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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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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

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*).

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

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.

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. 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.

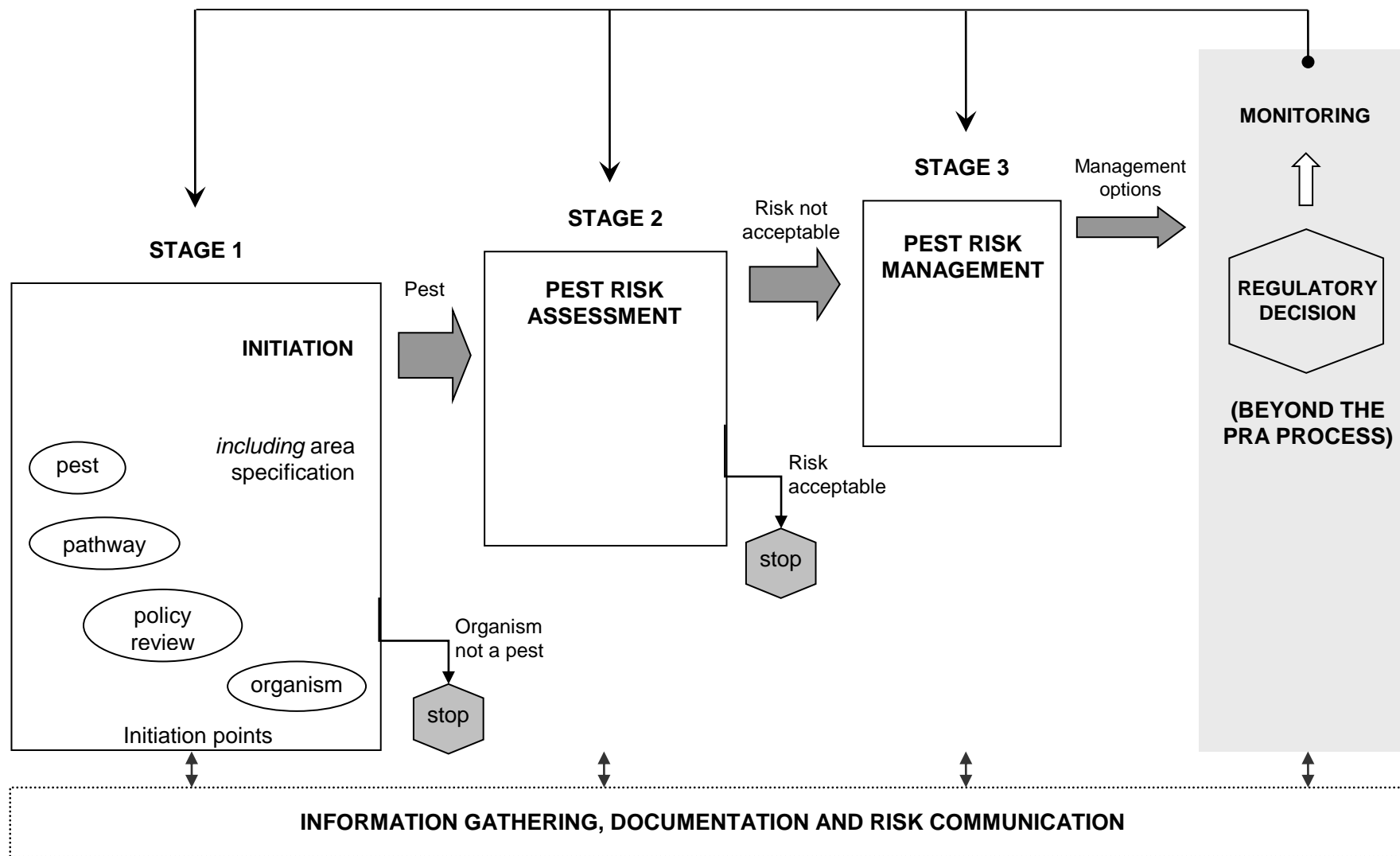
3.6 Avoidance of undue delay

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.

PEST RISK ANALYSIS FLOW CHART⁷

APPENDIX 1



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

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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INTRODUCTION

SCOPE

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

PURPOSE

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

REFERENCES

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- 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.

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 (D_{min})	The localized minimum absorbed dose within the process load [ISPM No. 18, 2003]
modern biotechnology	The application of: <ol 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. 28



**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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ANNEX 1

Adopted phytosanitary treatments

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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APPENDIX 1

Flow chart outlining the procedure for the recognition of pest free areas or areas of low pest prevalence (as per section 4)

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

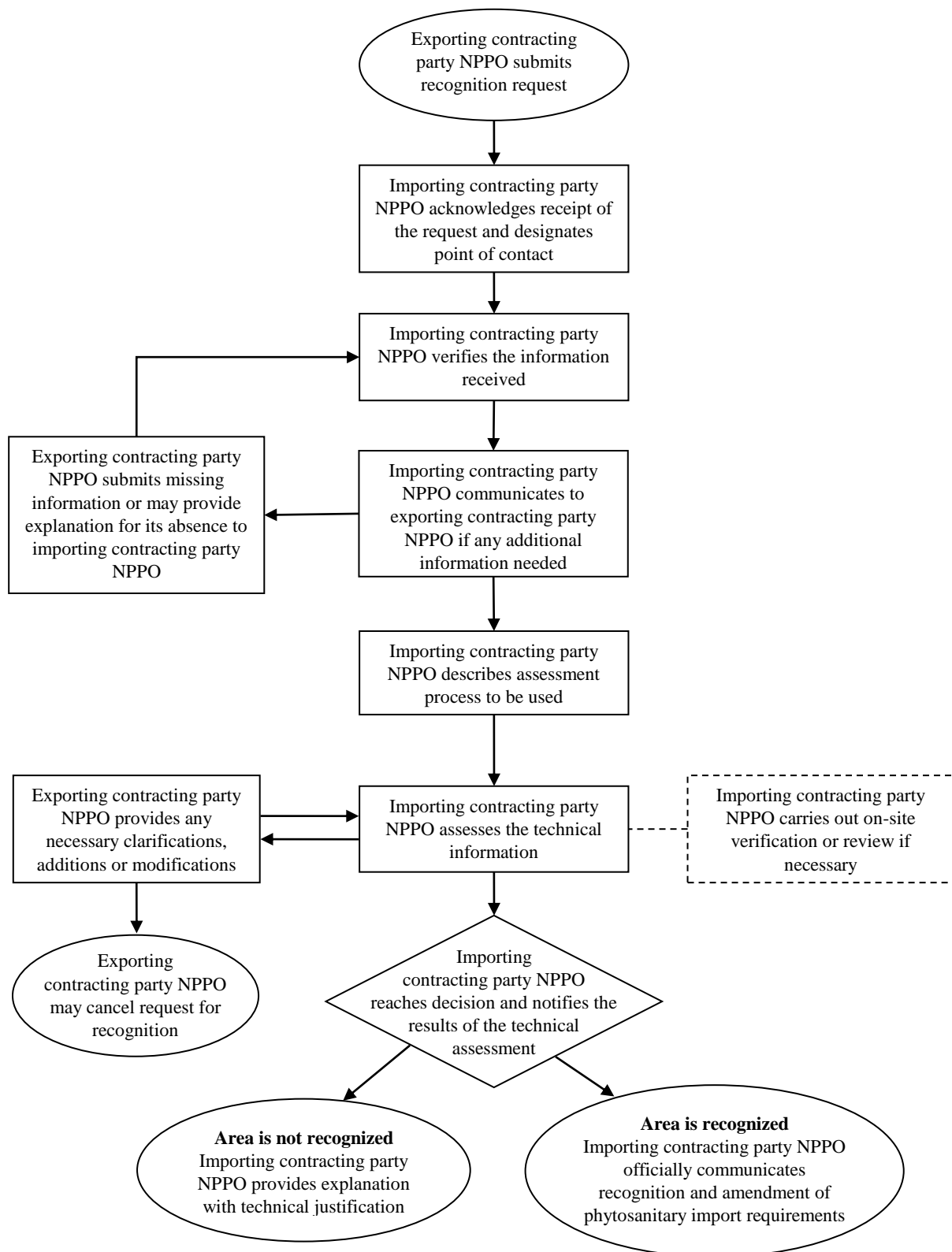
Usually pest free places of production and pest free production sites should not require recognition using the procedures described above (section 4). In this regard ISPM No. 10 (*Requirements for the establishment of pest free places of production and pest free production sites*) states that, for such 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.

APPENDIX 1

FLOW CHART OUTLINING THE PROCEDURE FOR THE RECOGNITION OF PEST FREE AREAS OR AREAS OF LOW PEST PREVALENCE (AS PER SECTION 4)¹



¹ This appendix is not an official part of the standard. It is provided for information only.



**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.

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

² This annex is an official part of the standard.

- collection and destruction of affected fruit
- 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.

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

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.

at the specified efficacy of detection and level of confidence and which the NPPO intends to detect in a consignment.

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

⁶ This appendix is not an official part of the standard. It is provided for information only.