November 2006

منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

COMMISSION ON PHYTOSANITARY MEASURES

Second Session

Rome, 26 – 30 March 2007

Adoption of International Standards

Agenda Item 9.2 of the Provisional Agenda

I. INTRODUCTION

1. This document presents six annexes which contain amendments and a new supplement to an existing ISPM, a revision of an existing ISPM and three new ISPMs. The Standards Committee (SC) recommends these annexes for adoption by the Commission on Phytosanitary Measures (CPM).

2. Annexes are as follows:

- Annex I contains amendments to ISPM No. 5 (*Glossary of phytosanitary term*s).
- Annex II is a revision of ISPM No. 2 (*Guidelines for pest risk analysis*). It is recommended that the title be changed to: *Framework for pest risk analysis*.
- Annexes III to V are new ISPMs:
  - *Phytosanitary treatments for regulated pests* (Annex III)
  - *Recognition of pest free areas and areas of low pest prevalence* (Annex IV)
  - *Establishment of areas of low pest prevalence for fruit flies* (Annex V).
- Annex VI is a supplement to ISPM No. 5 (*Glossary of phytosanitary terms*) on *Debarked and bark-free wood*.

3. In May 2006, the SC reviewed the drafts and approved them for country consultation. The drafts were sent in June 2006 for a 100 day consultation period. Technical, editorial and translation comments were received from 58 individual countries and the European Commission and its Members States. In addition to comments by countries, the Secretariat received comments from three Regional Plant Protection Organizations (RPPOs), namely: Comité Regional De Sanidad Vegetal Del Cono Sur (COSAVE), European and Mediterranean Plant Protection Organization (EPPO), and Organismo Internacional Regional De Sanidad Agropecuaria (OIRSA).

4. In 2006 seven IPPC regional workshops on draft ISPMs were organized to support the preparation of country comments and were attended by participants from Asia, French and English-speaking Africa, the Caribbean, Latin America, Near East and the Pacific. The Secretariat received over 2200 comments on the draft standards. The SC revised the draft standards as appropriate.

5. Members are invited to take the following points into account in preparation for the CPM and in accordance with the decision at the 6th Session of the Interim Commission on Phytosanitary Measures (ICPM-6) in 2004 in relation to the improvements of standard-setting procedures:

a) Members should endeavor to provide only substantive comments at meetings of the CPM.
b) Members should endeavour to provide comments in writing to the Secretariat at least 14 days before the CPM. The Secretariat will provide a copy of all comments received, in original form, at the start of the CPM.
c) Members should indicate comments that are strictly editorial (do not change the substance) and could be incorporated by the Secretariat as considered appropriate and necessary.
d) The electronic format/template for country comments should preferably be used for submitting comments and can be found on the IPP (www.ippc.int) or requested from the IPPC Secretariat.

6. In accordance with the decision of ICPM-6, comments that were received during the June-September 2006 consultation are available on the IPP (www.ippc.int). In addition, countries are invited to refer to the report of the SC (November 2006) for an overview of the main points of discussion.

II. AMENDMENTS TO ISPM NO. 5: GLOSSARY OF PHYTOSANITARY TERMS (ANNEX I)

7. The Glossary working group (GWG) meeting was held in Rome (Italy) in October 2005. It reviewed proposals for revision of existing terms and for the definition of new terms. The group consequently proposed amendments to the *Glossary of phytosanitary terms*, which were reviewed by the SC in May 2006 and sent for country consultation in June 2006.

8. In 2006, CPM-1 created the Technical Panel for the Glossary (TPG).

9. A total of 58 comments were compiled and submitted for review by the TPG at its meeting held in Rome (Italy) in October 2006 and by the SC working group (SC-7), and revised amendments were submitted to the SC in November 2006. The SC adjusted the amendments as appropriate and recommended them for adoption by the CPM.

10. The CPM is invited to:

1. *Adopt* the amendments to ISPM No. 5 (*Glossary of phytosanitary term*s), contained in Annex I.

III. REVISION OF ISPM NO. 2: FRAMEWORK FOR PEST RISK ANALYSIS (ANNEX II)

11. FAO Conference adopted ISPM No. 2 (*Guidelines for pest risk analysis*) in November 1995. In 2003, ICPM-5 identified the revision of the standard as a priority and included it in the IPPC standard setting work programme. An expert working group (EWG) meeting was held in January 2004 in Rome (Italy) and a revised version of the standard was submitted to the SC in April 2004. The SC decided that an additional EWG should be held to resolve, among other things, how the standard related to other ISPMs on pest risk analysis. A second version was drafted by an EWG that took place in June 2004 in Rome (Italy), and was reviewed by the SC in

April 2005. It was decided that a third EWG meeting should be held to further clarify some elements of the standard. The third EWG meeting was held in November 2005 in Niagara Falls (Canada) in conjunction with the International Workshop on Plant Health Risk Analysis. The SC reviewed the resulting draft in May 2006 and it was submitted for country consultation in June 2006.

12. A total of 469 comments were compiled and submitted for review by the steward and the SC-7, and a revised draft was submitted to the SC in November 2006. The SC adjusted the draft as appropriate and recommended it for adoption by the CPM.

13. The CPM is invited to:

1. *Adopt* as ISPM No. 2 (2007): *Framework for pest risk analysis*, contained in Annex II.

IV. PHYTOSANITARY TREATMENTS FOR REGULATED PESTS (ANNEX III)

14. In 2004, ICPM-6 created the Technical Panel on Phytosanitary Treatments (TPPT) and added the topic on research protocols for phytosanitary measures (treatments) to the IPPC standard setting work programme.

15. The SC at its April 2004 meeting approved a specification (TP No.3) for the TPPT and tasked the technical panel with the development of a procedure for the submission of new proposals for treatments and their evaluation by the TPPT. The SC at its November 2004 meeting modified and approved a specification (No.22) on the topic of research protocols for phytosanitary measures (treatments), which gave the flexibility for this work to be done by the TPPT.

16. The TPPT first met in Raleigh (USA) in December 2004 and, considering both the specification No. 22 and its tasks in specification TP No. 3, drafted a standard on requirements for the submission and evaluation of phytosanitary treatments. The SC at its April 2005 meeting approved the addition of this technical standard to the IPPC standard setting work programme under the subject area of the TPPT and reviewed the draft. The draft standard was sent for country consultation in 2005. A total of 384 comments were compiled and submitted for review by the steward and SC-7, and a revised draft was submitted to the SC in November 2005. The SC decided that the standard should be sent back to the steward and the TPPT for further review. The draft was revised and, after review by the SC in May 2006, sent for a second round of country consultation in June 2006.

17. A total of 403 comments were compiled and submitted for review by the steward and SC-7, and a revised draft was submitted to the SC in November 2006. The SC adjusted the draft as appropriate and recommended it for adoption by the CPM.

18. The CPM is invited to:

1. *Adopt* as an ISPM: *Phytosanitary treatments for regulated pests*, contained in Annex III.

V. RECOGNITION OF PEST FREE AREAS AND AREAS OF LOW PEST PREVALENCE (ANNEX IV)

19. In 2005, ICPM-7 added the topic of recognition of pest free areas and areas of low pest prevalence to the IPPC standard setting work programme. An EWG meeting was held in October 2005 in Rome (Italy) and, after review by the SC in May 2006, the draft standard was sent for country consultation in June 2006.

20. A total of 515 comments were compiled and submitted for review by the steward and SC-7, and a revised draft was submitted to the SC in November 2006. The SC adjusted the draft as appropriate and recommended it for adoption by the CPM.

21. The CPM is invited to:

1. *Adopt* as an ISPM: *Recognition of pest free areas and areas of low pest prevalence*, contained in Annex IV.

VI. ESTABLISHMENT OF AREAS OF LOW PEST PREVALENCE FOR FRUIT FLIES (TEPHRITIDAE) (ANNEX V)

22. ICPM-6 created the Technical Panel on Pest Free Areas and Systems Approaches for Fruit Flies (TPFF) and the SC in April 2004 approved the TPFF specification (TP No. 2), which outlined the subject area to be covered.

23. The SC at its November 2004 meeting approved the addition of a standard on the topic of areas of low pest prevalence for fruit flies to the IPPC standard setting work programme under the subject area of the TPFF, and approved the specification (No.28) for that topic..

24. At its second meeting in San Jose (Costa Rica) in September 2005, the TPFF reviewed a draft standard prepared by a consultant on the establishment of areas of low pest prevalence for fruit flies. After review by the SC in May 2006, the draft standard was sent for country consultation in June 2006.

25. A total of 524 comments were compiled and submitted for review by the steward and SC-7, and a revised draft was submitted to the SC in November 2006. The SC adjusted the draft as appropriate and recommended it for adoption by the CPM.

26. The CPM is invited to:

1. *Adopt* as an ISPM: *Establishment of areas of low pest prevalence for fruit flies (Tephritidae)*, contained in Annex V.

VII. SUPPLEMENT TO ISPM No. 5 (GLOSSARY OF PHYTOSANITARY TERMS): DEBARKED AND BARK-FREE WOOD (ANNEX VI)

27. ICPM-6 added the topic of debarking of wood to the IPPC standard setting work programme. An EWG was held in June 2005 in Aas (Norway) and, after review by the SC in May 2006, the draft standard was sent for country consultation in June 2006.

28. A total of 327 comments were compiled and submitted for review by the steward and SC-7, and a revised draft was submitted to the SC in November 2006. The SC adjusted the draft as appropriate, recommended that it should be a supplement to ISPM No. 5 (*Glossary of phytosanitary terms*) and recommended it for adoption by the CPM.

29. The CPM is invited to:

1. *Adopt* as a Supplement to ISPM No. 5 (*Glossary of phytosanitary terms*): *Debarked and bark-free wood*, contained in Annex VI.
2. *Note* that the proposed definition for “debarked wood” will replace the existing definition for “debarking” in ISPM No. 5 (*Glossary of phytosanitary terms*).

AMENDMENTS TO ISPM No. 5 (*GLOSSARY OF PHYTOSANITARY TERMS*)

1. NEW TERMS AND DEFINITIONS

phytosanitary security (of a consignment)	Maintenance of the integrity of a consignment and prevention of its infestation and contamination, by the application of appropriate phytosanitary measures
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

2. REVISED TERMS AND DEFINITIONS

buffer zone	An area surrounding or adjacent to an area officially delimited for phytosanitary purposes in order to minimize the risk of spread of the target pest into or out of the delimited area, and subject to phytosanitary or other control measures, if appropriate

3. PROPOSED DELETIONS FROM ISPM No. 5

- biological control
- reference specimen(s)

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 2

FRAMEWORK FOR PEST RISK ANALYSIS

(200-)

CONTENTS

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, 2006. 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* (in *Glossary of phytosanitary terms*, 2006). 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*).

For the purpose of country consultation, this section contains terms or definitions that are new or revised in the present draft standard. Once this standard has been adopted, the new and revised terms and definitions will be transferred into ISPM No. 5, and will not appear in the standard itself.

Revised terms and definitions

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
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)

New terms and definition

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)
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)

OUTLINE OF REQUIREMENTS

Pest risk analysis (PRA) provides a basis for determining 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 ISPM 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) is a science- and economics-based process that 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 scientific, technical 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 resolved[1].

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.

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 ISPM 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. These standards are conceptual and are not detailed operational or methodological guides 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 pests includes organisms that are pests because they directly affect uncultivated/unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms (see 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 impact[2]. 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.

[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*).

1.1 Initiation points

1.1.1 Identification of a pathway

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

- import is proposed of a commodity not previously imported or a commodity from a new area of origin
- 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 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. certification scheme) 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 is new to science or for which there is little information available
- 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. without any clear causal link
- 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 new to science, 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 (2004).

The primary indicator that a plant species may become a pest in the PRA area is the existence of reports of such harm having occurred 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.

It should be noted 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 without causing injury, except in the case where the biological control agent is used against weeds. Thus, when performing a PRA, the main concern is to look for potential injury to non-target organisms[3]. 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 new to science or for which only minimal information is available

In imported consignments or during surveillance, organisms may be detected that are difficult to identify (e.g. damaged specimen or unidentifiable life stages) or are new to science. Although in such cases the information available may be very limited, a decision may need to be made as to whether phytosanitary action is justified. When organisms have been detected that are difficult to identify, recommendations for phytosanitary measures may have to be made based on incomplete identification. The PRA allows a decision to be taken based on all available information. It also enables information gaps to be identified and recommendations for further studies to be specified.

It is recommended that 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 in order to improve certain properties of the organism. 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

[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.

- 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 cases 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. If, subsequent to the initiation stage, it is deemed unnecessary to conduct a pest risk assessment, the basis of the decision should be recorded if appropriate.

1.2.5 Intentional import of other organisms

In cases where a request is made to import an organism that may be a pest for scientific research, educational, industrial 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, the pest risk assessment may be carried out.

1.3 Defining the PRA area

The area to which the PRA refers has to be clearly defined. It may be the whole or part of a country or several countries. 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
- 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 the main 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 will be developed and others revised.

Table 1: Standards linked to ISPM No. 2

ISPM	Title	Coverage of PRA
ISPM No. 11 (2004)	*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*	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	*Pest risk analysis for regulated non-quarantine pests*	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)	*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*	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

[4] The present ISPMs No. 11 (2004) 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.

  - 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 monitoring programme 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.

3. Aspects Common to All PRA Stages

3.1 Uncertainty

Uncertainty is an integral 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; sampling from natural variability; subjective judgement; and sampling randomness. Diseases of uncertain aetiology 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. 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. Scientific publications as well as technical information such as data from surveys and interceptions may be relevant.

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
- 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 include[6]:

- 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.

[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.

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.

NPPOs are encouraged to communicate evidence of risks 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.

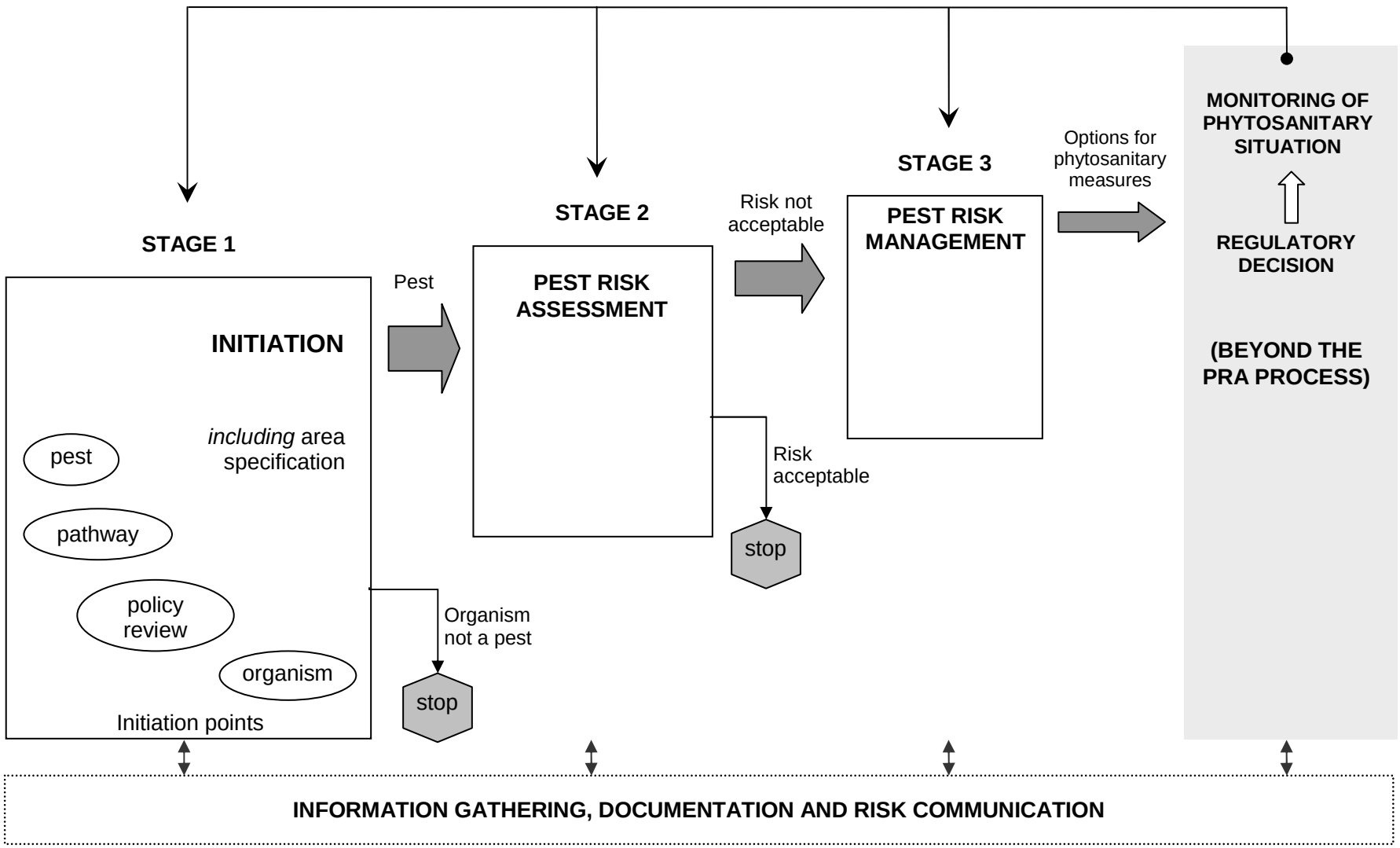
Consistency may be assured through, for example, the elaboration of generic decision criteria and procedural steps, training of individuals conducting PRA, and review of draft PRAs.

3.6 Avoidance of undue delay

In cases where other contracting parties are directly affected the NPPO should, on request, supply information about the anticipated time frame for completion of individual analyses, 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).

APPENDIX 1

PEST RISK ANALYSIS FLOW CHART[7]



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

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

PHYTOSANITARY TREATMENTS FOR REGULATED PESTS

(200-)

CONTENTS

INTRODUCTION

SCOPE

This standard presents in Annex 1 phytosanitary treatments evaluated and adopted by the 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 term*s, 2006. 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*).

For the purpose of country consultation, this section also contains terms or definitions that are new or revised in the present draft standard. Once this standard has been adopted, the new and revised terms and definitions will be transferred into ISPM No. 5, and will not appear in the standard itself.

New term and definition:

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.

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 commodities and 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).

For many years, NPPOs have utilized phytosanitary treatments 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, and they may also be relevant to the accreditation and/or approval of treatment facilities.

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.
- NPPOs are not obliged to use these treatments and may use other phytosanitary treatments for treating the same regulated pests or regulated articles.
- 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 Development and Adoption

The development 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" (provided in the *International Plant Protection Convention procedural manual*).

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)[2]. 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 the volumes of submissions are high, the relevant TPPT criteria listed in the *International Plant Protection Convention procedural manual* will be applied 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 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, 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 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).

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, treatment type, target regulated article(s), target pest(s), treatment schedule, other 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 (IPP, https://www.ippc.int).

[2] Contracting parties may have obligations related to treatments under other international agreements, e.g. The Montreal Protocol on Substances that Deplete the Ozone Layer (1999) and/or the Rotterdam Convention (1998).

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.

The experience or expertise in the subject area of the laboratory, organization and/or scientist(s) involved in producing the data, and whether the research utilized a quality assurance or accreditation programme in the development and/or testing of the phytosanitary treatment, will be considered when evaluating the data submitted. 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 varieties 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
    - type/cultivar (where varietal differences impact on treatment efficacy, data should be provided). The requirement for varietal testing should be based on evidence 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.

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)

- 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.

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)
- consideration of potential indirect effects[2] (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

- 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 may 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

RECOGNITION OF PEST FREE AREAS AND AREAS OF LOW PEST PREVALENCE

(200-)

CONTENTS

INTRODUCTION

SCOPE

This standard provides guidance for the recognition process for pest free areas and areas of low pest prevalence. It describes a procedure for the bilateral recognition of such areas. This standard does not include specified timelines for the recognition procedure.

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, 2006. 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 recognition.

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 (possibly as part of a systems approach), 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 pest free areas (PFAs) and areas of low pest prevalence (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*) states that contracting parties should ensure that their phytosanitary measures concerning consignments moving into their territories take into account the status of areas such as PFAs, ALPPs, pest free production sites or pest free places of production, as designated by the National Plant Protection Organizations (NPPOs) of the exporting countries (sections 2.3 and 2.14 of ISPM No. 1, 2006).

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 of ISPM No. 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 of ISPM No. 8).

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 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 guidance is given on use of procedures in particular cases.

2. General Principles

2.1 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.

2.2 Non-discrimination in the recognition of pest free areas and areas of low pest prevalence

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.

2.3 Avoidance of undue delay

Contracting parties should endeavour to recognize PFAs and ALPPs, and to resolve any disagreements related to recognition, without undue delay.

2.4 Transparency

Updates on progress between the importing and exporting contracting parties should be provided to the designated point of contact as mentioned 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 decisions on the recognition of PFAs and ALPPs available through the International Phytosanitary Portal.

2.5 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 establishing, designating and/or declaring PFAs 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, i.e. 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*)
- 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 way the pest status of the area has been established (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 absence of the pest in 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 eradication or suppression of a pest has recently been achieved, more detailed information and verification may be required, including items listed in section 4.1.

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 required
- cooperating in the organization of on-site verifications, 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 a technical explanation 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 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 formal process for recognition as described in this standard should not be needed.

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. 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 importing contracting party should designate a point of contact for communications relating to the request for recognition.

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. 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 a provisional timetable 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 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 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 provisional timetable, if established, the exporting contracting party should be notified, reasons provided and (if appropriate) a new timetable 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. 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, with technical justification, 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. And, 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

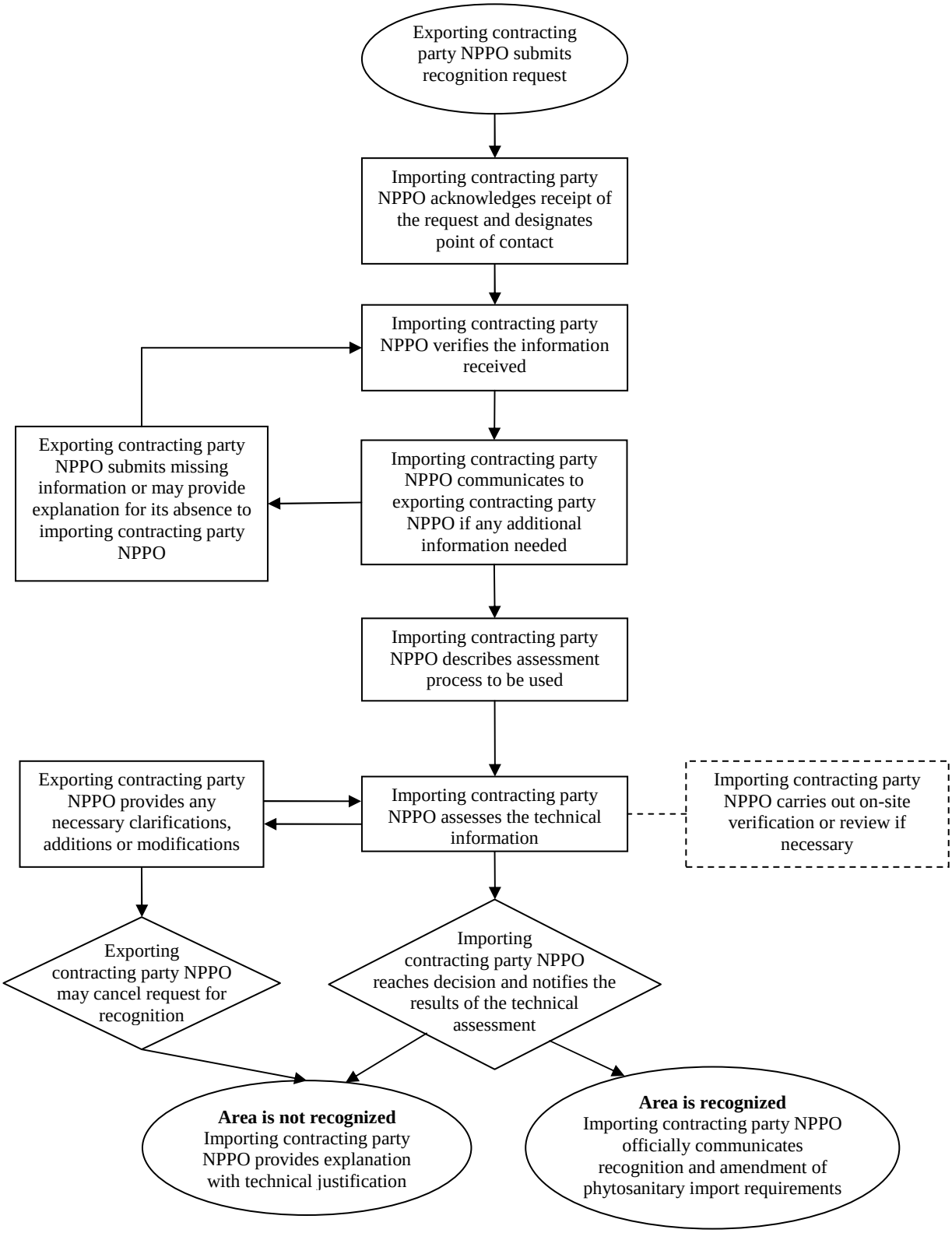
Pest free places of production and pest free production sites should not have to be recognized as such using the procedures described above (section 4). ISPM No. 10 (*Requirements for the establishment of pest free places of production and pest free production sites*) confirms that, for such places and sites, the issuance of a phytosanitary certificate for a consignment by the NPPO is sufficient to confirm that the requirements for a pest free place of production or a pest free production site have been fulfilled. The importing contracting party may require an appropriate additional declaration on the phytosanitary certificate to this effect (section 3.2 of ISPM No. 10).

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

ESTABLISHMENT OF AREAS OF LOW PEST PREVALENCE FOR FRUIT FLIES (TEPHRITIDAE)

(200-)

CONTENTS

INTRODUCTION

SCOPE

This standard provides guidelines for the establishment and maintenance of areas of low pest prevalence for fruit flies that may then be used as a pest risk management measure primarily to facilitate trade of fruits or to limit the impact of fruit flies in 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.
International Plant Protection Convention, 1997. FAO, Rome.
Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
Guidelines for pest eradication, 1998. ISPM No. 9, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.
Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.
Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, 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, 1995. ISPM No. 4, 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*).

ABBREVIATIONS USED IN THIS STANDARD

FF-ALPP	area of low pest prevalence for fruit flies
FF-PFA	pest free area for fruit flies
FTD	flies per trap per day
FTW	flies per trap per week

OUTLINE OF REQUIREMENTS

The general requirements for establishment and maintenance of an area of low pest prevalence for fruit flies (FF-ALPP) include:

- determination
- operational plans
- establishment of the parameter used to estimate the level of fruit fly prevalence
- documentation and review
- supervision activities.

For the establishment of the FF-ALPP, a parameter used to estimate fruit fly prevalence and the efficacy of trapping devices for surveillance shall be determined. Surveillance, control measures and corrective action planning are required for both establishment and maintenance. Corrective action planning is described in Annex 1.

Other specific requirements include the 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 Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO-SPS Agreement). The IPPC defines an area of low pest prevalence as "an area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures". The concept and provisions of areas of low pest prevalence are described in ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) and may be used as part of a systems approach (see 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 access to international markets for plant products that can host fruit flies. The high probability of introduction of fruit flies associated with a wide range of hosts results in restrictions imposed by many importing countries to accept fruits from areas in which these pests are established.

Therefore, there is a need to have an ISPM to provide specific guidelines for FF-ALPPs with the aim to facilitate trade and limit pest impacts in an area.

The decision to establish an FF-ALPP is closely linked to market access as well as to economic and operational feasibility.

Areas of low pest prevalence for fruit flies (FF-ALPPs) may occur naturally, or may be the result of the application of phytosanitary measures by an NPPO in an area that is a buffer zone protecting a FF-PFA, or a fruit fly free place of production or production site. In other instances, FF-ALPPs may be component stages of a fruit fly eradication process or the objective of a suppression programme.

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 areas of low pest prevalence for all pests including fruit flies and therefore ISPM No. 22 should be referred to in conjunction with the present standard.

Phytosanitary measures and specific procedures as further described in this standard may be required for the establishment and maintenance of an FF-ALPP. The decision to establish a formal FF-ALPP may be based on the technical factors provided in this standard. They include components such as pest biology and control methods.

In areas where the fruit flies are naturally of low pest prevalence, the status should be recognized according to the first paragraph of section 3.1.1 of ISPM No. 8 (*Determination of pest status in an area*).

An area can be defined as an FF-ALPP for one or more target fruit fly species. For FF-ALPPs covering multiple target fruit fly species, trapping devices and deployment densities should be specified and low pest prevalence levels determined for each target fruit fly species.

For export purposes, in most instances a specific systems approach based on an FF-ALPP along with other risk mitigation measures may be required for the target fruit fly species. A case where this may not be necessary, however, is the movement of host fruit from one FF-ALPP to another FF-ALPP of the same pest status within the same country or area according to the corresponding risk assessment.

An important factor in the establishment and maintenance of FF-ALPPs may be the support and participation of the public (especially the local community) close to the FF-ALPP and individuals who travel to or through the area, including parties with direct and indirect interests (further details are given in section 1.1 of ISPM No. 26: *Establishment of pest free areas for fruit flies (Tephritidae)*).

1.1 Determination of an FF-ALPP

General procedures for determination of an ALPP are described in section 2.1 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*). In addition, for the determination of an FF-ALPP, the target fruit fly species (one or more) is identified as well as delimitation of the area.

The following elements should also be considered for the determination of an FF-ALPP:

- delimitation of the area (extension, detailed maps or GPS coordinates showing the boundaries, natural barriers, entry points and host area locations, urban areas)
- target fruit fly species and its seasonal and spatial distribution within the area
- location and abundance of primary, secondary and occasional hosts.
- climatic characterization, for example rainfall, relative humidity, temperature, prevailing wind speed and direction.

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

In areas where prevalence of fruit flies is naturally at a low level because of climatic, geographical or other reasons (e.g. resistant hosts/varieties), low prevalence should be recognized according to 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, because of extraordinary climatic conditions or other reasons, corrective actions should be applied.

1.1.1 Delimitation of the area

The NPPO defines the limits of a proposed FF-ALPP. In most cases, FF-ALPPs do not require isolation.

Boundaries used to describe the delimitation of the FF-ALPP should be closely related to the relative presence of major hosts of the target fruit flies or adjusted to readily recognizable boundaries.

1.2 Operational plans

In most cases, an official operational plan is needed to specify the required phytosanitary procedures to establish and maintain an FF-ALPP, as per section 2.2 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*).

1.3 Establishment of the parameters used to estimate the level of fruit fly prevalence

Parameters used to determine the level of fruit fly prevalence in the FF-ALPP should be defined by the NPPO. The most widely used parameter is the number of flies per trap per day (FTD). This is usually expressed as an average of the total number of traps deployed in the whole area. 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 (see reference in Appendix 1).

If trapping is not possible, other parameters such as the number of larvae per fruit, per weight or per sample may be used (references for which can be found in Appendix 2 of ISPM No. 26: *Establishment of pest free areas for fruit flies (Tephritidae)*).

The FTD is a population index used to estimate the average 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 is used as baseline information to compare fruit fly populations among different places and/or times.

The FTD value 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:

$$FTD = \frac{F}{T \times D}$$

Where
F = total number of flies captured
T = number of inspected traps
D = average 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.

1.4 Documentation and record keeping

The phytosanitary measures used for the determination, establishment, verification and maintenance of an FF-ALPP should be adequately documented as part of phytosanitary procedures. They should be reviewed and updated regularly, including 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 standard operational procedures is prepared for the FF-ALPP.

For determination and establishment, documentation may include:
- delimitation records: (a) detailed maps showing the boundaries, natural barriers (if present) and entry points; (b) description of agro-ecological features such as the location of main host areas, marginal host areas and urban areas; and (c) meteorological conditions
- surveillance records: types of surveys, number and type of traps and lures, frequency of trap inspection, trap density, trap arrays, type, amount, date and frequency of fruit sampled, number of target fruit flies captured by species for each trap
- record of control measures used: 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. 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 importing country on request.

1.5 Supervision activities

The FF-ALPP programme, including regulatory control, surveillance procedures (for example trapping, fruit sampling) and corrective action planning, should comply with officially approved procedures. Such procedures should include official delegation of responsibility assigned to key personnel, for example:
- a person with defined authority and responsibility to ensure that the systems/procedures are implemented and maintained appropriately;
- entomologist(s) with responsibility for the authoritative identification of fruit flies to species level.

The NPPO should evaluate the operation of the procedures for establishment and maintenance of the FF-ALPP to ensure that effective management is maintained. Critical control points in which results should be monitored and processes actively managed include:
- operation of surveillance procedures
- surveillance capability
- trapping materials (traps, attractants) and procedures
- identification capability
- application of control measures
- documentation
- implementation of corrective actions, where applied.

2. Specific Requirements

2.1 Procedures to establish an FF-ALPP

The following should be developed and implemented:
- determination of the specified level of low prevalence
- surveillance system
- reduction of the target fruit fly species level
- reduction of the risk of entry of the target fruit fly species
- domestic declaration of low pest prevalence.

2.1.1 Determination of the specified level of low prevalence

For every FF-ALPP a specified level of low prevalence must be determined. The specified level determined by an FTD value or another parameter as stated under 1.3 will depend on the level of risk associated with the target fruit fly species-host-area interaction. Thus the biology of the target fruit flies, including number of generations per year, host range, temperature thresholds, behaviour, reproduction and dispersion capacity, plays a major role in determining appropriate FTD levels. For FF-ALPPs with several hosts present, the derived FTD level will need to reflect host diversity and abundance, host preference and host sequence for each target fruit fly species present. Although an FF-ALPP may have different FTD levels for each relevant target species, the level will remain fixed for the whole area and duration of the FF-ALPP operation.

Usually higher parameter values are used for secondary hosts of the target fruit fly species and lower parameter values are used for primary hosts of the target fruit fly species. However, in mixed host situations the FTD level will be based on technical information relating to the primary host in the area.

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 values at the same location, so that 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 corresponding trapping system should be stated as well.

Once an FTD has been derived 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 FTD is derived 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.

If an FF-ALPP is established for export of host fruit, the specified level should be established in conjunction with the importing country taking into account factors and elements previously mentioned.

2.1.2 Surveillance system

Prior to the establishment of an FF-ALPP, surveillance to assess the presence and abundance of the target fruit fly species should be undertaken for a period determined by its biology and behaviour, climatic characteristics of the area, host availability and as technically appropriate for at least 12 consecutive months.

Surveillance systems based on traps are similar in any type of fruit fly prevalence area. 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.

In some cases, the NPPO may complement trapping with fruit sampling for fruit fly surveillance and/or monitoring. 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. 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 abundance of fruit fly hosts should be recorded separately identifying commercial and major 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 defining and maintaining the phytosanitary status of the area.

The NPPO should have identification capabilities or have access to suitable specialists for 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.

2.1.3 Reduction of the target fruit fly species levels

Specific control measures may be applied to reduce fruit fly populations to or below the specified level of prevalence. Suppression of fruit fly populations may involve the use of more than one control option. Since the target fruit fly species are permanently present in the area, preventive and/or sustainable control measures to maintain fruit fly population at or below the specified level of low prevalence are necessary.

Phytosanitary measures to suppress fruit fly populations in FF-ALPPs include a number of preventive and/or corrective control methods, selected and combined into a strategy for suppression. Efforts should be made 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)
- biological control (e.g. natural enemies, SIT)
- cultural control (e.g. destruction of mature and fallen fruit, replacement of host plants by non-host plants, early harvesting, discouragement of intercropping with fruit fly host plants, pruning before the fruiting period, removal of shade trees, removal of untreated non-commercial hosts)
- mass trapping.

2.1.4 Reduction of the risk of entry of the target fruit fly species

Phytosanitary measures may be required to reduce the risk of entry of the specified pests into the FF-ALPP. These may include:

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

2.1.5 Domestic declaration of low pest prevalence

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

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

2.2 Maintenance of the FF-ALPP

Once an FF-ALPP is established, the NPPO should maintain the established documentation and verification procedures, and continue following phytosanitary procedures and movement controls and keeping records.

2.2.1 Surveillance

In order to maintain the FF-ALPP status, the NPPO should continue surveillance, as described in section 2.1.2 of the present standard.

2.2.2 Measures to establish and maintain specified levels of fruit fly

The NPPO should ensure that the control measures are applied to maintain the FF-ALPP as described in section 2.1.3.

If the monitored fruit fly level is observed to be increasing (but remains below the specified level for the area) a threshold for action established by the NPPO may be reached, at which point the NPPO may require implementation of additional control measures.

If additional measures are required to prevent the entrance of other target fruit fly species into the FF-ALPP, options to strengthen procedures include:

- physical and biological barriers, such as elimination around the FF-ALPP of host plants that fruit at the same time as the host commodity
- perimeter trap-hosts
- elimination of other primary or secondary hosts around the FF-ALPP
- reduction in the number of trees that provide shelter to fruit flies around the FF-ALPP.

2.2.3 Corrective action plans

A corrective action plan for the FF-ALPP should be applied by the NPPO when the population level surpasses the specified fruit fly low prevalence level. The corrective action plan should be based on the measures described in Annex 1.

2.3 Suspension, reinstatement and loss of FF-ALPP status

2.3.1 Suspension of FF-ALPP status

If the low pest prevalence specified level of the target fruit fly species is exceeded in an affected area within the FF-ALPP that can be identified and delimited, then the FF-ALPP may be redefined to suspend that area. When such a suspension is put in place, the criteria for lifting the suspension and restoring the original FF-ALPP status should be made clear. The NPPOs of interested importing countries should be notified 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 procedures are found (for example inadequate trapping or pest control measures).

If an FF-ALPP is suspended, an investigation by the NPPO should be initiated to determine the cause of the failure.

2.3.2 Reinstatement

Reinstatement of FF-ALPP status may take place:

- when the population level reaches the specified fruit fly low prevalence level and it is maintained for a period determined by the biology of the species and the prevailing environmental conditions
- when non-compliance to procedures have been corrected and verified.

Once technical conditions are achieved again, through the application of corrective actions contained in the plan, recognition of reinstatement should be carried out without undue delay.

2.3.3 Loss of status

If the specified low pest prevalence level of the target fruit fly species has been exceeded and, after the application of corrective actions, that level cannot be reached again, or if critical failures in the procedures occur and the integrity of the system is unlikely to be verified, then loss of FF-ALPP status should occur. Interested importing countries should be notified of any change in status (further information on pest reporting requirements is provided in ISPM No. 17: *Pest reporting*).

In order to achieve the FF-ALPP status again, the main procedures for establishment and maintenance outlined in this standard should be followed, taking into account all background information related to the area.

ANNEX 1

GUIDELINES ON CORRECTIVE ACTION PLANS FOR FRUIT FLIES IN AN FF-ALPP[1]

The detection of an outbreak, with a population level superior to the specified low prevalence level, of the target fruit fly species in the FF-ALPP should trigger a corrective action plan. The objective of the corrective action plan is to ensure suppression of the fruit fly to below the specified level for low prevalence as soon as possible. Even though the corrective action plan may be undertaken in coordination with and with the support of the private sector, the NPPO is responsible for leading it.

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 distribution within the area.

The elements required for implementation of a corrective action plan include:
- declaration of an outbreak
- 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(s), including provision of contact details of all parties involved.

Application of the corrective action plan

1. Declaration of an outbreak and first actions

The NPPO notifies interested stakeholders and parties, when initiating the application of a corrective action plan. The NPPO, or an NPPO-nominated agency, is responsible for supervising the implementation of corrective measures after the declaration of an outbreak.

2. Determination of the phytosanitary features of the outbreak

Immediately after the detection of an outbreak, a delimiting survey, which includes the deployment of additional traps, and usually fruit sampling of major-host fruits, as well as an increased trap inspection frequency, should be implemented to determine the size of the affected area and the level of the fruit fly prevalence.

3. Implementation of control measures in the affected area

Specific suppression actions should be immediately implemented in the affected area(s). Suppression actions may, as appropriate, include:
- selective insecticide-bait treatments (aerial and/or ground spraying and bait stations)
- sterile fly release
- male annihilation technique
- collection and destruction of affected fruit
- stripping and destruction of major host fruits, if possible.

4. 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*).

[1] This annex is an official part of the standard.

APPENDIX 1

GUIDELINES ON TRAPPING PROCEDURES[2]

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.

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

APPENDIX 2

SOME USES OF AREAS OF LOW PEST PREVALENCE FOR FRUIT FLIES[3]

FF-ALPPs are generally used:

- as a buffer zone for an FF-PFA, 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)
- 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).

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 is 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)*). These FF-ALPPs are usually established at the time of setting up the FF-PFA.

1.1 Determination of an FF-ALPP as a buffer zone

Determining procedures may include those listed in section 1.1. In addition, in delimiting the buffer zone, detailed maps may be included showing the boundaries of the area to be protected, location of major host areas, location of urban areas, entry points and control checkpoints. It is also relevant to include data related to natural biogeographical features such as prevalence of other primary or secondary hosts, climate, location of valleys, plains, deserts, rivers, lakes and sea, and those 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. The movement into the area of regulated articles that can host the target fruit fly species may 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

Procedures may include those listed in section 2.2. 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*).

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
- poor hosts, less attractive hosts or non-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 1.1. 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.

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

2.2 Maintenance of an FF-ALPP for export purposes

Maintenance procedures may include those listed in section 2.2. Surveillance and control measures should be applied throughout the fruiting seasons. 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 the major hosts that bear fruits during the off-season.

SUPPLEMENT TO ISPM No. 5 (*GLOSSARY OF PHYTOSANITARY TERMS*)

Supplement No. 3
DEBARKED AND BARK-FREE WOOD

1. Scope

This supplement provides practical guidance to National Plant Protection Organizations (NPPOs) on differentiating between debarked wood and bark-free wood, where removal of bark is required to reduce the risk of introduction and/or spread of quarantine pests associated with bark.

These guidelines do not specifically consider the effectiveness of other measures in combination with the removal of bark, nor do they provide technical justification for them.

2. References

Export certification system, 1997. ISPM No. 7, FAO, Rome.
Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines for pest risk analysis, 1995. ISPM No. 2, FAO, Rome
Guidelines for regulating wood packaging material in international trade, 2002. ISPM No. 15, 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.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No 14, FAO Rome.

Definitions

For the purpose of adoption, this sub-section contains terms or definitions that are new or revised in the present draft supplement. Once it has been adopted, the sub-section will be deleted, and the new and revised terms and definitions will be transferred into the main text of ISPM No. 5, and will not appear in the supplement.

New term and definition

bark	The layer of a woody trunk, branch or root outside the cambium

Revised terms and definitions

bark-free wood	Wood from which all bark, except ingrown bark around knots and bark pockets between rings of annual growth, has been removed
debarked wood*	Wood that has been subjected to any process designed to remove bark from wood. (Debarked wood is not necessarily bark-free wood)

* Note: this will replace the current term *debarking*.

3. Background

Wood with bark may be a pathway for the introduction and spread of some quarantine pests. The level of pest risk is dependent on a wide range of factors such as the pest, commodity type (e.g. round wood, sawn wood, wood chips), origin and any treatment applied to the wood.

Some NPPOs apply a requirement for debarked or bark-free wood as a phytosanitary measure. Different interpretations by NPPOs of what constitutes debarked and bark-free wood may have an impact on the international trade in wood.

This supplement does not provide technical justification for the use of measures requiring that wood be debarked or bark-free. It is intended solely to provide guidance to NPPOs that require this type of phytosanitary measure.

4. General Requirements

Debarking of logs may be undertaken by industry as part of wood processing designed to remove a large majority of the bark, and thereby producing debarked wood, regardless of phytosanitary concern.

Debarking using conventional industrial procedures usually does not remove all of the bark from logs. The amount of bark removed in debarking depends on a number of factors, for example, time of year of harvest, duration of storage before the debarking process, and the age and type of the machinery. However, it is generally recognized that up to 3 percent of bark from coniferous logs and up to 10 percent of bark from non-coniferous logs may remain after normal industrial debarking processes.

In terms of this standard, ingrown bark around knots (i.e. areas of bark from branches that have become encased during annual growth) and bark pockets (i.e. areas of bark between rings of annual growth) are usually not considered to present a different phytosanitary risk from that which may already have been determined to exist in relation to their surrounding wood. (A cross-sectional line drawing of wood is provided in Appendix 1.)

Commodity- and pest-specific standards exist and may include recommended guidelines on bark related to specific situations (e.g. ISPM No. 15: *Guidelines for regulating wood packaging in international trade*).

Where risks from bark on wood have been determined to be present and when the phytosanitary measures of debarked and bark-free wood are considered insufficient to ensure that all pest risks are sufficiently managed, these measures may be applied in combination with other measures. Additionally, in some cases the removal of bark from wood may increase the efficacy of other measures and may facilitate visual inspection.

4.1 Reduction of pest risk associated with bark

Removal of bark may reduce the phytosanitary risk from some insects by limiting the possibilities of cambial feeding by the larvae. For other insects, such as bark beetles, the debarking process may leave sufficient bark for the larvae to complete their life cycle. The area around branch bases, for example, is particularly attractive to some bark beetles and therefore the removal of bark is not always a sufficient phytosanitary measure. It may also have only a limited effect against some fungal organisms.

When determining import requirements for wood products, contracting parties should take into account that certain production processes eliminate pest risks associated with bark.

Although many pest risks are reduced by debarking, in some cases the residual bark that remains after debarking may present a risk. In such cases other phytosanitary measures may be required. One of these, based on technical justification, may be a requirement that the wood be bark-free.

4.2 Basis for regulating

Some importing NPPOs require debarked wood or bark-free wood as a phytosanitary measure.

Such phytosanitary measures should not be required where there is evidence that pest risk is adequately managed or absent. This may be because of the origin (which may be a pest free area), the species of pests present in the area, or the specific type of wood concerned. Importing NPPOs should determine whether the removal of bark is technically justified before requiring it as a phytosanitary measure.

Based on technical justification the removal of bark may be considered a sufficient phytosanitary measure where it is significantly effective against pests that are dependent on bark for some or all stages of their life cycle. Its use may be limited to certain times of the year, based on the period of emergence of pests in relevant exporting countries and further processing in the importing country, or may be combined with other measures where removal of bark is not sufficient to manage the phytosanitary risk when used alone.

5. Specific Requirements

5.1 Bark tolerances for debarked wood

Contracting parties may require debarked wood as a phytosanitary measure, based on technical justification. They may also set tolerances for residual levels of bark and, in addition to the criteria set out in ISPM No. 11

(*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004), take into account the following:

- species or group of species of tree in relation to pest life cycle
- bark thickness
- shape and size of remaining bark: for example a piece of bark the shape and size of a sheet of paper (e.g. A4 or letter-size) poses a higher risk than a long narrow strip of the same surface area
- for species dependent on bark, the relationship between infestation probability and the quantity of residual bark
- insect gallery size and configuration
- whether pest development occurs within the bark or beneath the bark
- moisture content and temperature of wood to sustain pest development
- climatic and seasonal conditions necessary to sustain pest development throughout the harvesting, storage and transport phases
- potential post-harvest infestation of residual bark and wood
- commodity type (round wood, sawn wood, wood chips)
- transferability of pests from one species of wood to another.

Where contracting parties require debarked wood as a phytosanitary measure based on technical justification without specifying a tolerance level of residual bark, they should expect that up to 3 percent of bark from coniferous logs and up to 10 percent of bark from non-coniferous logs may remain after normal industrial debarking processes. For sawn wood, the percentage of residual bark mentioned above should relate only to that part of the wood that has kept its natural round surface.

5.2 Bark-free wood as a phytosanitary measure

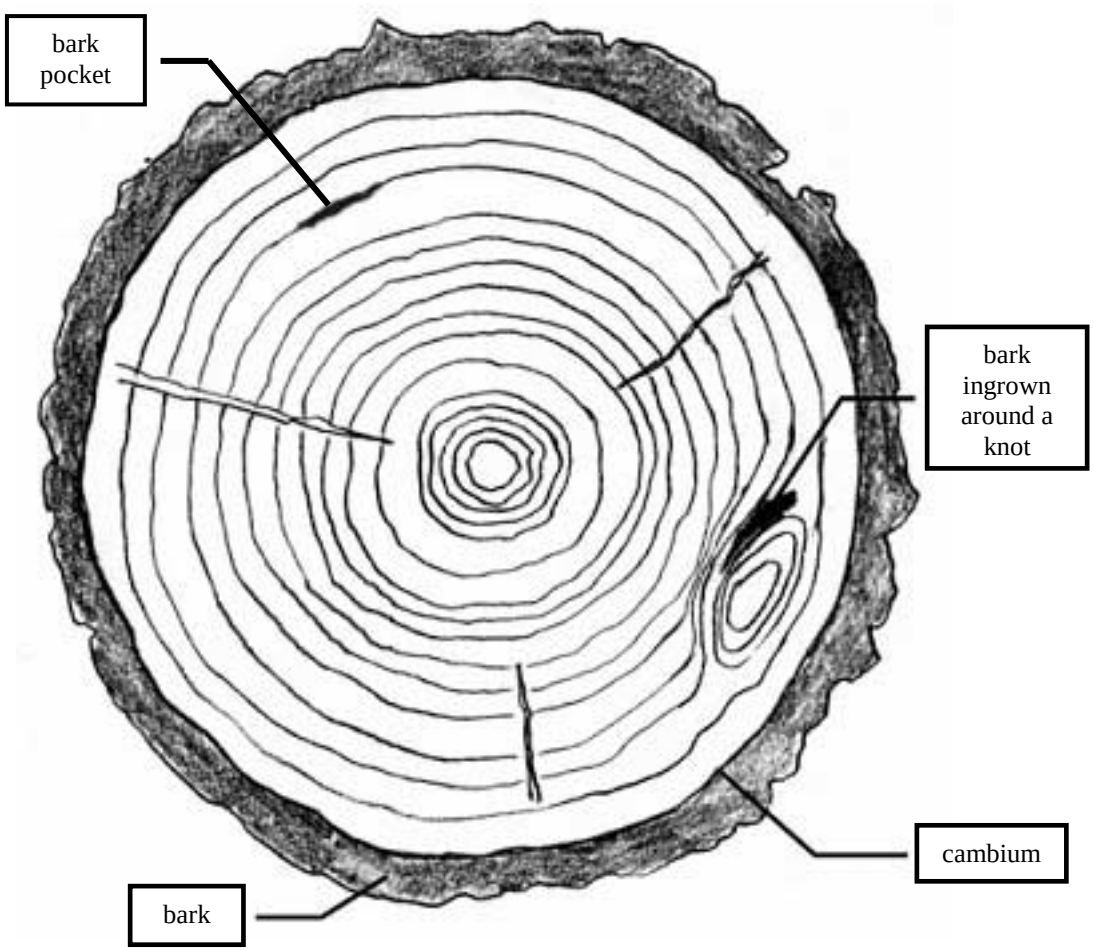
In cases where even small pieces of bark may present a risk, NPPOs may require that the wood be bark-free as a phytosanitary measure, based on technical justification. These cases may include:

- where a risk for a specific pest is identified and can be eliminated by complete removal of the bark
- when wood is subject to the application of another measure and that measure is insufficient to eliminate relevant pest risks associated with bark, including re-infestation
- where the presence of bark may reduce the efficacy of another measure required to mitigate pest risks from pests within the cambial layer.

Where importing NPPOs require that wood be bark-free, the commodity should not retain any visible indication of bark.

APPENDIX 1

CROSS-SECTIONAL LINE DRAWING OF WOOD[1]



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