



INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

1 to 31

(2008 edition)





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Produced by the Secretariat of the International Plant Protection Convention

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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.

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



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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.*” (Article VII.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 identified¹. 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 applied².

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.

ISPM No. 2



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 2

FRAMEWORK FOR PEST RISK ANALYSIS

(2007)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in March 2007.

INTRODUCTION

SCOPE

This standard provides a framework that describes the pest risk analysis (PRA) process within the scope of the IPPC. It introduces the three stages of pest risk analysis – initiation, pest risk assessment and pest risk management. The standard focuses on the initiation stage. Generic issues of information gathering, documentation, risk communication, uncertainty and consistency are addressed.

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Glossary of phytosanitary terms*, 2007. ISPM No. 5, FAO, Rome.
- Glossary supplement No. 2: Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations*. ISPM No. 5, FAO, Rome.
- Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, 2005. ISPM No. 3, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004. ISPM No. 11, FAO, Rome.
- Pest risk analysis for regulated non-quarantine pests*, 2004. ISPM No. 21, FAO, Rome.
- Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006. ISPM No. 1, FAO, Rome.
- The use of integrated measures in a systems approach for pest risk management*, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

The pest risk analysis (PRA) process is a technical tool used for identifying appropriate phytosanitary measures. The PRA process may be used for organisms not previously recognized as pests (such as plants, biological control agents or other beneficial organisms, living modified organisms), recognized pests, pathways and review of phytosanitary policy. The process consists of three stages: 1: Initiation; 2: Pest risk assessment; and 3: Pest risk management.

This standard provides detailed guidance on PRA Stage 1, summarizes PRA Stages 2 and 3, and addresses issues generic to the entire PRA process. For Stages 2 and 3 it refers to ISPMs No. 3, No. 11 and No. 21 dealing with the PRA process.

The PRA process is initiated in Stage 1 with the identification of an organism or pathway that may be considered for pest risk assessment, or as part of the review of existing phytosanitary measures, in relation to a defined PRA area. The first step is to determine or confirm whether or not the organism considered is a pest. If no pests are identified, the analysis need not continue. The analysis of pests identified in Stage 1 continues to Stages 2 and 3 using guidance provided in other standards. Information gathering, documentation and risk communication, as well as uncertainty and consistency, are issues common to all PRA stages.

BACKGROUND

Pest risk analysis (PRA) provides the rationale for phytosanitary measures for a specified PRA area. It evaluates scientific evidence to determine whether an organism is a pest. If so, the analysis evaluates the probability of introduction and spread of the pest and the magnitude of potential economic consequences in a defined area, using biological or other scientific and economic evidence. If the risk is deemed unacceptable, the analysis may continue by suggesting management options that can reduce the risk to an acceptable level. Subsequently, pest risk management options may be used to establish phytosanitary regulations.

For some organisms, it is known beforehand that they are pests, but for others, the question of whether or not they are pests should initially be resolved¹.

The pest risks posed by the introduction of organisms associated with a particular pathway, such as a commodity, should also be considered in a PRA. The commodity itself may not pose a pest risk but may harbour organisms that are pests. Lists of such organisms are compiled during the initiation stage. Specific organisms may then be analysed individually, or in groups where individual species share common biological characteristics.

Less commonly, the commodity itself may pose a pest risk. When deliberately introduced and established in intended habitats in new areas, organisms imported as commodities (such as plants for planting, biological control agents and other beneficial organisms, and living modified organisms (LMOs)) may pose a risk of accidentally spreading to unintended habitats causing injury to plants or plant products. Such risks may also be analysed using the PRA process.

The PRA process is applied to pests of cultivated plants and wild flora, in accordance with the scope of the IPPC. It does not cover the analysis of risks beyond the scope of the IPPC.

Provisions of other international agreements may address risk assessment (e.g. the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to that convention).

The PRA structure

The PRA process consists of three stages:

- Stage 1: Initiation
- Stage 2: Pest risk assessment
- Stage 3: Pest risk management.

Information gathering, documentation and risk communication are carried out throughout the PRA process. PRA is not necessarily a linear process because, in conducting the entire analysis, it may be necessary to go back and forth between various stages.

Revision of this standard

This revision of ISPM No. 2 particularly addresses the issues of:

- aligning the text with the 1997 revision of the IPPC
- aligning the text with further conceptual developments of the PRA scope and procedures as appearing in ISPMs No. 3, No. 11 and No. 21
- including regulated non-quarantine pests (RNQPs) in the description of the PRA process
- including organisms not known beforehand to be pests in the description of the PRA process
- including aspects common to all PRA stages in the description of the PRA.

Thus, this standard provides detailed guidance on PRA Stage 1 and issues generic to all PRA stages, and refers to other ISPMs (identified in Table 1) as appropriate for further analysis through PRA Stages 2 and 3. This standard is conceptual and is not a detailed operational or methodological guide for assessors. An overview of the full PRA process is illustrated in Appendix 1.

¹ The IPPC defines a pest as “any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products”. The understanding of the term “pests” includes organisms that are pests because they directly affect cultivated/managed or uncultivated/unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms (c.f. Annex 1 of ISPM No. 11, 2004).

Provisions of the IPPC regarding pest risk analysis

The International Plant Protection Convention (IPPC, 1997, Article VII.2a) requires that: “*Contracting parties shall not ... take any of the measures specified in paragraph 1 of this Article [i.e. phytosanitary measures] unless such measures are made necessary by phytosanitary considerations and are technically justified.*”

Article VI.1b requires that phytosanitary measures are: “*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.*”

“Technically justified” is defined in Article II.1 as: “*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.*”

Article IV.2f states that the responsibilities of the National Plant Protection Organization (NPPO) include “*the conduct of pest risk analyses*”. The issuing of regulations is a responsibility of the contracting party to the IPPC (Article IV.3c), although contracting parties may delegate this responsibility to the NPPO.

In conducting a PRA, the obligations established in the IPPC should be taken into account. Those of particular relevance to the PRA process include:

- cooperation in the provision of information
- minimal impact
- non-discrimination
- harmonization
- transparency
- avoidance of undue delay.

REQUIREMENTS

1. PRA Stage 1: Initiation

Initiation is the identification of organisms and pathways that may be considered for pest risk assessment in relation to the identified PRA area.

A PRA process may be triggered in the following situations (initiation points, section 1.1):

- a request is made to consider a pathway that may require phytosanitary measures
- a pest is identified that may justify phytosanitary measures
- a decision is made to review or revise phytosanitary measures or policies
- a request is made to determine whether an organism is a pest.

The initiation stage involves four steps:

- determination whether an organism is a pest (section 1.2)
- defining the PRA area (section 1.3)
- evaluating any previous PRA (section 1.4)
- conclusion (section 1.5).

When the PRA process has been triggered by a request to consider a pathway, the above steps are preceded by assembling a list of organisms of possible regulatory concern because they are likely to be associated with a pathway.

At this stage, information is necessary to identify the organism and its potential economic impact, which includes environmental impact². Other useful information on the organism may include its geographical distribution, host plants, habitats and association with commodities (or, for RNQP candidates, association with plants for planting). For pathways, information about the commodity, including modes of transport, and its intended end use, is essential.

1.1 Initiation points

1.1.1 Identification of a pathway

The need for a new or revised PRA for a specific pathway may arise in situations such as when

- import is proposed of a commodity not previously imported or a commodity from a new area of origin

² Further information on this aspect is provided in *Supplement no. 2 (Guidelines on the interpretation and application of potential economic importance and related terms including reference to environmental considerations)* to ISPM No. 5 (*Glossary of phytosanitary terms*).

- there is an intention to import for selection and/or scientific research a plant species or cultivar not yet introduced that could potentially be a host of pests
- a pathway other than commodity import is identified (natural spread, packing material, mail, garbage, compost, passenger baggage, etc.)
- a change in susceptibility of a plant to a pest is identified
- a change in virulence/aggressiveness or host range of a pest.

These are situations where the commodity itself is not a pest. When the commodity itself may be a pest, it should also be considered under section 1.1.4.

A list of organisms likely to be associated with the pathway should be assembled, including organisms that have not yet been clearly identified as pests. When a PRA is carried out for a commodity for which trade already exists, records of actual pest interceptions should be used as the basis for the listing of associated pests.

1.1.2 Identification of a pest

The need for a new or revised PRA on a specific recognized pest may arise in situations such as when

- an infestation or an outbreak of a new pest is discovered
- a new pest is identified by scientific research
- a pest is reported to be more injurious than previously known
- an organism is identified as a vector for other recognized pests
- there is a change in the status or incidence of a pest in the PRA area
- a new pest is intercepted on an imported commodity
- a pest is repeatedly intercepted at import
- a pest is proposed to be imported for research or other purpose.

In these situations, the fact that the organism is known to be a pest can be recorded in preparation for PRA Stage 2.

1.1.3 Review of phytosanitary policies

The need for a new or revised PRA may arise from situations such as when

- a national review of phytosanitary regulations, requirements or operations is undertaken
- an official control programme (e.g. a certification programme encompassing phytosanitary elements) is developed to avoid unacceptable economic impact of specified RNQPs in plants for planting
- an evaluation of a regulatory proposal of another country or international organization is undertaken
- a new system, process or procedure is introduced or new information made available that could influence a previous decision (e.g. results of monitoring; a new treatment or withdrawal of a treatment; new diagnostic methods)
- an international dispute on phytosanitary measures arises
- the phytosanitary situation in a country changes or political boundaries change.

In these situations, pests will already have been identified and this fact should be recorded in preparation for PRA Stage 2.

For existing trade, no new measures should be applied until the revision or new PRA has been completed, unless this is warranted by new or unexpected phytosanitary situations which may necessitate emergency measures.

1.1.4 Identification of an organism not previously known to be a pest

An organism may be considered for PRA in situations such as when

- a proposal is made to import a new plant species or variety for cropping, amenity or environmental purposes
- a proposal is made to import or release a biological control agent or other beneficial organism
- an organism is found which has not yet been fully named or described or is difficult to identify
- a proposal is made to import an organism for research, analysis or other purpose
- a proposal is made to import or release an LMO.

In these situations it would be necessary to determine if the organism is a pest and thus subject to PRA Stage 2. Section 1.2 provides further guidance in this matter.

1.2 Determination of an organism as a pest

Pre-selection or screening are terms sometimes used to cover the early step of determining whether an organism is a pest or not.

The taxonomic identity of the organism should be specified because any biological and other information used should be relevant to the organism in question. If the organism has not yet been fully named or described, then, to be determined as a pest, it should at least have been shown to be identifiable, consistently to produce injury to plants or plant products (e.g. symptoms, reduced growth rate, yield loss or any other damage) and to be transmissible or able to disperse.

The taxonomic level for organisms considered in PRA is usually the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In cases where levels below the species level are being analysed, the rationale for this distinction should include evidence of reported significant variation in factors such as virulence, pesticide resistance, environmental adaptability, host range or its role as a vector.

Predictive indicators of an organism are characteristics that, if found, would suggest the organism may be a pest. The information on the organism should be checked against such indicators, and if none are found, it may be concluded that the organism is not a pest, and the analysis may be ended by recording the basis of that decision.

The following are examples of indicators to consider:

- previous history of successful establishment in new areas
- phytopathogenic characteristics
- phytophagous characteristics
- presence detected in connection with observations of injury to plants, beneficial organisms, etc. before any clear causal link has been established
- belonging to taxa (family or genus) commonly containing known pests
- capability of acting as a vector for known pests
- adverse effects on non-target organisms beneficial to plants (such as pollinators or predators of plant pests).

Particular cases for analysis include plant species, biological control agents and other beneficial organisms, organisms which have not yet been fully named or described, or are difficult to identify, intentional import of organisms and LMOs. The pest potential of LM-plants should be determined as outlined in section 1.2.4.

1.2.1 Plants as pests

Plants have deliberately been spread among countries and continents for millennia, and new species or varieties of plants for cropping, amenity or environmental purposes are continually imported. Some plant species or cultivars transferred to regions beyond their natural range may escape from where they were initially released and invade unintended habitats such as arable land, natural or semi-natural habitats to become pests.

Plants as pests may also be introduced unintentionally into a country, for example as contaminants of seeds for sowing, grain for consumption or fodder, wool, soil, machinery, equipment, vehicles, containers or ballast water.

Plants as pests may affect other plants by competing for water, light, minerals, etc. or through direct parasitism and thus suppressing or eliminating other plants. Imported plants may also affect, by hybridization, plant populations under cultivation or in the wild flora, and may become pests for that reason. Further information is provided in the supplementary text on environmental risks in ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004).

The primary indicator that a plant species may become a pest in the PRA area is the existence of reports that the plant species has been recorded as a pest elsewhere. Some intrinsic attributes that may indicate that a plant species could be a pest include:

- adaptability to a wide range of ecological conditions
- strong competitiveness in plant stands
- high rate of propagation
- ability to build up a persistent soil-seed bank
- high mobility of propagules
- allelopathy
- parasitic capacity
- capacity to hybridize.

However, it should be noted that plants without such attributes may nevertheless become pests and that long time lags have often been observed between the introduction of a new plant species and evidence that the plant is a pest.

1.2.2 Biological control agents and other beneficial organisms

Biological control agents and other beneficial organisms are intended to be beneficial to plants. Thus, when performing

a PRA, the main concern is to look for potential injury to non-target organisms³. Other concerns may include:

- contamination of cultures of beneficial organisms with other species, the culture thereby acting as a pathway for pests
- reliability of containment facilities when such are required.

1.2.3 Organisms not yet fully described or difficult to identify

Organisms that have not yet been fully named or described or are difficult to identify (e.g. damaged specimen or unidentifiable life stages) may be detected in imported consignments or during surveillance, in which case a decision as to whether phytosanitary action is justified and recommendations for phytosanitary measures may need to be made. These should be based on a PRA using the information available, even if very limited. It is recommended that, in such cases, specimens are deposited in an accessible reference collection for future further examination.

1.2.4 Living modified organisms

LMOs are organisms that possess a novel combination of genetic material, obtained through the use of modern biotechnology and are designed to express one or more new or altered traits. Types of LMOs for which a PRA may be conducted include:

- plants for use in agriculture, horticulture or silviculture, bioremediation of soil, for industrial purposes, or as therapeutic agents (e.g. LMO plants with an enhanced vitamin profile)
- biological control agents and other beneficial organisms modified to improve their performance
- pests modified to alter their pathogenic characteristics.

The modification may result in an organism with a new trait that may now present a pest risk beyond that posed by the non-modified recipient or donor organisms, or similar organisms. Risks may include:

- increased potential for establishment and spread
- those resulting from inserted gene sequences that may act independently of the organism with subsequent unintended consequences
- potential to act as a vector for the entering of a genetic sequence into domesticated or wild relatives of that organism, resulting in an increase in the pest risk of that related organism
- in case of a modified plant species, the potential to act as a vector for the entering of an injurious genetic sequence into relatives of that species.

PRA is usually concerned with phenotypic rather than genotypic characteristics. However, genotypic characteristics should also be considered when assessing the pest risks of LMOs.

Predictive indicators more specific to LMOs include intrinsic attributes such as:

- phenotypic similarities or genetic relationships to known pest species
- introduced changes in adaptive characteristics that may increase the potential for introduction or spread
- phenotypic and genotypic instability.

For LMOs, identification requires information regarding the taxonomic status of the recipient and the donor organism, and description of the vector, the nature of the genetic modification, and the genetic sequence and its insertion site in the recipient genome.

Further potential risks of LMOs are outlined in Annex 3 to ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004). A PRA may be carried out to determine whether the LMO is a pest, and subsequently assess the pest risk.

1.2.5 Import of organisms for specific uses

When a request is made to import an organism that may be a pest for use in scientific research, education, industry or other purposes, the identity of the organism should be clearly defined. Information on the organism or closely related organisms may be assessed to identify indicators that it may be a pest. For organisms determined to be pests, pest risk assessment may be carried out.

1.3 Defining the PRA area

The area to which the PRA refers has to be clearly defined. It may be the whole or part of a country or several countries.

³ ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, 2005) recommends that NPPOs should conduct a PRA either before import or before release of biological control agents and other beneficial organisms.

Whereas information may be gathered from a wider geographical area, the analysis of establishment, spread and economic impact should relate only to the defined PRA area.

In PRA Stage 2, the *endangered* area is identified. In PRA Stage 3, the *regulated* area may, however, be designated as wider than the endangered area if technically justified and not in conflict with the principle of non-discrimination.

1.4 Previous pest risk analyses

Before performing a new PRA, a check should be made to determine if the organism, pest or pathway has ever been subjected to a previous PRA. The validity of any existing analysis should be verified because circumstances and information may have changed. Its relevance to the PRA area should be confirmed.

The possibility of using a PRA of a similar organism, pest or pathway may also be investigated, particularly when information on the specific organism is absent or incomplete. Information assembled for other purposes, such as environmental impact assessments of the same or a closely related organism, may be useful but cannot substitute for a PRA.

1.5 Conclusion of initiation

At the end of PRA Stage 1, pests and pathways of concern will have been identified and the PRA area defined. Relevant information will have been collected and pests identified as candidates for further assessment, either individually or in association with a pathway.

Organisms determined not to be pests and pathways not carrying pests need not be further assessed. The decision and rationale should be recorded and communicated, as appropriate.

Where an organism has been determined to be a pest the process may continue to PRA Stage 2. Where a list of pests has been identified for a pathway, pests may be assessed as groups, where biologically similar, or separately.

Where the PRA is specifically aimed at determining if the pest should be regulated as a quarantine pest, the process may proceed immediately to the pest categorization step of pest risk assessment (PRA Stage 2) of ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004). That ISPM is relevant for organisms that appear to meet the following criteria:

- not present in the PRA area or, if present, of limited distribution and subject to official control or being considered for official control
- having the potential to cause injury to plants or plant products in the PRA area
- having the potential to establish and spread in the PRA area.

Where the PRA is specifically aimed at determining if the pest should be regulated as an RNQP, the process may proceed immediately to the pest categorization step of pest risk assessment (PRA Stage 2) of ISPM No. 21 (*Pest risk analysis for regulated non-quarantine pests*). That ISPM is relevant for organisms that appear to meet the following criteria:

- present in the PRA area and subject to official control or being considered for official control
- plants for planting are a pathway for the pest in the PRA area
- having the potential to affect the intended use of plants for planting with an economically unacceptable impact in the PRA area.

2. Summary of PRA Stages 2 and 3

2.1 Linked standards

The PRA process for different pest categories is described in separate ISPMs, as summarized in Table 1. As circumstances change and techniques evolve, new standards may be developed and others revised.

Table 1: Standards linked to ISPM No. 2

ISPM	Title	Coverage of PRA
ISPM No. 11 (2004)	<i>Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms</i>	Specific guidance on PRA of quarantine pests including: - Stage 1: Initiation ⁴ - Stage 2: Pest risk assessment including environmental risks and LMO assessment - Stage 3: Pest risk management
ISPM No. 21	<i>Pest risk analysis for regulated non-quarantine pests</i>	Specific guidance on PRA of regulated non-quarantine pests including: - Stage 1: Initiation ⁴ - Stage 2: Pest risk assessment especially of plants for planting as the main source of infestation and economic impact on their intended use - Stage 3: Pest risk management
ISPM No. 3 (2005)	<i>Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms</i>	Specific guidance on pest risk management for biological control agents and beneficial organisms ⁵

2.2 Summary of PRA Stage 2: Pest risk assessment

Stage 2 involves several steps:

- pest categorization: the determination of whether the pest has the characteristics of a quarantine pest or RNQP, respectively
- assessment of introduction and spread
 - candidates for quarantine pests: the identification of the endangered area and assessment of the probability of introduction and spread
 - candidates for RNQPs: assessment of whether the plants for planting are or will be the main source of pest infestation, in comparison to other sources of infestation of the area
- assessment of economic impacts
 - candidates for quarantine pests: assessment of economic impacts, including environmental impacts
 - candidates for RNQPs: assessment of potential economic impacts associated with the intended use of plants for planting in the PRA area (including analysis of infestation threshold and tolerance level)
- conclusion, summarizing the overall pest risk on the basis of assessment results regarding introduction, spread and potential economic impacts for quarantine pests, or economically unacceptable impacts for regulated non-quarantine pests.

The outputs from pest risk assessment are used to decide if the pest risk management stage (Stage 3) is required.

2.3 Summary of PRA Stage 3: Pest risk management

Stage 3 involves the identification of phytosanitary measures that (alone or in combination) reduce the risk to an acceptable level.

Phytosanitary measures are not justified if the pest risk is considered acceptable or if they are not feasible (e.g. as may be the case with natural spread). However, even in such cases contracting parties may decide to maintain a low level of monitoring or audit regarding the pest risk to ensure that future changes in that risk are identified.

The conclusion of the pest risk management stage will be whether or not appropriate phytosanitary measures adequate to reduce the pest risk to an acceptable level are available, cost-effective and feasible.

In addition to standards for PRA (Table 1), other standards provide specific technical guidance to pest risk management options.

⁴ The present ISPMs No. 11 and No. 21, adopted before this revision of ISPM No. 2, include some guidance on PRA Stage 1 for quarantine pests and RNQPs, respectively.

⁵ ISPM No. 3 provides more detailed guidance appropriate to PRA Stage 1, for example with respect to the provision of necessary information, documentation and communication to relevant parties.

3. Aspects Common to All PRA Stages

3.1 Uncertainty

Uncertainty is a component of risk and therefore important to recognize and document when performing PRAs. Sources of uncertainty with a particular PRA may include: missing, incomplete, inconsistent or conflicting data; natural variability of biological systems; subjectiveness of analysis; and sampling randomness. Symptoms of uncertain causes and origin and asymptomatic carriers of pests may pose particular challenges.

The nature and degree of uncertainty in the analysis should be documented and communicated, and the use of expert judgement indicated. If adding or strengthening of phytosanitary measures are recommended to compensate for uncertainty, this should be recorded. Documentation of uncertainty contributes to transparency and may also be used for identifying research needs or priorities.

As uncertainty is an inherent part of PRA, it is appropriate to monitor the phytosanitary situation resulting from the regulation based on any particular PRA and to re-evaluate previous decisions.

3.2 Information gathering

Throughout the process, information should be gathered and analysed as required to reach recommendations and conclusions. Scientific publications as well as technical information such as data from surveys and interceptions may be relevant. As the analysis progresses, information gaps may be identified necessitating further enquiries or research. Where information is insufficient or inconclusive, expert judgement may be used if appropriate.

Cooperation in the provision of information and responding to requests for information made via the official contact point are IPPC obligations (Articles VIII.1c and VIII.2). When requesting information from other contracting parties, requests should be as specific as possible and limited to information essential to the analysis. Other agencies may be approached for information appropriate to the analysis.

3.3 Documentation

The principle of transparency requires that contracting parties should, on request, make available the technical justification for phytosanitary requirements. Thus, the PRA should be sufficiently documented. Documenting PRA has two levels:

- documenting the general PRA process
- documenting each analysis made.

3.3.1 Documenting the general PRA process

The NPPO should preferably document procedures and criteria of its general PRA process.

3.3.2 Documenting each specific PRA

For each particular analysis, the entire process from initiation to pest risk management should be sufficiently documented so that the sources of information and rationale for management decisions can be clearly demonstrated. However, a PRA does not necessarily need to be long and complex. A short and concise PRA may be sufficient provided justifiable conclusions can be reached after completing only a limited number of steps in the PRA process.

The main elements to be documented are:

- purpose of the PRA
- identity of the organism
- PRA area
- biological attributes of the organism and evidence of ability to cause injury
- for quarantine pests: pest, pathways, endangered area
- for RNQPs: pest, host, plants and/or parts or class of plants under consideration, sources of infestation, intended use of the plants
- sources of information
- nature and degree of uncertainty and measures envisaged to compensate for uncertainty
- for pathway-initiated analysis: commodity description and categorized pest list
- evidence of economic impact, which includes environmental impact
- conclusions of pest risk assessment (probabilities and consequences)
- decisions and justifications to stop the PRA process
- pest risk management: phytosanitary measures identified, evaluated and recommended
- date of completion and the NPPO responsible for the analysis, including if appropriate names of authors, contributors and reviewers.

Other aspects to be documented may include⁶:

- particular need for monitoring the efficacy of proposed phytosanitary measures
- hazards identified outside the scope of the IPPC and to be communicated to other authorities.

3.4 Risk communication

Risk communication is generally recognized as an interactive process allowing exchange of information between the NPPO and stakeholders. It is not simply a one-way movement of information or about making stakeholders understand the risk situation, but is meant to reconcile the views of scientists, stakeholders, politicians, etc. in order to:

- achieve a common understanding of the pest risks
- develop credible pest risk management options
- develop credible and consistent regulations and policies to deal with pest risks
- promote awareness of the phytosanitary issues under consideration.

At the end of the PRA, evidence supporting the PRA, the proposed mitigations and uncertainties should preferably be communicated to stakeholders and other interested parties, including other contracting parties, RPPOs and NPPOs, as appropriate.

If, subsequent to the PRA, phytosanitary requirements, restrictions or prohibitions are adopted, the contracting party shall immediately publish and transmit those to contracting parties that it believes may be directly affected (according to IPPC Article VII.2b) and on request make the rationale available to any contracting party (according to IPPC Article VII.2c).

If, subsequent to the PRA, phytosanitary requirements, restrictions or prohibitions are not adopted, contracting parties are encouraged to make this information available.

NPPOs are encouraged to communicate evidence of hazards other than pest risks (such as to animals or human health) to the appropriate authorities.

3.5 Consistency in PRA

It is recommended that an NPPO strives for consistency in its conduct of PRAs. Consistency offers numerous benefits, including:

- facilitation of the principles of non-discrimination and transparency
- improved familiarity with the PRA process
- increased efficiency in completing PRAs and managing related data
- improved comparability between PRAs conducted on similar products or pests, which in turn aids in development and implementation of similar or equivalent management measures.

Consistency may be assured through, for example, the elaboration of generic decision criteria and procedural steps, training of individuals conducting PRA, and review of draft PRAs.

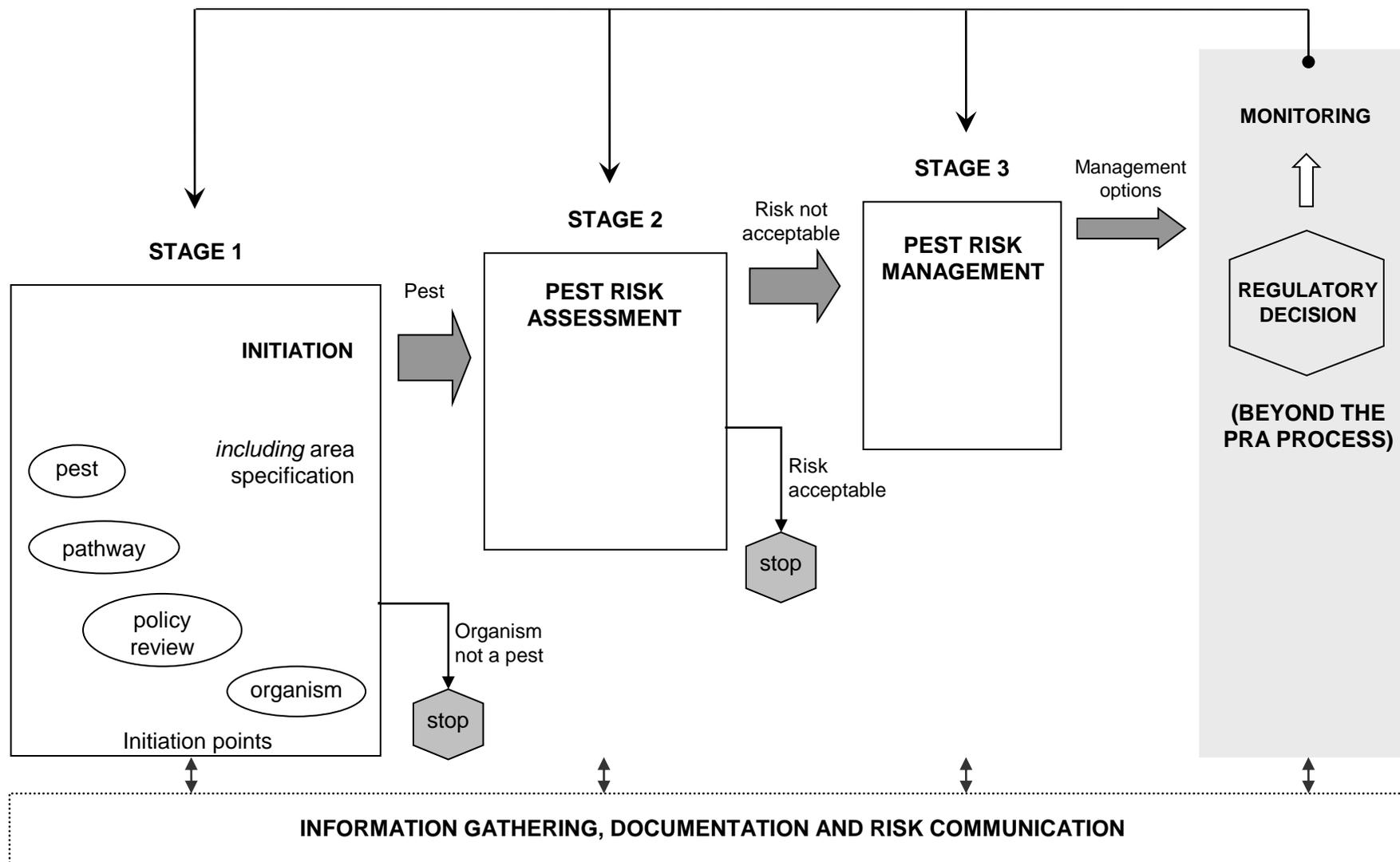
3.6 Avoidance of undue delay

Where other contracting parties are directly affected, the NPPO should, on request, supply information about the completion of individual analyses, and if possible the anticipated time frame, taking into account avoidance of undue delay (section 2.14 of ISPM No. 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006).

⁶ ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, 2005) lists additional documentation requirements in relation to such organisms.

APPENDIX 1

PEST RISK ANALYSIS FLOW CHART⁷



⁷ This appendix is not an official part of the standard. It is provided for information only.



**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



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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 standard¹ 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 organisms² (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 importer³. 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 risks⁴ 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 RPOs 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

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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.

ISPM No. 5



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 5

GLOSSARY OF PHYTOSANITARY TERMS

(2008)

Produced by the Secretariat of the International Plant Protection Convention



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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 Third session of the Commission on Phytosanitary Measures in 2008. 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]
bark	The layer of a woody trunk, branch or root outside the cambium [CPM, 2008]
bark-free wood	Wood from which all bark , except ingrown bark around knots and bark pockets between rings of annual growth, has been removed [ISPM No. 15, 2002; revised CPM, 2008]
beneficial organism	Any organism directly or indirectly advantageous to plants or plant products , including biological control agents [ISPM No. 3, 2005]
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]
buffer zone	An area surrounding or adjacent to an area officially delimited for phytosanitary purposes in order to minimize the probability of spread of the target pest into or out of the delimited area, and subject to phytosanitary or other control measures, if appropriate [ISPM No. 10, 1999; revised ISPM No. 22, 2005; CPM, 2007]
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]
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]
debarked wood	Wood that has been subjected to any process that results in the removal of bark . (Debarked wood is not necessarily bark-free wood .) [CPM, 2008; replacing debarking]
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 (see Glossary Supplement No. 2) [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]
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 consignment , field or place of production and consider it to be free from a specific pest [FAO, 1990]
free from (of a consignment, 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]
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]
integrity (of a consignment)	Composition of a consignment as described by its phytosanitary certificate or other officially acceptable document, maintained without loss, addition or substitution [CPM, 2007]
intended use	Declared purpose for which plants, plant products , 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]
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 [<i>Cartagena Protocol on Biosafety to the Convention on Biological Diversity</i> , 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]
minimum absorbed dose (Dmin)	The localized minimum absorbed dose within the process load [ISPM No. 18, 2003]
modern biotechnology	The application of: <ul style="list-style-type: none"> 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. [<i>Cartagena Protocol on Biosafety to the Convention on Biological Diversity</i> , 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 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 (for quarantine pests)	The probability of introduction and spread of a pest and the magnitude of the associated potential economic consequences (see Glossary Supplement No. 2) [ISPM No. 2, 2007]
pest risk (for regulated non-quarantine pests)	The probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact (see Glossary Supplement No. 2) [ISPM No. 2, 2007]

Pest Risk Analysis (agreed interpretation)	The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest , whether it should be regulated, and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC, 1997; ISPM No. 2, 2007]
pest risk assessment (for quarantine pests)	Evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences (see Glossary Supplement No. 2) [FAO, 1995; revised ISPM No. 11, 2001; ISPM No. 2, 2007]
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 (see Glossary Supplement No. 2) [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 (see Glossary Supplement No. 2) [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 pests , or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; ISPM, 2002]
<i>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).</i>	
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 (see Glossary Supplement No. 2) [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 <i>in vitro</i>	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 (see Glossary Supplement No. 2) [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 (see Glossary Supplement No. 2) [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 establishment) [ISPM No. 3, 1996]
release (of a consignment)	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]
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]
treatment schedule	The critical parameters of a treatment which need to be met to achieve the intended outcome (i.e. the killing, inactivation or removal of pests , or rendering pests infertile, or devitalization) at a stated efficacy [ISPM No. 28, 2007]
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 a 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 criteria¹ 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.

ISPM No. 6



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 6

GUIDELINES FOR SURVEILLANCE

(1997)

Produced by the Secretariat of the International Plant Protection Convention



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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.

ISPM No. 7



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 7

EXPORT CERTIFICATION SYSTEM

(1997)

Produced by the Secretariat of the International Plant Protection Convention



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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.

ISPM No. 8



**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



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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 evidence¹ 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 areas²

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 grown³

Present: only in protected cultivation

Present: seasonally

Present: but managed⁴

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.

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ISPM No. 9



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 9

***GUIDELINES FOR PEST ERADICATION
PROGRAMMES***

(1998)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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



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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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New Revised Text of the International Plant Protection Convention, 1997. FAO, Rome.
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



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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.

INTRODUCTION¹

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 habitat² (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.

SI 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).

SI 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.

SI 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.

SI 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).

SI 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.

SI 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.

SI 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.

SI 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.

SI 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 disinfection.

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.

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.

**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.

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.

ISPM No. 12



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 12

GUIDELINES FOR PHYTOSANITARY CERTIFICATES

(2001)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

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

Glossary of phytosanitary terms, 1999. ISPM No. 5, FAO, Rome.

New Revised Text of the International Plant Protection Convention, 1997. FAO, Rome.

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

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

REQUIREMENTS FOR PHYTOSANITARY CERTIFICATES

1. General Considerations

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

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

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

1.1 Purpose of phytosanitary certificates

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

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

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

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

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

1.2 Mode of issue

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

Alternatively, electronic certification may be used provided that:

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

1.3 Attachments

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

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

1.4 Unacceptable certificates

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

1.4.1 Invalid phytosanitary certificates

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

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

1.4.2 Fraudulent certificates

Fraudulent certificates include those:

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

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

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

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

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

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

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

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

2.1 Requirements for completing the phytosanitary certificate

(Headings in bold refer to the components of the model certificate)

The specific components of the phytosanitary certificate are explained as follows:

No. _____

This is the certificate identification number. It should be a unique serial number associated with an identification system that allows "trace-back", facilitates audits and serves for record keeping.

Plant Protection Organization of _____

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

TO: Plant Protection Organization(s) of _____

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

Section I. Description of Consignment**Name and address of exporter:** _____

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

Declared name and address of consignee: _____

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

Number and description of packages: _____

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

Distinguishing marks: _____

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

Place of origin: _____

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

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

Declared means of conveyance: _____

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

Declared point of entry: _____

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

Name of produce and quantity declared: _____

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

Botanical name of plants: _____

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

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

Certifying statement

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

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

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

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

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

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

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

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

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

Section II. Additional Declaration

Additional declarations should be only those containing information required by the importing country and not

otherwise noted on the certificate. Additional declarations should be kept to a minimum and be concise. The text of additional declarations may be specified in, for example, phytosanitary regulations, import permits or bilateral agreements. Treatment(s) should be indicated in Section III.

Section III. Disinfestation and/or Disinfection Treatment

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

Stamp of organization

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

Name of authorized officer, date and signature

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

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

Financial liability statement

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

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

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

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

3.1 Conditions for issuing a phytosanitary certificate for re-export

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

3.2 Conditions for issuing a phytosanitary certificate for an imported consignment

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

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

3.3 Transit

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

phytosanitary certificate. If the consignment is split up, combined with other consignments or repackaged, the NPPO should issue a phytosanitary certificate for re-export.

Model Phytosanitary Certificate

No. _____

Plant Protection Organization of _____
TO: Plant Protection Organization(s) of _____**I. Description of Consignment**Name and address of exporter: _____
Declared name and address of consignee: _____
Number and description of packages: _____
Distinguishing marks: _____
Place of origin: _____
Declared means of conveyance: _____
Declared point of entry: _____
Name of produce and quantity declared: _____
Botanical name of plants: _____

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

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

II. Additional Declaration**III. Disinfestation and/or Disinfection Treatment**Date _____ Treatment _____ Chemical (active ingredient) _____
Duration and temperature _____
Concentration _____
Additional information _____

Place of issue _____

(Stamp of Organization) Name of authorized officer _____

Date _____ (Signature) _____

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

* Optional clause

Model Phytosanitary Certificate for Re-Export

No. _____

Plant Protection Organization of _____ (contracting party of re-export)

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

I. Description of Consignment

Name and address of exporter: _____

Declared name and address of consignee: _____

Number and description of packages: _____

Distinguishing marks: _____

Place of origin: _____

Declared means of conveyance: _____

Declared point of entry: _____

Name of produce and quantity declared: _____

Botanical name of plants: _____

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

* Insert tick in appropriate boxes**II. Additional Declaration****III. Disinfestation and/or Disinfection Treatment**

Date _____ Treatment _____ Chemical (active ingredient) _____

Duration and temperature _____

Concentration _____

Additional information _____

Place of issue _____

(Stamp of Organization) Name of authorized officer _____

Date _____ (Signature) _____

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

** Optional clause



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 13

***GUIDELINES FOR THE NOTIFICATION OF
NON-COMPLIANCE AND EMERGENCY ACTION***

(2001)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

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

REFERENCES

- Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.
Export certification systems, 1997. ISPM No. 7, FAO, Rome.
Glossary of phytosanitary terms, 1999. ISPM No. 5, FAO, Rome.
Guidelines for phytosanitary certificates, ISPM No. 12, FAO, Rome.
New Revised Text of the International Plant Protection Convention, 1997. FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

The International Plant Protection Convention (IPPC, 1997) makes provision for contracting parties to report significant instances of non-compliance of imported consignments with phytosanitary requirements, including those related to documentation or to report appropriate emergency action, which is taken on the detection in the imported consignment of an organism posing a potential phytosanitary threat. The importing contracting party is required to notify the exporting contracting party as soon as possible regarding significant instances of non-compliance and emergency actions applied to imported consignments. The notification should identify the nature of non-compliance in such a way that the exporting contracting party may investigate and make the necessary corrections. Importing contracting parties may request a report of the results of such investigations.

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

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

REQUIREMENTS

1. Purpose of Notifications

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

2. The Use of Notification Information

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

3. Provisions of the IPPC Related to Notification

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

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

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

4. Basis for Notification

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

4.1 Significant instances of non-compliance

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

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

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

4.2 Emergency action

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

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

5. Timing of Notification

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

6. Information Included in a Notification

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

6.1 Required information

Notifications should include the following information:

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

6.2 Supporting information

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

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

6.3 Forms, codes, abbreviations or acronyms

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

6.4 Language

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

7. Documentation and Means of Communication

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

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

8. Pest Identification

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

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

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

When identifying pests, importing countries should:

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

9. Investigation of Non-compliance and Emergency Action

9.1 Non-compliance

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

9.2 Emergency action

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

10. Transit

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

11. Re-export

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



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 14

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

(2002)

Produced by the Secretariat of the International Plant Protection Convention

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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Glossary of phytosanitary terms*, 2001. ISPM No. 5, FAO, Rome.
- Guidelines for an integrated system of measures to mitigate pest risk (systems approach)*, 1998. V 1.2. COSAVE, Asuncion, Paraguay.
- Guidelines for pest risk analysis*, 1996. ISPM No. 2, FAO, Rome.
- Hazard analysis and critical control point system and guidelines for its application, annex to the recommended international code of practice - general principles of food hygiene*, 1969 (Revised 1997). Codex Alimentarius, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Pest risk analysis for quarantine pests*, 2001. ISPM No. 11, FAO, Rome.
- Principles of plant quarantine as related to international trade*, 1995. ISPM No. 1, FAO, Rome.
- Requirements for the establishment of pest free areas*, 1996. ISPM No. 4, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

REQUIREMENTS

1. Purpose of Systems Approaches

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

2. Characteristics of Systems Approaches

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

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

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

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

3. Relationship with PRA and Available Risk Management Options

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

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

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

The following summarizes many of the options commonly used:

Pre-planting

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

Pre-harvest

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

Harvest

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

Post harvest treatment and handling

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

Transportation and distribution

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

4. Independent and Dependent Measures

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

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

Example:

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

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

Example:

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

5. Circumstances for Use

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

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

6. Types of Systems Approaches

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

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

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

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

7. Efficacy of Measures

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

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

8. Developing Systems Approaches

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

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

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

The development of a systems approach involves:

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

9. Evaluating Systems Approaches

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

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

9.1 Possible outcomes of evaluation

These may include determination that the systems approach is:

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

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

10. Responsibilities

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

10.1 Importing country responsibilities

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

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

Importing countries, in consultation with the exporting country where appropriate should select least trade restrictive

measures where there are options.

Other responsibilities of the importing country may include to:

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

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

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

10.2 Exporting country responsibilities

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

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

Other responsibilities of the exporting country include:

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

APPENDIX

CRITICAL CONTROL POINT SYSTEM

A critical control point system would involve the following procedures:

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

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

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

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



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 15

***GUIDELINES FOR REGULATING WOOD PACKAGING
MATERIAL IN INTERNATIONAL TRADE***

(2002)

with modifications to Annex I (2006)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

This standard describes phytosanitary measures to reduce the risk of introduction and/or spread of quarantine pests associated with wood packaging material (including dunnage), made of coniferous and non-coniferous raw wood, in use in international trade.

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Export certification system*, 1997. ISPM No. 7, FAO, Rome.
- Glossary of phytosanitary terms*, 2001. ISPM No. 5, FAO, Rome.
- Guidelines for phytosanitary certificates*, 2001. ISPM No. 12, FAO, Rome.
- Guidelines on notification of non-compliance and emergency action*, 2001. ISPM No. 13, FAO, Rome.
- ISO 3166-1-ALPHA-2 CODE ELEMENTS (http://www.din.de/gremien/nas/nabd/iso3166ma/codlstp1/en_listp1.html)
- International Plant Protection Convention*, 1997. FAO, Rome.
- Principles of plant quarantine as related to international trade*, 1995. ISPM No. 1, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

REGULATORY REQUIREMENTS

1. Basis for Regulating

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

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

2. Regulated Wood Packaging Material

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

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

Wood packaging material such as veneer peeler cores¹, sawdust, wood wool, and shavings, and raw wood cut into thin² pieces may not be pathways for introduction of quarantine pests and should not be regulated unless technically justified.

3. Measures for Wood Packaging Material

3.1 Approved measures

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

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

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

Approved measures are specified in Annex I.

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

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

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

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

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

3.2 Measures pending approval

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

3.3 Other measures

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

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

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

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

3.4 Review of measures

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

OPERATIONAL REQUIREMENTS

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

4. Dunnage

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

5. Procedures Used Prior to Export

5.1 Compliance checks on procedures applied prior to export

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

5.2 Transit arrangements

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

6. Procedures upon Import

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

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

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

6.1 Measures for non-compliance at point of entry

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

6.2 Disposal

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

Incineration

Complete burning

Burial

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

Processing

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

Other methods

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

The methods should be applied with the least possible delay.

ANNEX I (modified in 2006)

APPROVED MEASURES ASSOCIATED WITH WOOD PACKAGING MATERIAL

Heat treatment (HT)

Wood packaging material should be heated in accordance with a specific time-temperature schedule that achieves a minimum wood core temperature of 56°C for a minimum of 30 minutes³.

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

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

Methyl bromide (MB) fumigation for wood packaging material (modified in 2006⁴)

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

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

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

List of most significant pests targeted by HT and MB

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

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

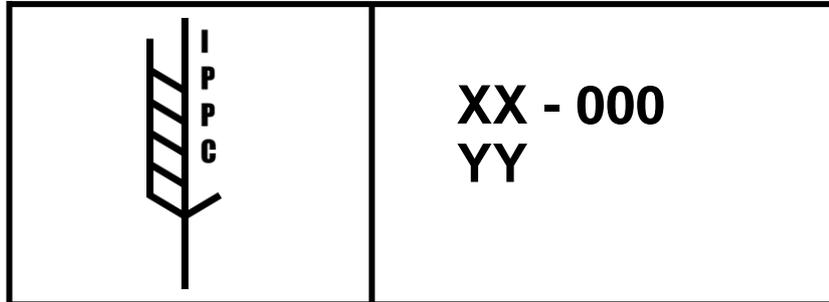
³ A minimum core temperature of 56° C for a minimum of 30 min. is chosen in consideration of the wide range of pests for which this combination is documented to be lethal and a commercially feasible treatment. Although it is recognized that some pests are known to have a higher thermal tolerance, quarantine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

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

ANNEX II

MARKING FOR APPROVED MEASURES

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



The mark should at minimum include the:

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

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

Markings should be:

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

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

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

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

ANNEX III

MEASURES BEING CONSIDERED FOR APPROVAL UNDER THIS STANDARD

Treatments⁵ being considered and which may be approved when appropriate data becomes available, include but are not limited to:

Fumigation

Phosphine
Sulfuryl fluoride
Carbonyl sulphide

CPI

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

Irradiation

Gamma radiation
X-rays
Microwaves
Infra red
Electron beam treatment

Controlled atmosphere

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



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 16

***REGULATED NON-QUARANTINE PESTS:
CONCEPT AND APPLICATION***

(2002)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.
- FAO. 1967. Types of losses caused by plant diseases, by J.C. Zadoks. FAO Symposium on crop losses. Rome, 2-6 October 1967, pp. 149-158.
- Glossary of phytosanitary terms*, 2001. ISPM No. 5, FAO, Rome.
- Glossary supplement no. 1: Guidelines on the interpretation and application of the concept of official control for regulated pests*, 2001. ISPM No. 5, FAO, Rome.
- Guidelines for pest risk analysis*, 1996. ISPM No. 2, FAO, Rome.
- Guidelines for surveillance*, 1998. ISPM No. 6, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Principles of plant quarantine as related to international trade*, 1995. ISPM No. 1, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

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

GENERAL REQUIREMENTS

1. Background

Certain pests that are not quarantine pests are subject to phytosanitary measures because their presence in plants for planting results in economically unacceptable impacts associated with the intended use of the plants. Such pests are known as regulated non-quarantine pests (RNQPs) and are present and often widespread in the importing country. Where official control is applied to plants for planting produced within countries to protect them from such pests, then the same or equivalent phytosanitary measures may be applied to those pests on imported plants for planting of the same species for the same intended use.

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

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

Article VII.1

With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:

- a) *prescribe and adopt phytosanitary measures...*
- b) *refuse entry or detain, or require treatment, destruction or removal ...*
- c) *prohibit or restrict the movement of regulated pests....*

Article VI.1

Contracting parties may require phytosanitary measures for quarantine pests and regulated non-quarantine pests, provided that such measures are:

- a) *no more stringent than measures applied to the same pests, if present within the territory of the importing 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.*

Article VI.2

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

Article IV.3

Each contracting party shall make provision, to the best of its ability, for the following:

- a) *the distribution of information within the territory of the contracting party regarding regulated pests and the means of their prevention and control ...*

Article VII.2i

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

ANNEX:

Text of the Model Phytosanitary Certificate:

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

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

**Optional clause*

3. Comparison between RNQPs and Other Pests

3.1 Comparison with quarantine pests

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

The table below provides a summary of the distinctions.

Comparison of Quarantine Pests and RNQPs

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

3.1.1 Pest status

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

3.1.2 Pathway

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

3.1.3 Economic impacts

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

3.1.4 Official control

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

3.2 Comparison with non-regulated pests

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

4. Criteria that Define RNQPs

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

4.1 "Plants for planting"

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

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

4.2 “Intended use”

The "intended use" of plants for planting may be:

- growing for direct production of other commodity classes (e.g. fruits, cut flowers, wood, grain, etc.)
- to remain planted (e.g. ornamentals)
- increasing the number of the same plants for planting (e.g. tubers, cuttings, seeds).

Risk of economically unacceptable impact varies with different pests, commodities, and intended use. Distinctions may be made between commercial use (involving a sale or intention to sell), and non-commercial use (not involving a sale and limited to a low number of plants for planting for private use), where such a distinction is technically justified.

4.3 “Those plants”

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

4.4 “Economically unacceptable impact”

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

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

Relevant factors in determining economically unacceptable impacts include:

- reduction of quantity of marketable yield (e.g. reduction in yield)
- reduction of quality (e.g. reduced sugar content in grapes for wine, downgrading of marketed product)
- extra costs of pest control (e.g. roguing, pesticide application)
- extra costs of harvesting and grading (e.g. culling)
- costs of replanting (e.g. due to loss of longevity of plants)
- loss due to the necessity of growing substitute crops (e.g. due to need to plant lower yielding resistant varieties of the same crop or different crops).

In particular cases, pest effects on other host plants at the place of production may be considered relevant factors.

4.5 “Regulated”

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

5. Relevant Principles and Obligations

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

5.1 Technical justification

Phytosanitary measures covering RNQPs should be technically justified as required by the IPPC (1997). The classification of a pest as an RNQP and any restrictions placed on the import of the plant species with which it is associated should be justified by pest risk analysis.

5.2 Risk assessment

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

5.3 Managed risk, minimal impact and equivalence

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

5.4 Non-discrimination

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

5.5 Transparency

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

6. Application

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

6.1 Host-pest interaction

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

6.2 Certification programmes¹

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

6.3 Tolerances

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

6.4 Non-compliance

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

Options include:

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

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

ISPM No. 17



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 17

PEST REPORTING

(2002)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Determination of pests status in an area*, 1998. ISPM No. 8, FAO, Rome.
Glossary of phytosanitary terms, 2001. ISPM No. 5, FAO, Rome.
Guidelines for pest eradication programmes, 1999. ISPM No.9, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for surveillance, 1998. ISPM No. 6, FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests, 2001. ISPM No. 11, FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

The International Plant Protection Convention (1997) requires countries to report on the occurrence outbreak, and spread of pests with the purpose of communicating immediate or potential danger. National Plant Protection Organizations (NPPOs) have the responsibility to collect pest information by surveillance and to verify the pest records thus collected. Occurrence, outbreak or spread of pests that are known (on the basis of observation, previous experience, or Pest Risk Analysis [PRA]) to be of immediate or potential danger should be reported to other countries, in particular to neighbouring countries and trading partners.

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

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

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

REQUIREMENTS

1. Provisions of the IPPC Regarding Pest Reporting

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

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

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

With these systems in operation, countries are able to fulfil the requirement under the IPPC:

"...to cooperate with one another to the fullest practicable extent in achieving the aims of this Convention (Article VIII.1), and in particular to cooperate in the exchange of information on plant pests, particularly the reporting of the occurrence, outbreak or spread of pests that may be of immediate or potential danger, in accordance with such procedures as may be established by the Commission ..."(Article VIII.1a).

2. Purpose of Pest Reporting

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

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

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

3. National Responsibilities

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

3.1 Surveillance

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

3.2 Sources of information

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

3.3 Verification and analysis

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

3.4 Motivation for domestic reporting

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

4. Reporting Obligations

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

4.1 Reporting of immediate or potential danger

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

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

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

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

4.2 Other pest reports

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

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

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

4.4 Reporting of pests in imported consignments

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

5. Initiation of Reports

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

5.1 Occurrence

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

5.2 Outbreak

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

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

5.3 Spread

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

5.4 Successful eradication

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

5.5 Establishment of Pest Free Area

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

6. Pest Reporting

6.1 Content of reports

A pest report should clearly indicate:

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

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

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

6.2 Timing of reporting

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

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

6.3 Mechanism of reporting and destination of reports

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

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

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

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

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

6.4 Good reporting practices

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

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

6.5 Confidentiality

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

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

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

6.6 Language

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

7. Additional Information

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

8. Review

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

9. Documentation

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



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 18

***GUIDELINES FOR THE USE OF IRRADIATION
AS A PHYTOSANITARY MEASURE***

(2003)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

This standard¹ provides technical guidance on the specific procedures for the application of ionizing radiation as a phytosanitary treatment for regulated pests or articles. This does not include treatments used for:

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

REFERENCES

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

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

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

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

International Plant Protection Convention, 1997. FAO, Rome.

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

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

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

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY MEASURE

1. Authority

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

2. Treatment Objective

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

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

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

2.1 Efficacy

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

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

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

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

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

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

- complete sterility;
- limited fertility of only one sex;
- egg laying and/or hatching without further development;
- altered behaviour; and
- sterility of F₁ generation.

3. Treatment

Ionizing radiation may be provided by radioactive isotopes (gamma rays from cobalt-60 or cesium-137), electrons generated from machine sources (up to 10 MeV), or by x-rays (up to 5 MeV) (limits set by Codex Alimentarius²). The unit of measurement for absorbed dose should be gray (Gy).

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

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

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

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

3.1 Application

Irradiation can be applied:

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

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

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

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

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

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

4. Dosimetry

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

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

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

4.1 Calibration of components of the dosimetry system

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

4.2 Dose mapping

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

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

4.3 Routine dosimetry

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

5. Approval of Facilities

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

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

6. Phytosanitary System Integrity

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

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

6.1 Phytosanitary security measures at the treatment facility

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

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

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

6.2 Labelling

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

6.3 Verification

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

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

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

7. Documentation by the Treatment Facility

The NPPO of the country where the facility is located is responsible for monitoring recordkeeping and documentation by the treatment facility and ensuring that records are available to concerned parties. As in the case of any phytosanitary

treatment, trace-back capability is essential.

7.1 Documentation of procedures

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

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

7.2 Facility records and traceability

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

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

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

8. Inspection and Phytosanitary Certification by the NPPO

8.1 Export inspection

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

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

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

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

8.2 Phytosanitary certification

Certification in accordance with the IPPC validates the successful completion of a treatment when required by the importing country. The Phytosanitary Certificate or its associated documentation should at least specifically identify the treated lot(s), date of treatment, the target minimum dose and the verified Dmin.

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

8.3 Import inspection

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

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

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

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

8.4 Verification methods for treatment efficacy in export and import inspection

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

8.5 Administration and documentation by the NPPO

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

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

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

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

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

9. Research

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

ANNEX 1

SPECIFIC APPROVED TREATMENTS

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

ANNEX 2

CHECKLIST FOR FACILITY APPROVAL

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

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

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

APPENDIX 1

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

ESTIMATED MINIMUM ABSORBED DOSES FOR CERTAIN RESPONSES FOR SELECTED PEST GROUPS³

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

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

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

REFERENCES

- International Atomic Energy Agency. 2002. International Database on Insect Disinfestation and Sterilization. (available at <http://www-ididas.iaea.org>).
- Hallman, G. J. 2001. Irradiation as a quarantine treatment. *In: Molins, R.A. (ed.) Food Irradiation Principles and Applications*. New York: J. Wiley & Sons. p. 113-130.
- Hallman, G. J. 2000. Expanding radiation quarantine treatments beyond fruit flies. *Agricultural and Forest Entomology*. 2:85-95.
- <http://www.iaea.org/icgfi> is also a useful website for technical information on food irradiation.

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

APPENDIX 2

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

RESEARCH PROTOCOL⁴

Research materials

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

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

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

Dosimetry

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

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

Estimation and confirmation of minimum absorbed dose for treatment

Preliminary Tests

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

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

Large Scale (Confirmatory) Tests

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

⁴ Based primarily on insect pest treatment research.

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

Recordkeeping

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



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 19

GUIDELINES ON LISTS OF REGULATED PESTS

(2003)

Produced by the Secretariat of the International Plant Protection Convention

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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.
Glossary of phytosanitary terms, 2003. ISPM No. 5, FAO, Rome.
Guidelines for Pest Risk Analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for Phytosanitary Certificates, 2001. ISPM No. 12, FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest Risk Analysis for quarantine pests including analysis of environmental risks, 2003. ISPM No. 11 Rev. 1, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

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

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

REQUIREMENTS

1. Basis for Lists of Regulated Pests

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

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

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

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

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

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

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

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

2. Purpose of Lists of Regulated Pests

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

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

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

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

3. Preparation of Lists of Regulated Pests

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

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

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

4. Information on Listed Pests

4.1 Required information

The required information to be associated with listed pests includes:

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

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

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

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

4.2 Supplementary information

Information that may be provided where appropriate includes:

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

4.3 NPPO responsibilities

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

5. Maintenance of Lists of Regulated Pests

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

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

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

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

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

6. Availability of Lists of Regulated Pests

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

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

6.1 Official availability

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

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

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

6.2 Requests for lists of regulated pests

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

Requests may be for:

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

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

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

6.3 Format and language

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

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

ISPM No. 20



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 20

***GUIDELINES FOR A PHYTOSANITARY
IMPORT REGULATORY SYSTEM***

(2004)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
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- Requirements for the establishment of pest free areas*, 1996. ISPM No. 4, FAO, Rome.
- Requirements for the establishment of pest free places of production and pest free production sites*, 1999. ISPM No. 10, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

REQUIREMENTS

1. Objective

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

2. Structure

The components of an import regulatory system are:

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

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

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

3. Rights, Obligations and Responsibilities

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

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

3.1 International agreements, principles and standards

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

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

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

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

3.2 Regional cooperation

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

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

4. Regulatory Framework

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

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

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

4.1 Regulated articles

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

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

Lists of regulated articles should be made publically available.

4.2 Phytosanitary measures for regulated articles

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

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

4.2.1 Measures for consignments to be imported

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

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

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

Measures that may be required during shipment include:

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

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

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

Measures that may be required after entry include:

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

Other measures that may be required include:

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

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

4.2.1.1 Provision for special imports

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

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

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

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

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

4.2.2 Import authorization

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

General authorization

General authorizations may be used:

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

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

Specific authorization

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

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

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

4.2.3 Prohibitions

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

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

4.3 Consignments in transit

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

4.4 Measures concerning non-compliance and emergency action

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

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

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

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

4.5 Other elements that may require a regulatory framework

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

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

4.6 Legal authority for the NPPO

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

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

5. Operation of an Import Regulatory System

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

5.1 Management and operational responsibilities of the NPPO

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

5.1.1 Administration

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

5.1.2 Regulatory development and revision

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

5.1.3 Surveillance

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

5.1.4 Pest risk analysis and pest listing

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

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

5.1.5 Audit and compliance checking

5.1.5.1 Audit of procedures in the exporting country

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

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

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

5.1.5.2 Compliance checking at import

There are three basic elements to compliance checking:

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

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

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

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

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

5.1.5.2.1 Inspection

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

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

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

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

5.1.5.2.2 Sampling

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

5.1.5.2.3 Testing including laboratory testing

Testing may be required for:

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

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

5.1.6 Non-compliance and emergency action

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

5.1.6.1 Action in case of non-compliance

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

- the detection of a listed quarantine pest associated with consignments for which it is regulated
- the detection of a listed RNQP present in an imported consignment of plants for planting at a level - which exceeds the required tolerance for those plants
- evidence of failure to meet prescribed requirements (including bilateral agreements or arrangements, or import permit conditions) such as field inspection, laboratory tests, registration of producers and/or facilities, lack of pest monitoring or surveillance
- the interception of a consignment which does not otherwise comply with the import regulations, such as because of the detected presence of undeclared commodities, soil or some other prohibited article or evidence of failure of specified treatments

- Phytosanitary Certificate or other required documentation invalid or missing
- prohibited consignments or articles
- failure to meet 'in-transit' measures.

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

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

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

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

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

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

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

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

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

5.1.6.2 Emergency action

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

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

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

Commonly encountered situations requiring emergency action include:

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

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

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

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

5.1.6.3 Reporting of non-compliance and emergency action

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

5.1.6.4 Withdrawal or modification of regulation

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

5.1.7 Systems for authorization of non-NPPO personnel

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

5.1.8 International liaison

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

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

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

5.1.9 Notification and dissemination of regulatory information

5.1.9.1 New or revised regulations

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

5.1.9.2 Dissemination of established regulations

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

5.1.10 National liaison

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

5.1.11 Settlement of disputes

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

5.2 Resources of the NPPO

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

5.2.1 Staff, including training

The NPPO should:

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

5.2.2 Information

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

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

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

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

5.2.3 Equipment and facilities

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

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

DOCUMENTATION, COMMUNICATION AND REVIEW**6. Documentation****6.1 Procedures**

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

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

6.2 Records

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

- documentation of pest risk analyses (in accordance with ISPM No. 11: *Pest risk analysis for quarantine pests*,

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

If appropriate, records may be kept of imported consignments:

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

7. Communication

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

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

8. Review Mechanism

8.1 System review

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

8.2 Incident review

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

ISPM No. 21



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 21

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

(2004)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Glossary of phytosanitary terms*, 2004. ISPM No. 5, FAO, Rome.
- Glossary supplement No. 1: *Guidelines on the interpretation and application of the concept of official control for regulated pests*, 2002. ISPM No. 5, FAO, Rome.
- Glossary supplement No. 2: *Guidelines on the interpretation and application of potential economic importance and related terms including reference to environmental considerations*, 2003. ISPM No. 5, FAO, Rome.
- Guidelines for pest risk analysis*, 1996. ISPM No. 2, FAO, Rome.
- Guidelines for surveillance*, 1997. ISPM No. 6, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004. ISPM No. 11, FAO, Rome.
- Principles of plant quarantine as related to international trade*, 1995. ISPM No. 1, FAO, Rome.
- Regulated non-quarantine pests: concept and application*, 2002. ISPM No. 16, FAO, Rome.
- Requirements for the establishment of pest free areas*, 1996. ISPM No. 4, FAO, Rome.
- Requirements for the establishment of pest free places of production and pest free production sites*, 1999. ISPM No. 10, FAO, Rome.
- The use of integrated measures in a systems approach for pest risk management*, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

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

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

BACKGROUND

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

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

Phytosanitary measures for RNQPs should be technically justified as required by the IPPC (1997). The classification of a pest as an RNQP and any restrictions placed on the import of the plant species with which it is associated should be justified by PRA.

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

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

1. Intended Use and Official Control

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

1.1 Intended use

The intended use of plants for planting may be:

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

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

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

1.2 Official control

“Regulated” in the definition of an RNQP refers to official control. RNQPs are subject to official control in the form of phytosanitary measures for their suppression in the specified plants for planting (see section 3.1.4 of ISPM No. 16: *Regulated non-quarantine pests: concept and application*).

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

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

An official control programme for RNQPs can be applied on a national, sub-national or local area basis (see ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1: *Guidelines on the interpretation and application of the concept of*

official control for regulated pests).

REQUIREMENTS

PEST RISK ANALYSIS FOR REGULATED NON-QUARANTINE PESTS

In most cases, the following steps will be applied sequentially in a PRA but it is not essential to follow a particular sequence. Pest risk assessment needs to be only as complex as is technically justified by the circumstances. This standard allows a specific PRA to be judged against the principles of necessity, minimal impact, transparency, equivalence, risk analysis, managed risk and non-discrimination set out in ISPM No 1: *Principles of plant quarantine as related to international trade* as well as the interpretation and application of official control (see ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1: *Guidelines on the interpretation and application of the concept of official control for regulated pests*).

2. Stage 1: Initiation

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

2.1 Initiation points

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

- identification of plants for planting that could act as a pathway for potential RNQPs
- the identification of a pest that could qualify as an RNQP
- the review or revision of phytosanitary policies and priorities, including phytosanitary elements of official certification schemes.

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

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

- new species of plants for planting are considered for regulation
- a change in susceptibility or resistance of plants for planting to a pest is identified.

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

2.1.2 PRA initiated by a pest

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

- identification, through scientific research, of a new risk posed by a pest (e.g. there is a change in pest virulence, or an organism is demonstrated to be a pest vector)
- detection in the PRA area of the following situations:
 - change in the prevalence or incidence of a pest
 - change in pest status (e.g. a quarantine pest has become widely distributed, or is no longer regulated as a quarantine pest)
 - presence of a new pest, not appropriate for regulation as a quarantine pest.

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

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

- consideration of an official control programme (e.g. certification scheme) including the strength of measures to be applied to a pest to avoid unacceptable economic impact of specified RNQP(s) in plants for planting in the PRA area
- in order to extend phytosanitary requirements to import of plants for planting that are already regulated in the PRA area
- the availability of a new system, process, plant protection procedure, or new information that could influence a previous decision (e.g. a new treatment or loss of a treatment, or a new diagnostic method)
- a decision is taken to review phytosanitary regulations, requirements or operations (e.g. a decision is made to reclassify a quarantine pest as an RNQP)

- a proposal made by another country, by a regional organization (RPPO) or by an international organization (FAO) is assessed
- a dispute arises on phytosanitary measures.

2.2 Identification of the PRA area

The PRA area should be identified in order to define the area to which official control is or is intended to be applied and for which information is needed.

2.3 Information

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

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

2.4 Review of previous PRAs

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

2.5 Conclusion of initiation

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

3. Stage 2: Pest Risk Assessment

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

- pest categorization
- assessment of the plants for planting as the main source of pest infestation
- assessment of economic impacts associated with the intended use of the plants for planting.

3.1 Pest categorization

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

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

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

3.1.1 Elements for categorization

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

- identity of the pest, host plant, part of plant under consideration and the intended use
- association of the pest with the plants for planting and the effect on their intended use
- pest presence and regulatory status
- indication of economic impact(s) of the pest on the intended use of the plants for planting.

3.1.1.1 Identity of the pest, host plant, part of plant under consideration and the intended use

The following should be clearly defined:

- the identity of the pest
- the host plant that is regulated or potentially to be regulated
- the plant part(s) under consideration (cuttings, bulbs, seeds, plants in tissue culture, rhizomes etc.)
- the intended use.

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

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

Also for the host, the taxonomic unit is generally the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In the case of levels below the species e.g. variety, there should be evidence demonstrating that factors such as difference in host susceptibility or resistance are significant enough to affect the phytosanitary status. Taxa for plants for planting above the species level (genera) or unidentified species of known genera should not be used unless all species in the genus are being evaluated for the same intended use.

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

The pest should be categorized taking into account its association with the plants for planting and the effect on the intended use. Where a PRA is initiated by a pest, more than one host may have been identified. Each host species and the plant part under consideration for official control should be assessed separately.

If it is clear from the categorization that the pest is not associated with the plants for planting or the plant part under consideration or does not affect the intended use of those plants, the PRA may stop at this point.

3.1.1.3 Pest presence and regulatory status

If the pest is present and if it is under official control (or being considered for official control) in the PRA area, the pest may meet the criteria for an RNQP and the PRA process may continue.

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

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

There should be clear indications that the pest causes an economic impact on the intended use of the plants for planting (see ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 2: *Guidelines on the understanding of potential economic importance and related terms*).

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

3.1.2 Conclusion of pest categorization

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

- plants for planting are a pathway, and
- it may cause unacceptable economic impact, and
- it is present in the PRA area, and
- it is or is expected to be under official control with respect to the specified plants for planting,

the PRA process should continue. If a pest does not fulfil all the criteria for an RNQP, the PRA process may stop.

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

Because the potential RNQP is present in the PRA area, it is necessary to determine whether plants for planting are the main source of pest infestation of those plants or not. In order to do this, all sources of infestation should be evaluated and the results presented in the PRA.

The evaluation of all the sources of infestation is based on the:

- life cycle of the pest and host, pest epidemiology and sources of pest infestation
- determination of the relative economic impact of the sources of pest infestation.

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

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

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

The identification of all the other sources of infestation is performed through the analysis of the pest and host life cycles. Different sources or pathways of pest infestation may include:

- soil
- water
- air
- other plants or plant products
- vectors of the pest
- contaminated machinery or modes of transport
- by-products or waste.

Pest infestation and spread may occur as a result of natural movement (including wind, vectors and waterways), human action or other means from these sources of infestation. The characteristics of the pathways should be examined.

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

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

The evaluation will address the importance of the pest infestation in the plants for planting on the epidemiology of the pest. The evaluation will also address the contribution of other sources of infestation to the development of the pest and its effect on the intended use. The importance of all these sources may be influenced by factors such as:

- the number of pest life cycles on the plants for planting (e.g. monocyclic or polycyclic pests)
- reproductive biology of the pest
- pathway efficiency, including mechanisms of dispersal and dispersal rate
- secondary infestation and transmission from the plants for planting to other plants
- climatological factors
- cultural practices, pre- and post-harvest
- soil types
- the susceptibility of the plants (e.g. young plant stages could be more or less susceptible to different pests; host resistance/susceptibility)
- presence of vectors
- presence of natural enemies and/or antagonists
- presence of other susceptible hosts
- pest prevalence in the PRA area
- impact or potential impact of the official control applied in the PRA area.

The different types and rates of pest transmission from the initial infestation in the plants for planting (seed to seed, seed to plant, plant to plant, within plant) may be important factors to consider. Their importance may depend on the intended use of the plants for planting and should be assessed accordingly. For example the same initial pest infestation may have significantly different impacts in/on seed for further propagation or plants for planting intended to remain planted.

Other factors may influence the evaluation of the plants for planting as the main source of infestation as compared to other sources. These may include pest survival and controls during production, transport or storage of the plants.

3.2.3 Conclusion of the assessment of the plants for planting as the main source of pest infestation

Pests that are mainly transmitted by the plants for planting and which affect the intended use of those plants are subjected to the next stage of the risk assessment to establish whether there are unacceptable economic impacts.

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

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

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

Wherever appropriate, quantitative data that will provide monetary values should be obtained. Qualitative data such as

relative production or quality levels before and after infestation by the pest may also be used. The economic impact resulting from the pest may vary depending on the intended use of the plants for planting and this should therefore be taken into account.

In cases where there is more than one source of infestation, the economic impact resulting from the pest on the plants for planting should be demonstrated to be the main source of the unacceptable economic impact.

3.3.1 Pest effects

As the pest is present in the PRA area, detailed information should be available about its economic impact in that area. Scientific data, regulatory and other information from the national and international literature should be consulted and documented as appropriate. Most of the effects considered during the economic analysis will be direct effects on the plants for planting and their intended use.

Relevant factors in determining economic impacts include:

- reduction of quantity of marketable yield (e.g. reduction in yield)
- reduction of quality (e.g. reduced sugar content in grapes for wine, downgrading of marketed product)
- extra costs of pest control (e.g. roguing, pesticide application)
- extra costs of harvesting and grading (e.g. culling)
- costs of replanting (e.g. due to loss of longevity of plants)
- loss due to the necessity of growing substitute crops (e.g. due to need to plant lower yielding resistant varieties of the same crop or different crops).

In particular cases, pest effects on other host plants at the place of production may be considered relevant factors. For example, some varieties or species of host plants may not be seriously affected by an infestation of the assessed pest. However, the planting of such an infested host plant may have a major effect on the more susceptible hosts at places of production in the PRA area. In such cases the assessment of the consequences of the intended use of those plants may include all relevant host plants grown at the place of production.

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

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

3.3.2 Infestation and damage thresholds in relation to the intended use

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

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

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

In cases where there is a lack of quantitative information on pest damage caused by the initial level of pest infestation in the plants for planting, expert judgement could be used on the basis of information obtained in sections 3.2.1 and 3.2.2.

3.3.3 Analysis of economic consequences

As determined above, most of the effects of a pest, e.g. damage, will be of a commercial nature within the country. These effects should be identified and quantified. It may be useful to consider the negative effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices.

3.3.3.1 Analytical techniques

There are analytical techniques that can be used in consultation with experts in economics to make a more detailed analysis of the economic effects of an RNQP. These should incorporate all of the effects that have been identified. These techniques (see section 2.3.2.3 of ISPM No. 11: *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004) may include:

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

Data on the economic impact of the pest on the intended use of the plants for planting should be available for the PRA area and an economic analysis may be available. For some effects of the pests there may be uncertainties or variability in the data and/or only qualitative information may be available. Areas of uncertainty and variability should be explained in the PRA.

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

3.3.4 Conclusion of the assessment of economic consequences

The output of the assessment of economic consequences described in this step should normally be in terms of a monetary value. The economic consequences can also be expressed qualitatively (such as relative profit before and after infestation) or using quantitative measures without monetary terms (such as tonnes of yield). Sources of information, assumptions and methods of analysis should be clearly specified. An assessment will need to be made as to whether the economic consequences are acceptable or unacceptable. If the economic consequences are considered acceptable (i.e. little damage or damage is largely from sources other than the plants for planting) then the PRA may stop.

3.4 Degree of uncertainty

Estimation of economic impact and the relative importance of sources of infestation may involve uncertainties. It is important to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs.

3.5 Conclusion of the pest risk assessment stage

As a result of the pest risk assessment, a quantitative or qualitative evaluation of the plants for planting being the main source of infestation of the pest and a corresponding quantitative or qualitative estimate of the economic consequences have been obtained and documented, or an overall rating could have been assigned.

Measures are not justified if the risk is considered acceptable or should be accepted because it is not manageable through official control (for example, natural spread from other sources of infestation). Countries may decide that an appropriate level of monitoring or audit is maintained to ensure that future changes in the pest risk are identified.

Where plants for planting have been identified as the main source of infestation for a pest and an unacceptable economic impact on the intended use of these plants has been demonstrated, pest risk management may be considered as appropriate (stage 3). These evaluations, together with associated uncertainties, are utilized in the pest risk management stage of the PRA.

4. Stage 3: Pest Risk Management

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

If the plants for planting are assessed as being the main source of infestation of the pests and the economic impact on the intended use of those plants is found to be unacceptable (stage 2), then risk management (stage 3) is used to identify possible phytosanitary measures with the aim of suppression and thereby will reduce the risk to, or below, an acceptable level.

The most commonly used option for pest risk management for an RNQP is the establishment of measures to achieve an appropriate pest tolerance level. The same tolerance level should be applied for domestic production and import requirements (see section 6.3 of ISPM No. 16: *Regulated non-quarantine pests: concept and application*).

4.1 Technical information required

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

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

4.2 Level and acceptability of risk

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

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

- reference to the existing acceptable level of risk for domestic production
- indexed to estimated economic losses
- expressed on a scale of risk tolerance
- compared with the level of risk accepted by other countries.

4.3 Factors to be taken into account in the identification and selection of appropriate risk management options

Appropriate measures should be chosen based on their effectiveness in limiting the economic impact of the pest on the intended use of the plants for planting. The choice should be based on the following considerations, which include several of the principles of plant quarantine as related to international trade (ISPM No. 1: *Principles of plant quarantine as related to international trade*):

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

4.3.1 Non-discrimination

There should be consistency between import and domestic requirements for a defined pest (see ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1: *Guidelines on the interpretation and application of the concept of official control for regulated pests*):

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

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

The measures should be as precise as possible concerning the species of plants for planting (including different classes,

for example within a certification scheme) and their intended use to prevent barriers to trade such as by limiting the import of products where this is not justified.

4.4 Tolerances

For RNQPs, the establishment of appropriate tolerances can be used to reduce the risk to an acceptable level. These tolerances should be based on the level of pest infestation (the infestation threshold) in plants for planting that result in an unacceptable economic impact. Tolerances are indicators that, if exceeded, are likely to result in unacceptable impacts on plants for planting. If infestation thresholds have been determined during the risk assessment stage, these should be considered in establishing appropriate tolerances. Tolerance levels should take into account appropriate scientific information including:

- intended use of the plants for planting
- biology, in particular epidemiological characteristics, of the pest
- susceptibility of the host
- sampling procedures (including confidence intervals), detection methods (with estimates of the precision), reliability of identification
- relationship between the pest level and the economic losses
- climate and cultural practices in PRA area.

The above information may be derived through reliable research and also through the following:

- experience with official control programmes within the country for the plants for planting concerned
- experience from certification schemes for the plants for planting
- history of imports of the plants for planting
- data regarding interactions between the plant, the pest and the growing conditions.

4.4.1 Zero tolerance

Zero tolerance is not likely to be a general requirement. A zero tolerance may be technically justified in situations or combination of situations such as:

- where plants for planting are the only source of pest infestation in relation to the intended use of those plants and any level of pest infestation would result in an unacceptable economic impact (e.g. nuclear stock for further propagation, or a virulent degenerative disease where the intended use is further propagation)
- the pest fulfils the defining criteria of an RNQP and an official control programme is in place requiring pest freedom in plants for planting (zero tolerance) for the same intended use for all domestic places of production or production sites. Similar requirements could be used as described in ISPM No. 10 (*Requirements for the establishment of pest free places of production and pest-free production sites*).

4.4.2 Selection of an appropriate tolerance level

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

4.5 Options to achieve the required tolerance levels

There are a number of options that may achieve the required tolerance. Certification schemes are often useful for attaining the required tolerance and may include elements that may be relevant for all of the management options. Mutual recognition of certification schemes may facilitate trade of healthy plant material. However some aspects of certification schemes (e.g. varietal purity) are not relevant (see section 6.2 of ISPM No. 16: *Regulated non-quarantine pests: concept and application*).

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

These options may be applied to:

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

Section 3.4 of ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004) also provides information on the identification and selection of risk management options.

4.5.1 Area of production

The following options may be applied to the area of production of the plants for planting:

- treatment
- area of low pest prevalence
- area where the pest is absent
- buffer zones (e.g. rivers, mountain ranges, urban areas)
- monitoring survey.

4.5.2 Place of production

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

- isolation (place or time)
- pest free place of production or pest free production site (see ISPM No. 10: *Requirements for the establishment of pest free places of production and pest free production sites*)
- integrated pest management
- cultural practices (e.g. roguing, pest and vector control, hygiene, preceding crop, previous treatment)
- treatments.

4.5.3 Parent stock

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

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

4.5.4 Consignment of plants for planting

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

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

4.6 Verification of the tolerance levels

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

4.7 Conclusion of pest risk management

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

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

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

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

5. Monitoring and review of phytosanitary measures

The principle of “modification” states: “As conditions change, and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of prohibitions, restrictions or requirements necessary for their success, or by removal of those found to be unnecessary” (ISPM No. 1: *Principles of plant quarantine as related to international trade*).

Thus, the implementation of particular phytosanitary measures should not be considered to be permanent. After application, the success of the measures in achieving their aim should be determined by monitoring. This may be achieved by monitoring the plants for planting at appropriate times and places and/or damage levels (economic impact). The information supporting the pest risk analysis should be periodically reviewed to ensure that any new information that becomes available does not invalidate the decision taken.

6. Documentation of pest risk analysis

The IPPC, 1997 (Article VII.2c) and the principle of “transparency” (ISPM No. 1: *Principles of plant quarantine as related to international trade*) require that contracting parties should, on request, make available the rationale for phytosanitary requirements. The whole process from initiation to pest risk management should be sufficiently documented so that when a request for the rationale for measures is received, or a dispute arises, or when measures are reviewed, the sources of information and rationale used in reaching the management decision can be clearly demonstrated.

The main elements of documentation are:

- purpose for the PRA
- pest, host, plants and/or parts or class of plants under consideration, pest list (if appropriate), sources of infestation, the intended use, PRA area
- sources of information
- categorized pest list
- conclusions of risk assessment
- risk management
- options identified.



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 22

***REQUIREMENTS FOR THE ESTABLISHMENT
OF AREAS OF LOW PEST PREVALENCE***

(2005)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.
- Glossary of phytosanitary terms*, 2004. ISPM No. 5, FAO, Rome.
- Guidelines for pest eradication programmes*, 1998. ISPM No. 9, FAO, Rome.
- Guidelines for surveillance*, 1997. ISPM No. 6, FAO, Rome.
- Guidelines for the notification of non-compliance and emergency action*, 2001. ISPM No. 13, FAO, Rome.
- International Plant Protection Convention*, 1997, FAO, Rome.
- Pest risk analysis for regulated non-quarantine pests*, 2004. ISPM No. 21, FAO, Rome.
- Regulated non-quarantine pests: concept and application*, 2002. ISPM No. 16, FAO, Rome.
- Requirements for the establishment of pest free areas*, 1996. ISPM No. 4, FAO, Rome.
- Requirements for the establishment of pest free places of production and pest free production sites*, 1999. ISPM No. 10, FAO, Rome.
- The use of integrated measures in a systems approach for pest risk management*, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

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

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

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

BACKGROUND

1. General Considerations

1.1 Concept of areas of low pest prevalence

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

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

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

1.2 Advantages in using areas of low pest prevalence

Advantages in using ALPPs include:

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

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

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

REQUIREMENTS

2. General Requirements

2.1 Determination of an area of low pest prevalence

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

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

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

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

2.2 Operational plans

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

3. Specific Requirements

3.1 Establishment of an ALPP

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

3.1.1 Determination of specified pest levels

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

3.1.2 Geographic description

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

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

3.1.3 Documentation and verification

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

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

3.1.4 Phytosanitary procedures

3.1.4.1 Surveillance activities

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

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

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

3.1.4.2 Reducing pest levels and maintaining low prevalence

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

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

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

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

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

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

3.1.4.4 Corrective action plan

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

3.1.5 Verification of an area of low pest prevalence

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

3.2 Maintenance of an area of low pest prevalence

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

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

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

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

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

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

level has been exceeded in the ALPP.

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

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

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

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

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

ISPM No. 23



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 23

GUIDELINES FOR INSPECTION

(2005)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Export certification system*, 1997. ISPM No. 7, FAO, Rome.
Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.
Guidelines on phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.
Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.
Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

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

REQUIREMENTS

1. General Requirements

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

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

1.1 Inspection objectives

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

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

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

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

Inspection can be used as a risk management procedure.

1.2 Assumptions involved in the application of inspections

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

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

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

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

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

1.3 Responsibility for inspection

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

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

1.4 Requirements for inspectors

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

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

The inspector may be required to inspect consignments for:

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

1.5 Other considerations for inspection

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

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

1.6 Inspection in relation to pest risk analysis

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

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

2. Specific Requirements

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

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

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

2.1 Examination of documents associated with a consignment

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

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

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

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

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

2.2 Verification of consignment identity and integrity

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

2.3 Visual examination

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

2.3.1 Pests

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

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

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

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

then sampling methodology should reflect this.

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

2.3.2 Compliance of phytosanitary requirements

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

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

2.4 Inspection methods

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

It is important that:

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

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

2.5 Inspection outcome

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

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

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

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

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

2.6 Review of inspection systems

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

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

2.7 Transparency

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



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 24

***GUIDELINES FOR THE DETERMINATION AND
RECOGNITION OF EQUIVALENCE OF
PHYTOSANITARY MEASURES***

(2005)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Export certification system*, 1997. ISPM No. 7, FAO Rome.
- Glossary of phytosanitary terms*, 2004. ISPM No. 5, FAO, Rome.
- Guidelines for pest risk analysis*, 1996. ISPM No. 2, FAO, Rome.
- Guidelines for regulating wood packaging material in international trade*, 2002. ISPM No. 15, FAO, Rome.
- Guidelines for the notification of non-compliance and emergency action*, 2001. ISPM No. 13, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004. ISPM No. 11, FAO, Rome.
- Principles of plant quarantine as related to international trade*, 1995. ISPM No. 1, FAO, Rome.
- The use of integrated measures in a systems approach for pest risk management*, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

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

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

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

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

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

REQUIREMENTS

1. General Considerations

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

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

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

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

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

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

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

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

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

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

2. General Principles and Requirements

2.1 Sovereign authority

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

2.2 Other relevant principles of the IPPC

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

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

2.3 Technical justification for equivalence

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

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

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

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

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

2.5 Information exchange

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

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

2.6 Technical assistance

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

2.7 Timeliness

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

3. Specific Requirements for the Application of Equivalence

3.1 Specific pests and commodities

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

3.2 Existing measures

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

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

3.3 Entry into consultation

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

3.4 Agreed procedure

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

3.5 Factors considered in determining equivalence

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

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

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

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

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

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

related specifically to the implementation of the phytosanitary measures proposed as equivalent.

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

3.6 Non-disruption of trade

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

3.7 Provision of access

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

3.8 Review and monitoring

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

3.9 Implementation and transparency

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

ANNEX 1

PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

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

Recommended steps are:

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

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

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

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

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

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

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

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

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

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



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 25

CONSIGNMENTS IN TRANSIT

(2006)

Produced by the Secretariat of the International Plant Protection Convention

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ENDORSEMENT

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

INTRODUCTION

SCOPE

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

REFERENCES

- Glossary of phytosanitary terms*, 2006. ISPM No. 5, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines for inspection, 2005. ISPM No. 23, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest reporting, 2002. ISPM No. 17, FAO, Rome.
Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

DEFINITIONS

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

OUTLINE OF REQUIREMENTS

International trade may involve the movement of consignments of regulated articles which pass through a country without being imported, under Customs¹ control. Such movements may present a phytosanitary risk to the country of transit. Contracting parties to the IPPC may apply measures to consignments in transit through their territories (Articles VII.1c and VII.2g of the IPPC, 1997), provided that the measures are technically justified and necessary to prevent the introduction and/or spread of pests (Article VII.4 of the IPPC, 1997).

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

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

BACKGROUND

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

Article VII.1c states:

“With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate . . . and, to this end, may . . . prohibit or restrict the movement of regulated pests into their territories”.

Article VII.4 states:

“Contracting parties may apply measures specified in this Article to consignments in transit through their territories only where such measures are technically justified and necessary to prevent the introduction and/or spread of pests”.

Article I.4 states:

“Where appropriate, the provisions of this Convention may be deemed by contracting parties to extend, in addition to plants and plant products, to storage places, packaging, conveyances, containers, soil and any other organism, object or material capable of harbouring or spreading plant pests, particularly where international transportation is involved”.

Transit involves the movement of consignments of regulated articles which pass through a country (further referred to as country of transit) without being imported. Consignments in transit constitute a potential pathway for the introduction and/or spread of pests to the country of transit.

Consignments in transit may pass through the country of transit remaining enclosed and sealed if necessary, without being split up or combined with other consignments, and without having their packaging changed. Under such conditions, the movement of consignments will, in many cases, not present a phytosanitary risk and will not require phytosanitary measures, especially if the consignments are transported in sealed containers². However, even under such conditions, contingency plans may be required to address unexpected situations, such as an accident during transit.

Consignments and their conveyances passing through a country may, however, also be transported or handled in such a manner that they do present a phytosanitary risk to that country. This may, for example, be the case when consignments are transported open rather than enclosed, or when they do not pass directly through the country but are held for a period of storage, or are split up, combined or repackaged, or if the means of transport changes (e.g. from ship to railway). In such cases, phytosanitary measures may be applied in the country of transit to prevent the introduction of pests into, and/or their spread within, that country.

It should be noted that the term ‘transit’ is not only used for phytosanitary purposes but is also the accepted name for the standard procedure for moving goods under Customs control. Customs control may include document verification, tracking (e.g. electronic), sealing, control of carrier and entry/exit control. Customs control by itself is not intended to guarantee phytosanitary integrity and security of consignments and thus will not necessarily offer protection against the introduction and/or spread of pests.

Transshipment is a particular aspect of transport of consignments between countries. It refers to the transfer of consignments from one conveyance (means of transport) to another (e.g. ship to ship at a seaport) during the transportation process. Usually transshipment takes place under Customs control within an area specified by Customs. Transshipment may occur in a transit country and is thus covered by this standard.

REQUIREMENTS

1. Risk Analysis for the Country of Transit

Risk analysis related to consignments in transit would be facilitated by the sharing of relevant pest risk analysis (PRA) information already obtained and/or developed by one or both of the NPPOs of the importing and exporting contracting parties.

1.1 Risk identification

In order to identify potential phytosanitary risks related to consignments in transit, the NPPO of the country of transit (from this point onwards, “the NPPO”) should collect and review relevant information.

² A standard, fully enclosed and secure transport container as commonly used in ocean going trade.

Elements of such information may include:

- procedures applied by Customs and other relevant services
- classes of commodities or regulated articles in transit and their country of origin
- means and methods of transport for consignments in transit
- regulated pests associated with the consignments in transit
- host distribution in the country of transit
- knowledge of transit route in the country of transit
- possibilities that pests may escape from consignments
- existing phytosanitary measures for consignments of commodities in transit
- types of packaging
- conditions of transport (refrigeration, modified atmosphere, etc.).

The NPPO may decide that consignments in transit that pose no potential phytosanitary risk, for instance when no pests regulated by the country of transit are associated with the consignments in transit, may move or continue to move without phytosanitary procedures.

The NPPO may also decide that consignments in transit that pose negligible phytosanitary risks, for example conveyances or packaging which are fully enclosed, sealed and secure, or when pests are regulated by the country of transit and are unlikely to escape from the consignment in transit, may move or continue to move without phytosanitary procedures..

If potential phytosanitary risks are identified, risk assessment for particular pests or commodities in transit is needed in order to identify the necessity and technical justification of any phytosanitary measure.

Only those phytosanitary risks which concern regulated pests of the country of transit or those pests that are under emergency action in that country should be considered.

1.2 Risk assessment

An assessment of the phytosanitary risks associated with the transit pathway should normally focus only on evaluating the probability of pests being introduced or spread from consignments in transit. The associated potential economic consequences should have been evaluated previously in the case of an existing regulated pest and therefore should not need to be repeated.

Guidance for the assessment of the probability of introduction and spread of a pest is provided in ISPM No. 11 (2004, *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*), in particular section 2.2. For consignments in transit, the following information may also be relevant:

- pathways for introduction and/or spread of regulated pests from the consignments in transit
- dispersal mechanism and mobility of the relevant pests
- means of transport (e.g. truck, rail, airplane, ship, etc.)
- phytosanitary security of the conveyance (e.g. closed, sealed, etc.)
- existence and type of packaging
- changes of configuration (e.g. combined, split, repacked)
- duration of transit or storage, and storage conditions
- route taken by the consignment prior to and within the country of transit
- frequency, volume and season of transit.

In cases where the NPPO, through risk assessment, has identified phytosanitary risks, pest risk management options can be considered.

1.3 Risk management

Based on risk assessment, consignments in transit may be classified by the NPPO into two broad risk management categories:

- transit requiring no further phytosanitary measures, or
- transit requiring further phytosanitary measures.

Further details on risk management are provided in ISPM No. 11 (2004, *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*).

1.3.1 Transit requiring no further phytosanitary measures

The NPPO, through the assessment of phytosanitary risk, may determine that Customs control alone is adequate. If this

is the case, the NPPO should not apply any phytosanitary measures in addition to Customs control.

1.3.2 Transit requiring further phytosanitary measures

The risk assessment for consignments in transit may conclude that specific phytosanitary measures are necessary. These may include the following:

- verification of consignment identity or integrity (further details provided in ISPM No. 23: *Guidelines for inspection*)
- phytosanitary movement document (e.g. transit permit)
- phytosanitary certificates (with transit requirements)
- designated entry and exit points
- verification of exit of the consignment
- mode of transport and designated transit routes
- regulation of the changes of configuration (e.g. combined, split, repacked)
- use of NPPO-prescribed equipment or facilities
- Customs facilities recognized by the NPPO
- phytosanitary treatments (e.g. pre-shipment treatments, treatments when consignment integrity is doubtful)
- consignment tracking while in transit
- physical conditions (e.g. refrigeration, pest-proof packaging and/or conveyance preventing spillage)
- use of NPPO-specific seals for conveyances or consignment
- specific carrier's emergency management plans
- transit time or season limits
- documentation in addition to that required by Customs
- inspection of consignment by NPPO
- packaging
- disposal of waste.

Such phytosanitary measures should only be applied for regulated pests of the country of transit or those pests that are under emergency action in that country.

1.3.3 Other phytosanitary measures

When appropriate phytosanitary measures for consignments in transit are not available or are impossible to apply, the NPPO may require that such consignments are subject to the same requirements as imports, which may include prohibition.

If consignments in transit are stored or repackaged in such a way that they present a phytosanitary risk, the NPPO may decide that the consignments should meet import requirements or subject them to other appropriate phytosanitary measures.

2. Establishment of a Transit System

The contracting party may develop a transit system for phytosanitary control of consignments in transit with the NPPO, Customs and other relevant authorities of their country as collaborators. The objective of such a transit system is to prevent the introduction into and/or spread within the country of transit of regulated pests associated with consignments in transit and their conveyances. Transit systems require a basis of a regulatory framework of phytosanitary legislation, regulations and procedures. The transit system is operated by the NPPO, Customs and other relevant authorities in cooperation as appropriate, and should ensure that prescribed phytosanitary measures are applied.

The NPPO has responsibility for the phytosanitary aspects of the transit system and establishes and implements phytosanitary measures necessary to manage phytosanitary risks, taking into account the transit procedures of Customs.

3. Measures for Non-compliance and Emergency Situations

The transit system may include measures, established by the NPPO, for non-compliance and emergency situations (for example, accidents in the country of transit which could lead to the unexpected escape of a regulated pest from a consignment moving in transit). ISPM No. 13 (*Guidelines for the notification of non-compliance and emergency action*) contains specific guidelines for the country of transit for issuing notices of non-compliance to the exporting country and, where appropriate, to the country of destination.

4. Cooperation and Domestic Communication

Cooperation between NPPOs and Customs and other authorities (for example, port authorities) is essential to establish and/or maintain an effective transit system and identify consignments of regulated articles in transit. Therefore specific agreement with Customs may be needed for the NPPO to be informed of, and have access to, consignments under

Customs control.

The NPPO may also establish cooperation and maintain communication with all stakeholders involved in transit as appropriate.

5. Non-discrimination

Consignments in transit should not be subject to more restrictive phytosanitary measures than those applied to consignments of the same phytosanitary status imported into that country of transit.

6. Review

The NPPO should, as necessary, review and adjust the transit system, the types of consignments in transit and the associated phytosanitary risks, in cooperation with relevant authorities and stakeholders as appropriate.

7. Documentation

Any transit system should be adequately described and documented.

Phytosanitary requirements, restrictions and prohibitions for consignments in transit should be made available, upon request, to any contracting party or parties that may be directly affected by such measures.



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 26

***ESTABLISHMENT OF PEST FREE AREAS FOR
FRUIT FLIES (TEPHRITIDAE)***

(2006)

Produced by the Secretariat of the International Plant Protection Convention

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ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in April 2006.

INTRODUCTION

SCOPE

This standard provides guidelines for the establishment of pest free areas for fruit flies (*Tephritidae*) of economic importance, and for the maintenance of their pest free status.

REFERENCES

- Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.
Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.
Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest reporting, 2002. ISPM No. 17, FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.
Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

The general requirements for establishing a fruit fly-pest free area (FF-PFA) include:

- the preparation of a public awareness programme
- the management elements of the system (documentation and review systems, record keeping), and
- supervision activities.

The major elements of the FF-PFA are:

- the characterization of the FF-PFA
- the establishment and maintenance of the FF-PFA.

These elements include the surveillance activities of trapping and fruit sampling, and official control on the movement of regulated articles. Guidance on surveillance and fruit sampling activities is provided in Appendices 1 and 2.

Additional elements include: corrective action planning, suspension, loss of pest free status and reinstatement (if possible) of the FF-PFA. Corrective action planning is described in Annex 1.

BACKGROUND

Fruit flies are a very important group of pests for many countries due to their potential to cause damage in fruits and to their potential to restrict access to international markets for plant products that can host fruit flies. The high probability of introduction of fruit flies associated with a wide range of hosts results in restrictions imposed by many importing countries to accept fruits from areas in which these pests are established. For these reasons, there is a need for an ISPM that provides specific guidance for the establishment and maintenance of pest free areas for fruit flies.

A pest free area is “an area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained” (ISPM No. 5: *Glossary of phytosanitary terms*). Areas initially free from fruit flies may remain naturally free from fruit flies due to the presence of barriers or climate conditions, and/or maintained free through movement restrictions and related measures (though fruit flies have the potential to establish there) or may be made free by an eradication programme (ISPM No. 9: *Guidelines for pest eradication programmes*). ISPM No. 4 (*Requirements for the establishment of pest free areas*) describes different types of pest free areas and provides general guidance on the establishment of pest free areas. However, a need for additional guidance on establishment and maintenance of pest free areas specifically for fruit flies (fruit fly-pest free areas, FF-PFA) was recognized. This standard describes additional requirements for establishment and maintenance of FF-PFAs. The target pests for which this standard was developed include insects of the order Diptera, family Tephritidae, of the genera *Anastrepha*, *Bactrocera*, *Ceratitis*, *Dacus*, *Rhagoletis* and *Toxotrypana*.

The establishment and maintenance of a FF-PFA implies that no other phytosanitary measures specific for the target species are required for host commodities within the PFA.

REQUIREMENTS

1. General Requirements

The concepts and provisions of ISPM No. 4 (*Requirements for the establishment of pest free areas*) apply to the establishment and maintenance of pest free areas for all pests including fruit flies and therefore ISPM No. 4 should be referred to in conjunction with this standard.

Phytosanitary measures and specific procedures as further described in this standard may be required for the establishment and maintenance of FF-PFA. The decision to establish a formal FF-PFA may be made based on the technical factors provided in this standard. They include components such as: pest biology, size of the area, pest population levels and dispersal pathway, ecological conditions, geographical isolation and availability of methods for pest eradication.

FF-PFAs may be established in accordance with this ISPM under a variety of different situations. Some of them require the application of the full range of elements provided by this standard, others require only the application of some of these elements.

In areas where the fruit flies concerned are not capable of establishment because of climatic, geographical or other reasons, absence should be recognized according to the first paragraph of section 3.1.2 of ISPM No. 8 (*Determination of pest status in an area*). If, however, the fruit flies are detected and can cause economic damage during a season (Article VII.3 of the IPPC), corrective actions should be applied in order to allow the maintenance of a FF-PFA.

In areas where the fruit flies are capable of establishment and known to be absent, general surveillance in accordance with section 3.1.2 of ISPM No. 8 (*Determination of pest status in an area*), is normally sufficient for the purpose of delimiting and establishing a pest free area. Where appropriate, import requirements and/or domestic movement restrictions against the introduction of the relevant fruit fly species into the area may be required to maintain the area free from the pest.

1.1 Public awareness

A public awareness programme is most important in areas where the risk of introduction is higher. An important factor in the establishment and maintenance of FF-PFAs is the support and participation of the public (especially the local community) close to the FF-PFA and individuals that travel to or through the area, including parties with direct and indirect interests. The public and stakeholders should be informed through different forms of media (written, radio, TV) of the importance of establishing and maintaining the pest free status of the area, and of avoiding the introduction or re-introduction of potentially infested host material. This may contribute to and improve compliance with the phytosanitary measures for the FF-PFA. The public awareness and phytosanitary education programme should be ongoing and may include information on:

- permanent or random checkpoints
- posting signs at entry points and transit corridors
- disposal bins for host material
- leaflets or brochures with information on the pest and the pest free area
- publications (e.g. print, electronic media)
- systems to regulate fruit movement
- non-commercial hosts
- security of the traps
- penalties for non-compliance, where applicable.

1.2 Documentation and record keeping

The phytosanitary measures used for the establishment and maintenance of FF-PFA should be adequately documented as part of phytosanitary procedures. They should be reviewed and updated regularly, including corrective actions, if required (see also ISPM No. 4: *Requirements for the establishment of pest free areas*).

The records of surveys, detections, occurrences or outbreaks and results of other operational procedures should be retained for at least 24 months. Such records should be made available to the NPPO of the importing country on request.

1.3 Supervision activities

The FF-PFA programme, including regulatory control, surveillance procedures (for example trapping, fruit sampling) and corrective action planning should comply with officially approved procedures.

Such procedures should include official delegation of responsibility assigned to key personnel, for example:

- a person with defined authority and responsibility to ensure that the systems/procedures are implemented and maintained appropriately;
- entomologist(s) with responsibility for the authoritative identification of fruit flies to species level.

The effectiveness of the programme should be monitored periodically by the NPPO of the exporting country, through review of documentation and procedures.

2. Specific Requirements

2.1 Characterization of the FF-PFA

The determining characteristics of the FF-PFA include:

- the target fruit fly species and its distribution within or adjacent to the area
- commercial and non-commercial host species
- delimitation of the area (detailed maps or GPS coordinates showing the boundaries, natural barriers, entry points and host area locations, and, where necessary, buffer zones)
- climate, for example rainfall, relative humidity, temperature, prevailing wind speed and direction.

Further guidance on establishing and describing a PFA is provided in ISPM No. 4 (*Requirements for the establishment of pest free areas*).

2.2 Establishment of the FF-PFA

The following should be developed and implemented:

- surveillance activities for establishment of the FF-PFA
- delimitation of the FF-PFA
- phytosanitary measures related to movement of host material or regulated articles
- pest suppression and eradication techniques as appropriate.

The establishment of buffer zones may also be necessary (as described in Section 2.2.1) and it may be useful to collect additional technical information during the establishment of the FF-PFA.

2.2.1 Buffer zone

In areas where geographic isolation is not considered adequate to prevent introduction to or reinfestation of a PFA or where there are no other means of preventing fruit fly movement to the PFA, a buffer zone should be established. Factors that should be considered in the establishment and effectiveness of a buffer zone include:

- pest suppression techniques which may be used to reduce the fruit fly population, including:
 - use of selective insecticide-bait
 - spraying
 - sterile insect technique
 - male annihilation technique
 - biological control
 - mechanical control, etc.
- host availability, cropping systems, natural vegetation
- climatic conditions
- the geography of the area
- capacity for natural spread through identified pathways
- the ability to implement a system to monitor the effectiveness of buffer zone establishment (e.g. trapping network).

2.2.2 Surveillance activities prior to establishment

A regular survey programme should be established and implemented. Trapping is the preferred option to determine fruit fly absence or presence in an area for lure/bait responsive species. However, fruit sampling activities may sometimes be required to complement the trapping programme in cases where trapping is less effective, for example when species are less responsive to specific lures.

Prior to the establishment of a FF-PFA, surveillance should be undertaken for a period determined by the climatic characteristics of the area, and as technically appropriate for at least 12 consecutive months in the FF-PFA in all relevant areas of commercial and non-commercial host plants to demonstrate that the pest is not present in the area. There should be no populations detected during the surveillance activities prior to establishment. A single adult detection, depending on its status (in accordance with ISPM No. 8: *Determination of pest status in an area*), may not disqualify an area from subsequent designation as a FF-PFA. For qualifying the area as a pest free area, there should be no detection of an immature specimen, two or more fertile adults, or an inseminated female of the target species during the survey period. There are different trapping and fruit sampling regimes for different fruit fly species. Surveys should be conducted using the guidelines in Appendices 1 and 2. These guidelines may be revised as trap, lure and fruit sampling efficiencies improve.

2.2.2.1 Trapping procedures

This section contains general information on trapping procedures for target fruit fly species. Trapping conditions may vary depending on, for example, the target fruit fly and environmental conditions. More information is provided in Appendix 1. When planning for trapping, the following should be considered:

Trap type and lures

Several types of traps and lures have been developed over decades to survey fruit fly populations. Fly catches differ depending on the types of lure used. The type of trap chosen for a survey depends on the target fruit fly species and the nature of the attractant. The most widely used traps include Jackson, McPhail, Steiner, open bottom dry trap (OBDT), yellow panel traps, which may use specific attractants (para-pheromone or pheromone lures that are male specific), or food or host odours (liquid protein or dry synthetic). Liquid protein is used to catch a wide range of different fruit fly species and capture both females and males, with a slightly higher percentage of females captured. However identification of the fruit flies can be difficult due to decomposition within the liquid bait. In traps such as McPhail, ethylene glycol may be added to delay decomposition. Dry synthetic protein baits are female biased, capture less non-target organisms and, when used in dry traps, may prevent premature decomposition of captured specimens.

Trap density

Trap density (number of traps per unit area) is a critical factor for effective fruit fly surveys and it should be designed based on target fruit fly species, trap efficiency, cultivation practices, and other biotic and abiotic factors. Density may change depending on the programme phase, with different densities required during the establishment of FF-PFA and the maintenance phase. Trap density also depends on the risk associated with potential pathways for entry into the designated PFA.

Trap deployment (determination of the specific location of the traps)

In a FF-PFA programme, an extensive trapping network should be deployed over the entire area. The trapping network layout will depend on the characteristics of the area, host distribution and the biology of the fruit fly of concern. One of the most important features of trap placement is the selection of a proper location and trap site within the host plant. The application of global positioning systems (GPS) and geographic information systems (GIS) are useful tools for management of a trapping network.

Trap location should take into consideration the presence of the preferred hosts (primary, secondary and occasional hosts) of the target species. Because the pest is associated with maturing fruit, the location including rotation of traps should follow the sequence of fruit maturity in host plants. Consideration should be given to commercial management practices in the area where host trees are selected. For example, the regular application of insecticides (and/or other chemicals) to selected host trees may have a false-negative effect on the trapping programme.

Trap servicing

The frequency of trap servicing (maintaining and refreshing the traps) during the period of trapping should depend on the:

- longevity of baits (attractant persistency)
- retention capacity
- rate of catch
- season of fruit fly activity
- placement of the traps
- biology of the species
- environmental conditions.

Trap inspection (checking the traps for fruit flies)

The frequency of regular inspection during the period of trapping should depend on:

- expected fruit fly activity (biology of the species)
- response of the target fruit fly in relation to host status at different times of the year
- relative number of target and non-target fruit flies expected to be caught in a trap
- type of trap used
- physical condition of the flies in the trap (and whether they can be identified).

In certain traps, specimens may degrade quickly making identification difficult or impossible unless the traps are checked frequently.

Identification capability

NPPOs should have in place, or have ready access to, adequate infrastructure and trained personnel to identify detected specimens of the target species in an expeditious manner, preferably within 48 hours. Continuous access to expertise may be necessary during the establishment phase or when implementing corrective actions.

2.2.2.2 Fruit sampling procedures

Fruit sampling may be used as a surveillance method in combination with trapping where trapping is less effective. It should be noted that fruit sampling is particularly effective in small-scale delimiting surveys in an outbreak area. However, it is labour-intensive, time consuming and expensive due to the destruction of fruit. It is important that fruit samples should be held in suitable condition to maintain the viability of all immature stages of fruit fly in infested fruit for identification purpose.

Host preference

Fruit sampling should take into consideration the presence of primary, secondary and occasional hosts of the target species. Fruit sampling should also take into account the maturity of fruit, apparent signs of infestation in fruit, and commercial practices (e.g. application of insecticides) in the area.

Focusing on high risk areas

Fruit sampling should be targeted on areas likely to have presence of infested fruits such as:

- urban areas
- abandoned orchards
- rejected fruit at packing facilities
- fruit markets
- sites with a high concentration of primary hosts
- entrance points into the FF-PFA, where appropriate.

The sequence of hosts that are likely to be infested by the target fruit fly species in the area should be used as fruit sampling areas.

Sample size and selection

Factors to be considered include:

- the required level of confidence
- the availability of primary host material in the field
- fruits with symptoms on trees, fallen or rejected fruit (for example at packing facilities), where appropriate.

Procedures for processing sampled fruit for inspection

Fruit samples collected in the field should be brought to a facility for holding, fruit dissection, pest recovery and identification. Fruit should be labeled, transported and held in a secure manner to avoid mixing fruits from different samples.

Identification capability

NPPOs should have in place, or have ready access to, adequate infrastructure and trained personnel to identify fruit fly immature stages and emerged adults of the target species in an expeditious manner.

2.2.3 Controls on the movement of regulated articles

Movement controls of regulated articles should be implemented to prevent the entry of target pests into the FF-PFA. These controls depend on the assessed risks (after identification of likely pathways and regulated articles) and may include:

- listing of the target fruit fly species on a quarantine pest list
- regulation of the pathways and articles that require control to maintain the FF-PFA
- domestic restrictions to control the movement of regulated articles into the FF-PFA
- inspection of regulated articles, examination of relevant documentation as appropriate and, where necessary for cases of non-compliance, the application of appropriate phytosanitary measures (e.g. treatment, refusal or destruction).

2.2.4 Additional technical information for establishment of a FF-PFA

Additional information may be useful during the establishment phase of FF-PFAs. This includes:

- historical records of detection, biology and population dynamics of the target pest(s), and survey activities for the designated target pest(s) in the FF-PFA
- the results of phytosanitary measures taken as part of actions following detections of fruit flies in the FF-PFA
- records of the commercial production of host crops in the area, an estimate of non-commercial production and the presence of wild host material
- lists of the other fruit fly species of economic importance that may be present in the FF-PFA.

2.2.5 Domestic declaration of pest freedom

The NPPO should verify the fruit fly free status of the area (in accordance with ISPM No. 8: *Determination of pest status in an area*) specifically by confirming compliance with the procedures set up in accordance with this standard (surveillance and controls). The NPPO should declare and notify the establishment of the FF-PFA, as appropriate.

In order to be able to verify the fruit fly free status in the area and for purposes of internal management, the continuing FF-PFA status should be checked after the PFA has been established and any phytosanitary measures for the maintenance of the FF-PFA have been put in place.

2.3 Maintenance of the FF-PFA

In order to maintain the FF-PFA status, the NPPO should continue to monitor the operation of the surveillance and control activities, continuously verifying the pest free status.

2.3.1 Surveillance for maintenance of the FF-PFA

After verifying and declaring the FF-PFA, the official surveillance programme should be continued at a level assessed as being necessary for maintenance of the FF-PFA. Regular technical reports of the survey activities should be generated (for example monthly). Requirements for this are essentially the same as for establishment of the FF-PFA (see Section 2.2) but with differences in density and trap locations dependent upon the assessed level of risk of introduction of the target species.

2.3.2 Controls on the movement of regulated articles

These are the same as for establishment of the FF-PFA (provided in Section 2.2.3).

2.3.3 Corrective actions (including response to an outbreak)

The NPPO should have prepared plans for corrective actions that may be implemented if the target pest(s) is detected in the FF-PFA or in host material from that area (detailed guidelines are provided in Annex 1), or if faulty procedures are found. This plan should include components or systems to cover:

- outbreak declaration according to criteria in ISPM No. 8 (*Determination of pest status in an area*) and notification
- delimiting surveillance (trapping and fruit sampling) to determine the infested area under corrective actions
- implementation of control measures
- further surveillance
- criteria for the reinstatement of freedom of the area affected by the outbreak
- responses to interceptions.

A corrective action plan should be initiated as soon as possible and in any case within 72 hours of the detection (of an adult or immature stage of the target pest).

2.4 Suspension, reinstatement or loss of a FF-PFA status

2.4.1 Suspension

The status of the FF-PFA or the affected part within the FF-PFA should be suspended when an outbreak of the target fruit fly occurs or based on one of the following triggers: detection of an immature specimen of the target fruit fly, two or more fertile adults as demonstrated by scientific evidence, or an inseminated female within a defined period and distance. Suspension may also be applied if procedures are found to be faulty (for example inadequate trapping, host movement controls or treatments).

If the criteria for an outbreak are met, this should result in the implementation of the corrective action plan as specified in this standard and immediate notification to interested importing countries' NPPOs (see ISPM No. 17: *Pest reporting*). The whole or part of the FF-PFA may be suspended or revoked. In most cases a suspension radius will delimit the affected part of the FF-PFA. The radius will depend on the biology and ecology of the target fruit fly. The same radius will generally apply for all FF-PFAs for a given target species unless scientific evidence supports any proposed deviation. Where a suspension is put in place, the criteria for lifting the suspension should be made clear. Interested importing countries' NPPOs should be informed of any change in FF-PFA status.

2.4.2 Reinstatement

Reinstatement should be based on requirements for establishment with the following conditions:

- no further detection of the target pest species for a period determined by the biology of the species and the prevailing environmental conditions¹, as confirmed by surveillance or;
- in the case of a fault in the procedures, only when the fault has been corrected.

2.4.3 Loss of FF-PFA status

If the control measures are not effective and the pest becomes established in the whole area (the area recognized as pest free), the status of the FF-PFA should be lost. In order to achieve again the FF-PFA, the procedures of establishment and maintenance outlined in this standard should be followed.

¹ The period starts from the last detection. For some species, no further detection should occur for at least three life cycles, however the required period should be based on scientific information including that provided by the surveillance systems in place.

ANNEX 1

GUIDELINES ON CORRECTIVE ACTION PLANS

The detection of a single fruit fly (adult or immature) of the target species in the FF-PFA should trigger enforcement of a corrective action plan.

In case of an outbreak, the objective of the corrective action plan is to ensure eradication of the pest to enable reinstatement of pest status in the affected area into the FF-PFA.

The corrective action plan should be prepared taking into account the biology of the target fruit fly species, the geography of the FF-PFA area, climatic conditions and host distribution within the area.

The elements required for implementation of a corrective action plan include:

- legal framework under which the corrective action plan can be applied
- criteria for the declaration of an outbreak
- time scales for the initial response
- technical criteria for delimiting trapping, fruit sampling, application of the eradication actions and establishment of regulatory measures
- availability of sufficient operational resources
- identification capability
- effective communication within the NPPO and with the NPPO (s) of the importing country(s), including provision of contact details of all parties involved.

Actions to apply the corrective action plan**1. Determination of the phytosanitary status of the detection (actionable or non actionable)**

1.1. If the detection is a transient non actionable occurrence (ISPM No. 8: *Determination of pests status in an area*), no further action is required.

1.2. If the detection of a target pest may be actionable, a delimiting survey, which includes additional traps, and usually fruit sampling as well as an increased trap inspection rate, should be implemented immediately after the detection to assess whether the detection represents an outbreak, which will determine necessary responsive actions. If a population is present, this action is also used to determine the size of the affected area.

2. Suspension of FF-PFA status

If after detection it is determined that an outbreak has occurred or any of the triggers specified in Section 2.4.1 is reached, the FF-PFA status in the affected area should be suspended. The affected area may be limited to parts of the FF-PFA or may be the whole FF-PFA.

3. Implementation of control measures in the affected area

As per ISPM No. 9 (*Guidelines for pest eradication programmes*), specific corrective or eradication actions should be implemented immediately in the affected area(s) and adequately communicated to the community. Eradication actions may include:

- selective insecticide-bait treatments
- sterile fly release
- total harvest of fruit in the trees
- male annihilation technique
- destruction of infested fruit
- soil treatment (chemical or physical)
- insecticide application.

Phytosanitary measures should be immediately enforced for control of movement of regulated articles that can host fruit flies. These measures may include cancellation of shipments of fruit commodities from the affected area and as appropriate, fruit disinfestation and the operation of road blocks to prevent the movement of infested fruit from the affected area to the rest of the pest free area. Other measures could be adopted if agreed by the importing country, for example treatment, increased surveys, supplementary trapping.

4. Criteria for reinstatement of a FF-PFA after an outbreak and actions to be taken

The criteria for determining that eradication has been successful are specified in section 2.4.2 and should be included in the corrective action plan for the target fruit fly. The time period will depend on the biology of the species and the prevailing environmental conditions. Once the criteria have been fulfilled the following actions should be taken:

- notification of NPPOs of importing countries
- reinstatement of normal surveillance levels
- reinstatement of the FF-PFA.

5. Notification of relevant agencies

Relevant NPPOs and other agencies should be kept informed of any change in FF-PFA status as appropriate, and IPPC pest reporting obligations observed (ISPM No. 17: *Pest reporting*).

APPENDIX 1

This appendix is for reference purposes only and is not a prescriptive part of the standard. The publication below is widely available, easily accessible and generally recognized as authoritative.

GUIDELINES ON TRAPPING PROCEDURES

Information about trapping is available in the following publication of the International Atomic Energy Agency (IAEA): *Trapping Guidelines for area-wide fruit fly programmes*, IAEA/FAO-TG/FFP, 2003. IAEA, Vienna.

APPENDIX 2

This appendix is for reference purposes only and is not a prescriptive part of the standard.

GUIDELINES FOR FRUIT SAMPLING

Information about sampling is available in the references listed below. The list is not exhaustive.

- Enkerlin, W.R.; Lopez, L.; Celedonio, H. (1996) Increased accuracy in discrimination between captured wild unmarked and released dyed-marked adults in fruit fly (Diptera: Tephritidae) sterile release programs. *Journal of Economic Entomology* **89**(4), 946-949.
- Enkerlin W.; Reyes, J. (1984) *Evaluacion de un sistema de muestreo de frutos para la deteccion de Ceratitis capitata (Wiedemann)*. 11 Congreso Nacional de Manejo Integrado de Plagas. Asociacion Guatemalteca de Manejo Integrado de Plagas (AGMIP). Ciudad Guatemala, Guatemala, Centro America.
- Programa Moscamed (1990) Manual de Operaciones de Campo. Talleres Graficos de la Nacion. Gobierno de Mexico. SAGAR/DGSV.
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- Wong, T.Y.; Nishimoto, J.I.; Mochizuki, N. (1983) Infestation patterns of Mediterranean fruit fly and the Oriental fruit fly (Diptera: Tephritidae) in the Kula area of Mavi, Hawaii. *Environmental Entomology* **12**(4): 1031-1039. IV Chemical control.

ISPM No. 27



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 27

DIAGNOSTIC PROTOCOLS FOR REGULATED PESTS

(2006)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in April 2006.

INTRODUCTION

SCOPE

This standard provides guidance on the structure and content of the International Plant Protection Convention (IPPC) diagnostic protocols for regulated pests. The protocols describe procedures and methods for the official diagnosis of regulated pests that are relevant for international trade. They provide at least the minimum requirements for reliable diagnosis of regulated pests.

REFERENCES

- Determination of pest status in an area*, 1998. ISPM No. 8. FAO, Rome.
Export certification system, 1997. ISPM No. 7. FAO, Rome.
Glossary of phytosanitary terms, 2006. ISPM No. 5. FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20. FAO, Rome.
Guidelines for inspection, 2005. ISPM No. 23. FAO, Rome.
Guidelines for pest eradication programmes, 1998. ISPM No. 9. FAO, Rome.
Guidelines for surveillance, 1997. ISPM No. 6. FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13. FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest reporting, 2002. ISPM No. 17. FAO, Rome.
Requirements for the establishment of areas of low pest prevalence, 2005. ISPM No. 22. FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM No. 4. FAO, Rome.
Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10. FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14. FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

This standard sets the framework for the content of diagnostic protocols, their purpose and use, their publication and their development. Diagnostic protocols for specific regulated pests are included as annexes to this standard.

Information relevant for diagnosis is provided in the diagnostic protocol on the specified regulated pest, its taxonomic position, and the methods to detect and identify it. Diagnostic protocols contain the minimum requirements for reliable diagnosis of the specified regulated pests and provide flexibility to ensure that methods are appropriate for use in the full range of circumstances. The methods included in diagnostic protocols are selected on the basis of their sensitivity, specificity and reproducibility, and information related to these factors is provided for each of these methods.

Detailed information and guidance for the detection of pests is provided on, for example, signs and/or symptoms associated with the pest, illustrations (where appropriate), developmental stages of the pest, and methods for detecting the pest in a commodity, as well as methods for extracting, recovering and collecting the pests from plants. Information and guidance for the identification of pests includes detailed information on morphological and morphometric methods, methods based on biological properties, and methods based on biochemical and molecular properties of the pest. Furthermore detailed guidance is provided on the records that should be kept.

Diagnostic protocols are intended to be used by laboratories performing pest diagnosis as part of phytosanitary measures. They are subject to review and amendment to take into account new developments in pest diagnosis. The standard also provides guidance on how these protocols will be initiated, developed, reviewed and published.

BACKGROUND

Proper pest detection and pest identification are crucial for the appropriate application of phytosanitary measures (see for example ISPM No. 4: *Requirements for the establishment of pest free areas*; ISPM No. 6: *Guidelines for surveillance*; ISPM No. 7: *Export certification system*; ISPM No. 9: *Guidelines for pest eradication programmes*; and ISPM No 20: *Guidelines for a phytosanitary import regulatory system*). In particular, contracting parties need proper diagnostic procedures for determination of pest status and pest reporting (ISPM No. 8: *Determination of pest status in an area*; ISPM No. 17: *Pest reporting*), and the diagnosis of pests in imported consignments (ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*).

National Plant Protection Organizations (NPPOs) have produced diagnostic protocols for regulated pests in order to adequately fulfil responsibilities according to Article IV of the IPPC (1997), in particular regarding surveillance, import inspections and export certification. In response to the need for regional harmonization, several Regional Plant Protection Organizations (RPPOs) have developed a significant number of regional diagnostic standards. This underlines the need for international harmonization, and those national and regional standards may form the basis for international protocols. Subsequently, the ICPM, at its Sixth session in 2004, recognized that there was a need for international diagnostic protocols within the framework of the IPPC and approved the formation of a Technical Panel on Diagnostic Protocols (TPDP) for that purpose.

PURPOSE AND USE OF DIAGNOSTIC PROTOCOLS

The purpose of harmonized diagnostic protocols is to support efficient phytosanitary measures in a wide range of circumstances and to enhance the mutual recognition of diagnostic results by NPPOs, which may also facilitate trade. Furthermore these protocols should aid the development of expertise and technical cooperation, and they may also be relevant to the accreditation and/or approval of laboratories.

In addition to the methods included in the diagnostic protocols presented in the annexes to this standard, NPPOs may use other methods for diagnosing the same pests (for example based on bilateral agreements). The protocols and their components annexed to this ISPM are considered to have the status of an ISPM or part thereof (see section 3 of this ISPM and article X of the IPPC). Therefore, contracting parties should take into account, as appropriate, these diagnostic protocols when using or requiring the use of diagnostic methods in particular where other contracting parties may be affected.

Diagnostic protocols describe procedures and methods for the detection and identification of regulated pests that are relevant to international trade.

Diagnostic protocols may be used in different circumstances that may require methods with different characteristics. Examples of such circumstances grouped according to an increased need for high sensitivity, specificity and reliability are:

- routine diagnosis of a pest widely established in a country
- general surveillance for pest status
- testing of material for compliance with certification schemes
- surveillance for latent infection by pests
- surveillance as part of an official control or eradication programme
- pest diagnostic associated with phytosanitary certification
- routine diagnosis for pests found in imported consignments
- detection of a pest in an area where it is not known to occur
- cases where a pest is identified by a laboratory for the first time
- detection of a pest in a consignment originating in a country where the pest is declared to be absent.

For example, in the case of routine diagnosis, the speed and cost of a test method may be more relevant than sensitivity or specificity. However, the identification of a pest by a laboratory or in an area for the first time may require methods with a high level of specificity and reproducibility. The significance of the outcome of a diagnosis is often dependent on proper sampling procedures. Such procedures are addressed by other ISPMs (under preparation).

Diagnostic protocols provide the minimum requirements for reliable diagnosis of regulated pests. This may be achieved by a single method or a combination of methods. Diagnostic protocols also provide additional methods to cover the full range of circumstances for which a diagnostic protocol may be used. The level of sensitivity, specificity and reproducibility of each method is indicated where possible. NPPOs may use these criteria to determine the method or combination of methods that are appropriate for the relevant circumstances.

Diagnostic protocols are intended to be used by laboratories performing pest diagnosis. Such laboratories may be established under or may be authorized by the NPPO to perform these activities in such manner that the results of the pest diagnosis may be considered as part of a phytosanitary measure of the NPPO.

The main elements of the procedure for the development of diagnostic protocols are presented in Appendix 1.

REQUIREMENTS

1. General Requirements for Diagnostic Protocols¹

Each protocol contains the methods and guidance necessary for the regulated pest(s) to be detected and positively identified by an expert (i.e. an entomologist, mycologist, virologist, bacteriologist, nematologist, weed-scientist, molecular biologist) or competent staff that are specifically trained.

The methods included in diagnostic protocols are selected on the basis of their sensitivity, specificity and reproducibility. In addition, the availability of equipment, the expertise required for these methods and their practicability (for example ease of use, speed and cost) are taken into account when selecting methods for inclusion in the diagnostic protocol. Usually these methods and their associated information should also be published. It may be necessary that some methods are validated before inclusion in the protocols. Such validation may include, for example, the use of a set of known samples, including controls, prepared to verify sensitivity, specificity and reproducibility.

Each diagnostic protocol usually describes more than one method to take into account the capabilities of laboratories and the situations for which the methods are applied. Such situations include diagnosis of different developmental stages of organisms, which require different methodologies, the need for an alternative diagnostic technique because of uncertainties of the initial diagnosis, as well as varying requirements for the level of sensitivity, specificity and reliability. For some purposes a single method may be sufficient, for other purposes a combination of methods may be necessary. Each protocol contains introductory information, information on the taxonomic position of the pest, methods for detection and identification of the pest, records to be kept, and references to appropriate scientific publications. In many cases a wide range of supplementary information is available which may support diagnosis, for example geographical distribution of the pest and host lists, but diagnostic protocols focus on the critical methods and procedures for pest diagnosis.

The aspects of quality assurance and in particular the reference materials that are required by diagnostic protocols (such as inclusion of positive and negative controls or collection of specimens) are specifically indicated in the corresponding section of the protocol.

2. Specific Requirements for a Diagnostic Protocol

Diagnostic protocols are arranged according to the following sections:

- Pest information
- Taxonomic information
- Detection
- Identification
- Records
- Contact points for further information
- Acknowledgements
- References.

2.1 Pest information

Brief information is provided on the pest, including, where appropriate, its life cycle, morphology, variation (morphological and/or biological), relationship with other organisms, host range (in general), effects on hosts, present and past geographical distribution (in general), mode of transmission and dissemination (vectors and pathways). When available, reference to a pest data sheet should also be provided.

2.2 Taxonomic information

¹ The following general provisions apply to all diagnostic protocols:

- Laboratory tests may involve the use of chemicals or equipment which present a certain hazard. In all cases, national safety procedures should be strictly followed;
- Use of names of chemicals or equipment in these diagnostic protocols implies no approval of them to the exclusion of others that may also be suitable;
- Laboratory procedures presented in the protocols may be adjusted to the standards of individual laboratories, provided that they are adequately validated.

This section provides information on the taxonomy of the pest involved and includes:

- name (current scientific name, author and year (for fungi, teleomorph name if known))
 - synonyms (including former names)
 - accepted common names, anamorph name of fungi (including synonyms)
 - acronym of viruses and viroids
- taxonomic position (including information on subspecies classifications where relevant).

2.3 Detection

This section of the diagnostic protocol provides information and guidance on:

- the plants, plant products or other articles capable of harbouring the pest
- the signs and/or symptoms associated with the pest (characteristic features, differences or similarities with signs and/or symptoms from other causes), including illustrations, where appropriate
- the part(s) of the plant, plant products or other articles on/in which the pest may be found
- the developmental stages of the pest that may be detected, together with their likely abundance and distribution on/in the plants/plant products or other articles
- the likely occurrence of the pest associated with developmental stages of the host(s), climatic conditions and seasonality
- methods for detecting the pest in the commodity (e.g. visual, hand lens)
- methods for extracting, recovering and collecting the pest from the plants, plant products or other articles, or for demonstrating the presence of the pest in the plants, plant products or other articles
- methods for indicating the presence of the pest in asymptomatic plant material or other materials (e.g. soil or water), such as ELISA² tests or culturing on selective media
- viability of the pest.

For all the methods included in this section, information is provided on their sensitivity, specificity and reproducibility, where relevant. Where appropriate, guidance is provided on positive and negative controls and reference material to be included in tests. Guidance is also provided on resolving possible confusion with similar signs and/or symptoms due to other causes.

2.4 Identification

This section provides information and guidance on methods that either used alone or in combination lead to the identification of the pest. When several methods are mentioned, their advantages/disadvantages are given as well as the extent to which the methods or combinations of methods are equivalent. A flow diagram may be presented if several methods are needed to identify the pest or many alternative methods are included.

Main types of methodologies used in diagnostic protocols include those based on morphological and morphometric characteristics, biological properties such as virulence or host range of a pest, and those based on biochemical and molecular properties. Morphological characteristics may be investigated directly or after culturing or isolation of the pest. Culturing and/ or isolation may also be required for biochemical and/or molecular assays. Details are provided when culturing or isolation procedures are necessary components of methods.

For morphological and morphometric identifications, details are provided, as appropriate, on:

- methods to prepare, mount and examine the pest (such as for light microscopy, electron microscopy and measurement techniques)
- identification keys (to family, genus, species)
- descriptions of the morphology of the pest or of its colonies, including illustrations of morphological diagnostic characteristics, and an indication of any difficulties in seeing particular structures
- comparison with similar or related species
- relevant reference specimens or cultures.

For biochemical or molecular identifications, each method (e.g. serological methods, electrophoresis, PCR³, DNA barcoding, RFLP⁴, DNA sequencing) is described separately in sufficient detail (including equipment, reagents and consumables) to perform the test. Where appropriate, reference may be made to methodology described in other diagnostic protocols annexed to this standard.

In cases where more than one method can be used reliably, other appropriate methods may be presented as alternative or

² Enzyme-Linked Immunosorbent Assay

³ Polymerase Chain Reaction

⁴ Restriction Fragment Length Polymorphism

supplementary methods, e.g. where morphological methods can be used reliably and appropriate molecular methods are also available.

Where appropriate, methods for isolation of pests from asymptomatic plants or plant products (such as tests for latent infection) are given, as well as methods for extraction, recovery and collection of pests from plant or other material. In these cases, methods may also be provided for direct identification of pests using biochemical or molecular tests on asymptomatic material.

For all the methods included in this section, information is provided on their sensitivity, specificity and reproducibility, where relevant. Where appropriate, guidance is provided on positive and negative controls and reference material to be included in tests. Guidance is also provided on removing possible confusion with similar and related species or taxa.

Diagnostic protocols provide guidance on the criteria for the determination of a positive or negative result for each method or information necessary to determine if an alternative method be applied.

Those cases where the use of appropriate controls for a specific technique, including where relevant reference material, is essential are clearly indicated in the protocol. When appropriate controls are not available, other tests, preferably based on different identification principles, may increase the certainty of the identification. Alternatively, a sample, specimen or, where appropriate, an image should be sent to another laboratory with experience in diagnosis of the suspected pest and possessing the required control or reference materials. Specimen(s) or material for reference purposes should be properly preserved.

Methods for quick, preliminary indications of identity (which will later need to be confirmed) may also be included in diagnostic protocols.

2.5 Records

This section provides information on the records that should be kept:

- scientific name of pest identified
- code or reference number of the sample (for traceability)
- nature of the infested material including scientific name of host where applicable
- origin (including the geographic location if known) of the infested material, and location of interception or detection
- description of signs or symptoms (including photographs where relevant), or their absence
- methods, including controls, used in the diagnosis and the results obtained with each method
- for morphological or morphometric methods, measurements, drawings or photographs of the diagnostic features (where relevant) and, if applicable, an indication of the developmental stage(s)
- for biochemical and molecular methods, documentation of test results such as photographs of diagnostic gels or ELISA printouts of results on which the diagnosis was based
- where appropriate, the magnitude of any infestation (how many individual pests found, how much damaged tissue)
- the name of the laboratory and, where appropriate, the name of the person(s) responsible for and/or who performed the diagnosis
- dates of collection of the sample, and of detection and identification of the pest.
- where appropriate, state of the pest, alive or dead, or viability of its development stages.

Evidence such as culture(s) of the pest, nucleic acid of the pest, preserved/mounted specimens or test materials (e.g. photograph of gels, ELISA plate printout results) should be retained, in particular in cases of non-compliance (ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*) and where pests are found for the first time (ISPM No. 17: *Pest reporting*). Additional items may be required under other ISPMs such as ISPM No. 8 (*Determination of pest status in an area*).

The period for which records should be kept depends on the purpose for which a diagnosis is made. In cases where other contracting parties may be adversely affected by the results of the diagnosis, records and evidence of the results of the diagnosis should be retained for at least one year.

2.6 Contact points for further information

Contact details of organizations or individuals with particular expertise on the pest(s) are provided; they may be consulted regarding details on the diagnostic protocol.

2.7 Acknowledgements

The name and address of the experts who wrote the first draft of the diagnostic protocol are given, together with those of any others who made major contributions.

2.8 References

References to accessible scientific publications and/or published laboratory manuals are given that may provide further guidance on the methods and procedures contained in the diagnostic protocol.

3. Publication of Diagnostic Protocols

Diagnostic protocols are published as annexes to this ISPM and thus are individual publications under the IPPC framework with a specific publication and/or revision date. If appropriate, they may also form part of other ISPMs. The process of their adoption includes stringent review by internationally acknowledged scientists/experts for the relevant discipline.

An index to the annexes is provided as Appendix 2 [Appendix 2 will be added to the standard when protocols have been approved].

APPENDIX 1

MAIN ELEMENTS OF PROCEDURES FOR DIAGNOSTIC PROTOCOLS

1. Development of Diagnostic Protocols

The TPDP will commission an expert to lead the development of a diagnostic protocol by adapting, as appropriate, protocols that have already been approved by RPPOs, or other international or national organizations, or by developing a new diagnostic protocol. The diagnostic protocol will be developed further by a small group of experts selected by the TPDP and will then be submitted, in cooperation with the IPPC Secretariat, to the TPDP which, when satisfied with the content, will submit it to the Standards Committee.

2. Review of Existing Diagnostic Protocols

TPDP members will review the diagnostic protocols in their discipline on an annual basis or as determined by the TPDP. A request for a revision to a diagnostic protocol may also be submitted by NPPOs, RPPOs or CPM subsidiary bodies through the IPPC Secretariat (ippc@fao.org), which will in turn forward it to the TPDP.

The TPDP will evaluate the request, identify those diagnostic protocols that require revision and oversee their revision. New methods should be at least equivalent to existing methods or provide a significant advantage for their worldwide application such as costs, sensitivity or specificity. Appropriate evidence should be provided to support any claims.

3. Requests for New Diagnostic Protocols

Requests for new diagnostic protocols, in addition to those identified in the work programme of the TPDP, should be sent by NPPOs, RPPOs or CPM subsidiary bodies through the IPPC Secretariat using a form for topics and priorities for standards, by 31 July of each year.



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 28

***PHYTOSANITARY TREATMENTS FOR
REGULATED PESTS***

(2007)

Produced by the Secretariat of the International Plant Protection Convention

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ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in March 2007.

INTRODUCTION

SCOPE

This standard presents in Annex 1 phytosanitary treatments evaluated and adopted by the Commission on Phytosanitary Measures (CPM). It also describes the requirements for submission and evaluation of the efficacy data and other relevant information on a phytosanitary treatment that can be used as a phytosanitary measure and that will be included in Annex 1 after its adoption.

The treatments are for the control of regulated pests on regulated articles, primarily those moving in international trade. The adopted treatments provide the minimum requirements necessary to control a regulated pest at a stated efficacy.

The scope of this standard does not include issues related to pesticide registration or other domestic requirements for approval of treatments (e.g. irradiation)¹.

REFERENCES

Glossary of phytosanitary terms, 2007. ISPM No. 5, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

Harmonized phytosanitary treatments support efficient phytosanitary measures in a wide range of circumstances and enhance the mutual recognition of treatment efficacy. Annex 1 to this standard contains those phytosanitary treatments which have been adopted by the CPM.

National Plant Protection Organizations (NPPOs) and Regional Plant Protection Organizations (RPPOs) may submit data and other information for the evaluation of efficacy, feasibility and applicability of treatments. The information should include a detailed description of the treatment, including efficacy data, the name of a contact person and the reason for the submission. Treatments that are eligible for evaluation include mechanical, chemical, irradiation, physical and controlled atmosphere treatments. The efficacy data should be clear and should preferably include data on the treatment under laboratory or controlled conditions as well as under operational conditions. Information on feasibility and applicability of the proposed treatment(s) should include items on cost, commercial relevance, level of expertise required to apply the treatment and versatility.

Submissions with complete information will be considered by the Technical Panel on Phytosanitary Treatments (TPPT), and if the treatment is deemed acceptable, it will be recommended to the CPM for adoption.

¹ The inclusion of a phytosanitary treatment in this ISPM does not create any obligation for a contracting party to approve the treatment or register or adopt it for use in its territory.

BACKGROUND

The purpose of the IPPC is “to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control” (Article I.1 of the IPPC, 1997). The requirement or application of phytosanitary treatments to regulated articles is a phytosanitary measure used by contracting parties to prevent the introduction and spread of regulated pests.

Article VII.1 of the IPPC 1997 states:

“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”.

Phytosanitary measures required by a contracting party shall be technically justified (Article VII.2a of the IPPC, 1997).

Phytosanitary treatments are used by NPPOs to prevent the introduction and spread of regulated pests. Many of these treatments are supported by extensive research data, and others are used based on historical evidence supporting their efficacy. In practice, many countries use the same treatments or similar treatments for specified pests; however, mutual recognition is often a complex and difficult process. Furthermore, there has previously been neither an internationally recognized organization or process to evaluate treatments for their efficacy nor a central repository for listing such treatments. The Interim Commission on Phytosanitary Measures, at its sixth session in 2004, recognized the need for international recognition of phytosanitary treatments of major importance and approved the formation of the TPPT for that purpose.

REQUIREMENTS

1. Purpose and Use

The purpose of harmonizing phytosanitary treatments is to support efficient phytosanitary measures in a wide range of circumstances and to enhance the mutual recognition of treatment efficacy by NPPOs, which may also facilitate trade. Furthermore, these treatment schedules should aid the development of expertise and technical cooperation. NPPOs are not obliged to use these treatments and may use other phytosanitary treatments for treating the same regulated pests or regulated articles.

Adopted phytosanitary treatments provide a means for the killing, inactivation or removal of pests, for rendering pests infertile or for devitalization, at a stated efficacy, and are relevant primarily to international trade. The level of efficacy, specificity and applicability of each treatment is indicated where possible. NPPOs may use these criteria to select the treatment or combination of treatments that are appropriate for the relevant circumstances.

When requiring phytosanitary treatments for imports, contracting parties should take into account the following points:

- Phytosanitary measures required by a contracting party shall be technically justified.
- Phytosanitary treatments contained in Annex 1 of this standard have the status of an ISPM and therefore should be considered accordingly.
- Regulatory regimes of exporting contracting parties may prevent certain treatments from being approved for use within their territories. Therefore efforts should be made to accept equivalent treatments where possible.

2. Process for Treatment Submission and Adoption

The submission process is initiated by a call for topics for standards (including topics for treatments) according to the "IPPC standard setting procedure" and the "Procedure and criteria for identifying topics for inclusion in the IPPC standard setting work programme". These procedures are provided on the International Phytosanitary Portal (<https://www.ippc.int>).

In particular, the following points apply to treatments:

- Once a topic for treatments (e.g. treatments for fruit flies or for pests on wood) has been added to the IPPC standard-setting work programme, the IPPC Secretariat, under direction of the Standards Committee (with recommendations from the TPPT), will call for the submissions and data on treatments on that topic.
- NPPOs or RPPOs submit treatments (accompanied by relevant information as requested in section 3) to the Secretariat.
- Only submissions of treatments that are deemed by the NPPO or RPPO to meet the requirements listed in this standard should be submitted, and it is recommended that these treatments have been approved for national use before their submission. Treatments include, but are not limited to, mechanical, chemical, irradiation, physical

(heat, cold) and controlled atmosphere treatments. NPPOs and RPPOs should take into account other factors when considering phytosanitary treatments for submission, such as the effects on human health and safety, animal health and the impact on the environment (as described in the preamble and Article I.1 of the IPPC, 1997 and in Article III of the IPPC, 1997 regarding relationship with other international agreements). Effects on the quality and intended use of the regulated article should also be considered.

- Treatment submissions will be evaluated based on the requirements listed in section 3. If large numbers of submissions are received, the TPPT will work with the Standards Committee to determine the priority for reviewing submissions.
- Treatments that meet the requirements listed in section 3 will be recommended and the treatment submitted, along with a report and a summary of the information evaluated, to the Standards Committee and in turn to the IPPC standard setting process. The report of the technical panel with the summary information and the SC report will be available to contracting parties. Further detailed information (as long as it is not confidential) will be available on request from the Secretariat.
- The CPM will adopt or reject a treatment. If adopted, the treatment is annexed to this standard.

3. Requirements for Phytosanitary Treatments

For the purpose of this standard, phytosanitary treatments should fulfil the following requirements:

- be effective in killing, inactivating or removing pests, or rendering pests infertile or for devitalization associated with a regulated article. The level of efficacy of the treatment should be stated (quantified or expressed statistically). Where experimental data is unavailable or insufficient, other evidence that supports the efficacy (i.e. historical and/or practical information/experience) should be provided.
- be well documented to show that the efficacy data has been generated using appropriate scientific procedures, including where relevant an appropriate experimental design. The data supporting the treatment should be verifiable, reproducible, and based on statistical methods and/or on established and accepted international practice; preferably the research should have been published in a peer-reviewed journal.
- be feasible and applicable for use primarily in international trade or for other purposes (e.g. to protect endangered areas domestically, or for research).
- not be phytotoxic or have other adverse effects.

Submissions of phytosanitary treatments should include the following:

- summary information
- efficacy data in support of the phytosanitary treatment
- information on feasibility and applicability.

3.1 Summary information

The summary information should be submitted by NPPOs or RPPOs to the Secretariat and should include:

- name of the treatment
- name of the NPPO or RPPO and contact information
- name and contact details of a person responsible for submission of the treatment
- treatment description (active ingredient(s), treatment type, target regulated article(s), target pest(s), treatment schedule, and other relevant information)
- reason for submission, including its relevance to existing ISPMs.

Submissions should utilize a form provided by the IPPC Secretariat and available on the International Phytosanitary Portal (<https://www.ippc.int>).

In addition, the NPPO or RPPO should describe the experience or expertise in the subject area of the laboratory, organization and/or scientist(s) involved in producing the data, and any quality assurance system or accreditation programme applied in the development and/or testing of the phytosanitary treatment. This information will be considered when evaluating the data submitted.

3.2 Efficacy data in support of the submission of a phytosanitary treatment

The source of all efficacy data (published or unpublished) should be provided in the submission. Supporting data should be presented clearly and systematically. Any claims on the efficacy must be substantiated by data.

3.2.1 Efficacy data under laboratory/controlled conditions

The life-cycle stage of the target pest for the treatment should be specified. Usually, the life stage(s) associated with the regulated article moving in trade is the stage for which a treatment is proposed and established. In some circumstances, e.g. where several life stages may occur on the regulated article, the most resistant life stage of the pest should be used

for testing a treatment. However, practical considerations should be taken into account, as well as pest control strategies aimed at exploiting more vulnerable or otherwise specific stages of a pest. If efficacy data is submitted for a life stage that is not considered to be the most resistant (e.g. if the most resistant life stage is not associated with the regulated article), rationale for this should be provided. The efficacy data provided should specify the statistical level of confidence supporting efficacy claims made for treatment of the specified life stage.

Where possible, data should be presented on methods used to determine the effective dose/treatment to demonstrate the range of efficacy of the treatment (e.g. dose/efficacy curves). Treatments can normally be evaluated only for the conditions under which they were tested. However, additional information can be provided to support any extrapolation if the scope of a treatment is to be extended (e.g. extension of the range of temperatures, inclusion of other cultivars or pest species). Where the information provided is adequate to demonstrate the effectiveness of the treatment, only a summary of relevant preliminary laboratory tests will be required. The materials and methods used in the experiments should be suitable for the use of the treatment at the stated efficacy.

The data provided should include detailed information on, but not limited to, the following elements:

Pest information

- identity of the pest to the appropriate level (e.g. genus, species, strain, biotype, physiological race), life stage, and if laboratory or field strain was used
- conditions under which the pests are cultured, reared or grown
- biological traits of the pest relevant to the treatment (e.g. viability, genetic variability, weight, developmental time, development stage, fecundity, freedom from disease or parasites)
- method of natural or artificial infestation
- determination of most resistant species/life stage (in the regulated article where appropriate).

Regulated article information

- type of regulated article and intended use
- botanical name for plant or plant product (where applicable)
 - type/cultivar. A requirement for varietal testing should be based on evidence that the varietal differences impact treatment efficacy, and data should be provided to support the requirement.
- conditions of the plant or plant product, for example:
 - whether it was free from non-target pest infestation, non-pest disorder or pesticide residue
 - size, shape, weight, stage of maturity, quality, etc.
 - whether infested at a susceptible growth stage
 - storage conditions after harvest.

Experimental parameters

- level of confidence of laboratory tests provided by the method of statistical analysis and the data supporting that calculation (e.g. number of subjects treated, number of replicate tests, controls)
- experimental facilities and equipment
- experimental design (e.g. randomized complete block design) if needed
- experimental conditions (e.g. temperature, relative humidity, diurnal cycle)
- monitoring of critical parameters (e.g. exposure time, dose, temperature of regulated article and ambient air, relative humidity)
- methodology to measure the effectiveness of the treatment (e.g. whether mortality is the proper parameter, whether the end-point mortality was assessed at the correct time, the mortality or sterility of the treated and control groups)
- determination of efficacy over a range of critical parameters, where appropriate, such as exposure time, dose, temperature, relative humidity and water content, size and density
- methodology to measure phytotoxicity, when appropriate
- dosimetry system, calibration and accuracy of measurements, if using irradiation.

3.2.2 Efficacy data using operational conditions

Treatments may be submitted for evaluation without going through the processes outlined in section 3.2.1 when there is sufficient efficacy data available from the operational application of the treatment. When a treatment has been developed under laboratory conditions, it should be validated by testing under operational or simulated operational conditions. Results of these tests should confirm that the application of the treatment schedule achieves the stated efficacy under conditions in which the treatment will be used.

Where treatment specifications differ for trials under operational conditions, the test protocol modifications should be

indicated. Supporting data may be presented from preliminary tests to refine the treatment schedule to establish the effective dose (e.g. temperature, chemical, irradiation) under operational conditions.

In some cases the method of achieving the effective dose will be different from the method established under laboratory conditions. Data that supports any extrapolation of laboratory results should be provided.

The same data requirements as listed in section 3.2.1 should also be provided for these tests. Other data required, depending on whether the treatments are carried out pre- or post-harvest, are listed below:

- factors that affect the efficacy of the treatment (e.g. for post-harvest treatments: packaging, packing method, stacking, timing of treatments (pre/post packaging or processing, in transit, on arrival)). The circumstances of the treatment should be stated, for example the efficacy of a treatment may be affected by packaging, and data should be provided to support all the circumstances that are applicable.
- monitoring of critical parameters (e.g. exposure time, dose, temperature of regulated article and ambient air, relative humidity). For example:
 - the number and placement of gas sampling lines (fumigation)
 - the number and placement of temperature/humidity sensors.

In addition, any special procedures that affect the success of the treatment (e.g. to maintain the quality of the regulated article) should be included.

3.3 Feasibility and applicability

Information should be provided, where appropriate, to evaluate if the phytosanitary treatment is feasible and applicable. This includes such items as:

- procedure for carrying out the phytosanitary treatment (including ease of use, risks to operators, technical complexity, training required, equipment required, facilities needed)
- cost of typical treatment facility and operational running costs if appropriate
- commercial relevance, including affordability
- extent to which other NPPOs have approved the treatment as a phytosanitary measure
- availability of expertise needed to apply the phytosanitary treatment
- versatility of the phytosanitary treatment (e.g. application to a wide range of countries, pests and commodities)
- the degree to which the phytosanitary treatment complements other phytosanitary measures (e.g. potential for the treatment to be used as part of a systems approach for one pest or to complement treatments for other pests)
- summary of available information of potential undesirable side-effects (e.g. impacts on the environment, impacts on non-target organisms, human and animal health)
- applicability of treatment with respect to specific regulated article/pest combinations
- technical viability
- phytotoxicity and other effects on the quality of regulated articles, when appropriate
- consideration of the risk of the target organism having or developing resistance to the treatment.

Treatment procedures should adequately describe the method for applying the treatment in a commercial setting.

4. Evaluation of Submitted Treatments

Submissions will be considered by the TPPT only when the information outlined in section 3 is fully addressed. The information provided will be evaluated against the requirements in section 3.

Due respect for confidentiality will be exercised when the confidential nature of information is indicated. In such cases, the confidential information within the submission should be clearly identified. Where confidential information is essential for the adoption of the treatment, the submitter will be requested to release the information. If the release of the information is not granted, the adoption of the treatment may be affected.

Treatments will be adopted only for the regulated articles and target species for which they were tested and for the conditions under which they were tested, unless data is presented to support extrapolation (e.g. to apply the treatment to a range of pest species or regulated articles).

If the submission fails to meet the requirements outlined in section 3, the reason(s) will be communicated to the contact identified on the submission. There may be a recommendation to provide additional information or to initiate further work (e.g. research, field testing, analysis).

5. Publication of Phytosanitary Treatments

After adoption by the CPM, phytosanitary treatments will be annexed to this standard.

6. Treatment Review and Re-evaluations

Contracting parties should submit to the IPPC Secretariat any new information that could have an impact on the treatments currently adopted by the CPM. The TPPT will review the data and revise the treatments if necessary through the normal standard-setting process.

ANNEX 1

ADOPTED PHYTOSANITARY TREATMENTS

Phytosanitary treatments will be included in this annex after adoption by the CPM.



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 29

***RECOGNITION OF PEST FREE AREAS AND AREAS OF
LOW PEST PREVALENCE***

(2007)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in March 2007.

INTRODUCTION

SCOPE

This standard provides guidance and describes a procedure for the bilateral recognition of pest free areas and areas of low pest prevalence. This standard does not include specified timelines for the recognition procedure. This standard also provides some considerations regarding pest free places of production and pest free production sites.

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.
- Establishment of pest free areas for fruit flies (Tephritidae)*, 2006. ISPM No. 26, FAO, Rome.
- Glossary of phytosanitary terms*, 2007. ISPM No. 5, FAO, Rome.
- Guidelines for a phytosanitary import regulatory system*, 2004. ISPM No. 20, FAO, Rome.
- Guidelines for pest eradication programmes*, 1998. ISPM No. 9, FAO, Rome.
- Guidelines for phytosanitary certificates*, 2001. ISPM No. 12, FAO, Rome.
- Guidelines for surveillance*, 1997. ISPM No. 6, FAO, Rome.
- Guidelines for the determination and recognition of equivalence of phytosanitary measures*, 2005. ISPM No. 24, FAO, Rome.
- Guidelines for the notification of non-compliance and emergency action*, 2001. ISPM No. 13, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Pest reporting*, 2002. ISPM No. 17, FAO, Rome.
- Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006. ISPM No. 1, FAO, Rome.
- Requirements for the establishment of areas of low pest prevalence*, 2005. ISPM No. 22, FAO, Rome.
- Requirements for the establishment of pest free areas*, 1996. ISPM No. 4, FAO, Rome.
- Requirements for the establishment of pest free places of production and pest free production sites*, 1999. ISPM No. 10, FAO, Rome.
- The use of integrated measures in a systems approach for pest risk management*, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

Recognition of pest free areas (PFAs) and areas of low pest prevalence (ALPPs) is a technical and administrative process to achieve acceptance of the phytosanitary status of a delimited area. Technical requirements for establishment of PFAs and ALPPs, as well as certain elements relating to recognition, are addressed in other International Standards for Phytosanitary Measures (ISPMs). In addition, many principles of the International Plant Protection Convention (IPPC, 1997) are relevant.

Contracting parties to the IPPC should proceed with a recognition process without undue delay. The process should be applied without discrimination between contracting parties. Contracting parties should endeavour to maintain transparency in all aspects of the recognition process.

The procedure described in this standard deals with those cases where detailed information and verification may be required, such as in areas in which eradication or suppression of a pest has recently been achieved. This procedure includes the following steps for the contracting parties: request for recognition; acknowledgement of receipt of the request and the accompanying information package; description of the process; assessment of the information provided; communication of the results of assessment; provision of official recognition. However, where the absence of the pest in an area and the PFA status can easily be determined, the procedure for recognition described in this standard (in section 4) may not be required or very little supporting information may be necessary.

Both exporting and importing contracting parties have specific responsibilities relating to the recognition of PFAs and ALPPs.

The recognition process should be sufficiently documented by contracting parties.

Some considerations on pest free places of production and pest free sites of production are also provided.

BACKGROUND

Exporting contracting parties may establish PFAs or ALPPs, among other reasons, in order to gain, maintain or improve market access. In any of these cases, where PFAs or ALPPs are established in accordance with the relevant ISPMs, recognition of such areas without undue delay is very important to exporting contracting parties.

Importing contracting parties, in meeting their appropriate level of protection and in accordance with requirements for technical justification, may consider PFAs or ALPPs as effective phytosanitary measures. Therefore, it may also be in the interests of the importing country to provide prompt recognition of such areas where they are established in accordance with the relevant ISPMs.

For recognition of PFAs and ALPPs, the following articles of the IPPC are relevant:

“The responsibilities of an official national plant protection organization shall include ... the designation, maintenance and surveillance of pest free areas and areas of low pest prevalence” (Article IV.2e);

“The contracting parties shall cooperate with one another to the fullest practicable extent in achieving the aims of this Convention ...” (Article VIII).

Article 6 (*Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence*) of the World Trade Organization’s Agreement on the Application of Sanitary and Phytosanitary Measures addresses the issue of recognition of PFAs and ALPPs.

REQUIREMENTS

1. General Considerations

Several ISPMs address the establishment of PFAs and ALPPs, and related issues. A range of ISPMs relate directly to the technical requirements for the establishment of PFAs and ALPPs, while many others contain provisions that may be applied in the formal process for recognition of such areas.

ISPM No. 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) includes operational principles on recognition of PFAs and ALPPs (sections 2.3 and 2.14).

ISPM No. 4 (*Requirements for the establishment of pest free areas*) points out that, since certain PFAs are likely to involve an agreement between trading partners, their implementation would need to be reviewed and evaluated by the NPPO of the importing country (section 2.3.4).

ISPM No. 8 (*Determination of pest status in an area*) provides guidance on the use of the phrase “pest free area declared” in pest records (section 3.1.2).

ISPM No. 10 (*Requirements for the establishment of pest free places of production and pest free production sites*) 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.

ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) describes the requirements and procedures for the establishment of ALPPs for regulated pests in an area and, to facilitate export, for pests regulated by an importing country only. This includes the identification, verification, maintenance and use of those ALPPs.

ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) describes the requirements for the establishment and maintenance of PFAs for the economically important species in the family Tephritidae.

Although the recognition of PFAs and ALPPs may generally be a bilateral process of information exchange between importing and exporting contracting parties, recognition may take place without a detailed process if agreed between the parties (for example without bilateral negotiations and verification activities).

Usually, pest free places of production and pest free production sites should not require a recognition process and, therefore, only some consideration is given in this standard on use of procedures in particular cases.

2. Related Principles

2.1 Recognition of pest free areas and areas of low pest prevalence

ISPM No. 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) states that “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”.

2.2 Sovereignty and cooperation

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 to plant health. A contracting party has sovereign authority to regulate the entry of plants, plant products and other regulated articles (Article VII.1 of the IPPC). Therefore a contracting party has the right to make decisions relating to recognition of PFAs and ALPPs.

However, countries also have other obligations and responsibilities, such as cooperation (Article VIII of the IPPC). Therefore, in order to promote cooperation, an importing contracting party should consider requests for recognition of PFAs and ALPPs.

2.3 Non-discrimination

In recognizing PFAs and ALPPs, the process used by the importing contracting party for assessing such requests from different exporting contracting parties should be applied in a non-discriminatory manner.

2.4 Avoidance of undue delay

Contracting parties should endeavour to recognize PFAs and ALPPs, and to resolve any disagreements related to recognition, without undue delay.

2.5 Transparency

Updates on progress between the importing and exporting contracting parties should be provided to the designated point of contact (further described in section 3.1), as appropriate or on request, to ensure that the recognition process is conducted in an open and transparent manner.

Any change in the status of the regulated pest in the area under consideration, or in the importing contracting party's territory, relevant to recognition shall be communicated appropriately and promptly as required by the IPPC (Article VIII.1a) and relevant ISPMs (e.g. ISPM No. 17: *Pest reporting*).

To improve transparency, contracting parties are encouraged to make available on the International Phytosanitary Portal decisions on PFAs and ALPPs that have been recognized (this information should be updated as appropriate).

2.6 Other relevant principles of the IPPC and its ISPMs

In recognizing PFAs and ALPPs, contracting parties should take into account the following rights and obligations held by contracting parties, and principles of the IPPC:

- minimal impact (Article VII.2g of the IPPC)
- modification (Article VII.2h of the IPPC)
- harmonization (Article X.4 of the IPPC)
- risk analysis (Articles II and VI.1b of the IPPC)
- managed risk (Article VII.2a and 2g of the IPPC)
- cooperation (Article VIII of the IPPC)
- technical assistance (Article XX of IPPC)
- equivalence (section 1.10 of ISPM No. 1).

3. Requirements for the Recognition of Pest Free Areas and Areas of Low Pest Prevalence

NPPOs are responsible for designation, maintenance and surveillance of PFAs and ALPPs within their territories (Article IV.2e of the IPPC). To establish PFAs or ALPPs and before asking for recognition, NPPOs should take into account the appropriate ISPMs that provide technical guidance, e.g. ISPM No. 4 (*Requirements for the establishment of pest free areas*) for PFAs, ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) for ALPPs, and ISPM No. 8 (*Determination of pest status in an area*).

They may also consider other technical guidance that may be developed on establishment of PFAs or ALPPs for specific regulated pests or groups of these pests.

The importing contracting party is responsible for determining the type of information that will be required, in order to recognize a PFA or ALPP, depending on the type of area and its geography, the method used to establish the pest status

of the area (pest free area or low pest prevalence area), the contracting party's appropriate level of protection, and other factors for which technical justifications exist.

Where the pest is absent from an area and the PFA status can easily be determined (for example in areas where no records of the pest have been made and, in addition, long term absence of the pest is known or absence is confirmed by surveillance), the process for recognition described in this standard (in section 4) may not be required or very little supporting information may be necessary. In such cases, absence of the pest should be recognized according to the first paragraph of section 3.1.2 of ISPM No. 8 (*Determination of pest status in an area*) without the need for detailed information or elaborate procedures.

In other cases, such as in areas where a pest has recently been eradicated (ISPM No. 9: *Guidelines for pest eradication programmes*) or suppressed, more detailed information and verification may be required, including items listed in section 4.1 of the present standard.

3.1 Responsibilities of contracting parties

The exporting contracting party is responsible for:

- requesting recognition of an established PFA or ALPP
- providing appropriate information on the PFA or ALPP
- designating a point of contact for the recognition process
- providing appropriate additional information if necessary for the recognition process
- cooperating in the organization of on-site verification visits, if requested.

The importing contracting party is responsible for:

- acknowledging receipt of the request and the associated information
- describing the process to be used for the recognition process including, if possible, an estimated time frame for the evaluation
- designating a point of contact for the recognition process
- technically assessing the information
- communicating and justifying the need for on-site verifications and cooperating in their organization
- communicating the results of the assessment to the exporting contracting party and:
 - if the area is recognized, promptly modifying any phytosanitary regulations, as appropriate;
 - if the area is not recognized, providing an explanation, including technical justification where applicable, to the exporting contracting party.

Importing contracting parties should limit any information or data requests associated with an assessment of recognition to those which are necessary.

3.2 Documentation

The whole process from initial request to final decision should be sufficiently documented by contracting parties so that the sources of information and rationale used in reaching the decision can be clearly identified and demonstrated.

4. Procedure for the Recognition of Pest Free Areas and Areas of Low Pest Prevalence

The steps described below are recommended for importing contracting parties in order to recognize PFAs and ALPPs of exporting contracting parties. However, in certain cases, as mentioned in the third paragraph of section 3, a process for recognition as described in this standard may not be required.

Normally, the exporting contracting party may wish to consult with the importing contracting party before submitting a request with the aim of facilitating the recognition process.

A flow chart outlining the following steps is provided in Appendix 1. Recommended steps proceed as described from section 4.1 to section 4.6.

4.1 Request for recognition by the NPPO of the exporting contracting party

The exporting contracting party submits its request for recognition of a PFA or ALPP to an importing contracting party. To support its request, the exporting contracting party provides a technical information package based on ISPM No. 4 (*Requirements for the establishment of pest free areas*) or ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) as appropriate. This information package should be sufficiently detailed to demonstrate objectively that the areas are, and are likely to remain, PFAs or ALPPs, as appropriate. The package may include the following information:

- the type of recognition requested, i.e. either a PFA or an ALPP
- location and description of the area to be recognized, with supporting maps, as appropriate
- pest(s) under consideration, and biology(ies) and known distribution relevant to the area (as described in ISPM No. 4 or ISPM No. 22 as appropriate)
- commodity(ies) or other regulated article(s) to be exported
- general information on hosts and their prevalence within the designated area
- phytosanitary measures and procedures applied for the establishment of the PFA or ALPP, and results of these measures
- phytosanitary measures and procedures applied to maintain the PFA or ALPP, and results of these measures
- relevant phytosanitary regulations relating to the PFA or ALPP
- record-keeping arrangements relating to the area, in accordance with the appropriate standards
- relevant information directly related to the request for recognition on the structure of and resources available to the NPPO of the exporting country
- a description of corrective action plans, including related communication arrangements with the importing country concerned
- other relevant information (e.g. recognition of the area in question by other contracting parties, and possible systems approaches relating to ALPPs).

The exporting contracting party should designate a point of contact for communication relating to the request for recognition.

4.2 Acknowledgement by the importing contracting party of receipt of the information package and indication of its completeness for assessment purposes

The NPPO of the importing contracting party should promptly acknowledge receipt of the request for recognition and of the accompanying information package to the NPPO of the exporting contracting party. The importing contracting party should designate a point of contact for communications relating to the request for recognition.

In commencing the assessment, the importing contracting party should, if possible, identify and communicate to the NPPO of the exporting contracting party if any significant component of the information package is missing, or if other significant information may be needed to assess the request.

The NPPO of the exporting contracting party should submit to the NPPO of the importing contracting party any missing information, or may provide an explanation for its absence.

Where an exporting contracting party resubmits a request for recognition of a PFA or ALPP (e.g. if further data is acquired, or new or additional procedures are implemented), the importing contracting party should take into consideration all information previously provided, if verification has been provided by the exporting contracting party that the information remains valid. If resubmission is due to a previous non-acceptance of a request for recognition, any relevant details in the corresponding technical explanation related to the previous assessment should also be taken into consideration. Likewise if a contracting party has withdrawn a PFA or ALPP (e.g. maintenance of the PFA or ALPP became uneconomic) and wishes to reinstate it, previous information should be considered. The assessment should be completed, without undue delay, by focusing on the revised or supplemental information and/or data provided, if appropriate.

4.3 Description of assessment process to be used by the importing contracting party

The importing contracting party should describe the process intended to be used in assessing the information package and in subsequently recognizing the PFA or ALPP, including any necessary legislative or administrative steps or requirements that will need to be completed. Furthermore, the importing contracting party is encouraged to establish if possible an anticipated timeframe for completion of the recognition process.

4.4 Assessment of the technical information

Once all the information has been received, the NPPO of the importing contracting party should carry out assessment of the information package, taking into account:

- provisions of the relevant ISPMs that specifically address either PFAs (ISPM No. 4: *Requirements for the establishment of pest free areas*) or ALPPs (ISPM No. 22: *Requirements for the establishment of areas of low pest prevalence*), including the following information:
 - systems used to establish the PFA or ALPP
 - phytosanitary measures to maintain the PFA or ALPP
 - checks to verify that the PFA or ALPP is being maintained

- other relevant ISPMs (in particular those described in section 1) depending on the type of recognition requested
- status of the pest in the territories of both contracting parties.

PFAs or ALPPs previously recognized by a third country or another contracting party may be considered as reference for the assessment process.

Clarification of the information provided may be required or additional information may be requested by the importing contracting party in order to complete the assessment. The exporting contracting party should respond to technical concerns raised by the importing contracting party by providing relevant information to facilitate completion of the assessment.

On-site verification or on-site review of operational procedures may be requested, where justified, based on the results of the ongoing assessment, records of previous trade between the two parties (in particular if there is a lack of information, interception records, non-compliance with import requirements), or previous recognition of areas between the two parties or by other parties. The schedule, agenda and content of the on-site verification or review should be agreed bilaterally, and access provided as necessary.

The assessment should be completed without undue delay. If at any stage progress is not proceeding in accordance with the anticipated timeframe, if established, the exporting contracting party should be notified. Upon request of the exporting contracting party, reasons should be provided and (if appropriate) a new timeframe prepared and provided by the importing contracting party to the exporting contracting party.

The exporting contracting party may request cancellation or postponement of the assessment at any time. Should the exporting contracting party request postponement of the assessment, this may result in changes in the anticipated timeframe. If the pest status or phytosanitary regulations change in the importing country, recognition of the PFA or ALPP may no longer be required and the assessment process may stop.

4.5 Notification of results of assessment

Upon completion of the assessment, the importing contracting party should reach a decision on the request and should notify the exporting contracting party of the results of its assessment; if the proposed PFA or ALPP will not be recognized, the importing contracting party should provide an explanation, including technical justification where applicable, for this decision.

In the event of a disagreement related to the rejection of a request for recognition of a PFA or ALPP, efforts should in the first instance be made bilaterally to resolve these disagreements.

4.6 Official recognition

In accordance with Article VII.2b of the IPPC: “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.” If the PFA or ALPP is recognized by the importing contracting party, this should be officially communicated to the exporting contracting party, clearly confirming the type of area recognized and identifying the relevant pest(s) for which such recognition applies. Where appropriate, amendment of the phytosanitary import requirements and any associated procedures of the importing contracting party should be made promptly.

4.7 Duration of recognition

Recognition of a PFA or ALPP should remain in effect unless:

- there is a change in pest status in the area concerned and it is no longer a PFA or ALPP.
- there are significant instances of non-compliance (as described in section 4.1 of ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*) related to the areas in question or related to the bilateral arrangement noted by the importing contracting party.

5. Considerations on Pest Free Places of Production and Pest Free Production Sites

Usually pest free places of production and pest free production sites should not require recognition using the procedures described above (section 4). In this regard ISPM No. 10 (*Requirements for the establishment of pest free places of production and pest free production sites*) states that, for such places and sites, “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.” (section 3.2 of ISPM No. 10).

However, ISPM No. 10 (in section 3.3) also indicates: “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.”

As described in ISPM No. 10: “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.” In such cases recognition may be based on the procedure recommended in section 4 of this standard or another bilaterally agreed procedure.

ISPM No. 30



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 30

***ESTABLISHMENT OF AREAS OF LOW PEST
PREVALENCE FOR FRUIT FLIES (TEPHRITIDAE)***

(2008)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in April 2008.

INTRODUCTION

SCOPE

This standard provides guidelines for the establishment and maintenance of areas of low pest prevalence for fruit flies (FF-ALPPs) by a National Plant Protection Organization (NPPO). Such areas may be utilised as official pest risk management measures alone, or as part of a systems approach, to facilitate trade of fruit fly host products, or to minimize the spread of regulated fruit flies within an area. This standard applies to fruit flies (Tephritidae) of economic importance.

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.
- Establishment of pest free areas for fruit flies (Tephritidae)*, 2006. ISPM No. 26, FAO, Rome.
- Glossary of phytosanitary terms*, 2008. ISPM No. 5, FAO, Rome.
- Guidelines for surveillance*, 1997. ISPM No. 6, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Pest reporting*, 2002. ISPM No. 17, FAO, Rome.
- Recognition of pest free areas and areas of low pest prevalence*, 2007. ISPM No. 29, FAO, Rome.
- Requirements for the establishment of areas of low pest prevalence*, 2005. ISPM No. 22, FAO, Rome.
- The use of integrated measures in a systems approach for pest risk management*, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

The general requirements for establishment and maintenance of an area of low pest prevalence for fruit flies (FF-ALPP) include:

- confirming the operational and economic feasibility of the FF-ALPP
- describing the purpose of the area
- listing the target fruit fly species(s) for the FF-ALPP
- operational plans
- determination of the FF-ALPP
- documentation and record keeping
- supervision activities.

For the establishment of the FF-ALPP, parameters used to estimate the level of fruit fly prevalence and the efficacy of trapping devices for surveillance should be determined as stated in Annex 1. Surveillance, control measures and corrective action planning are required for both establishment and maintenance. Corrective action planning is described in Annex 2.

Other specific requirements include phytosanitary procedures, as well as suspension, loss and reinstatement of the status of the FF-ALPP.

BACKGROUND

The International Plant Protection Convention (IPPC, 1997) contains provisions for areas of low pest prevalence (ALPPs), as does the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (Article VI of the WTO-SPS Agreement). ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) describes different types of ALPPs and provides general guidance on the establishment of ALPPs. ALPPs may also be used as part of a systems approach (ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*).

Fruit flies are a very important group of pests for many countries because of their potential to cause damage to fruits and restrict national and international trade for plant products that are hosts of fruit flies.

The high probability of introduction of fruit flies associated with a wide range of hosts results in restrictions imposed by many importing countries and the need for phytosanitary measures to be applied in exporting countries related to movement of host material or regulated articles to ensure that the risk of introduction is appropriately mitigated.

This standard provides guidance for the establishment and maintenance by the NPPO of FF-ALPPs with the aim to facilitate trade by minimizing the risk of introduction or spread of regulated fruit flies.

FF-ALPPs are generally used as buffer zones for fruit fly-pest free areas (FF-PFAs), fruit fly free places of production or fruit fly free production sites (either as a permanent buffer zone or as part of an eradication process), or for export purposes, usually in conjunction with other risk mitigation measures as a component of a systems approach (this may include all or part of an FF-ALPP that acts as a buffer zone).

They may occur naturally (and subsequently be verified, declared and monitored or otherwise managed); they may occur as a result of pest control practices during crop production that suppress the population of fruit flies in an area to limit their impact on the crop; or they may be established as a result of control practices that reduce the number of fruit flies in the area to a specified low level.

The decision to establish an FF-ALPP may be closely linked to market access as well as to economic and operational feasibility.

If an FF-ALPP is established for export of fruit fly host commodities, the parameters for establishment and maintenance of the FF-ALPP should be determined and agreed to in conjunction with the importing country and in consideration of the guidelines presented in this standard and in accordance with ISPM No. 29 (*Recognition of pest free areas and areas of low pest prevalence*).

The requirements for the establishment of FF-ALPPs in this standard can also be applied for movement of fruit between ALPPs within a country.

The target pests for which this standard was developed include insects of the order Diptera, family Tephritidae, of the genera *Anastrepha*, *Bactrocera*, *Ceratitis*, *Dacus*, *Rhagoletis* and *Toxotrypana*.

REQUIREMENTS

1. General Requirements

The concepts and provisions of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) apply to the establishment and maintenance of ALPPs for a specified pest, or a group of pests including fruit flies, and therefore ISPM No. 22 should be referred to in conjunction with this standard.

An FF-ALPP may be established in accordance with this standard under a variety of situations. Some may require the application of the full range of elements provided by this standard, whereas others may require the application of only some of those elements.

Phytosanitary measures and specific procedures as further described in this standard may be required for the establishment and maintenance of an FF-ALPP by the NPPO. The decision to establish an official FF-ALPP may be based on all or some of the technical factors provided in this standard, as appropriate. They include components such as pest biology and control methods, which will vary according to the species of fruit fly for which the FF-ALPP is being established.

The establishment of an official FF-ALPP should be considered against the overall operational and economic feasibility of establishing a programme to meet and maintain the low pest level and the objectives of the FF-ALPP.

An FF-ALPP may be applied to facilitate the movement of fruit fly hosts from one FF-ALPP to another of the same fruit fly pest status to protect areas endangered by a regulated fruit fly pest.

The essential prerequisite for establishment of an FF-ALPP is an area that exists naturally, or that can be established, and that can be delimited, monitored and verified by the NPPO to be of a specified fruit fly prevalence level. The area may be in place to protect an FF-PFA or support sustainable crop production, or may have developed in response to suppression or eradication actions. It may occur naturally as a result of climatic, biological or geographical factors that reduce or limit the fruit fly population through all or part of the year.

An area can be defined as an FF-ALPP for one or more target fruit fly species. However, for an FF-ALPP covering multiple target fruit fly species, trapping devices and their deployment densities and locations should be specified, and low pest prevalence levels determined for each target fruit fly species.

FF-ALPPs should include public awareness programmes of a similar nature as outlined in section 1.1 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

1.1 Operational plans

An official operational plan is needed to specify the phytosanitary procedures required to establish and maintain an FF-ALPP.

The operational plan should describe the main procedures to be carried out such as surveillance activities, procedures to maintain the specified level of low pest prevalence, the corrective action plan and any other procedures that are required to achieve the objective of the FF-ALPP.

1.2 Determination of an FF-ALPP

Elements to be considered in the determination of an FF-ALPP are as follows:

- delimitation of the area (size of location, detailed maps including an accurate description of the boundaries or Global Positioning System (GPS) coordinates showing the boundaries, natural barriers, entry points, location of commercial and, as appropriate, non-commercial hosts of the target fruit fly and urban areas)
- target fruit fly species and its/their seasonal and spatial distribution within the area
- location, abundance and seasonality of hosts, including wherever possible specifying primary (biologically preferred) hosts
- climatic characteristics, including rainfall, relative humidity, temperature, and prevailing wind speed and direction
- identification of factors limiting and keeping fruit fly population at low levels.

In areas where prevalence of fruit flies is naturally at a low level because of climatic, geographical or other reasons (e.g. natural enemies, availability of suitable hosts, host seasonality), the target fruit fly population may already be below the specified level of low pest prevalence without applying any control measures. In such cases, surveillance should be undertaken over an appropriate length of time to validate the low prevalence status and this status may be recognized in accordance with the examples listed in section 3.1.1 of ISPM No. 8 (*Determination of pest status in an area*). If, however, the fruit flies are detected above the specified level of low pest prevalence (e.g. because of extraordinary climatic conditions) corrective actions should be applied. Guidelines for corrective action plans are provided in Annex 2.

1.3 Documentation and record keeping

The phytosanitary procedures used for the determination, establishment, verification and maintenance of an FF-ALPP should be adequately documented. These procedures should be reviewed and updated regularly, including the corrective actions if required (as described in ISPM No. 22: *Requirements for the establishment of areas of low pest prevalence*). It is recommended that a manual of procedures relating to the operational plan be prepared for the FF-ALPP.

Documentation for determination and establishment may include:

- list of fruit fly hosts known to occur in the area, including seasonality and commercial fruit production in the area
- delimitation records: detailed maps showing the boundaries, natural barriers and points where fruits may enter the area; description of agro-ecological features such as soil type, the location of main host areas of target fruit fly, and marginal and urban host areas; and climatic conditions, for example rainfall, relative humidity, temperature, and prevailing wind speed and direction

- surveillance records:
 - trapping: types of surveys, number and type of traps and lures, frequency of trap inspection, trap density, trap array, trapping time and duration, number of target fruit flies captured by species for each trap, trap servicing
 - fruit sampling: type, quantity, date, frequency and result
- record of control measures used for fruit flies and other pests that may have an effect on fruit fly populations: type(s) and locations.

For verification and maintenance, documentation should include the data recorded to demonstrate the population levels of the target fruit fly species are below the specified level of low pest prevalence. The records of surveys and results of other operational procedures should be retained for at least 24 months. If the FF-ALPP is being used for export purposes, records should be made available to the NPPO of the relevant importing country on request and verification may take place if necessary.

Corrective action plans should also be developed and maintained (see section 2.4).

1.4 Supervision activities

The FF-ALPP programme, including applicable domestic regulations, surveillance procedures (e.g. trapping, fruit sampling) and corrective action plans, should comply with officially approved procedures. These procedures may include official delegation of responsibility assigned to key personnel, for example:

- a person with defined authority and responsibility to ensure that the systems/procedures are implemented and maintained appropriately
- entomologist(s) with responsibility for the identification of fruit flies to species level.

The NPPO should evaluate and audit the operation of the procedures for establishment and maintenance of the FF-ALPP to ensure that effective management is maintained even where the responsibility to carry out specific activities has been delegated to outside the NPPO. Supervision of operational procedures include:

- operation of surveillance procedures
- surveillance capability
- trapping materials (traps, attractants) and procedures
- identification capability
- application of control measures
- documentation and record keeping
- implementation of corrective actions.

2. Specific Requirements

2.1 Establishment of the FF-ALPP

Elements for consideration when establishing an FF-PFA are described in sections 2.1 and 2.2 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and may also be applied to an FF-ALPP as defined in following subsections.

2.1.1 Determination of the specified level of low pest prevalence

Specified levels of low pest prevalence will depend on the level of risk associated with the target fruit fly species–host–area interaction. These levels should be established by the NPPO of the country where the FF-ALPP is located and with sufficient precision to allow assessment of whether surveillance data and protocols are adequate to determine that pest prevalence is below these levels.

Individual NPPOs may draw on a variety of different factors when determining exactly what an appropriate level of pest prevalence should be for a given FF-ALPP. Some commonly considered factors include the following:

- levels stipulated by trading partners in order for trade to proceed
- levels in use by other NPPOs for the same or similar fruit fly species, hosts and agro-ecological conditions (including experience and historical data gained from the operation of other FF-ALPPs as to what levels are required to be maintained to achieve pest free fruits).

Establishment of the parameters used to estimate the level of fruit fly prevalence is described in Annex 1.

2.1.2 Geographical description

The NPPO defines the limits of a proposed FF-ALPP. Isolation of the area (physical or geographical) is not necessarily required for establishment of FF-ALPPs.

Boundaries used to describe the delimitation of the FF-ALPP should be established and closely related to the relative presence of hosts of the target fruit fly species or adjusted to readily recognizable boundaries.

2.1.3 Surveillance activities prior to establishment

Prior to the establishment of an FF-ALPP, surveillance to assess the presence and level of prevalence of the target fruit fly species should be undertaken for a period determined by its biology, behaviour, climatic characteristics of the area, host availability and appropriate technical considerations. This surveillance should continue for at least 12 consecutive months.

2.2 Phytosanitary procedures

2.2.1 Surveillance activities

Surveillance systems based on trapping are similar in any type of ALPP. The surveillance used in an FF-ALPP may include those processes described in ISPM No. 6 (*Guidelines for surveillance*), section 2.2.2.1 on trapping procedures of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and any other relevant scientific information.

Fruit sampling as a routine surveillance method is not widely used for monitoring fruit flies in low prevalence areas except in areas where sterile insect technique (SIT) is applied, where it may be a major tool.

The NPPO may complement trapping for adults with fruit sampling for larvae. Fruit sampling may be especially useful for surveillance for fruit flies when no traps are available. If larvae are detected in fruit sampling, it may be necessary to rear the larvae to adults in order to identify them. This is the case particularly if multiple species of fruit flies may be present. However, fruit sampling alone will not provide sufficient accuracy for describing the size of the population and should not be solely relied on to validate or verify the FF-ALPP status. Surveillance procedures may include those described in section 2.2.2.2 on fruit sampling procedures of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

The presence and distribution of fruit fly hosts should be recorded separately identifying commercial and non-commercial hosts. This information will help in planning the trapping and host sampling activities and may help in anticipating the potential ease or difficulty of establishing and maintaining the phytosanitary status of the area.

The NPPO should have, or have access to, appropriate identification capabilities for identification of the target fruit fly species detected during the surveys (whether adult or larvae). This capability should also exist for the ongoing verification of FF-ALPP status for the target fruit fly species.

2.2.2 Reduction and maintenance of target fruit fly species population level

Specific control measures may be applied to reduce fruit fly populations to or below the specified level of low pest prevalence. Suppression of fruit fly populations may involve the use of more than one control option; some of these are described in section 3.1.4.2 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) and Annex 1 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

Since the target fruit fly species are either endemic or established in the area, preventive control measures to maintain fruit fly populations at or below the specified level of low pest prevalence are nearly always necessary (some FF-ALPPs may occur naturally). Efforts should be made by NPPOs to select those measures with least environmental impact.

Available methods may include:

- chemical control (e.g. selective insecticide bait, aerial and ground spraying, bait stations and male annihilation technique)
- physical control (e.g. fruit bagging)
- use of beneficial organisms (e.g. natural enemies, SIT)
- cultural control (e.g. stripping and destruction of mature and fallen fruit, elimination or replacement of other host plants by non-host plants where appropriate, early harvesting, discouraging intercropping with fruit fly host plants, pruning before the fruiting period, use of perimeter trap hosts).

2.2.3 Phytosanitary measures related to movement of host material or regulated articles

Phytosanitary measures may be required to reduce the risk of entry of the specified pests into the FF-ALPP. These are outlined in section 3.1.4.3 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) and 2.2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

2.2.4 Domestic declaration of an FF-ALPP

The NPPO should verify the status of the FF-ALPP (in accordance with ISPM No. 8: *Determination of pest status in an area*) specifically by confirming compliance with the procedures established in accordance with this standard (surveillance and controls). The NPPO should declare and notify the establishment of the FF-ALPP, as appropriate.

To verify the status of the FF-ALPP and for purposes of internal management, the continuing FF-ALPP status should be verified after it has been established and any phytosanitary measures for the maintenance of the FF-ALPP have been put in place.

2.3 Maintenance of the FF-ALPP

Once the FF-ALPP is established, the NPPO should maintain the relevant documentation and verification procedures (auditable), and continue the application of phytosanitary procedures as described in section 2.2 of this standard.

2.3.1 Surveillance

In order to maintain the FF-ALPP status, the NPPO should continue surveillance, as described in section 2.2.1 of this standard.

2.3.2 Measures to maintain low prevalence levels of target fruit fly species

In most cases the control measures as identified in section 2.2.2 may be applied to maintain the FF-ALPP, since the target fruit flies are still present in the established area.

If the monitored fruit fly prevalence level is observed to be increasing (but remains below the specified level for the area), a threshold set by the NPPO for the application of additional control measures may be reached. At this point the NPPO may require implementation of such measures (e.g. as described in section 3.1.4.2 of ISPM No. 22: *Requirements for the establishment of areas of low pest prevalence*). This threshold should be set to provide adequate warning of potentially exceeding the specified level of low pest prevalence and avert suspension.

2.4 Corrective action plans

A corrective action plan for the FF-ALPP should be applied by the NPPO when the population level of the target fruit fly exceeds the specified level of low pest prevalence. Annex 2 provides guidelines on corrective action plans for FF-ALPPs.

2.5 Suspension, reinstatement and loss of FF-ALPP status

2.5.1 Suspension of FF-ALPP status

If the specified level of low pest prevalence of the target fruit fly species is exceeded either throughout the whole FF-ALPP area or within a part of the FF-ALPP, the entire FF-ALPP is normally suspended. However, where the affected area within the FF-ALPP can be identified and clearly delimited, then the FF-ALPP may be redefined to suspend only that area.

Relevant importing NPPOs should be notified without undue delay of these actions (further information on pest reporting requirements is provided in ISPM No. 17: *Pest reporting*).

Suspension may also apply if faults in the application of the procedures are found (for example, inadequate trapping, pest control measures or documentation).

If an FF-ALPP is suspended, an investigation by the NPPO should be initiated to determine the cause of the failure and introduce measures to prevent such failures from reoccurring.

When an FF-ALPP is suspended, the criteria for reinstatement should be made clear.

2.5.2 Reinstatement of FF-ALPP status

Reinstatement of FF-ALPP status applies only to suspended areas and may take place when:

- the population level no longer exceeds the specified level of low pest prevalence and this is maintained for a period determined by the biology of the target fruit fly species and the prevailing environmental conditions; and/or
- faulty procedures have been corrected and verified.

Once the specified level of low prevalence has been achieved and maintained as required above or procedural faults have been rectified through the application of corrective actions contained in the plan, the FF-ALPP status can be reinstated. If the FF-ALPP is established for export of host fruits, records regarding the reinstatement should be made

available to the NPPO of the relevant importing country(ies) on request and verification may take place if necessary.

2.5.3 Loss of FF-ALPP status

Loss of FF-ALPP status should occur after suspension if reinstatement has failed to take place within a justifiable time frame, taking into account the biology of the fruit fly target species. Relevant importing NPPOs should be notified without undue delay of the change in status of the FF-ALPP (further information on pest reporting requirements is provided in ISPM No. 17: *Pest reporting*).

In the event that FF-ALPP status is lost, the procedures for establishment and maintenance outlined in this standard should be followed to achieve the FF-ALPP status again, and should take into account all background information related to the area.

ANNEX 1

PARAMETERS USED TO ESTIMATE THE LEVEL OF FRUIT FLY PREVALENCE¹

Parameters used to determine the level of fruit fly prevalence in the FF-ALPP are defined by the NPPO. The most widely used parameter is flies per trap per day (FTD). More precise spatial data may be presented on the basis of trap density (i.e. FTD per unit area) or temporally for each trap present in an area over time.

The FTD is an index used to estimate the population by averaging the number of flies captured by one trap in one day. This parameter estimates the relative number of fruit fly adults in a given time and space. It provides baseline information to compare fruit fly populations among different places and/or time.

The FTD is the result of dividing the total number of captured flies by the product obtained from multiplying the total number of inspected traps by the average number of days the traps were exposed. The formula is as follows:

$$\text{FTD} = \frac{F}{T \times D}$$

Where

F = total number of flies captured

T = number of inspected traps

D = number of days traps were exposed in the field.

In cases where traps are regularly inspected on a weekly basis, or longer in the case of winter surveillance operations, the parameter may be “flies per trap per week” (FTW). It estimates the number of flies captured by one trap in one week. Thus, FTD can be obtained from FTW by dividing by 7. Any significant changes in the status of any parameters critical to the efficacy of the FF-ALPP should be reviewed and modified, as appropriate.

Specified levels of low pest prevalence, as expressed in FTD values, should be established in relation to the risk of infestation of the fruits that are intended to be protected by the FF-ALPP, and in relation to any specific related objectives of the FF-ALPP (e.g. fruit-fly free commodities for export). In situations where a single FF-ALPP contains more than one host species (i.e. the ALPP is intended to protect more than one target fruit fly host), the specified level of low pest prevalence should be based on scientific information relating to each host of the fruit fly species, the risks of infestation and comparative preferences of the target fruit fly species for the different hosts. However, in situations where the FF-ALPP is established to protect only one type of host, consideration should be given to the level of infestation expected on that host. In such situations, lower specified levels of low pest prevalence are usually established for the primary host(s) of the target fruit fly species and comparatively higher levels for secondary hosts.

The biology of the target fruit flies (including number of generations per year, host range, host species present in the area, temperature thresholds, behaviour, reproduction and dispersion capacity) plays a major role in establishing appropriate specified levels of low pest prevalence. For an FF-ALPP with several hosts present, the established specified levels of low pest prevalence should reflect host diversity and abundance, host preference and host sequence for each target fruit fly species present. Although an FF-ALPP may have different specified levels of low pest prevalence for each relevant fruit fly target species, those levels should remain fixed for the whole area and duration of the FF-ALPP operation.

Efficiency of the types of traps and attractants used to estimate the levels of the pest population and the procedures applied for servicing the traps should be taken into consideration. The rationale is that different trap efficiencies could lead to different FTD results at the same location for a given population, so they have a significant effect in measuring the prevalence level of the target fruit fly species. Thus, when specifying the level of low pest prevalence accepted in terms of an FTD value, the efficacy of the trapping system should be stated as well.

Once a specified level of low pest prevalence has been established for a given situation using a specific lure/attractant, the lure/attractant used in the FF-ALPP must not be changed or modified until an appropriate specified level of low pest prevalence is determined for the new formulation. For FF-ALPPs with multiple target fruit fly species present that are attracted to different lures/attractants, trap placement should take into consideration possible interactive effects between lures/attractants.

Fruit sampling can be used as a complementary surveillance method to trapping to assess the profile of the fruit fly population levels, particularly if traps are not available for target species. Fruit sampling should be done on known hosts. It should be taken into account that efficacy of fruit sampling depends on sample size, frequency and timing. Fruit sampling may include rearing larvae to identify the fruit fly species. If fruit cutting is done, the efficacy of visually detecting larvae should be considered. However, fruit sampling will not provide sufficient accuracy for describing the size of the population and should not be solely relied on to validate or verify the FF-ALPP status.

¹ This annex is an official part of the standard.

ANNEX 2

GUIDELINES ON CORRECTIVE ACTION PLANS FOR FRUIT FLIES IN AN FF-ALPP²

Faults in the procedures or their application (e.g. inadequate trapping or pest control measures, inadequate documentation) or the detection of a population level exceeding the specified level of low pest prevalence for the target fruit fly species in the FF-ALPP should trigger the application of a corrective action plan. The objective of the corrective action plan is to ensure procedures and their applications are adequate and suppression of the fruit fly population to below the specified level for low pest prevalence is achieved as soon as possible. It is the responsibility of the NPPO to ensure that appropriate corrective action plans are developed. Corrective action plans should not be repeatedly implemented because this may lead to a loss of FF-ALPP status and the need to re-establish the area in accordance with the guidelines of this standard.

The corrective action plan should be prepared taking into account the biology of the target fruit fly species, the geography of the FF-ALPP, climatic conditions, phenology, and host abundance and distribution within the area.

The elements required for implementation of a corrective action plan include:

- declaration of suspension of FF-ALPP of status, where appropriate
- legal framework under which the corrective action plan can be applied
- time scales for the initial response and follow-up activities
- delimiting survey (trapping and fruit sampling) and application of the suppression actions
- identification capability
- availability of sufficient operational resources
- effective communication within the NPPO and with the NPPO(s) of the relevant importing country(ies), including provision of contact details of all parties involved
- a detailed map and definition of the suspension area
- revision and rectification of operational procedures, or
- range of control measures available e.g. pesticides.

Application of the corrective action plan**1. Notice to implement corrective actions**

The NPPO notifies interested stakeholders and parties, including relevant importing countries, when initiating the application of a corrective action plan. The NPPO is responsible for supervising the implementation of corrective measures.

Notification should include the reason for initiating the plan i.e. faulty procedures or exceeding the specified level of low pest prevalence.

2. Determination of the phytosanitary status

Immediately after detecting a population level higher than the specified level of low pest prevalence, a delimiting survey (which may include the deployment of additional traps, fruit sampling of host fruits and increased trap inspection frequency) should be implemented to determine the size of the affected area and more precisely gauge the level of the fruit fly prevalence.

3. Suspension of FF-ALPP status

If the specified level of low pest prevalence of the target fruit fly species is exceeded or faulty procedures are found, the FF-ALPP status should be suspended as stated in section 2.5.1 of this standard.

4. Rectification of procedural faults

Faulty procedures and associated documentation should be immediately reviewed to identify the source of the fault(s). The source and corrective action taken should be documented and the modified procedures monitored to ensure compliance with the objectives of the FF-ALPP.

5. Implementation of control measures in the affected area

Specific suppression actions should immediately be implemented in the affected area(s). Available methods include:

- selective insecticide-bait treatments (aerial and/or ground spraying and bait stations)
- sterile insect technique
- male annihilation technique
- collection and destruction of affected fruit

² This annex is an official part of the standard.

- stripping and destruction of host fruits, if possible
- insecticide treatments (ground, cover).

6. Notification of relevant agencies

Relevant NPPOs and other agencies should be kept informed of corrective actions. Information on pest reporting requirements under the IPPC is provided in ISPM No. 17 (*Pest reporting*).

APPENDIX 1

GUIDELINES ON TRAPPING PROCEDURES³

Information about trapping is available in the following publication of the International Atomic Energy Agency (IAEA): *Trapping Guidelines for area-wide fruit fly programmes*, IAEA/FAO-TG/FFP, 2003. IAEA, Vienna.

This publication is widely available, easily accessible and generally recognized as authoritative.

³ This appendix is not an official part of the standard. It is provided for information only.

APPENDIX 2

TYPICAL APPLICATIONS OF AN FF-ALPP⁴**1. An FF-ALPP as a buffer zone**

In cases where the biology of the target fruit fly species is such that it is likely to disperse from an infested area into a protected area, it may be necessary to define a buffer zone with a low fruit fly prevalence (as described in ISPM No. 26: *Establishment of pest free areas for fruit flies (Tephritidae)*). Establishment of the FF-ALPP and FF-PFA should occur at the same time, enabling the FF-ALPP to be defined for the purpose of protecting the FF-PFA.

1.1 Determination of an FF-ALPP as a buffer zone

Determination procedures draw upon those listed in section 1.2 of this standard. In addition, in delimiting the buffer zone, detailed maps may be included showing the boundaries of the area to be protected, distribution of hosts, host location, urban areas, entry points and control checkpoints. It is also relevant to include data related to natural biogeographical features such as prevalence of other hosts, climate, and location of valleys, plains, deserts, rivers, lakes and sea, as well as other areas that function as natural barriers. The size of the buffer zone in relation to the size of the area being protected will depend on the biology of the target fruit fly species (including behaviour, reproduction and dispersal capacity), the intrinsic characteristics of the protected area, and the economic and operational feasibility of establishing the FF-ALPP.

1.2 Establishment of an FF-ALPP as a buffer zone

The establishment procedures are described in section 2.1 of this standard. The movement of relevant fruit fly host commodities into the area may need to be regulated. Additional information can be found in section 2.2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

1.3 Maintenance of an FF-ALPP as a buffer zone

Maintenance procedures include those listed in section 2.3 of this standard. Since the buffer zone has features similar to the area or place of production it protects, procedures for maintenance may include those listed for the FF-PFA as described in section 2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and sections 3.1.4.2, 3.1.4.3 and 3.1.4.4 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*). The importance of information dissemination may also be considered in the maintenance of an FF-ALPP as a buffer zone.

2. FF-ALPPs for export purposes

FF-ALPPs may be used to facilitate fruit exports from the area. In most cases the FF-ALPP is the main component of a systems approach as a pest risk mitigation measure. Examples of measures and/or factors used in conjunction with FF-ALPPs include:

- pre- and post-harvest treatments
- production of secondary hosts or non-hosts in preference to primary hosts
- export of host material to areas not at risk during particular seasons
- physical barriers (e.g. pre-harvest bagging, insect-proof structures).

2.1 Determination of an FF-ALPP for export purposes

Determining procedures may include those listed in section 1.2 of this standard. In addition, the following elements should be considered for the determination of an FF-ALPP:

- a list of products (hosts) of interest
- a list of other commercial and non-commercial hosts of the target fruit fly species present but not intended for export and their level of occurrence, as appropriate
- additional information such as any historical records in connection with biology, occurrence and control of the target fruit fly species or any other fruit fly species that may be present in the FF-ALPP.

2.2 Maintenance of an FF-ALPP for export purposes

Maintenance procedures may include those described in section 2.3.2 of this standard and should be applied if hosts are available. If appropriate, surveillance may continue at a lower frequency during the off-season period. This will depend on the biology of the target fruit fly species and its relationship with hosts present during the off-season period

⁴ This appendix is not an official part of the standard. It is provided for information only.

ISPM No. 31



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 31

***METHODOLOGIES FOR SAMPLING OF
CONSIGNMENTS***

(2008)

Produced by the Secretariat of the International Plant Protection Convention



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ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in April 2008.

INTRODUCTION

SCOPE

This standard provides guidance to National Plant Protection Organizations (NPPOs) in selecting appropriate sampling methodologies for inspection or testing of consignments to verify compliance with phytosanitary requirements.

This standard does not give guidance on field sampling (for example, as required for surveys).

REFERENCES

Cochran, W.G. 1977. *Sampling techniques*. 3rd edn. New York, John Wiley & Sons. 428 pp.

Glossary of phytosanitary terms, 2008. ISPM No. 5, FAO, Rome.

Guidelines for inspection, 2005. ISPM No. 23, FAO, Rome.

Guidelines for phytosanitary import regulatory systems, 2004, ISPM No. 20, FAO Rome.

Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, ISPM No. 11, 2004, FAO, Rome.

Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.

Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006. 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

The sampling methodologies used by NPPOs in selecting samples for the inspection of consignments of commodities moving in international trade are based on a number of sampling concepts. These include parameters such as acceptance level, level of detection, confidence level, efficacy of detection and sample size.

The application of statistically based methods, such as simple random sampling, systematic sampling, stratified sampling, sequential sampling or cluster sampling, provides results with a statistical confidence level. Other sampling methods that are not statistically based, such as convenience sampling, haphazard sampling or selective sampling, may provide valid results in determining the presence or absence of a regulated pest(s) but no statistical inference can be made on their basis. Operational limitations will have an effect on the practicality of sampling under one or another method.

In using sampling methodologies, NPPOs accept some degree of risk that non-conforming lots may not be detected. Inspection using statistically based methods can provide results with a certain level of confidence only and cannot prove the absence of a pest from a consignment.

BACKGROUND

This standard provides the statistical basis for, and complements, ISPMs No. 20 (*Guidelines for phytosanitary import regulatory systems*) and No. 23 (*Guidelines for inspection*). Inspection of consignments of regulated articles moving in trade is an essential tool for the management of pest risks and is the most frequently used phytosanitary procedure worldwide to determine if pests are present and/or the compliance with phytosanitary import requirements.

It is usually not feasible to inspect entire consignments, so phytosanitary inspection is performed mainly on samples obtained from a consignment. It is noted that the sampling concepts presented in this standard may also apply to other phytosanitary procedures, notably selection of units for testing.

Sampling of plants, plant products and other regulated articles may occur prior to export, at the point of import, or other points as determined by NPPOs.

It is important that sampling procedures established and used by NPPOs are documented and transparent, and take into account the principle of minimum impact (ISPM No. 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*), particularly because inspection based on sampling may lead to the refusal to issue a phytosanitary certificate, refusal of entry, or treatment or destruction of a consignment or part of a consignment.

Sampling methodologies used by NPPOs will depend on the sampling objectives (for example, sampling for testing) and may be solely statistically based or developed noting particular operational constraints. Methodologies developed to achieve the sampling objectives, within operational constraints, may not yield the same statistical confidence levels in the results as fully statistically based methods, but such methods may still give valid results depending on the desired sampling objective. If the sole purpose of sampling is to increase the chance of finding a pest, selective or targeted sampling is also valid.

OBJECTIVES OF SAMPLING OF CONSIGNMENTS

Sampling of consignments is done for inspection and/or testing in order to:

- detect regulated pests
- provide assurance that the number of regulated pests or infested units in a consignment does not exceed the specified tolerance level for the pest
- provide assurance of the general phytosanitary condition of a consignment
- detect organisms for which a phytosanitary risk has not yet been determined
- optimize the probability of detecting specific regulated pests
- maximize the use of available sampling resources
- gather other information such as for monitoring of a pathway
- verify compliance with phytosanitary requirements
- determine the proportion of the consignment infested.

It should be noted that inspection and/or testing based on sampling always involves a degree of error. The acceptance of some probability that the pests are present is inherent in the use of sampling procedures for inspection and/or testing. Inspection and/or testing using statistically based sampling methods can provide a level of confidence that the incidence of a pest is below a certain level, but it does not prove that a pest is truly absent from a consignment.

REQUIREMENTS

1. Lot Identification

A consignment may consist of one or more lots. Where a consignment comprises more than one lot, the inspection to determine compliance may have to consist of several separate visual examinations, and therefore the lots will have to be sampled separately. In such cases, the samples relating to each lot should be segregated and identified in order that the appropriate lot can be clearly identified if subsequent inspection or testing reveals non-compliance with phytosanitary requirements. Whether or not a lot will be inspected should be determined using factors stated in ISPM No. 23 (*Guidelines for inspection*, section 1.5).

A lot to be sampled should be a number of units of a single commodity identifiable by its homogeneity in factors such as:

- origin
- grower
- packing facility
- species, variety, or degree of maturity
- exporter

- area of production
- regulated pests and their characteristics
- treatment at origin
- type of processing.

The criteria used by the NPPO to distinguish lots should be consistently applied for similar consignments.

Treating multiple commodities as a single lot for convenience may mean that statistical inferences can not be drawn from the results of the sampling.

2. Sample Unit

Sampling first involves the identification of the appropriate unit for sampling (for example, a fruit, stem, bunch, unit of weight, bag or carton). The determination of the sample unit is affected by issues related to homogeneity in the distribution of pests through the commodity, whether the pests are sedentary or mobile, how the consignment is packaged, intended use, and operational considerations. For example, if determined solely on pest biology, the appropriate sample unit might be an individual plant or plant product in the case of a low-mobility pest, whereas in the case of mobile pests, a carton or other commodity container may be the preferred sample unit. However, when inspection is to detect more than one type of pest, other considerations (for example, practicality of using different sample units) may apply. Sample units should be consistently defined and independent from each other. This will allow NPPOs to simplify the process of making inferences from the sample to the lot or consignment from which the sample was selected.

3. Statistical and Non-Statistical Sampling

The sampling method is the process approved by the NPPO to select units for inspection and/or testing. Sampling for phytosanitary inspection of consignments or lots is done by taking units from the consignment or lot without replacement of the units selected¹. NPPOs may choose either a statistically based or non-statistical sampling methodology.

Sampling based on statistical or targeted methods is designed to facilitate the detection of a regulated pest(s) in a consignment and/or lot.

3.1 Statistically based sampling

Statistically based sampling methods involve the determination of a number of interrelated parameters and the selection of the most appropriate statistically based sampling method.

3.1.1 Parameters and related concepts

Statistically based sampling is designed to detect a certain percentage or proportion of infestation with a specific confidence level, and thus requires the NPPO to determine the following interrelated parameters: acceptance number, level of detection, confidence level, efficacy of detection and sample size. The NPPO may also establish a tolerance level for certain pests (for example, regulated non-quarantine pests).

3.1.1.1 Acceptance number

The acceptance number is the number of infested units or the number of individual pests that are permissible in a sample of a given size before phytosanitary action is taken. Many NPPOs determine this number to be zero for quarantine pests. For example, if the acceptance number is zero and an infested unit is detected in the sample then phytosanitary action will be taken. It is important to appreciate that a zero acceptance number within a sample does not imply a zero tolerance level in the consignment as a whole. Even if no pests are detected in the sample there remains a probability that the pest may be present in the remainder of the consignment, albeit at a very low level.

The acceptance number is linked to the sample. The acceptance number is the number of infested units or the number of individual pests that are permissible in the sample whereas the tolerance level (see section 3.1.1.6) refers to the status of the entire consignment.

3.1.1.2 Level of detection

The level of detection is the minimum percentage or proportion of infestation that the sampling methodology will detect at the specified efficacy of detection and level of confidence and which the NPPO intends to detect in a consignment.

¹ Sampling without replacement is selecting a unit from the consignment or lot without replacing the unit before the next units are selected. Sampling without replacement does not mean that a selected item cannot be returned to a consignment (except for destructive sampling); it means only that the inspector should not return it before selecting the remainder of the sample.

The level of detection may be specified for a pest, a group or category of pests, or for unspecified pests. The level of detection may be derived from:

- a decision based on pest risk analysis to detect a specified level of infestation (the infestation determined to present an unacceptable risk)
- an evaluation of the effectiveness of phytosanitary measures applied before inspection
- an operationally based decision that inspection intensity above a certain level is not practical.

3.1.1.3 Confidence level

The confidence level indicates the probability that a consignment with a degree of infestation exceeding the level of detection will be detected. A confidence level of 95% is commonly used. The NPPO may choose to require different confidence levels depending on the intended use of the commodity. For example, a higher confidence level for detection may be required for commodities for planting than for commodities for consumption, and the confidence level may also vary with the strength of the phytosanitary measures applied and historical evidence of non-compliance. Very high confidence level values quickly become difficult to achieve, and lower values become less meaningful for decision-making. A 95% confidence level means that the conclusions drawn from the results of sampling will detect a non-compliant consignment, on average, 95 times out of 100, and therefore, it may be assumed that, on average, 5% of non-compliant consignments will not be detected.

3.1.1.4 Efficacy of detection

The efficacy of detection is the probability that an inspection or test of an infested unit(s) will detect a pest. In general the efficacy should not be assumed to be 100%. For example, pests may be difficult to detect visually, plants may not express symptoms of disease (latent infection), or efficacy may be reduced as a result of human error. It is possible to include lower efficacy values (for instance, an 80% chance of detecting the pest when an infested unit is inspected) in the determination of sample size.

3.1.1.5 Sample size

The sample size is the number of units selected from the lot or consignment that will be inspected or tested. Guidance on determining the sample size is provided in Section 5.

3.1.1.6 Tolerance level

Tolerance level refers to the percentage of infestation in the entire consignment or lot that is the threshold for phytosanitary action.

Tolerance levels may be established for regulated non-quarantine pests (as described in ISPM No. 21: *Pest risk analysis for regulated non-quarantine pests*, section 4.4) and may also be established for conditions related to other phytosanitary import requirements (for example, bark on wood or soil on plant roots).

Most NPPOs have a zero tolerance level for all quarantine pests, taking into account probabilities of pest presence in the non-sampled units as described in section 3.1.1.1. However, an NPPO may determine to establish a tolerance level for a quarantine pest based on pest risk analysis (as described in ISPM No. 11: *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, section 3.4.1) and then determine sampling rates from this. For example, NPPOs may determine a tolerance level that is greater than zero because small numbers of the quarantine pest may be acceptable if the establishment potential of the pest is considered low or if the intended end use of the product (for example, fresh fruit and vegetables imported for processing) limits the potential of entry of the pest into endangered areas.

3.1.2 Links between the parameters and tolerance level

The five parameters (acceptance number, level of detection, confidence level, efficacy of detection and sample size) are statistically related. Taking into account the established tolerance level, the NPPO should determine the efficacy of the detection method used and decide upon the acceptance number in the sample; any two of the remaining three parameters can also be chosen, and the remainder will be determined from the values chosen for the rest.

If a tolerance level greater than zero has been established, the level of detection chosen should be equal to (or less than, if the acceptance number is greater than zero) the tolerance level to ensure that consignments having an infestation level greater than the tolerance level will be detected with the specified confidence level.

If no pests are detected in the sample unit, then the percentage of infestation in the consignment can not be stated beyond the fact that it falls below the level of detection at the stated confidence level. If the pest is not detected with the appropriate sample size, the confidence level gives a probability that the tolerance level is not exceeded.

3.1.3 Statistically based sampling methods

3.1.3.1 Simple random sampling

Simple random sampling results in all sample units having an equal probability of being selected from the lot or consignment. Simple random sampling involves drawing the sample units in accordance with a tool such as a random numbers table. The use of a predetermined randomization process is what distinguishes this method from haphazard sampling (described in section 3.2.2).

This method is used when little is known about the pest distribution or rate of infestation. Simple random sampling can be difficult to apply correctly in operational situations. To use this method, each unit should have an equal probability of selection. In cases where a pest is not distributed randomly through the lot, this method may not be optimal. Simple random sampling may require greater resources than other sampling methods. The application can be dependent on the type and/or configuration of the consignment.

3.1.3.2 Systematic sampling

Systematic sampling involves drawing a sample from units in the lot at fixed, predetermined intervals. However, the first selection must be made at random through the lot. Biased results are possible if pests are distributed in a manner similar to the interval chosen for sampling.

Two advantages of this method are that the sampling process may be automated through machinery and that it requires the use of a random process only to select the first unit.

3.1.3.3 Stratified sampling

Stratified sampling involves separating the lot into separate subdivisions (that is, strata) and then drawing the sample units from each and every subdivision. Within each subdivision, sample units are taken using a particular method (systematic or random). Under some circumstances, different numbers of sample units may be taken from each subdivision – for instance, the number of sample units may be proportional to the size of the subdivision, or based on prior knowledge concerning the infestation of the subdivisions.

If at all feasible, stratified sampling will almost always improve detection accuracy. The smaller variation associated with stratified sampling yields more accurate results. This is especially true when infestation levels may vary across a lot depending on packing procedures or storage conditions. Stratified sampling is the preferred choice when knowledge about the pest distribution is presumed and operational considerations will allow it.

3.1.3.4 Sequential sampling

Sequential sampling involves drawing a series of sample units using one of the above methods. After each sample (or group) is drawn, the data are accumulated and compared with predetermined ranges to decide whether to accept the consignment, reject the consignment or continue sampling.

This method can be used when a tolerance level greater than zero is determined and the first set of sample units does not provide sufficient information to allow a decision to be made on whether or not the tolerance level is exceeded. This method would not be used if the acceptance number in a sample of any size is zero. Sequential sampling may reduce the number of samples required for a decision to be made or reduce the possibility of rejecting a conforming consignment.

3.1.3.5 Cluster sampling

Cluster sampling involves selecting groups of units based on a predefined cluster size (for example, boxes of fruit, bunches of flowers) to make up the total number of sample units required from the lot. Cluster sampling is simpler to evaluate and more reliable if the clusters are of equal size. It is useful if resources available for sampling are limited and works well when the distribution of pests is expected to be random.

Cluster sampling can be stratified, and can use either systematic or random methods for selecting the groups. Of the statistically based methods, this method is often the most practical to implement.

3.1.3.6 Fixed proportion sampling

Sampling a fixed proportion of the units in the lot (for example, 2%) results in inconsistent levels of detection or confidence levels when lot size varies. As shown in Appendix 5, fixed proportion sampling results in changing confidence levels for a given level of detection, or in changing levels of detection for a given confidence level.

3.2 Non-statistically based sampling

Other sampling methods that are not statistically based, such as convenience sampling, haphazard sampling or selective or targeted sampling, may provide valid results in determining the presence or absence of a regulated pest(s). The following methods may be used based on specific operational considerations or when the goal is purely detection of pests.

3.2.1 Convenience sampling

Convenience sampling involves selecting the most convenient (for example, accessible, cheapest, fastest) units from the lot, without selecting units in a random or systematic manner.

3.2.2 Haphazard sampling

Haphazard sampling involves selecting arbitrary units without using a true randomization process. This may often appear to be random because the inspector is not conscious of having any selection bias. However, unconscious bias may occur, so that the degree to which the sample is representative of the lot is unknown.

3.2.3 Selective or targeted sampling

Selective sampling involves deliberately selecting samples from parts of the lot most likely to be infested, or units that are obviously infested, in order to increase the chance of detecting a specific regulated pest. This method may rely on inspectors who are experienced with the commodity and familiar with the pest's biology. Use of this method may also be triggered through a pathway analysis identifying a specific section of the lot with a higher probability of being infested (for example, a wet section of timber may be more likely to harbour nematodes). Because the sample is targeted, and hence statistically biased, a probabilistic statement about the infestation level in the lot can not be made. However, if the sole purpose of sampling is to increase the chance of finding a regulated pest(s), this method is valid. Separate samples of the commodity may be required to meet general confidence in detection of other regulated pests. The use of selective or targeted sampling may limit the opportunities to derive information about the overall pest status of the lot or consignment, because sampling is focused on where specific regulated pests are likely to be found not on the remainder of the lot or consignment.

4. Selecting a Sampling Method

In most cases the selection of an appropriate sampling method is necessarily dependent on information available about pest incidence and distribution in the consignment or lot as well as the operational parameters associated with the inspection situation in question. In most phytosanitary applications operational limitations will dictate the practicality of sampling under one or another method. Subsequently determining the statistical validity of practical methods will narrow the field of alternatives.

The sampling method that is ultimately selected by the NPPO should be operationally feasible and be the most appropriate to achieve the objective and be well documented for transparency. Operational feasibility is clearly linked to judgements concerning situation-specific factors, but should be consistently applied.

If sampling is undertaken to increase the chance of detecting a specific pest targeted sampling (described in section 3.2.3) may be the preferred option as long as the inspectors can identify the section(s) of the lot with a higher probability of being infested. Without this knowledge, one of the statistically based methods will be more appropriate. Non-statistically based sampling methods do not result in each unit having an equal probability of being included in the sample and do not allow for quantification of a confidence level or level of detection.

Statistically based methods will be appropriate if sampling is undertaken to provide information about the general phytosanitary condition of a consignment, to detect multiple quarantine pests or to verify compliance with phytosanitary requirements.

In selecting a statistically based method, consideration may be given to how the consignment has been treated in harvesting, sorting and packing, and the likely distribution of the pest(s) in the lot. Sampling methods may be combined: for instance, a stratified sample may have either random or systematic selection of sample units (or clusters) within strata.

If sampling is undertaken to determine whether a specific non-zero tolerance level has been exceeded, a sequential sampling method may be appropriate.

Once a sampling method has been selected and correctly applied, repeating the sampling with the aim of achieving a different result is unacceptable. Sampling should not be repeated unless considered necessary for specific technical reasons (for example, suspected incorrect application of sampling methodology).

5. Sample Size Determination

To determine the number of samples to be taken, the NPPO should select a confidence level (for example, 95%), a level of detection (for example, 5%) and an acceptance number (for example, zero), and determine the efficacy of detection (for example, 80%). From these values and the lot size, a sample size can be calculated. Appendices 2-5 set out the mathematical basis for sample size determination. Section 3.1.3 of this standard provides guidance on the most appropriate statistical based sampling method when considering the distribution of the pest in the lot.

5.1 Pests distribution unknown in the lot

Because sampling is done without replacement and the population size is finite, the hypergeometric distribution should be used to determine the sample size. This distribution gives a probability of detecting a certain number of infested units in a sample of a given size drawn from a lot of a given size, when a specific number of infested units exist in the lot (see Appendix 2). The number of infested units in the lot is estimated as the level of detection multiplied by the total number of units in the lot.

As lot size increases, the sample size required for a specific level of detection and confidence level approaches an upper limit. When the sample size is less than 5% of the lot size, the sample size can be calculated using either the binomial or Poisson distribution (see Appendix 3). All three distributions (hypergeometric, binomial and Poisson) give almost identical sample sizes for specific confidence and detection levels with large lot sizes, but binomial and Poisson distributions are easier to calculate.

5.2 Pest distribution aggregated in the lot

Most pest populations are aggregated to some degree in the field. Because commodities may be harvested and packed in the field without being graded or sorted, the distribution of infested units in the lot may be clustered or aggregated. Aggregation of infested units of a commodity will always lower the likelihood of finding an infestation. However, phytosanitary inspections are aimed at detection of infested units and/or pest(s) at a low level. The effect of aggregation of the infested units on the efficacy of detection of a sample and on the required sample size is small in most cases. When NPPOs identify that there is a high likelihood that there will be aggregation of infested units in the lot a stratified sampling method may help increase the chance of detecting an aggregated infestation.

When pests are aggregated, the calculation of sample size should ideally be performed using a beta-binomial distribution (see Appendix 4). However, this calculation requires knowledge of the degree of aggregation, which is generally not known and therefore this distribution may not be practical for general use. One of the other distributions (hypergeometric, binomial or Poisson) can be used; however, the confidence level of the sampling will decline as the degree of aggregation increases.

6. Varying Level of Detection

The choice of a constant level of detection may result in a varying number of infested units entering with imported consignments because lot size varies (for example, a 1% infestation level of 1000 units corresponds to 10 infested units, while a 1% infestation level of 10,000 units corresponds to 100 infested units). Ideally the selection of a level of detection will reflect in part the number of infested units entering on all consignments within a particular period of time. If NPPOs want to manage the number of infested units entering with each consignment as well, a varying level of detection may be used. A tolerance level would be specified in terms of a number of infested items per consignment, and the sample size would be set in order to give the desired confidence and detection levels.

7. Outcome of Sampling

The outcome of activities and techniques related to sampling may result in phytosanitary action being taken (further details can be found in ISPM No. 23: *Guidelines for inspection*, section 2.5).

APPENDIX 1

FORMULAE USED IN APPENDICES 2–5²

Formula No.	Purpose	Appendix No.
1	Probability of detecting i infested units in a sample.	2
2	Approximation for calculating the probability of finding no infested units.	2
3	Probability of detecting i infested units in a sample of n units (sample size is less than 5% of the lot size).	3
4	Binomial distribution probability of not observing an infested unit in a sample of n units.	3
5	Binomial distribution probability of observing at least one infested unit.	3
6	Binomial distribution formulae 5 and 6 rearranged to determine n .	3
7	Poisson distribution version of binomial formula 6	3
8	Poisson distribution probability of finding no infested units (simplified).	3
9	Poisson distribution probability of finding at least one infested unit (the confidence level).	3
10	Poisson distribution to determine the sample size for n .	3
11	Beta-binomial based sampling for aggregated spatial distribution	4
12	Beta-binomial – probability of not observing an infested unit after inspecting several lots (for a single lot)	4
13	Beta-binomial – probability of observing one or more infested units	4
14	Beta-binomial formulae 12 and 13 rearranged to determine m .	4

² This appendix is not an official part of the standard. It is provided for information only.

APPENDIX 2

CALCULATING SAMPLE SIZES FOR SMALL LOTS: HYPERGEOMETRIC-BASED SAMPLING (SIMPLE RANDOM SAMPLING)³

The hypergeometric distribution is appropriate to describe the probability of finding a pest in a relatively small lot. A lot is considered as small when the sample size is more than 5% of the lot size. In this case, sampling of one unit from the lot affects the probability of finding an infested unit in the next unit selected. Hypergeometric-based sampling is based on sampling without replacement.

It is also assumed that the distribution of the pest in the lot is not aggregated and that random sampling is used. This methodology can be extended for other schemes such as stratified sampling (further details can be found in Cochran, 1977).

The probability of detecting i infested units in a sample is given by

$$P(X = i) = \frac{\binom{A}{i} \binom{N - A}{n - i}}{\binom{N}{n}} \quad \text{Formula 1}$$

Where:

$$\binom{a}{b} = \frac{a!}{b!(a-b)!} \quad \text{where } a! = a(a-1)(a-2) \dots 1 \text{ and } 0! = 1$$

$P(X = i)$ is the probability of observing i infested units in the sample, where $i = 0, \dots, n$.

The confidence level corresponds to: $1 - P(X = i)$

A = number of infested units in the lot that could be detected if every unit in the lot was inspected or tested, given the efficacy of detection (level of detection $\times N \times$ efficacy, truncated to an integer)

i = number of infested units in the sample

N = number of units in the lot (size of the lot)

n = number of units in the sample (sample size)

In particular the approximation that can be used for the probability of finding no infested units is

$$P(X=0) = \left(\frac{N - A - u}{N - u} \right)^n \quad \text{Formula 2}$$

where $u = (n-1)/2$ (from Cochran, 1977).

Solving the equation to determine n is difficult arithmetically but can be done with approximation or through maximum likelihood estimation.

Tables 1 and 2 show sample sizes calculated for different lot sizes, levels of detection and confidence levels, when the acceptance number is 0.

³ This appendix is not an official part of the standard. It is provided for information only.

Table 1. Table of minimum sample sizes for 95% and 99% confidence levels at varying levels of detection according to lot size, hypergeometric distribution

Number of units in lot	P = 95% (confidence level)					P = 99% (confidence level)				
	% level of detection × efficacy of detection					% level of detection × efficacy of detection				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
25	24*	-	-	-	-	25*	-	-	-	-
50	39*	48	-	-	-	45*	50	-	-	-
100	45	78	95	-	-	59	90	99	-	-
200	51	105	155	190	-	73	136	180	198	-
300	54	117	189	285*	-	78	160	235	297*	-
400	55	124	211	311	-	81	174	273	360	-
500	56	129	225	388*	-	83	183	300	450*	-
600	56	132	235	379	-	84	190	321	470	-
700	57	134	243	442*	-	85	195	336	549*	-
800	57	136	249	421	-	85	199	349	546	-
900	57	137	254	474*	-	86	202	359	615*	-
1 000	57	138	258	450	950	86	204	368	601	990
2 000	58	143	277	517	1553	88	216	410	737	1800
3 000	58	145	284	542	1895	89	220	425	792	2353
4 000	58	146	288	556	2108	89	222	433	821	2735
5 000	59	147	290	564	2253	89	223	438	840	3009
6 000	59	147	291	569	2358	90	224	442	852	3214
7 000	59	147	292	573	2437	90	225	444	861	3373
8 000	59	147	293	576	2498	90	225	446	868	3500
9 000	59	148	294	579	2548	90	226	447	874	3604
10 000	59	148	294	581	2588	90	226	448	878	3689
20 000	59	148	296	589	2781	90	227	453	898	4112
30 000	59	148	297	592	2850	90	228	455	905	4268
40 000	59	149	297	594	2885	90	228	456	909	4348
50 000	59	149	298	595	2907	90	228	457	911	4398
60 000	59	149	298	595	2921	90	228	457	912	4431
70 000	59	149	298	596	2932	90	228	457	913	4455
80 000	59	149	298	596	2939	90	228	457	914	4473
90 000	59	149	298	596	2945	90	228	458	915	4488
100 000	59	149	298	596	2950	90	228	458	915	4499
200 000+	59	149	298	597	2972	90	228	458	917	4551

Values in table 1 marked with an asterisk (*) have been rounded down to a whole number because scenarios resulting in a fraction of a unit being infested (for example, 300 units with 0.5% infestation corresponds to 1.5 infested units in the shipment) are not possible. This means that the sampling intensity increases slightly, and may be greater for a shipment size where the number of infested units is rounded down than for a larger shipment where a larger number of infested units are calculated (for example, compare results for 700 and 800 units in the lot). It also means that a slightly lower proportion of infested units might be detected than the proportion indicated by the table, or that such infestation is more likely to be detected than the confidence level shown.

Values in table 1 marked with a dash (-) refer to scenarios presented that are not possible (less than one unit infested).

Table 2: Table of sample sizes for 80% and 90% confidence levels at varying levels of detection according to lot size, hypergeometric distribution

Number of units in lot	P = 80% (confidence level)					P = 90% (confidence level)				
	% level of detection × efficacy of detection					% level of detection × efficacy of detection				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
100	27	56	80	-	-	37	69	90	-	-
200	30	66	111	160	-	41	87	137	180	-
300	30	70	125	240*	-	42	95	161	270*	-
400	31	73	133	221	-	43	100	175	274	-
500	31	74	138	277*	-	43	102	184	342*	-
600	31	75	141	249	-	44	104	191	321	-
700	31	76	144	291*	-	44	106	196	375*	-
800	31	76	146	265	-	44	107	200	350	-
900	31	77	147	298*	-	44	108	203	394*	-
1 000	31	77	148	275	800	44	108	205	369	900
2 000	32	79	154	297	1106	45	111	217	411	1368
3 000	32	79	156	305	1246	45	112	221	426	1607
4 000	32	79	157	309	1325	45	113	223	434	1750
5 000	32	80	158	311	1376	45	113	224	439	1845
6 000	32	80	159	313	1412	45	113	225	443	1912
7 000	32	80	159	314	1438	45	114	226	445	1962
8 000	32	80	159	315	1458	45	114	226	447	2000
9 000	32	80	159	316	1474	45	114	227	448	2031
10 000	32	80	159	316	1486	45	114	227	449	2056
20 000	32	80	160	319	1546	45	114	228	455	2114
30 000	32	80	160	320	1567	45	114	229	456	2216
40 000	32	80	160	320	1577	45	114	229	457	2237
50 000	32	80	160	321	1584	45	114	229	458	2250
60 000	32	80	160	321	1588	45	114	229	458	2258
70 000	32	80	160	321	1591	45	114	229	458	2265
80 000	32	80	160	321	1593	45	114	229	459	2269
90 000	32	80	160	321	1595	45	114	229	459	2273
100 000	32	80	160	321	1596	45	114	229	459	2276
200 000	32	80	160	321	1603	45	114	229	459	2289

Values in table 2 marked with an asterisk (*) have been rounded down to a whole number because scenarios resulting in a fraction of a unit being infested (for example, 300 units with 0.5% infestation corresponds to 1.5 infested units in the shipment) are not possible. This means that the sampling intensity increases slightly, and may be greater for a shipment size where the number of infested units is rounded down than for a larger shipment where a larger number of infested units are calculated (for example, compare results for 700 and 800 units in the lot). It also means that a slightly lower proportion of infested units might be detected than the proportion indicated by the table, or that such infestation is more likely to be detected than the confidence level shown.

Values in table 2 marked with a dash (-) refer to scenarios presented that are not possible (less than one unit infested).

APPENDIX 3

SAMPLING OF LARGE LOTS: BINOMIAL OR POISSON BASED SAMPLING⁴

For large lots sufficiently mixed, the likelihood of finding an infested unit is approximated by simple binomial statistics. The sample size is less than 5% of the lot size. The probability of observing i infested units in a sample of n units is given by:

$$P(X=i) = \binom{n}{i} \phi p^i (1 - \phi p)^{n-i} \quad \text{Formula 3}$$

p is the average proportion of infested units (infestation level) in the lot and ϕ represents the percentage inspection efficacy divided by 100.

$P(X = i)$ is the probability of observing i infested units in the sample. The confidence level corresponds to: $1 - P(X = i)$, $i = 0, 1, 2, \dots, n$.

For phytosanitary purposes, the probability of not observing a pest specimen or symptom in the sample is determined. The probability of not observing an infested unit in a sample of n units is given by

$$P(X=0) = (1 - \phi p)^n \quad \text{Formula 4}$$

The probability of observing at least one infested unit is then:

$$P(X>0) = 1 - (1 - \phi p)^n \quad \text{Formula 5}$$

This equation can be rearranged to determine n

$$n = \frac{\ln[1 - P(X > 0)]}{\ln(1 - \phi p)} \quad \text{Formula 6}$$

The sample size n can be determined with this equation when the infestation level (p), efficacy (ϕ) and the confidence level ($1 - P(X > 0)$) are determined by the NPPO.

The binomial distribution can be approximated with the Poisson distribution. As n increases and p decreases, the binomial distribution equation given above tends to the Poisson distribution equation given below,

$$P(X=i) = \frac{(n\phi p)^i e^{-n\phi p}}{i!} \quad \text{Formula 7}$$

where e is the base-value of the natural logarithm.

The probability of finding no infested units simplifies to

$$P(X=0) = e^{-n\phi p} \quad \text{Formula 8}$$

The probability of finding at least one infested unit (the confidence level) is calculated as

$$P(X>0) = 1 - e^{-n\phi p} \quad \text{Formula 9}$$

Solving for n gives the following, which can be used to determine the sample size:

$$n = -\ln[1 - P(X>0)]/\phi p \quad \text{Formula 10}$$

Tables 3 and 4 show sample sizes when the acceptance number is 0, calculated for different levels of detection, efficacy and confidence levels with the binomial and Poisson distributions, respectively. A comparison of the case for 100% efficacy with the sample sizes in Table 1 (see Appendix 2) shows that the binomial and Poisson give very similar results to the hypergeometric distribution when n is large and p is small.

⁴ This appendix is not an official part of the standard. It is provided for information only.

Table 3: Table of sample sizes for 95% and 99% confidence levels at varying levels of detection, according to efficacy values where lot size is large and sufficiently mixed, binomial distribution

% efficacy	P = 95% (confidence level)					P = 99% (confidence level)				
	% level of detection					% level of detection				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
100	59	149	299	598	2995	90	228	459	919	4603
99	60	150	302	604	3025	91	231	463	929	4650
95	62	157	314	630	3152	95	241	483	968	4846
90	66	165	332	665	3328	101	254	510	1022	5115
85	69	175	351	704	3523	107	269	540	1082	5416
80	74	186	373	748	3744	113	286	574	1149	5755
75	79	199	398	798	3993	121	305	612	1226	6138
50	119	299	598	1197	5990	182	459	919	1840	9209
25	239	598	1197	2396	11982	367	919	1840	3682	18419
10	598	1497	2995	5990	29956	919	2301	4603	9209	46050

Table 4: Table of sample sizes for 95% and 99% confidence levels at varying levels of detection, according to efficacy values where lot size is large and sufficiently mixed, Poisson distribution

% efficacy	P = 95% (confidence level)					P = 99% (confidence level)				
	% level of detection					% level of detection				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
100	60	150	300	600	2996	93	231	461	922	4606
99	61	152	303	606	3026	94	233	466	931	4652
95	64	158	316	631	3154	97	243	485	970	4848
90	67	167	333	666	3329	103	256	512	1024	5117
85	71	177	353	705	3525	109	271	542	1084	5418
80	75	188	375	749	3745	116	288	576	1152	5757
75	80	200	400	799	3995	123	308	615	1229	6141
50	120	300	600	1199	5992	185	461	922	1843	9211
25	240	600	1199	2397	11983	369	922	1843	3685	18421
10	600	1498	2996	5992	29958	922	2303	4606	9211	46052

APPENDIX 4

**SAMPLING FOR PESTS WITH AN AGGREGATED DISTRIBUTION:
BETA-BINOMIAL BASED SAMPLING⁵**

In the case of aggregated spatial distribution, sampling can be adjusted to compensate for aggregation. For this adjustment to apply, it should be assumed that the commodity is sampled in clusters (for example, boxes) and that each unit in a chosen cluster is examined (cluster sampling). In such cases, the proportion of infested units, f , is no longer constant across all clusters but will follow a beta density function.

$$P(X=i) = \binom{n}{i} \frac{\prod_{j=0}^{i-1} (f + j\theta) \prod_{j=0}^{n-i-1} (1 - f + j\theta)}{\prod_{j=0}^{n-1} (1 + j\theta)} \quad \text{Formula 11}$$

f is the average proportion of infested units (infestation level) in the lot.

$P(X = i)$ is the probability of observing i infested units in a lot.

n = number of units in a lot.

\prod is the product function

θ provides a measure of aggregation for the j th lot where θ is $0 < \theta < 1$.

Phytosanitary sampling is often more concerned with the probability of not observing an infested unit after inspecting several batches. For a single batch, the probability that $X > 0$ is

$$P(X > 0) = 1 - \prod_{j=0}^{n-1} (1 - f + j\theta) / (1 + j\theta) \quad \text{Formula 12}$$

and the probability that each of several lots has no infested unit equals $P(X=0)^m$, where m is the number of lots. When f is low, equation 1 can be estimated by

$$\Pr(X=0) \approx (1 + n\theta)^{-(mf/\theta)} \quad \text{Formula 13}$$

The probability of observing one or more infested units is given by $1 - \Pr(X=0)$.

This equation can be rearranged to determine m

$$m = \frac{-\theta}{f} \left[\frac{\ln(1 - P(x > 0))}{\ln(1 + n\theta)} \right] \quad \text{Formula 14}$$

Stratified sampling offers a way of reducing the impact of aggregation. Strata should be chosen so that the degree of aggregation within the strata is minimized.

When the degree of aggregation and the confidence level are fixed, the size of the sample can be determined. Without the degree of aggregation, the sample size can not be determined.

Efficacy (ϕ values of less than 100% can be included by substituting ϕf for f in the equations.

⁵ This appendix is not an official part of the standard. It is provided for information only.

APPENDIX 5

COMPARISON OF HYPERGEOMETRIC AND FIXED
PROPORTION SAMPLING RESULTS⁶

Table 5: Confidence in the results of different sampling schemes for a 10% level of detection

Lot size	Hypergeometric-based sampling (random sampling)		Fixed proportion sampling (2%)	
	sample size	confidence level	sample size	confidence level
10	10	1	1	0.100
50	22	0.954	1	0.100
100	25	0.952	2	0.191
200	27	0.953	4	0.346
300	28	0.955	6	0.472
400	28	0.953	8	0.573
500	28	0.952	10	0.655
1 000	28	0.950	20	0.881
1 500	29	0.954	30	0.959
3 000	29	0.954	60	0.998

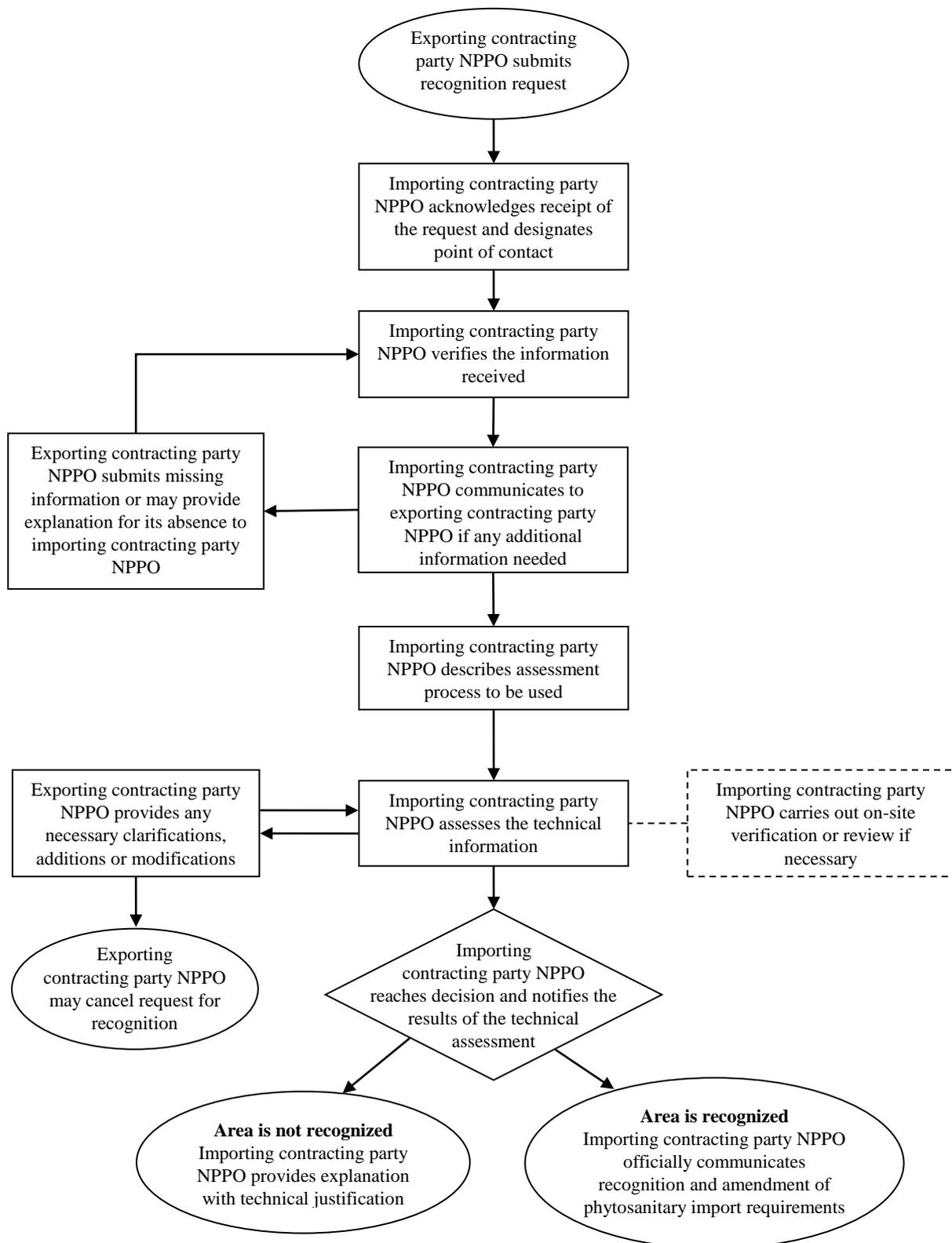
Table 6: Minimum levels that can be detected with 95% confidence using different sampling schemes

Lot size	Hypergeometric-based sampling (random sampling)		Fixed proportion sampling (2%)	
	sample size	minimum level of detection	sample size	minimum level of detection
10	10	0.10	1	1.00
50	22	0.10	1	0.96
100	25	0.10	2	0.78
200	27	0.10	4	0.53
300	28	0.10	6	0.39
400	28	0.10	8	0.31
500	28	0.10	10	0.26
1 000	28	0.10	20	0.14
1 500	29	0.10	30	0.09
3 000	29	0.10	60	0.05

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APPENDIX 1

FLOW CHART OUTLINING THE PROCEDURE FOR THE RECOGNITION OF PEST FREE AREAS OR AREAS OF LOW PEST PREVALENCE (AS PER SECTION 4)⁷



⁷ This appendix is not an official part of the standard. It is provided for information only.