# DRAFT REPORT

Rome, Italy, 15-19 November 2004 Standards Committee Fifth meeting

# REPORT OF THE FIFTH MEETING OF THE STANDARDS COMMITTEE

Rome, Italy: 15–19 November 2004



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS Rome, 2004

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#### 1. OPENING OF THE MEETING

Mr Vereecke welcomed the participants to the SC, and in particular the five additional members who were present as observers and whose nominations would be put forward to the ICPM in 2005. Mr Solh (Director of the Plant Protection Service, FAO) opened the meeting and stressed that FAO countries had recognized on numerous occasions the importance of IPPC activities. Despite an overall decline of FAO budgetary resources, substantially more resources had been made available to the IPPC from the organization. He hoped that this situation would be maintained in the future.

## 2. ADOPTION OF THE AGENDA

The provisional agenda was adopted with changes, and is shown in Appendix 1.

## 3. ADOPTION OF THE REPORT OF THE FOURTH MEETING OF THE STANDARDS COMMITTEE

It was commented that SC reports should be available as soon as possible after the meetings. It was noted that Mr Wolff had not been identified as steward for the Technical Panel on forest quarantine, during the last meeting, although this appeared in the report.

The SC approved the report.

# 4. REPORT OF THE MEETING OF THE STANDARDS COMMITTEE WORKING GROUP, STEWARD OR REPRESENTATIVE OVERVIEW OF DRAFT STANDARDS

Mr Vereecke congratulated the Standards Committee Working Group (SCWG (SC7)) on the amount of work done during the previous week and invited the Chairman of the SCWG, Mr Klag, to introduce the outcome of discussions on the drafts that had been revised by the SCWG to date, in relation to equivalence, inspection of consignments, areas of low pest prevalence, revision of ISPM No. 3. He noted that work on the draft ISPM on transit and on the draft amendments to the Glossary would continue during the week. Mr Klag and stewards for the draft ISPMs presented the main issues which had arisen during the meeting for each of the drafts.

As decided by ICPM-6 in 2004, country comments would be published on the IPP. A version of the table of country comments would incorporate steward, SCWG and, possibly, SC comments. The SC noted that the ICPM had asked that information on reactions to comments should be made available, and the SC discussed whether these modified tables should also be added to the IPP. If the tables were to be consolidated and published, this would entail considerable editorial and updating work for the Secretariat and for the SC. In addition, it noted that the resulting text in a draft ISPM would not necessary address an individual comment on a particular point, but was taking account of all comments on that point. The SC was also reluctant to put stewards' comments on the IPP, since the SC, and not stewards, is ultimately responsible for the redrafting. It was felt that making this information available on request to countries would suffice. Where such requests were received by the Secretariat, the Secretariat could use the reactions recorded in the tables to prepare a response to such an inquiry and could contact, as appropriate, stewards, the SCWG or the SC.

# 5. ADOPTION OF THE REPORT AND ANNEXES OF THE MEETING OF THE STANDARDS COMMITTEE WORKING GROUP IN JULY 2004

The Chairman invited comments on the report and appendices of the SCWG which had met in July 2004. The report was adopted. No written comments had been received from the SC on the appendices to the report following the meeting, but one member had verbal comments. The annexes were reviewed to consider verbal comments.

## 5.1 DOCUMENTS RELATING TO THE IMPROVEMENT OF STANDARD SETTING

A number of documents relating to the improvement of the standard setting process had been drafted following ICPM-6. The SC reviewed, adjusted and approved the following documents:

- Guidelines on the duties of members of the Standards Committee of the Interim Commission on Phytosanitary Measures (Appendix 2).
- Guidelines for the operation of expert working groups (Appendix 3).
- Guidelines on the role of a steward of an ISPM (see Appendix 4).
- Criteria for the formation and subsequent change of supplements, annexes and appendices in ISPMs (see Appendix 5).

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- Guidelines for an additional round of formal consultation. The SC proposed modifications of the procedures for the development and adoption of ISPMs (Annex I of the Rules of Procedure of the ICPM) to include guidelines for an additional round of formal consultation (see Appendix 6). It discussed how to proceed when it could not reach consensus. The draft provided for sending back the draft ISPM to either an EWG or for an additional round of consultation. It was decided to add the additional option of forwarding the draft to the ICPM for its consideration. There was some discussion on whether more details should be given to the ICPM as to the matters of concern. It was decided that these details would generally appear in the report of the SC or in the draft ISPM, and that no further details were needed. There was also discussion on whether reference should be made to the possible immediate adoption following such consideration by the ICPM, but it was decided that the ICPM could decide on options for each draft. It was noted that changes resulting from the adoption of the fast track process were not included in the steps of the present procedures, and the SC decided that a separate set of guidelines would be needed for the fast-track process. The SC asked the Secretariat to draft such guidelines for consideration of the SC in April 2005.

### 5.2 SUBMISSION FORM FOR ICPM WORK PROGRAMME TOPICS

The Secretariat noted that the SPTA had decided to add a box to this form, to outline which criteria from the *Procedures for identifying topics and priorities for standards* were used in identifying this subject as a proposal for a standard and annex these criteria to the form. The submission form was approved as presented in Appendix 7.

#### **5.3 SPECIFICATIONS**

The SC reviewed, adjusted and approved the following specifications:

- Technical Panel Specification No. 4 (Technical Panel on forest quarantine). The SC modified the specification and noted that some of the tasks should be adjusted depending on whether or not the TP on phytosanitary treatments would develop a research protocol for phytosanitary measures (treatments) (which was cross-referred to in the specification for TP No. 4). There was some debate in relation to the International Forest Quarantine Research Group (IFQRG) and on the discussions which had taken place at ICPM-6. The SC decided to delete the reference to the IFQRG in the tasks, while mentioning "relevant research groups", and to add a reference to the IFQRG reports in the references. The specification was approved as presented in Appendix 8.
- Specification No. 17 (Debarking of wood). The specification was approved as presented in Appendix 9.
- Specification No. 22 (Research protocols for phytosanitary measures (treatments)). The SC modified the specification in order to give the Secretariat flexibility as to whether the tasks in this specification would be carried out by the Technical Panel on phytosanitary treatments or by an EWG. The specification was approved as presented in Appendix 10.
- Specification No. 23 (Guidance for surveillance for specific pests: *Xanthomonas axonopodis* pv. *citri* [Citrus canker]). The specification was approved as presented in Appendix 11.
- Specification No. 24 (Post-entry quarantine facilities). The specification was approved as presented in Appendix 12.
- Specification No. 25 (Guidelines for formatting/drafting pest specific ISPMs). The specification approved as presented in Appendix 13.
- Specification No. 26 (Guidelines for formatting/drafting commodity specific ISPMs). The specification approved as presented in Appendix 14.

### 6. MATTERS ARISING FROM TECHNICAL PANELS

The SC took note of the work programmes of the TPs on diagnostic protocols and on pest free areas and systems approaches for fruit flies, and agreed that the TPs, working under the general direction of the SC, should continue to develop draft ISPMs relevant to their tasks outlined in their respective specifications. The substantial progress made at both TP meetings was noted.

## 6.1 TECHNICAL PANEL ON DIAGNOSTIC PROTOCOLS

Mr Unger reported on the TP on diagnostic protocols, noting that a draft standard on Guidelines for formatting specific diagnostic protocols for regulated pests, which had been drafted by an EWG had been reviewed and amended at the first meeting. This draft ISPM had subsequently been reviewed by the EWG, and the Steward of the EWG had received no further comments. The SC reviewed and approved the work programme. In reviewing the list of the 19 priority organisms for diagnostic protocols, the SC decided to add

citrus canker (*Xanthomonas axonopodis* pv. *citri*) to the list of highest priority work. It was noted that the criteria used for selecting priorities for diagnostic protocols would be mentioned in the report of the first meeting of the TP. The TP had proposed adjustments to its specification (Specification - Technical Panels No. 1). The specification was approved as presented in Appendix 15.

## 6.2 TECHNICAL PANEL ON PEST FREE AREAS AND SYSTEMS APPROACHES FOR FRUIT FLIES

Mr Ribeiro e Silva reported on the activities of this TP, noting that a draft standard on pest free areas for fruit flies had been prepared during the first meeting of this TP. The SC reviewed and approved the work programme. It reviewed the following specifications revised/prepared by the TP:

- Technical Panel Specification No. 2 (revision). The TP had proposed adjustments to its specification. The specification was approved as presented in Appendix 16.
- Specification No. 27 (Pest free areas for fruit flies). The specification was approved as presented in Appendix 17.
- Specification No. 28 (Areas of low pest prevalence for fruit flies). The specification was approved as presented in Appendix 18.
- Specification No. 29 (Systems Approach for fruit flies). The specification was approved as presented in Appendix 19.

#### 7. NOMINATION OF STEWARDS

The following SC members were chosen as stewards for the following EWG and/or Technical Panels:

Technical Panel					
Technical panel on forest quarantine	Greg Wolff				
Expert Working Groups					
EWG on classification of commodities by level of processing	Diego Quiroga				
EWG on guidelines for regulating potato micropropagation material and minitubers in international trade	Obbineni Reddy				
Expert Working Groups under the direction of Technical Panels					
EWG fruit fly pest free areas	Odilson Ribeiro e Silva				
EWG fruit fly systems approach	Mike Holtzhausen				
EWG fruit fly areas of low pest prevalence	Magda Gonzalez Arroyo				
EWG guidelines for formatting specific diagnostic protocols for regulated pests	Jens Unger				

## 8. PRIORITIES FOR THE WORK PROGRAMME

Most SC members were confused on the procedure which had been followed in 2004 and thought that the 140 topics submitted in 2003 had been included in the process for consideration as topics for new standards. This had not been the case, and only submissions coming from countries in 2004 had been considered. Regarding future submissions of topics and priorities by countries, the SC agreed that calls for topics should be annual, and that it should be made very clear that a new list would be compiled (and that lists from previous years would not be used). In practice, it meant that topics which had not been selected from the 2003 list of 144 topics and from the 2004 list would not be considered further unless resubmitted. The Secretariat was also requested, when sending a call for topics and priorities for standards to countries, to also attach a copy of the *Procedures for identifying topics and priorities for standards*.

The SC considered the suggestions for topics for standards as selected by the SPTA. The SPTA had identified three broad areas having higher priority (PRA for weeds; propagating material; soil and growing media), plus a number of other topics. The SC also considered existing ISPMs and additional topics which had emerged from SC discussions during the week. It agreed that the topics selected by the SC would be proposed to ICPM for addition to the work programme so that the development of specifications could start, but that priority would be given to the completion of draft ISPMs currently being developed. All topics were

first prioritized by individual members and then the SC discussed which topics should be given priority. A list of topics was agreed (see Appendix 20) and will be presented to the ICPM. The ICPM Chairperson invited SC members to discuss the agreed list in their regions to facilitate decisions at ICPM.

The SC identified the need to review existing ISPMs in order to give careful consideration as to which needed to be revised and added to the work programme. It agreed that this task should be carried out at its meeting in April 2005. It also asked that, in the future, the list of proposed new topics presented to the SC should be accompanied by additional details of the proposals taken from the submission forms, or that copies of the actual forms be available.

The SC had specific discussion on some of the topics, as follows:

**Soil and growing media**: a unique standard should be developed, which would cover soil and growing media and would combine several suggestions for topics for standards that had been submitted. This standard should be divided into 3 subject areas dealing with: soil and growing media alone (including in bulk); soil and growing media associated with plants; soil and growing media as a contaminant (including with used machinery).

**Plants for planting**. The SC identified the need for a general standard dealing with guidelines for the movement of plants for planting, but also the need for the subsequent development of individual standards dealing with individual components, in particular post-entry quarantine and certification programme. It discussed soil associated with plants for planting, and concluded that it should be considered in both standards, on plants for planting and on soil and growing media.

**PRA** for weeds. The SC noted that PRA for plants as pests was covered in ISPM No. 11 (Rev. 1), but this seemed to be insufficient since several countries had identified the need for further guidance. It debated whether ISPM No. 11 should be revised or separate document produced, but concluded that this decision should require a preliminary analysis of the needs. It was proposed that a call for case studies on conducting PRA for plants as pest (using ISPM No. 11) would be made to ICPM members by the Secretariat. Members would also be invited to identify specific areas of difficulty in applying the standard. In parallel, experts or groups should be contacted (e.g. authors of a weed risk assessment scheme in FAO; or RPPOs panels of experts etc.). A decision could then be made on how this topic should be included into the work programme.

**Inspection manual**. The SC recognized the importance of this topic, especially for developing countries, and decided to add it to the work programme so that work on a specification could start. The definition of the topic was rather vague at the moment, and could include items such as guidelines for the components of an inspection system; guidance for clearance of conveyances; inspection at points of entry etc. It could also be separated into individual elements of an inspection system, and several standards already dealt with components of inspection. The SC also noted that needs relating to inspection manuals could also be dealt with in relation to information exchange (to provide countries with relevant sources of information) or technical assistance (for the establishment of manuals and inspection framework).

**Topics related to existing Technical Panels.** The SC noted that several topics in the proposed list related directly to the work of the TPs on fruit flies and on phytosanitary treatments. It agreed that these topics should be considered by the relevant TPs when they developed their work programme.

**Bilateral work plans**. There were differences of opinion as to whether these were in the framework of the IPPC. Some members supported that guidance was needed on such work plans, which were needed for a proper operation of phytosanitary systems, and were covered under Article XVI of the IPPC. Others believed that the IPPC should concentrate on multilateral, rather than bilateral, issues. This item was not added to the proposed work programme.

**Transshipment**. The SC noted that there was still a possibility that this topic would be covered in the draft standard on transit and decided not to include this topic on the work programme until the draft ISPM on transit had been finalized.

Guidelines for regulating stored products in international trade. The SC recognized the importance of this topic, especially for the African continent, from which this proposal came.

**Organic fertilizer**. The SC decided to add this topic on the list although its components were not very clear at the moment. It noted that it might be possible to cover this issue under the standard for soil and growing media, except that this standard would already be quite large. It was decided to leave this topic separate. Interactions with the specification for soil and growing media should be considered (especially in relation to compost).

**Technical Panel on surveillance**. The SC agreed that standards on surveillance would be needed for individual pests, but noted that some priorities in this area were already covered (citrus canker with an expert working group and fruit flies by the TP on fruit flies). It also favoured a vertical approach, by pest or groups of pests.

## Review of ISPM No. 12 (Section 3.3 on transit)

The SC believed that section 3.3 of ISPM No. 12 is inaccurate. It is proposed that this section should be examined and rewritten. It was believed that this could be handled by the SC without the need for a EWG.

#### 9. GLOSSARY ISSUES

In reporting to the SC on amendments to the glossary, Mr Smith (steward for ISPM No. 5) noted that many comments had been received on points which had not been modified in definitions, and that the GWG had not had time to consider these comments, nor those relating to the need for new terms. He strongly advised that countries should receive sufficient information and guidance on the changes proposed and reasons for change, and be asked to restrict the range of their comments to the changes made. If countries felt that a more extensive revision of a term/definition is needed, they could propose it for the Glossary working group agenda.

It was noted that discussions on glossary terms often developed on points which had been extensively discussed over many years, and for which the existing definition constituted a widely agreed compromise. The SC noted that written explanations of why definitions were formulated in a certain way would be useful to the benefit of new members of the IPPC community. They could clarify some issues and limit proposed changes to the glossary. It would also be useful to share the historic memory of the glossary experts which had worked on these definitions for years. The SC decided that an annotated glossary, containing such explanations, should be developed. The SC should consider at the next meeting how this could be done.

## 10. FORMAT, PRINTING AND DISTRIBUTION OF ISPMS

The SC reviewed a paper describing an approach to compile ISPMs into a single handbook, in place of the current system of a separate green booklet for each ISPM. The approach followed previous discussions and points of agreement within the SC and the Glossary Working Group, and provided details on the timing of the publication of the handbook, how definitions would be handled and other matters. Some comments highlighted that the new format should take full advantage of electronic capabilities. Clarification was also requested that there would be an adequate number of paper-copies of the publication. Following the discussion, and in light of these comments, the SC supported the approach given in the paper. The Chair also gave members the opportunity to provide any additional comments later in the SC meeting. This approach will be forwarded to ICPM-7 for a decision.

# 11. ADMINISTRATIVE GUIDELINES FOR THE STRUCTURE OF STANDARD-SETTING DOCUMENTATION

The SC considered a draft on this topic, focusing on elements to consider in drafting ISPMs. Specific consideration was given to Section 2.3.2 of the paper, which contained draft guidance on use of the terms "should", "shall" and "may" in the context of ISPMs, and draft revised language on this point was developed. The remainder of the paper received a more general review. One comment suggested that the text be reorganized, recognizing that it will not be produced as a standard but as a more general guidance document. Another comment noted the usefulness of the document, but identified concerns about the text in Section 2.2 regarding the way in which types of standards were described. Questions were also raised about the annexes. The SC concluded that further comments may be sent in writing to Mr Klag, who would prepare a revised version for consideration at the SC meeting in April 2005.

# 12. DETAILED DISCUSSION AND APPROVAL OF DRAFTS STANDARDS FOR SUBMISSION TO THE ICPM

The SC discussed and modified individual drafts. Editorial comments remaining after the meeting could be submitted to the Secretariat before 24 November 2004. They would be incorporated as deemed appropriate by the Secretariat.

#### 12.1 GUIDELINES FOR INSPECTION OF CONSIGNMENTS

The SC considered some issues remaining after the SCWG meeting and modified the draft, which will be presented for adoption at ICPM-7. It noted that the original standard included many details on sampling. It had been agreed that all these details (from successive drafts and relevant country comments) would be transferred to the EWG on sampling. The draft on inspection now included a simple reference to the future draft ISPM on sampling. It had also been decided that the standard on inspection would be a stand alone document, and that approval would not wait for the development of the draft on sampling.

The SC noted that the draft mostly related to visual examination, but recognized that some additional tools were now used by inspectors as a help for inspection, such as X-rays or hand held ELISA kits. The scope of the standard was not changed, but this was acknowledged in the standard. The draft was approved as presented in Appendix 21.

# 12.2 REQUIREMENTS FOR THE ESTABLISHMENT, MAINTENANCE AND VERIFICATION OF AREAS OF LOW PEST PREVALENCE.

The SC considered some issues remaining after the SCWG meeting and modified the draft, which will be presented for adoption at ICPM-7. Some changes to existing definitions had been introduced in the draft, but had not yet been seen by the GWG. It was felt preferable that such proposals for changes should be reviewed by the GWG at its next meeting, and that some changes would not be changed in the current drafts (e.g. buffer zone in this standard). In addition, the application of this standard to regulated pests and non-regulated pests was discussed at length. Some amendments were made to the scope and section 3.1.4 to cover the case when ALPP could be put in place to facilitate exports for pests regulated in an importing country. The draft was approved as presented in Appendix 22.

# 12.3 REVISION OF ISPM NO. 3 (GUIDELINES FOR THE EXPORT, SHIPMENT, IMPORT AND RELEASE OF BIOLOGICAL CONTROL AGENTS AND BENEFICIAL ORGANISMS)

The SC considered some issues remaining after the SCWG meeting and modified the draft, which will be presented for adoption at ICPM-7.

Some particular points of discussion were as follows:

- References to impact on the environment had been introduced. An example of impact on non-target invertebrates was added, to recognize the fact that this was a major concern when exchanging biological control agents and other beneficial organisms, and a main point for which these exchanges had been regulated. A footnote was added that other international agreements should be considered in this respect.
- The Steward noted that there had been discussions on whether biological control agents were covered under regulated articles. At the time of the development of ISPM No. 20, the interpretation had been that only biological control agents "capable of harbouring or spreading pests" would be covered by the standard, and a footnote had been added to ensure that biological control agents per say would be covered. During current discussions on ISPM No. 3, it had been envisaged that all biological control agents might in fact be covered under the definition of regulated articles. The SC noted that suitable text had been added to this standard in this respect. It did not see a need to clarify this issue immediately, but concluded that the GWG should be asked to review this issue, by email, in relation to both of these standards, and make recommendations to the next meeting of the SC in April 2005.
- The SC noted that agreed interpretations had been developed and sent for country consultation for establishment and introduction, to ensure that the definitions applied not to pests but to all organisms, and therefore to biological control agents. It now appeared that these terms did not need to be defined in this particular standard, which removed the need for an agreed interpretation. One participant noted that introduction and establishment were commonly used in relation to PRA, at

stages when organisms had not yet been categorized at pests. The SC recommended that this issue could be addressed and clarified in the standards on PRA.

The draft as approved is presented in Appendix 23. The SC recognized the need for further guidance on issues dealt with by the revised ISPM No. 3 and recommended that an explanatory document and/or further guidelines should be developed after this standard had been adopted by ICPM.

# 12.4 GUIDELINES ON THE CONCEPT OF EQUIVALENCE OF PHYTOSANITARY MEASURES AND ITS APPLICATION IN INTERNATIONAL TRADE

The SCWG had developed a draft, in which sections had later been reorganized by the Steward (John Hedley) in order to take account of suggestions for restructuring the draft that had been received during country consultation. The SC studied and modified the draft, which will be presented for adoption at ICPM-7. The SC discussed links between the standard and the SPS agreement. It was noted that although the draft should be fully consistent with the SPS, it should also present the view of the phytosanitary community. The draft was approved as presented in Appendix 24.

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

The SCWG had not had time to review the draft during its meeting, and this was done by the SC. The draft will be presented for adoption at ICPM-7. Some specific points of discussion were:

- The SC noted that, as discussed under point 12.3 (section on *ISPM No. 3*), the agreed interpretations for establishment and introduction had only been developed in relation to the revised ISPM No. 3. Since there were not needed in this standard, they would be deleted from the proposed amendments to the Glossary.
- The proposed definition for tolerance had attracted many comments, and the Steward advised that it would be very difficult to reconcile the different points expressed and noted that this term would also be considered in the context of the draft on sampling. The SC agreed that this term should be withdrawn from the proposal, and should be discussed again by the GWG once the EWG on sampling has met.
- The steward of the draft on ALPP noted that the proposed definition of prevalence differed from the one included in the draft. After discussion, this issue appeared too difficult to resolve immediately, and the SC decided to send it to the GWG.
- It was discussed whether phytosanitary integrity covered the phytosanitary state of the consignment, in addition to the physical state. This issue could not be resolved and the term was sent back to the GWG.
- The SC noted that the definition for systems approach mentioned appropriate level of protection. After a more general discussion on this term, the SC decided to recommend that a supplement on appropriate level of protection should be included on the work programme.

The draft was approved as presented in Appendix 25.

## 12.6 GUIDELINES FOR CONSIGNMENTS IN TRANSIT

The SCWG had decided to review this draft standard last, as there were points of contention that needed further discussion. The SCWG did not have time to review this draft during its meeting, and the discussion was taken up during the meeting of the SC. Several issues of concern were identified in the standard:

- Definition of transit. There were conflicting ideas on what transit was. It was also thought that transit may have different meanings depending if the term was used for Customs' or NPPOs' purposes, and that this should be clarified.
- Customs and NPPOs. The draft included elements in relation to both Customs and NPPOs. Some countries comments supported that the draft should not mention Customs, but should only deal with NPPOs. Some participants noted that transit as a Customs procedure may be understood differently as transit as a phytosanitary matter, and this could be clarified in the standard. The way in which the relationship between NPPOs and Customs is expressed in the standard could be reviewed. Some participants noted that it would be difficult not to take into account the relationship between NPPOs and Customs in a standard on transit.
- An error in section 3.3 (*Transit*) of ISPM No. 12 (*Guidelines for phytosanitary certificates*) was identified by the SC and the SC supported the revision of that section. This was added to the topics

proposed for the work programme (Appendix 20). The revision should take account of the definition of consignments in transit.

- Whether transshipment was already, or could be, covered in the standard.
- Sections dealing with pest risk analysis are not appropriate and need to be modified, and the section on non-discrimination needs to be clarified.
- Whether small shipments such as courier services were covered by the standard.

The SC discussed how the draft should be developed further, and eventually decided that the Steward would redraft the standard in consultation with the EWG and some SC members (Diego Quiroga, Asna Booty Othman, Abdellah Challaoui, Mike Holtzhausen). It was hoped that the review would take care of the concerns expressed at country consultation. The new draft would then be reviewed by the SC at its April meeting, to take a decision on how the draft should be further processed.

# 13. CONSEQUENCE FOR STANDARD SETTING OF THE MEMORANDUM OF COOPERATION BETWEEN THE IPPC AND CBD SECRETARIATS

The SC noted that ICPM-6 had noted the Memorandum of cooperation between the Secretariats of the IPPC and of the Convention on Biological Diversity (CBD), and that possibilities for closer cooperation between the ICPM and the Conference of parties of the CBD would be envisaged. The SC discussed the place of the SC and of standard setting in this cooperation. The SC noted that, when reviewing and finalizing a standard, the SC should simply make sure that environmental aspects had been considered. It decided that this point could be discussed further at a future meeting.

# 14. EXCHANGE OF VIEWS ON THE PRESENT STANDARD SETTING PROCESS AND POSSIBLE IMPROVEMENTS

The Chairman invited comments on the operation of the standard setting process and on how the system had functioned in 2004. The following points were identified:

- *Time constraints after country consultation.* Little time was available between:
  - the deadline for submitting country comments to the Secretariat and the submission of compiled comments to the Stewards for review.
  - the review of compiled comments by the Stewards and the submission to the SCWG of the Stewards' reactions
  - the finalization of drafts after the SC and the deadline for translating and sending drafts to the ICPM.

As a consequence, little time was available for: compilation of comments by the Secretariat; consideration and processing of these comments by Stewards; review of the drafts prior to the SCWG. Due to the fact that the SC took place just after the SCWG, it also had no time at all to consider in advance the drafts prepared by the SCWG.

- Importance of stewards. Their work on the integration of country comments and of detailed reaction to each comment had facilitated the consideration of standards by the SCWG (and SC), and greatly facilitated transparency in the standard setting process. In particular, identifying in advance the difficult points of country comments, and having preliminary discussions on these points in the SCWG (before starting detailed review of the drafts) had helped solved many issue and speed up the process. However, the workload on stewards was high, and ways should be found to facilitate their work, and to give them more time. It was also noted that the SC was responsible for the drafts, and it should be ensured that not too much responsibility was put on stewards.
- *Importance of the SCWG*. The SCWG was essential to the screening and detailed review of the drafts prior to SC. However, there was a limit as to what it could achieve in one week (and could not be expected to process much more than 4 standards in one week).
- Need for the whole SC to consider appropriately the draft going for country consultation. This year, the SC had been split into two groups during the April meeting for the preparation of drafts for country consultation. Consequently all members had not reviewed all standards in detail before they went to country consultation, and some members thought that a quick overview was not sufficient.
- Need for the whole SC to have sufficient information on drafts before SCWG. The SC was currently not informed in advance of its meeting of the outcome of the SCWG, nor of the main points of concern arising from country comments and the way they had been dealt with.

Mr Hedley had prepared an outline of how a 2-year cycle for standard setting could be organized, in order to allow more time throughout the process, and to allow for the production oh high quality standards. The SC agreed that the current situation needed to be improved. During its discussions, members raised the following possibilities to be considered for future analysis of how to improve the standard setting system and its timing:

- *Need to reduce the numbers of comments received on draft ISPMs.* Suggestions for consideration to address this issue were:
  - to increase the quality of the drafts sent for country consultation (by allowing adequate consideration of the drafts by EWG and SC
  - to inform countries of the main points of concerns that were raised during EWG meetings, and how they had been solved (through EWG reports or notes to be drafted by the Secretariat or stewards and attached to the drafts at country consultation)
  - to make use of regional discussions (including regional workshops on draft ISPMs).
- Reducing time constraints. More time was needed at all stages to ensure that the quality of draft standards sent to the ICPM is satisfactory. In particular, the following points were identified: stewards should have more time to work on comments; SC should have time to study proposals by SCWG, and should be informed of the major points of concerns at country comments and how they had been resolved in the draft proposed. SC should be able to better review all texts going out for country consultation.
- *More use of TPs and EWGs*. The SC (or SCWG) was currently doing a lot of redrafting of the texts presented to it, which should not be its function, especially because they might not always have the best expertise for this. More use could be made of Technical Panels or EWG for referring back texts for which the SC had particular concern. Texts should be returned by the SC to TP or EWG before country consultation if particular concern arose (rather than redrafting themselves and changing the content extensively). Use of TPs or EWG could also be made after country comments had been received (for review of the comments as appropriate).
- Additional SC Working Group. The SCWG was very useful in the process, if the cycle of standard development was extended, there would be a possibility that a second similar group could be constituted and meet in parallel, for presenting drafts for finalization to the SC. This would allow to work on more standards since the SCWG could not be expected to process much more than its current 4 standards per week.

The SC concluded that a proposal should be made for future improvement of the system, but did not think that such a proposal should be presented to ICPM at this stage. It decided that a document taking account of the discussions should be developed, and should also take into account the financial implications for the organization and for countries, and of time/involvement needs for countries (experts) and Secretariat. This document would be prepared by the Secretariat in collaboration with Mr Hedley and would be reviewed by the SC at its April meeting, with the aim of presenting a document at ICPM-8 in 2006. It would be useful if the document could be available to SC members before ICPM-7 in 2005, so that wider discussions could start informally between delegates at this occasion.

### 15. NOMINATIONS FOR EWGS AND TPS

Mr Larson noted that the Secretariat would send an e-mail calling for nominations of experts for both TPs and EWGs. The deadline for submissions was agreed to be the 15<sup>th</sup> December 2004. It was decided that the requests for nominations would be sent to the SC and RPPOs, with copy to the Bureau and FAO Regional Plant Protection Officers.

### 16. DATES OF SC MEETINGS FOR 2005

- Sixth meeting of the SC: 25-29 April 2005 (Philippines / Nigeria rooms)
- SCWG: 31 October 4 November 2005 (Mexico room)
- Seventh meeting of the SC: 7-11 November 2005 (Mexico/Lebanon rooms)

These dates were discussed and it was noted that meetings held at FAO Headquarters needed to consider the FAO holidays and schedules in order to avoid conflict. It was also recognized that these dates might impact SC members individually but a compromise was reached on the above dates.

## STANDARDS COMMITTEE - FIFTH MEETING

15-19 November 2004, Rome

### PROVISIONAL AGENDA

- 1. Opening of the meeting
- 2. Adoption of the agenda
- 3. Adoption of the report of the Fourth Meeting of the Standards Committee
- 4. Report of the November 2004 Standards Committee Working Group, steward or representative overview of country comments on drafts standards followed by general discussion:
  - Guidelines on the concept of equivalence of phytosanitary measures and its application in international trade
  - Guidelines for inspection of consignments
  - Requirements for the establishment, maintenance and verification of areas of low pest prevalence.
  - Amendments to ISPM No. 5 (Glossary of phytosanitary terms)
  - Revision of ISPM No. 3 (Guidelines for the export, shipment, import and release of biological control agents and beneficial organisms)
  - Guidelines for consignments in transit

## 5. Adoption of the report and annexes of the July 2004 Working Group of the Standards Committee (discussion only on points that were previously submitted in written form)

- Specifications (needed for next year's work programme)
  - Technical Panel Specification No. 4 Technical Panel on forest quarantine
  - Specification No. 15 (1<sup>st</sup> revision) The use of integrated measures in a systems approach for pest risk management of citrus canker (*Xanthomonas axonopodis* pv. *citri*
  - Specification No. 17 Debarking of wood
  - Specification No. 22 Research protocols for phytosanitary measures
  - Specification No. 23 Guidance for surveillance for specific pests: *Xanthomonas axonopodis* pv. *citri* (citrus canker)
  - Specification No. 24 Post-entry quarantine facilities
  - Specification No. 25 Guidelines for formatting / drafting pest specific ISPMs
  - Specification No. 26 Guidelines for formatting / drafting commodity specific ISPMs
- Documents to be submitted to ICPM
  - Guidelines on the duties of members of the Standards Committee of the Interim Commission on Phytosanitary Measures
  - Guidelines for the operation of expert working groups
  - Guidelines for the role of a steward of an ISPM
  - Criteria for the formation and subsequent change of supplements, annexes and appendices in ISPMs
  - Guidelines for an additional round of formal consultation
- Submission form for ICPM work programme topics

#### 6. Business arising from Technical Panels

- Fruit Fly
  - Specification Technical Panels No. 2
  - Specification No. 27 Pest Free Areas for fruit flies
  - Specification No. 28 Areas of Low Pest Prevalence for fruit flies
  - Specification No. 29 Systems Approach for fruit flies
  - Work Programme for Fruit Fly TP
- Diagnostic Protocols
  - Specification Technical Panels No. 1
  - Priority For Diagnostic Protocols
  - Work Programme for Diagnostic Protocols TP

#### 7. Nomination of stewards

- Technical Panels
  - TP Forest Quarantine
- Expert Working Groups
  - EWG Classification of commodities by level of processing (replace De la Rosa Brachowicz)
  - EWG Guidelines for regulating potato micropropagation material and minitubers in international trade (replace Wolff)

## • Expert Working Groups under the direction of Technical Panels

- EWG fruit fly pest free areas
- EWG fruit fly systems approach

- EWG fruit fly areas of low pest prevalence
- EWG Guidelines for formatting specific diagnostic protocols for regulated pests
- 8. Priorities for standard setting
- 9. Glossary issues (the use of should, shall and must )
- 10. Format, printing and distribution of ISPMs
- 11. Administrative guidelines for the structure of standard-setting documentation
- 12. Detailed discussion and approval of drafts standards for submission to the ICPM
  - Guidelines on the concept of equivalence of phytosanitary measures and its application in international trade
  - Guidelines for inspection of consignments
  - Requirements for the establishment, maintenance and verification of areas of low pest prevalence.
  - Amendments to ISPM No. 5 (Glossary of phytosanitary terms)
  - Revision of ISPM No. 3 (Guidelines for the export, shipment, import and release of biological control agents and beneficial organisms)
  - Guidelines for consignments in transit

#### 13. Other business

- Analysis of the point of consideration for the SC resulting from the Memorandum of Cooperation between the IPPC and CBD Secretariat.
- Exchange of views on the present standard setting process

## 14. Dates of SC meetings for 2005

- Sixth meeting of the SC: 25-29 April 2005 (Rooms: Philippines / Nigeria)
- SCWG: 31 October 4 November 2005 (Rooms: Mexico)
- Seventh meeting of the SC: 7-11 November 2005 (Rooms: Mexico/Lebanon)

### 15. Overview of ISPMs and specifications in progress

#### 16. Close

#### GUIDELINES ON THE DUTIES OF MEMBERS OF THE STANDARDS COMMITTEE

(Approved by SC-5, November 2004)

#### 1. Introduction

ICPM-6 adopted the recommendations of the Informal Working Group on Strategic Planning and Technical Assistance (SPTA) on improvements in the current standard setting process. These included the production of brief guidelines on the roles and responsibilities of Standards Committee (SC) members by the IPPC Secretariat in consultation with the SC for approval by the ICPM. These guidelines should be provided to all SC members.

These recommendations arise from the difficulties that SC members may face in understanding their roles and responsibilities and aim at improving transparency in the standard setting process.

These difficulties may increase as the number of standards being developed increases (two per year to eleven in 2004), the turnover of members of the SC intensifies (three in 2003, eight in 2004 etc.) and the SC increases in size (1994 CEPM - 14 members, 2001 ISC - 16 members, 2005 SC - 25 members).

It was suggested that a more detailed practical guide would assist SC members in understanding their duties better and improve the efficiency of the standard setting process. This is in addition to the following documents (published in the IPPC Procedural Manual, first edition, 2004):

- Terms of Reference (TOR) for the SC
- Rules of Procedure (ROP) for the SC
- Outline of Procedures for the Elaboration of International Standards for Phytosanitary Measures.

#### 2. Purpose of the Standards Committee

The Standards Committee is an integral component of the standard setting process with the purpose of assisting the production of draft standards that are of sufficient quality to be adopted by the ICPM as International Standards for Phytosanitary Measures (ISPMs). The SC does not write standards but prepares draft ISPMs according to the standard-setting procedures, monitors each standard's development and ensures they have a consistent quality. The SC may also be assigned additional tasks by the ICPM.

The SC ensures that the standards:

- fulfil the specification for the standard
- fall within the scope of the IPPC
- · are technically based
- have scientific integrity
- follow the principles and policies of the ICPM
- are presented in the required format for standards
- are written in a simple, clear and focused language.

The ICPM has decided that the SC should be made up of experts from different regions. The ICPM intends that the committee include a diversity of global views on any subject it deals with. These views are used in the production of internationally harmonised standards. They encompass, for example, the views of different geographic regions of the world, developing and developed countries, tropical and temperate regions, continental and island nations, highly and sparsely populated countries with intensive agricultural or forestry interests etc. The choice of experts on a regional basis is a pragmatic choice to obtain a range of views that can produce internationally acceptable standards.

The primary purpose of the SC is to ensure that ISPMs help to protect plant health on a global scale. The SC members that are selected are expected to act as individual experts, not as country representatives. However, the views of the expert are usually those characteristic of the region the expert comes from.

In addition to assisting with the development of standards, the SC serves as a forum for other functions as directed by the ICPM. These types of functions could include the review of procedural and administrative documents to ensure they are consistent with the standard setting process and are feasible.

#### 3. Structure of the SC

The formation of the SC is outlined in the TORs for the SC. The whole body is referred to the SC and this body selects its own chair and vice chair. In addition, the SC members from each FAO region select a member to form the SC 7 who, in turn, select their own chair. The SC oversees the work of Expert Working Groups (EWGs) and Technical Panels (TPs) in particular through the use of specifications. The SC may decide to break into smaller working groups as necessary in order to deal with a heavy workload. Holding extraordinary meetings of the SC should be done in consultation with the Bureau.

## 4. Duties and associated tasks of SC members

During the standard setting process, SC members have a number of duties directly concerned with draft standards by virtue of their membership of the SC. These duties are listed in section 4.2 below. Normally, however, SC members

also undertake any one or several of a number of other roles within the standard drafting procedure. The duties of these roles are described in sections 4.5 and 4.6. The other duties of SC members are listed in the following sections.

#### 4.1 Procedural division of duties amongst SC members

SC members examine:

- draft standards before submitting them to the consultation process
- comments from the consultation process.

There are provisions for a smaller SC group, such as the SC 7 made up of one expert from each region or an SC working group, to take the place of the full committee as an economy measure. These provisions may not be used every year. Other members of the SC not included in the small group may contact members of the small group with appropriate advice.

Also, during meetings of the full SC, members may be grouped in smaller sub-groups so as to consider more material in the time available.

## 4.2 Basic duties directly related to the evaluation of draft standards

The basic duties of the SC member include:

- examination of draft standards from EWGs or TPs. Prior to the meeting, the SC member reads the drafts, considers the reports of the EWG or TP and prepares comments. The SC member presents any comments or changes to the draft to the SC meeting, usually held in May.
- examination of comments on draft standards after country consultation. The SC member reviews the country comments (except those relating to editing and translation), discusses them with the SC and proposes appropriate changes to the draft. This meeting is usually held in November.
- the making of consequential proposals to:
  - send draft standards for country consultation
  - approve the standard and send it to the ICPM for adoption
  - initiate a further round of consultation or
  - send the draft back to the EWG.

#### 4.3 Time requirements

The participation as a SC member may involve a considerable time input. The estimate of this time input would be:

- 3 4 weeks for meetings (depending on involvement in the SC7 and travel distance)
- 2 weeks to review draft standards
- 2 weeks to review country comments.

This may be increased if the SC member participates in regional workshops on draft standards and/or is a steward of an ISPM(s).

#### 4.4 Regional communication

SC members are requested, where possible, to assist with the communication of information regarding the draft standards to countries within their region. This could be done by discussing the issues with other regional experts, attending regional workshops on draft standards, or contributing to supplementary written information on the draft standards.

#### 4.5 Duties of SC members in an EWG when they are not a steward

The ICPM recommends that each EWG has one SC member within the group. The SC member can be a basic member of the group (see *Guidelines for the operation of EWGs*) or be a steward (see *Guidelines for the role of a steward of an ISPM* and section 4.6). The SC member may assist with the EWG more than an ordinary member because of their experience. The duties of an SC member of the EWG who is not a steward may include:

#### Prior to the meeting of the EWG:

- assist with the arrangements for the meeting
- offer their advice to others organizing the meeting.

## **During the EWG meeting:**

- explain the standard setting process, if necessary
- act as the chair or rapporteur if required
- participate as an expert
- assist the steward as required.

#### At the SC meeting:

act as a backup to the steward to explain the draft standard and the main discussion points during the EWG
meeting.

Frequently the SC member is the steward for the standard (see section 4.6).

#### 4.6 Duties of SC members in an EWG when they are a steward

It is intended that most EWGs will have a steward that is an SC member. The functions of a steward are described in detail in the *Guidelines for the role of a steward of an ISPM*. A brief summary of these duties are:

- participate in the selection of experts
- explain the standard setting process and the specifications to the EWG
- assist in the development of discussion papers
- assist the Secretariat in the organization and running of the meeting
- explain the main points of the draft standard to the SC and answer questions
- assist the SC in analyzing country comments.

#### 4.7 Examination of specifications for standards

The SC member carefully reviews the specifications for standards that are prepared by, or under the auspices of, the Secretariat.

The SC member reviews the specifications drafted by the Secretariat by:

- discussing to ensure the specifications will produce a globally acceptable standard
- ensuring the specifications accurately describe the title and the scope and purpose of the intended standard
- ensuring the tasks and other elements of the specifications are correctly identified
- proposing modifications if necessary.

### 4.8 The examination of procedural and administrative documents

The ICPM adopts procedural and administrative documents (e.g. TOR and ROP of various groups). These are reviewed by the SC to ensure they are consistent with the standard setting process and feasible. They are then amended if necessary and forwarded to the ICPM.

## 4.9 Other administrative duties

These include:

- designation and approval of the membership of EWGs and TPs
- designation and approval of stewards for EWGs
- approval of subjects for specific standards as proposed by the TPs
- establishment of open-ended discussion groups
- review of priorities for ISPMs proposed by the SPTA with the opportunity to add other priorities
- undertaking of other duties as requested by the ICPM.

#### **GUIDELINES FOR THE OPERATION OF EXPERT WORKING GROUPS**

#### 1. Introduction

These guidelines have been prepared to aid those assisting, involved in organizing or attending an Expert Working Group (EWG) meeting. The guidelines cover most of the requirements and procedures for the successful operation of an EWG. They are general guidelines so not all parts apply to every EWG meeting and some very specific requirements of some groups may not be included.

### 2. Funding

The main funding for EWG meetings comes from the FAO IPPC budget. This is normally supplemented by member countries or organizations covering participants' expenses [travel and daily subsistence allowance (DSA)]. In some instances, member countries or organizations have funded, or partially funded, an EWG on a specific subject. A member country, organization or agency offering such funding or providing any level of assistance in operating an EWG is referred to as a collaborator in this document.

Participation of the IPPC Secretariat is funded by FAO.

### 3. Organization

EWG meetings can only be organized for those topics which have been adopted under the topics and priorities for standards at the ICPM. The organization of EWG meetings is normally done by the IPPC Secretariat with varying levels of assistance from a collaborator.

### 3.1 Composition of the EWG

See the IPPC Procedural manual, first edition, 2004, section 4.3.

#### 3.2 Meetings held at FAO Rome or other FAO Offices

The IPPC Secretariat in general uses FAO offices to make logistical arrangements, including travel and DSA.

For a meeting at FAO in Rome, the IPPC Secretariat does not make hotel bookings, but names and addresses of accommodation are provided on the IPP (www.ippc.int).

## 3.3 Meetings held outside of FAO offices

Meetings held outside the FAO offices are usually arranged with the assistance of a collaborator. The collaborator may take various levels of involvement. A commonly operated system is where FAO enters into a letter of agreement with the collaborator (after agreeing on a budget) and transfers the funds needed for the meeting. The letter of agreement generally covers participants' expenses (travel and DSA) and may cover other items as appropriate. The collaborator is expected to make arrangements for participants' expenses, meeting rooms, photocopying, field trip etc.

In other cases the collaborator may fund the entire meeting (including participants' expenses, meeting room, photocopying, field trip etc.) or part of the meeting.

#### 4. Roles of meeting organizers and participants

## 4.1 IPPC Secretariat

The Secretariat is expected to:

- plan a meeting date and seek a collaborator
- provide resources for the meeting, if held on FAO premises
- approve budget being paid by the IPPC and, if necessary, prepare a letter of agreement
- send a letter of invitation to participants (especially for the purpose of obtaining visas) and interact with the FAO visa office if needed
- liaise with collaborator, steward and EWG participants as appropriate
- arrange with the steward for the production of discussion papers
- attempt to find a replacement if an EWG participant approved by the SC is not able to attend the meeting (and inform the SC of such changes)
- describe and explain the mode of operation of the EWG and the roles and responsibilities of participants (ICPM-6 Report, Appendix VIII *Improvement in the current standard setting process*)
- coordinate the organization of the meeting and be responsible for the production of the draft ISPM and meeting report.

## 4.2 Collaborator

The collaborator is expected to:

- select location, make local arrangements, make hotel bookings, book meeting rooms and arrange for coffee breaks, official dinner (if appropriate) and field trip (if appropriate)
- interact with embassies as needed for the purpose of obtaining visas
- provide meeting resources (see item 5)
- provide, where possible, a rapporteur (who could be regarded as a resource outside of the EWG)
- arrange for local transportation as appropriate, including airport transfer and transfer from the hotel to the meeting room (or provides suitable information)
- provide, as necessary, information on local transportation, local conditions, address of the hotel(s) and meeting venue, map, medical information etc.
- have facilities to provide copies of working papers and of documents drafted during the meeting, as appropriate.

#### 4.3 Steward

The steward is expected to:

- explain the requirements of the specification to the EWG at the time of its first meeting. Hence, the steward should have a good understanding of the specification for the standard. If some issues are unclear, the steward should discuss the matters with the Secretariat or members of the SC.
- liaise with the Secretariat to ensure that discussion papers are produced for the EWG meeting
- assist with the running of the meeting. In some instances, the steward may take the role of the chair of the group or of the discussion facilitator
- assist the Secretariat to complete the draft standard
- assist the Secretariat in the preparation of the meeting report.

These duties are discussed in more detail in the Guidelines for the role of a steward of an ISPM.

#### 4.4 Chair

The EWG chairperson is selected at the meeting. The function is that of a normal chair - to keep the meeting running smoothly and ensure participation by all experts - with some additional duties. The chairperson is expected to:

- act as facilitator of the group in its production of draft text
- assist the Secretariat, steward and rapporteur to prepare the EWG report
- be involved, where appropriate, with the steward in incorporating EWG comments into the draft standard.

#### 4.5 Experts

The experts in an EWG should:

- take responsibility for their travel and accommodation arrangements and visa requirements as requested by the meeting organizer. Experts are expected to be in attendance for the entirety of the EWG meeting and should plan to arrive before the meeting starts and depart after the meeting concludes. They should undertake whatever needs to be done in a timely manner so there are no urgent arrangements to be made by the organizers.
- prepare discussion papers, possibly consulting with national or regional experts, as requested
- actively participate in the EWG meeting and in e-mail discussions prior to and after the meeting, if appropriate
- study discussion papers prior to the meeting and develop specific comments and text as appropriate
- in reflecting their individual viewpoints, aim to produce a globally acceptable standard
- assist stewards as needed, particularly when reviewing country comments
- respond, as appropriate, with comments to draft ISPMs within the agreed time.

## 4.6 Rapporteur

Each EWG requires a rapporteur to take down the text for the draft standard and, where possible, to take notes on the meeting discussions. The rapporteur should have facility with the English language and be able to use a computer for note taking. This is an extremely important supporting function of the EWG. Where possible the rapporteur should not be a member of the EWG but be part of the supporting team. If a member of the EWG does have to act as rapporteur, that expert's contribution to the meeting discussions tends to be severely restricted. The rapporteur should, where possible, assist the Secretariat with the meeting report.

## 5. Meeting resources

The usual meeting resources are required for an EWG meeting. These include:

- a quiet room large enough to accommodate up to 10 people
- white boards, flip charts and marker pens
- computer and, preferably, a projector for the computer and an internet connection
- coffee/tea making facilities for work breaks
- copies of ISPMs, ICPM reports, dictionary.

#### 6. Time schedule for meeting

The meeting is scheduled by the Secretariat in coordination with interested parties and participants after the ICPM has agreed to the work programme. Meeting dates are posted on the IPP. Experts are nominated by member countries and RPPOs and the specific experts for any particular EWG are selected by the SC. Following this, the nominated Secretariat person and the steward arrange:

## At least 3 months prior to the meeting

The Secretariat:

• makes a call for discussion papers.

### At least 2 months prior to the meeting

The Secretariat:

- sends the discussion papers to the EWG members
- announces the meeting to participants by e-mail, indicating the date and place of the meeting, and sends out early personal invitations by e-mail and surface mail (in some cases via courier) to those members known to have less rapid national administrative procedures.

#### At least 1 month prior to the meeting

The Secretariat:

- asks experts to exchange comments on discussion papers
- sends a personal invitation letter by e-mail to each expert announcing the meeting (if not already done). When the meeting is in Rome, and for experts from countries not requiring a visa, paper copies of the letter of invitation may be sent only on request.
- asks experts if they have any specific needs
- forwards information provided by the collaborator.

#### The collaborator:

- sends a personal invitation letter
- provides to the Secretariat information as outlined in section 4.2.

#### EWG members:

- undertake to obtain authorization from their authorities, if appropriate
- reply to the IPPC Secretariat and request financial assistance for their expenses, if needed, immediately after they receive a copy of their e-mail invitation
- reply to the organizers as stated in the letter of invitation to acknowledge receipt of the invitation and inform the organizer of their attendance (this requirement facilitates the obtaining of building passes etc.)
- ensure their visa and travel arrangements are completed in time.

## At least 2 weeks prior to the meeting

The Secretariat forwards to the EWG members:

- an agenda for the meeting
- time and venue of the meeting
- planned meeting hours.

#### 7. Output of the meeting

The EWG should finish the meeting with a draft standard. Occasionally, this is not the case and further discussions via e-mail are required. However, these should be limited to one month after the EWG meeting and the draft should then be released to the Secretariat.

Where substantial work still needs to be done on the draft standard the Secretariat, in consultation with the steward and SC, arranges for a further meeting.

Each EWG meeting should produce a draft standard and a report (made available on the IPP) of the meeting (noting major discussion points or contentious issues). The steward should be familiar enough with the issues of the draft standard to be able to attend a SC meeting (often the steward is a SC member) and discuss the draft with the SC.

## 8. Post-meeting consideration of the draft ISPM

The Secretariat will distribute draft ISPMs to EWG members and request them to submit comments within the agreed period of time. The EWG members will submit their comments as appropriate to the Secretariat within this agreed time.

#### GUIDELINES ON THE ROLE OF A STEWARD OF AN ISPM

#### 1. Introduction

The management of the technical development of standards through the standard setting procedure has exceeded the capacity of the IPPC Secretariat. It was also recognized that there is a need to establish stronger links between Expert Working Groups (EWGs) and the SC. To deal with the workload, it has been suggested that some of the duties concerned with the preparation of standards and the associated procedures be taken on by stewards.

#### 2. Selection of stewards

Stewards are senior plant health officers or scientists who are familiar with the standard setting process. Proposed stewards should recognize that considerable time may be required (see section 4). Stewards should be drawn from the SC or membership of the EWG.

#### 3. Role of the steward

In general terms, the role of the steward is to assist with the development of a particular standard from the time of the drafting of the specification to the adoption the standard by the ICPM and to provide a linkage between the EWG and the SC. The functions of a steward will vary according to the nature and complexity of the standard and the requirements stated in the specification. The steward should assist the Secretariat to ensure that the EWG follows the IPPC standard setting procedures. The steward could be involved in the following sequence of normal standard development.

#### 3.1 Prior to the EWG meeting

If requested, the steward may be able to provide guidance to the IPPC Secretariat and the SC in relation to the selection of experts for the EWG. The steward should liaise with the Secretariat to ensure that discussion papers are produced for the EWG meeting.

#### 3.2 At the EWG meeting

The steward would be expected to:

- explain the requirements of the specification to the EWG at the time of its first meeting. Hence, the steward should have a good understanding of the specification for the standard. If some issues are unclear, the steward should discuss the matters with the Secretariat or members of the SC.
- assist with the running of the meeting. In some instances, the steward may take the role of the chair of the group or of the discussion facilitator
- assist the Secretariat to complete the draft standard
- assist the Secretariat in the preparation of the meeting report.

## 3.3 At the SC meeting that approves drafts for country consultation

The steward may attend the relevant SC meeting to assist the work on the standard that he or she is responsible for. If the steward cannot attend the SC meeting, he or she should provide documentation about the standard, brief a SC member or hold a conference call with the SC.

## 3.4 At regional workshops on draft ISPMs

In order to support country consultation, stewards should assist the Secretariat in preparing a presentation of their draft standards and by attending the workshops.

## 3.5 Prior to the SC meeting that approves standards for adoption at ICPM

In preparation for the meeting,, the steward should review country comments to facilitate the review of the comments by the SC, identifying the important or contentious issues within the comments and recommending amendments to the draft. Guidance for the steward's review will be provided by the IPPC Secretariat.

#### 3.6 At the SC meeting that approves standards for adoption at the ICPM

The steward, if not a member of the SC, may attend the relevant SC meeting to assist with discussions on the country comments. If the steward cannot attend the meeting, he or she should provide documentation about the standard, brief a SC member or hold a conference call with the SC.

#### 4. Conclusion

The level of involvement of the steward in the preparation of a standard will vary with the complexity of the standard. There is also likely to be limits on the time that some stewards can spend on this work and the travel expenditures regarding SC attendance. The estimated time requirements for the involvement of a steward in a single standard is approximately six weeks, including activities such as reading documents, developing discussion papers, attending the EWG meeting, reporting, reviewing country comments, attending SC meetings, or briefing SC member and preparation of a presentation for regional workshops on draft ISPMs. Contracting parties, and the Regional Plant Protection Organizations of which they are members, are encouraged to support the production of standards by supporting the work of stewards where this is possible.

## CRITERIA FOR THE FORMATION, CONTENT AND SUBSEQUENT CHANGE OF SUPPLEMENTS, ANNEXES AND APPENDICES IN ISPMs

There are several ways to add or change information in an ISPM and its component documents (supplements, annexes and appendices).

#### ISPMs may be:

- amended
- revised or
- have supplements, annexes and/or appendices added to them.

Supplements, annexes and appendices may be:

- amended or
- revised.

In general, a revision affects the entire document whereas an amendment affects a specific part or parts of the document.

### 1. Criteria for the formation, content and subsequent change of supplements

- Supplements are the mechanism that the ICPM uses in certain situations to add conceptual information that is supplemental to a standard and that provides additional text without changing existing text. This is different from amendments or revisions to a standard.
- Supplements to an ISPM are numbered sequentially with Arabic numerals.
- Supplements are the first component document to follow the body of the standard.
- Glossary (ISPM No. 5) supplements are used to clarify and explain complex phytosanitary terms and definitions which cannot be understood from a normal concise definition.
- Text from supplements may be integrated into the standard according to the decision of the ICPM. In this case, the integrated text should be clearly indicated by a symbol or other means, and the standard should carry the date of adoption of the supplement by the ICPM.
- Glossary supplements are attached to the end of the section containing terms and definitions, and are numbered sequentially in the order of adoption of the supplement by the ICPM.
- The date of adoption by the ICPM should be indicated in the amended or revised supplement.

## 2. Criteria for the formation, content and subsequent change of annexes

- An annex is an official part of a standard (prescriptive) and this should be stated in the header. An annex adds technical information to the standard. It is referred to in the main text of the standard.
- Annexes to an ISPM are numbered sequentially with Arabic numerals.
- Annexes follow the body of the standard and follow supplements, if present.
- Information in annexes does not affect the principles incorporated in the primary standard. They do not normally include conceptual information of relevance to the standard.
- Annexes may provide technical guidelines for phytosanitary treatments or procedures, including treatments, treatment schedules and diagnostic protocols. They may include tables and figures.
- Annexes may contain information that may need to be amended or revised to ensure that the specific information provided is consistent with and reflects current scientific knowledge and other relevant information. The circumstances under which amendments and revisions become necessary may include:
  - the approval of new guidelines, treatments or procedures
  - a change in existing methods
  - as a result of experiences with implementation of a particular standard.
- New annexes or amendments and revisions to existing annexes may be proposed following the *Procedures for identifying topics and priorities for standards* (Report of ICPM-4, Appendix XIV and section 5.1.3 of the IPPC Procedural Manual, First edition, 2004).
- Amendment or revision of annexes may be made without modifying the standard.
- The date of adoption by the ICPM should be indicated in the amended or revised annex.

#### 3. Criteria for the formation, content and subsequent change of appendices

- Appendices are not official parts of standards (for information only, not prescriptive) and this should be stated in the header.
- Appendices to an ISPM are numbered sequentially with Arabic numerals.
- Appendices should be the last component document in a standard.
- Appendices provide references or further information relevant to the standard.
- The date of adoption by the ICPM should be indicated in the amended or revised appendix.

## PROCEDURES FOR THE DEVELOPMENT AND ADOPTION OF INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

(Annex I of the Rules of Procedure of the ICPM)

#### Step 1

Proposals for a new International Standard for Phytosanitary Measures (ISPMs) or for the review or revision of an existing ISPM are submitted to the IPPC Secretariat using a submission form for ICPM work programme topics.

#### Step 2

A summary of proposals is submitted by the Secretariat to the ICPM. The ICPM identifies the topics and priorities for standard setting from among the proposals submitted to the Secretariat and the others that may be raised by the ICPM.

#### Step 3

Specifications for the standards identified as priorities by the ICPM are drafted by, or under the auspices of, the Secretariat. The draft specifications are submitted to the Standards Committee for approval/amendment and subsequently made available to Members and RPPOs for comment (60 days). Comment is by written submission to the Secretariat. Specifications are finalized by the Standards Committee taking into account the comments.

#### Step 4

The standard is drafted or revised by a Working Group designated by the Standards Committee and in accordance with the specification. The resulting draft standard is submitted to the Standards Committee for review.

#### Step 5

Draft standards approved by the Standards Committee are distributed to Members and RPPOs for consultation (100 days). Comment is by written submission to the Secretariat. Where appropriate, the Standards Committee may establish Open-ended Discussion Groups, as fora for further comment. Comments are summarized by the Secretariat and submitted to the Standards Committee.

#### Step 6

The draft standard is revised by the Secretariat in cooperation with the Standards Committee taking comments into account.

When the SC agrees on a final version of the draft standard it is submitted to the ICPM for adoption.

Based on comments the draft standard may be substantially changed (structurally and/or technically). In these cases the Standards Committee may decide to submit the draft for another round of consultation. In addition, when comments indicate a substantial disagreement over a part of the draft standard, the Standards Committee should decide whether to submit the draft to another round of consultation, return it to the Expert Working Group for redrafting, or to forward it to the ICPM for its consideration.

#### Step 7

The ISPM is established through formal adoption by the ICPM according to Rule X of the Rules of Procedure of the ICPM.

#### Sten 8

The ISPM is reviewed by the specified date or such other date as may be agreed upon by the ICPM.

Circumstances may arise where it would be appropriate to vary this procedure. These circumstances should be brought to the attention of the ICPM as soon as they arise, enabling the ICPM to assess them and to take action accordingly.

## Submission form for ICPM work programme topics

Complete the following and submit to the IPPC Secretariat no later than 31 July, 200-. Please use one form per topic. An electronic version is available at <a href="https://www.ippc.int">www.ippc.int</a>.

(Text in brackets given for explanatory purposes)

Proposed by: (Name of country or organization)							
<b>Contact:</b> (Contact information of an individual able to clarify issues relating to this submission)							
Name:							
Position and organization:							
Mailing address:							
Phone:							
Fax:							
Email:							
Type of topic: (Choose only one option from column A, B, C or D)							
A. New ISPM:	B. New component	C. Revision of:	D. Amendment to:				
[] Concept	to an existing ISPM:	[] ISPM	[] ISPM				
[] Pest specific [] Commodity specific	[] Supplement	[] Supplement [] Annex	[] Supplement [] Annex				
Reference	[] Annex [] Appendix	[] Annex [] Appendix	[] Appendix				
	<b>-</b> -		<b></b>				
Suggested title of flew ISFM	Suggested title of new ISPM or component: Title of document to be revised or amended:						
	res for Identifing topics and prio						
Subject: (Provide information on the topic of the document)							
<u>Purpose:</u> (Background information on why the document is needed and the intended outcome)							
Key areas to be addressed: (Specific subject matter to be contained in the document)							

Send submissions to:

E-mail: ippc@fao.org Fax: (+39) 06 5705 6347 Mail: IPPC Secretariat (AGPP)

Food and Agriculture Organization of the UN

Viale delle Terme di Caracalla

00100 Rome, Italy

Annex

#### Procedures for identifying topics and priorities for standards

( As adopted at ICPM 4)

New standards can be proposed by:

- NPPOs;
- RPPOs;
- the IPPC Secretariat: and
- the WTO-SPS Committee.

Other organizations, such as the CBD, could propose topics through the IPPC Secretariat.

Criteria for setting the topics and priorities of standards are the following:

- level of trade affected by non-existence of a particular standard;
- frequency with which a particular issue emerges as a repeated source of trade disruption;
- feasibility of applying an international standard at a global level;
- feasibility of developing and implementing the ISPM within a reasonable time schedule;
- stage of development of the international standard;
- relevance and utility to developing countries;
- emergency need for the international standard;
- relevance and value to the total framework of standards; and
- availability of expertise needed to develop the proposed international standard.

Topics for standards should fit into a loose framework of the following categories:

- urgent issues;
- foundation standards to address fundamental concepts (e.g. treatment efficacy or inspection methodology);
- developing country concerns; and
- review and updating of current standards, including the Glossary.

Further development of specific procedures for identifying topics and setting priorities for standards should be undertaken by the Working Group on Strategic Planning. These procedures should include provisions for consultation procedures.

The procedure to be followed is:

October - the Informal Working Group on Strategic Planning and Technical Assistance reviews submissions for new topics for standards and recommends strategic priorities for new standards, for which drafts have not yet been considered by the Standards Committee.

*April* - The Strategic priorities for new topics for standards identified by the Informal Working Group are reviewed and adopted by the ICPM. The priorities for ISPMs under development identified by the Standards Committee are reviewed and adopted by the ICPM.

June - The Secretariat, at the time that draft standards are sent to Members for consultation:

- requests submissions for new topics from Members; and
- communicates the recommendations adopted by the ICPM.

*November* - The Standards Committee reviews the topics submitted by members taking into account policy guidance from the Informal Working Group on Strategic Planning and Technical Assistance and formulates recommendations to submit to the ICPM.

April - The ICPM reviews the recommendations and decides the topics and priorities for the work programme.

#### SPECIFICATION FOR TECHNICAL PANELS NO. 4

Title: Technical Panel on forest quarantine

<u>Reason for the Technical Panel:</u> ICPM-6 identified the need for the formation of a Technical Panel on forest quarantine issues.

<u>Scope and purpose:</u> The Technical Panel on forest quarantine will deal with technical matters regarding forest quarantine issues. It will review relevant technical and scientific information to provide guidance to the SC as requested on development, amendment and revision of standards.

### Tasks:

The Technical Panel should:

- identify needed standards and recommend priorities for standards to the SC;
- identify standards that need further research and report this to the SC;
- in collaboration with the Technical Panel (TP) on phytosanitary treatments, develop a process for the submission of forest quarantine research information (e.g. data on alternative treatments for wood packaging) and, where appropriate, adjust the criteria for submitting and evaluating scientific research data for phytosanitary measures (treatments) for specific standards to meet forest quarantine needs;
- identify the extent to which the work of this panel overlaps with the work of other groups, such as the EWG on debarking of wood, the TP on phytosanitary treatments and relevant research groups, and ensure coordination with these groups to prevent duplication of work;
- as necessary, propose revisions for the existing treatment parameters provided in Annex I of ISPM No. 15;
- provide recommendations on alternative treatments for inclusion in Annex I of ISPM No. 15;
- analyse existing research data and identify knowledge gaps relating to the pest risks of bark remaining on wood and wood packaging material and make proposals to the SC.

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

Steward: Gregory Wolff.

Collaborator: FAO.

<u>Expertise of Technical Panel:</u> Expertise in forest quarantine issues from both the research and phytosanitary fields including practical experience. 4-7 participants (from several regions)

Participants: To be determined.

<u>Approval:</u> Introduced into the work programme by the ICPM at its Sixth session in April 2004. Specification reviewed by the extraordinary working group of the Standards Committee meeting in July 2004 and approved by the SC in November 2004.

References: Appropriate ISPMs, specifications and ICPM reports, IFQRG reports of meetings.

Title: Debarking of wood

## Reason for the standard:

Different interpretations by plant health authorities on what constitutes debarked wood –as opposed to complete freedom/absence of bark– often have an impact on the international trade of wood and wood products. Therefore, a standard is required to elaborate on what constitutes debarked wood.

## Scope and purpose:

The purpose of this standard is to provide an IPPC description of what constitutes debarked wood. This standard will, therefore, propose tolerances for bark on debarked wood and an approach to estimate surface coverage of bark on debarked wood.

## Tasks:

The Expert Working Group (EWG) should:

- choose an appropriate title for the draft standard;
- develop criteria to determine whether wood is or is not debarked, and clarify the difference between bark freedom and debarked;
- liaise with the Technical Panel on forest quarantine and other relevant EWGs regarding pest risks and results of research relating to debarking;
- estimate pest risks associated with remaining bark after debarking (for example, thickness, size of individual patches etc.);
- provide on site, visual inspection methodology for assessing bark amounts on wood including estimating surface area and thickness of bark present (which may be similar to keys for assessing area of leaf infection);
- propose tolerances for the presence of bark (area and thickness) on wood in cases where debarking is required;
- discuss whether this draft standard should be a stand-alone standard or a component of an existing standard (e.g. a supplement to the glossary).

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

Steward: Ringolds Arnitis.

Collaborators: EPPO.

Expertise of EWG: Research, phytosanitary and inspection experience. 6-8 experts.

<u>Participants:</u> To be determined. It is recommended that the EWG includes some experts from the Technical Panel on forest quarantine.

<u>Approval:</u> Introduced into the work programme by the ICPM at its sixth session in April 2004. Specification reviewed by the extraordinary working group of the Standards Committee meeting in July 2004 and approved by the SC in November 2004.

<u>References:</u> Relevant ISPMs and specifications and *Plant Pathology* or similar journals that have included visual keys for assessing surface area of leaf infection.

<u>Title:</u> Research protocols for phytosanitary measures (treatments)

<u>Reason for the standard:</u> There is a need for guidelines for the submission of scientific research data on phytosanitary measures (treatments) to be reviewed.

<u>Scope and purpose:</u> This standard provides criteria for submitting and evaluating scientific research data for phytosanitary measures (treatments) for specific standards.

#### Tasks:

The tasks of the Expert Working Group (EWG) will be to deal with phytosanitary treatments only.

## The EWG should:

- define the general criteria for research in phytosanitary treatments (for example how to measure the efficiency of the treatment);
- discuss and determine what items need to be in the research protocol for consideration;
- ensure all items needed for the evaluation of scientific research data is contained in the protocol.

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

Steward: John Hedley.

Collaborator: To be determined.

<u>Expertise of EWG:</u> Experience in research in phytosanitary treatments and general phytosanitary experience. 5-7 experts.

Participants: To be determined.

<u>Approval:</u> Introduced into the work programme by the ICPM at its sixth session in April 2004. Specification reviewed by the extraordinary working group of the Standards Committee meeting in July 2004 and approved by the SC in November 2004.

References: Relevant ISPMs and specifications.

<u>Title:</u> Guidelines for surveillance for specific pests: *Xanthomonas axonopodis* pv. *citri* (citrus canker).

<u>Reason for the standard:</u> Phytosanitary measures related to citrus canker often use area freedom or low pest prevalence. Claims about area freedom or low pest prevalence need to be based on surveillance and detection methodologies that have a sound technical and statistical base.

<u>Scope and purpose:</u> This standard provides specific guidelines on options for the surveillance and detection of citrus canker with a view to improve risk management decisions and facilitate the movement of citrus fruit.

The standard will provide a range of surveillance options relevant to area freedom and low pest prevalence. A range of detection methodologies will be provided including methodologies suitable for application by developing countries. Efficacy levels and confidence limits of the different options will be provided.

## Tasks:

The Expert Working Group (EWG) should:

- consider existing ISPMs, regional standards and other relevant documents produced by international organizations (see under References). Relevant import requirements or export certification schemes of individual countries may also be considered.
- consider and recommend relevant detection methodologies.
- draft a standard that incorporates sound statistical principles for surveillance and appropriate detection technology for *Xanthomonas axonopodis* pv. *citri*.

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

Steward: Lawrence G. Brown.

Collaborators: To be determined.

<u>Expertise of EWG:</u> 5-7 participants comprised primarily of surveillance and citrus canker detection experts and to include practical expertise in phytosanitary measures and the statistical basis of surveillance.

Participants: To be determined.

<u>Approval:</u> Introduced into the work programme by the ICPM at its Sixth Session in April 2004. Specification reviewed by the extraordinary working group of the Standards Committee meeting in July 2004 and approved by the SC in November 2004.

## References:

IPPC 1997; WTO-SPS Agreement; ISPM No. 4 (Requirements for the establishment of pest free areas); ISPM No. 6 (Guidelines for surveillance); ISPM No. 8 (Determination of pest status in an area); ISPM No. 9 (Guidelines for pest eradication programmes); ISPM No. 10 (Requirements for the establishment of pest free places of production and pest free production sites); draft standard on the Use of integrated measures in a systems approach for Xanthomonas axonopodis pv. citri (hasse) Vauterin et al, 1995 risk management in citrus fruit; previous versions of draft standards on this subject.

Title: Post-entry quarantine facilities

## Reason for the standard:

There is often a need for countries to import organisms for research or to supply new genetic plant material. However, such material has the potential to harbor plant pests and intentional importation can present a risk to plant health. Containment facilities are required during testing for potential pests in order to prevent the escape of such pests while plants are grown or organisms are multiplied.

## Scope and purpose:

This standard provides information on the design and operation of containment facilities at different security levels where organisms, including plants and biocontrol agents, can be grown in an environment where there is minimal potential for the escape of pests.

## Tasks:

The Expert Working Group (EWG) should:

- discuss the overall systems (administrative and technical aspects) which would provide different levels of security required to manage post-entry quarantine and identify possible topics for future ISPMs;
- discuss and determine what post-entry quarantine facilities are (i.e. contained field (fenced), laboratory, greenhouse). Develop guidelines for the safe handling of organisms, including plants and biocontrol agents, for research and possible release;
- develop comprehensive lists of conditions for laboratories, glasshouses etc. for different levels of security. For instance, growing plants with air-borne fungi may require strict containment requirements such as negative pressure and sealed doors and windows (high containment facility), while a facility importing exotic nematodes for research may only require minimal security and only deal with control of water and waste material (low containment facility);
- develop different requirements for different needs of infrastructure and expertise;
- develop specifications of different requirements, where appropriate. For instance, seals, doors, window screens, windows, furnishings, heating/cooling systems, disposal/sanitation etc.;
- elaborate on security measures such as signage, controlling access and plans for dealing with breaches that could result in unintentional releases.

<u>Provision of resources:</u> 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.

Steward: David Porritt.

Collaborators: To be determined.

<u>Expertise of EWG</u>: Interest and expertise in phytosanitary systems for import of organisms, including plants and biocontrol agents, and knowledge of relevant aspects of other standards. The experts should have practical expertise in post-entry quarantine facilities. 5-7 international phytosanitary experts.

<u>Participants:</u> To be determined.

<u>Approval:</u> Introduced into the work programme by the ICPM at its sixth session in April 2004. Specification reviewed by the extraordinary working group of the Standards Committee meeting in July 2004 and approved by the SC in November 2004.

<u>References:</u> National manuals and legislation, relevant ISPMs (including revised ISPM No. 3, draft or approved), regional standards and texts.

<u>Title:</u> Guidelines for formatting / drafting pest specific ISPMs

<u>Reason for the standard:</u> Pest specific standards are needed to deal with specific aspects of a particular pest as identified by the ICPM to help members with the application of phytosanitary measures and the specification of import requirements.

<u>Scope and purpose:</u> To give guidelines for formatting aspects of a data sheet of a pest and/or a phytosanitary measure related to this specific pest.

## Tasks:

The Expert Working Group (EWG) should:

- identify the aspects of pests and phytosanitary measures that may be considered for specific standards (for example identification, detection, relation between host and pest, biology, surveillance, pest free areas, control etc.);
- identify subject headings for pest specific ISPMs for each of the aspects identified;
- consider means of obtaining published information for use in pest specific standards;
- consider if standards can be developed for groups of pests, not just specific pests;
- consider how to publish and disseminate this type of standard;
- consider how pest specific standards (e.g. treatments, diagnostics, surveillance etc.) on the same pest could be integrated.

<u>Provision of resources:</u> 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.

Steward: John Hedley

Collaborator: To be determined.

<u>Expertise of EWG:</u> Experience in drafting pest specific standards and in collaborating with publishing organizations. 5-7 participants.

Participants: To be determined and to include members of related EWGs and TPs.

<u>Approval:</u> Introduced into the work programme by the ICPM at its Sixth session in April 2004. Specification reviewed by the extraordinary working group of the Standards Committee meeting in July 2004 and approved by the SC in November 2004.

References: Relevant ISPMs, specifications, regional and/or national standards.

<u>Title:</u> Guidelines for formatting / drafting commodity specific ISPMs.

Reason for the standard: Commodity specific standards are needed to deal with specific aspects of a particular traded commodity.

<u>Scope and purpose:</u> To give guidelines for formatting a list of pests associated with the commodity and phytosanitary measures related to the commodity.

## Tasks:

The Expert Working Group should:

- develop a format for listing pests associated with the commodity;
- develop a format for describing phytosanitary measures used in the management of the associated pests;
- consider other aspects that may be included in commodity specific ISPMs;
- identify the subject headings for commodity specific ISPMs;
- consider if standards can be developed for groups of commodities associated with a specific pest or group of pests and phytosanitary measures;
- consider means of obtaining published information for use in commodity specific standards;
- consider how to publish and disseminate this type of standard.

<u>Provision of resources:</u> 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.

Steward: John Hedley

Collaborator: To be determined.

<u>Expertise of EWG:</u> Experience in drafting commodity specific standards and in collaborating with publishing organizations. 5-7 participants.

Participants: To be determined and to include members of related EWGs and TPs.

<u>Approval:</u> Introduced into the work programme by the ICPM at its Sixth session in April 2004. Specification reviewed by the extraordinary working group of the Standards Committee meeting in July 2004 and approved by the SC in November 2004.

<u>References:</u> Relevant ISPMs, specifications, regional and/or national standards.

#### SPECIFICATION FOR TECHNICAL PANELS NO. 1 (1ST REVISION)

Title: Technical Panel to develop diagnostic protocols for specific pests.

<u>Reason for the Technical Panel</u>: ICPM-6 identified the need for diagnostic protocols for specific pests to be recommended to the Standards Committee. To do this, a Technical Panel on diagnostics was proposed.

<u>Scope and purpose</u>: The Technical Panel will produce diagnostic protocols for specific pests utilizing the format for diagnostic protocols established by the Expert Working Group.

#### Tasks:

- Identify priorities for specific protocols to be developed and submitted to the SC. Aspects to consider include:
  - availability of existing regional standards and/or protocols used by individual countries
  - suggestions for new protocols (i.e. those put forward by NPPOs, RPPOs, EWGs or other Technical Panels).
- Identify specialists.
- Produce or supervise the production of diagnostic protocols for specific pests as future annexes of ISPM Diagnostic
  protocols for pests.
- Submit to the SC draft diagnostic protocols for specific pests and where necessary revision of previously adopted protocols.

<u>Provision of resources</u>: 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.

Steward: Jens Unger.

Collaborator: To be determined.

Expertise: At least 5-7 participants comprised primarily of diagnostic (where appropriate taxonomic) experts with at least one representing each discipline: entomology, acarology, nematology, mycology, plant bacteriology, virology (including viroids and phytoplasma) and botany. Between them participants should have practical expertise in the use of morphological and molecular/biochemical diagnostic techniques, and in phytosanitary procedures.

Participants: To be determined.

<u>Approval</u>: Introduced into the work programme by the ICPM at its Sixth Session in 2004. Specification approved by the SC in April 2004. First revision approved by the SC in November 2004.

References: Regional standards; NPPO protocols; diagnostic manuals; EPPO protocols; ISTA; other relevant information.

#### SPECIFICATION FOR TECHNICAL PANELS NO. 2 (1ST REVISION)

Title: Technical Panel on pest free areas and systems approaches for fruit flies.

Reason for the Technical Panel: ICPM-6 identified the need for the formation of a Technical Panel on pest free areas and systems approaches for fruit flies.

<u>Scope and purpose:</u> A panel of fruit fly experts will review scientific and technical data in order to establish the technical requirements for the recognition of fruit flies pest free areas and systems approaches.

#### Tasks:

- Identify the most important fruit fly pest species for priority work.
- Identify case studies that could act as good examples for establishment of pest free areas and systems approaches for fruit flies.
- Develop standardized procedures by fruit fly species to establish fruit flies pest free areas, fruit flies areas of low pest prevalence and systems approaches, including collection of adequate information, surveys, detection and identification techniques, emergency measures to protect free areas and maintain systems approaches, evaluation, approval, and suspension procedures for fruit flies pest free areas.
- Develop a process, identify criteria needed, set up a protocol and define an evaluation method for the submission of research information.
- Establish the technical requirements for the recognition of fruit flies pest free areas, fruit flies areas of low pest prevalence and systems approaches, taking into account adequate biological and climatic parameters, applicability and recognition requirements.
- Develop a procedure to consult with international specialists to exchange information about fruit flies.
- Identify measures to be integrated in systems approaches for different species of fruit flies.
- Analyse the feasibility of the measures recommended and evaluate the cost/benefit of the measures, their technical justification and their relationship with the identified risk.
- Consider the relationship between the draft documents proposed and currently approved ISPMs relevant for this subject.
- Determine measures to be integrated in systems approaches for different species of fruit flies, considering the feasibility of the measures recommended and selecting the least trade restrictive.
- Submit draft standards to the SC including, where appropriate, for fast-track approval.

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

Steward: Odilson Ribeiro e Silva.

Collaborator: To be determined.

<u>Expertise:</u> 5-7 international phytosanitary experts that have interest and expertise in relevant aspects of quarantine, control and risk management of fruit flies.

Participants: To be determined.

<u>Approval:</u> Introduced into the work programme by the ICPM at its Sixth Session in 2004. Specification approved by the SC in April 2004. First revision approved by the SC in November 2004.

<u>References:</u> Relevant ISPMs; regional standards; national programs on fruit fly pest free areas and systems approaches; IAEA documentation.

Title: Pest free areas for fruit flies

Reason for the standard: ICPM-6 identified the need for the formation of a Technical Panel on pest free areas and systems approaches for fruit flies. One of the tasks given to the TP is to develop standardized procedures by fruit fly species to establish pest free areas (PFAs) for fruit flies. An Expert Working Group (EWG) will work under the direction of the TP to develop a standard on PFA for fruit flies.

<u>Scope and purpose:</u> This standard provides guidance on the establishment and maintenance of pest free areas for fruit flies. This guidance will be applicable for the most economically important fruit flies in the world.

#### Tasks:

The EWG should:

- 1. consider existing relevant ISPMs, and ensure consistency with other ISPMs and draft ISPMs in development;
- 2. identify the most important fruit fly pest species (and their major hosts ) for priority work;
- 3. develop a standardized method which can be followed to help create a fruit fly pest free area. Some suggested areas to consider are:
  - a. collection of adequate information
  - b. surveys, including specific technical information
  - c. detection
  - d. identification of pest(s)
  - e. corrective actions (including response to an outbreak)
  - f. maintenance
  - g. general operations
  - h. evaluation
  - i. approval
  - j. suspension, termination and reinstatement of areas.
- 4. identify the most practical method of presenting information in a standard for providing guidance in setting up a pest free area;
- 5. identify reference material for conducting surveys, identifying pests and treatments.

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

Steward: Odilson Ribeiro e Silva.

Collaborator: APPPC and Thailand

<u>Expertise</u>: 6-8 experts with general expertise in fruit flies with specific expertise in establishing a fruit fly pest free area. The group should also have expertise with more than one genus of fruit fly, have experience with fruit flies in several regions.

<u>Participants:</u> Same experts as gathered for the first meeting of the Technical Panel on pest free areas and systems approaches for fruit flies

<u>Approval:</u> Introduced into the work programme by the ICPM at its Sixth Session in April 2004. TP Specification No. 2 (Technical Panel on pest free areas and systems approaches for fruit flies), which tasked the TP to work on pest free areas for fruit flies, approved by the SC in April 2004. Present specification approved by the SC in November 2004.

#### References:

IPPC 1997; WTO-SPS Agreement; ISPMs No. 4, No. 6, No. 8, No. 9, No. 10, No. 14. Relevant draft ISPMs. Relevant regional standards; national programs on fruit fly pest free areas and systems approaches; IAEA documentation.

Title: Areas of low pest prevalence for fruit flies

Reason for the standard: ICPM-6 identified the need for the formation of a Technical Panel on pest free areas and systems approaches for fruit flies. One of the tasks given to the TP relates to systems approaches for fruit flies, which requires areas of low pest prevalence (ALPP) for fruit flies as a component. An Expert Working Group (EWG) will work under the direction of the TP to develop a standard on ALPPs for fruit flies.

The concept of areas of low pest prevalence is addressed in the IPPC and the WTO-SPS Agreement, and the standard should take into account these provisions as they apply to areas of low pest prevalence as well as least trade restrictive measures under both the IPPC and the WTO-SPS Agreement.

<u>Scope and purpose</u>: This standard provides guidance on the establishment and maintenance of areas of low pest prevalence for fruit flies.

#### Tasks:

#### The EWG should:

- 1. consider existing relevant ISPMs, and ensure consistency with other ISPMs and draft ISPMs in development;
- 2. consider criteria for defining, describing and determining ALPPs for fruit flies;
- 3. identify case studies that could act as good examples for establishment of ALPPs for fruit flies;
- 4. develop standardized procedures to establish and maintain ALPPs for fruit flies;
- 5. consider the need for guidance for establishing, maintaining and verifying ALPPs for fruit flies as appropriate (considering the existing guidance in the draft standard on PFAs for fruit flies) on:
  - a. surveillance
  - b. suppression
  - c. regulatory controls, where necessary
  - d. corrective actions
  - e. suspension, termination and reinstatement of areas.
- 6. consider whether guidance is required on the relationship between ALPPs for fruit flies to/from PFAs for fruit flies and/or pest free places of production;
- 7. consider situations where ALPP for fruit flies may or may not apply.

<u>Provision of resources:</u> 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.

Steward: to be determined

Collaborator: to be determined

<u>Expertise</u>: A consultant with experience in implementing PFAs and ALPPs for fruit flies and in systems approaches for fruit flies, and with regulatory experience on fruit flies. The consultant should also have expertise with more than one genus of fruit fly and have experience with fruit flies in several regions.

Participants: to be determined

<u>Approval:</u> Introduced into the work programme by the ICPM at its Sixth Session in April 2004. TP Specification No. 2 (Technical Panel on pest free areas and systems approaches for fruit flies), which tasked the TP to work on a systems approach which requires a component on ALPP for fruit flies, approved by the SC in April 2004. Present specification approved by the SC in November 2004.

## References:

IPPC 1997; WTO-SPS Agreement; ISPMs No. 4, No. 6, No. 8, No. 9, No. 10, No. 14; relevant draft ISPMs, appendix of the draft ISPM on areas of low pest prevalence (as modified by the steward) presented to the SC7 in November 2004 (*Guidance for the establishment of an ALPP for some insects*); relevant regional standards.

Title: The use of integrated measures in a systems approach for pest risk management of fruit flies

#### Reason for the standard:

ICPM-6 identified the need for the formation of a Technical Panel on pest free areas and systems approaches for fruit flies. One of the tasks given to the TP is to develop standardized procedures by fruit fly species to establish systems approaches for fruit flies.

ISPM No. 14 (*The use of integrated measures in a systems approach for pest risk management*) provides general guidelines related to pest risk management by the application of integrated measures in a systems approach, as an alternative to the application of a single phytosanitary measure or restrictive phytosanitary measures, with the objective of satisfying phytosanitary requirements.

Based on the biological characteristics of fruit flies, the commodities and the areas in which they occur, it is possible to integrate different measures in systems approaches for pest risk management for fruit flies to facilitate trade in fruit.

<u>Scope and purpose</u>: This standard provides specific guidelines on options for risk management of fruit flies by applying integrated phytosanitary measures in a systems approach to facilitate the movement of fruit.

#### Tasks:

The Expert Working Group should:

- 1. consider existing relevant ISPMs, and ensure consistency with other ISPMs and draft ISPMs in development;
- 2. incorporate relevant concepts of systems approaches (ISPM No. 14), including consideration of items such as:
  - a. general aspects of surveillance (keeping in mind that the technical aspects of surveillance are to be contained in draft standards on PFAs and ALPPs)
  - b. suppression strategies
  - c. good agricultural practice
  - d. inspections (field, packaging and pre-export)
  - e. identification capability
  - f. packing procedures, including treatments
  - g. post harvest safeguards (including transportation systems, fly-proof packaging)
  - h. relationship between infested areas, areas of low pest prevalence and pest free areas
  - i. documentation and record keeping
  - j. quality control
  - k. corrective actions.

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

Steward: to be determined.

<u>Collaborators:</u> to be determined.

<u>Expertise</u>: A group of 6-8 experts with expertise in fruit flies and having familiarity with pest risk analysis, ICPM standard setting procedures and systems approaches for fruit fly management. The group should also have expertise with more than one genus of fruit fly, and have experience with fruit flies in several regions.

Participants: to be determined.

<u>Approval:</u> Introduced into the work programme by the ICPM at its Sixth Session in April 2004. TP Specification No. 2 (Technical Panel on pest free areas and systems approaches for fruit flies), which tasked the TP to work on systems approaches for fruit flies, approved by the SC in April 2004. Present specification approved by the SC in November 2004.

References: IPPC 1997; WTO-SPS Agreement; ISPMs No. 4, No. 6, No. 8, No. 9, No. 10, No. 14. Relevant draft ISPMs.

## PRIORITIES FOR WORK PROGRAMME

- Standard : Soil and growing media
- Standard : Movement of plants for planting
- Standard: Post-entry quarantine/plants for planting
- Standard: Certification programmes for plants for planting
- PRA for plants as pests
- Supplement to ISPM No. 5: Guidelines on the understanding of "not widely distributed"
- Supplement to ISPM No. 5: appropriate level of protection
- Standard: Guidelines for pre-inspection / pre-clearance
- Standard: Guidelines for regulating stored products in international trade
- Standard: inspection manual
- Standard: import of organic fertilizers
- Revision of Section 3.3 of ISPM No. 12

# INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

**GUIDELINES FOR INSPECTION** 

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

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#### INTRODUCTION

## **SCOPE**

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

#### REFERENCES

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

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.

Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.

Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.

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

International Plant Protection Convention, 1997. FAO, Rome.

Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome

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

Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.

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

**DEFINITIONS**<sup>1</sup> consignment A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001] inspection Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly inspect] Person authorized by a National Plant Protection Organization to discharge inspector its functions [FAO, 1990] **IPPC** International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001] A number of units of a single commodity, identifiable by its homogeneity of lot composition, origin etc., forming part of a consignment [FAO, 1990] National Plant Protection Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization Organization (National)] 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

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]

The process of evaluating biological or other scientific and economic Pest Risk Analysis

evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC,

1997]

phytosanitary certification Use of phytosanitary procedures leading to the issue of a Phytosanitary

Certificate [FAO, 1990]

<sup>&</sup>lt;sup>1</sup> Terms marked with (\*) are new.

concerning consignments moving into that country

quarantine pest A pest of potential economic importance to the area endangered thereby and

not yet present there, or present but not widely distributed and being

officially controlled [FAO, 1990; revised FAO, 1995; IPPC 1997]

regulated article Any plant, plant product, storage place, packaging, conveyance, container,

soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved [FAO, 1990; revised FAO,

1995; IPPC, 1997]

regulated pest A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]

visual examination\* The physical examination of plants, plant products, or other regulated articles

using the unaided eye, lens, stereoscope or microscope to detect pests or

contaminants without testing or processing.

## **OUTLINE OF REQUIREMENTS**

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

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

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

## REQUIREMENTS

## 1. General Requirements

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

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

#### 1.1 Inspection objectives

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

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

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

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

Inspection can be used as a risk management procedure.

## 1.2 Assumptions involved in the application of inspections

As inspection of entire consignments is often not feasible, phytosanitary inspection is consequently often based on sampling<sup>2</sup>.

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

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

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

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

## 1.3 Responsibility for inspection

NPPOs have the responsibility for inspection. Inspections are carried out by NPPOs or under their authority (see also section 3.1 of ISPM No. 7: *Export certification system*; and section 5.1.5.2 of ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*; Articles IV.2a, IV.2c and V.2a of the IPPC, 1997).

### 1.4 Requirements for inspectors

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

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

The inspector may be required to inspect consignments for:

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

#### 1.5 Other considerations for inspection

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

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

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<sup>&</sup>lt;sup>2</sup> Guidance on sampling will be provided in the ISPM under development

## 1.6 Inspection in relation to pest risk analysis

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

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

## 2. Specific Requirements

The technical requirements for inspection involve three distinct procedures that should be designed with a view to ensuring technical correctness while also considering operational practicality. These procedures are:

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

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

### 2.1 Examination of documents associated with a consignment

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

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

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

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

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

#### 2.2 Verification of consignment identity and integrity

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

#### 2.3 Visual examination

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

#### 2.3.1 Pests

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

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

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

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

then sampling methodology should reflect this.

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

## 2.3.2 Compliance of phytosanitary requirements

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

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

#### 2.4 Inspection methods

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

It is important that:

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

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

## 2.5 Inspection outcome

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

If phytosanitary requirements are not met, further actions can be taken. These actions may be determined by the nature of the findings, considering pest level or other inspection objectives and the circumstances. Likewise, the consequences of detention or rejection require consideration of the circumstances and

alternatives. In some cases, corrective action may be taken (e.g. correcting documentation) while other situations may require stronger action such as treatment, rejection or the destruction of a consignment. All consignments should be safeguarded to maintain their phytosanitary integrity until decisions can be taken.

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

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

#### 2.6 Review of inspection systems

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

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

## 2.7 Transparency

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

## INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

## REQUIREMENTS FOR THE ESTABLISHMENT OF AREAS OF LOW PEST PREVALENCE

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

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#### INTRODUCTION

## SCOPE

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

#### REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.

Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.

Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.

Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

International Plant Protection Convention, 1997, FAO, Rome.

Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.

Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.

Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.

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

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

## **DEFINITIONS**<sup>3</sup>

area An officially defined country, part of a country or all or parts of several countries [FAO, 1990; revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary

Measures]

area of low pest prevalence An area, whether all of a country, part of a country, or all or parts of several

countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or

eradication measures [IPPC, 1997]

buffer zone\* An area in which a specific pest does not occur or occurs at a low level and is

officially controlled, that either encloses or is adjacent to an infested area, an infested place of production, an area of low pest prevalence, a pest free area, a pest free place of production or a pest free production site, and in which phytosanitary measures are

to prevent spread of the pest

containment Application of phytosanitary measures in and around an infested area to prevent

spread of a pest [FAO, 1995]

control (of a pest) Suppression, containment or eradication of a pest population [FAO, 1995]

delimiting survey Survey conducted to establish the boundaries of an area considered to be infested

by or free from a pest [FAO, 1990]

eradication Application of phytosanitary measures to eliminate a pest from an area [FAO,

1990; revised FAO, 1995; formerly eradicate]

IPPC International Plant Protection Convention, as deposited in 1951 with FAO in

Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]

monitoring survey Ongoing survey to verify the characteristics of a pest population [FAO, 1995]

National Plant Protection

Organization

Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization (National)]

official Established, authorized or performed by a National Plant Protection Organization

[FAO, 1990]

<sup>&</sup>lt;sup>3</sup> Term marked with (\*) is revised

Pest Free Area An area in which a specific pest does not occur as demonstrated by scientific

evidence and in which, where appropriate, this condition is being officially

maintained [FAO, 1995]

phytosanitary action An official operation, such as inspection, testing, surveillance or treatment,

undertaken to implement phytosanitary regulations or procedures [ICPM, 2001]

phytosanitary measure (agreed interpretation)

Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; ICPM, 2002]

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

phytosanitary procedure Any officially prescribed method for implementing phytosanitary regulations

including the performance of inspections, tests, surveillance or treatments in connection with regulated pests [FAO, 1990; revised FAO, 1995; CEPM, 1999;

ICPM, 2001]

phytosanitary regulation Official rule to prevent the introduction and/or spread of quarantine pests, or to

limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification [FAO, 1990; revised

FAO, 1995; CEPM, 1999; ICPM, 2001]

place of production Any premises or collection of fields operated as a single production or farming

unit. This may include production sites which are separately managed for

phytosanitary purposes [FAO, 1990; revised CEPM, 1999]

quarantine pest A pest of potential economic importance to the area endangered thereby and not

yet present there, or present but not widely distributed and being officially

controlled [FAO, 1990; revised FAO, 1995; IPPC 1997]

regulated article Any plant, plant product, storage place, packaging, conveyance, container, soil

and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international

transportation is involved [FAO, 1990; revised FAO, 1995; IPPC, 1997]

regulated non-quarantine pest A non-quarantine pest whose presence in plants for planting affects the intended

use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party [IPPC,

1997]

regulated pest A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]

standard Document established by consensus and approved by a recognized body, that

provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order

in a given context [FAO, 1995; ISO/IEC GUIDE 2:1991 definition]

suppression The application of phytosanitary measures in an infested area to reduce pest

populations [FAO, 1995; revised CEPM, 1999]

surveillance An official process which collects and records data on pest occurrence or absence

by survey, monitoring or other procedures [CEPM, 1996]

survey An official procedure conducted over a defined period of time to determine the

characteristics of a pest population or to determine which species occur in an area

[FAO, 1990; revised CEPM, 1996]

systems approach(es) The integration of different pest risk management measures, at least two of which

act independently, and which cumulatively achieve the appropriate level of

phytosanitary protection [ISPM No. 14, 2002]

treatment

Officially authorized procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003]

#### **OUTLINE OF REQUIREMENTS**

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

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

#### **BACKGROUND**

## 1. General Considerations

#### 1.1 Concept of areas of low pest prevalence

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

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

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

## 1.2 Advantages in using areas of low pest prevalence

Advantages in using ALPPs include:

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

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

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

#### REQUIREMENTS

#### 2. General Requirements

# 2.1 Determination of an area of low pest prevalence

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

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

- an area of production where products are intended for export
- an area under an eradication or suppression programme
- an area acting as a buffer zone to protect a PFA

- an area within a PFA which has lost its status and is under an emergency action plan
- as part of official control in relation to regulated non-quarantine pests (see ISPM No. 21: *Pest risk analysis for regulated non-quarantine pests*)
- an area of production in an infested area of a country from which products are intended to be moved to another ALPP in that country.

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

#### 2.2 Operational plans

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

#### 3. Specific Requirements

#### 3.1 Establishment of an ALPP

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

#### 3.1.1 Determination of specified pest levels

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

#### 3.1.2 Geographic description

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

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

## 3.1.3 Documentation and verification

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

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

#### 3.1.4 Phytosanitary procedures

#### 3.1.4.1 Surveillance activities

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

Surveillance data should be collected and documented to demonstrate that the populations of the specified pests do not exceed the specified pest levels in any areas of the proposed ALPP, and buffer zones where appropriate, and include surveys of cultivated and uncultivated hosts, or habitats in particular in the case where

the pest is a plant. The surveillance data should be relevant to the life cycles of the specified pests and should be statistically validated to detect and characterize the population levels of the pests.

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

#### 3.1.4.2 Reducing pest levels and maintaining low prevalence

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

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

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

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

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

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

# 3.1.4.4 Corrective action plan

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

## 3.1.5 Verification of an area of low pest prevalence

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

#### 3.2 Maintenance of an area of low pest prevalence

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

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

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

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

repeated failure of regulatory procedures

- incomplete documentation that jeopardises the integrity of the ALPP.

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

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

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

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

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

If an ALPP is suspended, an investigation should be initiated to determine the cause of the failure. Corrective actions, and if necessary additional safeguards, should be implemented to prevent recurrence of the failure. The suspension of the ALPP will remain in effect until it is demonstrated that populations of the pest are below the specified pest level for an appropriate period of time, or that the other deficiencies have been corrected. As with the initial establishment of an ALPP, the minimum period of time below the specified pest level(s) for reinstatement of ALPP status will depend on the biology of the specified pest(s). Once the cause of the failure has been corrected and the integrity of the system is verified, the ALPP can be reinstated.

# INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

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

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

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#### INTRODUCTION

## **SCOPE**

This standard<sup>4</sup> provides guidelines for risk management related to the export, shipment, import and release of biological control agents and other beneficial organisms. It lists the related responsibilities of contracting parties to the IPPC ('contracting parties'), NPPOs or other responsible authorities, importers and exporters. The standard addresses biological control agents capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), as well as sterile insects and other beneficial organisms (such as mycorrhizae and pollinators), and includes those packaged or formulated as commercial products. Provisions are also included for import for research in quarantine facilities of non-indigenous biological control agents and other beneficial organisms.

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

#### REFERENCES

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.

Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.

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

Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest reporting, 2002. ISPM No. 17, FAO, Rome.

Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

#### **DEFINITIONS**<sup>5</sup>

area	An officially defined country, part of a country or all or parts of several countries [FAO, 1990; revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]	
beneficial organism*	Any organism directly or indirectly advantageous to plants or plant products, including biological control agents	
biological control**	Pest control strategy making use of living natural enemies, antagonists, competitors or other biological control agents. [formerly biological control (biocontrol)]	
biological control agent**	A natural enemy, antagonist or competitor, or other organism, used for pest control	
competitor	An organism which competes with pests for essential elements (e.g. food, shelter) in the environment [ISPM $N^{\circ}$ 3, 1996]	
consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]	
control (of a pest)	Suppression, containment or eradication of a pest population [FAO, 1995]	
ecosystem	A dynamic complex of plant, animal and micro-organism communities and their abiotic environment interacting as a functional unit	
emergency measure	A phytosanitary regulation or procedure established as a matter of urgency in a new or unexpected phytosanitary situation. An emergency measure may or may not be a provisional measure [ICPM, 2001]	
entry (of a consignment)	Movement through a point of entry into an area [FAO, 1995]	
host range**	Species capable, under natural conditions, of sustaining a specific pest or other organism	

<sup>&</sup>lt;sup>4</sup> Nothing in this standard shall affect the rights or obligations of contracting parties under other international agreements.

<sup>5</sup> Terms marked with an (\*) are new, terms marked with an (\*\*) are revised

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Import Permit [to be added - revised definition presented for adoption in "amendments to the Glossary"]

infestation (of a Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection [CEPM, 1997; revised CEPM, 1999]

inundative release\*\* The release of large numbers of a mass-produced biological control agents or beneficial

organisms with the expectation of achieving a rapid effect

IPPC International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as

subsequently amended [FAO, 1990; revised ICPM, 2001]

legislation Any act, law, regulation, guideline or other administrative order promulgated by a

government [ISPM N° 3, 1996]

National Plant Protection

Organization

Official service established by a government to discharge the functions specified by the

IPPC [FAO, 1990; formerly Plant Protection Organization (National)]

natural enemy\*\* An organism which lives at the expense of another organism in its area of origin and which

may help to limit the population of that organism. This includes parasitoids, parasites,

predators, phytophagous organisms and pathogens

naturally occurring A component of an ecosystem or a selection from a wild population, not altered by artificial

means [ISPM N° 3, 1996]

NPPO National Plant Protection Organization [FAO, 1990; revised ICPM, 2001]

organism\*\* Any biotic entity capable of reproduction or replication in its naturally occurring state

pest Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or

plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]

Phytosanitary Certificate Certificate patterned after the model certificates of the IPPC [FAO, 1990]

phytosanitary measure Any legislation, regula

(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)

quarantine Official confinement of regulated articles for observation and research or for further

inspection, testing and/or treatment [FAO, 1990; revised FAO, 1995; CEPM, 1999]

reference specimen(s)\* Individual specimen(s) from a specific population conserved in a reference culture

collection and, where possible, in publicly available collection(s)

regulated article Any plant, plant product, storage place, packaging, conveyance, container, soil and any

other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is

involved [FAO, 1990; revised FAO, 1995; IPPC, 1997]

SIT sterile insect technique

sterile insect\* An insect that, as a result of a specific treatment, is unable to reproduce

sterile insect technique\* Method of pest control using area-wide inundative release of sterile insects to reduce

reproduction in a field population of the same species

treatment Officially authorized procedure for the killing, inactivation or removal of pests, or for

rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM No.

15, 2002; ISPM No. 18, 2003]

#### **OUTLINE OF REQUIREMENTS**

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

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

NPPOs and other responsible authorities should:

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

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

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

#### **BACKGROUND**

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

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

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

c) prohibit or restrict the movement of regulated pests into their territories;

d) prohibit or restrict the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into their territories."

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

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

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

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

The IPPC (1997) takes into account internationally approved principles governing the protection of the environment (Preamble). Its purpose includes promoting appropriate phytosanitary measures (Article I.1). Therefore, in carrying out pest risk assessment and analysis in accordance with this and other appropriate ISPMs, and in developing and applying related phytosanitary measures, contracting parties should consider the potential for broader environmental impacts resulting from releasing biological control agents and other beneficial organisms<sup>6</sup> (for example, impacts on non-target invertebrates).

Most of this standard is based on the premise that a biological control agent or other beneficial organism may be a potential pest itself, and in this sense Article VII.1c of the IPPC (1997) applies because contracting parties may prohibit or restrict the movement of regulated pests into their territories. In some situations, biological control agents and other beneficial organisms may act as a carrier or pathway for plant pests, hyperparasitoids, hyperparasites and entomopathogens. In this sense, biological control agents and other beneficial organisms may be considered to be regulated articles as described in Article VII.1 of the IPPC (1997) and ISPM No. 20: Guidelines for a phytosanitary import regulatory system.

## Purpose of the standard

The objectives of the standard are to:

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

Guidelines in support of these objectives are described that:

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

## REQUIREMENTS

# 1. Designation of Responsible Authority and Description of General Responsibilities

## 1.1 Contracting parties

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

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

## 1.2 General responsibilities

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

The NPPO or other responsible authority should:

- carry out pest risk analysis prior to import or release of biological control agents and other beneficial organisms
- ensure, when certifying exports, that the regulations of importing countries are complied with

<sup>&</sup>lt;sup>6</sup> Available expertise, instruments and work in international fora with competence in the area of risks to the environment should be taken into account as appropriate

<sup>6 /</sup> Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms

- provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biological control agents and other beneficial organisms
- ensure that biological control agents and other beneficial organisms are taken either directly to designated quarantine facilities or, if appropriate, passed to mass rearing facilities or directly for release into the environment
- ensure that importers and, where appropriate, exporters meet their responsibilities
- consider possible impacts on the environment, such as impacts on non-target invertebrates.

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

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

#### 2. Pest Risk Analysis

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

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

Most contracting parties require PRA to be completed prior to import and, as described in ISPM No. 20 (*Guidelines for a phytosanitary import regulatory system*), technical justification, such as through PRA, is required to determine if pests should be regulated and the strength of phytosanitary measures to be taken against them. Where applicable, if pest risk assessment of the proposed organism has not been undertaken or completed prior to import, it should be completed prior to release (see section 7). However, it is recognized that biological control agents and other beneficial organisms may need to be imported for research and evaluation in secure facilities prior to release. ISPM No. 20 also states that contracting parties may make special provision for the import of biological control agents and other beneficial organisms for scientific research, and that such imports may be authorized subject to the provision of adequate safeguards. The NPPO should be prepared for such imports with the expectation that, where necessary, a full PRA in accordance with ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) will be completed prior to release. When non-phytosanitary risks are identified, these may need to be referred to other appropriate authorities for possible action.

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

#### 3. Responsibilities of Contracting Parties prior to Import

## 3.1 Responsibilities of the importing contracting party

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

- 3.1.1 Promote awareness of, and compliance with this standard and introduce necessary phytosanitary measures to regulate the import, shipment or release of biological control agents and other beneficial organisms in its country, and make provision for effective enforcement.
- 3.1.2 Evaluate the documentation on the target pest and on the biological control agent and beneficial organisms supplied by the importer (see section 4) in relation to the level of acceptable risk. The contracting party should establish appropriate phytosanitary measures for import, shipment, quarantine facilities (including approval of research facilities, and phytosanitary measures for containment and disposal) or release of biological control agents appropriate to the assessed risk. If the biological control agent or other beneficial

organism is already present in the country, regulation may only be needed to ensure there is no contamination or infestation of this organism, or that interbreeding with local genotypes of the same species does not result in new phytosanitary risks. Inundative release may be restricted for these reasons.

- 3.1.3 Issue regulations stating requirements to be fulfilled by the exporting country, the exporter and the importer<sup>7</sup>. Where appropriate, these may include:
  - the issuing of an accompanying authorising document (import permit or licence)
  - phytosanitary certification, in accordance with ISPM No. 12: Guidelines for phytosanitary certificates
  - authoritative identification of organisms during quarantine and provision of a reference specimen
  - specification of the source of the biological control agent or other beneficial organism(s), including origin and/or point of production where relevant
  - precautions to be taken against inclusion of natural enemies of the biological control agent or other beneficial organism and of contamination or infestation
  - requirements regarding packaging for shipment during transport and storage
  - procedures for the disposal of packaging
  - means to validate documentation
  - means to validate the contents of consignments
  - conditions under which the package may be opened
  - designation of point(s) of entry
  - identification of the person or organization to receive the consignment
  - requirements for the facilities in which the biological control agent or other beneficial organisms may be held.
- 3.1.4 Ensure that procedures are in place for the documentation of:
  - pest risk analysis
  - the import (identity, origins, dates)
  - nurturing, rearing or multiplication
  - release (quantities released, dates, locations), and
  - any other relevant data.

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

- 3.1.5 If appropriate, ensure entry of consignments, and processing where required, through quarantine facilities. Where a country does not have secure quarantine facilities, import through a quarantine station in a third country, recognized by the importing contracting party, should be considered.
- 3.1.6 Consider, through the pest risk assessment process, the risk of introducing other organisms associated with the biological control agent or beneficial organism. Considerations (keeping in mind the principles of necessity and minimal impact) should include phytosanitary measures requiring the culturing of imported biological control agents and other beneficial organisms in quarantine before release. Culturing for at least one generation can help in ensuring purity of the culture and freedom from hyperparasites and pathogens or associated pests, as well as facilitating authoritative identification. This is particularly advisable when biological control agents and other beneficial organisms are collected from the wild.
- 3.1.7 Where possible, ensure the deposition in collections of authoritatively identified reference specimens of the imported biological control agent and beneficial organism (and host(s) where appropriate). It is preferable to deposit a series of specimens, where available, to accommodate natural variation.
- 3.1.8 In the case of sterile insect technique, the sterile insect may be marked to differentiate it from the wild insect.
- 3.1.9 Consider, through the pest risk assessment process (consistent with the principles of necessity and minimal impact), if, after a first import or release, further imports of the same biological control agent or other beneficial organism may be exempted from some or all of the requirements for import. The publication of lists of approved and prohibited biological control agents and other beneficial organisms may also be considered.

<sup>&</sup>lt;sup>7</sup> Provisions of other international agreements may address the import of biological control agents or other beneficial organisms (for example the Convention on Biological Diversity)

<sup>8 /</sup> Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms

#### 3.2 Responsibilities of the NPPO of an exporting country

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

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

# 4. Documentary responsibilities of importer prior to import

## 4.1 Documentary requirements related to the target organism

Prior to the first importation, the importer of biological control agents or other beneficial organisms should provide information as required by the NPPO or other responsible authority of the importing contracting party. For all biological control agents or other beneficial organisms, this information includes accurate identification of the target organism(s), generally at the species level. Where a biological control agent intended to control a pest is being imported, the information on the target pest may also include:

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

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

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

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

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

## 4.3 Documentary requirements related to potential hazards and emergency actions

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

- identifies potential health hazards and analyzes the risks<sup>8</sup> posed to staff operatives exposed when handling biological control agents or other beneficial organisms under laboratory, production and application conditions.
- details emergency action plans or procedures already in existence, should the biological control agent or beneficial organism display unexpected adverse properties (the NPPO or other responsible authority of the importing contracting party is responsible for developing or adopting emergency plans or procedures, as appropriate, for use within the importing country).

## 4.4 Documentary requirements related to research in quarantine

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

- the nature of the material proposed for importation
- the type of the research to be carried out

<sup>8</sup> Available expertise, instruments and work in international fora with competence in the area of risks to human health should be taken into account as appropriate.

- detailed description of containment facilities (including security and the competency and qualifications of the staff)
- an emergency plan that will be implemented in the case of an escape from the facility.

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

#### 5. Responsibilities of Exporter

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

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

## 5.1 Specific responsibilities regarding organisms intended for inundative release

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

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

#### 6.1 Inspection

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

#### 6.2 Quarantine

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

#### 6.3 Release

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

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

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

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

#### 7.1 Release

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

## 7.2 Documentation

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

## 7.3 Monitoring and evaluation

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

## 7.4 Emergency measures

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

# 7.5 Communication

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

## 7.6 Reporting

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

# INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

# GUIDELINES FOR THE DETERMINATION AND RECOGNITION OF EQUIVALENCE OF PHYTOSANITARY MEASURES

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

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#### INTRODUCTION

## **SCOPE**

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

#### REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.

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

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.

Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.

Guidelines for regulating wood packaging material in international trade, 2002. ISPM No. 15. FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

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

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

## **DEFINITIONS**<sup>1</sup>

commodity A type of plant, plant product, or other article being moved for trade or other

purpose [FAO, 1990; revised ICPM, 2001]

consignment A quantity of plants, plant products and/or other articles being moved from one

country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or

lots) [FAO, 1990; revised ICPM, 2001]

emergency action A prompt phytosanitary action undertaken in a new or unexpected phytosanitary

situation [ICPM, 2001]

equivalence (of phytosanitary

measures)\*

The situation where, for a specified pest risk, different phytosanitary measures

achieve a contracting party's appropriate level of protection.

fumigation Treatment with a chemical agent that reaches the commodity wholly or

primarily in a gaseous state [FAO, 1990; revised FAO, 1995]

IPPC International Plant Protection Convention, as deposited in 1951 with FAO in

Rome and as subsequently amended [FAO 1990; revised ICPM, 2001]

ISPM International Standard for Phytosanitary Measures [CEPM, 1996; revised

ICPM, 2001]

inspection Official visual examination of plants, plant products or other regulated articles

to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly inspect]

pest Any species, strain or biotype of plant, animal or pathogenic agent injurious to

plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]

pest risk assessment Evaluation of the probability of the introduction and spread of a pest and of the (for quarantine pests) associated potential economic consequences [FAO, 1995; revised ISPM No 11,

2001]

phytosanitary measure Any legislation, regulation or official procedure having the purpose to prevent (agreed interpretation) the introduction and/or spread of quarantine pests, or to limit the economic

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]

<sup>&</sup>lt;sup>1</sup> Term marked with (\*) is revised

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

PRA Pest Risk Analysis [FAO, 1995; revised ICPM, 2001]

regulated pest A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]

required response A specified level of effect for a treatment [ISPM No. 18, 2003]

surveillance An official process which collects and records data on pest occurrence or

absence by survey, monitoring or other procedures [CEPM, 1996]

systems approach(es) The integration of different pest risk management measures, at least two of

which act independently, and which cumulatively achieve the appropriate level

of phytosanitary protection [ISPM No. 14, 2002]

treatment Officially authorized procedure for the killing, inactivation or removal of pests,

or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO,

1995; ISPM No. 15, 2002; ISPM No. 18, 2003]

#### **OUTLINE OF REQUIREMENTS**

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

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

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

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

#### REQUIREMENTS

### 1. General Considerations

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

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

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

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

<sup>4 /</sup> Guidelines for the determination and recognition of equivalence of phytosanitary measures

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

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

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

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

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

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

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

#### 2. General Principles and Requirements

## 2.1 Sovereign authority

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

## 2.2 Other relevant principles of the IPPC

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

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

#### 2.3 Scientific justification for equivalence

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

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

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

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

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

## 2.5 Information exchange

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

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

## 2.6 Technical assistance

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

#### 2.7 Timeliness

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

## 3. Specific Requirements for the Application of Equivalence

## 3.1 Specific pests and commodities

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

# 3.2 Existing measures

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

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

#### 3.3 Entry into consultation

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

## 3.4 Agreed procedure

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

#### 3.5 Factors considered in determining equivalence

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

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

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

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

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

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

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

# 3.6 Non-disruption of trade

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

## 3.7 Provision of access

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

#### 3.8 Review and monitoring

After the recognition of equivalence, and to provide continued confidence in the equivalence arrangements,

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

# 3.9 Implementation and transparency

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

ANNEX 1

#### Recommendations for a procedure for the determination of equivalence

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

#### Recommended steps are:

- 1. The exporting contracting party communicates its interest in an equivalence determination to its trading partner, indicating the specified commodity, the regulated pest(s) of concern and the existing and proposed alternative measures, including relevant data. At the same time it may request from the importing contracting party the technical justification for the existing measures. In discussions on the determination of equivalence, an agreement including an outline of the steps involved, an agenda and a possible timetable may be established.
- 2. The importing contracting party should describe its existing measures in terms that will help to facilitate a comparison with alternative phytosanitary measures. To the best of its ability, the information provided by the importing contracting party should include the following:
- a) the purpose of the phytosanitary measures, including identification of the specific pest risk(s) that these measures are being used to mitigate
- b) to the extent possible, how the existing phytosanitary measures achieve the importing contracting party's appropriate level of protection
- c) the technical justification for the existing phytosanitary measures, including the PRA where appropriate
- d) any additional information that may assist the exporting contracting party in demonstrating that the proposed measures achieve the importing contracting party's appropriate level of protection.
- 3. The exporting contracting party provides the scientific information that it believes demonstrates equivalence of phytosanitary measures, and makes a request for equivalence. This information should be in a form suitable for comparison with the information provided by the importing contracting party and which therefore facilitates the necessary evaluation by the importing contracting party. This should include the following elements:
- a) the description of the proposed alternative measures
- b) the purpose of the measures
- c) to the extent possible, the contribution of the proposed alternative measures in achieving the importing contracting party's appropriate level of protection
- d) information on how the measures were evaluated (e.g. laboratory testing, statistical analysis, practical operational experience), and the performance of the measures in practice
- e) a comparison between the proposed alternative measures and the importing contracting party's existing measures for same pest risk
- f) information on technical and operational feasibility of the proposed alternative measures.
- 4. The importing contracting party receives and evaluates the proposed alternative phytosanitary measures, taking into account, but not being limited to the following:
- a) the submission from the exporting contracting party, including supporting information regarding the effectiveness of the proposed alternative measures
- b) the degree to which the alternative phytosanitary measures achieve the appropriate level of protection, either on the basis of qualitative or quantitative information
- c) information regarding the method, action and operation of the proposed alternative phytosanitary measures in preventing or reducing the specified pest risk
- d) the operational and economic feasibility of adopting the proposed alternative phytosanitary measures.

During the review process further clarification may be required. Additional information and/or access to operational procedures may be requested by the importing contracting party in order to complete the assessment. The exporting contracting party should respond to any technical concerns raised by the importing contracting party by providing relevant information and/or providing access to relevant information or sites to facilitate reviews, inspections or other verifications necessary for making an equivalence determination.

- 5. The importing contracting party should notify the exporting contracting party of its decision and provide, upon request, an explanation and scientific justification for its determination as quickly as possible.
- 6. In the event of a rejection of the request for equivalence, efforts should be made to resolve differences of opinion through bilateral dialogue.

- 7. If equivalence is recognized by the importing contracting party, implementation should be achieved by the prompt amendment of the import regulations and any associated procedures of the importing contracting party. The amendments should be communicated to contracting parties as soon as possible (Article VII.2b of the IPPC, 1997).
- 8. An audit and monitoring procedure may be established and included in the plan or arrangement which implements any recognized equivalence measures or programmes.

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

# 1. REVISED TERMS AND DEFINITIONS

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

## 2. NEW TERMS AND DEFINITIONS

2. The visit of the second			
habitat	Part of an ecosystem with conditions in which an organism naturally occurs or can establish		
pest risk assessment (for regulated non-quarantine pests)	Evaluation of the probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact		
pest risk management (for regulated non-quarantine pests)	Evaluation and selection of options to reduce the risk that a pest in plants for planting causes an economically unacceptable impact on the intended use of those plants		
phytosanitary import requirements	Specific phytosanitary measures established by an importing country concerning consignments moving into that country		
security (phytosanitary)	Maintenance of the integrity of a consignment by the appropriate phytosanitary measures		

# 3. DELETIONS

- Ecoarea
- Quarantine (of a biological control agent)

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