REPORT

Rome,
Italy,
13-17 November
2006

Standards Committee
November 2006

CONTENTS

1. OPENING OF THE MEETING

1. The Coordinator of the International Plant Protection Convention (IPPC) Secretariat welcomed the participants to the Standards Committee (SC) and opened the meeting.

2. The Chair noted that the SC members from Iran and Morocco were absent.

2. ADOPTION OF THE AGENDA

3. The provisional agenda was adopted as shown in Appendix 1 with one modification: to consider the draft ISPM *Establishment and maintenance of areas of low pest prevalence for fruit flies* first under agenda item 6.

4. Mr. Sakamura from Japan was elected as the rapporteur for the meeting

3. DOCUMENTS FOR SUBMISSION TO CPM-2 (MARCH 2007)

3.1 Terms of reference and Rules of procedure for Technical Panels

5. The development of Terms of reference (TORs) and Rules of procedure (ROPs) for technical panels (TPs) started in 2005 and continued over several meetings, including a review by the Informal Working Group on Strategic Planning and Technical Assistance (SPTA). The SC reviewed the TORs and ROPs, and approved them with some modifications.

6. One particular point of discussion was Rule 10 on languages. It was recognized that English was the working language of TPs, but it was noted that interpretation into other FAO languages by the country or organization hosting the meeting could be done whenever possible.

7. The SC discussed the oversight of TPs and concluded that, since the oversight of TPs had been given to the SC, the revised TORs and ROPs would be forwarded to the Commission on Phytosanitary Measures (CPM) for them to note.

8. *The SC approved the Terms of reference and Rules of procedure for technical panels as presented in Appendix 2. The CPM will be invited to note them.*

3.2 Annex 1 of the Rules of procedure of the CPM

9. CPM-1 (2006) had approved its ROPs and had decided that Annex 1 (*Outline of procedures for elaboration of ISPMs*) should be revised. The annex was updated taking into account existing procedures and ICPM/CPM decisions, and was reviewed by the SPTA. The SC modified the draft, which will be presented to CPM-2.

10. *The CPM will be invited to adopt the modified Annex 1 of the Rules of procedure of the CPM on standard setting as presented in Appendix 3.*

3.3 Procedures and criteria for identification of topics for the work programme

11. The SC considered the revision of the *Procedures and criteria for identifying topics for inclusion in the IPPC standard setting work programme*, and modified the draft.

12. A member noted that the environmental criteria should be extended to alternatives to plant protection products identified as being harmful for the environment and should not be limited to methyl bromide, especially now that the Technical panel on phytosanitary treatments (TPPT) would start developing specific treatments. The SC noted that this point had been added to cover methyl bromide, which was the only product currently mentioned in standards, and decided to leave the criteria on methyl bromide as presented.

13. *The CPM will be invited to adopt the revised procedure and criteria for identifying topics for inclusion in the IPPC standard setting work programme as presented in Appendix 4.*

3.4 Rule VII of the Rules of procedure of the CPM on observers

14. It was noted that changes made to the ROPs of the CPM at CPM-1 (2006) had excluded contracting parties from having the possibility to be observers at meetings of subsidiary bodies. This was not the intent

and could be rectified by adding a new point under Rule VII, which would allow contracting parties to attend subsidiary body meetings as observers.

15. *The CPM will be invited to adopt the revised Rule VII of the Rules of procedure of the CPM as presented in Appendix 5.*

3.5 Statement of commitment for participation in IPPC meetings

16. The SC reviewed the proposed statement of commitment. There was discussion on the usefulness of this statement. Although there were comments that this document would create more work for experts and not solve all the problems associated with nominees not attending or contributing to meetings, the SC generally thought that this document would be beneficial and in particular it would highlight expectations and help ensure that those expectations were communicated to supervisors of experts. The SC agreed that the CPM should be informed of the document.

17. Some concerns were raised in regards to travel assistance for those who need to attend multiple meetings in their role as steward. It was noted that ICPM-2 (1999) recommended that, whenever possible, members of the Standards Committee and those participating in standard setting activities voluntarily fund their travel and subsistence to attend meetings. These participants may request financial assistance from FAO for such activities, with the understanding that the priority for financial assistance is given to developing country participants.

18. *The CPM will be invited to agree to the concept of a written statement of commitment from nominees and to note the form as presented in Appendix 6.*

3.6 Declaration of interests for experts participating in IPPC meetings

19. The document was presented for information. The Director General (DG) of FAO has required that a declaration of interests form be submitted by all participants attending meetings organized by FAO (including meetings organized by the IPPC Secretariat). The FAO declaration of interests form had been amended by the IPPC Secretariat to be more useful for IPPC needs.

20. The SC noted the document and asked the IPPC Secretariat to clarify the use of the form and report back to the next SC meeting. Examples of the issues to be clarified include the scope (is it required for attendance at the CPM and subsidiary and other bodies, such as the SPTA, EWGs, TPs, etc.) and whether the form needed to be signed for every meeting, or only once with notification sent when previously declared interests change.

21. *The CPM will be invited to note the Declaration of interests for experts participating in IPPC meetings form as presented in Appendix 7.*

3.7 Adjustments to the IPPC standard setting work programme

22. The topics proposed by TPs for addition to the standard setting work programme were presented by the IPPC Secretariat.

23. The SC had a general discussion on addition to the work programme of topics for technical standards under the subject areas of each TP. It agreed that such additions did not need CPM adoption, as it was assumed that this permission had been given when each TP had been established by the CPM. The SC reiterated that TPs were under the direction of the SC and that it was appropriate for TPs to seek approval for addition of topics of technical standards to the work programme from the SC. Such topics added to the work programme will follow the existing standard setting procedures, including assignment of stewards and development of specifications prior to work commencing. It was assumed that these technical standards will be developed under the fast-track process, unless decided otherwise by the SC. For transparency, all new topics for technical standards under the subject area of each TP will be added to the standard setting work programme and presented to the CPM indicating that their addition was approved by the SC.

Technical panel on phytosanitary treatments (TPPT)

24. The SC agreed that two topics for treatments proposed by the TPPT had already been added to the work programme by the CPM, irradiation treatments through the revision of Annex 1 of ISPM No. 18

(*Guidelines for the use of irradiation as a phytosanitary measure*) and treatments associated with wood packaging material through the revision of ISPM No. 15 (*Guidelines for regulating wood packaging material in international trade*). It was noted that ISPM No. 15 treatments would involve both the TPPT and TPFQ, however the TPFQ is leading the work and is responsible for the further development of these treatments.

25. The TPPT will be meeting in December 2006 and as a result there may be some treatments presented via the fast-track process.

Technical panel on forest quarantine (TPFQ)

26. There was discussion on the topics proposed by the TPFQ for inclusion in its work programme. Some SC members felt that these topics could be considered as conceptual and have a broader impact than just forest quarantine. As a result of this discussion, the CPM will be invited to consider adding a topic on "Pest risks associated with transportation of goods by aircraft" to the work programme as a new conceptual standard with a high priority, to be worked on by an expert working group (EWG). In addition, the SC agreed with the TPFQ proposal to add the following three topics (priority indicated between brackets): International movement of wood (high); International movement of forest tree seeds (high); Forestry surveillance (normal).

27. With regard to "Forest surveillance", the SC noted that the TPFQ thought that guidance was lacking on surveillance for regulated forestry pests and the TP had proposed including guidance as a supplement to ISPM No. 6 (*Guidelines for surveillance*). It was thought that international practice would differ a lot, with the involvement of various bodies, and also that it might vary depending on the type of forest. The SC stressed that this topic should be directly linked to phytosanitary aspects of forest surveillance.

Technical panel on fruit flies (TPFF)

28. The SC agreed with the TPFF proposal to add the topic of "Determination of host susceptibility for fruit flies" with a high priority.

Technical panel on diagnostic protocols (TPDP)

29. The SC noted that it had already agreed at its May 2006 meeting with the TPDP proposal to add several topics for diagnostic protocols. In addition it agreed with the TPDP proposal to add the following two topics for diagnostic protocols (priority indicated between brackets): Identification of immature stages of fruit flies of economic importance by molecular techniques (high); *Sorghum halepense* (high).

30. *The CPM will be invited to note topics for technical standards under the subject area of each TP that have been approved by the SC and added to the IPPC standard setting work programme.*

4. UPDATE ON THE STANDARD SETTING WORK PROGRAMME

4.1 Decisions regarding TPs

31. Some TPs submitted decisions to the SC in relation to their work programme.

TPDP

32. The SC:

- agreed that diagnostic protocols be submitted through the fast-track process, reversing its earlier decision to send the first ones through the regular standard setting process. The first draft protocol (*Thrips palmi*) will be submitted to the Secretariat in December 2006.
- noted that the steward will cooperate with the Technical consultation of regional plant protection organizations (RPPOs) on activities related to reference laboratories, including liaising with the European and Mediterranean Plant Protection Organization (EPPO) regarding the development of a discussion paper on reference laboratories for the meeting of the Technical consultation of RPPOs in 2007.

TPFQ

33. The SC:

- noted a letter requesting NPPOs and RPPOs to participate in a survey of bark on ISPM No. 15-treated wood, which will be sent out on behalf of the TPFQ by the IPPC Secretariat. It is hoped to

have the results of the survey compiled prior to the next meeting of the TPFQ to provide information for the revision of ISPM No. 15.

34. In regards to ISPM No. 15 treatments, the SC urged the TPFQ to work closely with the TPPT and not to let administrative procedures delay the approval of new or revised treatments for ISPM No. 15, especially those treatments that reduce the use of methyl bromide.

Technical panel for the *Glossary* (TPG)

35. The SC:

- noted that the following points would be discussed at later agenda points: recommendations on definitions in draft standards (section 6.1), process for the review of ISPMs (section 9) and proposal on *regulated pests* (section 12.5).
- noted that some proposals for addition, deletion or modification of terms will be made as amendments to the *Glossary* in 2007
- noted that the annotated *Glossary* and paper on CBD terms will be developed further before the next meeting of the SC.

4.2 Adjustments regarding stewards

36. It was noted that some minor adjustments were needed to stewards. David Porritt, steward for the TPPT, will not be able to attend the next meeting of that panel, but it was decided to retain him as steward as it would be the only occasion he would not be able to attend the meeting. It was also noted that Abdellah Challaoui (Morocco) had been resigned from the SC and that as a consequence a replacement steward for the draft ISPM on *Post-entry quarantine facilities* was needed. Mazlan Saadon (Malaysia) was assigned the role of steward for this draft ISPM.

37. Regarding new topics under TPs, the SC allocated the following stewards:

- New topics for TPFQ: The steward of the TPFQ will act as steward for the following topics during the early stages of development: International movement of wood, International movement of forest tree seeds and Forest surveillance.
- New topic for TPFF: The steward of the TPFF will act as the steward for the following topic during the early stages of development: Determination of host susceptibility for fruit flies (Tephritidae).

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

38. Mr Holtzhausen (South Africa), who had been elected by the SC-7 as its chairperson, reported on the outcome of the meeting. He noted that the meeting had been attended by stewards for their respective drafts and their attendance was most useful. The SC-7 had reviewed and modified the amendments to the *Glossary* and four of the draft standards (Revision of ISPM No. 2*: Framework for pest risk analysis, Phytosanitary treatments for regulated pests, Recognition of pest free areas and areas of low pest prevalence and Debarked and bark-free wood*). It had started the review of the draft ISPM on *Establishment of areas of low pest prevalence for fruit flies* but had not completed it. The SC congratulated the SC-7 on the progress they had made on the drafts.

39. The Chair of the SC-7 noted that a substantial amount of editing had been undertaken on the draft ISPM on *Phytosanitary treatments for regulated pests*. The procedures to be used for submission and evaluation of treatments had been incorporated into the text. Large numbers of editorial changes had also been proposed for the draft ISPM on *Establishment of areas of low pest prevalence for fruit flies*, including an extensive restructuring of the text.

40. The SC was informed that there had been problems with the lack of indications of requirements for technical justification in certain parts of the draft ISPM on *Debarked and bark-free wood*. Due to this, the group was not clear whether the draft was suitable for submission to the CPM because technical elements included in the draft were not fully technically justified. However, work was carried out to correct this problem and the SC-7 suggested that the SC should consider whether this text should be a supplement to the *Glossary* or an independent standard.

6. DRAFT ISPMs FOR APPROVAL AND SUBMISSION TO CPM

6.1 Amendments to the ISPM No. 5 (*Glossary of phytosanitary terms)*

41. The steward of the TPG introduced the amended terms. *Phytosanitary integrity* had been amended to clarify that it relates to the composition of the consignment and additional wording added to specify that the composition was being maintained. Reference to "other officially acceptable documents" (e.g. invoices) was also included to widen the possibility of the use of the term. The SC agreed to the amended terms *phytosanitary integrity*, *phytosanitary security (of a consignment)* and *buffer zone*.

42. Some concern was raised regarding the fact that there was a new *Glossary* term for the physical status of a consignment and a term for the physical and phytosanitary status of a consignment but no term regarding the phytosanitary status only of a consignment.

43. The SC-7 had difficulty with the term *compliance procedure*. It sought guidance from the SC on whether this term should relate only to consignments, or whether it should be broadened. It had envisaged changes to the definition, and an alternative definition, and suggested that these should be sent back to the TPG for further consideration. Some SC members believed that it was useful to have a definition on *compliance procedure (for a consignment)*. The SC agreed that the definitions for *compliance procedure* and/or *compliance procedure (for a consignment)* should be sent back for further consideration by the TPG. The TPG should consider the use of the terms in adopted ISPMs and propose a solution.

44. The SC-7 agreed with the TPG proposal that the terms and definitions for *biological control* and *reference specimen* should be deleted from the *Glossary*. Regarding *biological control*, a definition including sterile insects was proposed at country consultation, but many comments opposed this change. When rediscussing the definition, the TPG had proposed that sterile insects would better be covered under the definition of *beneficial organism* (and a revised definition would be proposed at next country consultation). The definition of *biological control* was thought unnecessary, since it is well-known internationally, not used in a different sense in ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*), and that *biological control agent* is defined. Regarding *reference specimen*, a revised definition had been submitted for consultation because it was thought that a reference specimen for biological control would be a live specimen, i.e. different from reference specimens for other purposes. Since this did not seem to be the case, there was no need for a specific definition for a reference specimen for biological control agents, and reference specimen was considered a common term which did not need to be defined.

45. It was noted that the TPG would propose amendments to the definition of *beneficial organism* to cover biological control agents and sterile insects. This definition would be presented to the SC-7 at its next meeting as part of the amendments to the *Glossary*. It was noted that the current definition contained the wording "...directly or indirectly advantageous for plants...". This wording might have to be reconsidered since beneficial organisms covered biological control agents, and some of these might be used against plants that are considered invasive.

46. *The CPM will be invited to adopt the amendments to the Glossary as modified and presented in Appendix 8.*

6.2 Framework for pest risk analysis (Revision of ISPM No. 2)

47. As the steward was not present, the Chair of the SC-7 introduced the revised draft ISPM. The SC noted that there were differences in opinion as to the extent to which avoidance of undue delay should be detailed in ISPM No. 2. The SC noted that it was a general principle of the IPPC detailed in ISPM No. 1, and that it applied to all ISPMs. However, certain members of the SC considered that it was important to include specific reference in the text to countries providing information on the anticipated time frame for individual analyses (taking into account the avoidance of undue delay). Some members of the SC acknowledged that providing data schedules for completion of the PRA would be difficult, because this could imply a rigid procedure. The principle of avoidance of undue delay, however, should imply that countries conducting a PRA should indicate to trading partners the anticipated time frames for completion of analyses. The SC agreed to change the draft text to reflect these concerns. The SC recommended the draft for adoption by the CPM.

48. *The CPM will be invited to adopt the draft ISPM on Framework for pest risk analysis as modified and presented in Appendix 9.*

6.3 Phytosanitary treatments for regulated pests

49. As the steward was not present, the Chair of the SC-7 introduced the revised draft ISPM. The draft ISPM had been modified to include information on the purpose and use of treatments, and the process for their adoption. It clearly outlined the requirements that would be considered to evaluate the treatments. In addition, to allow the IPPC Secretariat to manage the submission form, the annex containing the form had been removed and the content of the form integrated into the text of the standard. The SC considered that the draft had been improved and provided clear information.

50. The issue of legal status and liability of treatments adopted in the annex of the standard was raised. It was felt that this was outside the jurisdiction of the SC.

51. The SC agreed that all new or revised treatments would be scrutinised according to this standard and annexed to it once adopted. The TPPT was encouraged to work with other TPs where appropriate.

52. There was a discussion on how to deal with treatments currently listed in ISPM No. 15, which is currently the only standard which contains adopted phytosanitary treatments. As an exception, it was agreed that ISPM No. 15 adopted treatments (current and future) would also be annexed to that standard. The SC recommended that the TPPT and the TPFQ continue to work together on the evaluation of new or revised ISPM No. 15 treatments. The evaluation of the efficacy of the treatment should be dealt with by the TPPT, whereas the TPFQ should help evaluate the feasibility and applicability of the treatment.

53. The SC clarified the text to reflect that the standard should not confer any obligations for NPPOs to use the adopted treatments. For example, NPPOs may develop bilateral arrangements based on the use of other treatments.

54. The SC discussed the procedures used to determine the priority for dealing with treatment evaluations if there is a large volume of submissions. The text was adjusted to refer to the criteria for prioritization of treatment submissions that was developed by the TPPT and which is included in the *Procedural manual*.

55. The SC recognized that there are circumstances where treatments are widely used but for which experimental data may not be available in the form specified in the draft ISPM. To address this, the SC added text which would allow the submission of treatments without experimental data where there is sufficient efficacy data available from operational application of the treatment. This meant that such treatments could also be evaluated.

56. The issue of confidentiality of certain information in treatment submissions was discussed. It was pointed out that although confidential information would need to be supplied and reviewed by the TPPT, there may also be a request from a contracting party to review this confidential information prior to adoption by the CPM. Text was added to indicate that refusal to release the confidential information in the above situation could affect the adoption of the treatment.

57. The SC added a reference to the Montreal Protocol and Rotterdam Convention in order to ensure that treatments adopted by the IPPC are not in conflict with other international agreements.

58. *The CPM will be invited to adopt the draft ISPM on Phytosanitary treatments for regulated pests as modified and presented in Appendix 10.*

6.4 Recognition of pest free areas and areas of low pest prevalence

59. The IPPC Secretariat gave a brief update of the status of the discussion by the SPS Committee at its recent meeting in October 2006 on the application of Article 6 (Pest and Disease Free Areas/Regionalisation) of the WTO SPS Agreement.

60. The steward then introduced the revised draft ISPM. The SC discussed the sovereignty of contracting parties. They noted that there are three areas in which a contracting party can exercise their sovereignty in relation to this subject. The first is that 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. The second is that contracting parties may establish domestically pest free areas (PFAs) or areas of low pest prevalence (ALPPs) in their own territory. Thirdly, an importing contracting party may recognize a PFA or ALPP in an exporting country's territory.

61. The SC noted that the flowchart was very helpful.

62. The SC made minor modifications to the text and recommended the draft for adoption.

63. *The CPM will be invited to adopt the draft ISPM on Recognition of pest free areas and areas of low pest prevalence as modified and presented in Appendix 11.*

6.5 Establishment of areas of low pest prevalence for fruit flies (Tephritidae)

64. The steward introduced the revised draft ISPM. The SC noted that the SC-7 had not been able to complete the review of this draft standard. It was also explained that most country comments had been incorporated. The draft standard had not undergone major modifications but had undergone a major reorganization. Some SC members felt that this major reorganization was a reason to submit the draft for another round of consultation.

65. An evening *ad hoc* working group was convened to complete the review of this draft standard and the resulting draft was presented to the SC for their consideration.

66. The SC considered changes that had been made to the draft standard as a result of the *ad hoc* working group meeting. Further issues were raised and considered. Several members of the SC pointed out that considerable changes to the structure and, in some cases, the content of the draft had been made. The SC noted that ICPM-6 (2004) had requested the SC to produce guidance concerning drafts which had been significantly modified and the criteria for returning drafts to expert drafting groups for further consideration and/or a further round of country consultation.

67. After discussion, the SC recommended that the draft be considered by the CPM but agreed that if the number of comments received on the draft prior to the CPM was too large to be considered during the meeting, then the draft would be withdrawn and sent to the TPFF for further consideration and another round of country consultation.

68. *The CPM will be invited to adopt the draft ISPM on Establishment of areas of low pest prevalence for fruit flies (Tephritidae) as modified and presented in Appendix 12.*

6.6 Debarked and bark-free wood

69. The steward introduced the revised draft ISPM. He pointed out that references to tolerances now related to industry standards rather than to scientific issues associated with assessing pest risks. He added that the guidance on setting tolerances had been removed as comments indicated that there was currently a lack of scientific evidence to support such tolerances. It was noted that the International Forest Quarantine Research Group (IFQRG) had considered the risks associated with bark at its meeting in October 2006 and had not felt that it could provide scientific support for proposing tolerances to reduce pest risks. The IFQRG would consider further data in 2007 and was hoping to make a recommendation at that time.

70. Some SC members expressed concerns about the value of the draft. The steward felt that the standard was needed as it would help define debarked wood and bark free wood for harmonized use. The SC felt that several problems with the draft had been resolved.

71. The SC discussed whether it was appropriate to recommend the document as a stand-alone standard or as a supplement to the *Glossary*. Some SC members also commented that the issue was linked with the revision of ISPM No. 15 and proposed that the draft should be sent for member consultation again along with

the revision of ISPM No. 15. After discussing this issue, the SC finally suggested that the draft be presented for adoption as a supplement to ISPM No. 5.

72. A question was raised on the term *debarking*, which would be replaced by the term *debarked wood*, and whether the deletion of *debarking* should also be proposed in the amendments to the *Glossary*. The SC was advised that a footnote on the term *debarked wood* could be included in the draft supplement indicating that the term *debarking* would be replaced with *debarked wood* in the *Glossary* after adoption of the draft supplement.

73. *The CPM will be invited to adopt, as a supplement to ISPM No. 5 (Glossary of phytosanitary terms), the text on Debarked and bark-free wood as modified and presented in Appendix 13.*

7. DRAFT SPECIFICATIONS FOR APPROVAL

74. The SC discussed the general content of specifications and noted some specifications were very detailed. The SC considered that there should be a balance with sufficient guidance for experts on tasks to be undertaken and flexibility so the experts can develop the concepts and tasks under consideration.

75. The IPPC Secretariat recommended that specifications should be simplified to remove some unnecessary parts that are repeated in all specifications, for example the sections *Provision of resources* and *Collaborator*. The SC noted that issues regarding funding of participation by experts were dependent on resources available to the IPPC Secretariat. The SC agreed with this but recommended that exceptions could be made to add these sections as appropriate, for example where a meeting is supported by an international organization or NPPO, or involvement is by a TP rather than an EWG.

76. The IPPC Secretariat emphasized the importance of the section on expertise as this is the main criteria used to select experts for expert drafting groups and precise guidance is appreciated.

77. The SC stressed that submission of discussion papers is encouraged from interested parties (such as contracting parties, NPPOs, RPPOs and international organizations) and from the participants in the expert drafting groups. The following statement will be added to all new specifications approved by the SC, following the section *References*: "*Participants and interested parties are encouraged to submit discussion papers to the IPPC Secretariat (ippc@fao.org) for consideration by the expert drafting group*."

7.1 Revision of ISPMs No. 7 and 12

78. The SC modified the draft, clarifying that the participants for the EWG should have expertise in export certification, knowledge of phytosanitary aspects of customs clearance of consignments and, preferably, knowledge of the IPPC work on electronic certification. In addition, it was felt that the EWG should focus on phytosanitary aspects and so references to provide guidance on legal aspects were removed.

79. *The SC approved the specification (no.38) as modified and presented in Appendix 14.*

7.2 Suppression and eradication procedures for fruit flies (Tephritidae)

80. The SC simplified the tasks in light of the considerations discussed under section 7 of this report.

81. *The SC approved the specification (no. 39) as modified and presented in Appendix 15.*

7.3 Development of Annex 1 (Specific approved treatments) of ISPM No. 18

82. The SC was reminded that this specification will be used by the TPPT at its meeting in December 2006. The SC modified the specification slightly to reflect that the irradiation treatments will be evaluated rather than developed, and that the evaluation of such treatments will use the procedure outlined in the draft ISPM on *Phytosanitary treatments for regulated pests*. The SC also changed the specification to reflect that all adopted irradiation treatments would be annexed to the treatment standard.

83. *The SC approved the specification (no. 40) as modified and presented in Appendix 16.*

7.4 Establishment of pest free places of production and pest free production sites for fruit flies (Tephritidae)

84. The tasks were modified slightly to require the TPFF to consider whether the standard should be an annex to another standard for fruit flies. The TPFF had discussed the issue of creating a single volume for the fruit fly standards once they are adopted; at that stage it will be possible to determine the best format for the document on fruit fly pest free places of production and production sites.

85. *The SC approved the specification (no. 41) as modified and presented in Appendix 17.*

7.5 Pre-clearance for regulated articles

86. The steward introduced the specification. There were differing views on this specification during country consultation. The term pre-clearance is defined in the *Glossary* and is used in ISPM No. 20 (*Guidelines for a phytosanitary import regulatory system*), so the SC recommended that one of the tasks of the EWG should be to clarify the use of the concept and term pre-clearance and consider the differences between pre-clearance and pre-inspection, if any, and, if necessary, propose a definition for pre-inspection and/or redefinition for pre-clearance.

87. Despite this, there were some concerns that pre-clearance is not in accordance with the IPPC. The SC requested the steward, in collaboration with the IPPC Secretariat, to develop a discussion paper for the FAO legal service to consider whether pre-clearance is in accordance with the IPPC. The discussion paper and the FAO legal opinion would be forwarded to the EWG for their consideration.

88. *The SC approved the specification (no. 42) as modified and presented in Appendix 18.*

89. The SC was not able to review the draft specifications on *Import of plant breeding material for scientific research and development purposes*, *Minimizing regulated pests in common stored products*, *Movement of soil and growing media in association with plants* and *Pest risk analysis for plants as quarantine pests*. These will be put on the agenda of the next SC meeting.

8. DRAFT SPECIFICATIONS FOR APPROVAL FOR COUNTRY CONSULTATION

90. The SC agreed to use e-mail to consider and, if appropriate, approve for member consultation the draft specifications for *Inspection manual* and *Movement of used equipment and machinery*

9. PROCEDURES FOR THE REVIEW OF ISPMs

91. The SC discussed the review of ISPMs. This included a review of adopted ISPMs which was proposed to be done by a consultant during 2007, depending on the availability of funding. It is envisaged that it would take three months to undertake the review, with a report produced for the TPG. The TPG would then report back to the SC for decisions. The SC agreed to the process for review and the TORs for the consultant.

92. The SC agreed that it would be preferable to also include draft ISPMs in this review, ideally after the SC-7 had incorporated country comments. It was noted that at the moment this was not possible because the SC-7 meeting is immediately followed by the SC. The SC agreed that under the current standard setting process, the review would take place during the regular TPG meeting, which is usually held before country comments are incorporated by the SC-7.

10. PROPOSALS TO IMPROVE THE STANDARD SETTING PROCESS

93. John Hedley (New Zealand) explained the document with proposals to improve the standard setting process. Some members of the SC were concerned about extending the time for the development of a draft ISPM, but the SC agreed that the main goal was to produce high quality drafts. The SC considered that the current system has some problems, in particular the short time scale for scrutiny of country comments by stewards. In addition, holding the SC-7 and SC meetings back to back does not allow the SC to reflect fully on changes made to the draft ISPMs by the SC-7 in the previous week.

94. The SC considered various options for improving the standard setting process. Most SC members stressed the importance of regional workshops. They present an opportunity for a large number of countries to go through a detailed scrutiny of draft ISPMs. They are also important for capacity building. Some SC

members recommended more regional workshops. One member proposed an international open-ended workshop at least one month prior to the CPM, where draft ISPMs would be discussed and which should minimise the discussion in CPM evening working groups.

95. The SC discussed the possibility of using two stewards for each draft ISPM. One member noted that the first steward should be an SC member and the second steward could be an expert in the topic of the draft ISPM, because of the increasingly technical nature of the topics under consideration.

96. The SC considered that the use of a professional editor had helped the development of draft ISPMs. However, an editor should not change the technical content of the drafts.

97. All SC members were fully supportive of the work of the SC-7. The SC noted that it would currently be virtually impossible to approve draft ISPMs without the work of the SC-7.

98. Most SC members were in favour of an extension of the standard setting process by one year. The most important change would be to separate the process of review of country comments by the SC-7 and the full consideration of the revised drafts by the SC.

99. The options of having two consultation periods for draft ISPMs and holding three meetings of the SC were also mentioned.

100. The SC asked the IPPC Secretariat, with John Hedley, to redraft the document based on the comments given and also on the comments from the report of the May 2006 meeting. The document should provide guidance on how the changes would be addressed by the CPM. This document would be discussed at the next SC meeting.

101. The Chair requested the SC members to ensure their respective CPM representatives were briefed on the issues regarding each draft ISPM and defend the SC's decisions in this regard.

11. IPPC PROCEDURAL MANUAL

102. The IPPC Secretariat updated the SC on the *Procedural manual*, which contains the decisions made by the CPM and SC, including procedures used in the standard setting process. All decisions made prior to and including the May 2006 SC meeting have been incorporated into the 2006 version of the manual. The IPPC Secretariat invited all SC members to propose, for consideration by the appropriate body, any updates or modifications they felt were needed.

12. DEFERRED DOCUMENTS

103. The SC made minor modifications to the *Guidelines on the duties of members of the SC* and *Guidelines on the role of a steward of an ISPM* and agreed to incorporate the documents into the *Procedural manual.*

104. *The SC approved the Guidelines on the duties of members of the SC (Appendix 19) and Guidelines on the role of a steward of an ISPM (Appendix 20) and noted that, where necessary, they can be modified using the SC's normal procedures.*

105. The SC noted the document *Consequence for standard setting of the Memorandum of Cooperation between the IPPC and CBD Secretariats* and felt this item no longer needed to be on the agenda. The SC also noted that ICPM-7 (2005) had made a major decision on this topic and, in addition, the *Procedure and criteria for identifying topics for inclusion in the IPPC standard setting work programme* now included environmental considerations.

106. The SC considered the document *Common procedures for technical panels,* which summarised the common tasks that applied to all the TPs and agreed with these points. The SC decided to include the document in the *Procedural manual*.

107. *The SC approved the document on common procedures for TPs (Appendix 21) and noted that, where necessary, it could be modified using the SC's normal procedures.*

108. The SC had no time to fully consider the discussion document on *Use of the term "regulated pests"* and decided to put it as one of the first points on the agenda for the next SC meeting.

13. OTHER BUSINESS

13.1 IPPC evaluation

109. The SC was invited by the IPPC evaluation team to an evening session. This session was attended by 12 members of the SC and took place concurrently with an evening session which was redrafting the draft ISPM on *Establishment of areas of low pest prevalence for fruit flies.* The evaluation team interviewed the SC asking questions about how the SC set priorities for topics for standards and the criteria they used, including how they took into account environmental issues. They asked the SC how they had used the fast-track process and if they anticipated any problems in its use. In addition they enquired on how the SC monitored the implementation of ISPMs.

14. DATE OF THE NEXT MEETING

110. The next meeting of the SC will be 5-9 November 2007.

111. It was noted that the SC-7 meeting from 30 April - 4 May 2007 will consider the following draft ISPMs:

- Alternative strategies to methyl bromide
- Appropriate level of protection
- Classification of commodities into phytosanitary risk categories
- Not widely distributed
- Sampling of consignments
- Systems approach for the pest risk management of fruit flies.

112. The draft ISPMs on *Export certification for potato minitubers and micropropagative material* and *Post-entry quarantine facilities* will not be considered at the May 2007 SC-7 meeting, but will be considered for member consultation the following year. This will allow stewards time to complete their redrafting.

15. ADOPTION OF THE REPORT

113. The SC adopted the report.

16. CLOSE

114. The Chair thanked the SC-7 for their work in preparing the draft ISPMs for the SC and congratulated the SC for their completion of the large amount of work on the agenda. He also thanked the FAO staff and the IPPC Secretariat staff for their work in preparing and conducting the meeting and in particular he thanked the interpreters and commented on how their efforts helped many SC members to express themselves more easily.

115. A member of the SC thanked the Chair for how he handled the diverse needs of the committee and helped keep them on track in order to accomplish their work and complete most of the agenda items.

Commission on Phytosanitary Measures

Standards Committee

13 - 17 November 2006
FAO Headquarters, Rome, Italy

AGENDA

AGENDA ITEM	DOCUMENT
1. Opening of the meeting	--
2. Adoption of the agenda • Report of the SC May 2006	2006-SC-Nov-01-Rev2 2006-SC-Nov-04
3. Documents for submission to CPM-2 (March 2007)	--
3.1 Terms of reference and rules of procedure for technical panels (approved by SPTA 2005, deferred since SC Nov 2005, modified by Secretariat and TP stewards)	2006-SC-Nov-17
3.2 Annex 1 of Rules of procedure of CPM and consolidation of standard setting procedures (approved by SPTA 2006)	2006-SC-Nov-26-Rev1
3.2.1 Procedures and criteria for identifying topics for inclusion in the IPPC standard setting work programme	2006-SC-Nov-25
3.3 Rule VII of CPM Rules of procedure: Observers to subsidiary bodies (approved by SPTA 2006)	2006-SC-Nov-21
3.4 Statement of commitment for participation in IPPC meetings (deferred since SC May 2006, approved by SPTA 2006)	2006-SC-Nov-23
3.5 Declaration of interests for experts (approved by SPTA 2006)	2006-SC-Nov-19
3.6 Adjustments to standard setting work programme	2006-SC-Nov-14
4. Standard setting work programme update	--
4.1 Update: IPPC standard setting work programme • Update on explanatory documents	2006-SC-Nov-15
4.2 Adjustments regarding stewards	2006-SC-Nov-15
5. Report of the SC-7	--
6. Draft ISPMs for review of country comments and redrafting	--
6.1 Amendments to the *Glossary* • Country comments	2006-SC-Nov-29
6.2 Revision of ISPM No. 2 (*Pest risk analysis*) • Country comments	2006-SC-Nov-30
6.3 Phytosanitary treatments for regulated pests • Country comments	2006-SC-Nov-31
6.4 Recognition of pest free areas and areas of low pest prevalence • Country comments	2006-SC-Nov-32
6.5 Establishment and maintenance of areas of low pest prevalence for fruit flies • Country comments	2006-SC-Nov-33
6.6 Debarked and bark-free wood • Country comments	2006-SC-Nov-34
7. Draft specifications for review of country comments and approval	--
7.1 Revision of ISPMs No. 7 and 12 in relation to transit and re-export	2006-SC-Nov-05
7.2 Suppression and eradication procedures for fruit flies (*Tephritidae*)	2006-SC-Nov-06
7.3 Annex 1, Specific approved treatments, ISPM No. 18	2006-SC-Nov-07

AGENDA ITEM	DOCUMENT
7.4 Establishment of pest free places of production and pest free production sites for fruit flies (Tephritidae)	2006-SC-Nov-08
7.5 Pre-inspection and pre-clearance for regulated articles intended for import	2006-SC-Nov-09
7.6 Importation of plant breeding material for scientific research and development purposes	2006-SC-Nov-10
7.7 Regulating stored products in international trade	2006-SC-Nov-11
7.8 Movement of soil and growing media in association with plants in international trade	2006-SC-Nov-12
7.9 Pest risk analysis for plants as quarantine pests	2006-SC-Nov-13
8. Draft specifications for approval for country consultation	--
8.1 Inspection manual	2006-SC-Nov-20
8.2 Movement of used equipment and machinery	2006-SC-Nov-37
9. Process for the review of ISPMs	2006-SC-Nov-22
10. Proposal to improve the standard setting process	2006-SC-Nov-35 2006-SC-Nov-38
11. IPPC procedural manual	--
12. Deferred documents	--
12.1 Guidelines on the duties of members of the SC (Deferred since SC April 2005)	2006-SC-Nov-28
12.2 Guidelines on the role of a steward of an ISPM (Deferred since SC April 2005)	2006-SC-Nov-24
12.3 Consequence for standard setting of the Memorandum of Cooperation between the IPPC and CBD Secretariats (Deferred since SC April 2005)	2006-SC-Nov-27
12.4 Technical panel joint procedures (Deferred since SC May 2006)	2006-SC-Nov-18
12.5 Discussion paper on the term *regulated* (Deferred since SC May 2006)	2006-SC-Nov-16
13. Other business	--
14. Adoption of the report	--
15. Date and venue of the next meeting	2006-SC-Nov-36
16. Close	--

TERMS OF REFERENCE AND RULES OF PROCEDURE FOR TECHNICAL PANELS

Terms of reference

1. Establishment of Technical Panels

Technical Panels (TPs) are standing committees established by the CPM and operating under the guidance of the Standards Committee (SC). TPs adhere to the IPPC procedure *Guidelines for the composition and organization of expert working groups*.

2. Scope of Technical Panels

TPs assist the SC in the development of International Standards for Phytosanitary Measures (ISPMs) in their specified subject areas.

3. Objective

The main objective of TPs is to oversee the development of standards, annexes, supplements, amendments or additions to standards in their specific subject areas, as well as advising the SC on scientific or technical matters.

4. Structure of Technical Panels

TPs should consist of 6-10 members representing a wide geographic area (including proportional developing country participation). In specific cases and depending on the subject area a TP may consist of more or less members according to the SC's decision.

5. Functions of Technical Panels

TPs operate under the guidance of the SC and serve as a forum for providing:

- draft standards, annexes, supplements, amendments or additions to standards in their specified subject areas and should, preferably submit such documents to the SC under the fast track procedure
- advice on country comments in their field of activity
- advice on topics and priorities for technical standard development in their field of activity, and
- other tasks as requested by the SC.

6. IPPC Secretariat

The Secretariat provides administrative, technical and editorial support as required by TPs. The Secretariat is responsible for reporting and record keeping.

7. Disestablishment of Technical Panels

When a TP has completed the specific work assigned to it, the SC should disestablish it.

Rules of procedure

Rule 1. Membership

Members of Technical Panels (TPs) should have the necessary scientific expertise and subject matter experience and should be able to participate and contribute to the proceedings. The steward is considered a full member of the TP.

Membership of TPs should be reviewed by the SC on a regular basis and may be adjusted as necessary, taking into account, in particular, changes in the needs of scientific or other expertise required and in the professional duties of the experts.

Rule 2. Procedure for Nomination and Selection of Technical Panel Members

Members of TPs are nominated and selected according to the *Guidelines for the composition and organization of expert working groups* and a list of TP members is published on the International Phytosanitary Portal (IPP).

Rule 3. Period of Membership

Members of TPs may serve for an undefined period. The SC may, in accordance with Rule 2 of the Rules of procedure, change or amend the membership of TPs.

Rule 4. Chair
The Chairpersons of TPs are elected at each meeting by their members.

Rule 5. Steward
Each TP should have a steward selected by the SC, and where possible, the steward should be a member of the SC. The steward is responsible for liaison between the SC and the TP, ensuring the TP follows the guidance given by the SC.

Rule 6. Other Participation by Stewards
Where a TP is drafting a standard, annex or supplement, the steward for this document should also participate in the meeting.

Rule 7. Sessions
TPs normally meet at least once a year. E-mail, teleconferencing and other modern communication methods should be used where possible to prepare and supplement face to face meetings of TPs.

TP members should work according to the general procedures for TPs developed by the SC and, where appropriate, according to their own working procedures which are included in the IPPC Procedural Manual.

Rule 8. Host and Rapporteur
A host and/or rapporteur from the country or organization hosting the meeting may participate in the meeting.

Rule 9. Approval
Approvals relating to draft documents and agreement on advice provided to the SC should be sought by consensus and communicated to the SC by the steward.

Rule 10. Observers
TPs should not allow observers. In specific cases, the Secretariat may however invite individuals with specific expertise, but the invited expert should not participate as a member.

Rule 11. Reports
Summary reports of TP meetings should be published on the IPP.

A report on the activities of a TP should be made to the SC by the steward of the TP advising the SC of the specific actions that they are requested to take.

Rule 12. Working Language
English will be the working language of TP meetings.

Rule 13. Amendments
Amendments to the Rules of procedures and the Terms of reference, if required, should be approved by the SC and noted by the CPM.

PROPOSED MODIFICATIONS TO ANNEX I OF THE CPM RULES OF PROCEDURE

ANNEX 1: IPPC STANDARD SETTING PROCEDURE

The process for the development of International Standards for Phytosanitary Measures (ISPMs) is divided into four stages:
- developing the IPPC standard setting work programme,
- drafting,
- member consultation,
- adoption and publication.

Detailed procedures and relevant ICPM/CPM decisions on many aspects of the standard setting process can be found in the IPPC Procedural Manual which is updated annually.

The process for the development of international standards is conducted under general considerations regarding:
- transparency (as part of Appendix VII of ICPM-2 (1999) and Appendix IX of ICPM-6 (2004))
- financial considerations (as part of Appendix VII of ICPM-2 (1999) and Appendix XI of ICPM-4 (2002))
- role of RPPOs (as part of Appendix VII of ICPM-2 (1999) and Appendix XIX of ICPM-7 (2005)).

Stage 1: Developing the IPPC standard setting work programme

Step 1: Call for topics
A call for topics is made by the IPPC Secretariat every two years. Detailed proposals for new topics or for the revision of existing ISPMs are submitted to the IPPC Secretariat.

Step 2: Adjustment and adoption of the IPPC standard setting work programme
The CPM adjusts and adopts the IPPC standard setting work programme, taking account of the strategic priorities identified by the Informal Working Group on Strategic Planning and Technical Assistance and the revised work programme proposed by the Standards Committee.

Stage 2: Drafting

Step 3: Development of a specification
For each topic or technical panel, the Standards Committee appoints a steward, who, in collaboration with the Secretariat, drafts a specification.

The draft specification is reviewed by the Standards Committee and then made available on the International Phytosanitary Portal (IPP) for a 60 day consultation period. Comments received by the IPPC Secretariat are compiled and submitted to the steward and Standards Committee for consideration. The specification is amended as necessary, approved by the Standards Committee and published on the IPP.

Step 4: Preparation of a draft standard
The standard is drafted or revised by an expert drafting group (expert working group or technical panel) in accordance with the relevant specification.

Regular process:	**Fast-track process:**
The resulting draft standard is submitted to the Standards Committee or Standards Committee working group at a meeting for review.	The resulting draft standard is submitted to the Standards Committee at any time by e-mail.
The Standards Committee decides whether to send it for member consultation, or to return it to the steward or to an expert drafting group, or to put it on hold.	The Standards Committee decides by e-mail whether to send it for member consultation, or to return it to the steward or to an expert drafting group, or to put it on hold, or to place it on the Standards Committee agenda for discussion.

Stage 3: Member consultation

Step 5: Member consultation

The draft standard is sent by the IPPC Secretariat to national plant protection organizations (NPPOs), regional plant protection organizations (RPPOs) and international organizations for consultation. The length of the consultation period is 100 days.

Regular process:	**Fast-track process:**
The draft is sent for member consultation following approval at the Standards Committee or Standards Committee working group meeting. Comment is by written submission to the Secretariat following guidelines. Comments are compiled by the Secretariat and submitted to the steward, the Standards Committee working group and the Standards Committee for consideration.	The draft is sent for member consultation following clearance by the Standards Committee, i.e. at any time, in appropriate FAO languages.

Comments are posted on the IPP.

Step 6: Review of the draft ISPM prior to CPM

Regular process:	**Fast-track process:**
The draft standard is revised by the Standards Committee and/or Standards Committee working group taking comments into account. The Standards Committee decides whether to forward the modified draft to the CPM for adoption, or to put it on hold, or to return it to the steward or to an expert drafting group, or submit it for another round of member consultation.	If no formal objections[1] are received, the draft standard is submitted to the CPM for adoption without discussion. If one or more formal objections are received, the Secretariat tries to resolve the issue(s) with the country(ies) concerned. If these issues are resolved without change to the draft text, the draft standard is submitted to the CPM for adoption without discussion. If these issues are not resolved, the draft is submitted to the Standards Committee and/or Standards Committee working group. The Standards Committee and/or Standards Committee working group examines the comments and modifies the draft standard if needed in consultation with the relevant technical panel. The Standards Committee decides whether to forward the modified draft to the CPM for adoption or to return it to the technical panel.

If members have concerns regarding their comments, they may contact Standards Committee members in their region to obtain a specific response to their comment.

[1] A formal objection should be a technically supported objection to the adoption of the draft standard in its current form, sent through the official contact point (IPPC contact point or if not available, FAO contact point). The Secretariat would not make any judgement about the validity of the objection – an objection with some technical discussion of the issue would be accepted as a formal objection.

Stage 4: Adoption and publication

Step 7: Adoption

Regular process:	**Fast track process:**
The draft standard is included on the agenda of the CPM for discussion and adoption. Comments on standards at CPM are sent at least 14 days before the meeting.	The draft standard is included on the agenda of the CPM: - for adoption without discussion if no formal objection were received, or if objections were resolved by the Secretariat with countries. - for discussion and adoption if objections were discussed by the Standards Committee.

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

The principle of adoption in CPM without discussion is approved, with the understanding that this principle would not limit the right of countries to make comments or intervene with comments.

Step 8: Publication

The ISPM is appended to the report of the CPM and published by the IPPC Secretariat, including on the IPP.

PROCEDURE AND CRITERIA FOR IDENTIFYING TOPICS FOR INCLUSION IN THE IPPC STANDARD SETTING WORK PROGRAMME

In establishing the topics for standards to be included in the IPPC standard setting work programme, the following procedure should be used:

1. The IPPC Secretariat calls for submissions for topics to be included in the standard setting work programme. A call is made every two years. It is sent to contracting parties, NPPOs, RPPOs and the WTO-SPS Committee, and is also posted on the International Phytosanitary Portal (IPP, www.ippc.int). Other organizations (such as the Convention on Biological Diversity), CPM subsidiary bodies and expert drafting groups can submit topics through the Secretariat in response to the call.

2. Detailed proposals for new topics or for the revision of existing ISPMs are submitted to the Secretariat (IPPC@fao.org) no later than the 31 July of the year the call for topics is made, using the submission form for CPM work programme topics available on the IPP. Submissions should identify the applicable criteria for justification of the proposed topic (Annex 1), and provide justification data where possible. Submissions should preferably be made in an electronic format.

3. A list of topics is compiled by the Secretariat from the submissions received. Submissions from previous years are not included in this compilation but may be re-submitted, as appropriate.

4. The compiled list of detailed proposals is presented to the Informal Working Group on Strategic Planning and Technical Assistance (SPTA). The SPTA reviews these submissions and identifies strategic priorities using the criteria for justification of proposed topics (Annex 1). Priority is given to submissions from contracting parties, CPM subsidiary bodies and expert drafting groups.

5. The Standards Committee, taking into account the SPTA strategic priorities and the criteria in Annex 1, reviews the current work programme and the compiled list of detailed proposals. It develops a revised work programme, adding, deleting or modifying topics as appropriate, giving each topic a recommended priority (high or normal), and deciding on topics that could be processed under the fast-track standard setting process within the framework of the subject areas specified by CPM.

6. The CPM reviews the work programme recommended by the Standards Committee. When a situation arises in which a standard is required urgently, the CPM inserts it into the standard setting work programme.

7. The CPM adjusts and adopts the standard setting work programme, including for each topic its priority. A revised standard setting work programme is attached as an appendix to the CPM meeting report.

Annex 1

Criteria for justification of proposed topics

Technical

1. Extent of evidence in support that the proposed standard is needed (scientific, historical and/or practical information/experience).
2. Credibility of evidence in support that the standard is needed (e.g. one or more NPPOs or RPPOs have requested it or one or more RPPOs have adopted a similar standard).

Practicality

3. Feasibility of adopting the standard within a reasonable time schedule.
4. Feasibility of implementing the standard at a global level (includes ease of implementation, technical complexity).
5. Stage of development of the standard (is it already widely used by NPPOs, RPPOs or an appropriate international organization).
6. Availability of expertise needed to develop the proposed international standard.
7. Ability of NPPOs to implement the standard.

Benefit/cost

8. Estimated value of trade affected by proposed standard given statistically in volume of trade and/or in value of trade, in addition the percentage of Gross Domestic Product of this trade should be indicated by the submitter if appropriate.
9. Estimated value of new trade opportunities provided by the approval of the proposed standard.

Environmental

10. Utility as a replacement to existing uses of methyl bromide as a phytosanitary measure or reduction in methyl bromide use as a result of the adoption of the proposed standard.
11. Utility in the management of invasive alien species.

Strategic

12. Frequency with which the issue addressed by the proposed standard emerges as a repeated source of trade disruption (e.g. disputes or need for repeated bilateral discussions, number of times per year trade is disrupted).
13. Relevance and utility to developing countries.
14. Coverage (application to a wide range of countries/pests/commodities).
15. Complements other standards (for example potential for the standard to be used as part of a systems approach for one pest or to complement treatments for other pests).
16. Foundation standards to address fundamental concepts (e.g. treatment efficacy or inspection methodology).
17. Expected standard longevity (i.e. future trade needs, chemicals likely to be banned or withdrawn would be low priority).
18. Emergency need for the standard.

CHANGE TO RULE VII OF THE RULES OF PROCEDURE OF THE CPM ON OBSERVERS TO SUBSIDIARY BODIES

1) Participation of observers to the Commission on Phytosanitary Measures (CPM) and its subsidiary bodies is covered under Rule VII of the Rules of procedures of the CPM (adopted at CPM-1) and this CPM rule is referenced to in Rule 7 of the Rules of procedure for the Standards Committee.

2) Rule VII of the CPM was updated from the Rules of procedure of the Interim Commission on Phytosanitary Measures to mention non-contracting parties. As written, the rule would in theory allow observers to attend subsidiary bodies from non-contracting parties but not from contracting parties. This was not the intention and may be easily corrected by adding a new point 1 to Rule VII of the Rules of procedure of the CPM as follows:

RULE VII
OBSERVERS

1. Any country that is a contracting party may attend subsidiary body meetings as an observer, upon request to the Secretary of the IPPC.

~~1~~2. Any country that is not a contracting party but is a Member of the Organization, as well as the United Nations, any of its specialized agencies and the International Atomic Energy Agency, may, upon request communicated to the Director-General, attend sessions of the Commission, and its subsidiary bodies, as an observer. Any such observer may submit memoranda and participate in discussions without a vote. Any country that is not a contracting party and is not a Member of the Organization, but is a Member of the United Nations, any of its specialized agencies or the International Atomic Energy Agency, may, upon request and subject to the provisions relating to the granting of the Observer Status in respect of Nations as provided for by the Basic Texts of the Organization, be invited to attend, in an observer capacity, sessions of the Commission or of its subsidiary bodies. The status of such Nations shall be governed by the relevant provisions of the Basic Texts of the Organization.

~~2~~3. Representatives of Regional Plant Protection Organizations shall be invited to attend all sessions of the Commission and its subsidiary bodies as observers. Any such observers may submit memoranda and participate in discussions without a vote.

~~3~~4. Subject to the provisions of paragraph ~~4~~ 5 of this Rule, the Director-General, taking into account guidance given by the Commission, may invite international (intergovernmental and non-governmental) organizations to attend sessions of the Commission in an observer capacity.

~~4~~5. Participation of international organizations in the work of the Commission and the relations between the Commission and such organizations shall be governed by the relevant provisions of the Constitution and other pertinent Basic Texts of the Organization. All such relations shall be dealt with by the Director-General, taking into account guidance given by the Commission

INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC)

STATEMENT OF COMMITMENT

Each nominee is requested to read the information listed and referenced in Appendix 1 for the relevant body and complete and sign this statement of commitment.

1. IPPC body (Standards Committee, Subsidiary Body on Dispute Settlement, Technical Panel, Expert Working Group, IPP Support Group, etc.): Expected meeting date and location, if relevant:

2. Nominee: I have read the information listed and referenced in Appendix 1 in regards to my nomination and if selected agree to undertake the tasks and responsibilities involved and commit the time required. I have also discussed the time commitment and financial resources[1] (as appropriate) with my employer to carry out my duties if my nomination is approved for the body indicated under section 1 above. _____ _____ Signature Date	
Contact details for nominee:	
Name: (LAST NAME in upper case, given names)	
E-mail:	
Phone:	
Fax:	
Mailing address:	

[1] As recommended by the second session of the Interim Commission on Phytosanitary Measures (1999), whenever possible, those participating in IPPC activities voluntarily fund their travel and subsistence to attend meetings. Participants may request financial assistance, with the understanding that resources are limited and the priority for financial assistance is given to developing country participants.

APPENDIX 1

General duties relevant to all bodies:
- allocate time, as appropriate, for travel to the meeting, attendance in the meeting and follow-up activities, as necessary
- consult and liaise with relevant national and international experts, as appropriate
- read all meeting documents prior to the meeting and provide discussion papers and/or comments, if necessary
- maintain a functioning e-mail address and join in e-mail discussions or conference calls falling outside of the meeting dates and times, if necessary
- participate as an individual expert in a personal capacity
- participate in relevant meetings for the duration of the term
- if unable to attend the meeting provide written notification to the IPPC Secretariat well in advance and before travel arrangements have been made
- other specific details may be found in the IPPC Procedural Manual (www.ippc.int/id/159891?language=en).

Standards Committee (SC) member duties, in addition to the above general duties:
- attend one to three SC meetings annually at FAO headquarters
- act as a steward for expert drafting group meetings held in various international locations
- participate in relevant regional workshops for reviewing draft ISPMs
- participate for the entirety of the 3 year term, as appropriate
- other duties as assigned.

Further details are provided in the following documents, found in the IPPC Procedural Manual:
- Terms of reference and Rules of procedure for the SC
- Guidelines on the duties of SC members
- Guidelines on the role and responsibilities of a steward of an ISPM.

Subsidiary Body on Dispute Settlement (SBDS) member duties, in addition to the above general duties:
- attend one annual meeting
- other duties as assigned.

Further details are provided in the following documents, found in the IPPC Procedural Manual:
- Terms of reference and Rules of procedure for the SBDS.

Technical panel member duties, in addition to the above general duties:
- attend at least one annual meeting
- long term commitment, no specified term
- other duties as assigned.

Further details are provided in the IPPC Procedural Manual:
- Terms of reference and Rules of procedure for TPs
- Guidelines for the composition and organization of expert working groups
- Guidelines for the operation of expert working groups.

Expert working group member duties, in addition to the above general duties:
- attend at least one week-long meeting.
- other duties as assigned.

Further details are provided in the IPPC Procedural Manual:
- Guidelines for the composition and organization of expert working groups
- Guidelines for the operation of expert working groups.

Diagnostic protocol editorial team member duties, in addition to the above general duties:
- on going e-mail consultation and liaison with lead author or discipline lead.

Further details are provided in ISPM No. 27 (*Diagnostic protocols for regulated pests*) and the IPPC Procedural Manual:
- Instructions to authors of diagnostic protocols.

IPP Support Group duties, in addition to the above general duties:
- attend at least one annual meeting
- e-mail consultation occasionally sought.

INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC)

DECLARATION OF INTERESTS FOR EXPERTS WITHIN THE FRAMEWORK OF THE IPPC

<Name of subsidiary body, expert working group, technical panel or support group>

<Date and location of meeting>

Each participant in the above-mentioned meeting must sign this form as evidence of his/her interests in relation to the meeting.

Public health considerations and protection of the environment are of primary importance in all Food and Agriculture Organization (FAO) and International Plant Protection Convention (IPPC) technical work. Measures need to be taken to ensure that the best possible assessment of scientific evidence is achieved in an independent atmosphere free of either direct or indirect pressures. Thus, to assure the technical integrity and impartiality of the work within the framework of the IPPC, it is necessary to avoid situations in which financial or other interests might affect the outcome of that work.

Each expert is therefore asked to declare any interests that could constitute a real, potential or apparent conflict of interest, with respect to his/her involvement in the meeting or work, between (1) commercial entities and the participant personally, and (2) commercial entities and the administrative unit with which the participant has an employment relationship. "Commercial entity" refers to any company, association (e.g., trade association), organization or any other entity of any nature whatsoever, with commercial interests.

What is a conflict of interest?

Conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom s/he has a similar close personal relationship), or immediate family (essentially the children, brothers, sisters or parents), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject-matter being considered. An **apparent conflict of interest** exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A **potential conflict of interest** exists with an interest which any reasonable person could be uncertain as to whether or not it should be reported.

Acting as a representative of a national government does not constitute a conflict of interest.

Different types of financial or other interests, whether personal or with the administrative unit with which the expert has an employment relationship, can be envisaged and the following list, which is not exhaustive, is provided for guidance. For example, the following types of situations should be declared:

1. A current proprietary interest in a substance, technology or process (e.g. ownership of a patent), to be considered in - or otherwise related to the subject matter of - the meeting or work
2. A current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject-matter of the meeting or work (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares)
3. An employment, consultancy, directorship, or other position during the past 4 years, whether or not paid, in any commercial entity which has an interest in the subject-matter of the meeting/work, or an ongoing negotiation concerning prospective employment or other association with such commercial entity
4. Performance of any paid work or research during the past 4 years commissioned by a commercial entity with interests in the subject-matter of the meetings or work
5. Payment or other support covering a period within the past 4 years, or an expectation of support for the future, from a commercial entity with an interest in the subject-matter of the meetings or work, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g. a grant or fellowship or other payment, e.g. for the purpose of financing a post or consultancy.

With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.

How to complete this declaration

This Declaration must be completed and submitted to the IPPC Secretariat at least 21 days before the start of the meeting. Any financial or other interests that could constitute a real, potential or apparent conflict of interest should be declared (1) with respect to yourself or partner, as well as (2) with respect to the administrative unit with which you have an employment relationship. Only the name of the commercial entity and the nature of the interest are required to be disclosed, no amounts need to be specified (though they may be, if you consider this information to be relevant to assessing the interest). With respect to items 1 and 2 in the list above, the interest should only be declared if it is current. With respect to items 3, 4 and 5, any interest during the past 4 years should be declared. If the interest is no longer current, please state the year when it ceased. With respect to item 5, the interest ceases when a financed post or fellowship is no longer occupied, or when support for an activity ceases.

Assessment and outcome

The information submitted will be used to assess whether the declared interests constitute an appreciable real, potential or apparent conflict of interest. Such conflict of interest will, depending on the situation, result in (i) you being asked not to take part in the portion of the discussion or work affecting that interest, (ii) being asked not to take part in the meeting or work altogether, or (iii) if deemed by the IPPC Secretariat to be appropriate to the particular circumstances, and with your agreement, you taking part in the meeting or work and your interest being publicly disclosed.

Information disclosed on this Form may be made available to persons outside of the IPPC only when the objectivity of the meeting or work has been questioned such that the Director-General of FAO considers disclosure to be in the best interests of the Organization, and then only after consultation with you.

Declaration

Have you or your partner any financial or other interest in the subject-matter of the meeting or work in which you will be involved, which may be considered as constituting a real, potential or apparent conflict of interest?

Yes: [__] **No:** [__] If yes, please give details in the box below.

Type of interest, e.g. patent, shares, employment, association, payment (including details on any compound work, etc.)	Name of commercial entity	Ownership Belongs to you, partner, immediate family or unit or someone else	Current interest? (or year ceased)

Is there anything else that could affect your objectivity or independence in the meeting or work, or the perception by others of your objectivity and independence?

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform the IPPC Secretariat of any change in these circumstances, including if an issue arises during the course of the meeting or work itself.

Signature	Date
Name	Institution

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

1. NEW TERMS AND DEFINITIONS

phytosanitary security (of a consignment)	Maintenance of the integrity of a consignment and prevention of its infestation and contamination, by the application of appropriate phytosanitary measures
integrity (of a consignment)	Composition of a consignment as described by its Phytosanitary Certificate or other officially acceptable document, maintained without loss, addition or substitution

2. REVISED TERMS AND DEFINITIONS

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

3. PROPOSED DELETIONS FROM ISPM No. 5

- biological control
- reference specimen(s)

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 2

FRAMEWORK FOR PEST RISK ANALYSIS

(200-)

CONTENTS

INTRODUCTION

SCOPE

This standard provides a framework that describes the pest risk analysis (PRA) process within the scope of the IPPC. It introduces the three stages of pest risk analysis – initiation, pest risk assessment and pest risk management. The standard focuses on the initiation stage. Generic issues of information gathering, documentation, risk communication, uncertainty and consistency are addressed.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
Glossary supplement No. 2: *Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations* (in *Glossary of phytosanitary terms*, 2006). ISPM No. 5, FAO, Rome.
Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms, 2005. ISPM No. 3, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.
Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006. ISPM No. 1, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

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

Revised terms and definitions

pest risk analysis (agreed interpretation)	The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it
pest risk assessment (for quarantine pests)	Evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences (see Glossary Supplement No. 2)

New terms and definition

pest risk (for quarantine pests)	The probability of introduction and spread of a pest and the magnitude of the associated potential economic consequences (see Glossary Supplement No. 2)
pest risk (for regulated non-quarantine pests)	The probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact (see Glossary Supplement No. 2)

OUTLINE OF REQUIREMENTS

Pest risk analysis (PRA) provides a basis for determining appropriate phytosanitary measures. The PRA process may be used for organisms not previously recognized as pests (such as plants, biological control agents or other beneficial organisms, living modified organisms), recognized pests, pathways and review of phytosanitary policy. The process consists of three stages: 1: Initiation; 2: Pest risk assessment; and 3: Pest risk management.

This standard provides detailed guidance on PRA Stage 1, summarizes PRA Stages 2 and 3, and addresses issues generic to the entire PRA process. For Stages 2 and 3 it refers to ISPM No. 3, No. 11 and No. 21 dealing with the PRA process.

The PRA process is initiated in Stage 1 with the identification of an organism or pathway that may be considered for pest risk assessment, or as part of the review of existing phytosanitary measures, in relation to a defined PRA area. The

first step is to determine or confirm whether or not the organism considered is a pest. If no pests are identified, the analysis need not continue. The analysis of pests identified in Stage 1 continues to Stages 2 and 3 using guidance provided in other standards. Information gathering, documentation and risk communication, as well as uncertainty and consistency, are issues common to all PRA stages.

BACKGROUND

Pest risk analysis (PRA) is a science- and economics-based process that provides the rationale for phytosanitary measures for a specified PRA area. It evaluates scientific evidence to determine whether an organism is a pest. If so, the analysis evaluates the probability of introduction and spread of the pest and the magnitude of potential economic consequences in a defined area, using scientific, technical and economic evidence. If the risk is deemed unacceptable, the analysis may continue by suggesting management options that can reduce the risk to an acceptable level. Subsequently, pest risk management options may be used to establish phytosanitary regulations.

For some organisms, it is known beforehand that they are pests, but for others, the question of whether or not they are pests should initially be resolved[1].

The pest risks posed by the introduction of organisms associated with a particular pathway, such as a commodity, should also be considered in a PRA. The commodity itself may not pose a pest risk but may harbour organisms that are pests. Lists of such organisms are compiled during the initiation stage. Specific organisms may then be analysed individually, or in groups where individual species share common biological characteristics.

Less commonly, the commodity itself may pose a pest risk. When deliberately introduced and established in intended habitats in new areas, organisms imported as commodities (such as plants for planting, biological control agents and other beneficial organisms, and living modified organisms (LMOs)) may pose a risk of accidentally spreading to unintended habitats causing injury to plants or plant products. Such risks may also be analysed using the PRA process.

The PRA process is applied to pests of cultivated plants and wild flora, in accordance with the scope of the IPPC. It does not cover the analysis of risks beyond the scope of the IPPC.

The PRA structure

The PRA process consists of three stages:

- Stage 1: Initiation
- Stage 2: Pest risk assessment
- Stage 3: Pest risk management.

Information gathering, documentation and risk communication are carried out throughout the PRA process. PRA is not necessarily a linear process because, in conducting the entire analysis, it may be necessary to go back and forth between various stages.

Revision of this standard

This revision of ISPM No. 2 particularly addresses the issues of:

- aligning the text with the 1997 revision of the IPPC
- aligning the text with further conceptual developments of the PRA scope and procedures as appearing in ISPM No. 3, No. 11 and No. 21
- including regulated non-quarantine pests (RNQPs) in the description of the PRA process
- including organisms not known beforehand to be pests in the description of the PRA process
- including aspects common to all PRA stages in the description of the PRA.

Thus, this standard provides detailed guidance on PRA Stage 1 and issues generic to all PRA stages, and refers to other ISPMs (identified in Table 1) as appropriate for further analysis through PRA Stages 2 and 3. These standards are conceptual and are not detailed operational or methodological guides for assessors. An overview of the full PRA process is illustrated in Appendix 1.

Provisions of the IPPC regarding pest risk analysis

The International Plant Protection Convention (IPPC, 1997, Article VII.2a) requires that: "*Contracting parties shall not ... take any of the measures specified in paragraph 1 of this Article* [i.e. phytosanitary measures] *unless such measures are made necessary by phytosanitary considerations and are technically justified*."

[1] The IPPC defines a pest as "*any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products*". The understanding of pests includes organisms that are pests because they directly affect uncultivated/unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms (see Annex 1 of ISPM No. 11, 2004).

Article VI.1b requires that phytosanitary measures are: "*limited to what is necessary to protect plant health and/or safeguard the intended use and can be technically justified by the contracting party concerned.*"

"Technically justified" is defined in Article II.1 as: "*justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information.*"

Article IV.2f states that the responsibilities of the National Plant Protection Organization (NPPO) include "*the conduct of pest risk analyses*". The issuing of regulations is a responsibility of the contracting party to the IPPC (Article IV.3c), although contracting parties may delegate this responsibility to the NPPO.

In conducting a PRA, the obligations established in the IPPC should be taken into account. Those of particular relevance to the PRA process include:
- cooperation in the provision of information
- minimal impact
- non-discrimination
- harmonization
- transparency
- avoidance of undue delay.

REQUIREMENTS

1. PRA Stage 1: Initiation

Initiation is the identification of organisms and pathways that may be considered for pest risk assessment in relation to the identified PRA area.

A PRA process may be triggered in the following situations (initiation points, section 1.1):
- a request is made to consider a pathway that may require phytosanitary measures
- a pest is identified that may justify phytosanitary measures
- a decision is made to review or revise phytosanitary measures or policies
- a request is made to determine whether an organism is a pest.

The initiation stage involves four steps:
- determination whether an organism is a pest (section 1.2)
- defining the PRA area (section 1.3)
- evaluating any previous PRA (section 1.4)
- conclusion (section 1.5).

When the PRA process has been triggered by a request to consider a pathway, the above steps are preceded by assembling a list of organisms of possible regulatory concern because they are likely to be associated with a pathway.

At this stage, information is necessary to identify the organism and its potential economic impact, which includes environmental impact[2]. Other useful information on the organism may include its geographical distribution, host plants, habitats and association with commodities (or, for RNQP candidates, association with plants for planting). For pathways, information about the commodity, including modes of transport, and its intended end use, is essential.

1.1 Initiation points

1.1.1 Identification of a pathway

The need for a new or revised PRA for a specific pathway may arise in situations such as when
- import is proposed of a commodity not previously imported or a commodity from a new area of origin
- there is an intention to import for selection and/or scientific research a plant species or cultivar not yet introduced that could potentially be a host of pests
- a pathway other than commodity import is identified (natural spread, packing material, mail, garbage, compost, passenger baggage, etc.)
- a change in susceptibility of a plant to a pest is identified
- a change in virulence/aggressiveness or host range of a pest.

These are situations where the commodity itself is not a pest. When the commodity itself may be a pest, it should also be considered under section 1.1.4.

[2] Further information on this aspect is provided in Supplement no. 2 (*Guidelines on the interpretation and application of* potential economic importance *and related terms including reference to environmental considerations*) to ISPM No. 5 (*Glossary of phytosanitary terms*).

A list of organisms likely to be associated with the pathway should be assembled, including organisms that have not yet been clearly identified as pests. When a PRA is carried out for a commodity for which trade already exists, records of actual pest interceptions should be used for the listing of associated pests.

1.1.2 Identification of a pest

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

- an infestation or an outbreak of a new pest is discovered
- a new pest is identified by scientific research
- a pest is reported to be more injurious than previously known
- an organism is identified as a vector for other recognized pests
- there is a change in the status or incidence of a pest in the PRA area
- a new pest is intercepted on an imported commodity
- a pest is repeatedly intercepted at import
- a pest is proposed to be imported for research or other purpose.

In these situations, the fact that the organism is known to be a pest can be recorded in preparation for PRA Stage 2.

1.1.3 Review of phytosanitary policies

The need for a new or revised PRA may arise from situations such as when

- a national review of phytosanitary regulations, requirements or operations is undertaken
- an official control programme (e.g. certification scheme) is developed to avoid unacceptable economic impact of specified RNQPs in plants for planting
- an evaluation of a regulatory proposal of another country or international organization is undertaken
- a new system, process or procedure is introduced or new information made available that could influence a previous decision (e.g. results of monitoring; a new treatment or withdrawal of a treatment; new diagnostic methods)
- an international dispute on phytosanitary measures arises
- the phytosanitary situation in a country changes or political boundaries change.

In these situations, pests will already have been identified and this fact should be recorded in preparation for PRA Stage 2.

For existing trade, no new measures should be applied until the revision or new PRA has been completed, unless this is warranted by new or unexpected phytosanitary situations which may necessitate emergency measures.

1.1.4 Identification of an organism not previously known to be a pest

An organism may be considered for PRA in situations such as when

- a proposal is made to import a new plant species or variety for cropping, amenity or environmental purposes
- a proposal is made to import or release a biological control agent or other beneficial organism
- an organism is found which is new to science or for which there is little information available
- a proposal is made to import an organism for research, analysis or other purpose
- a proposal is made to import or release an LMO.

In these situations it would be necessary to determine if the organism is a pest and thus subject to PRA Stage 2. Section 1.2 provides further guidance in this matter.

1.2 Determination of an organism as a pest

Pre-selection or screening are terms sometimes used to cover the early step of determining whether an organism is a pest or not.

The taxonomic identity of the organism should be specified because any biological and other information used should be relevant to the organism in question. If the organism has not yet been fully named or described, then, to be determined as a pest, it should at least have been shown to be identifiable, consistently to produce injury to plants or plant products (e.g. symptoms, reduced growth rate, yield loss or any other damage) and to be transmissible or able to disperse.

The taxonomic level for organisms considered in PRA is usually the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In cases where levels below the species level are being analysed, the rationale for this distinction should include evidence of reported significant variation in factors such as virulence, pesticide resistance, environmental adaptability, host range or its role as a vector.

Predictive indicators of an organism are characteristics that, if found, would suggest the organism may be a pest. The information on the organism should be checked against such indicators, and if none are found, it may be concluded that the organism is not a pest, and the analysis may be ended by recording the basis of that decision.

The following are examples of indicators to consider:
- previous history of successful establishment in new areas
- phytopathogenic characteristics
- phytophagous characteristics
- presence detected in connection with observations of injury to plants, beneficial organisms, etc. without any clear causal link
- belonging to taxa (family or genus) commonly containing known pests
- capability of acting as a vector for known pests
- adverse effects on non-target organisms beneficial to plants (such as pollinators or predators of plant pests).

Particular cases for analysis include plant species, biological control agents and other beneficial organisms, organisms new to science, intentional import of organisms and LMOs. The pest potential of LM-plants should be determined as outlined in section 1.2.4.

1.2.1 Plants as pests

Plants have deliberately been spread among countries and continents for millennia, and new species or varieties of plants for cropping, amenity or environmental purposes are continually imported. Some plant species or cultivars transferred to regions beyond their natural range may escape from where they were initially released and invade unintended habitats such as arable land, natural or semi-natural habitats to become pests.

Plants as pests may also be introduced unintentionally into a country, for example as contaminants of seeds for sowing, grain for consumption or fodder, wool, soil, machinery, equipment, vehicles, containers or ballast water.

Plants as pests may affect other plants by competing for water, light, minerals, etc. or through direct parasitism and thus suppressing or eliminating other plants. Imported plants may also affect, by hybridization, plant populations under cultivation or in the wild flora, and may become pests for that reason. Further information is provided in the supplementary text on environmental risks in ISPM No. 11 (2004).

The primary indicator that a plant species may become a pest in the PRA area is the existence of reports of such harm having occurred elsewhere. Some intrinsic attributes that may indicate that a plant species could be a pest include:
- adaptability to a wide range of ecological conditions
- strong competitiveness in plant stands
- high rate of propagation
- ability to build up a persistent soil-seed bank
- high mobility of propagules
- allelopathy
- parasitic capacity
- capacity to hybridize.

It should be noted that long time lags have often been observed between the introduction of a new plant species and evidence that the plant is a pest.

1.2.2 Biological control agents and other beneficial organisms

Biological control agents and other beneficial organisms are intended to be beneficial to plants without causing injury, except in the case where the biological control agent is used against weeds. Thus, when performing a PRA, the main concern is to look for potential injury to non-target organisms[3]. Other concerns may include:
- contamination of cultures of beneficial organisms with other species, the culture thereby acting as a pathway for pests
- reliability of containment facilities when such are required.

1.2.3 Organisms new to science or for which only minimal information is available

In imported consignments or during surveillance, organisms may be detected that are difficult to identify (e.g. damaged specimen or unidentifiable life stages) or are new to science. Although in such cases the information available may be very limited, a decision may need to be made as to whether phytosanitary action is justified. When organisms have been detected that are difficult to identify, recommendations for phytosanitary measures may have to be made based on

[3] ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, 2005) recommends that NPPOs should conduct a PRA either before import or before release of biological control agents and other beneficial organisms.

incomplete identification. The PRA allows a decision to be taken based on all available information. It also enables information gaps to be identified and recommendations for further studies to be specified.

It is recommended that specimens are deposited in an accessible reference collection for future further examination.

1.2.4 Living modified organisms

LMOs are organisms that possess a novel combination of genetic material, obtained through the use of modern biotechnology and are designed to express one or more new or altered traits in order to improve certain properties of the organism. Types of LMOs for which a PRA may be conducted include:

- plants for use in agriculture, horticulture or silviculture, bioremediation of soil, for industrial purposes, or as therapeutic agents (e.g. LMO plants with an enhanced vitamin profile)
- biological control agents and other beneficial organisms modified to improve their performance
- pests modified to alter their pathogenic characteristics.

The modification may result in an organism with a new trait that may now present a pest risk beyond that posed by the non-modified recipient or donor organisms, or similar organisms. Risks may include:

- increased potential for establishment and spread
- those resulting from inserted gene sequences that may act independently of the organism with subsequent unintended consequences
- potential to act as a vector for the entering of a genetic sequence into domesticated or wild relatives of that organism, resulting in an increase in the pest risk of that related organism
- in cases of a modified plant species, the potential to act as a vector for the entering of an injurious genetic sequence into relatives of that species.

PRA is usually concerned with phenotypic rather than genotypic characteristics. However, genotypic characteristics should also be considered when assessing the pest risks of LMOs.

Predictive indicators more specific to LMOs include intrinsic attributes such as:

- phenotypic similarities or genetic relationships to known pest species
- introduced changes in adaptive characteristics that may increase the potential for introduction or spread
- phenotypic and genotypic instability.

For LMOs, identification requires information regarding the taxonomic status of the recipient and the donor organism, and description of the vector, the nature of the genetic modification, and the genetic sequence and its insertion site in the recipient genome.

Further potential risks of LMOs are outlined in Annex 3 to ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004). A PRA may be carried out to determine whether the LMO is a pest, and subsequently assess the pest risk. If, subsequent to the initiation stage, it is deemed unnecessary to conduct a pest risk assessment, the basis of the decision should be recorded if appropriate.

1.2.5 Intentional import of other organisms

In cases where a request is made to import an organism that may be a pest for scientific research, educational, industrial or other purposes, the identity of the organism should be clearly defined. Information on the organism or closely related organisms may be assessed to identify indicators that it may be a pest. For organisms determined to be pests, the pest risk assessment may be carried out.

1.3 Defining the PRA area

The area to which the PRA refers has to be clearly defined. It may be the whole or part of a country or several countries. Whereas information may be gathered from a wider geographical area, the analysis of establishment, spread and economic impact should relate only to the defined PRA area.

In PRA Stage 2, the *endangered* area is identified. In PRA Stage 3, the *regulated* area may, however, be designated as wider than the endangered area if technically justified and not in conflict with the principle of non-discrimination.

1.4 Previous pest risk analyses

Before performing a new PRA, a check should be made to determine if the organism, pest or pathway has ever been subjected to a previous PRA. The validity of any existing analysis should be verified because circumstances and information may have changed. Its relevance to the PRA area should be confirmed.

The possibility of using a PRA of a similar organism, pest or pathway may also be investigated, particularly when information on the specific organism is absent or incomplete. Information assembled for other purposes, such as

environmental impact assessments of the same or a closely related organism, may be useful but cannot substitute for a PRA.

1.5 Conclusion of initiation

At the end of PRA Stage 1, pests and pathways of concern will have been identified and the PRA area defined. Relevant information will have been collected and pests identified as candidates for further assessment, either individually or in association with a pathway.

Organisms determined not to be pests and pathways not carrying pests need not be further assessed. The decision and rationale should be recorded and communicated, as appropriate.

Where an organism has been determined to be a pest the process may continue to PRA Stage 2. Where a list of pests has been identified for a pathway, pests may be assessed as groups, where biologically similar, or separately.

Where the PRA is specifically aimed at determining if the pest should be regulated as a quarantine pest, the process may proceed immediately to the pest categorization step of pest risk assessment (PRA Stage 2) of ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms,* 2004). That ISPM is relevant for organisms that appear to meet the following criteria:

- not present in the PRA area or, if present, of limited distribution and subject to official control
- having the potential to cause injury to plants or plant products in the PRA area
- having the potential to establish and spread in the PRA area.

Where the PRA is specifically aimed at determining if the pest should be regulated as an RNQP, the process may proceed immediately to the pest categorization step of pest risk assessment (PRA Stage 2) of ISPM No. 21 (*Pest risk analysis for regulated non-quarantine pests*). That ISPM is relevant for organisms that appear to meet the following criteria:

- present in the PRA area and subject to official control (or being considered for official control)
- plants for planting are the main pathway for the pest in the PRA area
- having the potential to affect the intended use of plants for planting with an economically unacceptable impact in the PRA area.

2. Summary of PRA Stages 2 and 3

2.1 Linked standards

The PRA process for different pest categories is described in separate ISPMs, as summarized in Table 1. As circumstances change and techniques evolve, new standards will be developed and others revised.

Table 1: Standards linked to ISPM No. 2

ISPM	Title	Coverage of PRA
ISPM No. 11 (2004)	*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*	Specific guidance on PRA of quarantine pests including: - Stage 1: Initiation[4] - Stage 2: Pest risk assessment including environmental risks and LMO assessment - Stage 3: Pest risk management
ISPM No. 21	*Pest risk analysis for regulated non-quarantine pests*	Specific guidance on PRA of regulated non-quarantine pests including: - Stage 1: Initiation[4] - Stage 2: Pest risk assessment especially of plants for planting as the main source of infestation and economic impact on their intended use - Stage 3: Pest risk management
ISPM No. 3 (2005)	*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*	Specific guidance on pest risk management for biological control agents and beneficial organisms[5]

2.2 Summary of PRA Stage 2: Pest risk assessment

[4] The present ISPMs No. 11 (2004) and No. 21, adopted before this revision of ISPM No. 2, include some guidance on PRA Stage 1 for quarantine pests and RNQPs, respectively.

[5] ISPM No. 3 provides more detailed guidance appropriate to PRA Stage 1, for example with respect to the provision of necessary information, documentation and communication to relevant parties.

Stage 2 involves several steps:

- pest categorization: the determination of whether the pest has the characteristics of a quarantine pest or RNQP, respectively
- assessment of introduction and spread
  - candidates for quarantine pests: the identification of the endangered area and assessment of the probability of introduction and spread
  - candidates for RNQPs: assessment of whether the plants for planting are or will be the main source of pest infestation, in comparison to other sources of infestation of the area
- assessment of economic impacts
  - candidates for quarantine pests: assessment of economic impacts, including environmental impacts
  - candidates for RNQPs: assessment of potential economic impacts associated with the intended use of plants for planting in the PRA area (including analysis of infestation threshold and tolerance level)
- conclusion, summarizing the overall pest risk on the basis of assessment results regarding introduction, spread and potential economic impacts for quarantine pests, or economically unacceptable impacts for regulated non-quarantine pests.

The outputs from pest risk assessment are used to decide if the pest risk management stage (Stage 3) is required.

2.3 Summary of PRA Stage 3: Pest risk management

Stage 3 involves the identification of phytosanitary measures that (alone or in combination) reduce the risk to an acceptable level.

Phytosanitary measures are not justified if the pest risk is considered acceptable or if they are not feasible (e.g. as may be the case with natural spread). However, even in such cases contracting parties may decide to maintain a monitoring programme regarding the pest risk to ensure that future changes in that risk are identified.

The conclusion of the pest risk management stage will be whether or not appropriate phytosanitary measures adequate to reduce the pest risk to an acceptable level are available, cost-effective and feasible.

In addition to standards for PRA (Table 1), other standards provide specific technical guidance to pest risk management options.

3. Aspects Common to All PRA Stages

3.1 Uncertainty

Uncertainty is an integral component of risk and therefore important to recognize and document when performing PRAs. Sources of uncertainty with a particular PRA may include: missing, incomplete, inconsistent or conflicting data; sampling from natural variability; subjective judgement; and sampling randomness. Diseases of uncertain aetiology and asymptomatic carriers of pests may pose particular challenges.

The nature and degree of uncertainty in the analysis should be documented and communicated, and the use of expert judgement indicated. If adding or strengthening of phytosanitary measures are recommended to compensate for uncertainty, this should be recorded. Documentation of uncertainty contributes to transparency and may also be used for identifying research needs or priorities.

As uncertainty is an inherent part of PRA, it is appropriate to monitor the phytosanitary situation resulting from the regulation based on any particular PRA and to re-evaluate previous decisions.

3.2 Information gathering

Throughout the process, information should be gathered and analysed as required to reach recommendations and conclusions. As the analysis progresses, information gaps may be identified necessitating further enquiries or research. Where information is insufficient or inconclusive, expert judgement may be used if appropriate. Scientific publications as well as technical information such as data from surveys and interceptions may be relevant.

Cooperation in the provision of information and responding to requests for information made via the official contact point are IPPC obligations (Articles VIII.1c and VIII.2). When requesting information from other contracting parties, requests should be as specific as possible and limited to information essential to the analysis. Other agencies may be approached for information appropriate to the analysis.

3.3 Documentation

The principle of transparency requires that contracting parties should, on request, make available the technical justification for phytosanitary requirements. Thus, the PRA should be sufficiently documented. Documenting PRA has two levels:

- documenting the general PRA process

- documenting each analysis made.

3.3.1 Documenting the general PRA process

The NPPO should preferably document procedures and criteria of its general PRA process.

3.3.2 Documenting each specific PRA

For each particular analysis, the entire process from initiation to pest risk management should be sufficiently documented so that the sources of information and rationale for management decisions can be clearly demonstrated. However, a PRA does not necessarily need to be long and complex. A short and concise PRA may be sufficient provided justifiable conclusions can be reached after completing only a limited number of steps in the PRA process.

The main elements to be documented are:
- purpose of the PRA
- PRA area
- biological attributes of the organism and evidence of ability to cause injury
- for quarantine pests: pest, pathways, endangered area
- for RNQPs: pest, host, plants and/or parts or class of plants under consideration, sources of infestation, intended use of the plants
- sources of information
- nature and degree of uncertainty and measures envisaged to compensate for uncertainty
- for pathway-initiated analysis: commodity description and categorized pest list
- evidence of economic impact, which includes environmental impact
- conclusions of pest risk assessment (probabilities and consequences)
- decisions and justifications to stop the PRA process
- pest risk management: phytosanitary measures identified, evaluated and recommended
- date of completion and the NPPO responsible for the analysis, including if appropriate names of authors, contributors and reviewers.

Other aspects to be documented may include[6]:
- particular need for monitoring the efficacy of proposed phytosanitary measures
- hazards identified outside the scope of the IPPC and to be communicated to other authorities.

3.4 Risk communication

Risk communication is generally recognized as an interactive process allowing exchange of information between the NPPO and stakeholders. It is not simply a one-way movement of information or about making stakeholders understand the risk situation, but is meant to reconcile the views of scientists, stakeholders, politicians etc. in order to:
- achieve a common understanding of the pest risks
- develop credible pest risk management options
- develop credible and consistent regulations and policies to deal with pest risks
- promote awareness of the phytosanitary issues under consideration.

At the end of the PRA, evidence supporting the PRA, the proposed mitigations and uncertainties should preferably be communicated to stakeholders and other interested parties, including other contracting parties, RPPOs and NPPOs, as appropriate.

NPPOs are encouraged to communicate evidence of risks other than pest risks (such as to animals or human health) to the appropriate authorities.

3.5 Consistency in PRA

It is recommended that an NPPO strives for consistency in its conduct of PRAs. Consistency offers numerous benefits, including:
- facilitation of the principles of non-discrimination and transparency
- improved familiarity with the PRA process
- increased efficiency in completing PRAs and managing related data
- improved comparability between PRAs conducted on similar products or pests, which in turn aids in development and implementation of similar or equivalent management measures.

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

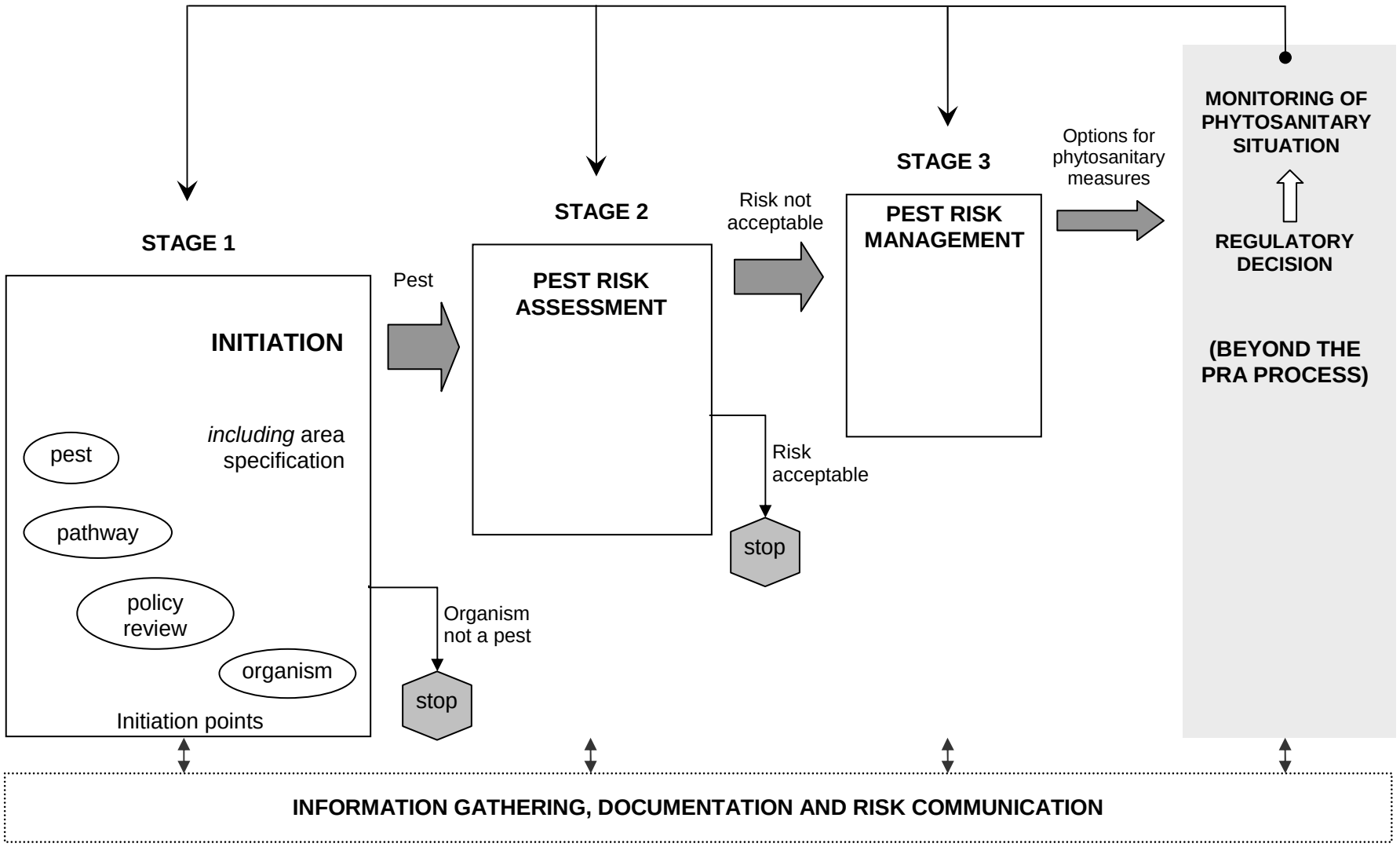
[6] ISPM No. 3 (Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms, 2005) lists additional documentation requirements in relation to such organisms.

3.6 Avoidance of undue delay

In cases where other contracting parties are directly affected the NPPO should, on request, supply information about the anticipated time frame for completion of individual analyses, taking into account avoidance of undue delay (section 2.14 of ISPM No. 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006).

APPENDIX 1

PEST RISK ANALYSIS FLOW CHART[1]



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

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

PHYTOSANITARY TREATMENTS FOR REGULATED PESTS

(200-)

CONTENTS

INTRODUCTION

SCOPE

This standard presents in Annex 1 phytosanitary treatments evaluated and adopted by the CPM. It also describes the requirements for submission and evaluation of the efficacy data and other relevant information on a phytosanitary treatment that can be used as a phytosanitary measure and that will be included in Annex 1 after its adoption.

The treatments are for the control of regulated pests on regulated articles, primarily those moving in international trade. The adopted treatments provide the minimum requirements necessary to control a regulated pest at a stated efficacy.

The scope of this standard does not include issues related to pesticide registration or other domestic requirements for approval of treatments (e.g. irradiation)[1].

REFERENCES

*Glossary of phytosanitary term*s, 2006. ISPM No. 5, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

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

New term and definition:

treatment schedule	The critical parameters of a treatment which need to be met to achieve the intended outcome (i.e. the killing, inactivation or removal of pests, or rendering pests infertile, or devitalization) at a stated efficacy.

OUTLINE OF REQUIREMENTS

Harmonized phytosanitary treatments support efficient phytosanitary measures in a wide range of circumstances and enhance the mutual recognition of treatment efficacy. Annex 1 to this standard contains those phytosanitary treatments which have been adopted by the CPM.

National Plant Protection Organizations (NPPOs) and Regional Plant Protection Organizations (RPPOs) may submit data and other information for the evaluation of efficacy, feasibility and applicability of treatments. The information should include a detailed description of the treatment, including efficacy data, the name of a contact person, and the reason for the submission. Treatments that are eligible for evaluation include mechanical, chemical, irradiation, physical and controlled atmosphere treatments. The efficacy data should be clear and should preferably include data on the treatment under laboratory or controlled conditions as well as under operational conditions. Information on feasibility and applicability of the proposed treatment(s) should include items on cost, commercial relevance, level of expertise required to apply the treatment and versatility.

Submissions with complete information will be considered by the Technical Panel on Phytosanitary Treatments (TPPT), and if the treatment is deemed acceptable, it will be recommended to the CPM for adoption.

BACKGROUND

The purpose of the IPPC is "*to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control*" (Article I.1 of the IPPC, 1997). The requirement or application of phytosanitary treatments to commodities and regulated articles is a phytosanitary measure used by contracting parties to prevent the introduction and spread of regulated pests.

Article VII.1 of the IPPC 1997 states:
"*contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:*

a) *prescribe and adopt phytosanitary measures concerning the importation of plants, plant products and other regulated articles, including, for example, inspection, prohibition on importation, and treatment*".

[1] The inclusion of a phytosanitary treatment in this ISPM does not create any obligation for a contracting party to approve the treatment or register or adopt it for use in its territory.

Phytosanitary measures required by a contracting party shall be technically justified (Article VII.2a of the IPPC, 1997).

For many years, NPPOs have utilized phytosanitary treatments to prevent the introduction and spread of regulated pests. Many of these treatments are supported by extensive research data, and others are used based on historical evidence supporting their efficacy. In practice, many countries use the same treatments or similar treatments for specified pests; however, mutual recognition is often a complex and difficult process. Furthermore, there has previously been neither an internationally recognized organization or process to evaluate treatments for their efficacy nor a central repository for listing such treatments. The Interim Commission on Phytosanitary Measures, at its sixth session in 2004, recognized the need for international recognition of phytosanitary treatments of major importance and approved the formation of the TPPT for that purpose.

REQUIREMENTS

1. Purpose and Use

The purpose of harmonizing phytosanitary treatments is to support efficient phytosanitary measures in a wide range of circumstances and to enhance the mutual recognition of treatment efficacy by NPPOs, which may also facilitate trade. Furthermore, these treatment schedules should aid the development of expertise and technical cooperation, and they may also be relevant to the accreditation and/or approval of treatment facilities.

Adopted phytosanitary treatments provide a means for the killing, inactivation or removal of pests, for rendering pests infertile or for devitalization, at a stated efficacy, and are relevant primarily to international trade. The level of efficacy, specificity and applicability of each treatment is indicated where possible. NPPOs may use these criteria to select the treatment or combination of treatments that are appropriate for the relevant circumstances.

When requiring phytosanitary treatments for imports, contracting parties should take into account the following points:

- Phytosanitary measures required by a contracting party shall be technically justified.
- Phytosanitary treatments contained in Annex 1 of this standard have the status of an ISPM and therefore should be considered accordingly.
- NPPOs are not obliged to use these treatments and may use other phytosanitary treatments for treating the same regulated pests or regulated articles.
- Regulatory regimes of exporting contracting parties may prevent certain treatments from being approved for use within their territories. Therefore efforts should be made to accept equivalent treatments where possible.

2. Process for Treatment Development and Adoption

The development process is initiated by a call for topics for standards (including topics for treatments) according to the "IPPC standard setting procedure" and the "Procedure and criteria for identifying topics for inclusion in the IPPC standard setting work programme" (provided in the *International Plant Protection Convention procedural manual*).

In particular, the following points apply to treatments:

- Once a topic for treatments (e.g. treatments for fruit flies or for pests on wood) has been added to the IPPC standard-setting work programme, the IPPC Secretariat, under direction of the Standards Committee (with recommendations from the TPPT), will call for the submissions and data on treatments on that topic.
- NPPOs or RPPOs submit treatments (accompanied by relevant information as requested in section 3) to the Secretariat.
- Only submissions of treatments that are deemed by the NPPO or RPPO to meet the requirements listed in this standard should be submitted, and it is recommended that these treatments have been approved for national use before their submission. Treatments include, but are not limited to, mechanical, chemical, irradiation, physical (heat, cold) and controlled atmosphere treatments. NPPOs and RPPOs should take into account other factors when considering phytosanitary treatments for submission, such as the effects on human health and safety, animal health and the impact on the environment (as described in the preamble and Article I.1 of the IPPC, 1997)[2]. Effects on the quality and intended use of the regulated article should also be considered.
- Treatment submissions will be evaluated based on the requirements listed in section 3. If the volumes of submissions are high, the relevant TPPT criteria listed in the *International Plant Protection Convention procedural manual* will be applied to determine the priority for reviewing submissions.
- Treatments that meet the requirements listed in section 3 will be recommended and the treatment submitted, along with a report and a summary of the information evaluated, to the Standards Committee and in turn to the IPPC standard setting process.
- The CPM will adopt or reject a treatment. If adopted, the treatment is annexed to this standard.

3. Requirements for Phytosanitary Treatments

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

For the purpose of this standard, phytosanitary treatments should fulfil the following requirements:
- be effective in killing, inactivating or removing pests, or rendering pests infertile or for devitalization associated with a regulated article. The level of efficacy of the treatment should be stated (quantified or expressed statistically). Where experimental data is unavailable, other evidence that supports the efficacy (i.e. historical and/or practical information/experience) should be provided.
- be well documented to show that the efficacy data has been generated using appropriate scientific procedures, including an appropriate experimental design. The data supporting the treatment should be verifiable, reproducible, and based on statistical methods and/or on established and accepted international practice; preferably the research should have been published in a peer-reviewed journal.
- be feasible and applicable for use primarily in international trade or for other purposes (e.g. to protect endangered areas domestically or for research).

Submissions of phytosanitary treatments should include the following:
- summary information
- efficacy data in support of the phytosanitary treatment
- information on feasibility and applicability.

3.1 Summary information

The summary information should be submitted by NPPOs or RPPOs to the Secretariat and should include:
- name of the treatment
- name of the NPPO or RPPO and contact information
- name and contact details of a person responsible for submission of the treatment
- treatment description (active ingredient, treatment type, target regulated article(s), target pest(s), treatment schedule, other information)
- reason for submission, including its relevance to existing ISPMs.

Submissions should utilize a form provided by the IPPC Secretariat and available on the International Phytosanitary Portal (IPP, https://www.ippc.int).

3.2 Efficacy data in support of the submission of a phytosanitary treatment

The source of all efficacy data (published or unpublished) should be provided in the submission. Supporting data should be presented clearly and systematically.

The experience or expertise in the subject area of the laboratory, organization and/or scientist(s) involved in producing the data, and whether the research utilized a quality assurance or accreditation programme in the development and/or testing of the phytosanitary treatment, will be considered when evaluating the data submitted. Any claims on the efficacy must be substantiated by data.

3.2.1 Efficacy data under laboratory/controlled conditions

The life-cycle stage of the target pest for the treatment should be specified. Usually, the life stage(s) associated with the regulated article moving in trade is the stage for which a treatment is proposed and established. In some circumstances, e.g. where several life stages may occur on the regulated article, the most resistant life stage of the pest should be used for testing a treatment. However, practical considerations should be taken into account, as well as pest control strategies aimed at exploiting more vulnerable or otherwise specific stages of a pest. If efficacy data is submitted for a life stage that is not considered to be the most resistant (e.g. if the most resistant life stage is not associated with the regulated article), rationale for this should be provided. The efficacy data provided should specify the statistical level of confidence supporting efficacy claims made for treatment of the specified life stage.

Where possible, data should be presented on methods used to determine the effective dose/treatment to demonstrate the range of efficacy of the treatment (e.g. dose/efficacy curves). Treatments can normally be evaluated only for the conditions under which they were tested. However, additional information can be provided to support any extrapolation if the scope of a treatment is to be extended (e.g. extension of the range of temperatures, inclusion of other varieties or pest species). Where the information provided is adequate to demonstrate the effectiveness of the treatment, only a summary of relevant preliminary laboratory tests will be required. The materials and methods used in the experiments should be suitable for the use of the treatment at the stated efficacy.

The data provided should include detailed information on, but not limited to, the following elements:

Pest information
- identity of the pest to the appropriate level (e.g. genus, species, strain, biotype, physiological race), life stage, and if laboratory or field strain was used
- conditions under which the pests are cultured, reared or grown

- biological traits of the pest relevant to the treatment (e.g. viability, genetic variability, weight, developmental time, development stage, fecundity, freedom from disease or parasites)
- method of natural or artificial infestation
- determination of most resistant species/life stage (in the regulated article where appropriate).

Regulated article information
- type of regulated article and intended use
- botanical name for plant or plant product
    - type/cultivar (where varietal differences impact on treatment efficacy, data should be provided). The requirement for varietal testing should be based on evidence to support the requirement.
    - conditions of the plant or plant product, for example:
        - whether it was free from non-target pest infestation, non-pest disorder or pesticide residue
        - size, shape, weight, stage of maturity, quality etc.
        - whether infested at a susceptible growth stage.

Experimental parameters
- level of confidence of laboratory tests provided by the method of statistical analysis and the data supporting that calculation (e.g. number of subjects treated, number of replicate tests, controls)
- experimental facilities and equipment
- experimental design (e.g. randomized complete block design)
- experimental conditions (e.g. temperature, relative humidity, diurnal cycle)
- monitoring of critical parameters (e.g. exposure time, dose, temperature of regulated article and ambient air, relative humidity)
- methodology to measure the effectiveness of the treatment (e.g. whether mortality is the proper parameter, whether the end-point mortality was assessed at the correct time, the mortality or sterility of the treated and control groups)
- determination of efficacy over a range of critical parameters, where appropriate, such as exposure time, dose, temperature, relative humidity and water content, size and density.

3.2.2 Efficacy data using operational conditions

Treatments may be submitted for evaluation without going through the processes outlined in section 3.2.1 when there is sufficient efficacy data available from the operational application of the treatment. When a treatment has been developed under laboratory conditions, it should be validated by testing under operational or simulated operational conditions. Results of these tests should confirm that the application of the treatment schedule achieves the stated efficacy under conditions in which the treatment will be used.

Where treatment specifications differ for trials under operational conditions, the test protocol modifications should be indicated. Supporting data may be presented from preliminary tests to refine the treatment schedule to establish the effective dose (e.g. temperature, chemical, irradiation) under operational conditions.

In some cases the method of achieving the effective dose will be different from the method established under laboratory conditions. Data that supports any extrapolation of laboratory results should be provided.

The same data requirements as listed in section 3.2.1 should also be provided for these tests. Other data required, depending on whether the treatments are carried out pre- or post-harvest, are listed below:
- factors that affect the efficacy of the treatment (e.g. for post-harvest treatments: packaging, packing method, stacking, timing of treatments (pre/post packaging or processing, in transit, on arrival)). The circumstances of the treatment should be stated, for example the efficacy of a treatment may be affected by packaging, and data should be provided to support all the circumstances that are applicable.
- monitoring of critical parameters (e.g. exposure time, dose, temperature of regulated article and ambient air, relative humidity). For example:
    - the number and placement of gas sampling lines (fumigation)
    - the number and placement of temperature/humidity sensors.

In addition, any special procedures that affect the success of the treatment (e.g. to maintain the quality of the regulated article) should be included.

3.3 Feasibility and applicability

Information should be provided, where appropriate, to evaluate if the phytosanitary treatment is feasible and applicable. This includes such items as:
- procedure for carrying out the phytosanitary treatment (including ease of use, risks to operators, technical complexity, training required, equipment required, facilities needed)
- cost of typical treatment facility and operational running costs if appropriate

- commercial relevance, including affordability
- extent to which other NPPOs have approved the treatment as a phytosanitary measure
- availability of expertise needed to apply the phytosanitary treatment
- versatility of the phytosanitary treatment (e.g. application to a wide range of countries, pests and commodities)
- the degree to which the phytosanitary treatment complements other phytosanitary measures (e.g. potential for the treatment to be used as part of a systems approach for one pest or to complement treatments for other pests)
- consideration of potential indirect effects[2] (e.g. impacts on the environment, impacts on non-target organisms, human and animal health)
- applicability of treatment with respect to specific regulated article/pest combinations
- technical viability
- phytotoxicity and other effects on the quality of regulated articles
- consideration of the risk of the target organism having or developing resistance to the treatment.

Treatment procedures should adequately describe the method for applying the treatment in a commercial setting.

4. Evaluation of Submitted Treatments

Submissions will be considered by the TPPT only when the information outlined in section 3 is fully addressed. The information provided will be evaluated against the requirements in section 3.

Due respect for confidentiality will be exercised when the confidential nature of information is indicated. In such cases, the confidential information within the submission should be clearly identified. Where confidential information is essential for the adoption of the treatment, the submitter may be requested to release the information. If the release of the information is not granted, the adoption of the treatment may be affected.

Treatments will be adopted only for the regulated articles and target species for which they were tested and for the conditions under which they were tested, unless data is presented to support extrapolation (e.g. to apply the treatment to a range of pest species or regulated articles).

If the submission fails to meet the requirements outlined in section 3, the reason(s) will be communicated to the contact identified on the submission. There may be a recommendation to provide additional information or to initiate further work (e.g. research, field testing, analysis).

5. Publication of Phytosanitary Treatments

After adoption by the CPM, phytosanitary treatments will be annexed to this standard.

6. Treatment Review and Re-evaluations

Contracting parties should submit to the IPPC Secretariat any new information that could have an impact on the treatments currently adopted by the CPM. The TPPT will review the data and revise the treatments if necessary through the normal standard-setting process.

ANNEX 1

ADOPTED PHYTOSANITARY TREATMENTS

Phytosanitary treatments will be included in this annex after adoption by the CPM.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

RECOGNITION OF PEST FREE AREAS AND AREAS OF LOW PEST PREVALENCE

(200-)

CONTENTS

INTRODUCTION

SCOPE

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

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Determination of pest status in an area, 1998. ISPM No. 8, FAO Rome.
Establishment of pest free areas for fruit flies (Tephritidae), 2006. ISPM No. 26, FAO, Rome.
Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.
Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.
Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.
Guidelines for the determination and recognition of equivalence of phytosanitary measures, 2005. ISPM No. 24, FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest reporting, 2002. ISPM No. 17, FAO, Rome.
Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006. ISPM No. 1, FAO, Rome.
Requirements for the establishment of areas of low pest prevalence, 2005. ISPM No. 22, FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.
Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

Recognition of pest free areas (PFAs) and areas of low pest prevalence (ALPPs) is a technical and administrative process to achieve acceptance of the phytosanitary status of a delimited area. Technical requirements for establishment of PFAs and ALPPs, as well as certain elements relating to recognition, are addressed in other International Standards for Phytosanitary Measures (ISPMs). In addition, many principles of the International Plant Protection Convention (IPPC, 1997) are relevant.

Contracting parties to the IPPC should proceed with a recognition process without undue delay. The process should be applied without discrimination between contracting parties. Contracting parties should endeavour to maintain transparency in all aspects of recognition.

The procedure described in this standard deals with those cases where detailed information and verification may be required, such as in areas in which eradication or suppression of a pest has recently been achieved. This procedure includes the following steps for the contracting parties: request for recognition; acknowledgement of receipt of the request and the accompanying information package; description of the process; assessment of the information provided; communication of the results of assessment; provision of official recognition. However, where the absence of the pest in an area and the PFA status can easily be determined the procedure for recognition described in this standard (in section 4) may not be required or very little supporting information may be necessary.

Both exporting and importing contracting parties have specific responsibilities relating to the recognition of PFAs and ALPPs.

The recognition process should be sufficiently documented by contracting parties.

Some considerations on pest free places of production and pest free sites of production are also provided.

BACKGROUND

Exporting contracting parties may establish PFAs or ALPPs, among other reasons, in order to gain, maintain or improve market access. In any of these cases, where PFAs or ALPPs are established in accordance with the relevant ISPMs, recognition of such areas without undue delay is very important to exporting contracting parties.

Importing contracting parties, in meeting their appropriate level of protection and in accordance with requirements for technical justification, may consider PFAs, or ALPPs (possibly as part of a systems approach), as effective phytosanitary measures. Therefore, it may also be in the interests of the importing country to provide prompt recognition of such areas where they are established in accordance with the relevant ISPMs.

For recognition of PFAs and ALPPs, the following articles of the IPPC are relevant:

"*The responsibilities of an official national plant protection organization shall include … the designation, maintenance and surveillance of pest free areas and areas of low pest prevalence*" (Article IV.2e);

"*The contracting parties shall cooperate with one another to the fullest practicable extent in achieving the aims of this Convention …*" (Article VIII).

Article 6 (*Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence*) of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures addresses the issue of recognition of pest free areas (PFAs) and areas of low pest prevalence (ALPPs).

REQUIREMENTS

1. General Considerations

Several ISPMs address the establishment of PFAs and ALPPs, and related issues.

A range of ISPMs relate directly to the technical requirements for the establishment of PFAs and ALPPs, while many others contain provisions that may be applied in the formal process for recognition of such areas.

ISPM No. 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) states that contracting parties should ensure that their phytosanitary measures concerning consignments moving into their territories take into account the status of areas such as PFAs, ALPPs, pest free production sites or pest free places of production, as designated by the National Plant Protection Organizations (NPPOs) of the exporting countries (sections 2.3 and 2.14 of ISPM No. 1, 2006).

ISPM No. 4 (*Requirements for the establishment of pest free areas*) points out that, since certain PFAs are likely to involve an agreement between trading partners, their implementation would need to be reviewed and evaluated by the NPPO of the importing country (section 2.3.4 of ISPM No. 4).

ISPM No. 8 (*Determination of pest status in an area*) provides guidance on the use of the phrase "pest free area declared" in pest records (section 3.1.2 of ISPM No. 8).

ISPM No. 10 (*Requirements for the establishment of pest free places of production and pest free production sites)* describes the requirements for the establishment and use of pest free places of production and pest free production sites as risk management options for meeting phytosanitary requirements for the import of plants, plant products and other regulated articles.

ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) describes the requirements and procedures for the establishment of ALPPs for regulated pests in an area and, to facilitate export, for pests regulated by an importing country only. This includes the identification, verification, maintenance and use of those ALPPs.

ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) describes the requirements for the establishment and maintenance of PFAs for the economically important species in the family Tephritidae.

Although the recognition of PFAs and ALPPs may generally be a bilateral process between importing and exporting contracting parties, recognition may take place without a detailed process if agreed between the parties (for example without bilateral negotiations and verification activities).

Usually, pest free places of production and pest free production sites should not require a recognition process and, therefore, only some guidance is given on use of procedures in particular cases.

2. General Principles

2.1 Sovereignty and cooperation

Contracting parties have sovereign authority, in accordance with applicable international agreements, to prescribe and adopt phytosanitary measures to protect plant health within their territories and to determine their appropriate level of protection to plant health. A contracting party has sovereign authority to regulate the entry of plants, plant products and other regulated articles (Article VII.1 of the IPPC). Therefore a contracting party has the right to make decisions relating to recognition of PFAs and ALPPs.

However, countries also have other obligations and responsibilities, such as cooperation (Article VIII of the IPPC). Therefore, in order to promote cooperation, an importing contracting party should consider requests for recognition of PFAs and ALPPs.

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

In recognizing PFAs and ALPPs, the process used by the importing contracting party for assessing such requests from different exporting contracting parties should be applied in a non-discriminatory manner.

2.3 Avoidance of undue delay

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

2.4 Transparency

Updates on progress between the importing and exporting contracting parties should be provided to the designated point of contact as mentioned in section 3.1, as appropriate or on request, to ensure that the recognition process is conducted in an open and transparent manner.

Any change in the status of the regulated pest in the area under consideration, or in the importing contracting party's territory, relevant to recognition shall be communicated appropriately and promptly as required by the IPPC (Article VIII.1a) and relevant ISPMs (e.g. ISPM No. 17: *Pest reporting*).

To improve transparency, contracting parties are encouraged to make decisions on the recognition of PFAs and ALPPs available through the International Phytosanitary Portal.

2.5 Other relevant principles of the IPPC and its ISPMs

In recognizing PFAs and ALPPs, contracting parties should take into account the following rights and obligations held by contracting parties, and principles of the IPPC:

- minimal impact (Article VII.2g of the IPPC)
- modification (Article VII.2h of the IPPC)
- harmonization (Article X.4 of the IPPC)
- risk analysis (Articles II and VI.1b of the IPPC)
- managed risk (Article VII.2a and 2g of the IPPC)
- cooperation (Article VIII of the IPPC)
- technical assistance (Article XX of IPPC)
- equivalence (section 1.10 of ISPM No. 1).

3. Requirements for the Recognition of Pest Free Areas and Areas of Low Pest Prevalence

NPPOs are responsible for establishing, designating and/or declaring PFAs within their territories (Article IV.2e of the IPPC). To establish PFAs or ALPPs and before asking for recognition, NPPOs should take into account:

- the appropriate ISPMs that provide technical guidance, i.e. ISPM No. 4 (*Requirements for the establishment of pest free areas*) for PFAs, ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) for ALPPs, and ISPM No. 8 (*Determination of pest status in an area*)
- other technical guidance that may be developed on establishment of PFAs or ALPPs for specific regulated pests or groups of these pests.

The importing contracting party is responsible for determining the type of information that will be required, in order to recognize a PFA or ALPP, depending on the type of area and its geography, the way the pest status of the area has been established (free area or low pest prevalence area), the contracting party's appropriate level of protection, and other factors for which technical justifications exist.

Where the absence of the pest in an area and the PFA status can easily be determined (for example in areas where no records of the pest have been made and, in addition, long term absence of the pest is known or absence is confirmed by surveillance), the process for recognition described in this standard (in section 4) may not be required or very little supporting information may be necessary. In such cases, absence of the pest should be recognized according to the first paragraph of section 3.1.2 of ISPM No. 8 (*Determination of pest status in an area*) without the need for detailed information or elaborate procedures.

In other cases, such as in areas where eradication or suppression of a pest has recently been achieved, more detailed information and verification may be required, including items listed in section 4.1.

3.1 Responsibilities of contracting parties

The exporting contracting party is responsible for:

- requesting recognition of an established PFA or ALPP
- providing appropriate information on the PFA or ALPP
- designating a point of contact for the recognition process
- providing appropriate additional information if required
- cooperating in the organization of on-site verifications, if requested.

The importing contracting party is responsible for:
- acknowledging receipt of the request and the associated information
- describing the process to be used for the recognition process including, if possible, an estimated time frame for the evaluation
- designating a point of contact for the recognition process
- technically assessing the information
- communicating and justifying the need for on-site verifications and cooperating in their organization
- communicating the results of the assessment to the exporting contracting party and:
    - if the area is recognized, promptly modifying any phytosanitary regulations, as appropriate;
    - if the area is not recognized, providing a technical explanation to the exporting contracting party.

Importing contracting parties should limit any information or data requests associated with an assessment of recognition to those which are necessary.

3.2 Documentation

The whole process from initial request to final decision should be sufficiently documented by contracting parties so that the sources of information and rationale used in reaching the decision can be clearly demonstrated.

4. Procedure for the Recognition of Pest Free Areas and Areas of Low Pest Prevalence

The steps described below are recommended for importing contracting parties in order to recognize PFAs and ALPPs of exporting contracting parties. However, in certain cases, as mentioned in the third paragraph of section 3, a formal process for recognition as described in this standard should not be needed.

Normally, the exporting contracting party may wish to consult with the importing contracting party before submitting a request with the aim of facilitating the recognition process.

A flow chart outlining the following steps is provided in Appendix 1. Recommended steps proceed as described from section 4.1 to section 4.6.

4.1 Request for recognition by the NPPO of the exporting contracting party

The exporting contracting party submits its request for recognition of a PFA or ALPP to an importing contracting party. To support its request, the exporting contracting party provides a technical information package based on ISPM No. 4 (*Requirements for the establishment of pest free areas*) or ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) as appropriate. This information package should be sufficiently detailed to demonstrate objectively that the areas are, and are likely to remain, PFAs or ALPPs, as appropriate. The package may include the following information:
- the type of recognition requested, i.e. either a PFA or an ALPP
- location and description of the area to be recognized, with supporting maps, as appropriate
- pest(s) under consideration, and biology(ies) and known distribution relevant to the area (as described in ISPM No. 4 or ISPM No. 22 as appropriate)
- commodity(ies) or other regulated article(s) to be exported
- general information on hosts and their prevalence within the designated area
- phytosanitary measures and procedures applied for the establishment of the PFA or ALPP, and results of these measures
- phytosanitary measures and procedures applied to maintain the PFA or ALPP, and results of these measures
- relevant phytosanitary regulations relating to the PFA or ALPP
- record-keeping arrangements relating to the area, in accordance with the appropriate standards
- relevant information directly related to the request for recognition on the structure of and resources available to the NPPO of the exporting country
- a description of corrective action plans, including related communication arrangements with the importing country concerned
- other relevant information (e.g. recognition of the area in question by other contracting parties, and possible systems approaches relating to ALPPs).

The exporting contracting party should designate a point of contact for communication relating to the request for recognition.

4.2 Acknowledgement by the importing contracting party of receipt of the information package and indication of its completeness for assessment purposes

The NPPO of the importing contracting party should promptly acknowledge receipt of the request for recognition and of the accompanying information package to the NPPO of the exporting contracting party. In commencing the assessment, the importing contracting party should, if possible, identify and communicate to the NPPO of the exporting contracting party if any significant component of the information package is missing, or if other significant information may be needed to assess the request. The importing contracting party should designate a point of contact for communications relating to the request for recognition.

The NPPO of the exporting contracting party should submit to the NPPO of the importing contracting party any missing information, or may provide an explanation for its absence.

Where an exporting contracting party resubmits a request for recognition of a PFA or ALPP (e.g. if further data is acquired, or new or additional procedures are implemented), the importing contracting party should take into consideration all information previously provided, if verification has been provided by the exporting contracting party that the information remains valid. If resubmission is due to a previous non-acceptance of a request for recognition, any relevant details in the corresponding technical explanation related to the previous assessment should also be taken into consideration. Likewise if a contracting party has withdrawn a PFA or ALPP (e.g. uneconomic) and wishes to reinstate it, previous information should be considered. The assessment should be completed, without undue delay, by focusing on the revised or supplemental information and/or data provided, if appropriate.

4.3 Description of assessment process to be used by the importing contracting party

The importing contracting party should describe the process intended to be used in assessing the information package and in subsequently recognizing the PFA or ALPP, including any necessary legislative or administrative steps or requirements that will need to be completed. Furthermore, the importing contracting party is encouraged to establish a provisional timetable for completion of the recognition process.

4.4 Assessment of the technical information

Once all the information has been received, the NPPO of the importing contracting party should carry out assessment of the information package, taking into account:

- provisions of the relevant ISPMs that specifically address either PFAs (ISPM No. 4: *Requirements for the establishment of pest free areas*) or ALPPs (ISPM No. 22: *Requirements for the establishment of areas of low pest prevalence*), including the following information:
  - systems used to establish the PFA or ALPP
  - phytosanitary measures to maintain the PFA or ALPP
  - checks to verify that the PFA or ALPP is being maintained
- other relevant ISPMs (in particular those described in section 1) depending on the type of recognition requested
- status of the pest in the territories of both contracting parties.

PFAs or ALPPs previously recognized by a third country may be considered as reference for the assessment process.

Clarification of the information provided may be required or additional information may be requested by the importing contracting party in order to complete the assessment. The exporting contracting party should respond to technical concerns raised by the importing contracting party by providing relevant information to facilitate completion of the assessment.

On-site verification or on-site review of operational procedures may be justified, based on the results of the ongoing assessment, records of previous trade between the two parties (in particular if there is a lack of information, interception records, non-compliance with import requirements), or previous recognition of areas between the two parties or by other parties. The schedule, agenda and content of the on-site verification or review should be agreed bilaterally, and access provided as necessary.

The assessment should be completed without undue delay. If at any stage progress is not proceeding in accordance with the provisional timetable, if established, the exporting contracting party should be notified, reasons provided and (if appropriate) a new timetable prepared and provided by the importing contracting party to the exporting contracting party.

The exporting contracting party may request cancellation or postponement of the assessment at any time. If the pest status or phytosanitary regulations change in the importing country, recognition of the PFA or ALPP may no longer be required and the assessment process may stop.

4.5 Notification of results of assessment

Upon completion of the assessment, the importing contracting party should reach a decision on the request and should notify the exporting contracting party of the results of its assessment; if the proposed PFA or ALPP will not be recognized, the importing contracting party should provide an explanation, with technical justification, for this decision.

In the event of a disagreement related to the rejection of a request for recognition of a PFA or ALPP, efforts should in the first instance be made bilaterally to resolve these disagreements.

4.6 Official recognition

In accordance with Article VII.2b of the IPPC: *"Contracting parties shall, immediately upon their adoption, publish and transmit phytosanitary requirements, restrictions and prohibitions to any contracting party or parties that they believe may be directly affected by such measures."* If the PFA or ALPP is recognized by the importing contracting party, this should be officially communicated to the exporting contracting party, clearly confirming the type of area recognized and identifying the relevant pest(s) for which such recognition applies. And, where appropriate, amendment of the phytosanitary import requirements and any associated procedures of the importing contracting party should be made promptly.

4.7 Duration of recognition

Recognition of a PFA or ALPP should remain in effect unless:

- there is a change in pest status in the area concerned and it is no longer a PFA or ALPP.
- there are significant instances of non-compliance (as described in section 4.1 of ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*) related to the areas in question or related to the bilateral arrangement noted by the importing contracting party.

5. Considerations on Pest Free Places of Production and Pest Free Production Sites

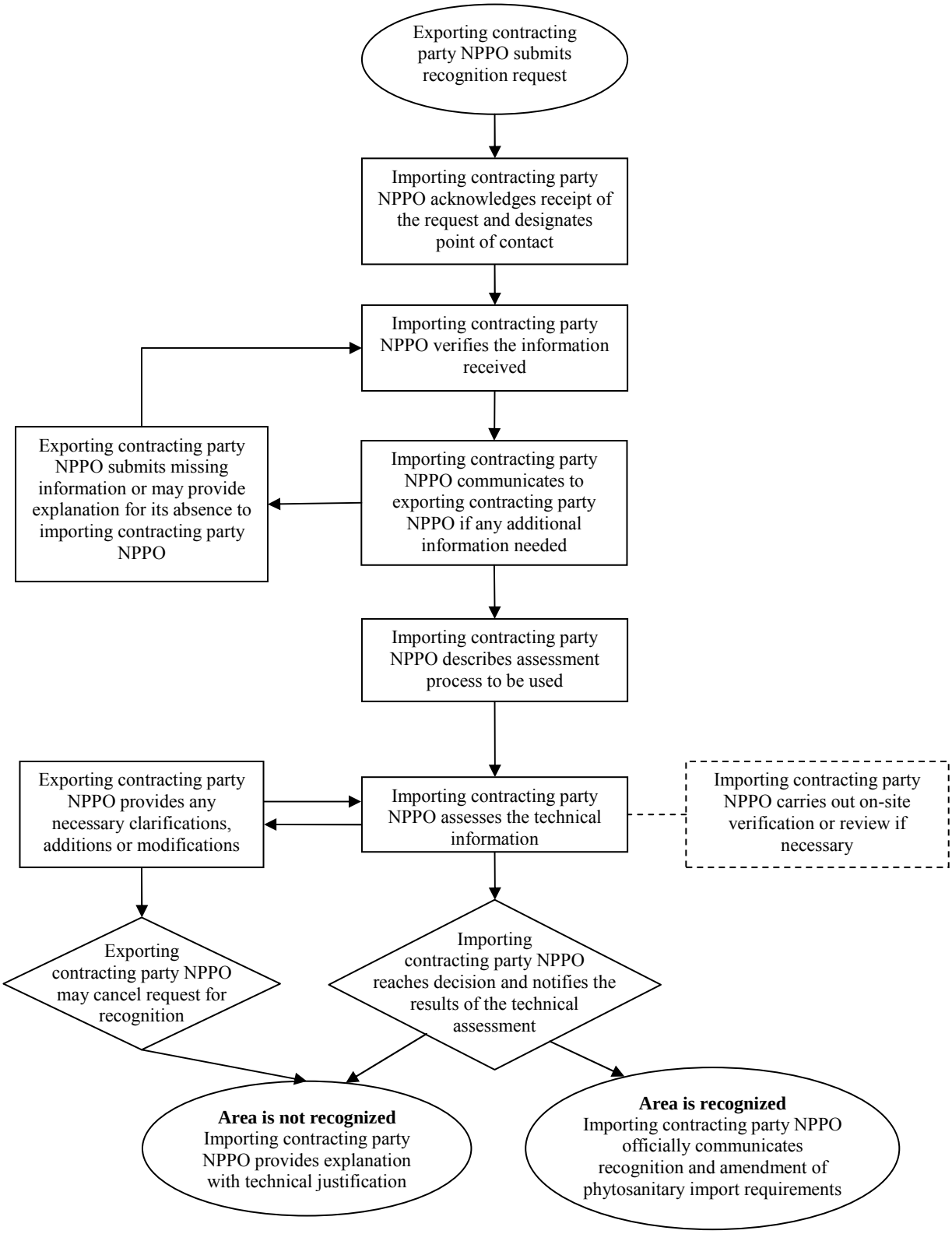
Pest free places of production and pest free production sites should not have to be recognized as such using the procedures described above (section 4). ISPM No. 10 (*Requirements for the establishment of pest free places of production and pest free production sites*) confirms that, for such places and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

ISPM No. 10 (in section 3.3) also indicates: "*The NPPO of the exporting country should, on request, make available to the NPPO of the importing country the rationale for establishment and maintenance of pest free places of production or pest free production sites. Where bilateral arrangements or agreements so provide, the NPPO of the exporting country should expeditiously provide information concerning establishment or withdrawal of pest free places of production or pest free production sites to the NPPO of the importing country.*"

As described in ISPM No. 10: *"When complex measures are needed to establish and maintain a pest free place of production or pest free production site, because the pest concerned requires a high degree of phytosanitary security, an operational plan may be needed. Where appropriate, such a plan would be based on bilateral agreements or arrangements listing specific details required in the operation of the system including the role and responsibilities of the producer and trader(s) involved."* In such cases recognition may be based on the procedure recommended in section 4 of this standard or another bilaterally agreed procedure.

APPENDIX 1

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



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

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

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

(200-)

CONTENTS

INTRODUCTION

SCOPE

This standard provides guidelines for the establishment and maintenance of areas of low pest prevalence for fruit flies that may then be used as a pest risk management measure primarily to facilitate trade of fruits or to limit the impact of fruit flies in an area. This standard applies to fruit flies (Tephritidae) of economic importance.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.
Establishment of pest free areas for fruit flies (Tephritidae), 2006. ISPM No. 26, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
Guidelines for pest eradication, 1998. ISPM No. 9, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.
Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.
Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
Requirements for the establishment of areas of low pest prevalence, 2005. ISPM No. 22, FAO, Rome.
Requirements for the establishment of pest free areas, 1995. ISPM No. 4, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

ABBREVIATIONS USED IN THIS STANDARD

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

OUTLINE OF REQUIREMENTS

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

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

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

Other specific requirements include the suspension, loss and reinstatement of the status of the FF-ALPP.

BACKGROUND

The International Plant Protection Convention (IPPC, 1997) contains provisions for areas of low pest prevalence (ALPPs), as does the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO-SPS Agreement). The IPPC defines an area of low pest prevalence as "an area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures". The concept and provisions of areas of low pest prevalence are described in ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) and may be used as part of a systems approach (see ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*).

Fruit flies are a very important group of pests for many countries because of their potential to cause damage to fruits and restrict access to international markets for plant products that can host fruit flies. The high probability of introduction of fruit flies associated with a wide range of hosts results in restrictions imposed by many importing countries to accept fruits from areas in which these pests are established.

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

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

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

REQUIREMENTS

1. General Requirements

The concepts and provisions of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence)* apply to the establishment and maintenance of areas of low pest prevalence for all pests including fruit flies and therefore ISPM No. 22 should be referred to in conjunction with the present standard.

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

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

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

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

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

1.1 Determination of an FF-ALPP

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

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

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

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

In areas where prevalence of fruit flies is naturally at a low level because of climatic, geographical or other reasons (e.g. resistant hosts/varieties), low prevalence should be recognized according to section 3.1.1 of ISPM No. 8 (*Determination of pest status in an area*). If, however, the fruit flies are detected above the specified level, because of extraordinary climatic conditions or other reasons, corrective actions should be applied.

1.1.1 Delimitation of the area

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

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

1.2 Operational plans

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

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

Parameters used to determine the level of fruit fly prevalence in the FF-ALPP should be defined by the NPPO. The most widely used parameter is the number of flies per trap per day (FTD). This is usually expressed as an average of the total number of traps deployed in the whole area. More precise spatial data may be presented on the basis of trap density (i.e. FTD per unit area) or temporally for each trap present in an area over time (see reference in Appendix 1).

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

The FTD is a population index used to estimate the average number of flies captured by one trap in one day. This parameter estimates the relative number of fruit fly adults in a given time and space. It is used as baseline information to compare fruit fly populations among different places and/or times.

The FTD value is the result of dividing the total number of captured flies by the product obtained from multiplying the total number of inspected traps by the average number of days the traps were exposed. The formula is as follows:

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

Where
F = total number of flies captured
T = number of inspected traps
D = average number of days traps were exposed in the field.

In cases where traps are regularly inspected on a weekly basis, or longer in the case of winter surveillance operations, the parameter may be “flies per trap per week” (FTW). It estimates the number of flies captured by one trap in one week. Thus, FTD can be obtained from FTW by dividing by 7.

1.4 Documentation and record keeping

The phytosanitary measures used for the determination, establishment, verification and maintenance of an FF-ALPP should be adequately documented as part of phytosanitary procedures. They should be reviewed and updated regularly, including corrective actions, if required (as described in ISPM No. 22: *Requirements for the establishment of areas of low pest prevalence*). It is recommended that a manual of standard operational procedures is prepared for the FF-ALPP.

For determination and establishment, documentation may include:

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

For verification and maintenance, documentation should include the data recorded to demonstrate the population levels of the target fruit fly species. The records of surveys and results of other operational procedures should be retained for at least 24 months. If the FF-ALPP is being used for export purposes, records should be made available to the NPPO of the importing country on request.

1.5 Supervision activities

The FF-ALPP programme, including regulatory control, surveillance procedures (for example trapping, fruit sampling) and corrective action planning, should comply with officially approved procedures. Such procedures should include official delegation of responsibility assigned to key personnel, for example:

- a person with defined authority and responsibility to ensure that the systems/procedures are implemented and maintained appropriately;

- entomologist(s) with responsibility for the authoritative identification of fruit flies to species level.

The NPPO should evaluate the operation of the procedures for establishment and maintenance of the FF-ALPP to ensure that effective management is maintained. Critical control points in which results should be monitored and processes actively managed include:

- operation of surveillance procedures
- surveillance capability
- trapping materials (traps, attractants) and procedures
- identification capability
- application of control measures
- documentation
- implementation of corrective actions, where applied.

2. Specific Requirements

2.1 Procedures to establish an FF-ALPP

The following should be developed and implemented:

- determination of the specified level of low prevalence
- surveillance system
- reduction of the target fruit fly species level
- reduction of the risk of entry of the target fruit fly species
- domestic declaration of low pest prevalence.

2.1.1 Determination of the specified level of low prevalence

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

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

Efficiency of the types of traps and attractants used to estimate the levels of the pest population and the procedures applied for servicing the traps should be taken into consideration. The rationale is that different trap efficiencies could lead to different FTD values at the same location, so that they have a significant effect in measuring the prevalence level of the target fruit fly species. Thus, when specifying the level of low pest prevalence accepted in terms of an FTD value, the corresponding trapping system should be stated as well.

Once an FTD has been derived for a given situation using a specific lure/attractant, the lure/attractant used in the FF-ALPP must not be changed or modified until an appropriate FTD is derived for the new formulation. For FF-ALPPs with multiple target fruit fly species present that are attracted to different lures/attractants, trap placement should take into consideration possible interactive effects between lures/attractants.

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

2.1.2 Surveillance system

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

Surveillance systems based on traps are similar in any type of fruit fly prevalence area. The surveillance used in an FF-ALPP may include those processes described in ISPM No. 6 (*Guidelines for surveillance*), section 2.2.2.1 on trapping procedures of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*), and any other relevant scientific information.

Fruit sampling as a routine surveillance method is not widely used for monitoring fruit flies in low prevalence areas except in areas where sterile insect technique (SIT) is applied, where it may be a major tool.

In some cases, the NPPO may complement trapping with fruit sampling for fruit fly surveillance and/or monitoring. However, fruit sampling will not provide sufficient accuracy for describing the size of the population and should not be solely relied on to validate or verify the FF-ALPP status. Surveillance procedures may include those described in section 2.2.2.2 on fruit sampling procedures of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

The presence and abundance of fruit fly hosts should be recorded separately identifying commercial and major non-commercial hosts. This information will help in planning the trapping and host sampling activities and may help in anticipating the potential ease or difficulty of defining and maintaining the phytosanitary status of the area.

The NPPO should have identification capabilities or have access to suitable specialists for the target fruit fly species detected during the surveys (whether adult or larvae). This capability should also exist for the ongoing verification of FF-ALPP status.

2.1.3 Reduction of the target fruit fly species levels

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

Phytosanitary measures to suppress fruit fly populations in FF-ALPPs include a number of preventive and/or corrective control methods, selected and combined into a strategy for suppression. Efforts should be made to select those measures with least environmental impact.

Available methods may include:

- chemical control (e.g. selective insecticide bait, aerial and ground spraying, bait stations and male annihilation technique)
- physical control (e.g. fruit bagging)
- biological control (e.g. natural enemies, SIT)
- cultural control (e.g. destruction of mature and fallen fruit, replacement of host plants by non-host plants, early harvesting, discouragement of intercropping with fruit fly host plants, pruning before the fruiting period, removal of shade trees, removal of untreated non-commercial hosts)
- mass trapping.

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

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

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

2.1.5 Domestic declaration of low pest prevalence

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

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

2.2 Maintenance of the FF-ALPP

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

2.2.1 Surveillance

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

2.2.2 Measures to establish and maintain specified levels of fruit fly

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

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

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

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

2.2.3 Corrective action plans

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

2.3 Suspension, reinstatement and loss of FF-ALPP status

2.3.1 Suspension of FF-ALPP status

If the low pest prevalence specified level of the target fruit fly species is exceeded in an affected area within the FF-ALPP that can be identified and delimited, then the FF-ALPP may be redefined to suspend that area. When such a suspension is put in place, the criteria for lifting the suspension and restoring the original FF-ALPP status should be made clear. The NPPOs of interested importing countries should be notified of these actions (further information on pest reporting requirements is provided in ISPM No. 17: *Pest reporting*).

Suspension may also apply if faults in the procedures are found (for example inadequate trapping or pest control measures).

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

2.3.2 Reinstatement

Reinstatement of FF-ALPP status may take place:

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

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

2.3.3 Loss of status

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

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

ANNEX 1

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

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

The corrective action plan should be prepared taking into account the biology of the target fruit fly species, the geography of the FF-ALPP, climatic conditions, phenology and host distribution within the area.

The elements required for implementation of a corrective action plan include:
- declaration of an outbreak
- legal framework under which the corrective action plan can be applied
- time scales for the initial response and follow-up activities
- delimiting survey (trapping and fruit sampling), and application of the suppression actions
- identification capability
- availability of sufficient operational resources
- effective communication within the NPPO and with the NPPO(s) of the relevant importing country(s), including provision of contact details of all parties involved.

Application of the corrective action plan

1. Declaration of an outbreak and first actions

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

2. Determination of the phytosanitary features of the outbreak

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

3. Implementation of control measures in the affected area

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

4. Notification of relevant agencies

Relevant NPPOs and other agencies should be kept informed of corrective actions. Information on pest reporting requirements under the IPPC is provided in ISPM No. 17 (*Pest reporting*).

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

APPENDIX 1

GUIDELINES ON TRAPPING PROCEDURES[2]

Information about trapping is available in the following publication of the International Atomic Energy Agency (IAEA): *Trapping Guidelines for area-wide fruit fly programmes*, IAEA/FAO-TG/FFP, 2003. IAEA, Vienna.

This publication is widely available, easily accessible and generally recognized as authoritative.

[2] This appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 2

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

FF-ALPPs are generally used:
- as a buffer zone for an FF-PFA, fruit fly free places of production or fruit fly free production sites (either as a permanent buffer zone or as part of an eradication process)
- for export purposes, usually in conjunction with other risk mitigation measures as a component of a systems approach (this may include all or part of an FF-ALPP that acts as a buffer zone).

1 An FF-ALPP as a buffer zone

In cases where the biology of the target fruit fly species is such that it is likely to disperse from an infested area into a protected area, it is necessary to define a buffer zone with a low fruit fly prevalence (as described in ISPM No. 26: *Establishment of pest free areas for fruit flies (Tephritidae)*). These FF-ALPPs are usually established at the time of setting up the FF-PFA.

1.1 Determination of an FF-ALPP as a buffer zone

Determining procedures may include those listed in section 1.1. In addition, in delimiting the buffer zone, detailed maps may be included showing the boundaries of the area to be protected, location of major host areas, location of urban areas, entry points and control checkpoints. It is also relevant to include data related to natural biogeographical features such as prevalence of other primary or secondary hosts, climate, location of valleys, plains, deserts, rivers, lakes and sea, and those areas that function as natural barriers. The size of the buffer zone in relation to the size of the area being protected will depend on the biology of the target fruit fly species (including behaviour, reproduction and dispersal capacity), the intrinsic characteristics of the protected area, and the economic and operational feasibility of establishing the FF-ALPP.

1.2 Establishment of an FF-ALPP as a buffer zone

The establishment procedures are described in section 2.1. The movement into the area of regulated articles that can host the target fruit fly species may be regulated. Additional information can be found in section 2.2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

1.3 Maintenance of an FF-ALPP as a buffer zone

Procedures may include those listed in section 2.2. Since the buffer zone has features similar to the area or place of production it protects, procedures for maintenance may include those listed for the FF-PFA as described in section 2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and sections 3.1.4.2, 3.1.4.3 and 3.1.4.4 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*).

2 FF-ALPPs for export purposes

FF-ALPPs may be used to facilitate fruit exports from the area. In most cases the FF-ALPP is the main component of a systems approach as a pest risk mitigation measure. Examples of measures and/or factors used in conjunction with FF-ALPPs include:
- pre- and post-harvest treatments
- poor hosts, less attractive hosts or non-hosts
- export of host material to areas not at risk during particular seasons
- physical barriers (e.g. pre-harvest bagging, insect-proof structures).

2.1 Determination of an FF-ALPP for export purposes

Determining procedures may include those listed in section 1.1. In addition, the following elements should be considered for the determination of an FF-ALPP:
- a list of products (hosts) of interest
- a list of other commercial and non-commercial hosts of the target fruit fly species present but not intended for export and their level of occurrence, as appropriate
- additional information such as any historical records in connection with biology, occurrence and control of the target fruit fly species or any other fruit fly species that may be present in the FF-ALPP.

2.2 Maintenance of an FF-ALPP for export purposes

Maintenance procedures may include those listed in section 2.2. Surveillance and control measures should be applied throughout the fruiting seasons. If appropriate, surveillance may continue at a lower frequency during the off-season period. This will depend on the biology of the target fruit fly species and its relationship with the major hosts that bear fruits during the off-season.

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

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

Supplement No. 3
DEBARKED AND BARK-FREE WOOD

1. Scope

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

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

2. References

Export certification system, 1997. ISPM No. 7, FAO, Rome.
Glossary of phytosanitary terms, 2006. ISPM No. 5, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines for pest risk analysis, 1995. ISPM No. 2, FAO, Rome
Guidelines for regulating wood packaging material in international trade, 2002. ISPM No. 15, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No 14, FAO Rome.

Definitions

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

New term and definition

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

Revised terms and definitions

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

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

3. Background

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

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

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

4. General Requirements

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

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

In terms of this standard, ingrown bark around knots (i.e. areas of bark from branches that have become encased during annual growth) and bark pockets (i.e. areas of bark between rings of annual growth) are usually not considered to

present a different phytosanitary risk from that which may already have been determined to exist in relation to their surrounding wood. (A cross-sectional line drawing of wood is provided in Appendix 1.)

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

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

4.1 Reduction of pest risk associated with bark

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

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

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

4.2 Basis for regulating

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

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

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

5. Specific Requirements

5.1 Bark tolerances for debarked wood

Contracting parties may require debarked wood as a phytosanitary measure, based on technical justification. They may also set tolerances for residual levels of bark and, in addition to the criteria set out in ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, 2004), take into account the following:

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

Where contracting parties require debarked wood as a phytosanitary measure based on technical justification without specifying a tolerance level of residual bark, they should expect that up to 3 percent of bark from coniferous logs and up to 10 percent of bark from non-coniferous logs may remain after normal industrial debarking processes. For sawn

wood, the percentage of residual bark mentioned above should relate only to that part of the wood that has kept its natural round surface.

5.2 Bark-free wood as a phytosanitary measure

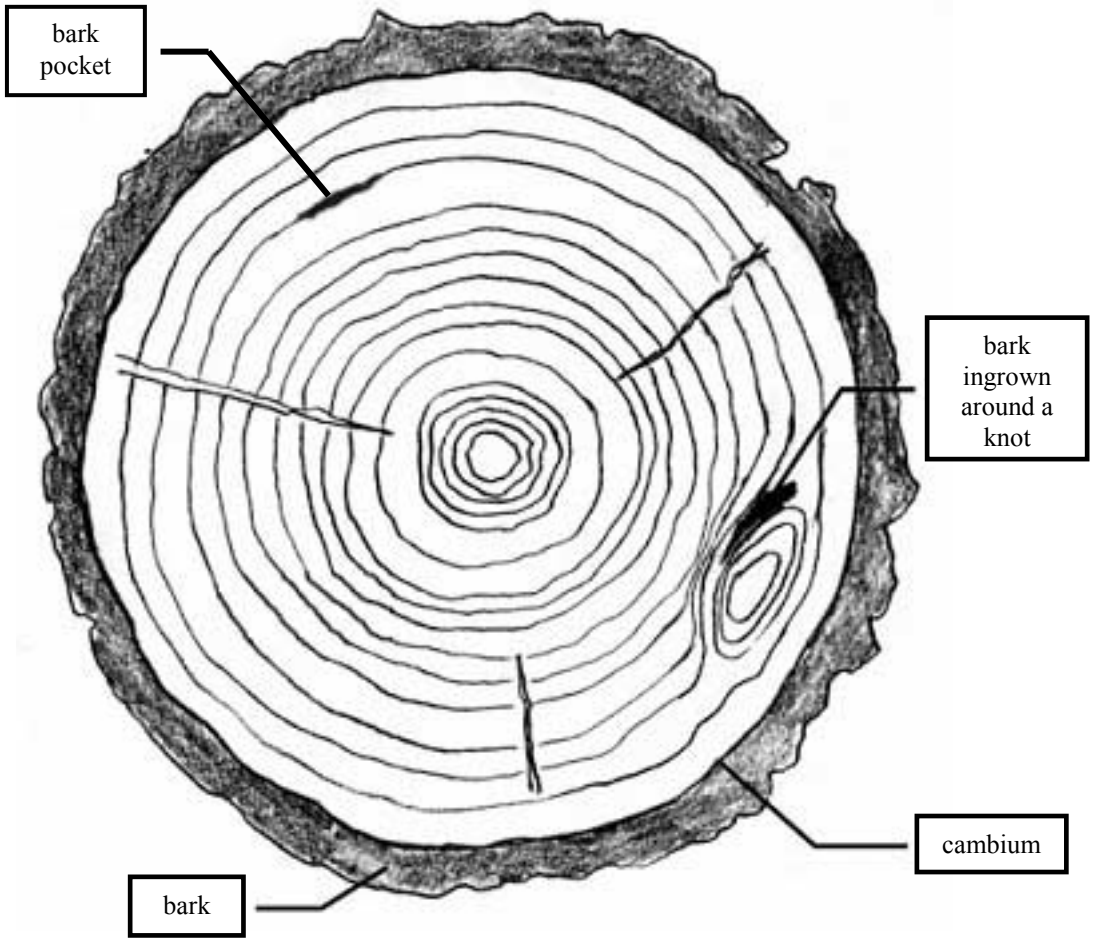
In cases where even small pieces of bark may present a risk, NPPOs may require that the wood be bark-free as a phytosanitary measure, based on technical justification. These cases may include:

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

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

APPENDIX 1

CROSS-SECTIONAL LINE DRAWING OF WOOD[1]



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

SPECIFICATION NO. 38

Title: Revision of ISPMs No. 7 and 12.

Reason for the revision: Currently there are two key ISPMs dealing with export certification: ISPM No. 7 (*Export certification system*) and ISPM No. 12 (*Guidelines for phytosanitary certificates*). These ISPMs also briefly address the procedures to follow in case of re-export and transit. As international trade has expanded and means of conveyance have diversified, there is a need to ensure that the two standards are consistent with one another and in respect to the guidance they provide, and that they provide additional guidance on re-export certification. In addition, these standards should be brought in line with all other existing standards, such as ISPM No. 20 (*Guidelines for a phytosanitary import system*) and ISPM No. 25 (*Consignments in transit*).

Scope and purpose: Existing ISPMs No. 7 and 12 will be reviewed for amendment to provide specific guidance on the procedures, which cover technical, administrative and operational aspects, including export issues related to re-export and consignment in transit.

Tasks: The expert drafting group should:

1. Review existing ISPMs relating to export certification (ISPMs No. 7 and 12, taking into account ISPMs No. 20, 23 and 25) and experiences of contracting parties with implementation of those standards.
2. Identify the main points to be amended, taking into account appropriate procedures for export and re-export certification, and clarifying the interaction in case of re-export and transit.
3. Make recommendations as appropriate to the SC on the use of the terms *country of origin* and *place of origin* in ISPMs No. 7 and 12.
4. Propose amendments related to the main points identified consistent with the IPPC and relevant ISPMs to the SC and inform the SC on those topics that may require further work.
5. Consider the most appropriate approach for providing the contents and key elements of the ISPMs, taking into account the inter-relationship between ISPMs No. 7 and 12 and present options to the SC.

Provision of resources: Funding for the meeting is provided by the IPPC Secretariat (FAO). As recommended by ICPM-2 (1999), whenever possible, those participating in standard setting activities voluntarily fund their travel and subsistence to attend meetings. Participants may request financial assistance, with the understanding that resources are limited and the priority for financial assistance is given to developing country participants.

Steward: Motoi Sakamura (Japan).

Expertise: 5-7 experts with general expertise and operational experiences in export certification. The group should also have knowledge on phytosanitary aspects of customs clearance of consignments and preferably knowledge on the IPPC work on electronic certification.

Approval: Introduced into the work programme by CPM-1 (2006). Specification approved by the Standards Committee in November 2006.

References: IPPC 1997; WTO-SPS Agreement; ISPMs No. 7, 12, 15, 20, 23, 25 and others as appropriate; discussion paper on the use of the term *country of origin* in ISPMs as modified by the SC in May 2006; possible recommendations by the working group revising all ISPMs.

Discussion papers: Participants and interested parties are encouraged to submit discussion papers to the IPPC Secretariat (ippc@fao.org) for consideration by the expert drafting group.

SPECIFICATION NO. 39

Title: Suppression and eradication procedures for fruit flies (*Tephritidae*).

Reason for the standard/support document: One of the tasks of the Technical panel on pest free areas and systems approaches for fruit flies (TPFF) is to develop International Standards for Phytosanitary Measures (ISPMs) on fruit fly pest free areas (FF-PFA), fruit fly areas of low pest prevalence (FF-ALPP), fruit fly free places of production (FFF-POP), fruit fly free production sites (FFF-PS) and fruit fly systems approaches (FF-SA). Fruit fly suppression and eradication is a critical element in the establishment, verification and maintenance of fruit fly low prevalence areas, free areas, free places of production and free production sites. Thus a guideline containing fruit fly suppression and eradication procedures is required as a support document for these ISPMs.

Scope and purpose: This standard will provide specific guidance on the technical procedures required to effectively suppress and eradicate fruit fly populations.

Tasks: The expert drafting group should:

1. Consider existing relevant ISPMs and ensure consistency with other ISPMs and draft ISPMs, in particular the draft ISPM on FF-PFA, and ISPMs under development, in particular FF-ALPP and FF-SA.
2. Consult all relevant technical and scientific literature on suppression and eradication procedures manuals available in the main operational programmes worldwide.
3. Draft a comprehensive suppression and eradication procedures guideline that includes the following aspects:
   a) suppression and eradication objectives
   b) suppression and eradication applications
   c) materials and equipment available for suppression and eradication including biocontrol agents (parasites, predators, sterile insects), baits, insecticides, pheromones, sprayers, vehicles, aircraft, etc.
   d) description of suppression and eradication procedures
   e) description of procedures for suppression of populations which have exceeded the set level of fruit fly low prevalence and eradication of outbreaks in fruit fly free areas (i.e. corrective action plan)
   f) quality control of materials used for suppression and eradication and good operational procedures, including minimal impact on environment
   g) target fruit fly species addressed
   h) documentation, record keeping and data management including harmonized data collection sheets
   i) verification procedures.

Provision of resources: Funding for the meeting is provided by the IPPC Secretariat (FAO). As recommended by ICPM-2 (1999), whenever possible, those participating in standard setting activities voluntarily fund their travel and subsistence to attend meetings. Participants may request financial assistance, with the understanding that resources are limited and the priority for financial assistance is given to developing country participants.

Steward: Odilson Ribeiro e Silva (Brazil).

Expertise: A group of 5-6 experts in fruit fly suppression and eradication techniques with experience in a number of fruit fly species of economic importance in several regions and having familiarity with CPM standard setting procedures and relevant ISPMs.

Participants: Technical panel on fruit flies (TPFF).

Approval: Introduced into the work programme by CPM-1 (2006). Specification approved by the Standards Committee in November 2006.

References: IPPC 1997; WTO-SPS Agreement; ISPMs No. 1, 3, 4, 8, 9, 10, and 14, relevant draft ISPMs and ISPMs under development (FF-ALPP and FF-SA), FAO and IAEA Guideline on Packing, Shipping and Release of Sterile Flies, relevant scientific literature.

Discussion papers: Participants and interested parties are encouraged to submit discussion papers to the IPPC Secretariat (ippc@fao.org) for consideration by the expert drafting group.

SPECIFICATION NO. 40

Title: Irradiation phytosanitary treatments for Annex 1 (Specific approved treatments) of ISPM No. 18 (*Guidelines for the use of irradiation as a phytosanitary measure*).

Reason for the annex: ISPM No. 18 (*Guidelines for the use of irradiation as a phytosanitary measure*) provides technical guidance on the specific procedures for the application of ionizing radiation as a phytosanitary treatment for regulated pests and articles.

Annex 1 of the standard (Specific approved treatments), which has not been completed to date, is intended to list CPM approved irradiation phytosanitary treatments.

Scope and purpose: The scope and purpose of ISPM No. 18 will remain unchanged, however work done under this specification will initiate the evaluation of phytosanitary irradiation treatments for specific applications that will be used in conjunction with this ISPM.

Tasks: The expert drafting group should:

1. Establish a prioritized list of quarantine pests and commodities and regulated articles of importance for which specific phytosanitary irradiation treatments may be effective.
2. In accordance with the priorities developed as a result of task 1, list and collect descriptions of existing phytosanitary irradiation treatments for the pests, commodities and articles listed, and review scientific and technical information relating to the application and efficacy of these treatments taking into account the process described in the draft ISPM on phytosanitary treatments.
3. Identify those phytosanitary irradiation treatments listed as part of task 2 that require additional research and communicate this, along with an indication of information requirements for which research is required, to the SC.
4. Establish specific or generic minimum effective doses for insect quarantine pests of importance alone or in commodities and regulated articles.
5. Establish specific or generic minimum effective doses for quarantine pests other than insects alone or in commodities and regulated articles.

Provision of resources: Funding for the meeting will be provided by extra-budgetary resources through the International Atomic Energy Agency (IAEA). As recommended by ICPM-2 (1999), whenever possible, those participating in standard setting activities voluntarily fund their travel and subsistence to attend meetings. Participants may request financial assistance, with the understanding that resources are limited and the priority for financial assistance is given to developing country participants.

Steward: David Porritt (Australia).

Collaborator: International Atomic Energy Agency (IAEA).

Expertise: Work to be done by the Technical panel on phytosanitary treatments (TPPT) with appropriate phytosanitary experts familiar with the use of irradiation as a phytosanitary treatment and a representative of the IAEA.

Participants: Technical panel on phytosanitary treatments (TPPT).

Approval: Introduced into the work programme by CPM-1 (2006). Specification approved by the Standards Committee in November 2006.

References: Relevant ISPMs; IAEA standards, meeting reports and recommendations of expert meetings; 7 CFR Parts 301, 318, and 319 APHIS/USDA; relevant NAPPO standards.

Discussion papers: Participants and interested parties are encouraged to submit discussion papers to the IPPC Secretariat (ippc@fao.org) for consideration by the expert drafting group.

SPECIFICATION NO. 41

Title: Establishment of pest free places of production and pest free production sites for fruit flies (Tephritidae).

Reason for the standard: One of the tasks of the Technical panel on pest free areas and systems approaches for fruit flies (TPFF) is to identify measures and develop standardized procedures to be integrated in systems approaches for different species of fruit flies, fruit fly free places of production (FFF-POP) and fruit fly free production sites (FFF-PS). The application of an ISPM on FFF-POP and FFF-PS may facilitate trade of different commodities produced.

Scope and purpose: This standard provides guidance on the establishment and maintenance of pest free places of production and pest free production sites for fruit flies of the family Tephritidae, as an option for managing the risk of fruit flies.

Tasks: The expert drafting group should:

1. Consider general comments presented by countries to this specification.
2. Review information already presented in the standard on *Establishment of pest free areas for fruit flies* (ISPM No. 26) and determine whether it is also applicable to FFF-POP and FFF-PS in part or in entirety, and describe the specific differences between a fruit fly pest free area (FF-PFA) and fruit fly pest free production site (FF-PFPS) and fruit fly pest free place of production (FF-PFPP) as appropriate.
3. Consider whether the guidance on FFF-POP and FFF-PS would be best presented as an annex or a supplement to another standard for fruit flies.
4. Consider existing relevant ISPMs and ensure consistency with other ISPMs and draft ISPMs in development.
5. Identify the most important species of the family Tephritidae and their major hosts.

Where existing information in the standard on *Establishment of pest free areas for fruit flies* is insufficient to apply to FFF-POP and FFF-PS, specific guidance should be developed as per the following tasks:

6. Develop a standardized method which can be followed when establishing and maintaining a FFF-POP and FFF-PS. Some suggested topics to consider are:
    - determination and establishment:
        - collection of adequate information of practical experiences that could be considered for background support
        - documentation and record keeping
        - surveillance activities: trapping/fruit rearing, including additional technical information
        - capability in identification of fruit flies
        - regulatory control, to prevent fruit fly reintroduction if appropriate
        - verification and declaration of fruit fly pest free sites or pest free places
    - maintenance of fruit fly pest free sites or pest free places:
        - surveillance activities
        - movement control of regulated articles
        - corrective actions (including response to an outbreak)
        - detection, suspension, reinstatement and loss of pest freedom status
        - communication of FFF-POP and FFF-PS status (including suspension, loss, or reinstatement) to relevant NPPOs and interested parties
    - quality control.
7. Consider relevant reference documents, annexes or appendices to this standard for corrective action plans, surveys, pest identification and treatments.
8. Consider whether guidance is required on the relationship between fruit fly areas of low pest prevalence, fruit fly pest free areas and systems approaches for fruit flies.

Provision of resources: Funding for the meeting is provided by the IPPC Secretariat (FAO). As recommended by ICPM-2 (1999), whenever possible, those participating in standard setting activities voluntarily fund their travel and subsistence to attend meetings. Participants may request financial assistance,

with the understanding that resources are limited and the priority for financial assistance is given to developing country participants.

Steward: Magda Gonzalez (Costa Rica).

Expertise: Experience in implementing PFA, FF-PFA, FFF-POP and FFF-PS and regulatory experience with fruit flies. Expertise with more than one genus of fruit fly and experience with fruit flies in several regions. Knowledge of ISPMs and good writing skills desirable.

Participants: Technical panel on fruit flies (TPFF).

Approval: Introduced into the work programme by CPM-1 (2006). Specification approved by the Standards Committee in November 2006.

References: IPPC 1997; WTO-SPS Agreement; ISPMs No. 4, 6, 8, 9, 10, 14 and 22. Relevant draft ISPMs. Relevant regional standards; national programmes on FF-PFA, FFF-POP and FFF-PS and systems approaches for fruit flies; IAEA documentation.

Discussion papers: Participants and interested parties are encouraged to submit discussion papers to the IPPC Secretariat (ippc@fao.org) for consideration by the expert drafting group.

SPECIFICATION NO. 42

Title: Pre-clearance for regulated articles.

Reasons for the standard: The movement of regulated articles in trade is increasing as international markets expand. This movement may also result in a higher risk of the introduction and/or spread of regulated pests associated with these articles.

It is the responsibility of the exporting contracting party to make arrangements for phytosanitary certification ensuring that exported consignments conform with the certifying statement of phytosanitary certificates issued. Inspection and related activities leading to the issuance of phytosanitary certificates should be carried out only by or under the authority of the official NPPO of the exporting country.

However, in exceptional cases, for facilitating trade logistics at the request of the exporting country, contracting parties may bilaterally negotiate an agreement for allowing clearance in the country of origin by the NPPO of the country of destination. Arrangements of that nature may be called pre-clearance. Also joint auditing of the export certification system to facilitate new trade may be called pre-clearance. The agreement should include procedures for the regular review, intensity reduction, phasing-out and termination of the arrangements.

Currently, some countries apply various arrangements of this kind. Arrangements differ significantly between countries and may in some cases turn out discriminatory and un-transparent. The standard will provide general guidance to criteria that may justify such arrangements and to their use and implementation compatible with the basic principles of the IPPC.

Scope and purpose: The document should provide guidance on the justification, establishing, reviewing, phasing out and terminating of pre-clearance arrangements and a model framework for pre-clearance programs (where justified), including criteria for terminating pre-clearance arrangements in favour of other phytosanitary measures.

Tasks: The expert drafting group should develop a document that will:

1. Consider the coverage of pre-clearance by the IPPC and its articles.
2. Consider whether this can be an annex or supplement to another existing standard.
3. Clarify the use of the concept and term pre-clearance and consider the differences between pre-inspection and pre-clearance, if any, and, if necessary, propose a definition for pre-inspection and/or redefinition for pre-clearance.
4. Provide criteria which may be used in the establishment of pre-clearance programs.
5. Identify and describe essential procedures required to ensure compliance with the phytosanitary measures of the importing country.
6. Develop a model framework for arrangements on pre-clearance programs, including consideration of allocation of costs of such programs to the parties involved and phase-out ('sunset clause') considerations.
7. Identify the roles and responsibilities of stakeholders (NPPOs, importers and exporters).

Provision of resources: Funding for the meeting is provided by the IPPC Secretariat (FAO). As recommended by ICPM-2 (1999), whenever possible, those participating in standard setting activities voluntarily fund their travel and subsistence to attend meetings. Participants may request financial assistance, with the understanding that resources are limited and the priority for financial assistance is given to developing country participants.

Steward: Mike Holtzhausen (South Africa)

Expertise: A working group of 5 to 7 experts with experience in establishment, implementation and maintenance of pre-inspection and pre-clearance programs.

Approval: Introduced into the work program by ICPM-7 (2005). Specification approved by the Standards Committee in November 2006.

References: Relevant ISPMs and other documents (e.g. NAPPO Regional Standards for Phytosanitary Measures (RSPM) No. 2: *Guidelines for Pre-clearance Programs*).

Discussion papers: Participants and interested parties are encouraged to submit discussion papers to the IPPC Secretariat (ippc@fao.org) for consideration by the expert drafting group.

GUIDELINES ON THE DUTIES OF MEMBERS OF THE STANDARDS COMMITTEE

1. Introduction

ICPM-6 (2004) 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. 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 Terms of reference and Rules of procedure for the SC and other relevant documents contained in the standard setting section of the IPPC Procedural Manual.

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 CPM 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 CPM.

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 CPM
- are presented in the required format for standards
- are written in a simple, clear and focused language.

The CPM has decided that the SC should be made up of experts from different regions. The CPM 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, 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 CPM. 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 Terms of Reference 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

drafting groups 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, maintaining the diversity of global views. Holding extraordinary meetings of the SC should be done in consultation with the Bureau.

4. Decision making

The SC is responsible to collectively make decisions presented for consideration to the CPM. These are recorded in the report of the SC. In certain cases, the SC may agree to use e-mail consultation on specific issues. However, the views of the SC members collected at SC meetings and recorded in SC reports on these issues should be taken into consideration.

5. 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 5.1 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 5.4 and 5.5. The other duties of SC members are listed in the following sections.

5.1 Basic duties directly related to the evaluation of draft standards

The basic duties of the SC member include:

- examination of draft standards from expert drafting groups. Prior to the meeting, the SC member reads the drafts, considers the reports of the expert drafting groups 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 CPM for adoption
  - initiate a further round of consultation or
  - send the draft back to the expert drafting group.

5.2 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 SC-7 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).

5.3 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.

5.4 Duties of SC members in an expert drafting group when they are not a steward

The CPM recommends that each expert drafting group have 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 5.5).The SC member may assist with the expert drafting group more than an ordinary member because of their experience. The duties of a SC member of the expert drafting group who is not a steward may include:

Prior to the meeting of the expert drafting group:

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

During the expert drafting group 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 expert drafting group meeting.

Frequently the SC member is the steward for the standard (see section 5.5).

5.5 Duties of SC members in an expert drafting group when they are a steward

It is intended that most expert drafting groups will have a steward that is a 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 expert drafting group
- 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 in the analysis of country comments.

5.6 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 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.

5.7 The examination of procedural and administrative documents

The CPM adopts procedural and administrative documents (e.g. terms of reference and rules of procedure 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 CPM.

5.8 Other administrative duties

These include:

- approval of the membership of expert drafting groups
- approval of stewards for expert drafting groups
- approval of subjects for specific standards as proposed by technical panels
- 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 CPM.

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 has also been recognized that there is a need to establish stronger links between expert drafting groups and the Standards Committee (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 if possible or from the membership of the expert drafting group.

3. Role of the steward

In general terms, the role of the steward is to oversee a technical panel or assist with the development of a particular standard from the time of the drafting of the specification to the adoption the standard by the Commission on Phytosanitary Measures (CPM) and to provide a linkage between the expert drafting group and the SC. The functions of a steward will vary according to the nature and complexity of the technical panel or standard and the requirements stated in the specification. The steward should assist the Secretariat to ensure that the expert drafting group follows the IPPC standard setting procedures. The steward could be involved in the following sequence of normal standard development.

3.1 Prior to the expert drafting group meeting

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

3.2 At the expert drafting group meeting

The steward would be expected to:

- explain the standard setting process
- explain the requirements of the specification to the expert drafting group 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
- 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 draft ISPMs 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 standard and by attending a workshop.

3.5 Prior to the SC meeting that approves draft ISPMs for adoption at CPM

In preparation for the meeting, the steward should review country comments according to the following guidelines:

- Sufficient time should be allocated to the task of reviewing country comments. In the interests of quality work it should be anticipated that 50 comments per day is the most that can usually be dealt with adequately.
- A standard response key is recommended for primary indication of how a comment has been acted on by the steward. This keyword should precede any other steward comments. There are four options:

- incorporated: where a comment has been acted upon and incorporated exactly as written
- modified: where the comment was acted on, but not exactly as written
- considered: where the comment has not been acted upon at all and has not been incorporated by the steward
- for consideration by SC: this may be where the comment has not been acted on by the steward, not because it has not been incorporated, but because consideration of the full SC is required. In addition, this keyword should be used to indicate where a comment has been acted upon, but it is still necessary to bring it to the attention of the SC for their awareness. This includes comments which the steward believes require review by the SC rather than the steward alone.

- In the interests of transparency for members of the SC, wherever a comment has not been incorporated, a response by the steward may provide some reasoning for this decision.
- To assist the SC, the steward may prepare a list of the comments that require their review. This list should identify (by number) every comment that has been identified as "for consideration by SC".
- As part of this task, the steward should also consider and act upon editorial comments as appropriate.

3.6 At the SC working group (SC-7) meeting that modifies draft ISPMs for the SC prior to being recommended for adoption at CPM

The steward, if not a member of the SC-7, is encouraged to attend the relevant SC-7 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.

3.7 Prior to the CPM meeting at which adoption of the ISPM is considered

Prior to the CPM meeting at which the draft standard is presented for adoption, stewards should be provided with copies of any written comments received. Where possible, the steward should review these comments and provide written suggestions on how best to respond to the comments, accompanied by rationale as appropriate.

3.8 At the CPM meeting at which adoption of the ISPM is considered

Where possible, the steward should participate in any special meeting on the draft standard that takes place at the CPM. This would allow the steward to participate in discussions, as appropriate, and indicate the expert drafting group's intention on various points that may arise.

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 meeting attendance. The estimated time requirements for the involvement of a steward in a single standard is at least eight weeks, including activities such as reading documents, developing discussion papers, attending the expert drafting group meeting, reporting, preparation of a presentation for regional workshops on draft ISPMs, reviewing country comments, attending SC or SC-7 meetings, or briefing SC members. 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.

COMMON PROCEDURES FOR TECHNICAL PANELS

Technical panels should:

1. Respond to requests for work by the CPM and its bodies as directed by the SC. Specific guidance is provided in the specification for each technical panel.

2. Propose topics for new or revised standards (including supplements, annexes, appendices or other components of standards) for inclusion in the CPM work programme. Include the following:
   - reason for inclusion in the work programme
   - priority
   - a draft specification (where appropriate)
   - whether it should be considered under the fast track procedure.

3. Identify work areas that need further research or investigation and propose a strategy for progression of the topic.

4. Identify whether the work of the technical panel overlaps with the work of other IPPC groups and ensure coordination with these groups to prevent duplication of work. Propose a mechanism for any interactions.

5. Consider outcomes and issues of relevant IPPC workshops or meetings or other relevant meetings and monitor technical and scientific progress in the relevant field. Where appropriate, make recommendations to the SC.

6. Propose an annual work programme for the technical panel taking into account the direction given by the SC.

7. Produce a report of each meeting, reporting on all the elements above and presenting, as relevant, new or revised technical panel procedures.

8. Annually produce an executive summary of the work of the technical panel for the SC, including recommendations for action. Report to the SC, through the steward, generally at the May meeting of the SC (or at the November meeting for specific topics if needed).

LIST OF PARTICIPANTS

STANDARDS COMMITTEE MEMBERS	
Mr. Gabriel Olayiwola ADEJARE Head, Technical and Diagnostics Plant Quarantine Service (FDA) P.M.B. 5672 Moor Plantation Ibadan, Oyo State NIGERIA Tel: (+234) 2 231 4183 Fax: (+234) 2 231 2601 E-mail: ladejare2003@yahoo.co.uk	Ms. Julie ALIAGA Program Director, International Standards Animal and Plant Health Inspection Service U.S. Department of Agriculture 4700 River Road, Unit 140 Riverdale, MD 20737 USA Tel: (+1) 301 734 0763 Fax: (+1) 301 734 7639 E-mail: julie.e.aliaga@aphis.usda.gov
Mr. Abdullah AL-SAYANI Director of Plant Quarantine General Directorate of Plant Protection Ministry of Agriculture and Irrigation P.O. Box 26, Zaied Street Sanáa YEMEN Tel: (+967) 1 563 328 Fax: (+967) 1 562 749 E-mail: p-quarantine@yemen.net.ye	Mr. Ringolds ARNITIS Director State Plant Protection Service Ministry of Agriculture Republikas lauk 2 Riga, LV-1981 LATVIA Tel: (+371) 702 7098 Fax: (+371) 702 7302 E-mail: ringolds.arnitis@vaad.gov.lv
Mr. Prabhakar CHANDURKAR Plant Protection Advisor to the Government of India Directorate of Plant Protection, Quarantine and Storage Department of Agriculture and Cooperation Ministry of Agriculture, NH IV Faridabad 121001 INDIA Tel: (+91) 12 9241 3985 Fax: (+91) 12 9241 2125 E-mail: ppa@nic.in	Mr. Sione FOLIAKI Deputy Director Department of Agriculture and Food Ministry of Agriculture, Food, Forests and Fisheries P.O. Box 14 Nuku'alofa TONGA Tel: (+676) 24257 Fax: (+676) 24922 E-mail: maf-qqmd@kalianet.to
Mr. Khidir GIBRIL MUSA Deputy General Manager Plant Protection Directorate P.O. Box 14 Khartoum North SUDAN Tel: (+249) 1 8533 8242; 912 138 939 Fax: (+249) 1 8533 9423 E-mail: khidrigibrilmusa@yahoo.com	Ms. Magda GONZÁLEZ ARROYO Departamento de Exportaciones Servicio Fitosanitario del Estado Ministerio de Agricultura y Ganaderia P.O. Box 70-3006 Barreal de Heredia COSTA RICA Tel: (+506) 260 6721 Fax: (+506) 260 6721 E-mail: mgonzalez@protecnet.go.cr
Mr. John HEDLEY Principal Adviser, International Coordination Biosecurity New Zealand Ministry of Agriculture and Forestry P.O. Box 2526 Wellington NEW ZEALAND Tel: (+64) 4 894 0428 Fax: (+64) 4 894 0731 E-mail: john.hedley@maf.govt.nz	Mr. Mike HOLTZHAUSEN Deputy Director Agricultural Products Inspection Services Private Bag X258 Pretoria 0001 SOUTH AFRICA Tel: (+27) 12 319 6100 Fax: (+27) 12 319 6350 E-mail: mikeh@nda.agric.za; netmike@absamail.co.za

STANDARDS COMMITTEE MEMBERS	
Mr. Robert KARYEIJA Principal Agricultural Inspector Department of Crop Protection Ministry of Agriculture P.O. Box 102 Entebbe UGANDA Tel: (+256) 41 322 458; 320 115; 712 985 542 Fax: (+256) 41 320 642 E-mail: robertkaryeija@yahoo.ca	Mr. Mohammad KATBEH BADER Head of Phytosanitary Department Ministry of Agriculture P.O. Box 11732 Area code 662 Amman JORDAN Tel: (+962) 6 568 6151 Fax: (+962) 6 568 6310 E-mail: katbehbader@moa.gov.jo
Mr. David OPATOWSKI Head Pest Risk Analysis Division Plant Protection and Inspection Services (PPIS) P.O. Box 78 Bet Dagan 50250 ISRAEL Tel: (+972) 3 968 1585; 506 241 745 Fax: (+972) 3 968 1571 E-mail: davido@moag.gov.il	Mr. Michael PHILIP Senior Agricultural Officer Ministry of Agriculture and Rural Development Division of Plant Protection and Quarantine P.O. Box 505, Graeme Hall Christ Church BARBADOS Tel: (+1) 246 428 4150 Fax: (+1) 246 428 7777; 420 8444 E-mail: eephilip@caribsurf.com
Mr. David PORRITT Senior Manager, Plant Biosecurity Biosecurity Australia Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra, ACT 2601 AUSTRALIA Tel: (+61) 2 6272 4633 Fax: (+61) 2 6272 3307 E-mail: david.porritt@affa.gov.au	Mr. Diego QUIROGA Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA) Paseo Colón 367, Piso 7 Buenos Aires ARGENTINA Tel: (+54) 11 4121 5244 Fax: (+54) 11 4342 7588 E-mail: dquiroga@senasa.gov.ar
Mr. Odilson RIBEIRO E SILVA Director Sanitary and Phytosanitary Matters Department Ministry of Agriculture, Cattle and Supply Esplanada dos Ministerios, Bloco D, Sala 352 Brasilia DF 70043-900 BRAZIL Tel: (+55) 613 218 2731 Fax: (+55) 613 225 4738 E-mail: odilson@agricultura.gov.br	Mr. Mazlan SAADON Deputy Director (Import and Export Control) Crop Protection and Plant Quarantine Division Department of Agriculture Jalan Gallagher 50632 Kuala Lumpur MALAYSIA Tel: (+60) 3 2697 7180 Fax: (+60) 3 2697 7164 E-mail: mazlan@doa.gov.my
Mr. Motoi SAKAMURA Principal Officer - Export and Domestic Quarantine Kobe Plant Protection Station Ministry of Agriculture, Forestry and Fisheries 1-1, Hatoba-cho, Chuou-ku Kobe 6500042 JAPAN Tel: (+81) 78 331 2384 Fax: (+81) 78 391 1757 E-mail: sakamuram@pps.go.jp	Mr. Jens-Georg UNGER Head Department for National and International Plant Health Biological Research Centre for Agriculture and Forestry Messeweg 11/12 38104 Braunschweig GERMANY Tel: (+49) 531 299 3370 Fax: (+49) 531 299 3007 E-mail: j.g.unger@bba.de
Mr. Marc VEREECKE Head of Sector Directorate-General - Health and Consumer Protection Phytosanitary Unit European Commission Rue de la Loi 200 B-1049 Bruxelles BELGIUM Tel: (+32) 2 296 3260 Fax: (+32) 2 296 9399 E-mail: marc.vereecke@ec.europa.eu	Mr. Fuxiang WANG Director Plant Quarantine Division National Agro-Technical Extension and Service Center Ministry of Agriculture No 20 Mai Zi Dian Street, Chaoyang District Beijing CHINA Tel: (+86) 10 6419 4524 Fax: (+86) 10 6419 4726 E-mail: wangfuxiang@agri.gov.cn

STANDARDS COMMITTEE MEMBERS	
Mr. Gregory WOLFF International Standards Adviser Plant Health Division Canadian Food Inspection Agency 59 Camelot Drive Ottawa, ON K1A 0Y9 CANADA Tel: (+1) 613 221 4354 Fax: (+1) 613 228 6602 E-mail: wolffg@inspection.gc.ca	

STANDARDS COMMITTEE MEMBERS - UNABLE TO ATTEND	
Mr. Ali ALIZADEH ALIABADI Director Plant Protection Organization of I. R. Iran P.O. Box 4568 Tabnak Avenue, Evin Tehran IRAN Tel: (+98) 21 240 2712 Fax: (+98) 21 240 3197 E-mail: a.alizadeh@agri-jahad.ir	Mr. Abdellah CHALLAOUI Ingénieur en chef Service de la protection des végétaux, des contrôles des semences et plantes B.P. 337 Tanger MOROCCO Tel: (+212) 3993 8780 / 1875; 6477 3107 Fax: (+212) 3993 8780 E-mail: challaoui@yahoo.fr

OBSERVERS	
Ms. Reinouw BAST-TJEERDE CPM Vice-Chairperson and Manager International Plant Protection Issues Plant Health Division Canadian Food Inspection Agency 59 Camelot Drive Ottawa, Ontario K1A 0Y9 CANADA Tel: (+1) 613 221 4344 Fax: (+1) 613 228 6602 E-mail: rbast@inspection.gc.ca	Ms. Marianna THEYSE Assistant Director Plant Health International Standards Directorate Plant Health Private Bag 14 Gezina 0031 SOUTH AFRICA Tel: (+27) 12 319 6091 Fax: (+27) 12 319 6101 E-mail: mariannat@nda.agric.za
Mr. Nico VAN OPSTAL Director General European and Mediterranean Plant Protection Organization (EPPO) 1 rue Le Nôtre 75016 Paris FRANCE Tel: (+33) 1 4520 7794 Fax: (+33) 1 4224 8943 E-mail: vanopstal@eppo.fr	

IPPC SECRETARIAT	
Mr. Brent LARSON, Standards officer Ms. Fabienne GROUSSET, Information officer Ms. Jane CHARD, Technical panels officer Ms. Stacie JOHNSTON, Standard setting assistant	IPPC Secretariat Food and Agriculture Organization of the UN Viale delle Terme di Caracalla 00153 Rome, Italy Tel: (+39) 06 5705 4812 Fax: (+39) 06 5705 4819 E-mail: ippc@fao.org