

REPORT

Rome,
Italy,
10–14 November
2003

**Standards
Committee
Third meeting**

**Meeting Report
AGP/2003**

**REPORT OF THE THIRD MEETING OF THE
STANDARDS COMMITTEE**

Rome, Italy: 10–14 November 2003



**FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2003**

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1. OPENING OF THE MEETING

The meeting was opened by Mr Vereecke, Chairperson of the Standards Committee (SC), who welcomed the participants to the Third Meeting in particular three new members of the SC: Mr Challaoui (Morocco), Mr Mahgoub (Sudan) and Mr Wolff (Canada). He noted that the Standards Committee Working Group (SC-7) had met the previous week to consider comments on draft standards received during country consultation.

2. ADOPTION OF THE AGENDA

The SC adopted the agenda, and added points on the outcomes of the Focus Group on Standards Development and of the Informal Working Group on Strategic Planning and Technical Assistance, on the clarification of the role of stewards for ISPMs, and on the finalization of the specification on guidelines for consignments in transit.

3. REPORT OF THE STANDARDS COMMITTEE WORKING GROUP (SC-7)

The SC noted that a detailed report of the SC-7 in May had been prepared during the meeting. This report had helped understanding the development of draft standards and would improve transparency. The SC agreed that the same type of report, which had originally been intended only to inform the SC20, should be prepared for future SC-7 May meetings, and should be made public after appropriate clearance from SC.

The SC was informed of the representatives which had taken part in the SC7 meeting of the previous week:

- Ms Asna Booty Othman (Asia)
- Mr Abdellah Challaoui (Africa)
- Mr Mohammad Katbeh Bader (Near East)
- Mr Narcy Klag (North America)
- Mr Alan Pemberton (Europe)
- Mr Odilson Ribeiro e Silva (Latin America and the Caribbean)

Mr Klag, Chairperson of the SC-7, reported that the tables of country comments presented to the SC-7 contained more than 300 comments per draft, some of them addressing several issues. The SC7 had been able to review comments and accordingly modify the two drafts on *Guidelines for an import regulatory system* and *Pest risk analysis for regulated non-quarantine pests*. It did not have time to consider in detail the draft supplement to ISPM No. 11 (*Pest risk analysis for quarantine pests*) on *Pest Risk Analysis for living modified organisms*. It also had not finalized the Specification No. 13 on an ISPM on guidelines for consignments in transit, and recommended that the SC-20 finalize it, noting that an Expert Working Group was scheduled in early 2004.

4. ADOPTION OF REPORT OF THE SECOND MEETING OF THE STANDARDS COMMITTEE

The report of the Second Meeting of the SC was considered and adopted by the SC.

5. GUIDELINES FOR A PHYTOSANITARY IMPORT REGULATORY SYSTEM

Mr Klag introduced the draft text prepared by the SC-7 and briefly explained changes recommended by the SC-7. Several country comments had been identified by the SC7 for discussion at the SC20. The SC considered these and modified the text accordingly. Three main issues were discussed.

Several country comments related to the fact that the standard applied to “phytosanitary” systems. The SC7 had included a general statement in the Scope of the draft to specify that legislation, regulation and measures in the standard referred to “phytosanitary”, and had also changed the title of the draft to “*Guidelines for a phytosanitary import regulatory system*”.

Concerns were raised on the respective obligations, rights and responsibilities of NPPOs versus contracting parties in the IPPC and how these were incorporated into the draft standard. The SC sought legal advice on this issue. Wording agreed upon by a majority of SC members was introduced

in various parts of the text, in particular to clarify that some obligations, rights and responsibilities are attributed to contracting parties in the IPPC, but that these may choose to assign some responsibilities to the NPPO.

Some countries preferred that the references in the “reference” section should be mentioned in chronological order. The SC envisaged several possible orders but finally concluded that the alphabetical order should be used, as currently, noting that each standard contained also a list of all current ISPMs ordered by number. The question had also been raised of the use of references to other ISPMs within the text. The SC believed that the use of references within ISPMs should be limited to essential ones. In the case of an explicit direction to use another ISPM, the phrasing “according to” could be used, possibly quoting the relevant section of the ISPM referred to. In the case of additional suggestions a wording such as “Information aboutis contained in ISPM ---” could be used. This would help clarify the purpose of references to other ISPMs.

6. PEST RISK ANALYSIS FOR REGULATED NON-QUARANTINE PESTS

Mr Klag presented the draft standard and explained the changes recommended by the SC-7. He noted that one important concern addressed by the SC-7 had been to clarify that the purpose of the risk management stage was to selected options which could be applied to achieve a tolerance level. Within the pest risk management stage, the selection of a tolerance level had also been clearly explained. Some concerns were raised by a number of countries over the need to demonstrate that the plants for planting are *the* main source of infestation that results in economically unacceptable impact. These countries considered that this requirement could result in real practical difficulties in applying the ISPM.

No guidance is given in ISPM No. 16 (*regulated non-quarantine pests*) on the exact meaning of “*the*” in this context. The SC noted that different interpretations could link it to the time of unacceptable economic impact in relation to all sources of infestation (the main source of infestation at the time the unacceptable impact is encountered) or to the conditions in the PRA area regarding other sources of infestation (i.e. the main source of infestation under the conditions of the PRA area). ISPM No. 16 also does not indicate if the influence of official control is to be considered or if the “main source” is established in comparison with the sum of the impact of all other sources, or just compared with any other individual source. If other sources are normally controlled (i.e. the ‘conditions’) in the PRA area and/or if further infestations from other sources occur but the original infestation will normally be expected to result in an unacceptable economic impact irrespective of further infestation, or if the further infestations are not the main source that results in the unacceptable economic impact, then it can be concluded that the plants for planting are the main source of infestation. The SC considered that it may be appropriate to change the phrase to “a main source of infestation”. However, since this phrasing originated directly from ISPM No. 16, it should not be changed in the draft standard. This was an essential issue for the whole concept of regulated non-quarantine pests, and the SC recommended that ISPM No. 16 should be reviewed in regard to this issue, with a priority to be decided by the ICPM.

7. SUPPLEMENT TO ISPM NO. 11 (PEST RISK ANALYSIS FOR QUARANTINE PESTS): PEST RISK ANALYSIS FOR LIVING MODIFIED ORGANISMS

The SC-7 had not had time to consider the comments on this draft and this was done by the SC-20. The SC was able to resolve all technical comments received. Some more general points of discussion are outlined below.

The PRA process as described in ISPM No. 11 includes three stages (initiation, risk assessment and risk management). Several South American countries had suggested that a fourth stage, risk communication, should be added. The SC considered this comment but noted that this issue was wider than LMOs, and could only be considered in a wider revision of ISPM No. 11.

A significant issue in the use of ISPM No. 11 for pest risk analysis for LMOs is the need to determine if the LMO being considered has any potential pest characteristics and therefore needs to be subject to pest risk analysis according to ISPM No. 11. This was covered in the draft in the “Initiation” section.

Different views were expressed in country comments as to where this “pre-screening” step should be included. Several proposals had been made for the structure of the standard. The SC noted that the pre-screening phase would be considered in the revision of ISPM No. 2, and that it would be possible to adopt a text for LMO as an interim measure, recognizing that it would later be revised.

Several structural proposals were made in relation with the structure of the standard and the position of the pre-screening stage. One was to move the pre-screening, and certain other elements, to an appendix. If it was determined that an LMO was a pest, then it would be possible to come back into ISPM No. 11 and carry out the analysis. The other was to leave the pre-screening phase within the initiation stage, but to adjust it (i.e. to move elements from 1.1.4 and 1.1.5 to different places of the standard, some earlier in initiation, and some in Stage 2 (risk assessment). The third position was to leave the text as it was.

The SC extensively discussed this issue. It could not reach an agreement on possible structural modifications to be made to the draft, but was in agreement on the following points, which would be included in the recommendations to be made to the ICPM.

- there were very few substantial technical comments on the draft LMO supplement indicating broad agreement with the technical content.
- most living modified organisms (LMOs) are not pests
- a significant issue in the use of ISPM No. 11 for pest risk analysis for LMOs is the need to determine if the LMO being considered has any potential pest characteristics and therefore needs to be subjected to pest risk analysis according to ISPM No. 11.
- the general issue of determining if an organism is a potential pest, and therefore should be subjected to pest risk analysis, will be considered in the revision of ISPM No. 2 (*Guidelines for pest risk analysis*) and it may be appropriate to revise the supplementary text on LMOs when the revision is completed.
- the supplementary text on LMOs can be proposed for adoption as it stands, and the ICPM should provide guidance to the Secretariat on how this new text should be incorporated with ISPM No. 11 Rev. 1.

In cases where the ICPM requests a supplement to an existing ISPM, it should provide guidance for the expert drafting group on how the supplement should be integrated with the text of the existing ISPM.

8. SPECIFICATIONS

8.1 SPECIFICATION NO. 13 - CONSIGNMENT IN TRANSIT

The SC-7 had not had time to finalize the specification for guidelines for consignments in transit. The SC-20 reviewed and finalized this specification.

8.2 SPECIFICATION NO. 3 - REVISION OF ISPM NO. 2 (GUIDELINES ON PEST RISK ANALYSIS)

The SC reviewed and slightly modified the specification No. 3 on the revision of ISPM No. 2 *Guidelines for pest risk analysis*, to reflect the discussion which arose from the draft supplement on PRA for living modified organisms, i.e. the need to determine if the LMO being considered has any potential pest characteristics and therefore needs to be subjected to pest risk analysis according to ISPM No. 11.

9. PRIORITIES FOR STANDARD SETTING

The meeting discussed priorities for standard setting in light of recent discussions in relation with standard-setting procedures and suggestions by the Strategic Planning and Technical Assistance Working Group (SPTA). The SPTA indicated a list of priorities for draft standards for 2004/2005. The SC agreed and slightly reworded the priorities designated by the SPTA and further recommended that these priorities be submitted to the ICPM for its consideration. These are:

CONCEPT STANDARDS

- Alternative strategies to methyl bromide
- Classification of commodities by level of processing and intended use and phytosanitary risk (including entry of consumption/low risk commodities, and risk analysis for low mobility pests on products for consumption)
- Electronic certification
- Import of plant breeding material
- Post-entry quarantine facilities
- Research protocols for phytosanitary measures
- Sampling.

The SC also recommended that meetings should be convened for some of the expert working groups which were originally due to meet by e-mail, recognizing that they would not be able to complete their task by e-mail:

- Glossary of phytosanitary terms
- Revision of ISPM No. 1 Principles of quarantine in relation to international trade,
- Citrus canker surveillance
- Efficacy of measures.

REFERENCE STANDARDS

- Guidelines for the formatting/drafting of commodity ISPMs
- Guidelines for the formatting/drafting of pest specific ISPMs

COMMODITY-SPECIFIC STANDARDS

- Export certification for potatoes
- Debarking of wood (possible fast-track procedure)

Mr Pemberton expressed doubts on the choice of potato, given the complexity and sensitivity of this topic, and thought that it may be better to choose a commodity that is expected to result in a less complex ISPM than potato.

FORMATION OF TECHNICAL PANELS

If the ICPM approved the fast-track procedure for standard-setting and the creation of Technical Panels, the SC recommended that three Technical Panels should be constituted initially. The precise work programme would depend on final specifications still to be developed but it was recommended that three Technical Panels address the following subject areas:

- diagnostic protocols for specific pests
- fruit flies – pest free areas and systems approaches
- treatments.

10. GLOSSARY ISSUES

After its meeting in February 2003, the Glossary Working Group had held discussions by e-mail, as planned in the work programme, in October 2003. Mr Smith, steward of the Glossary, reported on the different issues. The SC noted that e-mail discussions had proved to be more difficult and not all members had taken part in the discussions. A report of the outcome of the discussions will be prepared.

New terms in draft ISPMs. The GWG had held e-mail discussions on country comments made in relation to terms and definitions, and had suggested, for the three drafts, that the definitions should remain as they were. Comments relating to the modifications of terms/definitions or to the inclusion of new terms could be considered during the next meeting of the Glossary Working Group. The group had noted that the adoption of the standards should not be constrained with the need to add new definitions, which could be developed and approved later. The SC accepted this view and noted that modifications or new terms proposed would be considered at the next meeting of the GWG.

Environmental terms. At its last meeting in February 2003, the GWG had discussed the definitions of terms in the guiding principles of the CBD. In addition, ICPM-5 had requested that definitions of ecosystems, habitats and invasive alien species should be considered. The GWG started work on these issues by e-mail. Draft modified definitions and agreed interpretations had been prepared for terms in the guiding principles, and possible definitions for terms raised by the ICPM had been discussed. However, the SC took note that the GWG could not finalize this discussion by e-mail and would discuss it further in its face-to-face meeting. The ICPM should be informed of this activity.

Packaging. At its last meeting in February 2003, the GWG had agreed to develop a definition for packaging. It examined the draft new definition given in the draft on Guidelines for a phytosanitary import regulatory system, and concluded that this draft was suitable.

Use of "phytosanitary". It had previously been envisaged that the use of phytosanitary could be restricted to regulated pests, and that a definition or agreed interpretation should be developed. The GWG discussed this issue again and was not in favor of restricting this term to regulated pests, or of developing a definition or agreed interpretation. However, it proposed that whenever the term applied only to regulated pests in a glossary definition, this should be explicitly mentioned. Some changes were therefore proposed. The SC noted these changes, which are in Appendix VI. These would go through the normal approval process of country consultation.

Other modifications. At its previous meeting in February 2003, the Glossary Working Group had proposed a number of modifications to the current Glossary. As suggested by the SC-7 in May, strictly editorial modifications will be made by the Secretariat. The SC-20 was asked by e-mail to confirm this procedure. Another proposal, that "phytosanitary regulation or procedure" should be replaced, where it appears, by "phytosanitary measure" is presented in Appendix VI and will go through the normal approval process of country consultation. A few issues remaining from the February meeting of the GWG should be considered at its next meeting in February 2004.

11. FORMAT, PRINTING AND DISTRIBUTION OF ISPMs

At its meeting in February 2003 and during its e-mail discussions in October, the GWG had analyzed the advantages and disadvantages of publishing ISPMs in a single publication. It came to the conclusion that a single publication would be more convenient for users than the current individual booklets and would allow regular review for minor points of revision and editing. This type of publication could be adopted for one or several languages. Several formats could be adopted: a bound book (as OIE produces yearly for its standards) or a binder. The role of electronic version could also be envisaged. The Secretariat had started preparing a compiled English version of the current standards. One issue to be solved was that some ISPMs may contain an earlier version of certain glossary definitions. The Secretariat believed that this issue could be solved by making minor revisions as needed to ISPMs based on earlier definitions and/or if necessary maintaining the earlier definitions, as appropriate, in the standards concerned within the single publication.

The SC agreed that it would be useful for ISPMs to be published in a single publication. It supported that the quality of the publication and paper did not need to be as high as current "green books". It also favored a bound publication. In the future, when more standards would be available, it might be possible to divide the publication into several books. Different views were expressed on whether the glossary should remain a separate publication. The SC noted that the Secretariat should investigate further the issue of cost and resources, for different formats, and report to the SC meeting in May 2004 with a view to presenting a proposal to the ICPM in 2005.

The Secretariat invited the views of the SC on the distribution of ISPMs. Currently, they are first made available in the report of the ICPM, then edited and put on the IPP as soon as possible, and finally "green books" are published. These are mostly distributed on an *ad hoc* basis, especially during meetings. The SC recognized the use of electronic versions of ISPMs, and suggested that contact points should be notified by e-mail when new standards were added to the IPP, or these standards could be sent by e-mail. In addition, each contact point could receive 1 or 2 copies of each new ISPM,

and be informed that more copies were available on request. Groups of countries wishing to have special arrangements (such as RPPOs) would have to agree between themselves and notify the Secretariat.

12. SC20/SC7 TIMING AND MEMBERSHIP ISSUES

The Secretariat raised several issues in relation with the operation of the SC7-SC20. The SC noted that the system was new and could be reviewed in a few years when more experience would have been gained. The following points were noted.

SC20 membership. At the end of a 2-year term (basic duration of membership on the SC according to the rules), members can be renominated or replaced. The Secretariat will write to all ICPM members indicating that SC20 members from their regions will need to be renominated or replaced. Members will need to be confirmed at ICPM6.

Development of specifications. The May meeting of the SC-7 develops specifications based on the decisions by the ICPM on standards development, and these are then approved by the SC-20, by e-mail. This results in a considerable delay in developing specifications, and working groups need to be convened even before the specification is approved.

Formation of the SC-7. Membership and chair of the SC-7 is determined by the SC-20. However, the SC7 meets twice (May and November) before the first yearly meeting of SC-20. The SC noted that this would not be an issue in 2004 given the decision taken under point 13.

Replacement of casual vacancies in SC7. In case of a vacancy in the SC-7, the Secretariat could attempt, as this year, to fill the vacancy with another SC-20 member from that region, on an *ad-hoc* basis. The Secretariat could consult with the Chair of the SC-20, and the SC-20 would be informed of the replacement.

Approval of draft ISPMs for consultation. At its May meeting, the SC-7 develops the draft to be sent for country consultation, and the SC-20 has to approve them by e-mail. The SC acknowledged that, in practice, given the constraint of the 120 days for consultation, there was little time for examining the drafts.

Selection of experts and stewards. The SC-20 is supposed to nominate experts and stewards for the development of standards. In 2003, the Secretariat developed a list of members of working groups that was sent to SC-20 for comment resulting in an approved final list. The SC agreed that flexibility should be maintained in the selection of experts but it was necessary to update the IPP when any changes in membership of the working groups occurred. SC should still be informed of the final composition of the working groups, even if this was also maintained on the IPP.

13. STANDARDS COMMITTEE PROCEDURES AND COUNTRY CONSULTATION

The SC noted that, during country consultation, more than 300 comments had been received on each draft standard, some of them containing multiple issues. The SC-7 had been able to review only two of the drafts. The SC commented as follows, recognizing that one objective of improving the standard-setting process was to increase the number of countries commenting and the number of standards.

- if the ICPM approves the reduction of country consultation period to 90 days, this will leave more time for an appropriate consideration of comments in advance of the SC.
- stewards could be given a greater role in the process and could be asked to scan comments. They could also be asked to incorporate editorial comments in advance of the SC.
- it would be possible to convene the SC-20 for a longer period in November (instead of the SC-7 and SC-20). In the first part of the meeting, sub-groups could be formed to address different standards, and the full SC-20 could then have a general discuss as now.
- encouraging provision of comments in a standardized format, and provision of justification, would facilitate the process

- Regional Workshops on draft ISPMs could be, as far as possible, a forum where countries could prepare harmonized comments for submission to the SC.
- given the workload and the fact that standard-setting was a central activity for the IPPC, the SC-20 could meet in both May and November (1 week and 1 or 2 weeks).

The SC concluded that this issue would have to be reconsidered when the ICPM would have decided on the proposals for modification of the standard-setting process. It accepted that any solution, such as convening the SC20 for longer periods, holding parallel subgroups, increasing the role of stewards, would require additional financial and Secretariat's resources.

In the meantime, it was proposed that the SC-20 would meet in May (instead of just SC-7), and that the SC7-SC20 would meet in November (it could be decided later in 2004 whether to convene the full SC-20 for longer in November). Better use of stewards should also be made in the consideration of countries comments.

14. OTHER BUSINESS

Mr Pemberton expressed the concerns of some European countries over the integration of the supplement to ISPM No. 11 on analysis of environmental risks into ISPM No. 11 to produce ISPM No. 11 Rev. 1. Some considered that there should have been an opportunity to comment before the text was published. Regarding integration of the environmental supplement into ISPM, the SC noted that this had been a request from ICPM-5 "that the text of the supplement should be integrated into ISPM No. 11 as soon as possible".

It was noted that there was considerable confusion about the terms direct and indirect pest effects. The SC considered that clarification of these terms would be useful but that may result in the need to revise ISPM No. 11. The SC recommended that the ICPM put in the work programme a review of these terms and any consequential effects. This activity could be run by the SC in conjunction with the Glossary Working Group.

Mr Lopian, Chair of the ICPM, presented the recommendations of the Focus Group on Standard Development and of the Informal Working Group on Strategic Planning and Technical Assistance. The SC made recommendations for modification of recommendations to ICPM. One issue was the possibility, when a standard is submitted to ICPM but not adopted, that a second round of consultation would be needed. The SC noted that it should have a role in this process and suggested that "The ICPM should return the standard to the SC with guidance on the further steps needed, including the need for another round of consultation".

Mr Klag had produced a draft on *Administrative guidelines for the structure of International Standards for Phytosanitary Measures*. He suggested that this draft could be considered by e-mail.

15. DATE AND VENUE OF THE FOURTH MEETING OF THE STANDARDS COMMITTEE

As discussed in point 13 above, the SC-20 would meet on 26-30 April 2004. In November 2004, the SC7 would meet on 8-12 November, and the SC-20 from 15-19 November (subject to modification as detailed in point 13 above).

16. CLOSE

The Chairperson closed the meeting by expressing his appreciation for the work accomplished by both the SC-7 and the SC, and the completion of the three draft standards under study. He thanked SC members for their participation and the work accomplished during the past 2-years and the Secretariat. He noted that this would be Mr Pemberton's last SC meeting as he was retiring in a few weeks and thank him for his work on standards.

STANDARDS COMMITTEE

THIRD MEETING

10-14 November 2003

Rome

PROVISIONAL AGENDA

1. Opening of the meeting
2. Welcome address
3. Adoption of the agenda
4. Adoption of the report of the previous meeting
5. Approval of drafts standards for submission to the ICPM
 - Guidelines for an import regulatory system
 - Pest Risk Analysis for regulated non-quarantine pests
 - Supplement to ISPM No. 11 (*Pest Risk Analysis for quarantine pests*) on Pest Risk Analysis for living modified organisms
6. Priorities for standard setting
7. Glossary issues
8. Format, printing and distribution of ISPMs
9. SC20/SC7 timing and membership issues
10. Referencing ISPMs in other ISPMs
11. Other business
12. Close

**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

**GUIDELINES FOR A PHYTOSANITARY IMPORT
REGULATORY SYSTEM**



Secretariat of the International Plant Protection Convention
Food and Agriculture Organization of the United Nations
Rome, 200-

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INTRODUCTION

SCOPE

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

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DEFINITIONS¹

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]
biological control agent	A natural enemy, antagonist or competitor, and other self-replicating biotic entity used for pest control [ISPM N° 3, 1996]
commodity	A type of plant, plant product, or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
compliance procedure (for a consignment)	Official procedure used to verify that a consignment complies with stated phytosanitary requirements [CEPM, 1999]
consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]

¹ Terms marked with an (*) are new or revised

consignment in transit	A consignment that is not imported into a country but passes through it to another country, subject to official procedures which ensure that it remains enclosed, and is not split up, not combined with other consignments nor has its packaging changed [FAO, 1990; revised CEPM, 1996; CEPM 1999; ICPM, 2002 formerly <i>country of transit</i>]
detention	Keeping a consignment in official custody or confinement for phytosanitary reasons (see quarantine) [FAO, 1990; revised FAO, 1995; CEPM, 1999]
emergency action	A prompt phytosanitary action undertaken in a new or unexpected phytosanitary situation [ICPM, 2001]
entry (of a consignment)	Movement through a point of entry into an area [FAO, 1995]
entry (of a pest)	Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled [FAO, 1995]
infestation (of a commodity)	Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection [CEPM, 1997; revised CEPM, 1999]
inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly <i>inspect</i>]
inspector	Person authorized by a National Plant Protection Organization to discharge its functions [FAO, 1990]
intended use	Declared purpose for which plants, plant products, or other regulated articles are imported, produced, or used [ISPM N° 16, 2002]
interception (of a consignment)	The refusal or controlled entry of an imported consignment due to failure to comply with phytosanitary regulations [FAO, 1990; revised FAO, 1995]
introduction	The entry of a pest resulting in its establishment [FAO, 1990; revised FAO, 1995; IPPC, 1997]
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
monitoring	An official ongoing process to verify phytosanitary situations [CEPM, 1996]
NPPO	National Plant Protection Organization [FAO, 1990; ICPM, 2001]
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]

official control	The active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests (see Glossary Supplement No. 1) [ICPM, 2001]
packaging materials*	Product used in supporting, protecting or carrying a commodity [ISPM No. , 200- (the present ISPM, when adopted)]
pathway	Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]
pest categorization	The process for determining whether a pest has or has not the characteristics of a quarantine pest or those of a regulated non-quarantine pest [ISPM No. 11, 2001]
Pest Free Area	An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained [FAO, 1995]
pest free place of production	Place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period [ISPM No. 10, 1999]
Pest 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 action	An official operation, such as inspection, testing, surveillance or treatment, undertaken to implement phytosanitary regulations or procedures [ICPM, 2001]
Phytosanitary Certificate	Certificate patterned after the model certificates of the IPPC [FAO, 1990]
phytosanitary legislation	Basic laws granting legal authority to a National Plant Protection Organization from which phytosanitary regulations may be drafted [FAO, 1990; revised FAO, 1995]
phytosanitary measure (agreed interpretation)	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; 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]
plant products	Unmanufactured material of plant origin (including grain) and those manufactured products that, by their nature or that of their processing, may create a risk for the introduction and spread of pests [FAO, 1990; revised IPPC, 1997; formerly <i>plant product</i>]
planting (including replanting)	Any operation for the placing of plants in a growing medium, or by grafting or similar operations, to ensure their subsequent growth, reproduction or propagation [FAO, 1990; revised CEPM, 1999]
plants	Living plants and parts thereof, including seeds and germplasm [FAO, 1990; revised IPPC, 1997]
PRA	Pest Risk Analysis [FAO 1995; revised ICPM 2001]
pre-clearance	Phytosanitary certification and/or clearance in the country of origin, performed by or under the regular supervision of the National Plant Protection Organization of the country of destination [FAO, 1990; revised FAO, 1995]
prohibition	A phytosanitary regulation forbidding the importation or movement of specified pests or commodities [FAO, 1990; revised FAO, 1995]
quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing and/or treatment [FAO, 1990; revised FAO, 1995; CEPM, 1999]
quarantine 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]
Regional Plant Protection Organization	An intergovernmental organization with the functions laid down by Article IX of the IPPC [FAO, 1990; revised FAO, 1995; CEPM, 1999; formerly <i>plant protection organization (regional)</i>]
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]
restriction	A phytosanitary regulation allowing the importation or movement of specified commodities subject to specific requirements [CEPM, 1996, revised CEPM, 1999]
RNQP	Regulated non-quarantine pest [ISPM No. 16, 2002]
RPPO	Regional Plant Protection Organization [FAO, 1990; revised ICPM, 2001]
spread	Expansion of the geographical distribution of a pest within an area [FAO, 1995]
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 N° 14, 2002]
test	Official examination, other than visual, to determine if pests are present or to identify pests [FAO, 1990]
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 objective of a phytosanitary import regulatory system is to prevent the introduction of quarantine pests or limit the entry of regulated non-quarantine pests with imported commodities and other regulated articles. An import regulatory system should consist of two components: a regulatory framework of phytosanitary legislation, regulations and procedures; and an official service, the NPPO, responsible for operation or oversight of the system. The legal framework should include: legal authority for the NPPO to carry out its duties; measures with which imported commodities should comply; other measures (including prohibitions) concerning imported commodities and other regulated articles; and actions that may be taken when incidents of non-compliance or incidents requiring emergency action are detected. It may include measures concerning consignments in transit.

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

REQUIREMENTS

1. Objective

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

2. Structure

The components of an import regulatory system are:

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

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

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

3. Rights, Obligations, and Responsibilities

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

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

3.1 International agreements, principles and standards

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

The drafting, adoption and application of regulations require recognition of certain principles and concepts including:

- transparency
- sovereignty
- necessity
- non-discrimination
- minimal impact
- harmonization

- technical justification (such as through pest risk analysis)
- consistency
- managed risk
- modification
- emergency action and provisional measures
- equivalence
- pest free areas and areas of low pest prevalence.

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

3.2 Regional cooperation

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

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

4. Regulatory Framework

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

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

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

4.1 Regulated articles

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

- plants and plant products used for planting, consumption, processing, or any other purpose
- storage facilities
- packaging materials including dunnage

- conveyances and transport facilities
- soil, organic fertilizers and related materials
- organisms capable of harboring or spreading pests
- potentially contaminated equipment (such as used agricultural, military and earthmoving equipment)
- research and other scientific materials
- travellers' personal effects moving internationally
- international mail including international courier services
- pests and biological control agents².

Lists of regulated articles should be made publically available.

4.2 Phytosanitary measures for regulated articles

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

4.2.1 Measures for consignments to be imported

The regulations should specify the measures with which imported consignments³ of plants, plant products and other regulated articles should comply. These measures may be general, applying to all types of commodities, or the measures may be specific, applying to specified commodities from a particular origin. Measures may be required prior to entry, at entry or post entry. Systems approaches may also be used when appropriate.

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

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

Measures that may be required during shipment include:

- cold treatment
- maintenance of consignment integrity.

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

- documentation checks
- verification of consignment integrity

² Pests *per se* and biological control agents do not fall within the definition of 'regulated articles' (Article II.1 of the IPPC, 1997). However, where there is technical justification, they may be subjected to phytosanitary measures (IPPC, 1997; Article VI with respect to regulated pests, and Article VII.1c and VII.1d) and for the purposes of this standard may be considered as regulated articles.

³ For the purpose of this standard, import is considered to cover all consignments moving into the country (except in transit), including movement into free trade zones (including duty free areas and consignments in bond) and illegal consignments detained by other services.

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

Measures that may be required after entry include:

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

Other measures that may be required include:

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

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

4.2.1.1 Provision for special imports

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

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

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

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

4.2.2 Import authorization

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

General authorization

General authorizations may be used:

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

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

Specific authorization

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

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

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

4.2.3 Prohibitions

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

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

4.3 Consignments in transit

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

4.4 Measures concerning non-compliance and emergency action

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

Actions which may be taken when an imported consignment or other regulated articles, does not comply with regulations include:

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

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

4.5 Other elements that may require a regulatory framework

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

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

4.6 Legal authority for the NPPO

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

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

5. Operation of an Import Regulatory System

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

5.1 Management and operational responsibilities of the NPPO

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

5.1.1 Administration

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

5.1.2 Regulatory development and revision

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

5.1.3 Surveillance

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

5.1.4 Pest risk analysis and pest listing

Technical justification such as through pest risk analysis (PRA) is required to determine if pests should be regulated and the strength of phytosanitary measures to be taken against them (ISPM No. 11 Rev. 1: *Pest risk analysis for quarantine pests including analysis of environmental risks*)[reference to ISPM-- for PRA for RNQPs to be added, if adopted at ICPM6]. PRA may be done on a specific pest or on all the pests associated with a particular pathway (e.g. a commodity). A commodity may be classified by its level of processing and/or its intended use. Regulated pests should be listed (according to ISPM No. 19: *Guidelines on lists of regulated pests*) and lists of regulated pests should be made available (Article VII.2i of the IPPC, 1997). If appropriate international standards are available, measures should take account of such standards and should not be more stringent unless technically justified.

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

5.1.5 Audit and compliance checking

5.1.5.1 Audit of procedures in the exporting country

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

- production systems
- treatments
- inspection procedures

- phytosanitary management
- accreditation procedures
- testing procedures
- surveillance.

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

5.1.5.2 Compliance checking at import

There are three basic elements to compliance checking:

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

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

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

The NPPO is responsible for, and should undertake, the phytosanitary inspections, but may delegate these or other checks to other services or agencies (such as Customs).

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

5.1.5.2.1 Inspection

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

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

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

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

5.1.5.2.2 Sampling

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

5.1.5.2.3 Testing including laboratory testing

Testing may be required for:

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

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

5.1.6 Non-compliance and emergency action

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

5.1.6.1 Action in case of non-compliance

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

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

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

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

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

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

Refusal of entry or destruction - The consignment may be refused or destroyed in cases where the NPPO considers the consignment cannot be otherwise handled.

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

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

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

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

5.1.6.2 Emergency action

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

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

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

Commonly encountered situations requiring emergency action include:

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

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

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

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

5.1.6.3 Reporting of non-compliance and emergency action

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

5.1.6.4 Withdrawal or modification of regulation

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

5.1.7 Systems for authorization of non-NPPO personnel

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

5.1.8 International liaison

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

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

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

5.1.9 Notification and dissemination of regulatory information

5.1.9.1 New or revised regulations

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

5.1.9.2 Dissemination of established regulations

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

5.1.10 National liaison

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

5.1.11 Settlement of disputes

The implementation of an import regulatory system may give rise to disputes with the authorities of other countries. The NPPO should establish procedures for consultation and exchange of information with other NPPOs, and for settlement of such disputes “shall consult among themselves as soon as possible” without calling on formal international dispute-settlement procedures (Article XIII.1 of the IPPC, 1997).

5.2 Resources of the NPPO

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

5.2.1 Staff including training

The NPPO should:

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

5.2.2 Information

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

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

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

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

5.2.3 Equipment and facilities

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

- inspection, testing and consignment verification procedures

- communication and access to information (by electronic means as far as possible).

DOCUMENTATION, COMMUNICATION, AND REVIEW

6. Documentation

6.1 Procedures

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

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

6.2 Records

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

- documentation of pest risk analyses (in accordance with ISPM No. 11 Rev.1: *Pest risk analysis for quarantine pests including analysis of environmental risks*, and other relevant ISPMs)
- where established, documentation of pest free areas, areas of low pest prevalence, and official control programmes (including information on the distribution of the pests and the measures used to maintain the PFA or area of low pest prevalence)
- records of inspection, sampling and testing
- non-compliance and emergency action (in accordance with ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*).

If appropriate, records may be kept of imported consignments:

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

7. Communication

The NPPO should ensure it has communication procedures to contact importers and appropriate industry representatives within their own country, NPPOs of exporting countries and the Secretariats of the IPPC and the RPPO(s) of which they are a member.

8. Review Mechanism

8.1 System review

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

8.2 Incident review

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

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

PEST RISK ANALYSIS FOR REGULATED NON- QUARANTINE PESTS



Secretariat of the International Plant Protection Convention
Food and Agriculture Organization of the United Nations
Rome, 200-

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INTRODUCTION

SCOPE

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

REFERENCES

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

DEFINITIONS⁴

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]
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]
host range	Species of plants capable, under natural conditions, of sustaining a specific pest [FAO, 1990]
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]

⁴ Terms marked with an (*) are new or revised

intended use	Declared purpose for which plants, plant products, or other regulated articles are imported, produced or used [ISPM No.16, 2002]
IPPC	The 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)]
non-quarantine pest	Pest that is not a quarantine pest for an area [FAO, 1995]
NPPO	National Plant Protection Organization [FAO, 1990; ICPM, 2001]
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]
official control	The active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests (see Glossary Supplement No. 1) [ICPM, 2001]
pathway	Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]
pest categorization	The process for determining whether a pest has or has not the characteristics of a quarantine pest or those of a regulated non-quarantine pest [ISPM No. 11, 2001]
pest free place of production	Place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period [ISPM No. 10, 1999]
pest free production site	A defined portion of a place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period and that is managed as a separate unit in the same way as a pest free place of production [ISPM No. 10, 1999]
Pest Risk Analysis	The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC, 1997]

pest status (in an area)	Presence or absence, at the present time, of a pest in an area, including where appropriate its distribution, as officially determined using expert judgement on the basis of current and historical pest records and other information [CEPM, 1997; revised ICPM, 1998]
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]
<i>The agreed interpretation of the term phytosanitary measure accounts for the relationship of phytosanitary measures to regulated non-quarantine pests. This relationship is not adequately reflected in the definition found in Article II of the IPPC (1997).</i>	
phytosanitary 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]
planting (including replanting)	Any operation for the placing of plants in a growing medium, or by grafting or similar operations, to ensure their subsequent growth, reproduction or propagation [FAO, 1990; revised CEPM, 1999]
plants	Living plants and parts thereof, including seeds and germplasm [FAO, 1990; revised IPPC, 1997]
plants for planting	Plants intended to remain planted, to be planted or replanted [FAO, 1990]
PRA	Pest Risk Analysis [FAO, 1995; revised ICPM, 2001]
PRA area	Area in relation to which a Pest Risk Analysis is conducted [FAO, 1995]
quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC, 1997]
Regional Plant Protection Organization	An intergovernmental organization with the functions laid down by Article IX of the IPPC [FAO, 1990; revised FAO, 1995; CEPM, 1999; formerly plant protection organization (regional)]
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]
RNQP	Regulated non-quarantine pest [ISPM No. 16, 2002]

RPPO	Regional Plant Protection Organization [FAO, 1990; revised ICPM, 2001]
suppression	The application of phytosanitary measures in an infested area to reduce pest populations [FAO, 1995; revised CEPM, 1999]
technically justified	Justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information [IPPC, 1997]

OUTLINE OF REQUIREMENTS

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

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

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

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

BACKGROUND

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

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

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

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

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

1 Intended Use and Official Control

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

1.1 Intended use

The intended use of plants for planting may be:

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

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

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

1.2 Official control

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

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

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

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

REQUIREMENTS

PEST RISK ANALYSIS FOR REGULATED NON-QUARANTINE PESTS

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

2. Stage 1: Initiation

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

2.1 Initiation points

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

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

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

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

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

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

2.1.2 PRA initiated by a pest

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

- identification, through scientific research, of a new risk posed by a pest (e.g. there is a change in pest virulence, or an organism is demonstrated to be a pest vector)

- detection in the PRA area of the following situations:
 - change in the prevalence or incidence of a pest
 - change in pest status (e.g. a quarantine pest has become widely distributed, or is no longer regulated as a quarantine pest)
 - presence of a new pest, not appropriate for regulation as a quarantine pest.

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

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

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

2.2 Identification of the PRA area

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

2.3 Information

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

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

2.4 Review of previous PRAs

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

2.5 Conclusion of initiation

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

3. Stage 2: Pest Risk Assessment

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

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

3.1 Pest categorization

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

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

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

3.1.1 Elements for categorization

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

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

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

The following should be clearly defined:

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

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

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

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

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

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

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

3.1.1.3 Pest presence and regulatory status

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

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

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

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

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

3.1.2 Conclusion of pest categorization

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

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

the PRA process should continue. If a pest does not fulfil all the criteria for an RNQP, the PRA process may stop.

3.2 Assessment of the plants for planting as the main source of pest infestation

Because the potential RNQP is present in the PRA area, it is necessary to determine whether plants for planting are the main source of pest infestation of those plants or not. In order to do this, all sources of infestation should be evaluated and the results presented in the PRA.

The evaluation of all the sources of infestation is based on the:

- life cycle of the pest and host, pest epidemiology and sources of pest infestation
- determination of the relative economic impact of the sources of pest infestation.

In the analysis of the main source of pest infestation, consideration should be given to conditions in the PRA area and the influence of official control.

3.2.1 Life cycle of the pest and the host, pest epidemiology and sources of pest infestation

The aim of this part of the assessment is to evaluate the relationship between the pest and the plants for planting and to identify all the other sources of pest infestation.

The identification of all the other sources of infestation is performed through the analysis of the pest and host life cycles. Different sources or pathways of pest infestation may include:

- soil
- water
- air
- other plants or plant products
- vectors of the pest
- contaminated machinery or modes of transport

- by-products or waste.

Pest infestation and spread may occur as a result of natural movement (including wind, vectors, and waterways), human action or other means from these sources of infestation. The characteristics of the pathways should be examined.

3.2.2 Determination of the relative economic impact of the sources of pest infestation

The aim of this part of the assessment is to determine the importance of the pest infestation associated with the plants for planting relative to the other sources of infestation in the PRA area and the intended use of those plants. Information from section 3.2.1 should be used.

The evaluation will address the importance of the pest infestation in the plants for planting on the epidemiology of the pest. The evaluation will also address the contribution of other sources of infestation to the development of the pest and its effect on the intended use. The importance of all these sources may be influenced by factors such as:

- the number of pest life cycles on the plants for planting (e.g. monocyclic or polycyclic pests)
- reproductive biology of the pest
- pathway efficiency, including mechanisms of dispersal and dispersal rate
- secondary infestation and transmission from the plants for planting to other plants
- climatological factors
- cultural practices, pre- and post-harvest
- soil types
- the susceptibility of the plants (e.g. young plant stages could be more or less susceptible to different pests; host resistance/susceptibility)
- presence of vectors
- presence of natural enemies and/or antagonists
- presence of other susceptible hosts
- pest prevalence in the PRA area
- impact or potential impact of the official control applied in the PRA area.

The different types and rates of pest transmission from the initial infestation in the plants for planting (seed to seed, seed to plant, plant to plant, within plant) may be important factors to consider. Their importance may depend on the intended use of the plants for planting and should be assessed accordingly. For example the same initial pest infestation may have significantly different impacts in/on seed for further propagation or plants for planting intended to remain planted.

Other factors may influence the evaluation of the plants for planting as the main source of infestation as compared to other sources. These may include pest survival and controls during production, transport or storage of the plants.

3.2.3 Conclusion of the assessment of the plants for planting as the main source of pest infestation

Pests that are mainly transmitted by the plants for planting and which affect the intended use of those plants are subjected to the next stage of the risk assessment to establish whether there are unacceptable economic impacts.

Where plants for planting are found not to be the main source of infestation, the PRA may stop at this point. In cases where other sources of infestation are also relevant their contribution to the damage on the intended use of the plants for planting should be evaluated.

3.3 Assessment of economic impacts on the intended use of the plants for planting

Requirements described in this step indicate the information required to conduct an analysis to determine if there are unacceptable economic impacts. Economic impacts may have

previously been analysed for the development of official control programmes for the pest on plants for planting with the same intended use. The validity of any data should be checked as circumstances and information may have changed.

Wherever appropriate, quantitative data that will provide monetary values should be obtained. Qualitative data such as relative production or quality levels before and after infestation by the pest may also be used. The economic impact resulting from the pest may vary depending on the intended use of the plants for planting and this should therefore be taken into account.

In cases where there is more than one source of infestation, the economic impact resulting from the pest on the plants for planting should be demonstrated to be the main source of the unacceptable economic impact.

3.3.1 Pest effects

As the pest is present in the PRA area, detailed information should be available about its economic impact in that area. Scientific data, regulatory and other information from the national and international literature should be consulted and documented as appropriate. Most of the effects considered during the economic analysis will be direct effects on the plants for planting and their intended use.

Relevant factors in determining economic impacts include:

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

In particular cases, pest effects on other host plants at the place of production may be considered relevant factors. For example, some varieties or species of host plants may not be seriously affected by an infestation of the assessed pest. However, the planting of such an infested host plant may have a major effect on the more susceptible hosts at places of production in the PRA area. In such cases the assessment of the consequences of the intended use of those plants may include all relevant host plants grown at the place of production.

In some cases, economic consequences may only become apparent after a long period of time (e.g. a degenerative disease in a perennial crop, a pest with a long-lived resting stage). Furthermore, the infestation in the plants may result in contamination of places of production with a consequential impact on future crops. In such cases the consequences on intended use may extend beyond the first production cycle.

Pest consequences such as impacts on market access or environmental health are not considered relevant factors in determining economic impacts for RNQPs. The ability to act as a vector for other pests may nevertheless be a relevant factor.

3.3.2 Infestation and damage thresholds in relation to the intended use

Data, either quantitative or qualitative, should be available regarding the level of damage of the pest on the intended use of the plants for planting for all relevant sources of infestation in the PRA area. In cases where plants for planting are the only source of infestation, these data provide the basis for determining infestation thresholds and the resultant damage thresholds in relation to the economic impact on the intended use.

Where other sources of infestation are also relevant, their relative contribution to the total damage should be assessed. The proportion of damage caused by the pest on the plants for planting should be compared with the proportion from other sources to determine their relative contribution to the damage thresholds in relation to the intended use of those plants.

Determination of infestation thresholds will assist in the identification of appropriate tolerance levels at the pest risk management stage (see section 4.4).

In cases where there is a lack of quantitative information on pest damage caused by the initial level of pest infestation in the plants for planting, expert judgement could be used on the basis of information obtained in sections 3.2.1 and 3.2.2.

3.3.3 Analysis of economic consequences

As determined above, most of the effects of a pest, e.g. damage, will be of a commercial nature within the country. These effects should be identified and quantified. It may be useful to consider the negative effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices.

3.3.3.1 Analytical techniques

There are analytical techniques that can be used in consultation with experts in economics to make a more detailed analysis of the economic effects of an RNQP. These should incorporate all of the effects that have been identified. These techniques (see ISPM No. 11 Rev. 1: *Pest risk analysis for quarantine pests including analysis of environmental risks*, section 2.3.2.3) may include:

- *partial budgeting*: this will be adequate, if the economic effects induced by the action of the pest to producer profits are generally limited to producers and are considered to be relatively minor.
- *partial equilibrium*: this is recommended if, under point 3.3.3, there is a significant change in producer profits, or if there is a significant change in consumer demand. Partial equilibrium analysis is necessary to measure welfare changes, or the net changes arising from the pest impacts on producers and consumers.

Data on the economic impact of the pest on the intended use of the plants for planting should be available for the PRA area and an economic analysis may be available. For some effects of the pests there may be uncertainties or variability in the data and/or only qualitative information may be available. Areas of uncertainty and variability should be explained in the PRA.

The use of certain analytical techniques is often limited by the lack of data, by uncertainties in the data, and by the fact that for certain effects only qualitative information can be obtained. If quantitative measurement of the economic consequences is not feasible, qualitative information about the consequences may be provided. An explanation of how this information has been incorporated into decisions should also be provided.

3.3.4 Conclusion of the assessment of economic consequences

The output of the assessment of economic consequences described in this step should normally be in terms of a monetary value. The economic consequences can also be expressed qualitatively (such as relative profit before and after infestation) or using quantitative measures without monetary terms (such as tonnes of yield). Sources of information, assumptions and methods of analysis should be clearly specified. An assessment will need to be made as to whether the economic consequences are acceptable or unacceptable. If the economic consequences are considered acceptable (i.e. little damage or damage is largely from sources other than the plants for planting) then the PRA may stop.

3.4 Degree of uncertainty

Estimation of economic impact and the relative importance of sources of infestation may involve uncertainties. It is important to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs.

3.5 Conclusion of the pest risk assessment stage

As a result of the pest risk assessment, a quantitative or qualitative evaluation of the plants for planting being the main source of infestation of the pest and a corresponding quantitative or qualitative estimate of the economic consequences have been obtained and documented, or an overall rating could have been assigned.

Measures are not justified if the risk is considered acceptable or should be accepted because it is not manageable through official control (for example, natural spread from other sources of infestation). Countries may decide that an appropriate level of monitoring or audit is maintained to ensure that future changes in the pest risk are identified.

Where plants for planting have been identified as the main source of infestation for a pest and an unacceptable economic impact on the intended use of these plants has been demonstrated, pest risk management may be considered as appropriate(stage 3). These evaluations, together with associated uncertainties, are utilized in the pest risk management stage of the PRA.

4. Stage 3: Pest Risk Management

The conclusions from pest risk assessment are used to decide whether risk management is required and the strength of measures to be used.

If the plants for planting are assessed as being the main source of infestation of the pests and the economic impact on the intended use of those plants is found to be unacceptable (stage 2), then risk management (stage 3) is used to identify possible phytosanitary measures with the aim of suppression and thereby will reduce the risk to, or below, an acceptable level.

The most commonly used option for pest risk management for an RNQP is the establishment of measures to achieve an appropriate pest tolerance level. The same tolerance level should be applied for domestic production and import requirements (see section 6.3 of ISPM No. 16: *Regulated non-quarantine pests: concept and application*).

4.1 Technical information required

The decisions to be made in the pest risk management process will be based on the information collected during the preceding stages of PRA, particularly the biological information. This information will be comprised of:

- reasons for initiating the process
- importance of the plants for planting as a source of the RNQP
- evaluation of the economic consequences in the PRA area.

4.2 Level and acceptability of risk

In implementing the principle of managed risk, countries should decide what level of risk is acceptable for them.

The acceptable level of risk may be expressed in a number of ways, such as:

- reference to the existing acceptable level of risk for domestic production
- indexed to estimated economic losses
- expressed on a scale of risk tolerance
- compared with the level of risk accepted by other countries.

4.3 Factors to be taken into account in the identification and selection of appropriate risk management options

Appropriate measures should be chosen based on their effectiveness in limiting the economic impact of the pest on the intended use of the plants for planting. The choice should be based on the following considerations, which include several of the principles of plant quarantine as related to international trade (*ISPM No. 1: Principles of plant quarantine as related to international trade*):

- *Phytosanitary measures shown to be cost-effective and feasible* – The measure should not be more costly than the economic impact.
- *Principle of "minimal impact"* - Measures should not be more trade restrictive than necessary.
- *Assessment of existing phytosanitary requirements* - No additional measures should be imposed if existing measures are effective.
- *Principle of "equivalence"* - If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
- *Principle of "non-discrimination"* - Phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

4.3.1 Non-discrimination

There should be consistency between import and domestic requirements for a defined pest (see ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1: *Guidelines on the interpretation and application of the concept of official control for regulated pests*):

- import requirements should not be more stringent than domestic requirements
- domestic requirements should enter into force before or at the same time as import requirements
- domestic and import requirements should be the same or have an equivalent effect
- mandatory elements of domestic and import requirements should be the same
- the intensity of inspection of imported consignments should be the same as equivalent processes in domestic control programmes
- in the case of non-compliance, the same or equivalent actions should be taken on imported consignments as are taken domestically
- if a tolerance is applied within a national programme, the same tolerance should be applied to equivalent imported material, e.g. same class within a certification scheme or same stage of development. In particular, if no action is taken in the national official control programme because the infestation level does not exceed a particular level, then no action should be taken for an imported consignment if its infestation level does not exceed that same level. At entry, compliance with import tolerance may be determined by inspection or testing. The tolerance for domestic consignments should be determined at the last or most appropriate point where official control is applied
- if downgrading or reclassifying is permitted within a national official control programme, similar options should be available for imported consignments.

In cases where countries have, or are considering, import requirements for RNQPs in plants for planting that are not produced domestically, phytosanitary measures should be technically justified.

The measures should be as precise as possible concerning the species of plants for planting (including different classes within a certification scheme) and their intended use to prevent barriers to trade such as by limiting the import of products where this is not justified.

4.4 Tolerances

For RNQPs, the establishment of appropriate tolerances can be used to reduce the risk to an acceptable level. These tolerances should be based on the level of pest infestation (the infestation threshold) in plants for planting that result in an unacceptable economic impact.

Tolerances are indicators that, if exceeded, are likely to result in unacceptable impacts on plants for planting. If infestation thresholds have been determined during the risk assessment stage, these should be considered in establishing appropriate tolerances. Tolerance levels should take into account appropriate scientific information including:

- intended use of the plants for planting
- biology, in particular epidemiological characteristics, of the pest
- susceptibility of the host
- sampling procedures (including confidence intervals), detection methods (with estimates of the precision), reliability of identification
- relationship between the pest level and the economic losses
- climate and cultural practices in PRA area.

The above information may be derived through reliable research and also through the following:

- experience with official control programmes within the country for the plants for planting concerned
- experience from certification schemes for the plants for planting
- history of imports of the plants for planting
- data regarding interactions between the plant, the pest and the growing conditions.

4.4.1 Zero tolerance

Because the pest is already present, zero tolerance is not likely to be a general requirement. A zero tolerance may be technically justified in situations or combination of situations such as:

- where plants for planting are the only source of pest infestation in relation to the intended use of those plants and any level of pest infestation would result in an unacceptable economic impact (e.g. nuclear stock for further propagation, or a virulent degenerative disease where the intended use is further propagation)
- the pest fulfils the defining criteria of an RNQP and an official control programme is in place requiring pest freedom in plants for planting (zero tolerance) for the same intended use for all domestic places of production or production sites. Similar requirements could be used as described in ISPM No. 10 (*Requirements for the establishment of pest free places of production and pest-free production sites*).

4.4.2 Selection of an appropriate tolerance level

Based on the above analysis, a tolerance level should be selected which aims to avoid an unacceptable economic impact as assessed under 3.3.4.

4.5 Options to achieve the required tolerance levels

There are a number of options that may achieve the required tolerance. Certification schemes are often useful for attaining the required tolerance and may include elements that may be relevant for all of the management options. Mutual recognition of certification schemes may facilitate trade of healthy plant material. However some aspects of certification schemes (e.g. varietal purity) are not relevant (see section 6.2 of ISPM No. 16: *Regulated non-quarantine pests: concept and application*).

Management options may consist of a combination of two or more options (see ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*). Sampling, testing and inspection for the required tolerance may be relevant for all the management options.

These options may be applied to:

- area of production
- place of production
- parent stock
- consignment of plants for planting.

Section 3.4 of ISPM No. 11 Rev. 1 (*Pest risk analysis for quarantine pests including analysis of environmental risks*) also provides information on the identification and selection of risk management options.

4.5.1 Area of production

The following options may be applied to the area of production of the plants for planting:

- treatment
- area of low pest prevalence
- area where the pest does not occur
- buffer zones (e.g. rivers, mountain ranges, urban areas)
- monitoring survey.

4.5.2 Place of production

The following options may be applied to the place of production of the plants for planting to achieve a required tolerance:

- isolation (place or time)
- pest free place of production or pest free production site (see ISPM No. 10: *Requirements for the establishment of pest free places of production and pest free production sites*)
- integrated pest management
- cultural practices (e.g. roguing, pest and vector control, hygiene, preceding crop, previous treatment)
- treatments.

4.5.3 Parent stock

The following options may be applied to the parent stock of the plants for planting to achieve a required tolerance:

- treatment
- use of resistant varieties
- use of healthy planting material (e.g. tissue culture, thermotherapy)
- sorting and roguing
- selection of propagating material.

4.5.4 Consignment of plants for planting

The following options may be applied to consignment of plants for planting to achieve a required tolerance:

- treatment
- conditions of preparation and handling (e.g. storage, packaging and transport conditions)
- sorting, roguing, reclassification.

4.6 Verification of the tolerance levels

Inspection, sampling and testing might be needed to confirm that the plants for planting meet the tolerance level.

4.7 Conclusion of pest risk management

The conclusion of the risk management stage is the identification of:

- an appropriate tolerance level
- management options to achieve that tolerance level.

The result of the process is a decision on whether to accept the economic impact that could be caused by the pest. If there are risk management options that are acceptable, these options form the basis of phytosanitary regulations or requirements

Measures for RNQPs should only concern the plants for planting. Therefore only management options relating to consignments of plants for planting can be selected and included in

phytosanitary requirements. Other management options such as for the parent stock, place of production, or area of production may be included in phytosanitary requirements, but should be related to the tolerance which is required to be achieved. Measures proposed as equivalent should be evaluated. The information related to the efficacy of options which are proposed as alternatives should be provided on request to assist interested parties (both domestic industry as well as other contracting parties) in complying with the requirements. Confirmation that the tolerance has been achieved does not imply testing of all consignments, but testing or inspection may be used as an audit, as appropriate.

5 Monitoring and review of phytosanitary measures

The principle of “modification” states: “As conditions change, and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of prohibitions, restrictions or requirements necessary for their success, or by removal of those found to be unnecessary” (*ISPM No. 1: Principles of plant quarantine as related to international trade*).

Thus, the implementation of particular phytosanitary measures should not be considered to be permanent. After application, the success of the measures in achieving their aim should be determined by monitoring. This may be achieved by monitoring the plants for planting at appropriate times and places and/or damage levels (economic impact). The information supporting the pest risk analysis should be periodically reviewed to ensure that any new information that becomes available does not invalidate the decision taken.

6. Documentation of pest risk analysis

The IPPC, 1997 (Article VII.2c) and the principle of “transparency” (*ISPM No. 1: Principles of plant quarantine as related to international trade*) require that contracting parties should, on request, make available the rationale for phytosanitary requirements. The whole process from initiation to pest risk management should be sufficiently documented so that when a request for the rationale for measures is received, or a dispute arises, or when measures are reviewed, the sources of information and rationale used in reaching the management decision can be clearly demonstrated.

The main elements of documentation are:

- purpose for the PRA
- pest, host, plants and/or parts or class of plants under consideration, pest list (if appropriate), sources of infestation, the intended use, PRA area
- sources of information
- categorized pest list
- conclusions of risk assessment
- risk management
- options identified.

**Supplement to ISPM No. 11 (Pest risk analysis for quarantine pests)
PEST RISK ANALYSIS FOR LIVING MODIFIED ORGANISMS**

The purpose of this supplementary text is to provide detailed guidance to National Plant Protection Organizations (NPPOs) regarding the analysis of pest risk posed by living modified organisms (LMOs).

It is based on ISPM No. 11 (*Pest risk analysis for quarantine pests*), including the integrated supplement on environmental risks (as approved by the Interim Commission for Phytosanitary Measures in 2003). The supplementary text on LMOs is shown in boxes in the relevant sections.

The supplementary text is not a stand-alone document. It does not describe an independent PRA process for LMOs.

INTRODUCTION

SCOPE

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

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

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

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Glossary of phytosanitary terms*, 2002. ISPM No. 5, FAO, Rome.
- Guidelines for pest risk analysis*, 1996. ISPM No. 2, FAO, Rome.
- Guidelines for surveillance*, 1998. ISPM No. 6, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Principles of plant quarantine as related to international trade*, 1995. ISPM No. 1, FAO, Rome.
- Export Certification System*, 1997. ISPM No. 7, FAO, Rome
- Requirements for the establishment of pest free areas*, 1996. ISPM No. 4, FAO, Rome.
- Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.
- Requirements for the establishment of pest free places of production and pest-free production sites*, 1999. ISPM No. 10, FAO, Rome.

ADDITIONAL REFERENCES RELEVANT FOR LMOs

- Convention on Biological Diversity*, 1992. CBD, Montreal.
- Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2000. CBD, Montreal.
- Code of conduct for the import and release of biological control agents*, 1996. ISPM No. 3, FAO, Rome.
- Glossary of Biotechnology for Food and Agriculture*, 2002. Research and Technology Paper 9, FAO, Rome.
- Glossary of phytosanitary terms*, 2003. ISPM No. 5, FAO, Rome.
- Glossary supplement No. 1: Guidelines on the interpretation and application of the concept of official control for regulated pests*, 2002. ISPM No. 5, FAO, Rome.
- Glossary supplement No. 2: Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations*, 2003. ISPM No. 5, FAO, Rome.
- Guidelines for phytosanitary certificates*, 2001. ISPM No. 12, FAO, Rome.

DEFINITIONS AND ABBREVIATIONS

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]		
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]		
country of origin (of a consignment of plant products)	Country where the plants from which the plant products are derived were grown [FAO, 1990; revised CEPM, 1996; CEPM, 1999]		
country of origin (of a consignment of plants)	Country where the plants were grown [FAO, 1990; revised CEPM, 1996; CEPM, 1999]		
country of origin (of regulated articles other than plants and plant products)	Country where the regulated articles were first exposed to contamination by pests [FAO, 1990; revised CEPM, 1996; CEPM, 1999]		
endangered area	An area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss [FAO, 1990; revised CEPM, 1996; CEPM, 1999]		
entry (of a pest)	Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled [FAO, 1995]		
establishment	Perpetuation, for the foreseeable future, of a pest within an area after entry [FAO, 1990; revised FAO, 1995; IPPC, 1997; formerly established]		
introduction	The entry of a pest resulting in its establishment [FAO, 1990; revised FAO, 1995; IPPC, 1997]		
IPPC	The International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]		
National Organization	Plant	Protection	Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization (National)]
NPPO	National Plant Protection Organization [FAO, 1990; revised ICPM, 2001]		
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]		
pathway	Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995]		
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]		
pest categorization	The process for determining whether a pest has or has not the characteristics of a quarantine pest or those of a regulated non-quarantine pest [ISPM No. 11, 2001]		
Pest Free Area	An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained [FAO, 1995]		
pest free production site	A defined portion of a place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period and that is managed as a separate unit in the same way as a pest free place of production [ISPM No. 10, 1999]		

Pest Risk Analysis	The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC, 1997]
pest risk assessment (for quarantine pests)	Evaluation of the probability of the introduction and spread of a pest and of the associated potential economic consequences [FAO, 1995; revised ISPM No. 11, 2001]
pest risk management (for quarantine pests)	Evaluation and selection of options to reduce the risk of introduction and spread of a pest [FAO, 1995; revised ISPM No. 11, 2001]
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 the introduction and/or spread of pests [FAO, 1995; revised IPPC, 1997]
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]
post-entry quarantine	Quarantine applied to a consignment after entry [FAO, 1995]
PRA area	Area in relation to which a pest risk analysis is conducted [FAO, 1995]
prohibition	A phytosanitary regulation forbidding the importation or movement of specified pests or commodities [FAO, 1990; revised FAO, 1995]
quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC, 1997]
Regional Plant Protection Organization	An intergovernmental organization with the functions laid down by Article IX of the IPPC [FAO, 1990; revised FAO, 1995; CEPM, 1999; formerly Plant Protection Organization (Regional)]
RPPO	Regional Plant Protection Organization [FAO, 1990; revised ICPM, 2001]
spread	Expansion of the geographical distribution of a pest within an area [FAO, 1995]

NEW DEFINITIONS RELEVANT FOR LMOs

living modified organism	Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (<i>Cartagena Protocol on Biosafety to the Convention on Biological Diversity</i> , 2000)
LMO	Living modified organism
modern biotechnology	The application of: a. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or b. fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. (<i>Cartagena Protocol on Biosafety to the Convention on Biological Diversity</i> , 2000)

OUTLINE OF REQUIREMENTS

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

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

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

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

PEST RISK ANALYSIS FOR QUARANTINE PESTS

1. Stage 1: Initiation

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

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

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

A plant pest risk may be presented by:

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

1.1 Initiation points

The PRA process may be initiated as a result of:

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

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

1.1.1 PRA initiated by the identification of a pathway

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

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

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

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

1.1.2 PRA initiated by the identification of a pest

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

- an emergency arises on discovery of an established infestation or an outbreak of a new pest within a PRA area
- an emergency arises on interception of a new pest on an imported commodity
- a new pest risk is identified by scientific research
- a pest is introduced into an area
- a pest is reported to be more damaging in an area other than in its area of origin
- a pest is repeatedly intercepted
- a request is made to import an organism

- an organism is identified as a vector for other pests
- an organism is genetically altered in a way which clearly identifies its potential as a plant pest.

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

1.1.3 PRA initiated by the review or revision of a policy

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

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

1.1.4 Types of LMOs

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

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

1.1.5 Determining the potential for an LMO to be a pest

In order to be categorized as a pest, the LMO has to be injurious or potentially injurious to plants or plant products under conditions in the PRA area. This damage may be in the form of direct effects on plants or plant products, or indirect effects.

This supplementary text is relevant for LMOs only where there is potential for phytosanitary risks associated with some characteristic or property related to the genetic modification of the LMO. Other phytosanitary risks associated with the organism should be assessed under other appropriate sections of ISPM No. 11 or under other appropriate ISPMs.

Potential phytosanitary risks for LMOs may include:

a. Changes in adaptive characteristics which may increase the potential for introduction or spread, including invasiveness, for example alterations in:

- tolerance to adverse environmental conditions (e.g. drought, freezing, salinity etc.)
- reproductive biology
- dispersal ability of pests
- growth rate or vigour
- host range
- pest resistance
- pesticide (including herbicide) resistance or tolerance.

b. Adverse effects of gene flow or gene transfer including, for example:

- transfer of pesticide or pest resistance genes to compatible species
- the potential to overcome existing reproductive and recombination barriers resulting in pest risks
- potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity.

c. Adverse effects on non-target organisms including, for example:

- changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
- effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)
- capacity to vector other pests
- negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants.

d. Genotypic and phenotypic instability including, for example:

- reversion of an organism intended as a biocontrol agent to a virulent form.

e. Other injurious effects including, for example:

- phytosanitary risks presented by new traits in organisms that do not normally pose phytosanitary risk
- novel or enhanced capacity for virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences
- phytosanitary risks resulting from nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.

The potential phytosanitary risks identified above can also be associated with non-LMOs. The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.

If there is no indication that genetic modifications relating to physiological traits have phytosanitary risks, the LMO may require no further consideration.

It may be useful to consider potential risks in the context of risks posed by the non-modified recipients or parental organisms, or similar organisms, in the PRA area.

In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.

Factors that may result in the need to subject a LMO to stage 2 of the PRA include:

- Possible alteration of pest risk due to multiple traits or events
- Lack of knowledge about a particular modification event
- The credibility of information if it is an unfamiliar modification event
- Insufficient data on the behaviour of the LMO in environments similar to the PRA area
- Field experience, research trials or laboratory data indicating that the LMO may pose phytosanitary risks (see sub-sections a. to e. above)
- Where the LMO expresses characteristics such as invasiveness that are associated with pests under ISPM No. 11
- Existing conditions in the country (or PRA area) that may result in the LMO being a pest
 - Where there are PRAs for similar organisms (including LMOs) or risk analyses carried out for other purposes that indicate a pest potential
 - Experience in other countries.

Factors that may lead to the conclusion that an LMO is not a potential pest and/or requires no further consideration under ISPM No. 11 include:

- Where the genetic modification of the LMO is a familiar event that has previously been assessed by the NPPO (or other recognized experts or agencies) as having no phytosanitary risk
- Where the LMO is to be confined in a reliable containment system and not be released
- Evidence from research trials that the LMO is unlikely to be a pest under the use proposed
- Experience in other countries.

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

1.3 Information

Information gathering is an essential element of all stages of PRA. It is important at the initiation stage in order to clarify the identity of the pest(s), its/their present distribution and association with host plants, commodities, etc. Other information will be gathered as required to reach necessary decisions as the PRA continues.

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

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

Information gathering is an essential element of all stages of risk analysis. For LMOs, information required for a full risk analysis may include:

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

Information for risk analysis for LMOs may come from a variety of sources. The provision of official information regarding pest status is an obligation under the IPPC (Article VIII.1c) facilitated by official contact points (Article VIII.2). A country may have obligations to provide information about LMOs under other international agreements such as the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (2000; Cartagena Protocol). The Cartagena Protocol has a Biosafety Clearing-house that may contain relevant information. Information on LMOs is sometimes commercially sensitive and applicable obligations with regard to release and handling of information should be observed.

1.3.1 Previous PRA

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

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

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

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

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

2. Stage 2: Pest Risk Assessment

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

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

In most cases, these steps will be applied sequentially in a PRA but it is not essential to follow a particular sequence. Pest risk assessment needs to be only as complex as is technically justified by the circumstances. This standard allows a specific PRA to be judged against the principles of necessity, minimal impact, transparency, equivalence, risk analysis, managed risk and non-discrimination set out in ISPM No. 1: *Principles of plant quarantine as related to international trade* (FAO, 1995).

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

2.1 Pest categorization

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

In the evaluation of a pathway associated with a commodity, a number of individual PRAs may be necessary for the various pests potentially associated with the pathway. The opportunity to eliminate an organism or organisms from consideration before in-depth examination is undertaken is a valuable characteristic of the categorization process.

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

2.1.1 Elements of categorization

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

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

2.1.1.1 Identity of pest

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

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

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

In the case of LMOs, identification requires information regarding characteristics of the recipient or parent organism, the donor organism, the genetic construct, the gene or transgene vector and the nature of the genetic modification.

Given the technology used to produce LMOs, in most cases the identity of the LMO will be well defined. However, in some cases it may be appropriate to carry out risk assessment on a particular insert in various backgrounds or varieties/species. In these cases, detailed information on the various recipients is needed. Information as provided under section 1.3 may be adequate.

2.1.1.2 Presence or absence in PRA area

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

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

2.1.1.3 Regulatory status

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

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

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

2.1.1.4 Potential for establishment and spread in PRA area

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

For LMOs, the following should also be considered:

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

For more detailed guidance on the assessment of these characteristics, see section 1.1.5.

2.1.1.5 Potential for economic consequences in PRA area

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

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

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

2.1.2 Conclusion of pest categorization

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

2.2 Assessment of the probability of introduction and spread

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

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

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

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

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

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

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

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

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

2.2.1 Probability of entry of a pest

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

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

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

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

^{**} In the case of organisms that affect plants indirectly, through effects on other organisms, the terms host/habitat will extend also to those other organisms.

2.2.1.1 Identification of pathways for a PRA initiated by a pest

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

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

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

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

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

2.2.1.3 Probability of survival during transport or storage

Examples of factors to consider are:

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

2.2.1.4 Probability of pest surviving existing pest management procedures

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

2.2.1.5 Probability of transfer to a suitable host

Factors to consider are:

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

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

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

2.2.2 Probability of establishment

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

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

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

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

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

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

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

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

Factors to consider are:

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

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

2.2.2.2 Suitability of environment

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

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

2.2.2.3 Cultural practices and control measures

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

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

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

2.2.2.4 Other characteristics of the pest affecting the probability of establishment

These include:

- *Reproductive strategy of the pests and method of pest survival* - Characteristics, which enable the pest to reproduce effectively in the new environment, such as parthenogenesis/self-crossing, duration of the life cycle, number of generations per year, resting stage etc., should be identified.
- *Genetic adaptability* - Whether the species is polymorphic and the degree to which the pest has demonstrated the ability to adapt to conditions like those in the PRA area should be considered, e.g., host-specific races or races adapted to a wider range of habitats or to new hosts. This genotypic (and phenotypic) variability facilitates a pest's ability to withstand environmental fluctuations, to adapt to a wider range of habitats, to develop pesticide resistance and to overcome host resistance.
- *Minimum population needed for establishment* - If possible, the threshold population that is required for establishment should be estimated.

For LMOs, if there is evidence of genotypic and phenotypic instability, this should be considered.

It may also be appropriate to consider proposed production and control practices related to the LMO in the country of import.

2.2.3 Probability of spread after establishment

A pest with a high potential for spread may also have a high potential for establishment, and possibilities for its successful containment and/or eradication are more limited. In order to estimate the probability of spread of the pest, reliable biological information should be obtained from areas where the pest currently occurs. The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs and expert judgement used to assess the probability of spread. Case histories concerning comparable pests can usefully be considered. Examples of the factors to consider are:

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

In the case of plants to be imported, the assessment of spread concerns spread from the intended habitat or the intended use to an unintended habitat, where the pest may establish. Further spread may then occur to other unintended habitats.

The information on probability of spread is used to estimate how rapidly a pest's potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area of low potential economic importance and then spread to an area of high potential economic importance. In addition it may be important in the risk management stage when considering the feasibility of containment or eradication of an introduced pest.

Certain pests may not cause injurious effects on plants immediately after they establish, and in particular may only spread after a certain time. In assessing the probability of spread, this should be considered, based on evidence of such behaviour.

2.2.4 Conclusion on the probability of introduction and spread

The overall probability of introduction should be expressed in terms most suitable for the data, the methods used for analysis, and the intended audience. This may be quantitative or qualitative, since either output is in any case the result of a combination of both quantitative and qualitative information. The probability of introduction may be expressed as a comparison with that obtained from PRAs on other pests.

2.2.4.1 Conclusion regarding endangered areas

The part of the PRA area where ecological factors favour the establishment of the pest should be identified in order to define the endangered area. This may be the whole of the PRA area or a part of the area.

2.3 Assessment of potential economic consequences

Requirements described in this step indicate what information relative to the pest and its potential host plants should be assembled, and suggest levels of economic analysis that may be carried out using that information in order to assess all the effects of the pest, i.e. the potential economic consequences. Wherever appropriate, quantitative data that will provide monetary values should be obtained. Qualitative data may also be used. Consultation with an economist may be useful.

In many instances, detailed analysis of the estimated economic consequences is not necessary if there is sufficient evidence or it is widely agreed that the introduction of a pest will have unacceptable economic consequences (including environmental consequences). In such cases, risk assessment will primarily focus on the probability of introduction and spread. It will, however, be necessary to examine economic factors in greater detail when the level of economic consequences is in question, or when the level of economic consequences is needed to evaluate the strength of measures used for risk management or in assessing the cost-benefit of exclusion or control.

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

For LMOs, the following evidence should also be considered:

- potential economic consequences that could result from adverse effects on non-target organisms that are injurious to plants or plant products
- economic consequences that could result from pest properties.

For more detailed guidance on the assessment of these characteristics, see section 1.1.5.

2.3.1 Pest effects

In order to estimate the potential economic importance of the pest, information should be obtained from areas where the pest occurs naturally or has been introduced. This information should be compared with the situation in the PRA area. Case histories concerning comparable pests can usefully be considered. The effects considered may be direct or indirect.

The basic method for estimating the potential economic importance of pests in this section also applies to:

- pests affecting uncultivated/unmanaged plants;
- weeds and/or invasive plants; and
- pests affecting plants through effects on other organisms.

In the case of direct and indirect environmental effects, specific evidence is needed.

In the case of plants to be imported for planting, the long-term consequences for the intended habitat may be included in the assessment. Planting may affect further use or have a harmful effect on the intended habitat.

Environmental effects and consequences considered should result from effects on plants. Such effects, however, on plants may be less significant than the effects and/or consequences on other organisms or systems. For example, a minor weed may be significantly allergenic for humans or a minor plant pathogen may produce toxins that seriously affect livestock. However, the regulation of plants solely on the basis of their effects on other organisms or systems (e.g. on human or animal health) is outside the scope of this standard. If the PRA process reveals evidence of a potential hazard to other organisms or systems, this should be communicated to the appropriate authorities which have the legal responsibility to deal with the issue.

2.3.1.1 Direct pest effects

For identification and characterization of the direct effects of the pest on each potential host in the PRA area, or those effects which are host-specific, the following are examples that could be considered:

- known or potential host plants (in the field, under protected cultivation, or in the wild)
- types, amount and frequency of damage
- crop losses, in yield and quality
- biotic factors (e.g. adaptability and virulence of the pest) affecting damage and losses
- abiotic factors (e.g. climate) affecting damage and losses
- rate of spread
- rate of reproduction
- control measures (including existing measures), their efficacy and cost
- effect on existing production practices
- environmental effects.

For each of the potential hosts, the total area of the crop and area potentially endangered should be estimated in relation to the elements given above.

In the case of the analysis of environmental risks, examples of direct pest effects on plants and/or their environmental consequences that could be considered include:

- reduction of keystone plant species;
- reduction of plant species that are major components of ecosystems (in terms of abundance or size), and endangered native plant species (including effects below species level where there is evidence of such effects being significant);
- significant reduction, displacement or elimination of other plant species.

The estimation of the area potentially endangered should relate to these effects.

2.3.1.2 Indirect pest effects

For identification and characterization of the indirect effects of the pest in the PRA area, or those effects that are not host-specific, the following are examples that could be considered:

- effects on domestic and export markets, including in particular effects on export market access. The potential consequences for market access which may result if the pest becomes established, should be estimated. This involves considering the extent of any phytosanitary regulations imposed (or likely to be imposed) by trading partners
- changes to producer costs or input demands, including control costs
- changes to domestic or foreign consumer demand for a product resulting from quality changes

- environmental and other undesired effects of control measures
- feasibility and cost of eradication or containment
- capacity to act as a vector for other pests
- resources needed for additional research and advice
- social and other effects (e.g. tourism).

In the case of the analysis of environmental risks, examples of indirect pest effects on plants and/or their environmental consequences that could be considered include:

- significant effects on plant communities;
- significant effects on designated environmentally sensitive or protected areas;
- significant change in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, erosion, water table changes, increased fire hazard, nutrient cycling, etc.);
- effects on human use (e.g. water quality, recreational uses, tourism, animal grazing, hunting, fishing); and
- costs of environmental restoration.

Effects on human and animal health (e.g. toxicity, allergenicity), water tables, tourism, etc. could also be considered, as appropriate, by other agencies/authorities.

2.3.2 Analysis of economic consequences

2.3.2.1 Time and place factors

Estimations made in the previous section related to a hypothetical situation where the pest is supposed to have been introduced and to be fully expressing its potential economic consequences (per year) in the PRA area. In practice, however, economic consequences are expressed with time, and may concern one year, several years or an indeterminate period. Various scenarios should be considered. The total economic consequences over more than one year can be expressed as net present value of annual economic consequences, and an appropriate discount rate selected to calculate net present value.

Other scenarios could concern whether the pest occurs at one, few or many points in the PRA area and the expression of potential economic consequences will depend on the rate and manner of spread in the PRA area. The rate of spread may be envisaged to be slow or rapid; in some cases, it may be supposed that spread can be prevented. Appropriate analysis may be used to estimate potential economic consequences over the period of time when a pest is spreading in the PRA area. In addition, many of the factors or effects considered above could be expected to change over time, with the consequent effects of potential economic consequences. Expert judgement and estimations will be required.

2.3.2.2 Analysis of commercial consequences

As determined above, most of the direct effects of a pest, and some of the indirect effects will be of a commercial nature, or have consequences for an identified market. These effects, which may be positive or negative, should be identified and quantified. The following may usefully be considered:

- effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices
- effect of pest-induced changes in quantities demanded or prices paid for commodities by domestic and international consumers. This could include quality changes in products and/or quarantine-related trade restrictions resulting from a pest introduction.

2.3.2.3 Analytical techniques

There are analytical techniques which can be used in consultation with experts in economics to make a more detailed analysis of the potential economic effects of a quarantine pest. These should incorporate all of the effects that have been identified. These techniques may include:

- *partial budgeting*: this will be adequate, if the economic effects induced by the action of the pest to producer profits are generally limited to producers and are considered to be relatively minor
- *partial equilibrium*: this is recommended if, under point 2.3.2.2, there is a significant change in producer profits, or if there is a significant change in consumer demand. Partial equilibrium analysis is necessary to measure welfare changes, or the net changes arising from the pest impacts on producers and consumers
- *general equilibrium*: if the economic changes are significant to a national economy, and could cause changes to factors such as wages, interest rates or exchange rates, then general equilibrium analysis could be used to establish the full range of economic effects.

The use of analytical techniques is often limited by lack of data, by uncertainties in the data, and by the fact that for certain effects only qualitative information can be provided.

2.3.2.4 Non-commercial and environmental consequences

Some of the direct and indirect effects of the introduction of a pest determined in 2.3.1.1 and 2.3.1.2 will be of an economic nature, or affect some type of value, but not have an existing market which can be easily identified. As a result, the effects may not be adequately measured in terms of prices in established product or service markets. Examples include in particular environmental effects (such as ecosystem stability, biodiversity, amenity value) and social effects (such as employment, tourism) arising from a pest introduction. These impacts could be approximated with an appropriate non-market valuation method. More details on environment are given below.

If quantitative measurement of such consequences is not feasible, qualitative information about the consequences may be provided. An explanation of how this information has been incorporated into decisions should also be provided.

Application of this standard to environmental hazards requires clear categorization of environmental values and how they can be assessed. The environment can be valued using different methodologies, but these methodologies are best used in consultation with experts in economics. Methodologies may include consideration of "use" and "non-use" values. "Use"

values arise from consumption of an element of the environment, such as accessing clean water, or fishing in a lake, and also those that are non-consumptive, such as use of forests for leisure activities. "Non-use" values may be subdivided into:

- "option value" (value for use at a later date);
- "existence value" (knowledge that an element of the environment exists); and
- "bequest value" (knowledge that an element of the environment is available for future generations).

Whether the element of the environment is being assessed in terms of use or non-use values, methods exist for their valuation, such as market-based approaches, surrogate markets, simulated markets, and benefit transfer. Each has advantages, disadvantages and situations where it is particularly useful.

The assessment of consequences may be either quantitative or qualitative and in many cases, qualitative data is sufficient. A quantitative method may not exist to address a situation (e.g. catastrophic effects on a keystone species), or a quantitative analysis may not be possible (no methods available). Useful analyses can be based on non-monetary valuations (number of species affected, water quality), or expert judgement, if the analyses follow documented, consistent and transparent procedures.

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

2.3.3 Conclusion of the assessment of economic consequences

Wherever appropriate, the output of the assessment of economic consequences described in this step should be in terms of a monetary value. The economic consequences can also be expressed qualitatively or using quantitative measures without monetary terms. Sources of information, assumptions and methods of analysis should be clearly specified.

2.3.3.1 Endangered area

The part of the PRA area where presence of the pest will result in economically important loss should be identified as appropriate. This is needed to define the endangered area.

2.4 Degree of uncertainty

Estimation of the probability of introduction of a pest and of its economic consequences involves many uncertainties. In particular, this estimation is an extrapolation from the situation where the pest occurs to the hypothetical situation in the PRA area. It is important to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs.

It should be noted that the assessment of the probability and consequences of environmental hazards of pests of uncultivated and unmanaged plants often involves greater uncertainty than for pests of cultivated or managed plants. This is due to the lack of information, additional complexity associated with ecosystems, and variability associated with pests, hosts or habitats.

2.5 Conclusion of the pest risk assessment stage

As a result of the pest risk assessment, all or some of the categorized pests may be considered appropriate for pest risk management. For each pest, all or part of the PRA area may be identified as an endangered area. A quantitative or qualitative estimate of the probability of introduction of a pest or pests, and a corresponding quantitative or qualitative estimate of economic consequences (including environmental consequences), have been obtained and documented or an overall rating could have been assigned. These estimates, with associated uncertainties, are utilized in the pest risk management stage of the PRA.

3. Stage 3: Pest Risk Management

The conclusions from pest risk assessment are used to decide whether risk management is required and the strength of measures to be used. Since zero-risk is not a reasonable option, the guiding principle for risk management should be to manage risk to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources. Pest risk management (in the analytical sense) is the process of identifying ways to react to a perceived risk, evaluating the efficacy of these actions, and identifying the most appropriate options. The uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option.

In considering the management of environmental risks, it should be stressed that phytosanitary measures are intended to account for uncertainty and should be designed in proportion to the risk. Pest risk management options should be identified, taking account of the degree of uncertainty in the assessment of economic consequences, probability of introduction, and the respective technical justification of those options. In this respect, the management of risks to the environment caused by plant pests does not differ from the management of other plant pest risks.

3.1 Level of risk

The principle of "managed risk" (ISPM No. 1: Principles of plant quarantine as related to international trade) states that: "Because some risk of introduction of a quarantine pest always exists, countries shall agree to a policy of risk management when formulating phytosanitary measures." In implementing this principle, countries should decide what level of risk is acceptable to them.

The acceptable level of risk may be expressed in a number of ways, such as:

- reference to existing phytosanitary requirements
- indexed to estimated economic losses
- expressed on a scale of risk tolerance
- compared with the level of risk accepted by other countries.

For LMOs, the acceptable level of risk may also be expressed by comparison to the level of risk associated with similar or related organisms.

3.2 Technical information required

The decisions to be made in the pest risk management process will be based on the information collected during the preceding stages of PRA. This information will be composed of:

- reasons for initiating the process
- estimation of the probability of introduction to the PRA area
- evaluation of potential economic consequences in the PRA area.

3.3 Acceptability of risk

Overall risk is determined by the examination of the outputs of the assessments of the probability of introduction and the economic impact. If the risk is found to be unacceptable, then the first step in risk management is to identify possible phytosanitary measures that will reduce the risk to, or below an acceptable level. Measures are not justified if the risk is already acceptable or must be accepted because it is not manageable (as may be the case with natural spread). Countries may decide that a low level of monitoring or audit is maintained to ensure that future changes in the pest risk are identified.

3.4 Identification and selection of appropriate risk management options

Appropriate measures should be chosen based on their effectiveness in reducing the probability of introduction of the pest. The choice should be based on the following considerations, which include several of the *Principles of plant quarantine as related to international trade* (ISPM No. 1):

Phytosanitary measures shown to be cost-effective and feasible - The benefit from the use of phytosanitary measures is that the pest will not be introduced and the PRA area will, consequently, not be subjected to the potential economic consequences. The cost-benefit analysis for each of the minimum measures found to provide acceptable security may be estimated. Those measures with an acceptable benefit-to-cost ratio should be considered.

- *Principle of "minimal impact"* - Measures should not be more trade restrictive than necessary. Measures should be applied to the minimum area necessary for the effective protection of the endangered area.
- *Reassessment of previous requirements* - No additional measures should be imposed if existing measures are effective.
- *Principle of "equivalence"* - If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
- *Principle of "non-discrimination"* - If the pest under consideration is established in the PRA area but of limited distribution and under official control, the phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Likewise, phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

The principle of non-discrimination and the concept of official control also apply to:

- pests affecting uncultivated/unmanaged plants;
- weeds and/or invasive plants; and
- pests affecting plants through effects on other organisms.

If any of these become established in the PRA area and if official control is applied, then phytosanitary measures at import should not be more stringent than the official control measures.

The major risk of introduction of plant pests is with imported consignments of plants and plant products, but (especially for a PRA performed on a particular pest) it is necessary to consider the risk of introduction with other types of pathways (e.g. packing materials, conveyances, travellers and their luggage, and the natural spread of a pest).

The measures listed below are examples of those that are most commonly applied to traded commodities. They are applied to pathways, usually consignments of a host, from a specific origin. The measures should be as precise as possible as to consignment type (hosts, parts of plants) and origin so as not to act as barriers to trade by limiting the import of products where this is not justified. Combinations of two or more measures may be needed in order to reduce the risk to an acceptable level. The available measures can be classified into broad categories which relate to the pest status of the pathway in the country of origin. These include measures:

- applied to the consignment
- applied to prevent or reduce original infestation in the crop
- to ensure the area or place of production is free from the pest
- concerning the prohibition of commodities.

Other options may arise in the PRA area (restrictions on the use of a commodity), control measures, introduction of a biological control agent, eradication, and containment. Such options should also be evaluated and will apply in particular if the pest is already present but not widely distributed in the PRA area.

3.4.1 Options for consignments

Measures may include any combinations of the following:

- inspection or testing for freedom from a pest or to a specified pest tolerance; sample size should be adequate to give an acceptable probability of detecting the pest
- prohibition of parts of the host

- a pre-entry or post-entry quarantine system - this system could be considered to be the most intensive form of inspection or testing where suitable facilities and resources are available, and may be the only option for certain pests not detectable on entry
- specified conditions of preparation of the consignment (e.g. handling to prevent infestation or reinfestation)
- specified treatment of the consignment - such treatments are applied post-harvest and could include chemical, thermal, irradiation or other physical methods
- restrictions on end use, distribution and periods of entry of the commodity.

Measures may also be applied to restrict the import of consignments of pests. The concept of consignments of pests may be applied to the import of plants considered to be pests. These consignments may be restricted to species or varieties posing less risk.

For LMOs, as for other organisms, information may have been obtained concerning the risk management measures applied to the LMO in the country of export (see section 1.3). These should be assessed to determine if they are appropriate for the conditions in the PRA area and, if appropriate, the intended use.

For LMOs, measures may also include procedures for the provision of information on the phytosanitary integrity of consignments (e.g. tracing systems, documentation systems, identity preservation systems).

3.4.2 Options preventing or reducing infestation in the crop

Measures may include:

- treatment of the crop, field, or place of production
- restriction of the composition of a consignment so that it is composed of plants belonging to resistant or less susceptible species
- growing plants under specially protected conditions (glasshouse, isolation)
- harvesting of plants at a certain age or a specified time of year
- production in a certification scheme. An officially monitored plant production scheme usually involves a number of carefully controlled generations, beginning with nuclear stock plants of high health status. It may be specified that the plants be derived from plants within a limited number of generations.

Measures may be applied to reduce the probability that LMOs (or genetic material from LMOs) that pose a phytosanitary risk could be in other crops. These include:

- management systems (e.g. buffer zones, refugia)
- management of trait expression
- control of reproductive ability (e.g. male sterility)
- control of alternative hosts.

3.4.3 Options ensuring that the area, place or site of production or crop is free from the pest

Measures may include:

- pest-free area - requirements for pest-free area status are described in ISPM No. 4: Requirements for the establishment of pest free areas
- pest-free place of production or pest-free production site - requirements are described in ISPM No. 10: Requirements for the establishment of pest free places of production and pest-free production sites
- inspection of crop to confirm pest freedom.

3.4.4 Options for other types of pathways

For many types of pathways, the measures considered above for plants and plant products to detect the pest in the consignment or to prevent infestation of the consignment, may also be used or adapted. For certain types of pathways, the following factors should be considered:

- Natural spread of a pest includes movement of the pest by flight, wind dispersal, transport by vectors such as insects or birds and natural migration. If the pest is entering the PRA area by natural spread, or is likely to enter in the immediate future, phytosanitary measures may have little effect. Control measures applied in the area of origin could be considered. Similarly, containment or eradication, supported by suppression and surveillance, in the PRA area after entry of the pest could be considered.
- Measures for human travellers and their baggage could include targeted inspections, publicity and fines or incentives. In a few cases, treatments may be possible.
- Contaminated machinery or modes of transport (ships, trains, planes, road transport) could be subjected to cleaning or disinfestation.

3.4.5 Options within the importing country

Certain measures applied within the importing country may also be used. These could include careful surveillance to try and detect the entry of the pest as early as possible, eradication programmes to eliminate any foci of infestation and/or containment action to limit spread.

For plants to be imported, where there is a high level of uncertainty regarding pest risk, it may be decided not to take phytosanitary measures at import, but only to apply surveillance or other procedures after entry (e.g. by or under the supervision of the NPPO).

The potential for risk depends in part on the intended use. As for other organisms, certain intended uses (such as high security contained use) may significantly manage risk.

For LMOs, as with other pests, options within the country also include the use of emergency measures related to phytosanitary risks. Any emergency measures should be consistent with Article VII.6 of the IPPC (1997).

3.4.6 Prohibition of commodities

If no satisfactory measure to reduce risk to an acceptable level can be found, the final option may be to prohibit importation of the relevant commodities. This should be viewed as a measure of last resort and should be considered in light of the anticipated efficacy, especially in instances where the incentives for illegal import may be significant.

3.5 Phytosanitary certificates and other compliance measures

Risk management includes the consideration of appropriate compliance procedures. The most important of these is export certification (see ISPM No. 7: *Export certification system*). The issuance of phytosanitary certificates (see ISPM No. 12: *Guidelines for Phytosanitary Certificates*) provides official assurance that a consignment is "considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party." It thus confirms that the specified risk management options have been followed. An additional declaration may be required to indicate that a particular measure has been carried out. Other compliance measures may be used subject to bilateral or multilateral agreement.

Information on Phytosanitary Certificates regarding LMOs (as with any other regulated articles) should only be related to phytosanitary measures (see ISPM No. 12: *Guidelines for phytosanitary certificates*).

3.6 Conclusion of pest risk management

The result of the pest risk management procedure will be either that no measures are identified which are considered appropriate or the selection of one or more management options that have been found to lower the risk associated with the pest(s) to an acceptable level. These management options form the basis of phytosanitary regulations or requirements.

The application and maintenance of such regulations is subject to certain obligations, in the case of contracting parties to the IPPC.

Phytosanitary measures taken in relation to environmental hazards should, as appropriate, be notified to relevant competent authorities responsible for national biodiversity policies, strategies and action plans.

It is noted that the communication of risks associated with environmental hazards is of particular importance to promote awareness.

3.6.1 Monitoring and review of phytosanitary measures

The principle of "modification" states: "As conditions change, and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of prohibitions, restrictions or requirements necessary for their success, or by removal of those found to be unnecessary" (ISPM No. 1: *Principles of plant quarantine as related to international trade*).

Thus, the implementation of particular phytosanitary measures should not be considered to be permanent. After application, the success of the measures in achieving their aim should be determined by monitoring during use. This is often achieved by inspection of the commodity on arrival, noting any interceptions or any entries of the pest to the PRA area. The information supporting the pest risk analysis should be periodically reviewed to ensure that any new information that becomes available does not invalidate the decision taken.

4. Documentation of Pest Risk Analysis

4.1 Documentation requirements

The IPPC and the principle of "transparency" (ISPM No. 1: *Principles of plant quarantine as related to international trade*) require that countries should, on request, make available the rationale for phytosanitary requirements. The whole process from initiation to pest risk management should be sufficiently documented so that when a review or a dispute arises, the sources of information and rationale used in reaching the management decision can be clearly demonstrated.

The main elements of documentation are:

- purpose for the PRA
- pest, pest list, pathways, PRA area, endangered area
- sources of information
- categorized pest list
- conclusions of risk assessment
 - * probability
 - * consequences
- risk management
 - * options identified
- options selected.

COMMENTS ON THE SCOPE OF THE IPPC IN REGARD TO ENVIRONMENTAL RISKS

The full range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. The coverage of the IPPC definition of plant pests includes weeds and other species that have indirect effects on plants, and the Convention applies to the protection of wild flora. The scope of the IPPC also extends to organisms which are pests because they:

- *directly affect uncultivated/unmanaged plants*

Introduction of these pests may have few commercial consequences, and therefore they have been less likely to be evaluated, regulated and/or placed under official control. An example of this type of pest is Dutch elm disease (*Ophiostoma novo-ulmi*).

- *indirectly affect plants*

In addition to pests that directly affect host plants, there are those, like most weeds/invasive plants, which affect plants primarily by other processes such as competition (e.g. for cultivated plants: Canada thistle (*Cirsium arvense*) [weed of agricultural crops], or for uncultivated/unmanaged plants: Purple loosestrife (*Lythrum salicaria*) [competitor in natural and semi-natural habitats]).

- *indirectly affect plants through effects on other organisms*

Some pests may primarily affect other organisms, but thereby cause deleterious effects on plant species, or plant health in habitats or ecosystems. Examples include parasites of beneficial organisms, such as biological control agents.

To protect the environment and biological diversity without creating disguised barriers to trade, environmental risks and risks to biological diversity should be analyzed in a PRA.

**COMMENTS ON THE SCOPE OF THE IPPC
IN REGARD TO PEST RISK ANALYSIS FOR LMOs**

Phytosanitary risks that may be associated with an LMO are within the scope of the International Plant Protection Convention (IPPC) and should be considered using pest risk analysis (PRA) to make decisions regarding pest risk management.

The analysis of LMOs includes consideration of the following:

- Some LMOs may present a phytosanitary risk and therefore warrant a PRA. However other LMOs will not present a phytosanitary risks beyond those posed by related non-LMOs and therefore will not warrant a complete pest risk analysis. For example, modifications to change the physiological characteristics of a plant (e.g. ripening time, storage life) may not present any phytosanitary risk. The pest risk that may be posed by an LMO is dependent on a combination of factors, including the characteristics of the donor and recipient organisms, the genetic alteration, and the specific new trait or traits. Therefore, part of the supplementary text (see section 1.1.5) provides guidance on how to determine if an LMO is a potential pest.
- PRA may constitute only a portion of the overall risk analysis for import and release of a LMO. For example, countries may require the assessment of risks to human or animal health, or to the environment, beyond that covered by the IPPC. This standard only relates to the assessment and management of phytosanitary risks. As with other organisms or pathways assessed by an NPPO, LMOs may present other risks not falling within the scope of the IPPC. When an NPPO discovers potential for risks that are not of phytosanitary concern it may be appropriate to notify the relevant authorities.
- Phytosanitary risks from LMOs may result from certain traits introduced into the organism, such as those that increase the potential for establishment and spread (invasiveness), or from inserted gene sequences that do not alter the pest characteristics of the organism but that might act independently of the organism or have unintended consequences.
- In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.
- The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.
- Potential phytosanitary risks that may be associated with LMOs could also be associated with non-LMOs. It may be useful to consider risks associated with LMOs in the context of risks posed by the non-modified recipient or parental organisms, or similar organisms, in the PRA area.

SPECIFICATION NO. 3 (2ND REVISION)

Title: Revision of ISPM No. 2 (*Guidelines for pest risk analysis*)

Reason for revision: FAO Conference adopted ISPM No. 2 (*Guidelines for pest risk analysis*) in November 1995. This was before the revision of the IPPC and also before many National Plant Protection Organizations had experience with pest risk analysis. Subsequent revision of the IPPC and the rapid advancement of pest risk analysis in practice create the need for updating the guidance provided by ISPM No. 2. In particular, the standard provides no guidance in certain situations such as regulated non-quarantine pests, LMOs or biological control agents, and it has certain key deficiencies such as not considering the feasibility of measures in risk management.

Scope and purpose: ISPM No. 2 describes the process of pest risk analysis for phytosanitary purposes. The standard should provide general and conceptual guidance to pest risk analysis and an introduction to the more specific standards dealing with risk analysis under the IPPC.

Tasks:

The overall task is to undertake a review of ISPM No. 2 with the aim of reformulation into a new standard, general guidelines for PRA for phytosanitary purposes.

In particular, attention should be given to:

- consideration of an appropriate title;
- full alignment with IPPC (1997) and the agreed interpretation of the term phytosanitary measure;
- developing guidance to determine if an organism is a potential pest;
- consideration of PRA as it applies to RNQPs;
- consideration of whether elements of the PRA process that are common to all regulated pests, such as the initiation and categorization processes, should be covered in detail in ISPM No. 2, rather than in the specific PRA standards (ISPM No. 11 and the PRA for RNQP draft);
- consideration of measures in risk management (taking into account rights and obligations, including feasibility);
- revision of the figures;
- those situations where the original standard provided no guidance on intentional or unintentional introduction of:
 - living modified organisms (LMOs)
 - invasive plants
 - biocontrol agents, etc.

The review should take into account ISPM No. 11, including the supplement on environmental risks adopted at the Fifth session of the ICPM, the draft standard on PRA for regulated non-quarantine pests and the draft supplement to ISPM No. 11 on PRA for LMOs.

Provision of resources: Funding for meetings is provided from the regular programme of the IPPC Secretariat (FAO) except where expert participation is voluntarily funded by the expert's government.

Proposed work programme: Scheduled in the work programme for 2003-4.

Steward: Suparno Sa

Expertise: A working group of 5-7 experts having a combination of skills and experience, including a familiarity with SPS and IPPC principles and the development and application of PRA, a general knowledge of standard setting and representing diverse geographical regions.

Participants: to be determined

Approval: Incorporated into the work programme at the Fifth Session of the ICPM in 2003. Specification modified by the SC-7 in May 2003, and then following SC-20 comments obtained by e-mail. 2nd revision by the Standards Committee in November 2003.

References: ISPM No. 1; ISPM No. 2; ISPM No. 3; ISPM No. 11, including the supplement on environmental risks; draft standard on PRA for regulated non-quarantine pests; draft supplement on PRA for LMOs.

SPECIFICATION NO. 13

Title: Phytosanitary measures for consignments in transit

Reason for the standard: Transit of consignments of regulated articles is a measure which facilitates trade, since it allows consignments to be transported more rapidly and at less expense without application of the usual procedures at import and re-export. Countries should therefore evaluate whether they can allow a modification of import procedures for consignments of regulated articles in transit, provided adequate alternative simpler procedures are followed which adequately reduce risk.

Scope and purpose: The standard should provide guidance on appropriate procedures, particularly in relation to those which are in any case applied to consignments in transit for customs purposes. This standard recommends procedures to be followed in countries of transit, to allow consignments of regulated articles to pass in transit under procedures less stringent than those for import and re-export. Such procedures should also be evaluated to assure that they provide adequate protection to the ultimate importing country from any phytosanitary risks arising in the country of transit.

Tasks

In drafting a standard, the following transit scenarios should in particular be considered.

- Countries may evaluate whether normally prohibited commodities may enter and transit, and under what conditions.
- They may evaluate whether commodities normally subject to certain restrictions at import may be exempted wholly or partly from those restrictions, or be subjected to other lighter restrictions.
- Consideration of the relationship between domestic measures and transit measures, in order to avoid more restrictive measures for articles of same phytosanitary risk.
- Where it is possible for the commodities to pass in transit for customs purposes, countries may evaluate whether the customs procedures are in themselves sufficient for their phytosanitary security, or whether they need to be supplemented by other procedures.
- Countries may also consider whether consignments in transit are exposed to infestation or contamination by pests which may present a risk to other countries (in transit or at final import) and whether appropriate procedures can be proposed to reduce these risks.
- Consider the components of an in-transit system such as arrangements for arrival in the country, safeguarding, routes of travel, tracking and requirements related to departure from the transit country.

Provision of resources: To be determined

Proposed work programme: To be determined

Steward: Ringolds Arnitis

Collaborator: EPPO

Expertise: To be determined

Participants: A working group of 5-7 phytosanitary experts.

Approval: Introduced into the work programme by the ICPM at its fifth session, April 2003. Approved by the Standards Committee in November 2003.

References: To be determined

ISSUES ARISING FROM THE GLOSSARY WORKING GROUP

These proposals will go through the normal process of country consultation in 2004. They might be completed by further proposals after the next meeting of the Glossary Working Group in February 2004. A report of the outcome of the Glossary e-mail discussions is being prepared.

Use of phytosanitary

It is proposed to modify the following definitions which contained the word "phytosanitary", to make it clear that the restricted meaning "related to regulated pests" applies in these cases.

additional declaration - A statement that is required by an importing country to be entered on a Phytosanitary Certificate and which provides specific additional information pertinent to the condition of a consignment in relation to regulated pests

compliance procedure - Official procedure used to verify that a consignment complies with stated requirements in relation to regulated pests

detention - Keeping a consignment in official custody or confinement, as a phytosanitary measure (see quarantine)

import permit - Official document authorizing importation of a commodity in accordance with specified requirements in relation to regulated pests

systems approaches - The integration of different management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of protection against regulated pests

Other definitions containing the word "phytosanitary" can remain as they are, since the word either forms part of a glossary term like "phytosanitary measure" or is used in an unrestricted sense.

Two modifications arising from the meeting of the Glossary Working Group in February 2003

It is proposed that terms which use the words "*phytosanitary regulation or procedure*" can now be changed to "*phytosanitary measure*", because of the agreed interpretation for phytosanitary measure.

The following changes will therefore be proposed:

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.

phytosanitary action - An official operation, such as inspection, testing, surveillance or treatment, undertaken to implement phytosanitary measures.

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