002; revised ICPM, 2005]
technically justified	Justified on the basis of conclusions reached by using an appropriate **pest risk analysis** or, where applicable, another comparable examination and evaluation of available scientific information [IPPC, 1997]
test	**Official** examination, other than visual, to determine if **pests** are present or to identify **pests** [FAO, 1990]
transience	Presence of a **pest** that is not expected to lead to **establishment** [ISPM No. 8, 1998]
transit	See **consignment in transit**
transparency	The principle of making available, at the international level, **phytosanitary measures** and their rationale [FAO, 1995; revised CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]

treatment	**Official** procedure for the killing, **inactivation** or removal of pests, or for rendering **pests** infertile or for **devitalization** [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003; ICPM, 2005]
visual examination	The physical examination of plants, **plant products**, or other **regulated articles** using the unaided eye, lens, stereoscope or microscope to detect **pests** or **contaminants** without **testing** or processing [ISPM No. 23, 2005]
wood	A **commodity class** for round wood, sawn wood, wood chips or dunnage, with or without bark [FAO, 1990; revised ICPM, 2001]
wood packaging material	**Wood** or wood products (excluding paper products) used in supporting, protecting or carrying a **commodity** (includes **dunnage**) [ISPM No. 15, 2002]

Supplement No. 1

GUIDELINES ON THE INTERPRETATION AND APPLICATION OF THE CONCEPT OF OFFICIAL CONTROL FOR REGULATED PESTS

1. Purpose

The words *officially controlled* express an essential concept in the definition of a quarantine pest. *The Glossary of phytosanitary terms* defines official as "established, authorized or performed by an NPPO" and control as "suppression, containment or eradication of a pest population". However, for phytosanitary purposes, the concept of *official control* is not adequately expressed by the combination of these two definitions. The purpose of this guideline is to describe more precisely the interpretation of the concept of official control and its application in practice.

2. Scope

This guideline refers only to the official control of regulated pests. For the purposes of this guideline, the relevant regulated pests are both quarantine pests that are present in an importing country but not widely distributed and regulated non-quarantine pests.

3. Definition

Official control is defined as:

The active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests.

4. General Requirements

Official control is subject to the "principles of plant quarantine as related to international trade," in particular the principles of non-discrimination, transparency, equivalence and risk analysis.

In the case of a quarantine pest that is present but not widely distributed, and where appropriate in the case of certain regulated non-quarantine pests, the importing country should define the infested area(s), endangered area(s) and protected area(s).

Official control includes:

- eradication and/or containment in the infested area(s)
- surveillance in the endangered area(s)
- measures related to controls on movement into and within the protected area(s) including measures applied at import.

All official control programmes have elements that are mandatory. At minimum, programme evaluation and pest surveillance are required in official control programmes to determine the need for and effect of control to justify measures applied at import for the same purpose. Measures applied at import should be consistent with the principle of non-discrimination (see section 5.1 below).

For quarantine pests, eradication and containment may have an element of suppression. For regulated non-quarantine pests, suppression may be used to avoid unacceptable economic impact as it applies to the intended use of plants for planting.

5. Specific Requirements

5.1 Non-discrimination

The principle of non-discrimination between domestic and import requirements is fundamental. In particular, requirements for imports should not be more stringent than the effect of official control in an importing country. There should therefore be consistency between import and domestic requirements for a defined pest:

- import requirements should not be more stringent than domestic 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. 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. Compliance with import tolerance is generally determined by inspection or testing at entry, whereas the tolerance for domestic consignments should be determined at the last 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.

5.2 Transparency

The import and domestic requirements for official control should be documented and made available, on request.

5.3 Technical justification (risk analysis)

Domestic and import requirements should be technically justified and result in non-discriminatory risk management.

5.4 Enforcement

The domestic enforcement of official control programmes should be equivalent to the enforcement of import requirements. Enforcement should include:

- a legal basis
- operational implementation
- evaluation and review
- official action in case of non-compliance.

5.5 Mandatory nature of official control

Official control is mandatory in the sense that all persons involved are legally bound to perform the actions required. The scope of official control programmes for quarantine pests is completely mandatory (e.g. procedures for eradication campaigns), whereas the scope for regulated non-quarantine pests is mandatory only in certain circumstances (e.g. official certification programmes).

5.6 Area of application

An official control programme can be applied at national, sub-national or local area level. The area of application of official control measures should be specified. Any import restrictions should have the same effect as the measures applied internally for official control.

5.7 NPPO authority and involvement in official control

Official control should:

- be established or recognized by the national government or the NPPO under appropriate legislative authority
- be performed, managed, supervised or, at minimum, audited/reviewed by the NPPO
- have enforcement assured by the national government or the NPPO
- be modified, terminated or lose official recognition by the national government or the NPPO.

Responsibility and accountability for official control programmes rests with the national government. Agencies other than the NPPO may be responsible for aspects of official control programmes, and certain aspects of official control programmes may be the responsibility of sub-national authorities or the private sector. The NPPO should be fully aware of all aspects of official control programmes in their country.

References

Report of the ICPM open-ended working group on official control, 22-24 March 2000, Bordeaux, France, IPPC Secretariat, FAO, Rome.

Supplement No. 2

GUIDELINES ON THE UNDERSTANDING OF *POTENTIAL ECONOMIC IMPORTANCE* AND RELATED TERMS INCLUDING REFERENCE TO ENVIRONMENTAL CONSIDERATIONS

1. Purpose and Scope

These guidelines provide the background and other relevant information to clarify *potential economic importance* and related terms, so that such terms are clearly understood and their application is consistent with the International Plant Protection Convention (IPPC) and the International Standards for Phytosanitary Measures (ISPM). These guidelines also show the application of certain economic principles as they relate to the IPPC's objectives, in particular in protecting uncultivated/unmanaged plants, wild flora, habitats and ecosystems with respect to invasive alien species that are plant pests.

These guidelines clarify that the IPPC:

- can account for environmental concerns in economic terms using monetary or non-monetary values;
- asserts that market impacts are not the sole indicator of pest consequences;
- maintains the right of members to adopt phytosanitary measures with respect to pests for which the economic damage caused to plants, plant products or ecosystems within an area cannot be easily quantified.

They also clarify, with respect to plant pests, that the scope of the IPPC covers the protection of cultivated plants in agriculture (including horticulture or forestry), uncultivated/unmanaged plants, wild flora, habitats and ecosystems.

2. Background

The IPPC has historically maintained that the adverse consequences of plant pests, including those concerning uncultivated/unmanaged plants, wild flora, habitats and ecosystems, are measured in economic terms. References to the terms *economic effects, economic impacts, potential economic importance* and *economically unacceptable impact* and the use of the word *economic* in the IPPC and in ISPMs has resulted in some misunderstanding of the application of such terms and of the focus of the IPPC.

The scope of the Convention applies to the protection of wild flora resulting in an important contribution to the conservation of biological diversity. However, it has been misinterpreted that the IPPC is only commercially focused and limited in scope. It has not been clearly understood that the IPPC can account for environmental concerns in economic terms. This has created issues of harmonization with other agreements, including the Convention on Biological Diversity and the Montreal Protocol on Substances that Deplete the Ozone Layer.

3. Economic Terms and Environmental Scope of the IPPC and ISPMs

The economic terms found in the IPPC and ISPMs may be categorized as follows.

Terms requiring judgement to support policy decisions:

- *potential economic importance* (in the definition for *quarantine pest*);
- *economically unacceptable impact* (in the definition for *regulated non-quarantine pest*);
- *economically important loss* (in the definition for *endangered area*).

Terms related to evidence that supports the above judgements:

- *limit the economic impact* (in the definition for *phytosanitary regulation* and the agreed interpretation of *phytosanitary measure*);
- *economic evidence* (in the definition for *Pest Risk Analysis*);
- *cause economic damage* (in Article VII.3 of the IPPC, 1997);
- *direct and indirect economic impacts* (in ISPM No. 11 and ISPM No. 16);
- *economic consequences and potential economic consequences* (in ISPM No. 11);
- *commercial and non-commercial consequences* (in ISPM No. 11).

ISPM No. 2 refers to *environmental damage* as a factor to consider in the assessment of potential economic importance. Section 2.2.3 includes many items demonstrating the broad scope of economic impacts that is intended to be covered.

ISPM No. 11 notes in section 2.1.1.5 with respect to pest categorization, that there should be a clear indication that the pest is likely to have an unacceptable economic impact, which may include environmental impact, in the PRA area. Section 2.3 of the standard describes the procedure for assessing potential economic consequences of an introduction of a pest. Effects may be considered to be direct or indirect. Section 2.3.2.2 addresses analysis of commercial

consequences. Section 2.3.2.4 provides guidance on the assessment of the non-commercial and environmental consequences of pest introduction. It acknowledges that certain types of effects may not apply to an existing market that can be easily identified, but it goes on to state that the impacts could be approximated with an appropriate non-market valuation method. This section notes that if a quantitative measurement is not feasible, then this part of the assessment should at least include a qualitative analysis and an explanation of how the information is used in the risk analysis. *Environmental or other undesirable effects of control measures* are covered in section 2.3.1.2 (Indirect effects) as part of the analysis of economic consequences. Where a risk is found to be unacceptable, Section 3.4 provides guidance on the selection of risk management options, including measurements of cost-effectiveness, feasibility and least trade restrictiveness.

In April 2001 the ICPM recognized that under the IPPC's existing mandate, to take account of environmental concerns, further clarification should include consideration of the following five proposed points relating to potential environmental risks of plant pests:

- reduction or elimination of endangered (or threatened) native plant species;
- reduction or elimination of a keystone plant species (a species which plays a major role in the maintenance of an ecosystem);
- reduction or elimination of a plant species which is a major component of a native ecosystem;
- causing a change to plant biological diversity in such as way as to result in ecosystem destabilization;
- resulting in control, eradication or management programs that would be needed if a quarantine pest was introduced, and impacts of such programs (e.g. pesticides or the release of non-indigenous predators or parasites) on biological diversity.

Thus it is clear, with respect to plant pests, that the scope of the IPPC covers the protection of cultivated plants in agriculture (including horticulture and forestry), uncultivated/unmanaged plants, wild flora, habitats and ecosystems.

4. Economic Considerations in PRA

4.1 Types of economic effect

In PRA, economic effects should not be interpreted to be only market effects. Goods and services not sold in commercial markets can have economic value and economic analysis encompasses much more than the study of market goods and services. The use of the term *economic effects* provides a framework in which a wide variety of effects (including environmental and social effects) may be analysed. Economic analysis uses a monetary value as a measure to allow policy makers to compare costs and benefits from different types of goods and services. This does not preclude the use of other tools such as qualitative and environmental analyses that may not use monetary terms.

4.2 Costs and benefits

A general economic test for any policy is to pursue the policy if its benefit is at least as large as its cost. Costs and benefits are broadly understood to include both market and non-market aspects. Costs and benefits can be represented by both quantifiable measurements and qualitative measurements. Non-market goods and services may be difficult to quantify or measure but nevertheless are essential to consider.

Economic analysis for phytosanitary purposes can only provide information with regard to costs and benefits, and does not judge if one distribution is necessarily better than another distribution of costs and benefits of a specific policy. In principle, costs and benefits should be measured regardless to whom they occur. Given that judgments about the preferred distribution of costs and benefits are policy choices, these should have a rational relationship to phytosanitary considerations.

Costs and benefits should be counted whether they occur as a direct or indirect result of a pest introduction or if a chain of causation is required before the costs are incurred or the benefits realized. Costs and benefits associated with indirect consequences of pest introductions may be less certain than costs and benefits associated with direct consequences. Often, there is no monetary information about the cost of any loss that may result from pests introduced into natural environments. Any analysis should identify and explain uncertainties involved in estimating costs and benefits and assumptions should be clearly stated.

5. Application

The following criteria[1] should be met before a plant pest is deemed to have *potential economic importance*:

- a potential for introduction in the PRA area;
- the potential to spread after establishment; and
- a potential harmful impact on plants, for example:
  - crops (for example loss of yield or quality); or
  - the environment, for example damage to ecosystems, habitats, or species; or
  - some other specified value, for example recreation, tourism, aesthetics.

As stated in Section 3, environmental damage, arising from the introduction of a plant pest, is one of the types of damage recognized by the IPPC. Thus, with respect to the third criterion above, contracting parties to the IPPC have the right to adopt phytosanitary measures even with respect to a pest that only has the potential for environmental damage. Such action should be based upon a Pest Risk Analysis that includes the consideration of evidence of potential environmental damage. When indicating the direct and indirect impact of pests on the environment, the nature of the harm or losses arising from a pest introduction should be specified in Pest Risk Analysis.

In the case of regulated non-quarantine pests, because such pest populations are already established, introduction in an area of concern and environmental effects are not relevant criteria in the consideration of *economically unacceptable impacts* (see ISPM No. 16: *Regulated non-quarantine pests: concept and application*).

References

International Plant Protection Convention, 1997. FAO, Rome.
Guidelines for Pest Risk Analysis, 1996. ISPM No. 2, FAO, Rome.
Pest Risk Analysis for quarantine pests, 2001. ISPM No. 11, FAO, Rome.
Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.
Report of the Third Session of the Interim Commission on Phytosanitary Measures (includes the working group document in Appendix XII), 2001. FAO, Rome.

[1] With respect to the first and second criteria, IPPC (1997) Article VII.3 states that for pests which may not be capable of establishment, measures taken against these pests must be technically justified.

APPENDIX

This appendix provides additional clarification of some terms used in this supplement. It is not a prescriptive part of this supplement.

Economic analysis: It primarily uses monetary values as a measure to allow policy makers to compare costs and benefits from different types of goods and services. It encompasses more than the study of market goods and services. Economic analysis does not prevent the use of other measures that do not use a monetary value; for example, qualitative or environmental analysis.

Economic effects: This includes market effects as well as non-market effects, such as environmental and social considerations. Measurement of the economic value of environmental effects or social effects may be difficult to establish. For example, the survival and well being of another species or the value of the aesthetics of a forest or a jungle. Both qualitative and quantitative worth may be considered in measuring economic effects.

Economic impacts of plant pests: This includes both market measures as well as those consequences that may not be easy to measure in direct economic terms, but which represent a loss or damage to cultivated plants, uncultivated plants or plant products.

Economic value: This is the basis for measuring the cost of the effect of changes (e.g. in biodiversity, ecosystems, managed resources or natural resources) on human welfare. Goods and services not sold in commercial markets can have economic value. Determining economic value does not prevent ethical or altruistic concerns for the survival and well-being of other species based on cooperative behaviour.

Qualitative measurement: This is the valuation of qualities or characteristics in other than monetary or numeric terms.

Quantitative measurement: This is the valuation of qualities or characteristics in monetary or other numeric terms.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 6

GUIDELINES FOR SURVEILLANCE

(1997)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the 29th Session of the FAO Conference in November 1997.

INTRODUCTION

SCOPE

This standard describes the components of survey and monitoring systems for the purpose of pest detection and the supply of information for use in pest risk analyses, the establishment of pest free areas and, where appropriate, the preparation of pest lists.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Bayer coding system, 1996. European and Mediterranean Plant Protection Organization, Paris.
Glossary of phytosanitary terms, 1997. ISPM No. 5, FAO, Rome.
International Plant Protection Convention, 1992. 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

Under the international standard for phytosanitary measures: Principles of plant quarantine as related to international trade, countries are required to justify their phytosanitary measures on the basis of pest risk analysis. These principles also endorse the concept of "pest free areas", a description of which is provided in the standard: Requirements for the establishment of pest free areas. These concepts are also referred to in the World Trade Organization's "Agreement on the Application of Sanitary and Phytosanitary Measures". The collecting and recording of pest information is fundamental to all these concepts. The implication is that National Plant Protection Organizations (NPPOs) should be in a position to validate declarations of the absence or limited distribution of quarantine pests.

There are two major types of surveillance systems:

- general surveillance
- specific surveys.

General surveillance is a process whereby information on particular pests which are of concern for an area is gathered from many sources, wherever it is available and provided for use by the NPPO.

Specific surveys are procedures by which NPPOs obtain information on pests of concern on specific sites in an area over a defined period of time.

The verified information acquired may be used to determine the presence or distribution of pests in an area, or on a host or commodity, or their absence from an area (in the establishment and maintenance of pest free areas).

REQUIREMENTS

1. General Surveillance

1.1 Sources

Within countries there are many sources of pest information. These sources may include: NPPOs, other national and local government agencies, research institutions, universities, scientific societies (including amateur specialists), producers, consultants, museums, the general public, scientific and trade journals, unpublished data and contemporary observations. In addition, the NPPO may obtain information from international sources such as FAO, Regional Plant Protection Organizations (RPPOs), etc.

1.2 Collection, storage and retrieval of information

To utilize data from these sources, it is recommended that NPPOs develop a system whereby appropriate information on the particular pest(s) of concern is collected, verified and compiled.

Components of such a system should include:

- the NPPO or another institution designated by the NPPO acting as the national repository for plant pest records
- a record keeping and retrieval system
- data verification procedures
- communication channels to transfer information from the sources to the NPPO.

Components of such a system may also include:

- incentives to report such as:
  - legislative obligations (for the general public or specific agencies)
  - cooperative agreements (between the NPPO and specific agencies)
  - use of contact personnel to enhance communication channels to and from NPPOs
  - public education/awareness programmes.

1.3 Use of information

Information gathered through such general surveillance will most often be used:

- to support NPPO declarations of pest freedom
- to aid early detection of new pests
- for reporting to other organizations such as RPPOs and FAO
- in the compilation of host and commodity pest lists and distribution records.

2. Specific Surveys

Specific surveys may be detection, delimiting or monitoring surveys. These are official surveys and should follow a plan which is approved by the NPPO.

The survey plan should include:

- definition of the purpose (e.g. early detection, assurances for pest free areas, information for a commodity pest list) and the specification of the phytosanitary requirements to be met
- identification of the target pest(s)
- identification of scope (e.g. geographical area, production system, season)
- identification of timing (dates, frequency, duration)
- in the case of commodity pest lists, the target commodity
- indication of the statistical basis, (e.g. level of confidence, number of samples, selection and number of sites, frequency of sampling, assumptions)
- description of survey methodology and quality management including an explanation of:
  - sampling procedures (e.g. attractant trapping, whole plant sampling, visual inspection, sample collection and laboratory analysis); the procedure would be determined by the biology of pest and/or purpose of survey
  - diagnostic procedures
  - reporting procedures.

2.1 Pest surveys

Surveys for specific pests will provide information to be used mainly:

- to support NPPO declarations of pest freedom

but also:

- to aid early detection of new pests
- for reporting to other organizations such as RPPOs and FAO.

The selection of suitable survey sites may be determined by the:

- previously reported presence and distribution of the pest
- biology of the pest
- distribution of host plants of the pest and especially of their areas of commercial production
- climatic suitability of sites for the pest.

The timing of survey procedures may be determined by:

- the life cycle of the pest
- the phenology of the pest and its hosts
- the timing of pest management programmes
- whether the pest is best detected on crops in active growth or in the harvested crop.

For pests which are only likely to be present as a result of recent introduction, the selection of suitable survey sites may in addition relate, for example, to points of possible entry, possible pathways of spread, sites where imported commodities are marketed, and sites where imported commodities are used as planting material.

The selection of survey procedures may be determined by the type of sign or symptom by which the pest can be recognized, and by the accuracy or sensitivity of techniques used to test for the pest.

2.2 Commodity or host surveys

Specific commodity surveys can provide useful information for pest lists of commodities produced under specific cultural practices. Surveys could also be used for the preparation of host pest lists where data from general surveillance is lacking.

The selection of suitable survey sites may be determined by:

- geographical distribution of production areas and/or their size
- pest management programmes (commercial and non-commercial sites)
- cultivars present
- points of consolidation of the harvested commodity.

Survey procedures will be timed in relation to crop harvesting and will depend on the selection of a sampling technique appropriate to the type of harvested commodity.

2.3 Targeted and random sampling

Surveys should normally be designed to favour detection of specific pests concerned. However, the survey plan should also include some random sampling to detect unexpected events. It should be noted that if a quantitative indication of the prevalence of a pest in an area is required, the results from targeted surveys will be biased and may not provide an accurate assessment.

3. Good Surveillance Practice

Personnel involved in general surveillance should be adequately trained in appropriate fields of plant protection and data management. Personnel involved in surveys should be adequately trained, and where appropriate audited, in sampling methods, preservation and transportation of samples for identification and record keeping associated with samples. Appropriate equipment and supplies should be used and maintained adequately. The methodology used should be technically valid.

4. Technical Requirements for Diagnostic Services

The NPPO should provide appropriate diagnostic services to support general surveillance and specific survey activities, or ensure access to such services. Characteristics of the diagnostic services include:

- expertise in disciplines relevant to pest (and host) identification
- adequate facilities and equipment
- access to specialists for verification where necessary
- facilities for record keeping
- facilities for processing and storing of voucher specimens
- use of standard operating procedures, where appropriate and available.

Verification of diagnoses by other recognized authorities will provide increased confidence in the survey results.

5. Record Keeping

The NPPO should keep appropriate records derived from general surveillance and specific surveys. Information kept should be appropriate for the intended purpose, for example support of specific pest risk analyses, establishment of pest free areas and preparation of pest lists. Voucher specimens should be deposited, where appropriate.

Information in the records should include to the extent possible:

- scientific name of pest and Bayer code if available
- family/order
- scientific name of host and Bayer code if available, and plant part affected or means of collection (e.g. attractant trap, soil sample, sweep net)
- locality, e.g. location codes, addresses, coordinates
- date of collection and name of collector
- date of identification and name of identifier
- date of verification and name of verifier
- references, if any
- additional information, e.g. nature of host relationship, infestation status, growth stage of plant affected, or found only in greenhouses.

Reports of pest occurrence on commodities need not be so specific on locality or verification, but should refer precisely to the exact type of commodity, the collector and the date, and if appropriate the means of collection.

Reports of new occurrences of pests should also include information on any measures taken, and such reports made available on request.

6. Transparency

The NPPO should on request, distribute reports of pest presence, distribution, or absence derived from general surveillance and specific surveys. Reports should be adequately referenced in relation to pest occurrences.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 7

EXPORT CERTIFICATION SYSTEM

(1997)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the 29th Session of the FAO Conference in November 1997.

INTRODUCTION

SCOPE

This standard describes the components of a national system for the issuance of phytosanitary certificates.

REFERENCES

Glossary of phytosanitary terms, 1997. ISPM No. 5, FAO, Rome.
International Plant Protection Convention, 1992. 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 its contracting parties to make arrangements to issue phytosanitary certificates certifying compliance with the phytosanitary regulations of other contracting parties. This standard describes an export certification system to produce valid and credible phytosanitary certificates. Exported consignments certified under these systems should meet the current phytosanitary requirements of the importing country.

The basic elements of the phytosanitary certification process include:

- ascertaining the relevant phytosanitary requirements of the importing country (including import permits if required)
- verifying that the consignment conforms to those requirements at the time of certification
- issuing a phytosanitary certificate.

The requirements for a certification system to fulfil these functions comprise the following:

- legal authority
- management responsibility, including resources, documentation, communication and review mechanism.

REQUIREMENTS

The framework for a certification system includes the following components.

1. Legal Authority

The National Plant Protection Organization (NPPO) should have the sole authority by legislative or administrative means for control and issuance of phytosanitary certificates.

In using this authority, the NPPO should:

- bear the legal authority for its actions
- implement safeguards against potential problems such as conflicts of interest and fraudulent use of certificates.

The NPPO may have the authority to prevent the export of consignments which do not meet an importing country's requirements.

2. Management Responsibility

The NPPO should:

- have a management system that ensures that all requirements, including certification specifications, legislative requirements and administrative requirements are satisfied
- identify a person or office responsible for the export certification system
- identify the duties and lines of communication of all personnel with certification-related responsibilities
- ensure that adequate personnel and resources are available to undertake the following functions:
  - maintenance of information on importing country phytosanitary requirements as needed
  - production of operational instructions to ensure that importing country phytosanitary requirements are satisfied
  - inspection and testing of consignments and associated conveyances
  - identification of organisms found during inspection of consignments
  - verification of the authenticity and integrity of phytosanitary procedures
  - completion and issue of phytosanitary certificates
  - document storage and retrieval
  - training
  - dissemination of certification-related information
  - review regularly the effectiveness of its export certification system
  - development of bilateral protocols if necessary.

3. Resources

3.1 Staff

The NPPO should have personnel with a level of expertise appropriate for the duties and responsibilities of the positions being occupied. NPPOs should have or have access to personnel with training and experience in:

- performing inspections of plants, plant products and other regulated articles for purposes related to the issuance of phytosanitary certificates
- identification of plants and plant products
- detection and identification of pests
- performing or supervising phytosanitary treatments required for the certification in question
- survey, monitoring and control activities related to phytosanitary certification
- constructing appropriate certification systems and formulating instructions from importing country phytosanitary requirements
- auditing of accredited personnel and certification systems, where appropriate.

Except for the issuance of phytosanitary certificates, non-governmental personnel may be accredited by the NPPO to carry out specified certification functions. To be accredited, such personnel should be qualified and skilled, and responsible to the NPPO. To ensure independence in their exercise of official functions, they should be subject to restrictions equivalent to those for government officials and have no financial interest in the outcome.

3.2 Information on importing country phytosanitary requirements

The NPPO should, to the extent possible, maintain official current information concerning the import requirements of its trading partners. It may be useful for the exporter to obtain information on the current import requirements for the country of destination and supply it to the NPPO.

3.3 Technical information

The NPPO should provide the personnel involved in phytosanitary certification with adequate technical information concerning quarantine pests, and to the extent possible, non-quarantine pests, for the importing countries including:

- their presence and distribution within the exporting country
- the biology, surveillance, detection and identification of the pests
- pest management, where appropriate.

3.4 Equipment

The NPPO should ensure that adequate equipment and facilities are available to carry out inspection, testing, consignment verification and phytosanitary certification procedures.

4. Documentation

4.1 Phytosanitary certificates

The model phytosanitary certificates as described in the Annex of the IPPC should be used. The phytosanitary certificate should contain sufficient information to clearly identify the consignment to which it relates. The phytosanitary certificate should not carry other information, of a non-phytosanitary nature.

The validity of phytosanitary certificates should not be indefinite but limited in duration (prior to export), to the extent the NPPOs deem appropriate, to ensure phytosanitary and physical integrity. Appropriate disclaimers related to legal liability may be included on the phytosanitary certificate issued.

4.2 Phytosanitary certificate for re-export

Before issuing a phytosanitary certificate for re-export of a consignment, the NPPO should first examine the original phytosanitary certificate issued by the country of origin and determine whether the requirements of the country of destination are more stringent, the same, or less stringent than those satisfied by the phytosanitary certificate.

If the consignment is repacked, additional inspection should be carried out, whatever the stringency of the requirements. If, however, the consignment is not repacked, two cases arise. If the requirements are the same or less stringent, no additional inspection will be required. If the requirements are more stringent, additional inspection should be carried out.

If the country of destination has special requirements (e.g. field inspection) that cannot be fulfilled by the country of re-export, no phytosanitary certificate for re-export can be issued unless this special item has been included or declared on the original phytosanitary certificate or if equivalent laboratory tests agreed by the country of destination can be done on samples. When regular re-export exists, or is started, suitable procedures for satisfying these special requirements may be agreed between the NPPOs of the countries of origin and re-export.

If the country of re-export does not require a phytosanitary certificate for the commodity in question but the country of destination does, and the requirements can be fulfilled by visual inspections or laboratory testing of samples, the country of re-export may issue a normal phytosanitary certificate with the country of origin indicated in brackets.

4.3 Procedures

The NPPO should maintain guidance documents, procedures and work instructions as appropriate covering every aspect of the certification system.

Key elements include:

- instructions relating to phytosanitary certificates:
  - control over issuance (manual or electronic)
  - identification of issuing officers
  - inclusion of additional declarations
  - completion of the treatment section of the certificate
  - certified alterations
  - completion of phytosanitary certificates
  - signature and delivery of phytosanitary certificates
- instructions relating to other components:
  - procedures for working with industry
  - sampling, inspection and verification procedures
  - security over official seals/marks
  - consignment identification, traceability, and security
  - record keeping.

4.4 Records

In general, records should be kept concerning all activities mentioned in this standard.

A copy of each phytosanitary certificate should be retained for purposes of validation and "trace back".

For each consignment for which a phytosanitary certificate is issued, records should be kept as appropriate on:

- any inspection, testing, treatment or other verification which was conducted on a consignment basis
- the names of the personnel who undertook these tasks
- the date on which the activity was undertaken
- the results obtained
- any samples taken.

It may be useful to keep equivalent records for those non-conforming consignments for which phytosanitary certificates were not issued.

The NPPO should be able to retrieve these records when required, over an appropriate period of time. The use of secure electronic storage and retrieval is recommended for standardized documentation of records.

4.5 Consignment tracing

Consignments and their certification should be traceable as appropriate through all stages of production, handling and transport to the point of export. If the NPPO becomes aware after certification that an exported consignment may not have complied with the importing country's phytosanitary requirements, the importing country's NPPO should be so advised as soon as practicable.

5. Communication

5.1 Within the exporting country

The NPPO should have procedures in place for timely communication to relevant personnel and to industry concerning changes in:

- importing country phytosanitary requirements
- pest status and geographical distribution
- operational procedures.

The NPPO may put in place, for non-conforming consignments, a procedure which enables rapid communication to all affected industry parties and certification personnel. This is in order to facilitate resolution of the problem and to prevent re-submission of the consignment unless approved corrective action has been undertaken.

5.2 Outside the exporting country

The NPPO should:

- liaise with the nominated representatives of relevant NPPOs to discuss phytosanitary requirements
- make available a contact point for importing country NPPOs to report cases of non-compliance
- liaise with the relevant Regional Plant Protection Organizations and other international organizations in order to facilitate the harmonization of phytosanitary measures and the dissemination of technical and regulatory information.

6. Review Mechanism

6.1 System review

The NPPO should periodically review the effectiveness of all aspects of its export certification system and implement changes to the system if required.

6.2 Incident review

The NPPO should establish procedures for investigating reports from importing countries of non-conforming consignments covered by a phytosanitary certificate. If requested, a report of the outcome of the investigation should be supplied to the importing country.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 8

DETERMINATION OF PEST STATUS IN AN AREA

(1998)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in November 1998.

INTRODUCTION

SCOPE

This standard describes the content of a pest record, and the use of pest records and other information in the determination of pest status in an area. Descriptions of pest status categories are provided as well as recommendations for good reporting practices.

REFERENCES

Glossary of phytosanitary terms, 1999. 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.
International Plant Protection Convention, 1992. FAO, Rome.
New Revised Text of the International Plant Protection Convention, 1997. 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*). The term and definition below were adopted as part of the present ISPM, but were amended subsequent to adoption of the standard. The new definition of this term does not conform to the use of the term in the present ISPM, and this term and definition are retained for the purpose of the present standard only, until it has been revised.

outbreak	An isolated pest population, recently detected and expected to survive for the immediate future.

OUTLINE OF REQUIREMENTS

Pest records are essential components of the information used to establish the status of a pest in an area. All importing and exporting countries need information concerning the status of pests for risk analysis, the establishment of and compliance with import regulations, and the establishment and maintenance of pest free areas.

A *pest record* provides information concerning the presence or absence of a pest, the time and location of the observations, host(s) where appropriate, the damage observed, as well as references or other relevant information pertaining to a single observation. The reliability of pest records is based on consideration of the data in regard to the collector/identifier, the means of technical identification, the location and date of the record, and the recording/publication of the record.

The *determination of pest status* requires expert judgement concerning the information available on the present-day occurrence of a pest in an area. Pest status is determined using information from individual pest records, pest records from surveys, data on pest absence, findings of general surveillance, and scientific publications and databases.

Pest status is outlined in this standard in terms of three categories incorporating various final determinations:

- *presence* of the pest - leading to determinations such as “present in all parts of the country”, “present in some areas only”, etc.
- *absence* of the pest - leading to determinations such as “no pest records”, “pest eradicated”, “pest no longer present”, etc.
- *transience* of the pest - leading to determinations such as “non-actionable”, “actionable, under surveillance”, and “actionable, under eradication”.

To facilitate international cooperation among contracting parties in meeting their obligations in reporting the occurrence, outbreak or spread of pests, the National Plant Protection Organizations (NPPOs), or other organizations or persons involved in recording the presence, absence, or transience of pests, should follow good reporting practices. These practices concern the use of accurate, reliable data for pest records, the sharing of pest status information in a timely manner, respecting the legitimate interests of all parties concerned, and taking into account the pest status determinations in this standard.

GENERAL REQUIREMENTS FOR DETERMINATION OF PEST STATUS

1. Purposes of Pest Status Determination

A pest record is documented evidence[1] that indicates the presence or absence of a specific pest at a particular location and certain time, within an area, usually a country, under described circumstances. Pest records are used in conjunction with other information for the determination of the status of the given pest in the area.

In general, the provision of reliable pest records and the determination of pest status are vital components of a number of activities covered under the International Plant Protection Convention (IPPC) and by the principles noted in the ISPM No. 1: *Principles of plant quarantine as related to international trade*, and the international standards for phytosanitary measures that have been developed from them.

Importing countries need pest status information to:

- conduct a pest risk analysis (PRA) on a pest in another country
- establish phytosanitary regulations to prevent the entry, establishment or spread of a pest
- conduct a PRA on a non-quarantine pest in their own territory with a view to regulating it.

Exporting countries need pest status information to:

- comply with import regulations by not exporting consignments infested with the regulated pests of the importing country
- meet requests for information from other countries for the purpose of PRA on pests in their territory.

All countries may use pest status information for:

- PRA purposes
- planning national, regional or international pest management programmes
- establishing national pest lists
- establishing and maintaining pest free areas.

Information on the status of a pest in areas, countries and regions may be used to establish the global distribution of a pest.

2. Pest Records

2.1 Pest record

The ISPM No. 6: *Guidelines for surveillance* describes the elements of information from general surveillance and specific surveys that may be included in a pest record. The basic information needed in a pest record includes the following:

- current scientific name of the organism including, as appropriate, subspecific terms (strain, biotype, etc.)
- life stage or state
- taxonomic group
- identification method
- year, and month if known, recorded; normally the day will only be required for specific circumstances (e.g. the first detection of a particular pest, pest monitoring)
- locality, e.g. location codes, addresses, geographical coordinates; important conditions such as if under protected cultivation (e.g. greenhouses) should be indicated
- scientific name of host, as appropriate
- host damage, or circumstances of collection (e.g. trap or soil sample), as appropriate
- prevalence, indication of the level of pest presence or pest numbers
- bibliographical references, if any.

A list of references is noted in the Appendix to this standard for consultation in the preparation of a pest record.

2.2 Reliability

Pest record information is available from many sources and has varying levels of reliability. Some key components are identified in the following table. Although the table ranks the categories in descending order of relative reliability, it must be recognized that these are not rigid and are only designed to provide guidance in evaluating the record. In particular, it should be noted that pests differ in the level of expertise needed for their identification.

NPPOs have responsibility to provide accurate information on pest records upon request.

[1] Including electronic documentation.

Table. Guidance for Evaluating the Reliability of a Pest Record (Sources listed from most reliable to least reliable)

1. Collector/Identifiers	2. Technical identification	3. Location and date	4. Recording/Publication
a. Taxonomic specialist	a. Discriminating biochemical or molecular diagnosis (if available)	a. Delimiting or detection surveys	a. NPPO record/RPPO publication (where refereed)
b. Professional specialist, diagnostician	b. Specimen or culture maintained in official collection, taxonomic description by specialist	b. Other field or production surveys	b. Scientific or technical journal refereed
c. Scientist	c. Specimen in general collection	c. Casual or incidental field observation, possibly with no defined location/date	c. Official historical record
d. Technician	d. Description and photo	d. Observation with/in products or by-products; interception	d. Scientific or technical journal non-refereed
e. Expert amateur	e. Visual description only	e. Precise location and date not known	e. Specialist amateur publication
f. Non-specialist	f. Method of identification not known		f. Unpublished scientific or technical document
g. Collector/identifier not known			g. Non-technical publication; periodical/ newspaper
			h. Personal communication; unpublished

3. Pest Status in an Area

3.1 Describing pest status in an area

Determination of pest status requires expert judgement on the current distribution of a pest in an area. This judgement is based on a synthesis of pest records and information from other sources. Both current and historical records are used in assessing the present-day situation. Pest status can be described under the following categories:

3.1.1 Presence

A pest is present if records indicate that it is indigenous or introduced. If a pest is present and sufficient reliable records are available, then it may be possible to characterize its distribution using phrases, or a combinations of phrases, such as the following examples:

Present: in all parts of the area
Present: only in some areas[2]
Present: except in specified pest free areas
Present: in all parts of the area where host crop(s) are grown
Present: only in some areas where host crop(s) are grown[3]
Present: only in protected cultivation
Present: seasonally
Present: but managed[4]
Present: subject to official control
Present: under eradication
Present: at low prevalence.

Other similar descriptive phrases may be used, as appropriate. If few reliable records are available, it will be difficult to characterize the distribution.

As appropriate, it is useful to characterize the prevalence of the pest (e.g. common, occasional, rare), and the level of damage and/or losses caused by the pest on relevant hosts.

[2] Specify where possible.
[3] Specify where possible.
[4] According to: (details to be listed).

3.1.2 Absence

If there are no records of the presence of the pest in the general surveillance data of an area, it may be reasonable to conclude that a pest is or has always been absent. This may be supported by specific records of absence.

It is also possible to conclude that a pest is absent even if there are pest records suggesting the contrary. These different situations are described below. Absence may also be confirmed by specific surveys (see ISPM No. 6: *Guidelines for surveillance*) and, in that case, the phrase "**confirmed by survey**" should then be added. Similarly, when a pest free area is established according to the appropriate ISPM, (see ISPM No. 4: *Requirements for the establishment of pest free areas*) the phrase "Pest free area declared" should be added.

Absent: no pest records
General surveillance indicates that the pest is absent now and has never been recorded.

Absent: pest eradicated
Pest records indicate that the pest was present in the past. A documented pest eradication programme was conducted and was successful (see ISPM No. 9: *Guidelines for pest eradication programmes*). Surveillance confirms continued absence.

Absent: pest no longer present
Pest records indicate that the pest was transient or established in the past, but general surveillance indicates the pest is no longer present. The reason(s) may include:

- climate or other natural limitation to pest perpetuation
- changes in hosts cultivated
- changes in cultivars
- changes in agricultural practices.

Absent: pest records invalid
Pest records indicate the presence of a pest, but the conclusion is reached that the records are invalid or no longer valid, as in the following officially declared cases:

- changes in taxonomy
- misidentification
- erroneous record
- changes in national borders where reinterpretation of the record may be needed.

Absent: pest records unreliable
Pest records indicate the presence of a pest, but the determination leads to the conclusion that the records are unreliable, as in the following officially declared cases:

- ambiguous nomenclature
- outdated identification or diagnostic methods
- records cannot be considered reliable (see Table).

Absent: intercepted only
The pest has only been reported on consignments at a point of entry or initial destination or while under detention before release, treatment or destruction. Surveillance confirms that the pest has not established.

3.1.3 Transience

Pest status is considered transient when a pest is present but establishment is not expected to occur based on technical evaluation. There are three types of transience:

Transient: non-actionable
The pest has only been detected as an individual occurrence or isolated population not expected to survive and no phytosanitary measures have been applied.

Transient: actionable, under surveillance
The pest has been detected as an individual occurrence or an isolated population that may survive into the immediate future, but is not expected to establish. Appropriate phytosanitary measures, including surveillance are being applied.

Transient: actionable, under eradication
The pest has been detected as an isolated population which may survive into the immediate future and, without phytosanitary measures for eradication, may establish. Appropriate phytosanitary measures have been applied for its eradication.

3.2 Determination of pest status in an area

Determination of the status of a pest is provided by an NPPO. It results in deciding upon the most appropriate description of the pest status in an area (see Section 3.1) based on supporting information. This may include:

- individual pest records
- pest records from surveys
- records or other indication of pest absence
- results of general surveillance
- information from scientific publications and databases
- phytosanitary measures used to prevent introduction or spread
- other information relevant to assessing pest absence or presence.

The reliability and consistency of the information should be considered. In particular, careful judgement is needed when there is conflicting information.

4. Recommended Reporting Practices

Contracting parties have obligations under the IPPC (see New Revised Text: Article VIII 1a) to report "the occurrence, outbreak or spread of pests", of which, in the terms of this standard, information pertaining to "pest status in an area" is a part. This standard is not concerned with reporting obligations, but with the quality of the reported information. Accurate reports are an essential part of the international cooperation to facilitate trade. Failure to discover and report pests, or inaccurate, incomplete, untimely, or misinterpreted reports can lead to the establishment of unjustified trade barriers, or to the introduction and/or spread of pests.

Persons or organizations involved in collecting pest records should follow the recommendations in this standard, and provide the NPPO with accurate and complete details before reporting the information generally.

To observe good reporting practices, NPPOs should:

- base determinations of pest status in an area on the most reliable and timely information available
- take into account the categories and pest status determinations set out in this standard when exchanging pest status information between countries
- inform the NPPO of trading partners as soon as possible, and their Regional Plant Protection Organization (RPPO) where appropriate, of relevant changes in pest status and especially reports of newly established pests
- report interceptions of regulated pests which suggest a change in pest status in the exporting country to other countries only after consultation with the exporting country
- when becoming aware of an otherwise unreported record of a pest in another country, the NPPO may report it to other countries or RPPOs only after informing and where possible consulting with the NPPO concerned
- exchange pest status information in conformity with Articles VII (2j) and VIII (1a and 1c) of the IPPC to the extent practicable, and in a medium and language acceptable to both parties
- correct erroneous records as soon as possible.

APPENDIX

USEFUL REFERENCES

This listing is for reference purposes only. 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.

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INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 9

GUIDELINES FOR PEST ERADICATION PROGRAMMES

(1998)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in November 1998.

INTRODUCTION

SCOPE

This standard describes the components of a pest eradication programme which can lead to the establishment or re-establishment of pest absence in an area.

REFERENCES

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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*). The term and definition below were adopted as part of the present ISPM, but were amended subsequent to adoption of the standard. The new definition of this term does not conform to the use of the term in the present ISPM, and this term and definition are retained for the purpose of the present standard only, until it has been revised.

outbreak	An isolated pest population, recently detected and expected to survive for the immediate future.

OUTLINE OF REQUIREMENTS

A programme for pest eradication may be developed by a National Plant Protection Organization (NPPO) as:

- an emergency measure to prevent establishment and/or spread of a pest following its recent entry (re-establish a pest free area), or
- a measure to eliminate an established pest (establish a pest free area).

After a preliminary investigation that includes the consideration of data collected at the site(s) of detection or occurrence, the extent of the infestation, information on the biology and potential economic impact of the pest, current technology and available resources for eradication, a cost-benefit analysis of the pest eradication programme should be undertaken. Whenever possible, it is also useful to gather information concerning the geographical origin of the pest, and pathways for its reintroduction. Pest risk analysis (PRA) provides a scientific basis for informed decision-making (see ISPM No. 2: Guidelines for pest risk analysis). From these studies, one or more options should be made available to decision-makers. However, in an emergency situation, the benefits of speed of action in preventing spread may outweigh the benefits normally achieved through a more structured approach.

The eradication process involves three main activities: surveillance, containment, and treatment and/or control measures.

When an eradication programme is completed, the absence of the pest must be verified. The verification procedure should use criteria established at the beginning of the programme and should be supported by adequate documentation of programme activities and results. The verification stage is integral to the programme, and should involve independent analysis if trading partners require this reassurance. Successful programmes result in a declaration of eradication by the NPPO. When unsuccessful, all aspects of the programme should be reviewed, including the biology of the pest to determine if new information is available, and the cost-benefit of the programme.

GENERAL REQUIREMENTS FOR PEST ERADICATION PROGRAMMES

This standard provides guidance on the development of a pest eradication programme and for reviewing the procedures of an existing eradication programme. In most instances, the pests considered for these programmes have newly entered the area where eradication is undertaken, and emergency eradication measures may be needed. However, eradication programmes may also be directed toward established exotic pests or indigenous pests in defined areas.

1. General Information and Planning Processes

1.1 Evaluation of pest reports

NPPOs should systematically evaluate pest reports and the impact of these pests to determine if eradication is required. This evaluation will involve reporting to an official contact point and assessment by experts capable of considering the importance of the pest report and of recommending a course of action.

1.2 Contingency plans

It is desirable to have contingency plans to address specific pests or pest groups that have a high potential for introduction, and for which an eradication plan is deemed to be both feasible and necessary, before the pest is found in an area. The development of such plans is advantageous because it provides additional time for deliberation, evaluation and research necessary to ensure that an eradication programme is well designed and can be executed quickly and effectively. Such plans are particularly important where cooperative programmes are anticipated, as they allow for the actions of cooperating parties to be specified and agreed upon prior to implementing the programme. Knowledge gained from previous successful eradication programmes can be extremely useful for developing contingency plans or judging the feasibility of eradication programmes under consideration. A general contingency plan is also particularly useful for ensuring rapid action in the case of emergency eradication measures.

It should be recognized that the biology of pests varies considerably as do the technologies available for eradication. Therefore, not all the factors listed in this standard for consideration will be of value in planning every eradication programme.

1.3 Reporting requirements and information sharing

Verification of the occurrence of a new pest of immediate or potential danger initiates the process that leads to reporting requirements for the NPPO under the International Plant Protection Convention (see New Revised Text: Article VII 2j and Article VIII 1a and 1c) and is described in the ISPM No. 8: Determination of pest status in an area.

Prior to the implementation of a pest eradication programme, public information programmes or other means for sharing information with broader audiences such as growers, residents, and local governments, should be considered for raising the level of awareness and understanding of the programme.

2. Decision to Undertake an Eradication Programme

The decision to undertake an eradication programme results from an evaluation of the circumstances of detection of a pest, its identification, the risk identified by a pest-initiated PRA, estimation of the present and potential distribution of the pest, and assessment of the feasibility of conducting an eradication programme. It is normally good practice to give due consideration to all the elements recommended. However, this approach may be limited in practice by the availability of data and resources. Particularly in cases where emergency eradication measures seem necessary (e.g. recent entry of a pest capable of rapid dispersal), the need to take action rapidly should be carefully balanced and may outweigh the benefits of more detailed analyses and planning.

2.1 Initiation

The eradication programme may be initiated by detection of a new pest arising from general surveillance or specific surveys (see ISPM No. 6: Guidelines for surveillance). In the case of established pests, the eradication programme will be initiated by policy considerations (e.g. a decision taken to establish a pest free area).

2.2 Identification

Accurate identification of the pest is essential so that the appropriate means of eradication can be selected. NPPOs should proceed with the identification process recognizing that it may have to withstand scientific or legal challenge. Therefore, it may be appropriate to have the identification confirmed by acknowledged independent experts.

Identification may be immediate when the pest is easily and confidently recognized by the NPPO.

Identification methods may range from recognition based only on morphological characteristics to more sophisticated bioassay, chemical or genetic analyses. The method ultimately adopted by the NPPO will depend on the organism in question and the most widely accepted and practical means to confirm identification.

In cases where a conclusive identification is not immediately possible, the actions to be taken may be justified by other factors such as the extent of damage to host plants. In these circumstances it is important to conserve specimens for possible future analysis.

2.3 Estimating present and potential pest distribution

An estimate of the present distribution of the pest is necessary for both new and established pests. The potential distribution is usually of greater importance for new pests, but may have relevance as well in evaluating established pests. The data elements identified for initial investigation include a level of detail not necessarily required for a programme directed toward established pests.

2.3.1 Initial investigation

Data associated with the detection of a new pest, the geographical origin of the pest, and the pathway, should be compiled and reviewed. This information is not only useful for decision-making related to eradication, but is also helpful for identifying and correcting weaknesses in pest exclusion systems that may have contributed to the entry of the pest.

2.3.1.1 Data gathered at the site of detection or occurrence

Information should be gathered concerning the pest and conditions at the site of detection or occurrence, including:

- geographical location
- hosts infested at the site
- extent and impact of damage and level of pest prevalence
- how the pest was detected and identified
- recent imports of plants or plant products
- history of the pest on the property or in the area
- movement of people, products, equipment, conveyances
- mechanism of spread within the area
- climatic and soil conditions
- condition of infested plants
- cultivation practices.

2.3.1.2 Geographical origin

To the extent possible, information should be obtained on the country or area most likely to be the origin of the pest. Information concerning countries of re-export or transit may also be considered when attempting to determine the source and pathway.

2.3.1.3 Pathways of the pest

To the extent possible, the NPPO should determine the pathways by which the pest may have entered or spread, to ensure that eradication programmes are not jeopardized by new pest entries, and to help identify potential exclusion options. Pathway information includes identifying the commodities or items that may have carried the pest as well as the possible mode of movement. Where there is a possible association with newly imported plants or plant products, similar material should be located and examined.

2.3.2 Survey for distribution

The preliminary processes should provide sufficient information to determine if a survey is required.

Surveys may be of various types:

- delimiting survey at each outbreak
- survey based on pathway studies
- other targeted surveys.

These surveys should be designed and executed to provide the level of statistical confidence necessary for the results to be meaningful for regulatory purposes.

In cases where survey data are to provide the basis for establishing a pest free area for export purposes, it may be desirable to consult trading partners in advance to determine the quantity and quality of data necessary to meet their phytosanitary requirements.

2.3.3 Predicting spread

Data collected during a preliminary investigation should be used to estimate the potential for spread and the anticipated rate of spread, and to identify endangered areas.

2.4 Feasibility of undertaking an eradication programme

An estimate of the impact and extent of the infestation, the potential for spread, and the anticipated rate of spread is necessary to judge the feasibility of an eradication programme. PRA provides a scientific basis for this estimate (see ISPM No. 2: Guidelines for pest risk analysis). Possible eradication options and cost-benefit factors should also be considered.

2.4.1 Biological and economic information

Information needs to be obtained on:

- pest biology
- potential hosts
- potential spread and anticipated rate of spread
- possible eradication strategies:
  - financial and resource costs
  - availability of the technology
  - logistical and operational limitations
- impact on industry and the environment:
  - without eradication
  - with each eradication option identified.

2.4.2 Conducting cost-benefit analysis for eradication programmes

One of the first actions to be taken is the preparation of a list of the most feasible eradication techniques. The total cost and the cost-benefit ratio for each strategy should be estimated over the short and long term. The option to take no action, or to take a pest management approach, should be considered as well as eradication options.

All feasible options should be described or discussed with decision-makers. Anticipated advantages and disadvantages, including cost-benefit should be outlined to the extent possible. One or more options should be recommended, recognizing that the ultimate decision requires consideration of the technical options, cost-benefit, the availability of resources, and political and socio-economic factors.

3. Eradication Process

The eradication process involves the establishment of a management team followed by the conduct of the eradication programme, which should, where possible, follow an established plan. Three main activities are included in the programme:

- surveillance: to fully investigate the distribution of the pest
- containment: to prevent the spread of the pest
- treatment: to eradicate the pest when it is found.

Direction and coordination should be provided by a management authority (normally the NPPO), ensuring that criteria are established to determine when eradication has been achieved and that appropriate documentation and process controls exist to provide sufficient confidence in the results. It may be necessary to consult with trading partners over some aspects of the eradication process.

3.1 Establishment of a management team

A management team is established to provide direction and coordination to eradication activities once it has been decided to undertake an eradication programme. The size of the management team will vary depending on the scope of the programme and the resources available to the NPPO. Large programmes may require a steering committee or an advisory group including the various interest groups that may be affected. Where a programme includes several countries, a regional steering committee should be considered.

The management team should have responsibility for:

- ensuring that the eradication programme meets the agreed criteria for successful eradication
- formulating, implementing, and modifying as necessary an eradication plan
- ensuring programme operators have appropriate authority and training to undertake their duties
- financial and resource management

- appointing and defining duties of operators, ensuring operators understand their responsibilities, and documenting their activities
- managing communication, including a public relations programme
- communicating with affected parties, e.g. growers, traders, other government departments and non-governmental organizations
- implementing an information management system, including programme documentation and appropriate record-keeping
- daily management of the programme
- continuous monitoring and evaluation of critical elements
- periodic overall programme review.

3.2 Conducting the eradication programme

3.2.1 Surveillance

A delimiting survey should be completed either initially or to confirm earlier surveys. Monitoring surveys should then continue in accordance with the eradication plan to check the distribution of the pest and assess the effectiveness of the eradication programme (see ISPM No 6: Guidelines for surveillance). Surveillance may include a pathway analysis to identify the source of the pest and its possible spread, the inspection of clonally and/or contact-linked material, inspection, trapping, and aerial observation. This may also include targeted inquiries to growers, those responsible for storage and handling facilities, and the public.

3.2.2 Containment

The NPPO should define a quarantine area using surveillance information. The initial investigations will provide information that is used to identify plants, plant products, or other articles whose movement out of the quarantine area needs to be regulated to prevent the spread of the pest. Owners of affected plants, plant products and other regulated articles should be notified of the regulations. Others interested or affected by regulations should also be provided with adequate information. It may be appropriate to verify compliance using methods described in the eradication plan.

Arrangements should be made for the release of plants, plant products or other regulated articles from the quarantine area, by clearance following verification of compliance with phytosanitary measures such as inspection, treatment or destruction. Provision should be made for the withdrawal of regulations when an eradication programme has been declared to be successful.

3.2.3 Treatment and/or control measures

Methods to eradicate pests may include:

- host destruction
- disinfestation of equipment and facilities
- chemical or biological pesticide treatment
- soil sterilants
- leaving land fallow
- host-free periods
- the use of cultivars that suppress or eliminate pest populations
- restriction of subsequent cropping
- trapping, lures or other physical control methods
- inundative release of biological control agents
- use of sterile insect technique
- processing or consumption of infested crop.

In most cases, eradication will involve the use of more than one treatment option. The selection of treatment and/or control options may be limited by legislative restrictions or other factors. In such situations, exceptions for emergency or limited use may be available to the NPPO.

3.3 Verification of pest eradication

This involves verification by the management authority (normally the NPPO) that the criteria for successful pest eradication established at the beginning of the programme have been achieved. The criteria may specify the intensity of the detection method and how long the survey must continue to verify the absence of the pest. The minimum period of time of pest freedom to verify eradication will vary according to the biology of the pest, but should take into consideration factors such as:

- sensitivity of detection technology
- ease of detection

- life cycle of the pest
- climatic effects
- efficacy of treatment.

The eradication plan should specify the criteria for a declaration of eradication and steps for the withdrawal of regulations.

3.4 Documentation

NPPOs should ensure that records are kept of information supporting all stages of the eradication process. It is essential that NPPOs maintain such documentation in case trading partners request information to support claims of pest freedom.

3.5 Declaration of eradication

A declaration of eradication by the NPPO follows the completion of a successful eradication programme. The status of the pest in the area is then **'absent: pest eradicated'** (see ISPM No. 8: *Determination of pest status in an area*). It involves communication with affected and interested parties, as well as appropriate authorities concerning the fulfilment of programme objectives. Programme documentation and other relevant evidence supporting the declaration should be made available to other NPPOs upon request.

4. Programme Review

Throughout the eradication, the programme should be subject to periodic review to analyse and assess information gathered, to check that objectives are being achieved, and/or to determine if changes are required. Reviews should take place at:

- any time when unforeseen circumstances are encountered that could affect the programme
- pre-set intervals
- the termination of the programme.

Where the criteria for eradication are not met, the eradication plan should be reviewed. This review should take into account any newly gained knowledge that might have contributed to that result. Cost-benefit factors and operational details should be reviewed to identify inconsistencies with initial predictions. Depending on the outcome, a new eradication plan may be developed or altered to become a pest suppression or pest management programme.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 10

REQUIREMENTS FOR THE ESTABLISHMENT OF PEST FREE PLACES OF PRODUCTION AND PEST FREE PRODUCTION SITES

(1999)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in October 1999.

INTRODUCTION

SCOPE

This standard describes the requirements for the establishment and use of pest free places of production and pest free production sites as risk management options for meeting phytosanitary requirements for the import of plants, plant products and other regulated articles.

REFERENCES

Glossary of phytosanitary terms, 1999. ISPM No. 5, FAO, Rome.
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Principles of plant quarantine as related to international trade, 1995. ISPM 1, FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.
Determination of Pest Status in an Area, 1998. ISPM No. 8, 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 uses the concept of "pest freedom" to allow exporting countries to provide assurance to importing countries that plants, plant products and other regulated articles are free from a specific pest or pests and meet the phytosanitary requirements of the importing country when imported from a pest free place of production. In circumstances where a defined portion of a place of production is managed as a separate unit and can be maintained pest free, it may be regarded as a pest free production site. The use of pest free places of production or pest free production sites is dependent on the use of criteria concerning the biology of the pest, the characteristics of the place of production, the operational capabilities of the producer, and the requirements and responsibilities of the National Plant Protection Organization (NPPO).

Requirements for the establishment and maintenance of a pest free place of production or a pest free production site as a phytosanitary measure by the NPPO, include:

- systems to establish pest freedom
- systems to maintain pest freedom
- verification that pest freedom has been attained or maintained
- product identity, consignment integrity and phytosanitary security.

Where necessary, a pest free place of production or a pest free production site also includes the establishment and maintenance of an appropriate buffer zone.

Administrative activities required to support a pest free place of production or pest free production site involve documentation of the system and the maintenance of adequate records concerning the measures taken. Review and audit procedures undertaken by the NPPO are essential to support assurance of pest freedom and for system appraisal. Bilateral agreements or arrangements may also be needed.

1. CONCEPT OF A PEST FREE PLACE OF PRODUCTION OR PEST FREE PRODUCTION SITE

1.1 Application of a Pest Free Place of Production and Pest Free Production Site

A "pest free place of production" is a: "place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period". It provides a means for an exporting country, if so required by an importing country, to ensure that consignments of plants, plant products or other regulated articles produced on, and/or moved from, the place of production are free from the pest concerned, because it has been shown to be absent from that place over a relevant period of time. Pest freedom is established by surveys and/or growing season inspections and maintained as necessary by other systems to prevent the entry of the pest into the place of production. The operations are supported by appropriate documentation.

Depending on the pest concerned, local circumstances and the acceptable level of risk for the importing country, an adequate level of security may be achieved by different intensities of measures, ranging from a simple growing-season inspection in the year of export to a complex system of surveys and supporting procedures maintained over several years.

The concept of a pest free place of production can be applied to any premises or collection of fields operated as a single production unit. The producer applies the required measures to the entire place of production.

Where a defined portion of a place of production can be managed as a separate unit within a place of production, it may be possible to maintain that site pest free. In such circumstances, the place of production is considered to contain a pest free production site.

Where the biology of the pest is such that it is likely to enter the place of production or production site from adjacent areas, it is necessary to define a buffer zone around the place of production or production site within which appropriate phytosanitary measures are applied. The extent of the buffer zone and the nature of the phytosanitary measures will depend on the biology of the pest and the intrinsic characteristics of the place of production or production site.

1.2 Distinction between a Pest Free Place of Production or a Pest Free Production Site and a Pest Free Area

The concept of the pest free place of production is distinct from that of the pest free area (see ISPM No. 4: Requirements for the establishment of pest free areas). The pest free area has the same objective as the pest free place of production but is implemented in a different way. Every distinction between a pest free place of production and a pest free area applies equally to a pest free production site.

A pest free area is much larger than a place of production, includes many places of production and may extend to a whole country or parts of several countries. A pest free area may be isolated by a natural barrier or an appropriate usually large buffer zone. A pest free place of production may be situated in an area where the pest concerned is prevalent and is isolated, if at all, by creating a buffer zone in its immediate vicinity. A pest free area is generally maintained over many years without interruption, whereas the status of a pest free place of production may be maintained for only one or a few growing seasons. A pest free area is managed as a whole, by the NPPO of the exporting country. A pest free place of production is managed individually by the producer, under the supervision and responsibility of the NPPO. If the pest is found in a pest free area, the status of the whole area is called into question. If it is found in a pest free place of production, that place loses its status but other places of production in the area operating the same system are not directly affected. These distinctions may not always apply in particular cases. A place of production lying in a pest free area may satisfy, by that fact, the requirements for a pest free place of production, although the importing country may require verification.

The choice of a pest free place of production or pest free area as a management option will depend on the actual distribution of the pest concerned in the exporting country, on the characteristics of the pest and on administrative considerations. Both systems can offer adequate phytosanitary security: the main security of the pest free area lies in the common application of measures to an area covering many places of production; the main security of the pest free place of production arises from the fact that management procedures, surveys and inspections are applied specifically and intensively to it.

2. GENERAL REQUIREMENTS

2.1 Critical Factors for Pest Free Places of Production or Pest Free Production Sites

The possibility of ensuring that a place of production or a production site is pest free depends on:

- characteristics of the pest
- characteristics of the place of production and production site
- operational capabilities of the producer
- requirements and responsibilities of the NPPO.

2.1.1 Characteristics of the pest

A place of production or a production site can be declared free from a given pest to an adequate degree of security if the characteristics of the pest are suitable for this. Suitable characteristics may include the following:

- the natural spread of the pest (or its vectors, if appropriate) is slow and over short distances
- the possibilities for artificial spread of the pest are limited
- the pest has a limited host range
- the pest has a relatively low probability of survival from previous seasons
- the pest has a moderate or low rate of reproduction
- sufficiently sensitive methods for detection of the pest are available, either by visual inspection or by tests applied in the field or in the laboratory, at the appropriate season
- as far as possible, factors in the biology of the pest (e.g. latency) and in the management of the place of production do not interfere with detection.

The availability of effective and practical measures for control and management of the pest is also an advantage in establishing and maintaining a pest free place of production or pest free production site.

2.1.2 Characteristics of the place of production or production site

The basic definition of a "place of production" should be satisfied (i.e. operated as a single production or farming unit). Depending on the pest concerned and local circumstances, a place of production and production site as well as the buffer zone, as appropriate, may also require some of the following additional characteristics:

- location at a sufficient distance from possible sources of pest infestation, with appropriate isolation (advantage being taken of physical features that can act as barriers to pest movement)
- clear delimitation, with officially recognized boundaries
- access to the buffer zone (if appropriate)
- absence, in the place of production or production site of hosts of the pest other than those meeting the conditions for export
- absence in the buffer zone (if appropriate) of hosts of the pest or adequate control of the pest on these hosts.

2.1.3 Operational capabilities of the producer

The producer should have defined management, technical and operational capabilities which are considered by the NPPO to be adequate to prevent the pest from entering the place of production or production site, and to maintain pest freedom by the application of appropriate phytosanitary measures. The producer or NPPO should also have the ability to apply appropriate phytosanitary measures in the buffer zone if necessary.

2.1.4 Requirements and responsibilities of the NPPO

The NPPO should define the particular requirements which a producer must meet in order that its declaration of a pest free place of production or pest free production site gives the required level of phytosanitary security. The NPPO is responsible for the surveys, inspections and other systems that verify pest freedom. For any given pest and host, the management systems required are generally widely known and can be used in any country. Where appropriate, the NPPO may provide training in these management systems. The NPPO should check the regulations of the importing country and/or bilaterally establish conditions to ensure that compliance can be achieved.

2.2 Establishment and Maintenance of Pest Free Places of Production or Pest Free Production Sites

There are four main components the NPPO should consider in establishing and maintaining pest free places of production or pest free production sites. These are:

- systems to establish pest freedom
- systems to maintain pest freedom
- verification that pest freedom has been attained or maintained
- product identity, consignment integrity and phytosanitary security.

2.2.1 Systems to establish pest freedom

The NPPO should normally specify a set of conditions to be met by the producer, enabling the place of production or production site to be subsequently declared pest free. These requirements will concern the characteristics of the place of production or production site (and the buffer zone, if appropriate) and the operational capabilities of the producer. Formal agreements may be required between the producers (or their organizations) and the NPPO to ensure that specific measures are taken.

In some cases, the NPPO may require that pest freedom should be verified by official surveys for one or more years

before the year in which consignments are certified for export. The methods used to verify freedom in this way may be the same as, or different from, those used for verifying freedom in the year of export (see section 2.2.3). In other cases, the NPPO may only require that pest freedom be verified in the year of production. In any case, the objective of the NPPO and the producers will generally be to maintain the pest free status of a place of production or production site continuously over a period of years. Specific provisions should be made for the withdrawal of pest free status if the pest is detected in the pest free place of production or pest free production site or a buffer zone meant to be pest free, and for the eventual re-establishment and verification of pest free status, including investigation into the cause and consideration of the measures to prevent future failure.

In the case where pest free production sites are established, delimiting surveys may be used to determine their extent.

2.2.2 Systems to maintain pest freedom

The NPPO should generally require that specific measures be applied to the place of production or production site (and buffer zone, if appropriate) before and/or during the growing season, and is responsible for general supervision of the place of production or production site to ensure that these requirements are met. Their aim is to prevent the introduction of the pest into the place of production or production site, or to destroy previously undetected infestations. These measures may include:

- preventive measures (e.g. pest free propagating material, elimination of other hosts)
- exclusion measures (e.g. physical barriers, screens, controls on equipment, machinery, plants, soil and growing media)
- pest control measures (e.g. cultural methods, treatments, and resistant cultivars).

The producer should be required to:

- notify the NPPO of any suspected or actual occurrences of the pest
- maintain relevant records of cultural and pest control procedures for the time period designated by the NPPO.

2.2.3 Verification that pest freedom has been attained or maintained

The verification of pest free status is done by NPPO personnel or by persons duly authorized by the NPPO, who undertake the specific surveys to assess the pest free status of the place of production or production site (and the buffer zone, if required). These most often take the form of field inspections (also known as growing-season inspections), but may also include other detection methods (sampling followed by laboratory testing, trapping, soil tests, etc.).

Pest free status may be verified by a stated number or frequency of inspections or tests (e.g. three inspections at monthly intervals). The inspections or other procedures may concern a single growing season, or may be required over several seasons. Inspection or testing of the harvested commodity may be required at the place of production or production site. Pest freedom over a number of years may also be required and the growing of host plants on the site in previous years may be prohibited.

Verification procedures should be based on a design, which should relate to the division of the place of production into individual plots, and may, according to the pest and its symptoms, be conducted by overall estimation or by taking samples. The prevalence of the pest in the area surrounding the pest free place of production or pest free production site may influence the intensity of the survey required.

2.2.4 Product identity, consignment integrity and phytosanitary security

Verification measures may be needed to maintain the identity of the product (labelling to ensure traceability to the pest free place of production) and the integrity of the consignment. The phytosanitary security of the product should be maintained after harvest.

2.3 Buffer Zone Requirements

In appropriate cases, the establishment and maintenance of a pest free place of production or pest free production site include procedures related to the buffer zone associated with the place of production or production site.

The extent of the buffer zone should be determined by the NPPO, on the basis of the distance over which the pest is likely to spread naturally during the course of the growing season. Monitoring surveys should be conducted at adequate frequency over one or more growing seasons. The action to be taken, if the pest is detected in the buffer zone, will depend on the requirements of the NPPO. The pest free status of the place of production or production site may be withdrawn or appropriate control measures may be required in the buffer zone. In any case, access for surveys or control measures should be verified in advance. If appropriate, adequate procedures may be established to support the assurance that pest freedom is maintained (local reporting/notification and publicity, local regulation, control/elimination of detected pests).

3. DOCUMENTATION AND REVIEW

The measures taken in establishing and maintaining a pest free place of production or pest free production site, including those taken in the buffer zone, if appropriate, should be adequately documented and periodically reviewed. The NPPO should institute procedures for on-site audit, review and systems' appraisal.

3.1 General Records

Documentation should be available, as appropriate, on the administrative system applied by the NPPO for the establishment of pest free places of production or pest free production sites in general, and in relation to the particular pest(s) concerned. This includes details of the surveillance systems used (including inspection, survey and monitoring), of the procedures for reaction to pest presence, and of the procedures to ensure product identity, consignment integrity and phytosanitary security.

Documentation should also be available, as appropriate, on the specific actions taken at a place of production or a production site and any associated buffer zone in relation to the approval of pest free status for a particular growing season, including the results of surveys and the pest management records (e.g. types and dates of phytosanitary treatments, use of resistant cultivars).

The procedures for withdrawal and reinstatement of pest free status should be documented.

When complex measures are needed to establish and maintain a pest free place of production or pest free production site, because the pest concerned requires a high degree of phytosanitary security, an operational plan may be needed. Where appropriate, such a plan would be based on bilateral agreements or arrangements listing specific details required in the operation of the system including the role and responsibilities of the producer and trader(s) involved.

3.2 Additional Declaration on Phytosanitary Certificates

The issuance of a phytosanitary certificate for a consignment by the NPPO confirms that the requirements for a pest free place of production or a pest free production site have been fulfilled. The importing country may require an appropriate additional declaration on the phytosanitary certificate to this effect.

3.3 Provision of Information

The NPPO of the exporting country should, on request, make available to the NPPO of the importing country the rationale for establishment and maintenance of pest free places of production or pest free production sites. Where bilateral arrangements or agreements so provide, the NPPO of the exporting country should expeditiously provide information concerning establishment or withdrawal of pest free places of production or pest free production sites to the NPPO of the importing country.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 11

PEST RISK ANALYSIS FOR QUARANTINE PESTS INCLUDING ANALYSIS OF ENVIRONMENTAL RISKS AND LIVING MODIFIED ORGANISMS

(2004)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

ISPM No. 11 was endorsed by the Interim Commission on Phytosanitary Measures in April 2001. In April 2003, the Interim Commission on Phytosanitary Measures endorsed a supplement to ISPM No. 11 (Pest risk analysis for quarantine pests) on analysis of environmental risk and agreed that it should be integrated into ISPM No. 11. This resulted in ISPM No. 11 Rev. 1 (Pest risk analysis for quarantine pests including analysis of environmental risks). In April 2004, the Interim Commission on Phytosanitary Measures endorsed a supplement on pest risk analysis for living modified organisms (LMOs) and agreed that it should be integrated into ISPM No. 11 Rev. 1. This has been done to produce the present standard, ISPM No. 11 (2004). The supplementary text on environmental risks is marked with "*S1*" and the supplementary text on LMOs is marked with "*S2*".

The Interim Commission on Phytosanitary Measures acknowledges the collaboration and support of the Secretariat of the Convention on Biological Diversity, as well as the participation of experts from Parties to the Convention, in the preparation of the supplements to ISPM No. 11.

INTRODUCTION[1]

SCOPE

The standard provides details for the conduct of pest risk analysis (PRA) to determine if pests are quarantine pests. It describes the integrated processes to be used for risk assessment as well as the selection of risk management options.

S1 It also includes details regarding the analysis of risks of plant pests to the environment and biological diversity, including those risks affecting uncultivated/unmanaged plants, wild flora, habitats and ecosystems contained in the PRA area. Some explanatory comments on the scope of the IPPC in regard to environmental risks are given in Annex 1.

S2 It includes guidance on evaluating potential phytosanitary risks to plants and plant products posed by living modified organisms (LMOs). This guidance does not alter the scope of ISPM No. 11 but is intended to clarify issues related to the PRA for LMOs. Some explanatory comments on the scope of the IPPC in regard to PRA for LMOs are given in Annex 2.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
S2 *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2000. CBD, Montreal.
S2 *Code of conduct for the import and release of biological control agents*, 1996. ISPM No. 3, FAO, Rome.
S2 *Convention on Biological Diversity*, 1992. CBD, Montreal.
Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.
Export certification system, 1997. ISPM No. 7, FAO, Rome
S2 *Glossary of Biotechnology for Food and Agriculture*, 2002. Research and Technology Paper 9, FAO, Rome.
Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.
S2 *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.
S2 *Glossary supplement No. 2: Guidelines on the understanding 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.
S2 *Guidelines for phytosanitary certificates*, 2001. ISPM No. 12, 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.
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*).

[1] Throughout this text, *S1* indicates the supplementary text on environmental risks and *S2* the supplementary text on living modified organisms. See complete explanation in the section *Endorsement* on page 1.

OUTLINE OF REQUIREMENTS

The objectives of a PRA are, for a specified area, to identify pests and/or pathways of quarantine concern and evaluate their risk, to identify endangered areas, and, if appropriate, to identify risk management options. Pest risk analysis (PRA) for quarantine pests follows a process defined by three stages:

Stage 1 (initiating the process) involves identifying the pest(s) and pathways that are of quarantine concern and should be considered for risk analysis in relation to the identified PRA area.

Stage 2 (risk assessment) begins with the categorization of individual pests to determine whether the criteria for a quarantine pest are satisfied. Risk assessment continues with an evaluation of the probability of pest entry, establishment, and spread, and of their potential economic consequences (including environmental consequences - S1).

Stage 3 (risk management) involves identifying management options for reducing the risks identified at stage 2. These are evaluated for efficacy, feasibility and impact in order to select those that are appropriate.

PEST RISK ANALYSIS FOR QUARANTINE PESTS

1. Stage 1: Initiation

The aim of the initiation stage is to identify the pest(s) and pathways which are of quarantine concern and should be considered for risk analysis in relation to the identified PRA area.

S2 Some LMOs may present a phytosanitary risk and therefore warrant a PRA. However other LMOs will not present phytosanitary risks beyond those posed by related non-LMOs and therefore will not warrant a complete PRA. Thus, for LMOs, the aim of the Initiation stage is to identify those LMOs that have the characteristics of a potential pest and need to be assessed further, and those which need no further assessment under ISPM No. 11.

S2 LMOs are organisms that have been modified using techniques of modern biotechnology to express one or more new or altered traits. In most cases, the parent organism is not normally considered to be a plant pest but an assessment may need to be performed to determine if the genetic modification (i.e. gene, new gene sequence that regulates other genes, or gene product) results in a new trait or characteristic that may present a plant pest risk.

S2 A plant pest risk from LMOs may be presented by:

- the organism(s) with the inserted gene(s) (i.e. the LMO)
- the combination of genetic material (e.g. gene from plant pests such as viruses) or
- the consequences of the genetic material moving to another organism.

1.1 Initiation points

The PRA process may be initiated as a result of:

- the identification of a pathway that presents a potential pest hazard
- the identification of a pest that may require phytosanitary measures
- the review or revision of phytosanitary policies and priorities.

S1 The initiation points frequently refer to "pests". The IPPC defines a pest as "any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products." In applying these initiation points to the specific case of plants as pests, it is important to note that the plants concerned should satisfy this definition. Pests directly affecting plants satisfy this definition. In addition, many organisms indirectly affecting plants also satisfy this definition (such as weeds/invasive plants). The fact that they are injurious to plants can be based on evidence obtained in an area where they occur. In the case of organisms where there is insufficient evidence that they affect plants indirectly, it may nevertheless be appropriate to assess on the basis of available pertinent information, whether they are potentially injurious in the PRA area by using a clearly documented, consistently applied and transparent system. This is particularly important for plant species or cultivars that are imported for planting.

S2 The types of LMOs that an NPPO may be asked to assess for phytosanitary risk include:

- plants for use (a) as agricultural crops, for food and feed, ornamental plants or managed forests; (b) in bioremediation (as an organism that cleans up contamination); (c) for industrial purposes (e.g. production of enzymes or bioplastics); (d) as therapeutic agents (e.g. pharmaceutical production)
- biological control agents modified to improve their performance in that role
- pests modified to alter their pathogenic characteristic and thereby make them useful for biological control (see ISPM No. 3: Code of conduct for the import and release of exotic biological control agents)
- organisms genetically modified to improve their characteristics such as for biofertilizer or other influences on soil, bioremediation or industrial uses.

S2 In order to be categorized as a pest, an LMO has to be injurious or potentially injurious to plants or plant products under conditions in the PRA area. This damage may be in the form of direct effects on plants or plant products, or indirect effects. For guidance on the process of determining whether an LMO has the potential to be a pest, refer to Annex 3, Determining the potential for a living modified organism to be a pest.

1.1.1 PRA initiated by the identification of a pathway

The need for a new or revised PRA of a specific pathway may arise in the following situations:

- international trade is initiated in a commodity not previously imported into the country (usually a plant or plant product, including genetically altered plants) or a commodity from a new area or new country of origin
- new plant species are imported for selection and scientific research purposes
- a pathway other than commodity import is identified (natural spread, packing material, mail, garbage, passenger baggage, etc.).

A list of pests likely to be associated with the pathway (e.g. carried by the commodity) may be generated by any combination of official sources, databases, scientific and other literature, or expert consultation. It is preferable to prioritize the listing, based on expert judgement on pest distribution and types of pests. If no potential quarantine pests are identified as likely to follow the pathway, the PRA may stop at this point.

S2 The phrase "genetically altered plants" is understood to mean plants obtained through the use of modern biotechnology.

1.1.2 PRA initiated by the identification of a pest

A requirement for a new or revised PRA on a specific pest may arise in the following situations:

- an emergency arises on discovery of an established infestation or an outbreak of a new pest within a PRA area
- an emergency arises on interception of a new pest on an imported commodity
- a new pest risk is identified by scientific research
- a pest is introduced into an area
- a pest is reported to be more damaging in an area other than in its area of origin
- a pest is repeatedly intercepted
- a request is made to import an organism
- an organism is identified as a vector for other pests
- an organism is genetically altered in a way which clearly identifies its potential as a plant pest.

S2 The phrase "genetically altered" is understood to include obtained through the use of modern biotechnology.

1.1.3 PRA initiated by the review or revision of a policy

A requirement for a new or revised PRA originating from policy concerns will most frequently arise in the following situations:

- a national decision is taken to review phytosanitary regulations, requirements or operations
- a proposal made by another country or by an international organization (RPPO, FAO) is reviewed
- a new treatment or loss of a treatment system, a new process, or new information impacts on an earlier decision
- a dispute arises on phytosanitary measures
- the phytosanitary situation in a country changes, a new country is created, or political boundaries have changed.

1.2 Identification of PRA area

The PRA area should be defined as precisely as possible in order to identify the area for which information is needed.

1.3 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(s), its/their present distribution and association with host plants, commodities, etc. Other information will be gathered as required to reach necessary decisions as the PRA continues.

Information for PRA may come from a variety of sources. The provision of official information regarding pest status is an obligation under the IPPC (Art. VIII.1c) facilitated by official contact points (Art. VIII.2).

S1 For environmental risks, the variety of sources of information will generally be wider than traditionally used by NPPOs. Broader inputs may be required. These sources may include environmental impact assessments, but it should be recognized that such assessments usually do not have the same purpose as PRA and cannot substitute for PRA.

S2 For LMOs, information required for a full risk analysis may include:

- name, identity and taxonomic status of the LMO (including any relevant identifying codes) and the risk management measures applied to the LMO in the country of export
- taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism
- description of the nucleic acid or the modification introduced (including genetic construct) and the resulting genotypic and phenotypic characteristics of the LMO
- details of the transformation process
- appropriate detection and identification methods and their specificity, sensitivity and reliability
- intended use including intended containment
- quantity or volume of the LMO to be imported.

S2 Information regarding pest status is an obligation under the IPPC (Article VIII.1c) facilitated by official contact points (Article VIII.2). A country may have obligations to provide information about LMOs under other international agreements such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000; Cartagena Protocol). The Cartagena Protocol has a Biosafety Clearing-house that may contain relevant information. Information on

LMOs is sometimes commercially sensitive and applicable obligations with regard to release and handling of information should be observed.

1.3.1 Previous PRA

A check should also be made as to whether pathways, pests or policies have already been subjected to the PRA process, either nationally or internationally. If a PRA exists, its validity should be checked as circumstances and information may have changed. The possibility of using a PRA from a similar pathway or pest, that may partly or entirely replace the need for a new PRA, should also be investigated.

1.4 Conclusion of initiation

At the end of Stage 1, the initiation point, the pests and pathways of concern and the PRA area will have been identified. Relevant information has been collected and pests have been identified as possible candidates for phytosanitary measures, either individually or in association with a pathway.

S2 For LMOs at the end of Stage 1 an NPPO may decide that the LMO:

- is a potential pest and needs to be assessed further in Stage 2 or
- is not a potential pest and needs no further analysis under ISPM No. 11 (but see also the following paragraph).

S2 PRA under the IPPC only relates to the assessment and management of phytosanitary risks. As with other organisms or pathways assessed by an NPPO, LMOs may present other risks not falling within the scope covered by the IPPC. For LMOs, PRA may constitute only a portion of the required overall risk analysis. For example, countries may require the assessment of risks to human or animal health or to the environment beyond that covered by the IPPC. When an NPPO discovers potential for risks that are not phytosanitary it may be appropriate to notify the relevant authorities.

2. Stage 2: Pest Risk Assessment

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

- pest categorization
- assessment of the probability of introduction and spread
- assessment of potential economic consequences (including environmental impacts).

In most cases, these 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 (FAO, 1995).

S2 For LMOs, from this point forward in PRA, it is assumed that the LMO is being assessed as a pest and therefore "LMO" refers to an LMO that is a potential quarantine pest due to new or altered characteristics or properties resulting from the genetic modification. The risk assessment should be carried out on a case-by-case basis. LMOs that have pest characteristics unrelated to the genetic modification should be assessed using the normal procedures.

2.1 Pest categorization

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

In the evaluation of a pathway associated with a commodity, a number of individual PRAs may be necessary for the various pests potentially associated with the pathway. 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 relatively little information, however information should be sufficient to adequately carry out the categorization.

2.1.1 Elements of categorization

The categorization of a pest as a quarantine pest includes the following primary elements:

- identity of the pest
- presence or absence in the PRA area
- regulatory status
- potential for establishment and spread in PRA area
- potential for economic consequences (including environmental consequences) in the PRA area.

2.1.1.1 Identity of pest

The identity of the pest should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological and other information used in the assessment is relevant to the organism in question. If this is not possible because the causal agent of particular symptoms has not yet been fully identified, then it should have been shown to produce consistent symptoms and to be transmissible.

The taxonomic unit for the pest is generally species. The use of a higher or lower taxonomic level should be supported by scientifically sound rationale. In the case of levels below the species, this should include evidence demonstrating that factors such as differences in virulence, host range or vector relationships are significant enough to affect phytosanitary status.

In cases where a vector is involved, the vector may also be considered a pest to the extent that it is associated with the causal organism and is required for transmission of the pest.

S2 In the case of LMOs, identification requires information regarding characteristics of the recipient or parent organism, the donor organism, the genetic construct, the gene or transgene vector and the nature of the genetic modification. Information requirements are set out under section 1.3.

2.1.1.2 Presence or absence in PRA area

The pest should be absent from all or a defined part of the PRA area.

S2 In the case of LMOs, this should relate to the LMO of phytosanitary concern.

2.1.1.3 Regulatory status

If the pest is present but not widely distributed in the PRA area, it should be under official control or expected to be under official control in the near future.

S1 Official control of pests presenting an environmental risk may involve agencies other than the NPPO. However, it is recognized that ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1 on official control, in particular Section 5.7, applies.

S2 In the case of LMOs, official control should relate to the phytosanitary measures applied because of the pest nature of the LMO. It may be appropriate to consider any official control measures in place for the parent organism, donor organism, transgene vector or gene vector.

2.1.1.4 Potential for establishment and spread in PRA area

Evidence should be available to support the conclusion that the pest could become established or spread in the PRA area. The PRA area should have ecological/climatic conditions including those in protected conditions suitable for the establishment and spread of the pest and where relevant, host species (or near relatives), alternate hosts and vectors should be present in the PRA area.

S2 For LMOs, the following should also be considered:

- changes in adaptive characteristics resulting from the genetic modification that may increase the potential for establishment and spread
- gene transfer or gene flow that may result in the establishment and spread of pests, or the emergence of new pests
- genotypic and phenotypic instability that could result in the establishment and spread of organisms with new pest characteristics, e.g. loss of sterility genes designed to prevent outcrossing.

S2 For more detailed guidance on the assessment of these characteristics, see Annex 3.

2.1.1.5 Potential for economic consequences in PRA area

There should be clear indications that the pest is likely to have an unacceptable economic impact (including environmental impact) in the PRA area.

S1 Unacceptable economic impact is described in ISPM No. 5, Glossary of phytosanitary terms, Supplement No. 2: Guidelines on the understanding of potential economic importance and related terms.

S2 In the case of LMOs, the economic impact (including environmental impact) should relate to the pest nature (injurious to plants and plant products) of the LMO.

2.1.2 Conclusion of pest categorization

If it has been determined that the pest has the potential to be a quarantine pest, the PRA process should continue. If a pest does not fulfil all of the criteria for a quarantine pest, the PRA process for that pest may stop. In the absence of sufficient information, the uncertainties should be identified and the PRA process should continue.

2.2 Assessment of the probability of introduction and spread

Pest introduction is comprised of both entry and establishment. Assessing the probability of introduction requires an analysis of each of the pathways with which a pest may be associated from its origin to its establishment in the PRA area. In a PRA initiated by a specific pathway (usually an imported commodity), the probability of pest entry is evaluated for the pathway in question. The probabilities for pest entry associated with other pathways need to be investigated as well.

For risk analyses that have been initiated for a specific pest, with no particular commodity or pathway under consideration, the potential of all probable pathways should be considered.

The assessment of probability of spread is based primarily on biological considerations similar to those for entry and establishment.

S1 With respect to a plant being assessed as a pest with indirect effects, wherever a reference is made to a host or a host range, this should be understood to refer instead to a suitable habitat[2] (that is a place where the plant can grow) in the PRA area.

S1 The intended habitat is the place where the plants are intended to grow and the unintended habitat is the place where the plants are not intended to grow.

S1 In the case of plants to be imported, the concepts of entry, establishment and spread have to be considered differently.

S1 Plants for planting that are imported will enter and then be maintained in an intended habitat, probably in substantial numbers and for an indeterminate period. Accordingly, Section 2.2.1 on Entry does not apply. The risk arises because of the probability that the plant may spread from the intended habitat to unintended habitats within the PRA area, and then establish in those habitats. Accordingly, section 2.2.3 may be considered before section 2.2.2. Unintended habitats may occur in the vicinity of the intended habitat in the PRA area.

S1 Imported plants not intended to be planted may be used for different purposes (e.g. used as bird seed, as fodder, or for processing). The risk arises because of the probability that the plant may escape or be diverted from the intended use to an unintended habitat and establish there.

S2 Assessing the probability of introduction of an LMO requires an analysis of both intentional or unintentional pathways of introduction, and intended use.

2.2.1 Probability of entry of a pest

The probability of entry of a pest depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. The higher the number of pathways, the greater the probability of the pest entering the PRA area.

Documented pathways for the pest to enter new areas should be noted. Potential pathways, which may not currently exist, should be assessed. Pest interception data may provide evidence of the ability of a pest to be associated with a pathway and to survive in transport or storage.

S1 In the case of plants to be imported, the plants will enter and an assessment of probability of entry will not be required. Therefore this section does not apply. However, this section does apply to pests that may be carried by such plants (e.g. weed seeds with seeds imported for planting).

S2 This section is not relevant to LMOs imported for intentional release into the environment.

[2] In the case of organisms that affect plants indirectly, through effects on other organisms, the terms host/habitat will extend also to those other organisms.

2.2.1.1 Identification of pathways for a PRA initiated by a pest

All relevant pathways should be considered. They can be identified principally in relation to the geographical distribution and host range of the pest. Consignments of plants and plant products moving in international trade are the principal pathways of concern and existing patterns of such trade will, to a substantial extent, determine which pathways are relevant. Other pathways such as other types of commodities, packing materials, persons, baggage, mail, conveyances and the exchange of scientific material should be considered where appropriate. Entry by natural means should also be assessed, as natural spread is likely to reduce the effectiveness of phytosanitary measures.

S2 For LMOs, all relevant pathways of introduction should be considered (intentional and unintentional).

2.2.1.2 Probability of the pest being associated with the pathway at origin

The probability of the pest being associated, spatially or temporally, with the pathway at origin should be estimated. Factors to consider are:

- prevalence of the pest in the source area
- occurrence of the pest in a life-stage that would be associated with commodities, containers, or conveyances
- volume and frequency of movement along the pathway
- seasonal timing
- pest management, cultural and commercial procedures applied at the place of origin (application of plant protection products, handling, culling, roguing, grading).

2.2.1.3 Probability of survival during transport or storage

Examples of factors to consider are:

- speed and conditions of transport and duration of the life cycle of the pest in relation to time in transport and storage
- vulnerability of the life-stages during transport or storage
- prevalence of pest likely to be associated with a consignment
- commercial procedures (e.g. refrigeration) applied to consignments in the country of origin, country of destination, or in transport or storage.

2.2.1.4 Probability of pest surviving existing pest management procedures

Existing pest management procedures (including phytosanitary procedures) applied to consignments against other pests from origin to end-use, should be evaluated for effectiveness against the pest in question. The probability that the pest will go undetected during inspection or survive other existing phytosanitary procedures should be estimated.

2.2.1.5 Probability of transfer to a suitable host

Factors to consider are:

- dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host
- whether the imported commodity is to be sent to a few or many destination points in the PRA area
- proximity of entry, transit and destination points to suitable hosts
- time of year at which import takes place
- intended use of the commodity (e.g. for planting, processing and consumption)
- risks from by-products and waste.

Some uses are associated with a much higher probability of introduction (e.g. planting) than others (e.g. processing). The probability associated with any growth, processing, or disposal of the commodity in the vicinity of suitable hosts should also be considered.

S2 For LMOs, the probability of gene flow and gene transfer should also be considered, when there is a trait of phytosanitary concern that may be transferred.

2.2.2 Probability of establishment

In order to estimate the probability of establishment of a pest, reliable biological information (life cycle, host range, epidemiology, survival etc.) should be obtained from the areas where the pest currently occurs. The situation in the PRA area can then be compared with that in the areas where it currently occurs (taking account also of protected environments such as glass- or greenhouses) and expert judgement used to assess the probability of establishment. Case histories concerning comparable pests can be considered. Examples of the factors to consider are:

- availability, quantity and distribution of hosts in the PRA area
- environmental suitability in the PRA area
- potential for adaptation of the pest

- reproductive strategy of the pest
- method of pest survival
- cultural practices and control measures.

In considering probability of establishment, it should be noted that a transient pest (see ISPM No. 8: Determination of pest status in an area) may not be able to establish in the PRA area (e.g. because of unsuitable climatic conditions) but could still have unacceptable economic consequences (see IPPC Art. VII.3).

S1 In the case of plants to be imported, the assessment of the probability of establishment concerns the unintended habitats.

S2 For LMOs, the survival capacity without human intervention should also be considered.

S2 In addition, where gene flow is a concern in the PRA area, the probability of expression and establishment of a trait of phytosanitary concern should be considered.

S2 Case histories concerning comparable LMOs or other organisms carrying the same construct can be considered.

2.2.2.1 Availability of suitable hosts, alternate hosts and vectors in the PRA area

Factors to consider are:

- whether hosts and alternate hosts are present and how abundant or widely distributed they may be
- whether hosts and alternate hosts occur within sufficient geographic proximity to allow the pest to complete its life cycle
- whether there are other plant species, which could prove to be suitable hosts in the absence of the usual host species
- whether a vector, if needed for dispersal of the pest, is already present in the PRA area or likely to be introduced
- whether another vector species occurs in the PRA area.

The taxonomic level at which hosts are considered should normally be the "species". The use of higher or lower taxonomic levels should be justified by scientifically sound rationale.

2.2.2.2 Suitability of environment

Factors in the environment (e.g. suitability of climate, soil, pest and host competition) that are critical to the development of the pest, its host and if applicable its vector, and to their ability to survive periods of climatic stress and complete their life cycles, should be identified. It should be noted that the environment is likely to have different effects on the pest, its host and its vector. This needs to be recognized in determining whether the interaction between these organisms in the area of origin is maintained in the PRA area to the benefit or detriment of the pest. The probability of establishment in a protected environment, e.g. in glasshouses, should also be considered.

Climatic modelling systems may be used to compare climatic data on the known distribution of a pest with that in the PRA area.

2.2.2.3 Cultural practices and control measures

Where applicable, practices employed during the cultivation/production of the host crops should be compared to determine if there are differences in such practices between the PRA area and the origin of the pest that may influence its ability to establish.

S2 For plants that are LMOs, it may also be appropriate to consider specific cultural, control or management practices.

Pest control programs or natural enemies already in the PRA area which reduce the probability of establishment may be considered. Pests for which control is not feasible should be considered to present a greater risk than those for which treatment is easily accomplished. The availability (or lack) of suitable methods for eradication should also be considered.

2.2.2.4 Other characteristics of the pest affecting the probability of establishment

These include:

- *Reproductive strategy of the pests and method of pest survival* - Characteristics, which enable the pest to reproduce effectively in the new environment, such as parthenogenesis/self-crossing, duration of the life cycle, number of generations per year, resting stage etc., should be identified.
- *Genetic adaptability* - Whether the species is polymorphic and the degree to which the pest has demonstrated

the ability to adapt to conditions like those in the PRA area should be considered, e.g., host-specific races or races adapted to a wider range of habitats or to new hosts. This genotypic (and phenotypic) variability facilitates a pest's ability to withstand environmental fluctuations, to adapt to a wider range of habitats, to develop pesticide resistance and to overcome host resistance.

- *Minimum population needed for establishment* - If possible, the threshold population that is required for establishment should be estimated.

S2 For LMOs, if there is evidence of genotypic and phenotypic instability, this should be considered.

S2 It may also be appropriate to consider proposed production and control practices related to the LMO in the country of import.

2.2.3 Probability of spread after establishment

A pest with a high potential for spread may also have a high potential for establishment, and possibilities for its successful containment and/or eradication are more limited. In order to estimate the probability of spread of the pest, reliable biological information should be obtained from areas where the pest currently occurs. The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs and expert judgement used to assess the probability of spread. Case histories concerning comparable pests can usefully be considered. Examples of the factors to consider are:

- suitability of the natural and/or managed environment for natural spread of the pest
- presence of natural barriers
- the potential for movement with commodities or conveyances
- intended use of the commodity
- potential vectors of the pest in the PRA area
- potential natural enemies of the pest in the PRA area.

S1 In the case of plants to be imported, the assessment of spread concerns spread from the intended habitat or the intended use to an unintended habitat, where the pest may establish. Further spread may then occur to other unintended habitats.

The information on probability of spread is used to estimate how rapidly a pest's potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area of low potential economic importance and then spread to an area of high potential economic importance. In addition it may be important in the risk management stage when considering the feasibility of containment or eradication of an introduced pest.

S1 Certain pests may not cause injurious effects on plants immediately after they establish, and in particular may only spread after a certain time. In assessing the probability of spread, this should be considered, based on evidence of such behaviour.

2.2.4 Conclusion on the probability of introduction and spread

The overall probability of introduction should be expressed in terms most suitable for the data, the methods used for analysis, and the intended audience. This may be quantitative or qualitative, since either output is in any case the result of a combination of both quantitative and qualitative information. The probability of introduction may be expressed as a comparison with that obtained from PRAs on other pests.

2.2.4.1 Conclusion regarding endangered areas

The part of the PRA area where ecological factors favour the establishment of the pest should be identified in order to define the endangered area. This may be the whole of the PRA area or a part of the area.

2.3 Assessment of potential economic consequences

Requirements described in this step indicate what information relative to the pest and its potential host plants should be assembled, and suggest levels of economic analysis that may be carried out using that information in order to assess all the effects of the pest, i.e. the potential economic consequences. Wherever appropriate, quantitative data that will provide monetary values should be obtained. Qualitative data may also be used. Consultation with an economist may be useful.

In many instances, detailed analysis of the estimated economic consequences is not necessary if there is sufficient evidence or it is widely agreed that the introduction of a pest will have unacceptable economic consequences (including environmental consequences). In such cases, risk assessment will primarily focus on the probability of introduction and spread. It will, however, be necessary to examine economic factors in greater detail when the level of economic

consequences is in question, or when the level of economic consequences is needed to evaluate the strength of measures used for risk management or in assessing the cost-benefit of exclusion or control.

S2 In the case of LMOs, the economic impact (including environmental impact) should relate to the pest nature (injurious to plants and plant products) of the LMO.

S2 For LMOs, the following evidence should also be considered:

- potential economic consequences that could result from adverse effects on non-target organisms that are injurious to plants or plant products
- economic consequences that could result from pest properties.

S2 For more detailed guidance on the assessment of these characteristics, see Annex 3.

2.3.1 Pest effects

In order to estimate the potential economic importance of the pest, information should be obtained from areas where the pest occurs naturally or has been introduced. This information should be compared with the situation in the PRA area. Case histories concerning comparable pests can usefully be considered. The effects considered may be direct or indirect.

S1 The basic method for estimating the potential economic importance of pests in this section also applies to:

- pests affecting uncultivated/unmanaged plants
- weeds and/or invasive plants and
- pests affecting plants through effects on other organisms.

S1 In the case of direct and indirect environmental effects, specific evidence is needed.

S1 In the case of plants to be imported for planting, the long-term consequences for the intended habitat may be included in the assessment. Planting may affect further use or have a harmful effect on the intended habitat.

S1 Environmental effects and consequences considered should result from effects on plants. Such effects, however, on plants may be less significant than the effects and/or consequences on other organisms or systems. For example, a minor weed may be significantly allergenic for humans or a minor plant pathogen may produce toxins that seriously affect livestock. However, the regulation of plants solely on the basis of their effects on other organisms or systems (e.g. on human or animal health) is outside the scope of this standard. If the PRA process reveals evidence of a potential hazard to other organisms or systems, this should be communicated to the appropriate authorities which have the legal responsibility to deal with the issue.

2.3.1.1 Direct pest effects

For identification and characterization of the direct effects of the pest on each potential host in the PRA area, or those effects which are host-specific, the following are examples that could be considered:

- known or potential host plants (in the field, under protected cultivation, or in the wild)
- types, amount and frequency of damage
- crop losses, in yield and quality
- biotic factors (e.g. adaptability and virulence of the pest) affecting damage and losses
- abiotic factors (e.g. climate) affecting damage and losses
- rate of spread
- rate of reproduction
- control measures (including existing measures), their efficacy and cost
- effect on existing production practices
- environmental effects.

For each of the potential hosts, the total area of the crop and area potentially endangered should be estimated in relation to the elements given above.

S1 In the case of the analysis of environmental risks, examples of direct pest effects on plants and/or their environmental consequences that could be considered include:

- reduction of keystone plant species;
- reduction of plant species that are major components of ecosystems (in terms of abundance or size), and endangered native plant species (including effects below species level where there is evidence of such effects being significant);
- significant reduction, displacement or elimination of other plant species.

S1 The estimation of the area potentially endangered should relate to these effects.

2.3.1.2 Indirect pest effects

For identification and characterization of the indirect effects of the pest in the PRA area, or those effects that are not host-specific, the following are examples that could be considered:

- effects on domestic and export markets, including in particular effects on export market access. The potential consequences for market access which may result if the pest becomes established, should be estimated. This involves considering the extent of any phytosanitary regulations imposed (or likely to be imposed) by trading partners
- changes to producer costs or input demands, including control costs
- changes to domestic or foreign consumer demand for a product resulting from quality changes
- environmental and other undesired effects of control measures
- feasibility and cost of eradication or containment
- capacity to act as a vector for other pests
- resources needed for additional research and advice
- social and other effects (e.g. tourism).

S1 In the case of the analysis of environmental risks, examples of indirect pest effects on plants and/or their environmental consequences that could be considered include:

- significant effects on plant communities
- significant effects on designated environmentally sensitive or protected areas
- significant change in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, erosion, water table changes, increased fire hazard, nutrient cycling, etc.)
- effects on human use (e.g. water quality, recreational uses, tourism, animal grazing, hunting, fishing); and
- costs of environmental restoration.

S1 Effects on human and animal health (e.g. toxicity, allergenicity), water tables, tourism, etc. could also be considered, as appropriate, by other agencies/authorities.

2.3.2 Analysis of economic consequences

2.3.2.1 Time and place factors

Estimations made in the previous section related to a hypothetical situation where the pest is supposed to have been introduced and to be fully expressing its potential economic consequences (per year) in the PRA area. In practice, however, economic consequences are expressed with time, and may concern one year, several years or an indeterminate period. Various scenarios should be considered. The total economic consequences over more than one year can be expressed as net present value of annual economic consequences, and an appropriate discount rate selected to calculate net present value.

Other scenarios could concern whether the pest occurs at one, few or many points in the PRA area and the expression of potential economic consequences will depend on the rate and manner of spread in the PRA area. The rate of spread may be envisaged to be slow or rapid; in some cases, it may be supposed that spread can be prevented. Appropriate analysis may be used to estimate potential economic consequences over the period of time when a pest is spreading in the PRA area. In addition, many of the factors or effects considered above could be expected to change over time, with the consequent effects of potential economic consequences. Expert judgement and estimations will be required.

2.3.2.2 Analysis of commercial consequences

As determined above, most of the direct effects of a pest, and some of the indirect effects will be of a commercial nature, or have consequences for an identified market. These effects, which may be positive or negative, should be identified and quantified. The following may usefully be considered:

- effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices
- effect of pest-induced changes in quantities demanded or prices paid for commodities by domestic and international consumers. This could include quality changes in products and/or quarantine-related trade restrictions resulting from a pest introduction.

2.3.2.3 Analytical techniques

There are analytical techniques which can be used in consultation with experts in economics to make a more detailed analysis of the potential economic effects of a quarantine pest. These should incorporate all of the effects that have been identified. These techniques 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 2.3.2.2, 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
- *general equilibrium*: if the economic changes are significant to a national economy, and could cause changes to factors such as wages, interest rates or exchange rates, then general equilibrium analysis could be used to establish the full range of economic effects.

The use of analytical techniques is often limited by lack of data, by uncertainties in the data, and by the fact that for certain effects only qualitative information can be provided.

2.3.2.4 Non-commercial and environmental consequences

Some of the direct and indirect effects of the introduction of a pest determined in 2.3.1.1 and 2.3.1.2 will be of an economic nature, or affect some type of value, but not have an existing market which can be easily identified. As a result, the effects may not be adequately measured in terms of prices in established product or service markets. Examples include in particular environmental effects (such as ecosystem stability, biodiversity, amenity value) and social effects (such as employment, tourism) arising from a pest introduction. These impacts could be approximated with an appropriate non-market valuation method. More details on environment are given below.

If quantitative measurement of such 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.

S1 Application of this standard to environmental hazards requires clear categorization of environmental values and how they can be assessed. The environment can be valued using different methodologies, but these methodologies are best used in consultation with experts in economics. Methodologies may include consideration of "use" and "non-use" values. "Use" values arise from consumption of an element of the environment, such as accessing clean water, or fishing in a lake, and also those that are non-consumptive, such as use of forests for leisure activities. "Non-use" values may be subdivided into:

- "option value" (value for use at a later date)
- "existence value" (knowledge that an element of the environment exists) and
- "bequest value" (knowledge that an element of the environment is available for future generations).

S1 Whether the element of the environment is being assessed in terms of use or non-use values, methods exist for their valuation, such as market-based approaches, surrogate markets, simulated markets, and benefit transfer. Each has advantages, disadvantages and situations where it is particularly useful.

S1 The assessment of consequences may be either quantitative or qualitative and in many cases, qualitative data is sufficient. A quantitative method may not exist to address a situation (e.g. catastrophic effects on a keystone species), or a quantitative analysis may not be possible (no methods available). Useful analyses can be based on non-monetary valuations (number of species affected, water quality), or expert judgement, if the analyses follow documented, consistent and transparent procedures.

S1 Economic impact is described in ISPM No. 5: Glossary of phytosanitary terms, Supplement No. 2: Guidelines on the understanding of potential economic importance and related terms.

2.3.3 Conclusion of the assessment of economic consequences

Wherever appropriate, the output of the assessment of economic consequences described in this step should be in terms of a monetary value. The economic consequences can also be expressed qualitatively or using quantitative measures without monetary terms. Sources of information, assumptions and methods of analysis should be clearly specified.

2.3.3.1 Endangered area

The part of the PRA area where presence of the pest will result in economically important loss should be identified as appropriate. This is needed to define the endangered area.

2.4 Degree of uncertainty

Estimation of the probability of introduction of a pest and of its economic consequences involves many uncertainties. In particular, this estimation is an extrapolation from the situation where the pest occurs to the hypothetical situation in the PRA area. 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.

S1 It should be noted that the assessment of the probability and consequences of environmental hazards of pests of uncultivated and unmanaged plants often involves greater uncertainty than for pests of cultivated or managed plants. This is due to the lack of information, additional complexity associated with ecosystems, and variability associated with pests, hosts or habitats.

2.5 Conclusion of the pest risk assessment stage

As a result of the pest risk assessment, all or some of the categorized pests may be considered appropriate for pest risk management. For each pest, all or part of the PRA area may be identified as an endangered area. A quantitative or qualitative estimate of the probability of introduction of a pest or pests, and a corresponding quantitative or qualitative estimate of economic consequences (including environmental consequences), have been obtained and documented or an overall rating could have been assigned. These estimates, with associated uncertainties, are utilized in the pest risk management stage of the PRA.

3. 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. Since zero-risk is not a reasonable option, the guiding principle for risk management should be to manage risk to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources. Pest risk management (in the analytical sense) is the process of identifying ways to react to a perceived risk, evaluating the efficacy of these actions, and identifying the most appropriate options. The uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option.

S1 In considering the management of environmental risks, it should be stressed that phytosanitary measures are intended to account for uncertainty and should be designed in proportion to the risk. Pest risk management options should be identified, taking account of the degree of uncertainty in the assessment of economic consequences, probability of introduction, and the respective technical justification of those options. In this respect, the management of risks to the environment caused by plant pests does not differ from the management of other plant pest risks.

3.1 Level of risk

The principle of "managed risk" (ISPM No. 1: Principles of plant quarantine as related to international trade) states that: "Because some risk of introduction of a quarantine pest always exists, countries shall agree to a policy of risk management when formulating phytosanitary measures." In implementing this principle, countries should decide what level of risk is acceptable to them.

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

- reference to existing phytosanitary requirements
- indexed to estimated economic losses
- expressed on a scale of risk tolerance
- compared with the level of risk accepted by other countries.

S2 For LMOs, the acceptable level of risk may also be expressed by comparison to the level of risk associated with similar or related organisms, based on their characteristics and behaviour in a similar environment to the PRA area.

3.2 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. This information will be composed of:

- reasons for initiating the process
- estimation of the probability of introduction to the PRA area
- evaluation of potential economic consequences in the PRA area.

3.3 Acceptability of risk

Overall risk is determined by the examination of the outputs of the assessments of the probability of introduction and the economic impact. If the risk is found to be unacceptable, then the first step in risk management is to identify possible phytosanitary measures that will reduce the risk to, or below an acceptable level. Measures are not justified if the risk is already acceptable or must be accepted because it is not manageable (as may be the case with natural spread). Countries may decide that a low level of monitoring or audit is maintained to ensure that future changes in the pest risk are identified.

3.4 Identification and selection of appropriate risk management options

Appropriate measures should be chosen based on their effectiveness in reducing the probability of introduction of the pest. 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):

- *Phytosanitary measures shown to be cost-effective and feasible* - The benefit from the use of phytosanitary measures is that the pest will not be introduced and the PRA area will, consequently, not be subjected to the potential economic consequences. The cost-benefit analysis for each of the minimum measures found to provide acceptable security may be estimated. Those measures with an acceptable benefit-to-cost ratio should be considered.
- *Principle of "minimal impact"* - Measures should not be more trade restrictive than necessary. Measures should be applied to the minimum area necessary for the effective protection of the endangered area.
- *Reassessment of previous requirements* - No additional measures should be imposed if existing measures are effective.
- *Principle of "equivalence"* - If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
- *Principle of "non-discrimination"* - If the pest under consideration is established in the PRA area but of limited distribution and under official control, the phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Likewise, phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

S1 The principle of non-discrimination and the concept of official control also apply to:

- pests affecting uncultivated/unmanaged plants
- weeds and/or invasive plants and
- pests affecting plants through effects on other organisms.

S1 If any of these become established in the PRA area and if official control is applied, then phytosanitary measures at import should not be more stringent than the official control measures.

The major risk of introduction of plant pests is with imported consignments of plants and plant products, but (especially for a PRA performed on a particular pest) it is necessary to consider the risk of introduction with other types of pathways (e.g. packing materials, conveyances, travellers and their luggage, and the natural spread of a pest).

The measures listed below are examples of those that are most commonly applied to traded commodities. They are applied to pathways, usually consignments of a host, from a specific origin. The measures should be as precise as possible as to consignment type (hosts, parts of plants) and origin so as not to act as barriers to trade by limiting the import of products where this is not justified. Combinations of two or more measures may be needed in order to reduce the risk to an acceptable level. The available measures can be classified into broad categories which relate to the pest status of the pathway in the country of origin. These include measures:

- applied to the consignment
- applied to prevent or reduce original infestation in the crop
- to ensure the area or place of production is free from the pest
- concerning the prohibition of commodities.

Other options may arise in the PRA area (restrictions on the use of a commodity), control measures, introduction of a biological control agent, eradication, and containment. Such options should also be evaluated and will apply in particular if the pest is already present but not widely distributed in the PRA area.

3.4.1 Options for consignments

Measures may include any combinations of the following:

- inspection or testing for freedom from a pest or to a specified pest tolerance; sample size should be adequate to give an acceptable probability of detecting the pest
- prohibition of parts of the host
- a pre-entry or post-entry quarantine system - this system could be considered to be the most intensive form of inspection or testing where suitable facilities and resources are available, and may be the only option for certain pests not detectable on entry
- specified conditions of preparation of the consignment (e.g. handling to prevent infestation or reinfestation)
- specified treatment of the consignment - such treatments are applied post-harvest and could include chemical, thermal, irradiation or other physical methods
- restrictions on end use, distribution and periods of entry of the commodity.

Measures may also be applied to restrict the import of consignments of pests.

S1 The concept of consignments of pests may be applied to the import of plants considered to be pests. These consignments may be restricted to species or varieties posing less risk.

S2 For LMOs, as for other organisms, information may have been obtained concerning the risk management measures applied to the LMO in the country of export (see section 1.3). These should be assessed to determine if they are appropriate for the conditions in the PRA area and, if appropriate, the intended use.

S2 For LMOs, measures may also include procedures for the provision of information on the phytosanitary integrity of consignments (e.g. tracing systems, documentation systems, identity preservation systems).

3.4.2 Options preventing or reducing infestation in the crop

Measures may include:

- treatment of the crop, field, or place of production
- restriction of the composition of a consignment so that it is composed of plants belonging to resistant or less susceptible species
- growing plants under specially protected conditions (glasshouse, isolation)
- harvesting of plants at a certain age or a specified time of year
- production in a certification scheme. An officially monitored plant production scheme usually involves a number of carefully controlled generations, beginning with nuclear stock plants of high health status. It may be specified that the plants be derived from plants within a limited number of generations.

S2 Measures may be applied to reduce the probability that LMOs (or genetic material from LMOs) that pose a phytosanitary risk could be in other crops. These include:

- management systems (e.g. buffer zones, refugia)
- management of trait expression
- control of reproductive ability (e.g. male sterility)
- control of alternative hosts.

3.4.3 Options ensuring that the area, place or site of production or crop is free from the pest

Measures may include:

- pest-free area - requirements for pest-free area status are described in ISPM No. 4: *Requirements for the establishment of pest free areas*
- pest-free place of production or pest-free production site - requirements are described in ISPM No. 10: *Requirements for the establishment of pest free places of production and pest-free production sites*
- inspection of crop to confirm pest freedom.

3.4.4 Options for other types of pathways

For many types of pathways, the measures considered above for plants and plant products to detect the pest in the consignment or to prevent infestation of the consignment, may also be used or adapted. For certain types of pathways, the following factors should be considered:

- Natural spread of a pest includes movement of the pest by flight, wind dispersal, transport by vectors such as insects or birds and natural migration. If the pest is entering the PRA area by natural spread, or is likely to enter in the immediate future, phytosanitary measures may have little effect. Control measures applied in the area of origin could be considered. Similarly, containment or eradication, supported by suppression and surveillance, in the PRA area after entry of the pest could be considered.
- Measures for human travellers and their baggage could include targeted inspections, publicity and fines or incentives. In a few cases, treatments may be possible.
- Contaminated machinery or modes of transport (ships, trains, planes, road transport) could be subjected to cleaning or disinfestation.

3.4.5 Options within the importing country

Certain measures applied within the importing country may also be used. These could include careful surveillance to try and detect the entry of the pest as early as possible, eradication programmes to eliminate any foci of infestation and/or containment action to limit spread.

S1 For plants to be imported, where there is a high level of uncertainty regarding pest risk, it may be decided not to take phytosanitary measures at import, but only to apply surveillance or other procedures after entry (e.g. by or under the supervision of the NPPO).

S2 The potential for risk from LMO pests depends in part on the intended use. As for other organisms, certain intended uses (such as high security contained use) may significantly manage risk.

S2 For LMOs, as with other pests, options within the country also include the use of emergency measures related to phytosanitary risks. Any emergency measures should be consistent with Article VII.6 of the IPPC (1997).

3.4.6 Prohibition of commodities

If no satisfactory measure to reduce risk to an acceptable level can be found, the final option may be to prohibit importation of the relevant commodities. This should be viewed as a measure of last resort and should be considered in light of the anticipated efficacy, especially in instances where the incentives for illegal import may be significant.

3.5 Phytosanitary certificates and other compliance measures

Risk management includes the consideration of appropriate compliance procedures. The most important of these is export certification (see ISPM No. 7: *Export certification system*). The issuance of phytosanitary certificates (see ISPM No. 12: *Guidelines for Phytosanitary Certificates*) provides official assurance that a consignment is "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." It thus confirms that the specified risk management options have been followed. An additional declaration may be required to indicate that a particular measure has been carried out. Other compliance measures may be used subject to bilateral or multilateral agreement.

S2 Information on Phytosanitary Certificates regarding LMOs (as with any other regulated articles) should only be related to phytosanitary measures (see ISPM No. 12: *Guidelines for phytosanitary certificates*).

3.6 Conclusion of pest risk management

The result of the pest risk management procedure will be either that no measures are identified which are considered appropriate or the selection of one or more management options that have been found to lower the risk associated with the pest(s) to an acceptable level. These management options form the basis of phytosanitary regulations or requirements.

The application and maintenance of such regulations is subject to certain obligations, in the case of contracting parties to the IPPC.

S1 Phytosanitary measures taken in relation to environmental hazards should, as appropriate, be notified to relevant competent authorities responsible for national biodiversity policies, strategies and action plans.

S1 It is noted that the communication of risks associated with environmental hazards is of particular importance to promote awareness.

3.6.1 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 during use. This is often achieved by inspection of the commodity on arrival, noting any interceptions or any entries of the pest to the PRA area. 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.

4. Documentation of Pest Risk Analysis

4.1 Documentation requirements

The IPPC and the principle of "transparency" (ISPM No. 1: *Principles of plant quarantine as related to international trade*) require that countries 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 review or a dispute arises, 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, pest list, pathways, PRA area, endangered area
- sources of information
- categorized pest list
- conclusions of risk assessment
  - probability
  - consequences
- risk management
  - options identified
- options selected.

S1 **ANNEX 1**

COMMENTS ON THE SCOPE OF THE IPPC IN REGARD TO ENVIRONMENTAL RISKS

The full range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. The coverage of the IPPC definition of plant pests includes weeds and other species that have indirect effects on plants, and the Convention applies to the protection of wild flora. The scope of the IPPC also extends to organisms which are pests because they:

- *directly affect uncultivated/unmanaged plants*

Introduction of these pests may have few commercial consequences, and therefore they have been less likely to be evaluated, regulated and/or placed under official control. An example of this type of pest is Dutch elm disease (Ophiostoma novo-ulmi).

- *indirectly affect plants*

In addition to pests that directly affect host plants, there are those, like most weeds/invasive plants, which affect plants primarily by other processes such as competition (e.g. for cultivated plants: Canada thistle (Cirsium arvense) [weed of agricultural crops], or for uncultivated/unmanaged plants: Purple loosestrife (Lythrum salicaria) [competitor in natural and semi-natural habitats]).

- *indirectly affect plants through effects on other organisms*

Some pests may primarily affect other organisms, but thereby cause deleterious effects on plant species, or plant health in habitats or ecosystems. Examples include parasites of beneficial organisms, such as biological control agents.

To protect the environment and biological diversity without creating disguised barriers to trade, environmental risks and risks to biological diversity should be analyzed in a PRA.

S2 **ANNEX 2**

COMMENTS ON THE SCOPE OF THE IPPC IN REGARD TO PEST RISK ANALYSIS FOR LIVING MODIFIED ORGANISMS

Phytosanitary risks that may be associated with a living modified organism (LMO) are within the scope of the International Plant Protection Convention (IPPC) and should be considered using pest risk analysis (PRA) to make decisions regarding pest risk management.

The analysis of LMOs includes consideration of the following:

- Some LMOs may present a phytosanitary risk and therefore warrant a PRA. However other LMOs will not present a phytosanitary risks beyond those posed by related non-LMOs and therefore will not warrant a complete PRA. For example, modifications to change the physiological characteristics of a plant (e.g. ripening time, storage life) may not present any phytosanitary risk. The pest risk that may be posed by an LMO is dependent on a combination of factors, including the characteristics of the donor and recipient organisms, the genetic alteration, and the specific new trait or traits. Therefore, part of the supplementary text (see Annex 3) provides guidance on how to determine if an LMO is a potential pest.
- PRA may constitute only a portion of the overall risk analysis for import and release of a LMO. For example, countries may require the assessment of risks to human or animal health, or to the environment, beyond that covered by the IPPC. This standard only relates to the assessment and management of phytosanitary risks. As with other organisms or pathways assessed by an NPPO, LMOs may present other risks not falling within the scope of the IPPC. When an NPPO discovers potential for risks that are not of phytosanitary concern it may be appropriate to notify the relevant authorities.
- Phytosanitary risks from LMOs may result from certain traits introduced into the organism, such as those that increase the potential for establishment and spread, or from inserted gene sequences that do not alter the pest characteristics of the organism but that might act independently of the organism or have unintended consequences.
- In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.
- The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.
- Potential phytosanitary risks that may be associated with LMOs could also be associated with non-LMOs. It may be useful to consider risks associated with LMOs in the context of risks posed by the non-modified recipient or parental organisms, or similar organisms, in the PRA area.

S2 **ANNEX 3**

DETERMINING THE POTENTIAL FOR A LIVING MODIFIED ORGANISM TO BE A PEST

This annex is relevant for living modified organisms (LMOs) only where there is potential for phytosanitary risks from the LMO associated with some characteristic or property related to the genetic modification. Other phytosanitary risks associated with the organism should be assessed under other appropriate sections of ISPM No. 11 or under other appropriate ISPMs.

The information requirements outlined in section 1.3 may be needed in determining the potential for an LMO to be a pest.

Potential phytosanitary risks for LMOs
Potential phytosanitary risks for LMOs may include:

a. Changes in adaptive characteristics which may increase the potential for introduction or spread, for example alterations in:

- tolerance to adverse environmental conditions (e.g. drought, freezing, salinity etc.)
- reproductive biology
- dispersal ability of pests
- growth rate or vigour
- host range
- pest resistance
- pesticide (including herbicide) resistance or tolerance.

b. Adverse effects of gene flow or gene transfer including, for example:

- transfer of pesticide or pest resistance genes to compatible species
- the potential to overcome existing reproductive and recombination barriers resulting in pest risks
- potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity.

c. Adverse effects on non-target organisms including, for example:

- changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
- effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)
- capacity to vector other pests
- negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants.

d. Genotypic and phenotypic instability including, for example:

- reversion of an organism intended as a biocontrol agent to a virulent form.

e. Other injurious effects including, for example:

- phytosanitary risks presented by new traits in organisms that do not normally pose phytosanitary risk
- novel or enhanced capacity for virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences
- phytosanitary risks resulting from nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.

The potential phytosanitary risks identified above can also be associated with non-LMOs. The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.

If there is no indication that new traits resulting from genetic modifications have phytosanitary risks, the LMO may require no further consideration.

It may be useful to consider potential risks in the context of risks posed by the non-modified recipients or parental organisms, or similar organisms, in the PRA area.

In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.

Factors that may result in the need to subject a LMO to stage 2 of the PRA include:

- lack of knowledge about a particular modification event
- the credibility of information if it is an unfamiliar modification event
- insufficient data on the behaviour of the LMO in environments similar to the PRA area
- field experience, research trials or laboratory data indicating that the LMO may pose phytosanitary risks (see sub-sections a. to e. above)
- where the LMO expresses characteristics that are associated with pests under ISPM No. 11
- existing conditions in the country (or PRA area) that may result in the LMO being a pest
- where there are PRAs for similar organisms (including LMOs) or risk analyses carried out for other purposes that indicate a pest potential
- experience in other countries.

Factors that may lead to the conclusion that an LMO is not a potential pest and/or requires no further consideration under ISPM No. 11 include:

- where the genetic modification in similar or related organisms has previously been assessed by the NPPO (or other recognized experts or agencies) as having no phytosanitary risk
- where the LMO is to be confined in a reliable containment system and not be released
- evidence from research trials that the LMO is unlikely to be a pest under the use proposed
- experience in other countries.