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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

INTERIM COMMISSION ON PHYTOSANITARY MEASURES

Seventh Session

Rome, 4 - 8 April 2005

Adoption of International Standards

Agenda Item 7.3 of the Provisional Agenda

I. INTRODUCTION

1. Five documents, given in Annexes I-V are submitted to the ICPM for consideration.

Three of these documents are new ISPMs:

- *Requirements for the establishment of areas of low pest prevalence*
- *Guidelines for inspection*
- *Guidelines for the determination and recognition of equivalence of phytosanitary measures.*

One is a revision to an existing ISPM: ISPM No. 3 (*Code of conduct for the import and release of exotic biological control agents*). It was agreed to change the title to: *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms.*

One gives amendments to an existing ISPM: ISPM No. 5 (*Glossary of phytosanitary terms*).

2. These drafts were reviewed by the Standards Committee (SC) in May 2004, and as a result were sent out on 20 June 2004 for the 100 days country consultation. Technical, translation and editorial comments were received from 45 individual countries and the EC and its Members States. In addition to comments by countries, the Secretariat received comments from 4 Regional Plant Protection Organizations (RPPOs), namely: Asia and Pacific Plant Protection Commission (APPPC), Comité Regional De Sandidad Vegetal Del Cono Sur (COSAVE), European and Mediterranean Plant Protection Organization (EPPO) and Pacific Plant Protection Organization (PPPO). Comments arising from 7 IPPC Regional workshops on draft ISPMs were also considered (attended by over 100 countries from Asia, the Caribbean, French-speaking Africa, Latin America, Near East, Pacific and the Southern African Development Community (SADC)). The Secretariat received over 2000 comments (technical, translation and editorial) on these draft standards, i.e. an average of 400 comments per standard. It called upon the steward of each standard to review comments, and make recommendations. The use of the stewards has proved to be an efficient method of analyzing comments and providing feedback to the SC. The SC considered the comments and the recommendations of the stewards when revising the draft standards.

3. According to the decision at the 6th Session of the ICPM (April 2004) in relation to the improvements of standard-setting procedures (Appendix IX, point 3 of the report), countries are invited to take the following points into account:

a) Members should endeavour to provide only substantive comments at meetings of the ICPM.

b) Members should endeavour to provide comments in writing to the Secretariat at least 14 days before the ICPM. The Secretariat will provide a copy of all comments received, in original form at the start of the ICPM.

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/matrix for country comments should preferably be used for submitting comments and can be found on the IPP (https://www.ippc.int) or be requested to the IPPC Secretariat).

4. As decided at the 6th Session of the ICPM (April 2004), comments from individual countries are available on the IPP (https://www.ippc.int). In addition, countries are invited to refer to the report of the SC (November 2004) for an overview of the main points of discussions.

II. REQUIREMENTS FOR THE ESTABLISHMENT OF AREAS OF LOW PEST PREVALENCE (ANNEX I)

5. The 5th session of the ICPM (April 2003) added the topic of areas of low pest prevalence to the work programme. The Expert Working Group on requirements for the establishment of areas of low pest prevalence met in December 2003 in Monterrey, Mexico, in collaboration with the Plant Protection Service of Mexico and the North American Plant Protection Organization (NAPPO). The draft was reviewed by the SC in May 2004 and submitted for country consultation in June 2004.

6. 390 comments were compiled and submitted for the review of the steward and SC-7. In November 2004, the draft was adjusted by the Standards Committee Working Group (SC-7) and SC, and recommended for adoption by the ICPM.

7. The ICPM is invited to:

Adopt as an ISPM: *Requirements for the establishment of areas of low pest prevalence,* contained in Annex I.

III. GUIDELINES FOR INSPECTION (ANNEX II)

8. Several meetings of Expert Working Groups on guidelines for inspection procedures took place between 1994 and 1999. In 1999, the IPPC Secretariat noted that country comments on this draft standard were diverse and substantial. It was agreed that further work was needed. In March 2004, an Expert Working Group met in Riverdale, Maryland (USA) to develop the draft further. This draft was reviewed by the SC in May 2004 and submitted for country consultation in June 2004. The SC decided that this standard should only focus on inspection and removed sampling portions from the draft to be reviewed in the future by an Expert Working Group working on a standard on sampling.

9. 604 comments were compiled and submitted for the review of the steward and SC-7. In November 2004, the draft was adjusted by the SC-7 and SC, and recommended for adoption by the ICPM.

10. The ICPM is invited to:

Adopt as an ISPM: *Guidelines for inspection,* contained in Annex II.

IV. *GUIDELINES FOR THE DETERMINATION AND RECOGNITION OF EQUIVALENCE OF PHYTOSANITARY MEASURES (ANNEX III)*

11. A request was made by the WTO Committee on the Application of Sanitary and Phytosanitary Measures (SPS Committee) to the three standard-setting organizations in relation to the concept of equivalence. The 4th Session of the ICPM (March 2002) added the topic of equivalence to the work programme. The Expert Working Group on equivalence met in September 2003 in Brugge, Belgium, in collaboration with the Plant Protection Service of Belgium and the European and Mediterranean Plant Protection Organization (EPPO). The draft was reviewed by the SC in May 2004 and submitted for country consultation in June 2004.

12. 320 comments were compiled and submitted for the review of the steward and SC-7. In November 2004, the draft was further adjusted by the SC-7 and SC, and recommended for adoption by the ICPM.

13. The ICPM is invited to:

> *Adopt* as an ISPM: *Guidelines for the determination and recognition of equivalence of phytosanitary measures*, contained in Annex III.

V. REVISION OF ISPM NO. 3: GUIDELINES FOR THE EXPORT, SHIPMENT, IMPORT AND RELEASE OF BIOLOGICAL CONTOL AGENTS AND OTHER BENEFICIAL ORGANISMS (ANNEX IV)

14. FAO Conference adopted ISPM No. 3 (*Code of conduct for the import and release of exotic biological control agents*) in November 1995 before the revision of the IPPC in 1997. The 2nd Session of the ICPM (October 1999) considered initiatives and activities of the Convention on Biological Diversity (CBD) that may have implications for the IPPC, including issues related to genetically modified organisms, biosafety and invasive species. The ICPM established an Exploratory Open-Ended Working Group to consider theses implications and this group met in June 2000 at FAO Headquarters in Rome, and was followed by an additional open-ended join consultation on IPPC-CBD collaboration in February 2001 in Bangkok, Thailand. As a result of these meetings, it was recommended that ISPM No. 3 be amended "to include consideration of risk of spread of biological control organisms to other countries". An Expert Working Group met in December 2003 at FAO Headquarters in Rome to revise ISPM No. 3. The draft was reviewed by the SC in May 2004 and submitted for country consultation in June 2004.

15. 548 comments were compiled and submitted for the review of the steward and SC-7. The draft was adjusted by the SC-7 and SC in November 2004, and recommended for adoption by the ICPM.

16. The ICPM is invited to:

> *Adopt* as ISPM No. 3: *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, contained in Annex IV.

VI. AMENDMENTS TO ISPM NO. 5 (ANNEX V)

17. The Glossary Working Group met in Paris, France in February 2004. The Glossary Working Group is a unique working group composed of a standing membership with representatives of each FAO language. In addition to considering new and revised terms in draft standards, it reviewed proposals for revision of existing terms and for definition of new terms. The group consequently proposed amendments to the Glossary, which were reviewed by the SC in May 2004 and sent for country consultation in June 2004.

18. 159 comments were compiled and reviewed by the Glossary Working Group at a meeting at FAO Headquarters, Rome, in October 2004. In November 2004, the draft was adjusted by the SC, and recommended for adoption by the ICPM.

19. The ICPM is invited to:

Adopt the amendments to ISPM No. 5 (*Glossary of phytosanitary terms*), contained in Annex V, noting that the new or revised terms and definitions adopted in new standards will also become amendments to the Glossary.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

REQUIREMENTS FOR THE ESTABLISHMENT OF AREAS OF LOW PEST PREVALENCE

Secretariat of the International Plant Protection Convention
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, ----

CONTENTS

INTRODUCTION

SCOPE

This standard describes the requirements and procedures for the establishment of areas of low pest prevalence (ALPP) for pests regulated in the area and, to facilitate export, for pests regulated by the importing country. This includes the identification, verification, maintenance and use of those ALPPs.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.
Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.
Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.
Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
International Plant Protection Convention, 1997, FAO, Rome.
Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.
Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.
Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS[1]

area	An officially defined country, part of a country or all or parts of several countries [FAO, 1990; revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]
area of low pest prevalence	An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures [IPPC, 1997]
buffer zone*	An area in which a specific pest does not occur or occurs at a low level and is officially controlled, that either encloses or is adjacent to an infested area, an infested place of production, an area of low pest prevalence, a pest free area, a pest free place of production or a pest free production site, and in which phytosanitary measures are to prevent spread of the pest
containment	Application of phytosanitary measures in and around an infested area to prevent spread of a pest [FAO, 1995]
control (of a pest)	Suppression, containment or eradication of a pest population [FAO, 1995]
delimiting survey	Survey conducted to establish the boundaries of an area considered to be infested by or free from a pest [FAO, 1990]
eradication	Application of phytosanitary measures to eliminate a pest from an area [FAO, 1990; revised FAO, 1995; formerly eradicate]

[1] Term marked with (*) is revised

IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
monitoring survey	Ongoing survey to verify the characteristics of a pest population [FAO, 1995]
National Plant Protection Organization	Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization (National)]
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]
Pest Free Area	An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained [FAO, 1995]
phytosanitary action	An official operation, such as inspection, testing, surveillance or treatment, undertaken to implement phytosanitary regulations or procedures [ICPM, 2001]
phytosanitary measure (agreed interpretation)	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; ICPM, 2002]

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

phytosanitary procedure	Any officially prescribed method for implementing phytosanitary regulations including the performance of inspections, tests, surveillance or treatments in connection with regulated pests [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
phytosanitary regulation	Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
place of production	Any premises or collection of fields operated as a single production or farming unit. This may include production sites which are separately managed for phytosanitary purposes [FAO, 1990; revised CEPM, 1999]
quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC 1997]
regulated article	Any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved [FAO, 1990; revised FAO, 1995; IPPC, 1997]

regulated non-quarantine pest	A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party [IPPC, 1997]
regulated pest	A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]
standard	Document established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context [FAO, 1995; ISO/IEC GUIDE 2:1991 definition]
suppression	The application of phytosanitary measures in an infested area to reduce pest populations [FAO, 1995; revised CEPM, 1999]
surveillance	An official process which collects and records data on pest occurrence or absence by survey, monitoring or other procedures [CEPM, 1996]
survey	An official procedure conducted over a defined period of time to determine the characteristics of a pest population or to determine which species occur in an area [FAO, 1990; revised CEPM, 1996]
systems approach(es)	The integration of different pest risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of phytosanitary protection [ISPM No. 14, 2002]
treatment	Officially authorized procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003]

OUTLINE OF REQUIREMENTS

The establishment of an ALPP is a pest management option used to maintain or reduce a pest population below a specified level in an area. This standard provides guidelines on procedures for establishment, maintenance, verification and use of an ALPP.

A specified low pest level should be determined taking into consideration the overall operational and economic feasibility of establishing a programme to meet or maintain this level, and the objective for which an ALPP is to be established. Surveillance of the specified pest is a key component in establishing and maintaining an ALPP. Actions to take if the status of an ALPP changes, and for suspension and reinstatement of an ALPP, are also provided.

BACKGROUND

1. General Considerations

1.1 Concept of areas of low pest prevalence

The concept of areas of low pest prevalence (ALPP) is referred to in the IPPC and the *Agreement on Sanitary and Phytosanitary Measures* of the World Trade Organization (WTO-SPS Agreement).

The IPPC (1997) defines an ALPP as "an area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures" (Article II). Furthermore, Article IV.2e states that the responsibilities of the NPPO includes the protection of endangered areas and the designation, maintenance and surveillance of pest free areas (PFAs) and ALPPs.

Article 6 of the WTO-SPS Agreement is entitled "Adaptation to regional conditions, including pest or disease-free areas and areas of low pest or disease prevalence". It further elaborates on the responsibilities of member countries for ALPPs.

1.2 Advantages in using areas of low pest prevalence

Advantages in using ALPPs include:

- removal of the need for post-harvest treatment(s) when the specified pest level is not exceeded
- for some pests, biological control methods that rely on low pest populations being present may reduce pesticide use
- facilitation of market access for products from areas that were previously excluded
- less restrictive movement controls including movement of commodities may be permitted from:
  - an ALPP to or through a pest free area (PFA), if the commodity is pest free
  - one ALPP to or through another ALPP, if the commodity has equivalent pest risk.

1.3 Distinction between an area of low pest prevalence and a pest free area

The main difference between an ALPP and a PFA is that the presence of the pest below a specified population level is accepted in an ALPP, whereas the pest is absent from a PFA. When the pest is present in an area, the choice of establishing an ALPP or attempting to establish a PFA as a pest management option will depend on the characteristics of the pest, its distribution in the area of concern and the factors that determine this distribution, the overall operational and economic feasibility of the programme, and the objective for the establishment of a specific ALPP or PFA.

REQUIREMENTS

2. General Requirements

2.1 Determination of an area of low pest prevalence

The establishment of an ALPP is a pest management option used to maintain or reduce the pest population below a specified level in an area. It may be used to facilitate the movement of commodities out of areas where the pest is present such as for domestic movement or for exports, and reduces or limits pest impact in the area. An ALPP can be established for pests across a broad range of environmental conditions and hosts, and should also take into account the biology of the pest and the characteristics of the area. Since ALPPs may be established for different purposes, the size and description of the ALPP will depend on the purpose.

Examples of where an ALPP may be established by an NPPO according to this standard are:

- an area of production where products are intended for export
- an area under an eradication or suppression programme
- an area acting as a buffer zone to protect a PFA
- an area within a PFA which has lost its status and is under an emergency action plan
- as part of official control in relation to regulated non-quarantine pests (see ISPM No. 21: *Pest risk analysis for regulated non-quarantine pests*)

- an area of production in an infested area of a country from which products are intended to be moved to another ALPP in that country.

Where an ALPP is established and host materials are intended to be exported, they may be subject to additional phytosanitary measures. In this way, an ALPP would be part of a systems approach. Systems approaches are detailed in ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*. Such systems may be very efficient in mitigating the pest risk down to a level acceptable for the importing country and thus, in some cases, the pest risk may be reduced to that of host material originating from a PFA.

2.2 Operational plans

In most cases an official operational plan which specifies the required phytosanitary procedures that a country is applying is needed. If it is intended to use an ALPP to trade with another country, such plan may have the form of a specific work plan as part of a bilateral arrangement between the NPPOs of both importing and exporting contracting parties, or may be a general requirement of an importing country, which should be made available to it on request. It is recommended that the exporting country consults with the importing country in the early stages of the process in order to ensure that importing country requirements are met.

3. Specific Requirements

3.1 Establishment of an ALPP

Low pest prevalence can occur naturally or be established through the development and application of phytosanitary measures aimed at controlling the pest(s).

3.1.1 Determination of specified pest levels

Specified levels for the relevant pests should be established by the NPPO of the country where the ALPP is located, with sufficient precision to allow assessment of whether surveillance data and protocols are adequate to determine that pest prevalence is below these levels. Specified pest levels may be established through PRA, for example as described in ISPMs No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*) and No. 21 (*Pest risk analysis for regulated non-quarantine pests*). If the ALPP is intended to facilitate exports, the specified levels should be established in conjunction with the importing country.

3.1.2 Geographic description

The NPPO should describe the ALPP with supporting maps demonstrating the boundaries of the area. Where appropriate, the description may also include the places of production, the host plants in proximity to commercial production areas, as well as the natural barriers and/or buffer zones which may isolate the area.

It may be useful to indicate how the size and configuration of the natural barriers and buffer zones contribute to the exclusion or management of the pest, or why they serve as a barrier to the pest.

3.1.3 Documentation and verification

The NPPO should verify and document that all procedures are implemented. The elements of this process should include:

- documented procedures to be followed (i.e. procedural manual)
- implemented procedures and record keeping of these procedures
- audit of procedures
- developed and implemented corrective actions.

3.1.4 Phytosanitary procedures

3.1.4.1 Surveillance activities

The status of the relevant pest situation in the area, and when appropriate of the buffer zone, should be

determined by surveillance (as described in ISPM No. 6: *Guidelines for surveillance*) during appropriate periods of time and at a level of sensitivity that will detect the specified pest at the specified level with an appropriate level of confidence. Surveillance should be conducted according to protocols for the specified pest(s). These protocols should include how to measure if the specified pest level has been maintained, e.g. type of trap, number of traps per hectare, acceptable number of pest individuals per trap per day or week, number of samples per hectare that need to tested or inspected, part of the plant to be tested or inspected, etc.

Surveillance data should be collected and documented to demonstrate that the populations of the specified pests do not exceed the specified pest levels in any areas of the proposed ALPP, and buffer zones where appropriate, and include surveys of cultivated and uncultivated hosts, or habitats in particular in the case where the pest is a plant. The surveillance data should be relevant to the life cycles of the specified pests and should be statistically validated to detect and characterize the population levels of the pests.

When establishing an ALPP, technical reports of the specified pest(s) detections, and results of the surveillance activities should be recorded and maintained for a sufficient number of years, depending on the biology, reproductive potential and host range of the specified pests. However to supplement this information, data should be provided for as many years as possible, prior to the establishment of the ALPP.

3.1.4.2 Reducing pest levels and maintaining low prevalence

Phytosanitary procedures should be documented and applied to meet pest(s) levels in cultivated and uncultivated hosts, or habitats in particular in the case where the pest is a plant, in the proposed ALPP. Phytosanitary procedures should be relevant to the biology and behaviour of the specified pests. Examples of procedures used to meet a specified pest level are: removing alternative and/or alternate hosts; applying pesticides; releasing biological control agents; using high density trapping techniques to capture the pest.

When establishing an ALPP, control activities should be recorded for a sufficient number of years, depending on the biology, reproductive potential and host range of the specified pest(s). However to supplement this information, data should be provided for as many years as possible, prior to the establishment of the ALPP.

3.1.4.3 Reducing the risk of entry of specified pest(s)

In case an ALPP is established for a regulated pest, phytosanitary measures may be required to reduce the risk of entry of the specified pests into the ALPP (ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*). These may include:

- regulation of the pathways and of the articles that require control to maintain the ALPP. All pathways into and out of the ALPP should be identified. This may include the designation of points of entry, and requirements for documentation, treatment, inspection or sampling before or at entry into the area.
- maintenance of sampling records
- identification of intercepted specimens of specified pests
- verification of documents
- confirmation of the application and effectiveness of required treatments
- documentation of any other phytosanitary procedures.

An ALPP may be established for pests regulated domestically or to facilitate exports for pests regulated in an importing country. When an ALPP is established for a pest that is not a regulated pest for that area, measures to reduce the risk of entry may also be applied. However, such measures should not restrict trade of plant and plant products into the country, or discriminate between imported and nationally-

produced commodities.

3.1.4.4 Corrective action plan

The NPPO should have a documented plan to be implemented if a specified pest level is exceeded in the ALPP, or when appropriate in the buffer zones (section 3.3 describes other situations where the status of an ALPP may change). The plan may include a delimiting survey to determine the area in which the specified pest level has been exceeded, commodity sampling, pesticide applications and/or other suppression activities. Corrective actions should also address all of the pathways.

3.1.5 Verification of an area of low pest prevalence

The NPPO of the country where the ALPP is to be established should verify that the measures necessary to meet the requirements of the ALPP are in place. This includes verification that all aspects of the documentation and verification procedures described in section 3.1.3 are implemented. If the area is being used for exports, the NPPO of the importing country may also want to verify compliance.

3.2 Maintenance of an area of low pest prevalence

Once an ALPP is established, the NPPO should maintain the established documentation and verification procedures, and continue following phytosanitary procedures and movement controls and keeping records. Records should be retained for at least the two previous years or as long as necessary to support the programme. If the ALPP is being used for export purposes, records should be made available to the importing country upon request. In addition, established procedures should be routinely audited, at least once a year.

3.3 Change in the status of an area of low pest prevalence

The main cause leading to a change in the status of an ALPP is the detection of the specified pest(s) at a level exceeding the specified pest level(s) within the ALPP.

Other examples that may cause a change in status of an ALPP and lead to the need to take action are:

- repeated failure of regulatory procedures
- incomplete documentation that jeopardises the integrity of the ALPP.

The change of status should result in the implementation of the corrective action plan as specified in Section 3.1.4.4 of this standard. The corrective actions should be initiated as soon as possible after confirmation that the specified pest level has been exceeded in the ALPP or detection of pest(s) during inspection of host products.

Depending on the outcome of the actions taken, the ALPP may be:

- continued (status not lost), if the phytosanitary actions taken (as part of the corrective action plan in the case of detection of specified pests above a specified pest levels) have been successful
- continued, if a failure of regulatory actions or other deficiencies has been rectified
- redefined to exclude a certain area, if the specified pest level of a pest is exceeded in a limited area that can be identified and isolated
- suspended (status lost).

If the ALPP is being used for export purposes, the importing country may require that such situations and associated activities are reported to it. Additional guidance is provided by ISPM No. 17: *Pest reporting*.

3.4 Suspension and reinstatement of the status of an area of low pest prevalence

If an ALPP is suspended, an investigation should be initiated to determine the cause of the failure. Corrective actions, and if necessary additional safeguards, should be implemented to prevent recurrence of the failure. The suspension of the ALPP will remain in effect until it is demonstrated that populations of the pest are below the specified pest level for an appropriate period of time, or that the other

deficiencies have been corrected. As with the initial establishment of an ALPP, the minimum period of time below the specified pest level(s) for reinstatement of ALPP status will depend on the biology of the specified pest(s). Once the cause of the failure has been corrected and the integrity of the system is verified, the ALPP can be reinstated.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

GUIDELINES FOR INSPECTION

Secretariat of the International Plant Protection Convention
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, ----

CONTENTS

INTRODUCTION

SCOPE

This standard describes procedures for the inspection of consignments of plants, plant products and other regulated articles at import and export. It is focused on the determination of compliance with phytosanitary requirements, based on visual examination, documentary checks, and identity and integrity checks.

REFERENCES

Export certification system, 1997. ISPM No. 7, FAO, Rome.
Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.
Guidelines on phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome
Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.
Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS[1]

consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]
inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly inspect]
inspector	Person authorized by a National Plant Protection Organization to discharge its functions [FAO, 1990]
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
lot	A number of units of a single commodity, identifiable by its homogeneity of composition, origin etc., forming part of a consignment [FAO, 1990]
National Plant Protection Organization	Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization (National)]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]

[1] Terms marked with (*) are new.

Pest Free Area	An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained [FAO, 1995]
Pest Risk Analysis	The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC, 1997]
phytosanitary certification	Use of phytosanitary procedures leading to the issue of a Phytosanitary Certificate [FAO, 1990]
phytosanitary import requirement*	Specific phytosanitary measures established by an importing country concerning consignments moving into that country
quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC 1997]
regulated article	Any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved [FAO, 1990; revised FAO, 1995; IPPC, 1997]
regulated pest	A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]
visual examination*	The physical examination of plants, plant products, or other regulated articles using the unaided eye, lens, stereoscope or microscope to detect pests or contaminants without testing or processing.

OUTLINE OF REQUIREMENTS

National Plant Protection Organizations (NPPOs) have the responsibility for "*the inspection of consignments of plants and plant products moving in international traffic and, where appropriate, the inspection of other regulated articles, particularly with the object of preventing the introduction and/or spread of pests.*" (Article IV.2c of the IPPC, 1997).

Inspectors determine compliance of consignments with phytosanitary requirements, based on visual examination for detection of pests and regulated articles, and documentary checks, and identity and integrity checks. The result of inspection should allow an inspector to decide whether to accept, detain or reject the consignment, or whether further analysis is required.

NPPOs may determine that consignments should be sampled during inspection. The sampling methodology used should depend on the specific inspection objectives and relate to the probability of detection of specified regulated pests or non-specified organisms not yet regulated as pests but which could be potential pests.

REQUIREMENTS

1. General Requirements

The responsibilities of an NPPO include "*the inspection of consignments of plants and plant products moving in international traffic and, where appropriate, the inspection of other regulated articles, particularly with the object of preventing the introduction and/or spread of pests*" (Article IV.2c of the IPPC, 1997).

Consignments may consist of one or more commodities or lots. Where a consignment is comprised of more than one commodity or lot, the inspection to determine compliance may have to consist of several separate visual examinations. Throughout this standard, the term "consignment" is used, but it should be recognized that the guidance provided for consignments may apply equally to individual lots within a consignment.

1.1 Inspection objectives

The objective of inspection of consignments is to confirm compliance with import or export requirements relating to quarantine pests or regulated non-quarantine pests. It often serves to verify the efficacy of other phytosanitary measures taken at a previous stage in time.

An export inspection is used to ensure that the consignment meets specified phytosanitary requirements of the importing country at the time of inspection. An export inspection of a consignment may result in the issuance of a phytosanitary certificate for the consignment in question.

Inspection at import is used to verify compliance with phytosanitary import requirements. Inspection may also be carried out generally for the detection of non-specified organisms not yet regulated as pests but which could be potential pests.

The collection of samples for laboratory testing or the verification of pests may be included in the inspection procedure.

Inspection can be used as a risk management procedure.

1.2 Assumptions involved in the application of inspections

As inspection of entire consignments is often not feasible, phytosanitary inspection is consequently often based on sampling[2].

The use of inspection as a means to determine or verify the pest level of a consignment is based on the following assumptions:

- the pests of concern are visually detectable
- inspection is operationally practical and
- some probability of pests being undetected is recognized.

There is some probability of pests being undetected when inspection is used. This is because inspection is usually based on sampling, which may not involve visual examination of 100% of the lot or consignment, and also because inspection is not 100% effective for detecting a specified pest on the consignment or samples examined. When inspection is used as a risk management procedure, there is also a certain probability that a pest which is present in a consignment or lot may not be detected.

The size of a sample for inspection purposes is normally determined on the basis of a specified regulated pest associated with a specific commodity. It may be more difficult to determine the sample size in cases where inspection of consignments is targeted at several or all regulated pests.

1.3 Responsibility for inspection

NPPOs have the responsibility for inspection. Inspections are carried out by NPPOs or under their authority (see also section 3.1 of ISPM No. 7: *Export certification system*; and section 5.1.5.2 of ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*; Articles IV.2a, IV.2c and

[2] Guidance on sampling will be provided in the ISPM under development

V.2a of the IPPC, 1997).

1.4 Requirements for inspectors

As authorized officers or agents by the NPPO, inspectors should have:

- authority to discharge their duties and accountability for their actions
- technical qualifications and competencies, especially in pest detection
- knowledge of, or access to capability in, identification of pests, plants and plant products and other regulated articles
- access to appropriate inspection facilities, tools and equipment
- written guidelines (such as regulations, manuals, pest data sheets)
- knowledge of the operation of other regulatory agencies where appropriate
- objectivity and impartiality.

The inspector may be required to inspect consignments for:

- compliance with specified import or export requirements
- specified regulated pests
- organisms not yet regulated as pests, but which could be potential pests.

1.5 Other considerations for inspection

The decision to use inspection as a phytosanitary measure involves consideration of many factors, including in particular the phytosanitary requirements of the importing country and the pests of concern. Other factors that require consideration may include:

- the mitigation measures taken by the exporting country
- whether inspection is the only measure or combined with other measures
- commodity type and intended use
- place/area of production
- consignment size and configuration
- volume, frequency and timing of shipments
- experience with origin/shipper
- means of conveyance and packaging
- available financial and technical resources (including pest diagnostic capabilities)
- previous handling and processing
- sampling design characteristics necessary to achieve the inspection objectives
- difficulty of pest detection on a specific commodity
- experience and the results of previous inspections
- perishability of the commodity (see also Article VII.2e of the IPPC, 1997)
- effectiveness of the inspection procedure.

1.6 Inspection in relation to pest risk analysis

Pest risk analysis (PRA) provides the basis for technical justification for phytosanitary import requirements. PRA also provides the means for developing lists of regulated pests requiring phytosanitary measures, and identifies those for which inspection is appropriate and/or identifies commodities that are subject to inspection. If new pests are reported during inspection, PRA is also used for evaluating these pests and developing recommendations for appropriate actions when necessary.

When considering inspection as an option for risk management and the basis for phytosanitary decision making, it is important to consider both technical and operational factors associated with a particular type and level of inspection. Such an inspection may be required to detect specified regulated pests at the desired level and confidence depending on the risk associated with them (see also ISPM No. 11: *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004, and ISPM No. 21: *Pest risk analysis for regulated non-quarantine pests*).

2. Specific Requirements

The technical requirements for inspection involve three distinct procedures that should be designed with a

view to ensuring technical correctness while also considering operational practicality. These procedures are:

- examination of documents associated with a consignment
- verification of consignment identity and integrity
- visual examination for pests and other phytosanitary requirements (such as freedom from soil).

Certain aspects of inspection may differ depending on the purpose, such as for import/export purposes, or verification/risk management purposes.

2.1 Examination of documents associated with a consignment

Import and export documents are examined to ensure that they are:

- complete
- consistent
- accurate
- valid and not fraudulent (see section 1.4 of ISPM No. 12 *Guidelines for phytosanitary certificates*).

Documents that may be associated with import and/or export certification include*:*

- phytosanitary certificate/re-export phytosanitary certificates
- manifest (including bills of lading, invoice)
- import permit
- treatment documents/certificates, marks (such as provided for in ISPM No. 15: *Guidelines on regulating wood packaging material in international trade*) or other indicators of treatment
- certificate of origin
- field inspection certificates/reports
- producer/packing records
- certification programme documents (e.g. seed potato certification programmes, pest free area documentation)
- inspection reports
- commercial invoices
- laboratory reports.

Problems encountered with either import or export documents should be investigated first with the parties providing the documents before further action is taken.

2.2 Verification of consignment identity and integrity

The inspection for identity and integrity involves checking to ensure that the consignment is accurately described by its documents. The identity check verifies whether the type of plant or plant product or species is in accordance with the phytosanitary certificate. The integrity check verifies if the consignment is clearly identifiable and the quantity and status is as stated in the phytosanitary certificate. This requires a physical examination of the consignment to confirm the identity and integrity, including checking for seals, safety conditions and other relevant physical aspects of the shipment that may be of phytosanitary concern. Actions taken based on the result will depend on the extent and nature of the problem encountered.

2.3 Visual examination

Related aspects of visual examination include its use for pest detection and for verifying compliance with phytosanitary requirements.

2.3.1 Pests

A sample is taken from consignments/lots to determine if a pest is present, or if it exceeds a specified level. The ability to detect in a consistent manner the presence of a regulated pest with the desired confidence level requires practical and statistical considerations, such as the probability of detecting the pest, the size of the lot, the desired level of confidence, the sample size and the intensity of the inspection (see ISPM on sampling [under development]).

If the objective of inspection is the detection of specified regulated pests to meet phytosanitary import requirements, then the sampling method should be based on a probability of detecting the pest that satisfies the corresponding phytosanitary requirements.

If the objective of the inspection is the verification of the general phytosanitary condition of a consignment/lot, such as when:

- no specified regulated pests have been identified
- no specified pest level has been identified for regulated pests
- the aim is to detect pests when there has been a failure of a phytosanitary measure,

then sampling methodology should reflect this.

The sampling method adopted should be based on transparent technical and operational criteria, and should be consistently applied (see also ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*).

2.3.2 Compliance of phytosanitary requirements

Inspection can be used to verify the compliance with some phytosanitary requirements. Examples include:

- treatment
- degree of processing
- freedom from contaminants (e.g. leaves, soil)
- required growth stage, variety, colour, age, degree of maturity etc.
- absence of unauthorized products
- consignment packaging and shipping requirements
- origin of consignment/lots
- point of entry.

2.4 Inspection methods

The inspection method should be designed either to detect the specified regulated pests on or in the commodity being examined, or to be used for a general inspection for non-specified organisms not yet regulated as pests. The inspector visually examines units in the sample until the target or other pest has been detected or all sample units have been examined. At that point, the inspection may cease. However, additional sample units may be examined if the NPPO needs to gather additional information concerning the pest(s) and the commodity, for example if the pest is not observed, but signs or symptoms are. The inspector may also have access to other non visual tools (e.g. hand-held ELISA kits, X-ray machines) to assist the inspection process.

It is important that:

- examination of the sample be undertaken as soon as reasonably possible after the sample has been drawn and that the sample is as representative of the consignment/lot as possible.
- techniques are reviewed to take account of experience gained with the technique and of new technical developments.
- procedures are put in place to ensure the independence, integrity, traceability and security of samples for each consignment/lot.
- results of the inspection are documented.

Inspection procedures should be in accordance with the PRA where appropriate, and should be consistently applied.

2.5 Inspection outcome

The result of the inspection allows a decision to be made as to whether the consignment meets phytosanitary requirements. If phytosanitary requirements are met, consignments for exports may be provided with appropriate certification, e.g. phytosanitary certificates, and consignments for import will be released.

If phytosanitary requirements are not met, further actions can be taken. These actions may be determined by the nature of the findings, considering pest level or other inspection objectives and the circumstances. Likewise, the consequences of detention or rejection require consideration of the circumstances and alternatives. In some cases, corrective action may be taken (e.g. correcting documentation) while other situations may require stronger action such as treatment, rejection or the destruction of a consignment. All consignments should be safeguarded to maintain their phytosanitary integrity until decisions can be taken.

In many cases, pests or signs of pests that have been detected may require identification or a specialized analysis in a laboratory or by a specialist before a determination can be made on the phytosanitary status of the consignment. It may be decided that emergency measures are needed where new or previously unknown pests are found. A system for properly documenting and maintaining samples and/or specimens should be in place to ensure trace-back to the relevant consignment and to facilitate later review of the results if necessary.

In cases of repeated non-compliance, amongst other actions, the intensity and frequency of inspections for certain consignments may be increased.

2.6 Review of inspection systems

NPPOs should conduct periodic reviews of import and export inspection systems to validate the appropriateness of their design and to determine any course of adjustments needed to ensure that they are technically sound.

Audits should be conducted in order to review the validity of the inspection systems. An additional inspection may be a component of the audit.

2.7 Transparency

As part of the inspection process, information concerning inspection procedures for a commodity should be documented and made available on request to the parties concerned in application of the transparency principle (ISPM No. 1: *Principles of plant quarantine as related to international trade*). This information may be part of bilateral arrangements covering the phytosanitary aspects of a commodity trade.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

GUIDELINES FOR THE DETERMINATION AND RECOGNITION OF EQUIVALENCE OF PHYTOSANITARY MEASURES

Secretariat of the International Plant Protection Convention
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, ----

CONTENTS

INTRODUCTION

SCOPE

This standard describes the principles and requirements that apply for the determination and recognition of equivalence of phytosanitary measures. It also describes a procedure for equivalence determinations in international trade.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Export certification system, 1997. ISPM No. 7, FAO Rome.
Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for regulating wood packaging material in international trade, 2002. ISPM No. 15. FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS[1]

commodity	A type of plant, plant product, or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]
emergency action	A prompt phytosanitary action undertaken in a new or unexpected phytosanitary situation [ICPM, 2001]
equivalence (of phytosanitary measures)*	The situation where, for a specified pest risk, different phytosanitary measures achieve a contracting party's appropriate level of protection.
fumigation	Treatment with a chemical agent that reaches the commodity wholly or primarily in a gaseous state [FAO, 1990; revised FAO, 1995]
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO 1990; revised ICPM, 2001]
ISPM	International Standard for Phytosanitary Measures [CEPM, 1996; revised ICPM, 2001]
inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly inspect]

[1] Term marked with (*) is revised

pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]
pest risk assessment (for quarantine pests)	Evaluation of the probability of the introduction and spread of a pest and of the associated potential economic consequences [FAO, 1995; revised ISPM No 11, 2001]
phytosanitary measure (agreed interpretation)	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; ICPM, 2002]

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

PRA	Pest Risk Analysis [FAO, 1995; revised ICPM, 2001]
regulated pest	A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]
required response	A specified level of effect for a treatment [ISPM No. 18, 2003]
surveillance	An official process which collects and records data on pest occurrence or absence by survey, monitoring or other procedures [CEPM, 1996]
systems approach(es)	The integration of different pest risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of phytosanitary protection [ISPM No. 14, 2002]
treatment	Officially authorized procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003]

OUTLINE OF REQUIREMENTS

Equivalence is one of the IPPC general principles (ISPM No. 1: *Principles of plant quarantine as related to international trade*).

Equivalence generally applies to cases where phytosanitary measures already exist for a specific pest associated with trade in a commodity. Equivalence determinations are based on the specified pest risk and equivalence may apply to individual measures, a combination of measures, or integrated measures in a systems approach.

A determination of equivalence requires an assessment of phytosanitary measures to determine their effectiveness in mitigating a specified pest risk(s). The determination of equivalence of measures may also include an evaluation of the exporting contracting party's phytosanitary systems or programs that support implementation of those measures. Normally, the determination involves a sequential process of information exchange and evaluation, and is generally an agreed procedure between importing and exporting contracting parties. Information is provided in a form that allows the evaluation of existing and proposed measures for their ability to meet the importing contracting party's appropriate level of protection[2].

The exporting contracting party may request information from the importing contracting party on the contribution that its existing measures make to meeting its appropriate level of protection. The exporting contracting party may propose an alternative measure(s), indicating how this measure achieves the required level of protection, and this is evaluated by the importing contracting party. In some cases, such as where technical assistance is provided, importing contracting parties may make proposals for alternative phytosanitary measures. Contracting parties should endeavour to undertake equivalence determinations and resolve any differences within a reasonable period of time.

[2] This term is defined in the *Agreement on the Application of Sanitary and Phytosanitary Measures* of the World Trade Organization (WTO-SPS Agreement). Many WTO members otherwise refer to this concept as the "acceptable level of risk".

REQUIREMENTS

1. General Considerations

Equivalence is described as general principle No. 7 in ISPM No. 1 (*Principles of plant quarantine as related to international trade*, 1993): "*Equivalence: Countries shall recognize as being equivalent those phytosanitary measures that are not identical but which have the same effect*". Furthermore, the concept of equivalence and the obligation of contracting parties to observe the principle of equivalence is an integral element in other existing ISPMs. In addition, equivalence is described in Article 4 of the WTO-SPS Agreement.

The process of recognizing equivalence is the objective examination of alternative phytosanitary measures proposed to determine if they achieve the appropriate level of protection of an importing country as indicated by existing measures of that country.

Contracting parties recognize that alternative phytosanitary measures can achieve their appropriate level of protection. Therefore, while not formalized under the title of “equivalence”, there is widespread application of equivalence in current phytosanitary practices.

To manage a specified pest risk and achieve a contracting party's appropriate level of protection, equivalence may be applied to:

- an individual measure,
- a combination of measures, or
- integrated measures in a systems approach.

In the case of a systems approach, alternative measures may be proposed as equivalent to one or more of the integrated measures, rather than changing the entire systems approach. Equivalence arrangements are applicable for commodities rather than for individual consignments.

The evaluation for equivalence of phytosanitary measures may not be limited to an assessment of the measures alone, but may also involve consideration of aspects of the export certification system or other factors associated with the implementation of pest risk management measures.

This standard provides guidelines for situations where an importing contracting party has a phytosanitary measure in place, or is proposing a new measure, and an exporting contracting party proposes an alternative measure to achieve the importing contracting party’s appropriate level of protection. The alternative measure is then evaluated for equivalence.

In some cases importing contracting parties list a number of phytosanitary measures that are considered to achieve their appropriate level of protection. Contracting parties are encouraged to include two or more equivalent measures for regulated articles as part of their import regulations. This allows for taking into account different or changing phytosanitary situations in exporting countries. These measures may differ in the extent to which they achieve or exceed the contracting party’s appropriate level of protection. The evaluation of the equivalence of such measures listed by an importing contracting party is not the primary subject of this standard.

Although equivalence is generally a bilateral process between importing and exporting contracting parties, multilateral arrangements for comparing alternative measures take place as part of the standard setting process of the IPPC. For example, there are alternative measures approved in ISPM No 15: *Guidelines for regulating wood packaging material in international trade*.

2. General Principles and Requirements

2.1 Sovereign authority

Contracting parties have sovereign authority, in accordance with applicable international agreements, to apply phytosanitary measures to protect plant health within their territories and to determine their appropriate level of protection to plant health. As part of a contracting party’s sovereign authority to regulate plants, plant products and other regulated articles (Article VII.1 of the IPPC, 1997), a contracting party has the right to make decisions relating to determinations of equivalence. In order to promote cooperation in achieving the aims of the Convention (Article

VIII.1 of the IPPC, 1997), an importing contracting party should consider and, as appropriate, evaluate the equivalence of phytosanitary measures.

2.2 Other relevant principles of the IPPC

In equivalence evaluations, contracting parties should take into account the following principles:

- minimal impact (Article VII.2g of the IPPC, 1997)
- modification (Article VII.2h of the IPPC, 1997)
- transparency (Articles VII.2b, 2c, 2i and VIII.1a of the IPPC, 1997)
- harmonization (Article X.4 of the IPPC, 1997)
- risk analysis (Articles II and VI.1b of the IPPC, 1997)
- managed risk (Article VII.2a and 2g of the IPPC, 1997)
- non-discrimination (Article VI.1a of the IPPC, 1997).

2.3 Scientific justification for equivalence

Assessments of equivalence should be risk-based, using an evaluation of available scientific information, either through PRA or by evaluation of the existing measures and the proposed measures. The exporting contracting party has the responsibility for providing the scientific justification to demonstrate that the alternative measures reduce the specified pest risk and that they achieve the appropriate level of protection of the importing contracting party. In some cases (e.g. as described in section 3.2), however, importing contracting parties may propose alternative measures for the exporting contracting party to consider. This information may be qualitative and/or quantitative as long as comparison is possible.

Although the alternative measures need to be examined, a new complete pest risk assessment may not necessarily be required since, as trade in the commodity is already occurring, the importing country should have at least some PRA-related data.

2.4 Non-discrimination in the application of the equivalence of phytosanitary measures

The principle of non-discrimination requires that when equivalence of phytosanitary measures is granted for one exporting contracting party, this should also apply to contracting parties with the same phytosanitary status and similar conditions for the same commodity and/or pest. Therefore, an importing contracting party which recognizes the equivalence of alternative phytosanitary measures of an exporting contracting party should ensure that it acts in a non-discriminatory manner. This applies both to applications from third countries for recognition of the equivalence of the same or similar measures, and to the equivalence of any domestic measures.

It should be recognized that equivalence of phytosanitary measures does not, however, mean that when a specific measure is granted equivalence for one exporting contracting party, this applies automatically to another contracting party for the same commodity or pest. Phytosanitary measures should always be considered in the context of the pest status and phytosanitary regulatory system of the exporting contracting party, including the policies and procedures.

2.5 Information exchange

Contracting parties have obligations under the IPPC to provide and exchange information, which should be made available for equivalence determinations. This includes making available, on request, the rationale for phytosanitary requirements (Article VII.2c of the IPPC, 1997) and cooperating to the extent practicable in providing technical and biological information necessary for pest risk analysis (Article VIII of the IPPC, 1997). Contracting parties should aim to limit any data requests associated with an evaluation of equivalence to those which are necessary for this evaluation.

To facilitate discussions on equivalence the importing contracting party should, on request, provide information describing how its existing measures reduce the risk of the specified pest and how they achieve its appropriate level of protection. This information may be provided in either quantitative or qualitative terms. Such information should assist the exporting contracting party in understanding the existing measures. It may also help the exporting contracting party to explain how its proposed alternative measures reduce the pest risk and achieve the importing contracting party's appropriate level of protection.

2.6 Technical assistance

In accordance with Article XX of the IPPC (1997), contracting parties are encouraged to consider providing technical assistance for the development of measures based on equivalence if requested by another contracting party.

2.7 Timeliness

Contracting parties should endeavour to determine the equivalence of phytosanitary measures and to resolve any differences within a reasonable period of time.

3. Specific Requirements for the Application of Equivalence

3.1 Specific pests and commodities

The process of comparing alternative phytosanitary measures for the purpose of determining their equivalence usually relates to a specified export commodity and specified regulated pests identified through pest risk analysis.

3.2 Existing measures

Equivalence generally applies to cases where the importing contracting party has already existing measures for the current trade concerned. However, it may also apply where new measures are proposed by the importing contracting party. Usually an exporting contracting party presents an alternative measure that is intended to achieve the importing contracting party's appropriate level of protection. In some cases, such as where technical assistance is being provided, contracting parties may propose alternative measures for the consideration of other contracting parties.

Where new commodities are presented for importation and no measures exist, contracting parties should refer to ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms,* 2004) and ISPM No. 21 (*Pest risk analysis for regulated non-quarantine pests*) for the normal PRA procedure.

3.3 Entry into consultation

When requested, contracting parties are encouraged to enter into consultations with the aim of facilitating a determination of equivalence.

3.4 Agreed procedure

Contracting parties should agree on a procedure to determine equivalence. This may be based on the procedure described in Annex 1 of this standard or another agreed procedure.

3.5 Factors considered in determining equivalence

The determination of the equivalence of phytosanitary measures depends on a number of factors. These may include:

- the effect of the measure as demonstrated in laboratory or field conditions
- the examination of relevant literature on the effect of the measure
- the results of experience in the practical application of the measure
- the factors affecting the implementation of the measure (e.g. the policies and procedures of the contracting party).

The effect of phytosanitary measures implemented in a third country may be considered as reference. Information on the measure is used by the importing contracting party to assess the contribution of the alternative measure in reducing the pest risk to a level that provides the appropriate level of protection.

When comparing existing measures and measures proposed as equivalent, importing and exporting contracting parties should assess the ability of the measures to reduce a specified pest risk. The proposed measures should be assessed for their ability to achieve the importing contracting party's appropriate level of protection. In cases where the effects of both the existing measures and the proposed measures are expressed in the same way (i.e. the same type of required response), the

effects may be compared directly for their ability to reduce the pest risk. For example, a fumigation treatment and a cold treatment may be compared for their effects based on mortality.

Where measures are expressed differently, they may be difficult to compare directly. In such cases, the proposed measures should be assessed for their ability to achieve the importing contracting party's appropriate level of protection. This may require data to be converted or extrapolated so that common units are used before comparison is possible. For example, effects such as mortality and an area of low pest prevalence may be compared if considered in relation to pest freedom at an agreed level of confidence (for example per shipment or per year).

When determining equivalence, a comparison of specific technical requirements of the existing and proposed measures may suffice. In some circumstances, however, the determination of whether a proposed measure achieves the appropriate level of protection may need to be considered in relation to the capacity of the exporting country to apply this measure**.** In the cases where trade is already established between contracting parties, this provides knowledge about and experience with the exporting contracting party's phytosanitary regulatory systems (e.g. legal, surveillance, inspection, certification, etc.) This knowledge and experience should strengthen confidence between parties and assist, if necessary, with the evaluation of an equivalence proposal. In relation to such information, an importing contracting party may require updated information, when technically justified, of procedures of the exporting contracting party related specifically to the implementation of thee phytosanitary measures proposed as equivalent.

The final acceptance of a proposed measure may depend on practical considerations such as availability/approval of the technology, unintended effects of the proposed measure (e.g. phytotoxicity), and operational and economic feasibility.

3.6 Non-disruption of trade

A submission of a request for recognition of equivalence should not in itself alter the way in which trade occurs; it is not a justification for disruption or suspension of existing trade or existing phytosanitary import requirements.

3.7 Provision of access

In order to support an importing contracting party's consideration of an equivalence request, the exporting contracting party should facilitate access by the importing contracting party to relevant sites to conduct any reviews, inspections or verifications for an equivalence determination when technically justified.

3.8 Review and monitoring

After the recognition of equivalence, and to provide continued confidence in the equivalence arrangements, contracting parties should implement the same review and monitoring procedures as for similar phytosanitary measures. These may include assurance procedures such as audits, periodic checks, reporting of non-compliances (see also ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*) or other forms of verification.

3.9 Implementation and transparency

To achieve the required transparency, amendment of regulations and related procedures should also be made available to other interested contracting parties.

ANNEX 1

Recommendations for a procedure for the determination of equivalence

The procedure that trading partners utilise to determine equivalence may vary depending on the circumstances. However, the interactive procedure described below is recommended for assessing phytosanitary measures in order to make a determination as to their equivalence.

Recommended steps are:

1. The exporting contracting party communicates its interest in an equivalence determination to its trading partner, indicating the specified commodity, the regulated pest(s) of concern and the existing and proposed alternative measures, including relevant data. At the same time it may request from the importing contracting party the technical justification for the existing measures. In discussions on the determination of equivalence, an agreement including an outline of the steps involved, an agenda and a possible timetable may be established.

2. The importing contracting party should describe its existing measures in terms that will help to facilitate a comparison with alternative phytosanitary measures. To the best of its ability, the information provided by the importing contracting party should include the following:

a) the purpose of the phytosanitary measures, including identification of the specific pest risk(s) that these measures are being used to mitigate
b) to the extent possible, how the existing phytosanitary measures achieve the importing contracting party's appropriate level of protection
c) the technical justification for the existing phytosanitary measures, including the PRA where appropriate
d) any additional information that may assist the exporting contracting party in demonstrating that the proposed measures achieve the importing contracting party's appropriate level of protection.

3. The exporting contracting party provides the scientific information that it believes demonstrates equivalence of phytosanitary measures, and makes a request for equivalence. This information should be in a form suitable for comparison with the information provided by the importing contracting party and which therefore facilitates the necessary evaluation by the importing contracting party. This should include the following elements:

a) the description of the proposed alternative measures
b) the purpose of the measures
c) to the extent possible, the contribution of the proposed alternative measures in achieving the importing contracting party's appropriate level of protection
d) information on how the measures were evaluated (e.g. laboratory testing, statistical analysis, practical operational experience), and the performance of the measures in practice
e) a comparison between the proposed alternative measures and the importing contracting party's existing measures for same pest risk
f) information on technical and operational feasibility of the proposed alternative measures.

4. The importing contracting party receives and evaluates the proposed alternative phytosanitary measures, taking into account, but not being limited to the following :

a) the submission from the exporting contracting party, including supporting information regarding the effectiveness of the proposed alternative measures
b) the degree to which the alternative phytosanitary measures achieve the appropriate level of protection, either on the basis of qualitative or quantitative information
c) information regarding the method, action and operation of the proposed alternative phytosanitary measures in preventing or reducing the specified pest risk
d) the operational and economic feasibility of adopting the proposed alternative phytosanitary measures.

During the review process further clarification may be required. Additional information and/or access to operational procedures may be requested by the importing contracting party in order to complete the assessment. The exporting contracting party should respond to any technical concerns raised by the

importing contracting party by providing relevant information and/or providing access to relevant information or sites to facilitate reviews, inspections or other verifications necessary for making an equivalence determination.

5. The importing contracting party should notify the exporting contracting party of its decision and provide, upon request, an explanation and scientific justification for its determination as quickly as possible.

6. In the event of a rejection of the request for equivalence, efforts should be made to resolve differences of opinion through bilateral dialogue.

7. If equivalence is recognized by the importing contracting party, implementation should be achieved by the prompt amendment of the import regulations and any associated procedures of the importing contracting party. The amendments should be communicated to contracting parties as soon as possible (Article VII.2b of the IPPC, 1997).

8. An audit and monitoring procedure may be established and included in the plan or arrangement which implements any recognized equivalence measures or programmes.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

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

Secretariat of the International Plant Protection Convention
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 20...

CONTENTS

INTRODUCTION

SCOPE

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

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

REFERENCES

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest reporting, 2002. ISPM No. 17, FAO, Rome.
Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

DEFINITIONS[2]

area	An officially defined country, part of a country or all or parts of several countries [FAO, 1990; revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]
beneficial organism*	Any organism directly or indirectly advantageous to plants or plant products, including biological control agents
biological control**	Pest control strategy making use of living natural enemies, antagonists, competitors or other biological control agents. [formerly biological control (biocontrol)]
biological control agent**	A natural enemy, antagonist or competitor, or other organism, used for pest control
competitor	An organism which competes with pests for essential elements (e.g. food, shelter) in the environment [ISPM N° 3, 1996]
consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]
control (of a pest)	Suppression, containment or eradication of a pest population [FAO, 1995]

[1] Nothing in this standard shall affect the rights or obligations of contracting parties under other international agreements.
[2] Terms marked with an (*) are new, terms marked with an (**) are revised

ecosystem	A dynamic complex of plant, animal and micro-organism communities and their abiotic environment interacting as a functional unit
emergency measure	A phytosanitary regulation or procedure established as a matter of urgency in a new or unexpected phytosanitary situation. An emergency measure may or may not be a provisional measure [ICPM, 2001]
entry (of a consignment)	Movement through a point of entry into an area [FAO, 1995]
host range**	Species capable, under natural conditions, of sustaining a specific pest or other organism
Import Permit	[to be added - revised definition presented for adoption in "amendments to the Glossary"]
infestation (of a commodity)	Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection [CEPM, 1997; revised CEPM, 1999]
inundative release**	The release of large numbers of a mass-produced biological control agents or beneficial organisms with the expectation of achieving a rapid effect
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
legislation	Any act, law, regulation, guideline or other administrative order promulgated by a government [ISPM N° 3, 1996]
National Plant Protection Organization	Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization (National)]
natural enemy**	An organism which lives at the expense of another organism in its area of origin and which may help to limit the population of that organism. This includes parasitoids, parasites, predators, phytophagous organisms and pathogens
naturally occurring	A component of an ecosystem or a selection from a wild population, not altered by artificial means [ISPM N° 3, 1996]
NPPO	National Plant Protection Organization [FAO, 1990; revised ICPM, 2001]
organism**	Any biotic entity capable of reproduction or replication in its naturally occurring state
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]
Phytosanitary Certificate	Certificate patterned after the model certificates of the IPPC [FAO, 1990]
phytosanitary measure	Any legislation, regulation or official procedure having the purpose to prevent

(agreed interpretation)	the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; ICPM, 2002]

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

quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing and/or treatment [FAO, 1990; revised FAO, 1995; CEPM, 1999]
reference specimen(s)*	Individual specimen(s) from a specific population conserved in a reference culture collection and, where possible, in publicly available collection(s)
regulated article	Any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved [FAO, 1990; revised FAO, 1995; IPPC, 1997]
SIT	sterile insect technique
sterile insect*	An insect that, as a result of a specific treatment, is unable to reproduce
sterile insect technique*	Method of pest control using area-wide inundative release of sterile insects to reduce reproduction in a field population of the same species
treatment	Officially authorized procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003]

OUTLINE OF REQUIREMENTS

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

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

NPPOs and other responsible authorities should:

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

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

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

BACKGROUND

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

The IPPC (1997) contains the following provision in relation to the regulation of biological control agents and other beneficial organisms. Article VII.1 states:

"With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may: ...
c) prohibit or restrict the movement of regulated pests into their territories;
d) prohibit or restrict the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into their territories."

Section 4.1 of ISPM No. 20 (*Guidelines for a phytosanitary import regulatory system*), contains a reference to the regulation of biological control agents; it states:

"*Imported commodities that may be regulated include articles that may be infested or contaminated with regulated pests. ... The following are examples of regulated articles: ... pests and biological control agents.*"

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

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

The IPPC (1997) takes into account internationally approved principles governing the protection of the environment (Preamble). Its purpose includes promoting appropriate phytosanitary measures (Article I.1). Therefore, in carrying out pest risk assessment and analysis in accordance with this and other appropriate ISPMs, and in developing and applying related phytosanitary measures, contracting parties should consider the potential for broader environmental impacts resulting from releasing biological control agents and other beneficial organisms[3] (for example, impacts on non-target invertebrates).

Most of this standard is based on the premise that a biological control agent or other beneficial organism may be a potential pest itself, and in this sense Article VII.1c of the IPPC (1997) applies because contracting parties may prohibit or restrict the movement of regulated pests into their territories. In some situations,

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

biological control agents and other beneficial organisms may act as a carrier or pathway for plant pests, hyperparasitoids, hyperparasites and entomopathogens. In this sense, biological control agents and other beneficial organisms may be considered to be regulated articles as described in Article VII.1 of the IPPC (1997) and ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*.

Purpose of the standard

The objectives of the standard are to:

- facilitate the safe export, shipment, import and release of biological control agents and other beneficial organisms by providing guidelines for all public and private bodies involved, particularly where national legislation and regulations for their use does not exist.
- describe the need for cooperation between importing and exporting countries so that:
    - benefits to be derived from using biological control agents are achieved with minimal adverse effects
    - practices which ensure efficient and safe use while minimizing environmental risks due to improper handling or use are promoted.

Guidelines in support of these objectives are described that:

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

REQUIREMENTS

1. Designation of Responsible Authority and Description of General Responsibilities

1.1 Contracting parties

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

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

1.2 General responsibilities

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

The NPPO or other responsible authority should:

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

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

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

2. Pest Risk Analysis

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

Pest risk assessment should be conducted in accordance with ISPM No. 2 (*Guidelines for pest risk analysis*) and/or stage 2 of ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) as appropriate, taking into account uncertainties, and potential environmental consequences, as provided for in those standards. In addition to conducting pest risk assessment, contracting parties should also consider possible impacts on the environment, such as impacts on non-target invertebrates.

Most contracting parties require PRA to be completed prior to import and, as described in ISPM No. 20 (*Guidelines for a phytosanitary import regulatory system*), technical justification, such as through PRA, is required to determine if pests should be regulated and the strength of phytosanitary measures to be taken against them. Where applicable, if pest risk assessment of the proposed organism has not been undertaken or

completed prior to import, it should be completed prior to release (see section 7). However, it is recognized that biological control agents and other beneficial organisms may need to be imported for research and evaluation in secure facilities prior to release. ISPM No. 20 also states that contracting parties may make special provision for the import of biological control agents and other beneficial organisms for scientific research, and that such imports may be authorized subject to the provision of adequate safeguards. The NPPO should be prepared for such imports with the expectation that, where necessary, a full PRA in accordance with ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms,* 2004) will be completed prior to release. When non-phytosanitary risks are identified, these may need to be referred to other appropriate authorities for possible action.

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

3. Responsibilities of Contracting Parties prior to Import

3.1 Responsibilities of the importing contracting party

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

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

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

3.1.3 Issue regulations stating requirements to be fulfilled by the exporting country, the exporter and the importer[4]. Where appropriate, these may include:

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

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

- requirements for the facilities in which the biological control agent or other beneficial organisms may be held.

3.1.4 Ensure that procedures are in place for the documentation of:
- pest risk analysis
- the import (identity, origins, dates)
- nurturing, rearing or multiplication
- release (quantities released, dates, locations), and
- any other relevant data.

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

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

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

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

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

3.1.9 Consider, through the pest risk assessment process (consistent with the principles of necessity and minimal impact), if, after a first import or release, further imports of the same biological control agent or other beneficial organism may be exempted from some or all of the requirements for import. The publication of lists of approved and prohibited biological control agents and other beneficial organisms may also be considered.

3.2 Responsibilities of the NPPO of an exporting country

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

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

4. Documentary responsibilities of importer prior to import

4.1 Documentary requirements related to the target organism

Prior to the first importation, the importer of biological control agents or other beneficial organisms should provide information as required by the NPPO or other responsible authority of the importing

contracting party. For all biological control agents or other beneficial organisms, this information includes accurate identification of the target organism(s), generally at the species level. Where a biological control agent intended to control a pest is being imported, the information on the target pest may also include:

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

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

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

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

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

4.3 Documentary requirements related to potential hazards and emergency actions

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

- identifies potential health hazards and analyzes the risks[5] posed to staff operatives exposed when handling biological control agents or other beneficial organisms under laboratory, production and application conditions.
- details emergency action plans or procedures already in existence, should the biological control agent or beneficial organism display unexpected adverse properties (the NPPO or other responsible authority of the importing contracting party is responsible for developing or adopting emergency plans or procedures, as appropriate, for use within the importing country).

4.4 Documentary requirements related to research in quarantine

In addition to the information described in points 4.1 – 4.3, an importer of biological control agents or other beneficial organisms proposed for research in quarantine only, should also provide the following information:

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

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

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

5. Responsibilities of Exporter

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

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

5.1 Specific responsibilities regarding organisms intended for inundative release

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

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

6.1 Inspection

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

6.2 Quarantine

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

6.3 Release

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

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

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

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

7.1 Release

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

7.2 Documentation

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

7.3 Monitoring and evaluation

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

7.4 Emergency measures

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

7.5 Communication

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

7.6 Reporting

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

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

1. REVISED TERMS AND DEFINITIONS

Additional Declaration	A statement that is required by an importing country to be entered on a Phytosanitary Certificate and which provides specific additional information on a consignment in relation to regulated pests
compliance procedure (for a consignment)	Official procedure used to verify that a consignment complies with stated requirements in relation to regulated pests
chemical pressure impregnation	Treatment of wood with a chemical preservative through a process of pressure in accordance with an official technical specification
detention	Keeping a consignment in official custody or confinement, as a phytosanitary measure (see quarantine)
ecosystem	A dynamic complex of plant, animal and micro-organism communities and their abiotic environment interacting as a functional unit
emergency measure	A phytosanitary measure established as a matter of urgency in a new or unexpected phytosanitary situation. An emergency measure may or may not be a provisional measure.
heat treatment	The process in which a commodity is heated until it reaches a minimum temperature for a minimum period of time according to an official technical specification
Import Permit	Official document authorizing importation of a commodity in accordance with specified phytosanitary import requirements
phytosanitary action	An official operation, such as inspection, testing, surveillance or treatment, undertaken to implement phytosanitary measures.
phytosanitary procedure	Any official method for implementing phytosanitary measures including the performance of inspections, tests, surveillance or treatments in connection with regulated pests
systems approach(es)	The integration of different risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of protection against regulated pests
treatment	Official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization

2. NEW TERMS AND DEFINITIONS

habitat	Part of an ecosystem with conditions in which an organism naturally occurs or can establish
pest risk assessment (for regulated non-quarantine pests)	Evaluation of the probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact

pest risk management (for regulated non-quarantine pests)	Evaluation and selection of options to reduce the risk that a pest in plants for planting causes an economically unacceptable impact on the intended use of those plants
phytosanitary import requirements	Specific phytosanitary measures established by an importing country concerning consignments moving into that country
security (phytosanitary)	Maintenance of the integrity of a consignment by the appropriate phytosanitary measures

3. DELETIONS

- Ecoarea
- Quarantine (of a biological control agent)