REPORT

**Rome,
Italy,
29 March -
02 April
2004**

Sixth Interim Commission on Phytosanitary Measures

Food and Agriculture Organization of the United Nations

Report of the

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2004

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Report of the Sixth Session of the Interim Commission on Phytosanitary Measures

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SIXTH INTERIM COMMISSION ON PHYTOSANITARY MEASURES

Rome, 29 March - 02 April 2004

REPORT

1. OPENING OF THE SESSION

1. The Chairperson, Mr Lopian opened the meeting by welcoming the delegates. Mr Solh (Director of the Agricultural Plant Production and Protection Division, FAO) gave an opening statement on behalf of Ms Fresco (Assistant Director-General, Agriculture Department). He welcomed delegates on behalf of the Director General of FAO.

2. Mr Solh noted the range of issues on the agenda and made some observations about the past year's activities and the challenges ahead. He announced that FAO Conference had agreed to increase funding for IPPC activities. He noted that this increase had been adopted despite a very difficult budget climate and recognized the importance of the IPPC to Member Countries.

3. The importance of the ICPM in the harmonization of plant protection and facilitation of trade while preventing pest spread was highlighted. The ICPM was reminded that it needed to continue to play a principal role in international developments on this issue. The proposed changes in the standard-setting process were seen as a positive step forward in maximising the quality and quantity of standards.

4. The critical need to assist and support developing countries to fully participate in the IPPC was raised. Mr Solh emphasized the importance of the Special Trust Fund and the use of Regional Workshops in assisting developing countries. New Zealand and Canada were thanked for their contributions to the Special Trust Fund and members were urged to follow their example. The importance of information exchange was highlighted and Mr Solh noted that 2004 should see much increased use of the International Phytosanitary Portal (IPP) for this purpose.

5. The ICPM noted the Statement of Competence and Voting Rights Submitted by the European Community and its Member States[1].

1.1 Appointment of Rapporteur

6. Mr Kurzweil (Austria) was elected by the ICPM as rapporteur.

2. ADOPTION OF THE AGENDA

7. The Chairperson noted that Mr Chinappen, Vice-Chairperson of the ICPM, was unwell and therefore unable to attend the meeting. Mr Komayombi (Uganda) was appointed as Vice-Chairperson for the present meeting.

8. The agenda was adopted (Appendix I[2]). It was noted that several changes in the sequence of agenda items would be made.

3. REPORT BY THE CHAIRPERSON[3]

9. Mr Lopian noted that the most important issue for the IPPC in 2003-2004 had been its financial situation. An increased budget had been approved by FAO Conference in November 2003

[1] ICPM 04 INF-17
[2] ICPM04/1 – Rev 1
[3] ICPM 04 INF-3

under the Regular Programme of FAO for the biennium 2004-2005. Some of the resources for this biennium would come from arrears, which were available for a limited time. He stressed that, since the business plan foresaw a significant budget increase for the next biennium (2006-2007), an increased support to IPPC activities would be needed. The Bureau of the ICPM and the Strategic Planning and Technical Assistance Working Group (SPTA) believed that long-term funding strategies would be necessary. He invited members to take this into account in future discussions.

10. The Chairperson highlighted the vital importance of standard-setting activities and on the recognized need to increase the number of standards. This issue had been extensively discussed in 2003, and several groups had finalized proposals in relation to the improvement of standard setting and to a fast-track procedure for standards.

11. An important event in 2003 had been the organization of an IPPC Workshop on “Invasive Alien Species and the International Plant Protection Convention”, with the support of the German Government. It had been attended by 110 participants with a large participation from developing countries. Proceedings would be published. This success may raise the thought that such IPPC workshops could be organized on a regular basis on important topics. It was clarified that the report of this workshop would not constitute an official document of the IPPC, but would be for information.

12. The Chairperson also noted the cooperation between the IPPC and other organizations. The Secretariats of the IPPC and of the Convention on Biological Diversity (CBD) had signed a Memorandum of Cooperation. Cooperation between these organizations could also include joint activities of their relevant governing bodies. Regarding the Agreement on Sanitary and Phytosanitary Measures of the World Trade Organization (SPS Agreement of WTO), the SPS Committee had engaged in the clarification of some articles of the SPS Agreement, which might have an impact on the IPPC and its standards. He believed that the three standard setting organizations under the SPS Agreement (IPPC, Office International des Epizooties and Codex Alimentarius of FAO) could investigate future joint activities to promote synergies and avoid overlap.

13. The Chairperson emphasized the importance of the Special Trust Fund. This fund was now active and contributions had been received from New Zealand and Canada. He noted that, at the SPS Committee in March 2004, countries had been invited to contribute to such Trust Funds established under standard-setting organizations. The Special Trust Fund of the IPPC was designed for the benefit of developing countries. By ensuring their effective participation in all IPPC activities, it would ultimately lead to a better phytosanitary situation worldwide. The Chairperson invited potential donor countries and organizations present at the ICPM to contribute to the Special Trust Fund.

4. REPORT BY THE SECRETARIAT[4]

4.1 Standard Setting

14. The Secretariat summarized the standard-setting activities undertaken during 2003. Due to additional resources, all items on the work programme for standard setting had been initiated and several Expert Working Group (EWG) meetings had been convened. The Third Meeting of the Standards Committee (SC) had resulted in the approval of two draft standards and one supplement to a standard for submission to the ICPM for consideration and subsequent approval.

15. Progress on finalizing draft standards by e-mail was slow and, in consultation with the ICPM Bureau and the SC, several EWG had been able to convene face-to-face meetings.

16. The Secretariat reported on the Workshop on "Invasive alien species and the IPPC", an international consultation of participants from national phytosanitary services and environmental protection agencies which had been convened in Braunschweig, Germany in September 2003. This

[4] ICPM 04 INF-4

workshop had reviewed the use of International Standards on Phytosanitary Measures (ISPM) for the management of invasive alien species, in particular ISPMs on pest risk analysis. As a result of this meeting, another workshop on pest risk analysis was being planned in Canada in autumn 2005.

17. The Secretariat reported that the International Forest Quarantine Research Group (IFQRG) had met in February of 2004 to review the issues on treatments for wood packaging. Several sub-committees had been formed to continue the review and prepare recommendations on this subject.

4.2 Information Exchange

18. The Secretariat reported on the information exchange work programme. This programme included the continued distribution of ISPMs in all FAO official languages, official correspondence with Members, the distribution of IPPC promotional material and the updating of official contact point information. It had become apparent that many Members were not providing the Secretariat with the latest official contact point information. This negatively impacted on official communication and countries were urged to update this information as soon as possible.

19. The IPP continued to be developed and the IPP Support Group had first met in January 2004. Its recommendations were in the process of being implemented. The IPP CD-Rom was distributed at the meeting.

4.3 Dispute Settlement

20. After consultation between the IPPC Secretariat and the Chairperson of the Subsidiary Body on Dispute Settlement (SBDS), it had been decided that the SBDS would meet during the ICPM and the Chairperson would report later during the present meeting.

4.4 Technical Assistance

21. The Secretariat presented its activities in support of the development of phytosanitary capacity of members. It noted the facilitation of developing countries to attend the ICPM and workshops convened by the Secretariat, through funds provided by the EU, COSAVE, Germany, Australia and the US.

22. The Secretariat planned to convene an Informal Working Group on Technical Assistance, as agreed to by ICPM 5, in 2004, to provide guidance to the Secretariat and recommendations to the ICPM. Other technical assistance activities were reported under other agenda items.

4.5 Maintenance of an Effective and Efficient Administrative Framework

23. The ICPM noted activities of the Secretariat related to the maintenance of an effective and efficient administrative framework, in particular the publication of reports and standards, and the organization of meetings that concerned the mechanism of standard setting and forward planning. It thanked the North American Plant Protection Organization (NAPPO) and the European and Mediterranean Plant Protection Organization (EPPO) for their valuable assistance on translation issues.

4.6 Promotion of the IPPC and Cooperation with Relevant International Organizations

24. The Secretariat reported that it had been represented at a range of meetings with international and regional organizations including WTO-SPS, CBD and the World Bank. A lack of human resources had limited participation in other meetings. It noted that, resources permitting, an informal working group on research and educational liaison, which had been planned for early 2004, would be held before the next meeting of the SPTA.

5. REPORT OF THE 15TH TECHNICAL CONSULTATION AMONG REGIONAL PLANT PROTECTION ORGANIZATIONS

25. The Chairperson of the 15th Technical Consultation (TC) among Regional Plant Protection Organizations (RPPOs), Mr Ivess (New Zealand) introduced the report[5]. The TC had noted the widespread support for increased funding for the IPPC and actions taken in their various regions. It had discussed the status of implementation of the ISPMs in RPPOs' member countries and highlighted the need for supporting activities to increase implementation of the ISPMs. Several issues of concern had been discussed regarding the implementation of ISPM No. 15 (*Guidelines for regulating wood packaging material in international trade*). The TC had provided comments on the recommendations of the Focus Group regarding proposals for improving the current standard setting process and for a fast-track mechanism for standard setting. The Inter-African Phytosanitary Council announced that the 16th TC would take place in 2004 in Nairobi, Kenya.

26. The ICPM:
1. Noted the report.

6. REPORT OF OBSERVER ORGANIZATIONS

6.1 Report of the Activities of the Sanitary and Phytosanitary Committee and other Relevant WTO activities in 2003

27. The WTO representative presented a report which provided a summary of the activities and decisions of the WTO-SPS Committee during 2003[6]. She identified the work of relevance to the ICPM and IPPC, including: equivalence; regionalization; monitoring the use of international standards; technical assistance. She summarized the phytosanitary trade concerns raised in the SPS Committee in 2003 and in the first meeting of 2004. The WTO encouraged the ICPM to continue its work on ISPMs on equivalence and efficacy of measures, and in addition requested the ICPM to pursue further work on regionalization. A document containing excerpts on phytosanitary concerns raised in the WTO-SPS committee from 1995 to 2003, "Specific Trade concerns" (G/SPS/204/Rev.4), was referred to and distributed. Regarding the monitoring of international standards, the WTO representative noted that several concerns regarding implementation of ISPM No. 15 had been raised in the SPS Committee in 2003 and again at the first meeting in 2004. Regarding technical assistance, she thanked the Secretariat for its contribution in participating in WTO–SPS technical assistance workshops and encouraged the IPPC to continue its participation in these workshops. Concerning dispute settlement, the WTO representative indicated that, in 2003, dispute settlement reports had been issued in the case regarding trade restrictions due to *Erwinia amylovora*, and that three new dispute settlement panels had been established to consider complaints alleging violation of the SPS Agreement. She noted that it was likely that the panels examining these new complaints would seek scientific advice, including from phytosanitary experts.

28. The ICPM:
1. *Noted* the information contained in the report.
2. *Agreed* to take into account relevant issues in this report when developing the ICPM work programme.

6.2 Report on the Convention on Biological Diversity

29. The CBD representative summarized the decisions from the Seventh meeting of the Conference of the Parties and the First meeting of the Conference of the Parties of the Convention serving as the meeting of the Parties to the Cartagena Protocol on Biosafety. In particular, the CBD representative referred to the decision requesting the Executive Secretary to develop a joint work

[5] ICPM 04 INF-5
[6] ICPM 04 INF-6

programme on invasive alien species with the ICPM, and to the decision inviting international organizations to provide any guidance material related to risk assessment and risk management of living modified organisms.

30. The ICPM:
1. *Noted* the information contained in the report[7].
2. *Agreed* to take into account relevant issues in this report when developing the ICPM work programme.

7. STRATEGIC DIRECTION NO. 1: THE DEVELOPMENT, ADOPTION AND MONITORING OF THE IMPLEMENTATION OF INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES (ISPMS) (STANDARD SETTING)

7.1 Report of the Standards Committee

31. Mr Vereecke, Chairperson of the SC, presented a report of the activities of the SC in 2003[8].

32. The SC-7 had met twice during the year with Mr Klag as the Chairperson. The SC-7 had agreed to minor modifications to the model specifications for standards. These involved adding a section on "reason for the standard/reason for revision" and modification of the section on "scope" to "scope and purpose". Seven draft specifications had been produced according to the modified model. These had been finalized and approved by SC-20 by email, placed on the IPP and provided to the relevant expert working groups. The SC-7 had identified suitable stewards for the standards. Stewards were approved by SC-20 in consultation with the Secretariat.

33. The SC-7 had considered four draft standards. Three of these had been approved for country consultation with modifications. The SC-7 did not consider that the draft standard on efficacy of measures was ready for country consultation. In order to better target work on this standard, the SC-7 had revised the specification, particularly with regard to the scope of the standard. The SC-7 had noted that this standard had been a priority for 2002 but was not listed on the 2003 work programme. However, because this ISPM could not be completed last year, the SC-7 considered it should remain a priority for the current years work programme.

34. The SC had considered the concerns expressed by ICPM-5 that transparency on the consideration of comments by the SC should be improved. It was noted that this issue had been considered extensively by the Focus Group on standards development in developing recommendations on improvements in the standard setting process which would be dealt with under a separate agenda item in this ICPM.

35. The November meeting of the SC-7 had considered over 1200 comments provided on the three draft standards that had been sent for country consultation. Consideration of country comments could not be completed by the SC-7 and this work had been completed by the SC-20 meeting, back-to-back with SC-7. The final draft of the three standards were proposed for adoption during this ICPM. With regard to the draft standard on pest risk analysis for living modified organisms, the SC-20 had noted that there was broad agreement on the technical content of the supplement but significant differences had remained on how the text should be incorporated into ISPM No. 11. The SC-20 had agreed to request ICPM-6 to provide guidance on this issue. The November meeting of the SC-20 had also finalized two specifications for new standards.

36. Mr Vereecke raised a number of issues related to the SC-7/SC-20 working pattern. These included the inability for all SC members to attend meetings and the work load imposed by the very large number of comments received (1200 in 2003 compared to 315 in 2002). However, despite these

[7] ICPM 04 CRP-5
[8] ICPM 04 CRP-9

issues, the SC had been able to complete all of its work in 2003. A number of issues related to the SC were discussed under other agenda items.

7.2 Adoption of International Standards

37. The Secretariat introduced the three documents for consideration by the ICPM, which consisted of two new standards (*Guidelines for a phytosanitary import regulatory system*, *Pest risk analysis for regulated non-quarantine pests*) and of a supplement to ISPM No. 11 on *Pest risk analysis for living modified organisms*. Open-ended working groups were established to consider the draft standards and the issues raised.

7.2.1 *Guidelines for a phytosanitary import regulatory system*

38. The open-ended working group was chaired by Mr Ribeiro e Silva (Brazil). The group adjusted the text[9] based on comments made in the plenary.

39. The ICPM:
1. *Adopted* the standard *Guidelines for a phytosanitary import regulatory system* (Appendix II)
2. *Recommended* that the Glossary Working Group should review the understanding of the current relationship between *infestation* and *infection* in relation to latency.

7.2.2 *Pest risk analysis for regulated non-quarantine pests*

40. The open-ended working group was chaired by Mr Canale (ICPM Vice-Chairperson). The group adjusted the text[10] based on a small number of comments made in the plenary.

41. The ICPM:
1. *Adopted* the standard *Pest risk analysis for regulated non-quarantine pests* (Appendix III).
2. *Noted* the suggestion by the Glossary Working Group that the definitions for *pest risk assessment (for regulated non-quarantine pests)* and *pest risk management (for regulated non-quarantine pests)* should be reinstated in the standard. It *requested* that these terms should go out for country consultation with the next amendments to the Glossary.
3. *Noted* concerns raised on the terminology "the main source of infestation" in the standard. It *considered* that it may be more appropriate to use the terminology "a main source of infestation". It *suggested* that this issue might have to be revisited once more experience had been gained with regulated non-quarantine pests.

7.2.3 Supplement to ISPM No. 11 (*Pest risk analysis for quarantine pests*) on pest risk analysis for living modified organisms

42. The open-ended working group was chaired by Mr Roberts (IPPC Secretariat). The group adjusted the text[11] based on comments made in the plenary.

43. The representative of Norway supported adoption of the draft ISPM but noted that this should be without prejudice to the provisions of the Cartagena Protocol on Biosafety of the Convention on Biological Diversity.

44. The ICPM:
1. *Adopted* the supplement to ISPM No. 11 (*Pest risk analysis for quarantine pests*) on pest risk analysis for living modified organisms (Appendix IV).

[9] ICPM 04/2 Annex I
[10] ICPM 04/2 Annex II
[11] ICPM 04/2 Annex III

2. *Requested* that the Secretariat should remove the boxes around the text and carry out any minor editorial changes relating to the removal of the boxes that do not affect the meaning.
3. *Requested* the Secretariat to identify in a clear way the text originating from the original ISPM No. 11 (adopted in 2001), from the supplement on analysis of environmental risks (adopted in 2003) and from the supplement on pest risk analysis for living modified organisms (adopted in 2004).
4. *Requested* the Secretariat make clear, in the section on *Endorsement*, the ICPM adoption of the different sections.
5. *Decided* that the final version as prepared by the Secretariat be approved by the Standards Committee before printing and distribution.

7.3 Topics and Priorities for Standards

45. The Secretariat introduced a paper on topics and priorities for standards[12]. In 2003, work had been initiated on all items in the work programme. However, it was noted that work on standards by e-mail was slow and that the Secretariat was forecasting face-to-face meetings on these standards whenever possible. It was noted that specifications for standards had to be developed and approved by the Standards Committee prior to work by a Technical Panel or an Expert Working Group. To allow ample time for the development of specifications, a work programme covering at least 2 years was required.

46. Various suggestions for new standards were presented. The Chairperson indicated that these ideas would be noted by the Secretariat and included on the list provided to the SPTA for developing suggestions for standards development for ICPM-7. The Secretariat reported that it continued to maintain a database of all suggestions for new standards.

47. Priority will continue to be given to work that has already been started in order to finalize existing draft standards.

48. The ICPM will consider the development of a phytosanitary quarantine treatment manual after the submission of draft specifications. The US agreed to draft specifications on a treatment manual for presentation to the SC in April 2004.

49. With regard to a concept standard on electronic certification, it was noted that a UN group was working on certain aspects of electronic certification. The Secretariat was asked to invite a representative from this group to submit a report to ICPM-7 and on the basis of that report consider further work on this subject.

50. The ICPM:
1. *Endorsed* the action of the Secretariat in facilitating wherever possible the completion of standards that are already at an advanced stage of development.
2. *Adopted* the topics as outlined in Appendix V giving high priority to some standards, as indicated.
3. *Agreed* to have proposals for topics for new standards submitted by NPPOs, RPPOs and the WTO-SPS Committee on an annual basis no later that the 1st of October of each year.

7.4 Implementation of ISPM No. 15: *Guidelines for Regulating Wood Packaging Material in International Trade*[13]

51. The Secretariat noted that problems with the wood packaging mark in ISPM No. 15 had been resolved in 2003 and many countries were now moving to fully implement the requirements and provisions of this ISPM.

[12] ICPM 04/3
[13] ICPM 04/4, ICPM 04 INF-7

52. It was indicated that data on methyl bromide treatments, and proposals from companies for alternative treatments, had been referred to the International Forest Quarantine Research Group (IFQRG) for scientific advice. The IFQRG had convened in February 2004.

53. It was noted that a presentation had been made to the SPTA about practical problems in implementation of ISPM No. 15 in areas such as repaired wood packaging, old wood packaging material and treated sawn wood. The SPTA had recognized that it was important to identify difficulties, and move to resolve them.

54. Dr. Eric Allen, chairperson of the IFQRG, briefed the ICPM on the IFQRG meeting held in February 2004 in Rome. The IFQRG is an independent body that brings phytosanitary and scientific communities together for discussion and collaborative research on forest quarantine matters. Sub-committees of this group address subjects such as ionizing radiation, bark infestation research, fumigation and heat treatment, global interception database and implementation. Several delegations asked that the SC should coordinate the work of the IFQRG. However, it was noted that the IFQRG is not an official body of the ICPM and could not be coordinated by the SC.

55. It was noted that ICPM-5 requested the IFQRG to utilize their expertise to review scientific data on treatments of wood. Treatment recommendations would be provided to Expert Working Groups and the Standards Committee for their consideration.

56. Several countries raised questions about the ISPM No. 15 mark. The legal office of FAO indicated that the process to register the mark had been ongoing since the last ICPM. FAO had applied for registration through a collective registration process under the Madrid Agreement Concerning Registration of Marks and its Related Protocol, and in certain countries not party to this Agreement or Protocol on the basis of advice from the office handling registrations and in light of limited available resources. In total, FAO had applied to register the mark in 82 countries.

57. The legal office also noted that the mark was available for use by all contracting parties and FAO members, in accordance with ISPM No. 15. It was not necessary for the mark to be registered in a particular country in order for that country to be able to use it. The mark was authorized for use by NPPOs and any user authorized by an NPPO in its country. In accordance with ISPM No. 15, the NPPO needed to have a system in place to assure proper use of the mark.

58. The legal office also noted that it was not necessary for countries to have a supplemental (license) agreement to use the mark, unless required by the laws of a particular country. An agreement had been developed for one country. In summary, the legal office highlighted that the mark was fully available for use by all countries, in accordance with ISPM No. 15.

59. Other legal questions related to the timing to implement ISPM No. 15. It was asked whether concerns relating to the efficacy of methyl bromide as a treatment could delay implementation. The legal office noted that the standard was validly adopted in March 2002 and therefore was in effect.

60. The Chairperson then invited comments on implementation of ISPM No. 15 generally. Many delegations indicated they were having difficulties implementing the standard. Comments addressed the following:

- efficacy of methyl bromide treatment, and whether this should delay or change implementation
- whether implementation could be delayed, in light of difficulties in putting the necessary systems and procedures in place for approved treatments
- the technical justification of the application of the standard taking account of the conditions in the exporting and importing countries
- whether the treatments are technically and economically feasible, and how this relates to development of alternative treatments
- assistance to developing countries

- a proposal for a 2 – 3 day meeting to address these items
- whether implementation actions could be posted on the IPP.

61. An open-ended working group, chaired by Mr van der Graaff (IPPC Secretariat), discussed implementation issues. It discussed the efficacy of methyl bromide treatment and alternatives to methyl bromide. It recommended to refer these issues to the Standards Committee, which may seek additional scientific advice from the IFQRG. The working group also discussed issues concerning the timing of the implementation of the standard. The group recommended a draft text for consideration.

62. The ICPM:
1. *Decided* that issues on methyl bromide treatment and alternatives to methyl bromide be referred to the Standards Committee which may seek additional scientific advice from the IFQRG.
2. *Agreed* that any changes to ISPM No. 15 would be subjected to the normal standard setting process and approved by the ICPM.
3. *Recognized* the current difficulties of many countries, especially developing countries, in implementing ISPM No. 15. It therefore *recommended* that members take into account the provisions of paragraph 3.3 of ISPM No. 15, where appropriate.
4. *Encouraged* members, especially developed countries, to assist countries in achieving implementation of the standard in accordance with Article X of the IPPC.
5. *Agreed* to a workshop on the practical application of ISPM No. 15 in accordance with the outline laid down in Appendix VI and subject to the availability of extra-budgetary resources.

8. STRATEGIC DIRECTION NO. 5: THE MAINTENANCE OF AN EFFECTIVE AND EFFICIENT ADMINISTRATIVE FRAMEWORK

8.1 Acceptance of the New Revised Text of the IPPC and Issues Related to Coming into Force

63. The Secretariat presented a paper on this agenda item[14]**.** The paper provided a status report on adherences to the Convention and acceptances of the New Revised Text, and identified steps (and model forms) for additional countries to submit their adherences and/or acceptances. The paper also identified possible actions that will need to be taken for the transition from the current procedures to entry into force of the New Revised Text. The ICPM was informed by the Secretariat that the number of contracting parties to the IPPC had increased to 127, and that 56 contracting parties had accepted the New Revised Text.

64. Following discussion, the ICPM:
1. *Noted* the analysis of issues provided in Annex 1 of ICPM 04 INF-8.
2. *Urged* contracting parties that have not accepted the new revised text to do so as soon as possible.
3. *Urged* FAO Members and non-member States that are not contracting parties to the IPPC to become contracting parties and accept the new revised text as soon as possible.
4. *Requested* the Secretariat to prepare a document, for review at ICPM-7, containing draft recommendations on topics identified in Part 4 of Annex 1 (of ICPM 04 INF-8) that could be forwarded to the first meeting of the Commission on Phytosanitary Measures for its consideration.

8.2 Report of the 5th Meeting of the Informal Working Group on Strategic Planning and Technical Assistance

65. A summary of the 5th Meeting of the Informal Working Group on Strategic Planning and Technical Assistance (SPTA) was presented to the ICPM[15]. The ICPM was informed that all the substantial issues discussed at this meeting were dealt with under separate ICPM agenda items.

[14] ICPM 04 INF-8
[15] ICPM 04 INF-9

66. The ICPM:
1. *Noted* the report of the SPTA.

8.3 Financial Report

67. The Secretariat presented the financial report for 2003, including expenditures and extra-budgetary resources available[16]. It was noted that arrears money from assessed contributions had been available, which was an exceptional situation. The extra-budgetary resources available in 2003 had allowed work to start on all standards of the work programme.

68. The ICPM:
1. *Noted* the report.

8.4 Budget Plan

69. The Secretariat introduced the budget plan for 2004[17] and noted that this was still subject to discussion by the FAO Programme and Finance Committee in May. Sufficient funds should be available to execute the business plan for 2004-2005. However, a lower level of activity would have to be planned for 2006-2007, unless additional resources could be found.

70. The ICPM:
1. *Noted* the budget plan.

8.5 Special Trust Fund

71. The Special Trust Fund[18] and its financial guidelines had been approved at ICPM-5. The SPTA had later made recommendations with regard to the allocation of funds, to standard setting activities, Phytosanitary Capacity Evaluation and information exchange. The funds received from New Zealand and Canada were reported. The Secretariat outlined that the Special Trust Fund was subject to FAO's policy for charges for administrative and operational support, and noted that the guidelines should be reviewed accordingly.

72. Regarding the allocation of funds, the meeting agreed that 15% of the Special Trust Fund should be allocated to special technical assistance as determined by the ICPM, for example to help developing countries with implementation of ISPM No. 15. It was agreed that the funds from the Special Trust Fund allocated to Phytosanitary Capacity Evaluation (PCE) should be increased at the expense of information exchange. The ICPM amended the table on future expenditures of funds for the trust fund.

73. The ICPM:
1. *Agreed* to the Secretariat developing a strategy for promoting the Special Trust Fund and encouraging donors to contribute to it.
2. *Agreed* that the first $US500,000 received be used to support attendance at the ICPM and at regional workshops on draft ISPMs, and technical assistance for the implementation of ISPMs, with additional funds allocated to the PCE and information exchange.
3. *Agreed* that funding for PCE, information exchange and general operating expenses should not exceed 30% of the total funds received.
4. *Agreed* to the proposed allocations of funding to different activities shown in Appendix VII.
5. *Agreed* that the updated financial guidelines for the Special Trust Fund be submitted to the next session of the ICPM, in consultation with the SPTA and the Bureau.

[16] ICPM 04 INF-10
[17] ICPM 04 INF-11
[18] ICPM 04/5, ICPM 04/5 Add-1

6. *Agreed* that point 12.1 of the financial guideline be amended to read "Administrative expenditures charged according to FAO's financial rules, regulations and current policy on project support costs".
7. *Thanked* the EC for its generous contribution to participants' travel, and New Zealand and Canada for their contribution to the Special Trust Fund.

8.6 Strategic Plan and Business Plan

74. The Secretariat introduced the item[19]. The Strategic Plan had been considered in detail by the SPTA. The SPTA had recommended that the Plan be redrafted in 2004 as part of a general review of the work programme, the Business Plan and the Strategic Plan. It had recommended that a Focus Group be convened to carry out this activity, and also consider long-term funding arrangements for the IPPC. Several members made proposals for modifications. The ICPM referred these modifications to the Focus Group for consideration.

75. The ICPM:
1. *Noted* the revised Strategic Plan (see Appendix VIII).
2. *Decided* that a Focus Group undertake a review of the ICPM activities and update the Strategic and Business Plans for consideration by the SPTA in 2004 and the ICPM in 2005.
3. *Decided* that the Focus Group also analyze long-term funding options for consideration by the SPTA in 2004 and the ICPM in 2005.

8.7 Improvements to the Standard Setting Procedure

76. The Chairperson presented the improvements to the standard setting procedure as proposed by the Focus Group and amended by the SPTA and the TC of RPPOs[20]. Comments were made in the plenary on issues including the proposed reduction of the length of consultation period from 120 to 90 days, the proposed mechanisms to increase transparency, the establishment and operation of Technical Panels (TP), the role of stewards, the out-of-session approval of standards, the work load of the SC. An open-ended working group was established to consider the issues expressed in the plenary, and resolved outstanding issues. It was chaired by Mr Ashby (UK).

77. The ICPM:
1. *Noted* the report of the Focus Group[21].
2. *Noted* the recommendations on the Focus Group report from the Technical Consultation of RPPOs and the SPTA summarized in Annex A of ICPM 04/7.
3. *Adopted* the recommendations of the SPTA on improvements in the current standards setting process, as amended (Appendix IX), noting the need for the SC to draft guidelines for stewards.
4. *Adopted* the recommendations of the SPTA on the proposed fast-track standard setting process, as amended (Appendix X).
5. *Limited* the role of TPs to the fast-track standard setting process and to providing technical advice to the Standards Committee when requested. However, it recognized that there may be occasions when it is appropriate to seek advice from TPs for some standards being developed under the regular standard setting process.
6. *Approved* the principle of adoption in ICPM without discussion, with the understanding that this principle would not limit the right of countries to make comments or intervene with comments.
7. *Agreed* to the reduction of the consultation period from 120 days to 100 days, for both the regular and fast-track standard setting processes.
8. *Decided* to put the improvement of the current standard setting process and the fast-track standard setting process in place on a trial basis, for one and two years respectively, and *requested* the Standards Committee to report back to the ICPM on the use of TPs.

[19] ICPM 04/6
[20] ICPM 04/7
[21] ICPM 04 INF-2

9. *Requested* the Secretariat to post the English version of standards for country consultation on the IPP as soon as available and prior to official dispatch, and to continue to post other languages once translated.
10. *Requested* the Secretariat to continue to send out a hardcopy of the standards to the IPPC contact points in NPPOs.
11. *Decided* that the 100 day consultation period will begin from the date these documents are mailed.
12. *Encouraged* IPPC contact points in NPPOs to send their national official comments by e-mail.

13. *Adopted* the changes proposed by the SPTA to section 5 of the Terms of Reference of the Standards Committee to allow for the establishment and disestablishment of technical panels (see Appendix XI).
14. *Agreed* that changes proposed by the SPTA to the Terms of Reference of the Standards Committee be referred to the SC and SPTA for consideration with other proposed changes for the development of recommendations for amendment of the Terms of Reference to be submitted to ICPM-7.

8.8 Composition of the Standards Committee

78 The ICPM considered a proposal submitted by the Asian regional group on the increase of membership in the Standards Committee to improve the regional balance[22]. This proposal was adopted with an amendment.

79. The timing of the implementation of the increase of the Standards Committee membership and the terms of reference were reviewed in an open-ended working group chaired by Ms Thomas (Jamaica). The working group resolved all outstanding issues.

80. The ICPM:
1. *Amended* the number of Standards Committee members laid down in the Terms of Reference as follows (per FAO region): Africa (4), Asia (4), Europe (4), Latin America and the Caribbean (4), Near East (4), North America (2), Southwest Pacific (3).
2. *Decided* that the five new Standards Committee members would be nominated by their respective regions and submitted to the Secretariat by the end of September 2004. These new members would be invited to attend the November 2004 Standards Committee meeting as observers. They would be confirmed by ICPM-7.
3. *Requested* the Standards Committee Terms of Reference and Rules of Procedure be analyzed by the Standards Committee and SPTA. Resulting changes would be submitted to ICPM-7 for consideration.
4. *Requested* the SC and SPTA to consider specifically the following points: items listed in Appendix XI of the present report, items from document (ICPM 04 CRP-8) on the mechanism of substitution or replacement of members of the Standard Committee, the removal of the 6 year limit, the increase in the term of membership to 3 years, how often the SC should meet, the number of expert working groups that may be formed, and issues raised in the report of the Standards Committee Chairperson (ICPM 04 CRP-9).

8.9 Selection of the Standards Committee Chair and Membership of the Standards Committee Working Group

81. In introducing the item[23], the Secretariat informed the ICPM that, with the election of a new Standards Committee, there was a need for a full meeting of the SC in May in order to select the SC-7. In addition, the volume of work facing the Standards Committee also indicated the need for full sessions of the Standards Committee in May 2004 and 2005. It was suggested that this change be permanent, but it was agreed to review this in two years time at the ICPM.

[22] ICPM 04/8
[23] ICPM 04/9

82. The ICPM:
1. *Agreed* to a full session of the Standards Committee in April/May, for both 2004 and 2005.

8.10 Role and Functions of the Informal Working group on Strategic Planning and Technical Assistance

83. The Secretariat presented a paper on the role and function of the SPTA[24]. The recommendations made by the SPTA on its long term role and composition were considered, commented on and amended. Several members proposed that the SPTA become a more formal and permanent body.

84. The ICPM:
1. *Recognized* the very important role the SPTA has played and its contribution to increasing the profile of and the funding for the IPPC.
2. *Recognized* that the linkage between Strategic Planning and Technical Assistance was important.
3. *Recognized* that the open-ended nature of the working group had allowed the input of those particularly interested in this subject and had allowed flexibility.
4. *Noted* that there were some shortcomings in the current operation of the SPTA.
5. *Agreed* that a proposal on a sound structure be developed by the Focus Group, analyzed by the SPTA and be submitted to ICPM-7.
6. *Decided* that the Secretariat facilitate the participation of two representatives from developing countries per FAO region at the next SPTA.
7. *Agreed* that an Expert Working Group is to be convened to consider technical assistance.
8. *Agreed* that the SPTA maintain overall administrative and financial oversight of technical assistance matters.

8.11 Role and functions of Regional Plant Protection Organizations

85. The Secretariat introduced the document presenting recommendations made by the SPTA on the future role and functions of RPPOs[25].

86. The ICPM:
1. *Agreed* that a group including three representatives of RPPOs would meet in 2004 to consider the role and function of RPPOs, back-to-back with the Focus Group on the Business Plan and Strategic Plan. The RPPOs would be responsible for choosing their representatives.
2. *Agreed* that the group would analyse the possible roles and functions of the RPPOs with regard to the Convention and consider which of the strategic goals and directions RPPOs could provide support for.
3. *Decided* that an analysis of the current functions and capacities of RPPOs be provided as an input to the group.
4. *Decided* that the report of this group would be sent to the 16th Technical Consultation among RPPOs for comment and, through the SPTA, be submitted for discussion at the ICPM.
5. *Noted* that RPPOs have already consulted to select three representatives (Comite de Sanidad Vegetal del Cono Sur - COSAVE, European and Mediterranean Plant Protection Organization - EPPO, Inter-African Phytosanitary Council - IAPSC).

8.12 Procedures for Urgent Alteration or Suspension of ISPMs after Adoption

87. In response to the request of the SPTA, the Secretariat presented a paper examining whether and in what circumstances a recommendation may be made to suspend implementation of an ISPM outside ordinary procedures[26].

[24] ICPM 04/10
[25] ICPM 04/11
[26] ICPM 04 INF-12

88. The reasons for which FAO had a duty to recommend suspension of the original "no-bug" logo of ISPM No. 15 were described. This unforeseen situation could have led to significant adverse operational, legal and financial impacts on the ability of FAO to carry out its mandates and responsibilities. In the event that a future action poses such a risk on the ability of FAO to carry out its mandate, appropriate responsive action may again be needed.

89. Following discussion, the ICPM:
1. *Noted* that emergency suspension or withdrawal of an approved ISPM or elements of an ISPM, as had occurred in the case of the original ISPM No. 15 logo, was an extremely unlikely event.
2. *Noted* that each situation needed to be evaluated on a case by case basis and that it was impossible to predict the circumstances where emergency suspension and/or withdrawal of an ISPM may be needed.
3. *Noted* that the ICPM functions within the framework of FAO and therefore FAO had the responsibility and mandate for the governance of the ICPM (decision making and financial), and to protect the interest of Parties under exceptional and urgent circumstances.
4. *Noted* that under this mandate FAO had the responsibility to act quickly in cases where a risk was posed to the ability of FAO to carry out its core responsibilities and requirements under the FAO Constitution and Basic Texts governing its operations.
5. *Noted* the importance of promoting transparency and consultation between FAO and the appropriate bodies established under the IPPC with respect to any such possible action, but also that circumstances may arise (for example with some types of legal action) where there were requirements for confidentiality and it may not be possible to provide at a certain stage full details to the ICPM.
6. *Agreed* that, where recommendations relating to the emergency suspension or withdrawal of an approved ISPM were being considered by FAO:

a) As far as possible any recommendations should be discussed and endorsed by an emergency meeting of the Bureau.
b) ICPM should be informed of any recommendations and justifications as soon as possible.

90. In relation to the phrase "and endorse" in point 6.a), it was noted that the question of endorsement by the Bureau was important to allow the FAO Director General to take its views into account. However, the Bureau had not received any delegation to decide on questions involving legal or financial liability. In this sense, the Bureau was not financially or legally liable for any endorsement it might or might not make. In addition, any such endorsement did not legally bind the FAO Director General, who had to act in accordance with the Basic Texts of the Organization, and Rule VIII.3 and other provisions of the ICPM Rules of Procedure.

9. STRATEGIC DIRECTION NO. 2: INFORMATION EXCHANGE

9.1 Report on the International Phytosanitary Portal and the Information Exchange Work Programme

91. The Secretariat presented a report on the International Phytosanitary Portal (IPP) and the information exchange work programme[27]. It reported that experience had shown that a substantial amount of the official contact point information was incorrect, which was having a negative impact on the members' and Secretariat's ability to communicate in an appropriate and timely manner. Official contact point nominations received directly from the NPPO did not satisfy the requirements stipulated in article VIII of the IPPC, as nominations were the responsibility of contracting parties.

92. The Secretariat reported that the IPP is currently being upgraded and revised based on the guidance given by the IPP Support Group meeting in January 2004. Improvements since January related in particular to the stability and the basic display of information. A major upgrade was planned for around August, which would include a significant re-design to incorporate substantial

[27] ICPM 04 INF-13

improvements in display, navigation and speed, more powerful search, improved security and stability, pest reporting function, improved data entry (with an IPP users manual) and improved content. The Secretariat was in the process of developing a capacity-building programme to increase awareness of the information exchange obligations, of the IPP as a tool to fulfil these obligations and of how countries could participate in the IPP. The Secretariat was in the process of developing this capacity-building programme and its implementation would depend on the availability of both human and financial resources.

93. The need for a substantial capacity building programme in relation with information exchange obligations was recognized. The Secretariat should make best use of planned IPPC regional workshops, RPPO meetings and other specific meetings to provide information and training on the IPP.

94. The need for the development and updating of IPPC advocacy documents was recognized and it was suggested that this material be made available through the IPP.

95. The ICPM:
1. *Agreed* on the urgent need for members to update official contact point information, and noted that FAO representatives could facilitate this process.
2. *Reminded* members that official contact points are responsible for the dissemination of information as appropriate in their country.
3. *Recalled* the information exchange obligations under the IPPC and urged Members to provide and update information as required.
4. *Requested* the Secretariat to produce a flow-chart explaining information exchange and document dissemination under the IPPC.
5. *Requested* the Secretariat in consultation with the Support Group on information exchange to draft a work programme on information exchange and submit it through the SPTA to ICPM-7 for adoption.

10. STRATEGIC DIRECTION NO. 3: THE PROVISION OF DISPUTE SETTLEMENT MECHANISMS

10.1 Report of the Subsidiary Body on Dispute Settlement

96. The Chairperson of the Subsidiary Body on Dispute Settlement (SBDS) reported that the SBDS had met during the ICPM session. It was concerned that the IPPC dispute settlement process had not been utilized yet, despite the number of trade disputes that are raised through the SPS Committee. The SBDS had discussed possible reasons for this lack of use and would appreciate advice from members in this regard.

97. The SBDS had discussed the possibility to produce a draft advocacy document to promote the IPPC dispute settlement process and a draft IPPC Dispute Settlement Procedural Manual.

98. The ICPM:
1. *Noted* the verbal report of the Chairperson of the SBDS.
2. *Agreed* that the work programme for the SBDS should include the production of an advocacy document for the IPPC dispute settlement process, the development of an IPPC Dispute Settlement Procedural Manual, and the production of an experts roster system that can be used for relevant nominations.

10.2 Adoption of the Terms of Reference for the Subsidiary Body on Dispute Settlement

99. The Chairperson of the SBDS introduced the proposed Terms of Reference for the SBDS[28]. A minor editorial error was corrected.

[28] ICPM 04/12

100. The ICPM:
1. *Adopted* the Terms of Reference of the SBDS, as amended (Appendix XII).
2. *Noted* concerns expressed on the name of the SBDS and agreed that this issue would be included on the agenda for ICPM-7.

11. STRATEGIC DIRECTION NO. 4: THE DEVELOPMENT OF THE PHYTOSANITARY CAPACITY OF MEMBERS BY PROMOTING THE PROVISION OF TECHNICAL ASSISTANCE

11.1 Report on the Phytosanitary Capacity Evaluation Tool

101. The Secretariat introduced the report[29] and noted that in 2003/2004 the PCE was applied in over 30 countries. This tool has been particularly useful for establishing a baseline for gauging the capacity gap between the current phytosanitary situation and what is needed to meet the requirements of the international standards. A number of countries expressed their appreciation of the technical assistance provided with the application of the PCE.

102. Several countries emphasized the need to analyze the PCE as it was noted that the tool would be utilized by many other countries in the future, thus there was a necessity to determine whether the intended benefits are being derived from its application.

103. The ICPM:
1. *Encouraged* the Secretariat to support further regional PCE workshops for the better understanding and implementation of the tool.
2. *Noted* the report and endorsed the anticipated work programme.
3. *Endorsed* the proposal to conduct an analysis of the application of the PCE.

11.2 Technical Assistance Work Programme

104. The Secretariat summarized the activities of the phytosanitary technical assistance activities under the FAO Technical Assistance Programme, technical support by the Secretariat and the Special Programme for Food Security (SPFS)[30].

105. The regional workshops on the PCE, the Regional workshops on draft ISPMs, as well as technical assistance provided to Regional Plant Protection Organizations were noted. Several members expressed the need for an evaluation of the impact of technical cooperation projects provided by FAO to ensure maximum benefit is derived from such projects in light of the limited financial resources provided through them. The PCE tool was identified as one mechanism to effect such evaluations.

106. The representative of Canada informed the ICPM of the formation of an International Phytosanitary Risk Analysis Network and urged collaboration and financial support for this initiative.

107. The representative of Uruguay noted the technical assistance being provided to CARICOM Governments through the Secretariat and offered COSAVE's support through the FAO Technical Cooperation Programme.

108. Several countries requested a work programme on the Technical Assistance Programme of the IPPC. The Secretariat clarified that much of the work on technical assistance is on demand. It provides Technical Staff Support Services to the Technical Cooperation Programme of FAO and the programme itself is not within the direct control of the IPPC. Countries may make requests for technical assistance using these procedures established by FAO for this purpose.

[29] ICPM 04 INF-14
[30] ICPM 04/13

109. The ICPM:
1. *Noted* the offer of technical assistance for Regional Plant Protection Organizations from Uruguay on behalf of COSAVE.
2. *Noted* the report of the Secretariat on the technical assistance work programme.
3. *Endorsed* the request for the Secretariat to facilitate as many Regional technical workshops on draft ISPMs as possible.

11.3 Policy on the Production of Explanatory Documents, Training Guides and other Supporting Documentation

110. The Strategic Planning and Technical Assistance working group noted the demand for explanatory documents, manuals and similar documents to help countries implement provisions of the IPPC and ISPMs. The Secretariat presented the recommendations of the SPTA[31] and noted that the SPTA had reviewed similar activities of other international organizations. The SPTA recommendations were reviewed and amended.

111. The ICPM:
1. *Endorsed* a policy to allow explanatory documents, training guides and similar documents to be developed and distributed under the auspices of the Secretariat.
2. *Decided* that these documents be reviewed by experts acting under the auspices of the Secretariat before publication, but that the draft documents would be made available to the SC which may comment in the reviewing process.
3. *Decided* that these documents would be published under the name of the author acting under the auspices of the Secretariat, with a clear disclaimer that these cannot be taken as an official legal interpretation of the IPPC or its related documents, and are produced for public information purposes only.
4. *Decided* that these documents be placed on the IPP.

12. STRATEGIC DIRECTION NO. 6: PROMOTION OF IPPC AND COOPERATION WITH RELEVANT INTERNATIONAL ORGANIZATIONS

12.1 Memorandum of Cooperation between the CBD and IPPC Secretariats

112. The Secretariat introduced the Memorandum of Cooperation between the CBD and IPPC Secretariats[32].

113. The representative of Canada stressed the importance to members of the ICPM of keeping their countries focal points for the Convention on Biological Diversity informed on progress and developments within the IPPC, particularly to the new supplement to ISPM No. 11 on pest risk analysis for living modified organisms.

114. The ICPM:
1. *Noted* the Memorandum of Cooperation.
2. *Invited* the ICPM Bureau to explore possibilities for closer cooperation between the ICPM and the Conference of parties of the CBD and report to the SPTA and the ICPM-7.

13. CALENDAR

115. The Secretariat presented the calendar[33], and noted that it was tentative and would be adjusted depending on the availability of funding and budget resources.

[31] ICPM 04/14
[32] ICPM 04 INF-15, ICPM 04 CRP-4
[33] ICPM 04 CRP-13

116. The ICPM:
1. *Noted* the proposed calendar (Appendix XIII).

14. ELECTION OF OFFICERS

14.1 Election of Officers for the ICPM and Membership of Subsidiary Bodies

117. The Secretariat introduced information on election of officers for the ICPM and membership of subsidiary bodies[34].

14.2 Nominations for Membership of Standards Committee

118. The Secretariat introduced the nominations for the Standards Committee as received from the various FAO regional bodies.

119. The ICPM:
1. *Confirmed* the nominations for the Standards Committee as listed in Appendix XIV.

14.3 Nominations for Membership of Subsidiary Body on Dispute Settlement

120. The Secretariat introduced the nominations for the Subsidiary Body for Dispute Settlement as received from the various FAO regional bodies.

121. The ICPM:
1. *Confirmed* the nominations for the SBDS as listed in Appendix XV.

15. OTHER BUSINESS

122. The WTO representative elaborated on the differences between the WTO dispute settlement process and the IPPC dispute settlement process. It was noted that according to the SPS Agreement, when a dispute involves scientific or technical issues the dispute panel should seek advice from appropriate scientific and technical experts. The experts are usually selected from lists provided by the relevant standard setting organization referenced in the SPS agreement. For plant health this is the IPPC.

123. The WTO representative encouraged members of the ICPM to consider using the IPPC dispute settlement mechanism, particularly for disputes involving highly technical matters. Use of the IPPC mechanism did not mean that the dispute could not be taken to the WTO later.

124. The EC and its Member States noted that ICPM-5 had not provided clear guidelines on the incorporation of the supplementary text on *Analysis of environmental risks* into ISPM No. 11. It expressed concern that there had been no verification process regarding this integration. It requested clarification from the Secretariat on this issue and the status of ISPM No. 11 Rev.1.

125. The Secretariat stated that ICPM-5 had approved the text of this supplement and requested that it be integrated into ISPM No. 11 as soon as possible. The ICPM had not specified any specific approval process for the integration or requested that the revised standard be sent out for further country consultation. In accordance with this decision the Secretariat had integrated the text, and had printed and distributed the revised version of the ISPM (ISPM No. 11 Rev. 1). The Secretariat noted the guidance provided by ICPM on the integration of the supplement on living modified organisms into ISPM No. 11.

[34] ICPM 04 INF-16

126. The representative of Australia made a statement about freedom from the disease karnal bunt caused by the fungus *Tilletia indica*. This was in response to claims that this disease organism was found in a shipment of wheat from Australia. It was stated that, consistent with ISPM No. 8 the status of karnal bunt disease is determined as being "absent: no pest records". Survey work to be completed shortly is expected to confirm the status as being "absent: confirmed by survey". Further information on this issue will be provided on the IPP in the near future.

127. Several members requested clarification with regard to the coming into force of the New Revised Text of the IPPC (1997) and if that text would apply to countries not having adopted the amendments. The Secretariat informed the ICPM that entry into force would apply to all contracting parties. Therefore, those which have not ratified the New Revised Text would nevertheless be fully participating in the activities of the Commission. The Secretariat noted that the FAO Conference, in adopting the New Revised Text of the IPPC in 1997, had agreed that it did not contain new obligations.

128. One representative highlighted general concerns about the risks of living modified organisms and noted that the supplement on risk analysis for living modified organisms only dealt with plant health risks.

129. The Chairperson thanked the delegations and also the members of the SC which were finishing their mandate for their contribution in the development of recent standards.

16. DATE AND VENUE OF THE NEXT MEETING

130. The ICPM *decided* that the next meeting would be held from 4 to 8 April 2005 in Rome, Italy.

17. ADOPTION OF THE REPORT

131. The ICPM *adopted* the report.

132. The representative of Jamaica thanked, on behalf of developing countries, the European Commission, Canada and New Zealand for their financial support which had allowed the participation of an increased number of developing countries to fully take part in the activities of the ICPM.

INTERIM COMMISSION ON PHYTOSANITARY MEASURES

29 March - 2 April 2004

AGENDA

1. Opening of the Session
   1.1 Appointment of rapporteur
2. Adoption of the Agenda
   2.1 Provisional agenda
   2.2 Annotated provisional agenda
3. Report by the Chairperson
4. Report of the Secretariat
5. Report of the 15th Technical Consultation among Regional Plant Protection Organizations
6. Report of Observer Organizations
   6.1 Report of the Activities of the Sanitary and Phytosanitary Committee and other Relevant WTO activities in 2003
   6.2 Report on the Convention on Biological Diversity
7. Strategic Direction No. 1: The Development, Adoption and Monitoring of the Implementation of International Standards for Phytosanitary Measures (ISPMs) (Standard Setting)
   7.1 Report of the Standards Committee
   7.2 Adoption of International Standards
   7.3 Topics and Priorities for Standards
   7.4 Implementation of ISPM No. 15: Guidelines for Regulating Wood Packaging Material in International Trade
8. Strategic direction No. 5: The Maintenance of an Effective and Efficient Administrative Framework
   8.1 Acceptance of the New Revised Text of the IPPC and Issues Related to Coming Into Force.
   8.2 Report of the 5th Meeting of the Informal Working Group on Strategic Planning and Technical Assistance
   8.3 Financial Report
   8.4 Budget Plan
   8.5 Special Trust Fund
   8.6 Strategic Plan and Business Plan
   8.7 Improvements to the Standard Setting Procedure
   8.8 Composition of the Standards Committee
   8.9 Selection of the Standards Committee Chair and Membership of the Standards Committee Working Group
   8.10 Role and Functions of the Informal Working group on Strategic Planning and Technical Assistance
   8.11 Role and Function of Regional Plant Protection Organizations
   8.12 Procedures for Urgent Alteration or Suspension of ISPMs after Adoption
9. Strategic Direction No. 2: Information exchange
   9.1 Report on the International Phytosanitary Portal and the Information Exchange Work Programme
10. Strategic direction No. 3: The provision of Dispute Settlement Mechanisms
    10.1 Report of the Subsidiary Body on Dispute Settlement
    10.2 Adoption of the Terms of Reference for the Subsidiary Body on Dispute Settlement
11. Strategic Direction No. 4: The Development of the Phytosanitary Capacity of Members by Promoting the Provision of Technical Assistance

11.1 Report on the Phytosanitary Capacity Evaluation Tool
11.2 Technical Assistance Work Programme
11.3 Policy on the Production of Explanatory Documents, Training Guides and other Supporting Documentation.

12. Strategic Direction No. 6: Promotion of IPPC and Cooperation with Relevant International Organizations
12.1 Memorandum of Cooperation between the CBD and IPPC Secretariats

13. Calendar

14. Election of Officers
14.1 Election of Officers for the ICPM and Membership of Subsidiary Bodies
14.2 Nominations for Membership of Standards Committee
14.3 Nominations for Membership of Subsidiary Body on Dispute Settlement

15. Other Business

16. Date and Venue of the Next Meeting

17. Adoption of the Report

Publication No. 20
April 2004

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

GUIDELINES FOR A PHYTOSANITARY IMPORT REGULATORY SYSTEM

Secretariat of the International Plant Protection Convention
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2004

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INTRODUCTION

SCOPE

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

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

DEFINITIONS[1]

area of low pest prevalence	An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures [IPPC, 1997]
biological control agent	A natural enemy, antagonist or competitor, and other self-replicating biotic entity used for pest control [ISPM No. 3, 1996]
commodity	A type of plant, plant product, or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
compliance procedure (for a consignment)	Official procedure used to verify that a consignment complies with stated phytosanitary requirements [CEPM, 1999]
consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]
consignment in transit	A consignment that is not imported into a country but passes through it to another country, subject to official procedures which ensure that it remains enclosed, and is not split up, not combined with other consignments nor has its packaging changed [FAO, 1990; revised CEPM, 1996; CEPM 1999; ICPM, 2002 formerly *country of transit*]

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

detention	Keeping a consignment in official custody or confinement for phytosanitary reasons (see quarantine) [FAO, 1990; revised FAO, 1995; CEPM, 1999]
emergency action	A prompt phytosanitary action undertaken in a new or unexpected phytosanitary situation [ICPM, 2001]
entry (of a consignment)	Movement through a point of entry into an area [FAO, 1995]
entry (of a pest)	Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled [FAO, 1995]
infestation (of a commodity)	Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection [CEPM, 1997; revised CEPM, 1999]
inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly *inspect*]
inspector	Person authorized by a National Plant Protection Organization to discharge its functions [FAO, 1990]
intended use	Declared purpose for which plants, plant products, or other regulated articles are imported, produced, or used [ISPM No. 16, 2002]
interception (of a consignment)	The refusal or controlled entry of an imported consignment due to failure to comply with phytosanitary regulations [FAO, 1990; revised FAO, 1995]
introduction	The entry of a pest resulting in its establishment [FAO, 1990; revised FAO, 1995; IPPC, 1997]
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
monitoring	An official ongoing process to verify phytosanitary situations [CEPM, 1996]
NPPO	National Plant Protection Organization [FAO, 1990; ICPM, 2001]
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]
official control	The active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests (see Glossary Supplement No. 1) [ICPM, 2001]
packaging *	Material used in supporting, protecting or carrying a commodity [ISPM No. 20, 2004]
pathway	Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]

pest categorization	The process for determining whether a pest has or has not the characteristics of a quarantine pest or those of a regulated non-quarantine pest [ISPM No. 11, 2001]
Pest Free Area	An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained [FAO, 1995]
pest free place of production	Place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period [ISPM No. 10, 1999]
Pest Risk Analysis	The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC, 1997]
phytosanitary action	An official operation, such as inspection, testing, surveillance or treatment, undertaken to implement phytosanitary regulations or procedures [ICPM, 2001]
Phytosanitary Certificate	Certificate patterned after the model certificates of the IPPC [FAO, 1990]
phytosanitary legislation	Basic laws granting legal authority to a National Plant Protection Organization from which phytosanitary regulations may be drafted [FAO, 1990; revised FAO, 1995]
phytosanitary measure (agreed interpretation)	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; ICPM, 2002]

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

phytosanitary procedure	Any officially prescribed method for implementing phytosanitary regulations including the performance of inspections, tests, surveillance or treatments in connection with regulated pests [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
phytosanitary regulation	Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
plant products	Unmanufactured material of plant origin (including grain) and those manufactured products that, by their nature or that of their processing, may create a risk for the introduction and spread of pests [FAO, 1990; revised IPPC, 1997; formerly *plant product*]
planting (including replanting)	Any operation for the placing of plants in a growing medium, or by grafting or similar operations, to ensure their subsequent growth, reproduction or propagation [FAO, 1990; revised CEPM,1999]
plants	Living plants and parts thereof, including seeds and germplasm [FAO, 1990; revised IPPC, 1997]
PRA	Pest Risk Analysis [FAO 1995; revised ICPM 2001]

pre-clearance	Phytosanitary certification and/or clearance in the country of origin, performed by or under the regular supervision of the National Plant Protection Organization of the country of destination [FAO, 1990; revised FAO, 1995]
prohibition	A phytosanitary regulation forbidding the importation or movement of specified pests or commodities [FAO, 1990; revised FAO, 1995]
quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing and/or treatment [FAO, 1990; revised FAO, 1995; CEPM, 1999]
quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC 1997]
Regional Plant Protection Organization	An intergovernmental organization with the functions laid down by Article IX of the IPPC [FAO, 1990; revised FAO, 1995; CEPM, 1999; formerly *plant protection organization (regional)*]
regulated article	Any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved [FAO, 1990; revised FAO, 1995; IPPC, 1997]
regulated non-quarantine pest	A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party [IPPC, 1997]
regulated pest	A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]
restriction	A phytosanitary regulation allowing the importation or movement of specified commodities subject to specific requirements [CEPM, 1996, revised CEPM, 1999]
RNQP	Regulated non-quarantine pest [ISPM No. 16, 2002]
RPPO	Regional Plant Protection Organization [FAO, 1990; revised ICPM, 2001]
spread	Expansion of the geographical distribution of a pest within an area [FAO, 1995]
systems approach(es)	The integration of different pest risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of phytosanitary protection [ISPM No. 14, 2002]
test	Official examination, other than visual, to determine if pests are present or to identify pests [FAO, 1990]
treatment	Officially authorized procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003]

OUTLINE OF REQUIREMENTS

The objective of a phytosanitary import regulatory system is to prevent the introduction of quarantine pests or limit the entry of regulated non-quarantine pests with imported commodities and other regulated articles. An import regulatory system should consist of two components: a regulatory framework of phytosanitary legislation, regulations and procedures; and an official service, the NPPO, responsible for operation or oversight of the system. The legal framework should include: legal authority for the NPPO to carry out its duties; measures with which imported commodities should comply; other measures (including prohibitions) concerning imported commodities and other regulated articles; and actions that may be taken when incidents of non-compliance or incidents requiring emergency action are detected. It may include measures concerning consignments in transit.

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

REQUIREMENTS

1. Objective

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

2. Structure

The components of an import regulatory system are:

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

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

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

3. Rights, Obligations and Responsibilities

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

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

3.1 International agreements, principles and standards

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

The drafting, adoption and application of regulations require recognition of certain principles and concepts such as in ISPM No. 1 (*Principles of plant quarantine as related to international trade*), including:

- transparency
- sovereignty
- necessity
- non-discrimination

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

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

3.2 Regional cooperation

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

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

4. Regulatory Framework

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

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

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

4.1 Regulated articles

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

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

- soil, organic fertilizers and related materials
- organisms capable of harboring or spreading pests
- potentially contaminated equipment (such as used agricultural, military and earthmoving equipment)
- research and other scientific materials
- travellers' personal effects moving internationally
- international mail including international courier services
- pests and biological control agents[2].

Lists of regulated articles should be made publically available.

4.2 Phytosanitary measures for regulated articles

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

4.2.1 Measures for consignments to be imported

The regulations should specify the measures with which imported consignments[3] of plants, plant products and other regulated articles should comply. These measures may be general, applying to all types of commodities, or the measures may be specific, applying to specified commodities from a particular origin. Measures may be required prior to entry, at entry or post entry. Systems approaches may also be used when appropriate.

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

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

Measures that may be required during shipment include:

- treatment (for example appropriate physical or chemical treatments)
- maintenance of consignment integrity.

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

- documentation checks
- verification of consignment integrity
- verification of treatment during shipment
- phytosanitary inspection

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

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

- testing
- treatment
- detention of consignments pending the results of testing or verification of the efficacy of treatment.

Measures that may be required after entry include:

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

Other measures that may be required include:

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

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

4.2.1.1 Provision for special imports

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

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

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

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

4.2.2 Import authorization

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

General authorization

General authorizations may be used:

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

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

Specific authorization

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

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

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

4.2.3 Prohibitions

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

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

4.3 Consignments in transit

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

4.4 Measures concerning non-compliance and emergency action

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

Actions which may be taken when an imported consignment or other regulated articles does not comply with regulations and is initially refused entry include:

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

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

4.5 Other elements that may require a regulatory framework

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

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

4.6 Legal authority for the NPPO

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

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

5. Operation of an Import Regulatory System

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

5.1 Management and operational responsibilities of the NPPO

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

5.1.1 Administration

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

5.1.2 Regulatory development and revision

The issuing of phytosanitary regulations is a government (contracting party) responsibility (Article IV.3c of the IPPC, 1997). Consistent with this responsibility, governments may make the development and/or revision of phytosanitary regulations the responsibility of their NPPO. This action may be under the initiative of the NPPO in consultation or cooperation

with other authorities as appropriate. Appropriate regulations should be developed, maintained and reviewed as necessary and in compliance with applicable international agreements, through the normal legal and consultative processes of the country. Consultation and collaboration with relevant agencies as well as affected industries and appropriate private sector groups can be helpful in increasing the understanding and acceptance of regulatory decisions by the private sector and is often useful for the improvement of regulations.

5.1.3 Surveillance

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

5.1.4 Pest risk analysis and pest listing

Technical justification such as through pest risk analysis (PRA) is required to determine if pests should be regulated and the strength of phytosanitary measures to be taken against them (ISPM No. 11 : *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004; ISPM No. 21: *Pest risk analysis for regulated non-quarantine pests*). PRA may be done on a specific pest or on all the pests associated with a particular pathway (e.g. a commodity). A commodity may be classified by its level of processing and/or its intended use. Regulated pests should be listed (according to ISPM No. 19: *Guidelines on lists of regulated pests*) and lists of regulated pests should be made available (Article VII.2i of the IPPC, 1997). If appropriate international standards are available, measures should take account of such standards and should not be more stringent unless technically justified.

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

5.1.5 Audit and compliance checking

5.1.5.1 Audit of procedures in the exporting country

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

- production systems
- treatments
- inspection procedures
- phytosanitary management
- accreditation procedures
- testing procedures
- surveillance.

An importing country should make known the scope of any audit. The arrangements for such audits are normally written into a bilateral agreement, arrangement or work programme associated with import facilitation. Such arrangements may extend to clearance of consignments within the exporting country for entry into the importing country which usually facilitates a minimum of procedures at entry to the importing country. These types of audit procedure should not be applied as a permanent measure and should be considered satisfied as soon as the procedures in the exporting country have been validated. This

approach, in its limitation on the length of its application, may differ from ongoing pre-clearance inspections mentioned in section 5.1.5.2.1. The results of audits should be made available to the NPPO of the exporting country.

5.1.5.2 Compliance checking at import

There are three basic elements to compliance checking:

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

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

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

Phytosanitary inspections should be carried out by, or under the authority of, the NPPO.

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

5.1.5.2.1 Inspection

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

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

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

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

5.1.5.2.2 Sampling

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

5.1.5.2.3 Testing including laboratory testing

Testing may be required for:

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

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

5.1.6 Non-compliance and emergency action

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

5.1.6.1 Action in case of non-compliance

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

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

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

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

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

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

Destruction - The consignment may be destroyed in cases where the NPPO considers the consignment cannot be otherwise handled.

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

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

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

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

5.1.6.2 Emergency action

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

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

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

Commonly encountered situations requiring emergency action include:

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

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

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

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

5.1.6.3 Reporting of non-compliance and emergency action

The reporting of interceptions, instances of non-compliance and emergency action is an obligation for contracting parties to the IPPC so that exporting countries understand the basis

for phytosanitary actions taken against their products on import and to facilitate corrections in export systems. Systems are needed for the collection and transmission of such information.

5.1.6.4 Withdrawal or modification of regulation

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

5.1.7 Systems for authorization of non-NPPO personnel

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

5.1.8 International liaison

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

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

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

5.1.9 Notification and dissemination of regulatory information

5.1.9.1 New or revised regulations

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

5.1.9.2 Dissemination of established regulations

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

5.1.10 National liaison

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

5.1.11 Settlement of disputes

The implementation of an import regulatory system may give rise to disputes with the authorities of other countries. The NPPO should establish procedures for consultation and

exchange of information with other NPPOs, and for settlement of such disputes "shall consult among themselves as soon as possible" prior to considering calling on formal international dispute-settlement procedures (Article XIII.1 of the IPPC, 1997).

5.2 Resources of the NPPO

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

5.2.1 Staff, including training

The NPPO should:

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

5.2.2 Information

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

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

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

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

5.2.3 Equipment and facilities

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

- inspection, sampling, testing, surveillance and consignment verification procedures
- communication and access to information (by electronic means as far as possible).

DOCUMENTATION, COMMUNICATION AND REVIEW

6. Documentation

6.1 Procedures

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

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

6.2 Records

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

- documentation of pest risk analyses (in accordance with ISPM No. 11 : *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004, and other relevant ISPMs)
- where established, documentation of pest free areas, areas of low pest prevalence, and official control programmes (including information on the distribution of the pests and the measures used to maintain the PFA or area of low pest prevalence)
- records of inspection, sampling and testing
- non-compliance and emergency action (in accordance with ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*).

If appropriate, records may be kept of imported consignments:

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

7. Communication

The NPPO should ensure that it has communication procedures to contact:

- importers and appropriate industry representatives
- NPPOs of exporting countries
- the Secretariat of the IPPC
- the Secretariats of the RPPO(s) of which it is a member.

8. Review Mechanism

8.1 System review

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

8.2 Incident review

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

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INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

PEST RISK ANALYSIS FOR REGULATED NON-QUARANTINE PESTS

Secretariat of the International Plant Protection Convention
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2004

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INTRODUCTION

SCOPE

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

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
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Guidelines for pest risk analysis, 1996. ISPM No. 2, FAO, Rome.
Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.
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Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.
Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.
Requirements for the establishment of pest free areas, 1996. ISPM No. 4, FAO, Rome.
Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

area	An officially defined country, part of a country or all or parts of several countries [FAO, 1990; revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]
area of low pest prevalence	An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures [IPPC, 1997]
consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]
host range	Species of plants capable, under natural conditions, of sustaining a specific pest [FAO, 1990]
infestation (of a commodity)	Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection [CEPM, 1997; revised CEPM, 1999]
intended use	Declared purpose for which plants, plant products, or other regulated articles are imported, produced or used [ISPM No.16, 2002]

IPPC	The International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
monitoring survey	Ongoing survey to verify the characteristics of a pest population [FAO, 1995]
National Plant Protection Organization	Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization (National)]
non-quarantine pest	Pest that is not a quarantine pest for an area [FAO, 1995]
NPPO	National Plant Protection Organization [FAO, 1990; ICPM, 2001]
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]
official control	The active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests (see Glossary Supplement No. 1) [ICPM, 2001]
pathway	Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]
pest categorization	The process for determining whether a pest has or has not the characteristics of a quarantine pest or those of a regulated non-quarantine pest [ISPM No. 11, 2001]
pest free place of production	Place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period [ISPM No. 10, 1999]
pest free production site	A defined portion of a place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period and that is managed as a separate unit in the same way as a pest free place of production [ISPM No. 10, 1999]
Pest Risk Analysis	The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC, 1997]
pest status (in an area)	Presence or absence, at the present time, of a pest in an area, including where appropriate its distribution, as officially determined using expert judgement on the basis of current and historical pest records and other information [CEPM, 1997; revised ICPM, 1998]
phytosanitary measure (agreed interpretation)	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; ICPM, 2002]

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

phytosanitary regulation	Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
planting (including replanting)	Any operation for the placing of plants in a growing medium, or by grafting or similar operations, to ensure their subsequent growth, reproduction or propagation [FAO, 1990; revised CEPM, 1999]
plants	Living plants and parts thereof, including seeds and germplasm [FAO, 1990; revised IPPC, 1997]
plants for planting	Plants intended to remain planted, to be planted or replanted [FAO, 1990]
PRA	Pest Risk Analysis [FAO, 1995; revised ICPM, 2001]
PRA area	Area in relation to which a Pest Risk Analysis is conducted [FAO, 1995]
quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC, 1997]
Regional Plant Protection Organization	An intergovernmental organization with the functions laid down by Article IX of the IPPC [FAO, 1990; revised FAO, 1995; CEPM, 1999; formerly plant protection organization (regional)]
regulated non-quarantine pest	A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party [IPPC, 1997]
regulated pest	A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]
RNQP	Regulated non-quarantine pest [ISPM No. 16, 2002]
RPPO	Regional Plant Protection Organization [FAO, 1990; revised ICPM, 2001]
suppression	The application of phytosanitary measures in an infested area to reduce pest populations [FAO, 1995; revised CEPM, 1999]
technically justified	Justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information [IPPC, 1997]

OUTLINE OF REQUIREMENTS

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

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

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

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

BACKGROUND

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

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

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

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

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

1. Intended Use and Official Control

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

1.1 Intended use

The intended use of plants for planting may be:

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

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

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

1.2 Official control

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

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

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

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

REQUIREMENTS

PEST RISK ANALYSIS FOR REGULATED NON-QUARANTINE PESTS

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

2. Stage 1: Initiation

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

2.1 Initiation points

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

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

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

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

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

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

2.1.2 PRA initiated by a pest

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

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

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

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

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

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

2.2 Identification of the PRA area

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

2.3 Information

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

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

2.4 Review of previous PRAs

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

2.5 Conclusion of initiation

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

3. Stage 2: Pest Risk Assessment

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

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

3.1 Pest categorization

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

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

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

3.1.1 Elements for categorization

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

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

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

The following should be clearly defined:

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

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

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

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

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

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

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

3.1.1.3 Pest presence and regulatory status

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

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

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

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

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

3.1.2 Conclusion of pest categorization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Requirements described in this step indicate the information required to conduct an analysis to determine if there are unacceptable economic impacts. Economic impacts may have previously been analysed for the development of official control programmes for the pest on plants for planting with the same intended use. The validity of any data should be checked as circumstances and information may have changed.

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

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

3.3.1 Pest effects

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

Relevant factors in determining economic impacts include:

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

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

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

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

3.3.2 Infestation and damage thresholds in relation to the intended use

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

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

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

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

3.3.3 Analysis of economic consequences

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

3.3.3.1 Analytical techniques

There are analytical techniques that can be used in consultation with experts in economics to make a more detailed analysis of the economic effects of an RNQP. These should incorporate all of the effects that have been identified. These techniques (see section 2.3.2.3 of ISPM No. 11: *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) may include:

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

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

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

3.3.4 Conclusion of the assessment of economic consequences

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

3.4 Degree of uncertainty

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

3.5 Conclusion of the pest risk assessment stage

As a result of the pest risk assessment, a quantitative or qualitative evaluation of the plants for planting being the main source of infestation of the pest and a corresponding quantitative or

qualitative estimate of the economic consequences have been obtained and documented, or an overall rating could have been assigned.

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

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

4. Stage 3: Pest Risk Management

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

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

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

4.1 Technical information required

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

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

4.2 Level and acceptability of risk

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

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

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

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

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

- *Phytosanitary measures shown to be cost-effective and feasible* – The measure should not be more costly than the economic impact.
- *Principle of "minimal impact"* – Measures should not be more trade restrictive than necessary.

- *Assessment of existing phytosanitary requirements* – No additional measures should be imposed if existing measures are effective.
- *Principle of "equivalence"* – If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
- *Principle of "non-discrimination"* – Phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

4.3.1 Non-discrimination

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

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

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

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

4.4 Tolerances

For RNQPs, the establishment of appropriate tolerances can be used to reduce the risk to an acceptable level. These tolerances should be based on the level of pest infestation (the infestation threshold) in plants for planting that result in an unacceptable economic impact. Tolerances are indicators that, if exceeded, are likely to result in unacceptable impacts on plants for planting. If infestation thresholds have been determined during the risk assessment stage, these should be considered in establishing appropriate tolerances. Tolerance levels should take into account appropriate scientific information including:

- intended use of the plants for planting
- biology, in particular epidemiological characteristics, of the pest
- susceptibility of the host
- sampling procedures (including confidence intervals), detection methods (with estimates of the precision), reliability of identification

- relationship between the pest level and the economic losses
- climate and cultural practices in PRA area.

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

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

4.4.1 Zero tolerance

Zero tolerance is not likely to be a general requirement. A zero tolerance may be technically justified in situations or combination of situations such as:

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

4.4.2 Selection of an appropriate tolerance level

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

4.5 Options to achieve the required tolerance levels

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

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

These options may be applied to:

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

Section 3.4 of ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) also provides information on the identification and selection of risk management options.

4.5.1 Area of production

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

- treatment
- area of low pest prevalence
- area where the pest is absent
- buffer zones (e.g. rivers, mountain ranges, urban areas)

- monitoring survey.

4.5.2 Place of production

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

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

4.5.3 Parent stock

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

- treatment
- use of resistant varieties
- use of healthy planting material
- sorting and roguing
- selection of propagating material.

4.5.4 Consignment of plants for planting

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

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

4.6 Verification of the tolerance levels

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

4.7 Conclusion of pest risk management

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

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

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

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

5. Monitoring and review of phytosanitary measures

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

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

6. Documentation of pest risk analysis

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

The main elements of documentation are:

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

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

Note: this supplement will be integrated into ISPM No. 11 according to the instructions given under paragraph 44 of the present report, before the printing and distribution of the standard.

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

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

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

INTRODUCTION

SCOPE

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

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

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

REFERENCES

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

ADDITIONAL REFERENCES RELEVANT FOR LMOs

Convention on Biological Diversity, 1992. CBD, Montreal.
Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000. CBD, Montreal.
Code of conduct for the import and release of biological control agents, 1996. ISPM No. 3, FAO, Rome.
Glossary of Biotechnology for Food and Agriculture, 2002. *Research and Technology Paper* 9, FAO, Rome.
Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.
Glossary supplement No. 1: Guidelines on the interpretation and application of the concept of official control for regulated pests, 2002. ISPM No. 5, FAO, Rome.
Glossary supplement No. 2: Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations, 2003. ISPM No. 5, FAO, Rome.
Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.

DEFINITIONS AND ABBREVIATIONS

area	An officially defined country, part of a country or all or parts of several countries [FAO, 1990; revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]
commodity	A type of plant, plant product or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]
country of origin (of a consignment of plant products)	Country where the plants from which the plant products are derived were grown [FAO, 1990; revised CEPM, 1996; CEPM, 1999]
country of origin (of a consignment of plants)	Country where the plants were grown [FAO, 1990; revised CEPM, 1996; CEPM, 1999]
country of origin (of regulated articles other than plants and plant products)	Country where the regulated articles were first exposed to contamination by pests [FAO, 1990; revised CEPM, 1996; CEPM, 1999]
endangered area	An area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss [FAO, 1990; revised CEPM, 1996; CEPM, 1999]
entry (of a pest)	Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled [FAO, 1995]
establishment	Perpetuation, for the foreseeable future, of a pest within an area after entry [FAO, 1990; revised FAO, 1995; IPPC, 1997; formerly established]
introduction	The entry of a pest resulting in its establishment [FAO, 1990; revised FAO, 1995; IPPC, 1997]
IPPC	The International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
National Plant Protection Organization	Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization (National)]
NPPO	National Plant Protection Organization [FAO, 1990; revised ICPM, 2001]
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]
pathway	Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]
pest categorization	The process for determining whether a pest has or has not the characteristics of a quarantine pest or those of a regulated non-quarantine pest [ISPM No. 11, 2001]
Pest Free Area	An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained [FAO, 1995]
pest free production site	A defined portion of a place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period and that is managed as a separate unit in the same way as a pest free place of production [ISPM No. 10, 1999]
Pest Risk Analysis	The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC, 1997]

pest risk assessment (for quarantine pests)	Evaluation of the probability of the introduction and spread of a pest and of the associated potential economic consequences [FAO, 1995; revised ISPM No. 11, 2001]
pest risk management (for quarantine pests)	Evaluation and selection of options to reduce the risk of introduction and spread of a pest [FAO, 1995; revised ISPM No. 11, 2001]
Phytosanitary Certificate	Certificate patterned after the model certificates of the IPPC [FAO, 1990]
Phytosanitary measure	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of pests [FAO, 1995; revised IPPC, 1997]
phytosanitary regulation	Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
post-entry quarantine	Quarantine applied to a consignment after entry [FAO, 1995]
PRA area	Area in relation to which a pest risk analysis is conducted [FAO, 1995]
prohibition	A phytosanitary regulation forbidding the importation or movement of specified pests or commodities [FAO, 1990; revised FAO, 1995]
quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC, 1997]
Regional Plant Protection Organization	An intergovernmental organization with the functions laid down by Article IX of the IPPC [FAO, 1990; revised FAO, 1995; CEPM, 1999; formerly Plant Protection Organization (Regional)]
RPPO	Regional Plant Protection Organization [FAO, 1990; revised ICPM, 2001]
spread	Expansion of the geographical distribution of a pest within an area [FAO, 1995]

NEW DEFINITIONS RELEVANT FOR LMOs

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

OUTLINE OF REQUIREMENTS

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

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

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

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

PEST RISK ANALYSIS FOR QUARANTINE PESTS

1. Stage 1: Initiation

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

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

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

A plant pest risk may be presented by:
- the organism(s) with the inserted gene(s) (i.e. the LMO)
- the combination of genetic material (e.g. gene from plant pests such as viruses) or
- the consequences of the genetic material moving to another organism.

1.1 Initiation points

The PRA process may be initiated as a result of:
- the identification of a pathway that presents a potential pest hazard
- the identification of a pest that may require phytosanitary measures
- the review or revision of phytosanitary policies and priorities.

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

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

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

LMO has the potential to be a pest, refer to Annex III, *Determining the potential for a living modified organism to be a pest.*

1.1.1 PRA initiated by the identification of a pathway

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

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

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

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

1.1.2 PRA initiated by the identification of a pest

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

- an emergency arises on discovery of an established infestation or an outbreak of a new pest within a PRA area
- an emergency arises on interception of a new pest on an imported commodity
- a new pest risk is identified by scientific research
- a pest is introduced into an area
- a pest is reported to be more damaging in an area other than in its area of origin
- a pest is repeatedly intercepted
- a request is made to import an organism
- an organism is identified as a vector for other pests
- an organism is genetically altered in a way which clearly identifies its potential as a plant pest.

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

1.1.3 PRA initiated by the review or revision of a policy

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

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

1.2 Identification of PRA area

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

1.3 Information

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

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

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

Information gathering is an essential element of all stages of risk analysis. For LMOs, information required for a full risk analysis may include:
- name, identity and taxonomic status of the LMO (including any relevant identifying codes) and the risk management measures applied to the LMO in the country of export
- taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism
- description of the nucleic acid or the modification introduced (including genetic construct) and the resulting genotypic and phenotypic characteristics of the LMO
- details of the transformation process
- appropriate detection and identification methods and their specificity, sensitivity and reliability
- intended use including intended containment
- quantity or volume of the LMO to be imported.

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

1.3.1 **Previous PRA**

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

1.4 Conclusion of initiation

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

For LMOs at the end of Stage 1 an NPPO may decide that the LMO:
- is a potential pest and needs to be assessed further in Stage 2 or
- is not a potential pest and needs no further analysis under ISPM No. 11 (but see also the following paragraph).

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

2. Stage 2: Pest Risk Assessment

The process for pest risk assessment can be broadly divided into three interrelated steps:
- pest categorization
- assessment of the probability of introduction and spread
- assessment of potential economic consequences (including environmental impacts).

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

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

2.1 **Pest categorization**

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

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

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

2.1.1 **Elements of categorization**

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

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

2.1.1.1 Identity of pest

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

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

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

In the case of LMOs, identification requires information regarding characteristics of the recipient or parent organism, the donor organism, the genetic construct, the gene or transgene vector and the nature of the genetic modification. Information requirements are set out under section 1.3**.**

2.1.1.2 Presence or absence in PRA area

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

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

2.1.1.3 Regulatory status

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

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

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

2.1.1.4 Potential for establishment and spread in PRA area

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

For LMOs, the following should also be considered:

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

For more detailed guidance on the assessment of these characteristics, see Annex III.

2.1.1.5 Potential for economic consequences in PRA area

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

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

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

2.1.2 Conclusion of pest categorization

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

2.2 Assessment of the probability of introduction and spread

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

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

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

With respect to a plant being assessed as a pest with indirect effects, wherever a reference is made to a host or a host range, this should be understood to refer instead to a suitable habitat[1] (that is a place where the plant can grow) in the PRA area.

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

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

[1] In the case of organisms that affect plants indirectly, through effects on other organisms, the terms host/habitat will extend also to those other organisms.

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

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

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

2.2.1 Probability of entry of a pest

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

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

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

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

2.2.1.1 Identification of pathways for a PRA initiated by a pest

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

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

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

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

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

2.2.1.3 Probability of survival during transport or storage

Examples of factors to consider are:

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

2.2.1.4 Probability of pest surviving existing pest management procedures

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

2.2.1.5 Probability of transfer to a suitable host

Factors to consider are:

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

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

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

2.2.2 Probability of establishment

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

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

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

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

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

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

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

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

Factors to consider are:

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

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

2.2.2.2 Suitability of environment

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

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

2.2.2.3 Cultural practices and control measures

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

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

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

2.2.2.4 Other characteristics of the pest affecting the probability of establishment

These include:

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

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

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

2.2.3 Probability of spread after establishment

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

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

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

The information on probability of spread is used to estimate how rapidly a pest's potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area of low potential economic importance and then spread to an area of high potential economic importance.

In addition it may be important in the risk management stage when considering the feasibility of containment or eradication of an introduced pest.

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

2.2.4 Conclusion on the probability of introduction and spread

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

2.2.4.1 Conclusion regarding endangered areas

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

2.3 Assessment of potential economic consequences

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

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

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

For LMOs, the following evidence should also be considered:
- potential economic consequences that could result from adverse effects on non-target organisms that are injurious to plants or plant products
- economic consequences that could result from pest properties.

For more detailed guidance on the assessment of these characteristics, see Annex III.

2.3.1 Pest effects

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

The basic method for estimating the potential economic importance of pests in this section also applies to:
- pests affecting uncultivated/unmanaged plants;
- weeds and/or invasive plants; and
- pests affecting plants through effects on other organisms.

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

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

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

2.3.1.1 Direct pest effects

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

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

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

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

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

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

2.3.1.2 Indirect pest effects

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

- effects on domestic and export markets, including in particular effects on export market access. The potential consequences for market access which may result if the pest becomes established, should be estimated. This involves considering the extent of any phytosanitary regulations imposed (or likely to be imposed) by trading partners
- changes to producer costs or input demands, including control costs
- changes to domestic or foreign consumer demand for a product resulting from quality changes
- environmental and other undesired effects of control measures
- feasibility and cost of eradication or containment
- capacity to act as a vector for other pests
- resources needed for additional research and advice
- social and other effects (e.g. tourism).

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

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

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

2.3.2 Analysis of economic consequences

2.3.2.1 Time and place factors

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

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

2.3.2.2 Analysis of commercial consequences

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

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

2.3.2.3 Analytical techniques

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

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

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

2.3.2.4 Non-commercial and environmental consequences

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

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

Application of this standard to environmental hazards requires clear categorization of environmental values and how they can be assessed. The environment can be valued using different methodologies, but these methodologies are best used in consultation with experts in economics. Methodologies may include consideration of "use" and "non-use" values. "Use" values arise from consumption of an element of the environment, such as accessing clean water, or fishing in a lake, and also those that are non-consumptive, such as use of forests for leisure activities. "Non-use" values may be subdivided into:

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

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

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

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

2.3.3 Conclusion of the assessment of economic consequences

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

2.3.3.1 Endangered area

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

2.4 Degree of uncertainty

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

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

2.5 Conclusion of the pest risk assessment stage

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

3. Stage 3: Pest Risk Management

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

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

3.1 Level of risk

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

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

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

For LMOs, the acceptable level of risk may also be expressed by comparison to the level of risk associated with similar or related organisms, based on their characteristics and behaviour in a similar environment to the PRA area.

3.2 Technical information required

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

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

3.3 Acceptability of risk

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

3.4 Identification and selection of appropriate risk management options

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

- *Phytosanitary measures shown to be cost-effective and feasible* - The benefit from the use of phytosanitary measures is that the pest will not be introduced and the PRA area will, consequently, not be subjected to the potential economic consequences. The cost-benefit analysis for each of the minimum measures found to provide acceptable security may be estimated. Those measures with an acceptable benefit-to-cost ratio should be considered.
- *Principle of "minimal impact"* - Measures should not be more trade restrictive than necessary. Measures should be applied to the minimum area necessary for the effective protection of the endangered area.
- *Reassessment of previous requirements* - No additional measures should be imposed if existing measures are effective.
- *Principle of "equivalence"* - If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
- *Principle of "non-discrimination"* - If the pest under consideration is established in the PRA area but of limited distribution and under official control, the phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Likewise, phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

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

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

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

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

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

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

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

3.4.1 Options for consignments

Measures may include any combinations of the following:

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

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

For LMOs, as for other organisms, information may have been obtained concerning the risk management measures applied to the LMO in the country of export (see section 1.3). These should be

assessed to determine if they are appropriate for the conditions in the PRA area and, if appropriate, the intended use.

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

3.4.2 Options preventing or reducing infestation in the crop

Measures may include:

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

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

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

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

Measures may include:

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

3.4.4 Options for other types of pathways

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

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

3.4.5 Options within the importing country

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

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

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

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

3.4.6 Prohibition of commodities

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

3.5 Phytosanitary certificates and other compliance measures

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

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

3.6 Conclusion of pest risk management

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

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

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

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

3.6.1 Monitoring and review of phytosanitary measures

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

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

4. Documentation of Pest Risk Analysis

4.1 Documentation requirements

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

The main elements of documentation are:

- purpose for the PRA
- pest, pest list, pathways, PRA area, endangered area
- sources of information
- categorized pest list
- conclusions of risk assessment

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        *       probability
        *       consequences
-       risk management
        *       options identified
-       options selected.
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ANNEX I

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

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

- *directly affect uncultivated/unmanaged plants*

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

- *indirectly affect plants*

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

- *indirectly affect plants through effects on other organisms*

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

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

ANNEX II

COMMENTS ON THE SCOPE OF THE IPPC IN REGARD TO PEST RISK ANALYSIS FOR LIVING MODIFIED ORGANISMS

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

The analysis of LMOs includes consideration of the following:

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

ANNEX III

DETERMINING THE POTENTIAL FOR A LIVING MODIFIED ORGANISM TO BE A PEST

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

The information requirements outlined in section 1.3 may be needed in determining the potential for an LMO to be a pest.

Potential phytosanitary risks for LMOs

Potential phytosanitary risks for LMOs may include:

a. Changes in adaptive characteristics which may increase the potential for introduction or spread, for example alterations in:
- tolerance to adverse environmental conditions (e.g. drought, freezing, salinity etc.)
- reproductive biology
- dispersal ability of pests
- growth rate or vigour
- host range
- pest resistance
- pesticide (including herbicide) resistance or tolerance.

b. Adverse effects of gene flow or gene transfer including, for example:
- transfer of pesticide or pest resistance genes to compatible species
- the potential to overcome existing reproductive and recombination barriers resulting in pest risks
- potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity.

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

d. Genotypic and phenotypic instability including, for example:
- reversion of an organism intended as a biocontrol agent to a virulent form.

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

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

If there is no indication that new traits resulting from genetic modifications have phytosanitary risks, the LMO may require no further consideration.

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

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

Factors that may result in the need to subject a LMO to stage 2 of the PRA include:
- lack of knowledge about a particular modification event
- the credibility of information if it is an unfamiliar modification event
- insufficient data on the behaviour of the LMO in environments similar to the PRA area
- field experience, research trials or laboratory data indicating that the LMO may pose phytosanitary risks (see sub-sections a. to e. above)
- where the LMO expresses characteristics that are associated with pests under ISPM No. 11
- existing conditions in the country (or PRA area) that may result in the LMO being a pest
- where there are PRAs for similar organisms (including LMOs) or risk analyses carried out for other purposes that indicate a pest potential
- experience in other countries.

Factors that may lead to the conclusion that an LMO is not a potential pest and/or requires no further consideration under ISPM No. 11 include:
- where the genetic modification in similar or related organisms has previously been assessed by the NPPO (or other recognized experts or agencies) as having no phytosanitary risk
- where the LMO is to be confined in a reliable containment system and not be released
- evidence from research trials that the LMO is unlikely to be a pest under the use proposed
- experience in other countries.

TOPICS AND PRIORITIES FOR STANDARDS

High priorities are indicated in bold.

a) **Concept standards**

1. Alternative strategies to methyl bromide
2. Classification of commodities by level of processing and intended use and phytosanitary risk
3. Import of plant breeding material
4. Sampling
5. Electronic certification
6. Post-entry quarantine facilities
7. Research protocols for phytosanitary measures.

b) **Reference standards**

1. Guidelines for the formatting/drafting of commodity ISPMs
2. Guidelines for the formatting/drafting of pest specific ISPMs.

c) **Commodity specific standards**

1. Export certification for potato minitubers and micropropagative material
2. Debarking of wood

d) **Technical Panels**

1. Diagnostic protocols for specific pests
2. Pest free areas and systems approaches for fruit flies
3. Treatments
4. Forest quarantine.

PROVISIONAL OUTLINE AND PROGRAMME FOR A WORKSHOP ON ISPM NO. 15

(Report of a meeting of the Friends of the Chair)

A "Friends of the Chair" meeting took place during ICPM-6 to develop a provisional programme for an IPPC workshop on the practical application of ISPM No. 15.

General considerations:	Global workshop aiming at especially developing countries.
Aims:	The workshop should address practical solutions on how to implement and meet the provisions of ISPM No. 15. It should provide information on how ISPM No. 15 is implemented in different countries (special consideration should be given to developing countries which have already implemented ISPM No. 15) to assist especially developing countries in setting up adequate infrastructures and systems.
Target group:	Members of NPPOs or associated organizations on a decision-maker or operational level.
Date of meeting:	Before end of January 2005
Place:	Open, depending on funding received
Programme outline:	Provisionally the workshop could be structured in three main sessions with several sub-sections: A. Establishment of an export certification system for wood packaging material - guidance on developing a marking programme - verification of treatment facilities - assessment of manufacturers and repairers - guidance on marking - guidance on marking of dunnage - guidance on chain of custody - control of repairers - health and safety of inspectors B. Establishment of an import regulatory system for wood packaging material - guidance on chain of custody - guidance on import inspection and sampling - health and safety of inspectors C. Specific problems and their solution in implementing ISPM No. 15 - practical solutions to specified problems (before the workshop questions may be raised to participants on their specific problems. These questions may then be discussed during the session)
Funding:	The workshop is subject to the availability of extra budgetary funds.
Organization:	Steering Committee for organization. Local structures to be used (host country or organization). FAO structure to be used for selecting and managing travel for participants requiring assistance.

ALLOCATION OF FUNDS FROM THE SPECIAL TRUST FUND

ACTIVITY	ALLOCATION OF FUNDS
Standards setting activities	
Travel to the ICPM	25%
Participation in Standards Committee and expert working groups	5 %
Regional workshops on draft ISPMs	25 %
Technical assistance for implementation of ISPMs	15 %
Phytosanitary Capacity Evaluation	17 %
Information exchange	10 %
General operating expenses	3 %
TOTAL	100%

STRATEGIC PLAN 2004

The Strategic Plan incorporating minor changes suggested by the SPTA is shown below in table form.

STRATEGIC DIRECTIONS AND GOALS

Strategic Direction No. 1: The development, adoption and monitoring of the implementation of International Standards for Phytosanitary Measures (ISPMs)

Setting international phytosanitary standards is a basic and unique role identified in the IPPC, particularly given the status accorded IPPC standards as a result of the WTO SPS Agreement. Internationally accepted phytosanitary standards form the basis for the harmonization of phytosanitary measures that protect natural and cultivated plant resources while ensuring fair and safe trade. An increased number of international standards is necessary to facilitate international trade as envisaged by the WTO SPS Agreement.

Goals	Timing	Priority	Means
1.1 Maintain an effective standard development and adoption system using the ICPM and SC			
1.1.1 Increase the number of standards to meet targets established in the ICPM work programme	Ongoing	High	ICPM
1.1.2 Develop specific standards where relevant concept standards are in place	Ongoing	High	ICPM
1.1.3 Develop concept standards where necessary for the preparation of specific standards in priority areas	Ongoing	High	ICPM
1.1.4 Involve RPPO cooperation in the development of ISPMs	Ongoing	Low	ICPM and Secretariat
1.2 Improve the standard-setting mechanism			
1.2.1 Establish "Guidelines on the establishment of commodity or pest-specific standards"	Ongoing	Medium	ICPM
1.3 Ensure that ISPMs take account of the protection of the environment			
1.3.1 Establish a mechanism to review standards to ensure they take account of the protection of the environment	Ongoing	High	ICPM, Bureau and Secretariat
1.4 Increase transparency and participation in the standard-setting process			
1.4.1 Develop efficient information sharing systems concerning standard-setting activities and procedures-	Ongoing	Medium	ICPM and Secretariat
1.5 Facilitate the implementation of standards			
1.5.1 Establish explanatory documents corresponding to ISPMs if needed	Ongoing	Medium	SC
1.5.2 Investigate the feasibility of including implementation programs in the standard setting process	2004	Medium	ICPM
1.5.3 Encourage RPPOs to assist their members in the implementation of ISPMs	Ongoing	Medium	ICPM

Strategic direction No. 2: Information exchange

This strategic direction covers members and the IPPC Secretariat's obligations to provide information as specified in the IPPC and information exchange that may be specified by the ICPM or in ISPMs, including such information as pest lists, pest reports, and phytosanitary measures. Information exchange activities ensure that members communicate officially on phytosanitary regulations and other issues of phytosanitary significance, and determine the means by which the IPPC Secretariat makes them available to other members.

Goals	Timing	Priority	Means
2.1 Establish procedures for pest reporting and information exchange			
2.1.1 Promote increased access and use of electronic communication/Internet	Ongoing	Medium	Secretariat
2.1.2 Develop the IPP for provision of official information by countries	2004	High	Secretariat
2.1.3 Establish systems to identify sources of information on pests	2004	Medium	Working group

Strategic Direction No. 3: The provision of dispute settlement mechanisms

This relates to the non-binding dispute settlement provisions contained in Article XIII of the IPPC (1997). The ICPM is charged to develop rules and procedures for dispute settlement under the IPPC. The Convention explicitly recognizes the complimentary role of the IPPC in this area given the formal binding dispute settlement process that exists under the WTO.

Goals	Timing	Priority	Means
3.1 Increase awareness of dispute settlement mechanism			
3.1.1 Develop information material concerning the requirements for effective preparation of a dispute settlement	2004	Medium	Subsidiary body
3.2 Provide supporting information on IPPC and other dispute settlement systems			
3.2.1 Establish an inventory of other dispute settlement systems	2004	Medium	Subsidiary body
3.2.2 Provide rulings/precedents from dispute settlements (e.g. WTO)	2004	Medium	Subsidiary body

Strategic Direction No. 4: The development of the phytosanitary capacity of Members by promoting the provision of technical assistance

Article XX in the IPPC (1997) requires members to promote the provision of technical assistance especially to developing contracting parties, either bilaterally or through appropriate international organizations with the purpose of facilitating implementation of the IPPC. Adequate capacity and infrastructure for all Members are critical to accomplish the IPPC's goals.

Goals	Timing	Priority	Means
4.1 Develop and maintain methods and tools for individual countries to evaluate their phytosanitary capacity as well as their needs and demands for technical assistance			
4.1.1 Maintain and update Phytosanitary Capacity Evaluation (PCE)	Ongoing	Medium	SPTA and Secretariat
4.1.2 Promote use of the PCE	Ongoing	Medium	Secretariat and Bureau
4.1.3 Identify and develop additional technical assistance tools	Ongoing	Medium	SPTA and Secretariat
4.2 Promote technical cooperation to support the working programme of the ICPM			
4.2.1 Organize a minimum of four workshops per year to improve the understanding of the draft standards and promote the implementation of existing standards.	Ongoing	High	Secretariat
4.2.2 Increase assistance for the establishment, revision and updating of national legislation	Ongoing	High	Secretariat
4.2.3 Provide legal advice on phytosanitary legal and associated institutional issues to the ICPM	In process	High	Secretariat
4.2.4 Establish a process to identify and rank priorities for the ICPM's activities in technical assistance	2004	Medium	ICPM
4.3 Assist members obtain technical assistance from donors.			
4.3 Provide information to help Members obtain technical assistance from donors	2004	High	Bureau and Secretariat
4.4 Promote the improvement and development of RPPOs			
4.4.1 Develop a policy on the roles and functions of the RPPOs in relation to the IPPC.	2004	High	ICPM
4.4.2 Assist RPPOs in the establishment of information systems	Ongoing	Medium	Members and the Secretariat
4.5 Increase the participation by developing countries in IPPC activities			
4.5.1 Work to ensure that funds are contributed to the Special Trust Fund to support developing country involvement	Ongoing	High	Secretariat and ICPM
4.5.2 Facilitate the attendance of developing countries at SPTA, expert working groups and other ICPM meetings.	Ongoing	High	Secretariat

Strategic direction No. 5: The maintenance of an effective and efficient administrative framework

To function effectively, the ICPM must establish organizational structures and procedures, identify funding mechanisms, and address various support and administrative functions, including internal review and evaluation mechanisms. This strategic direction is to make provision for the ICPM to address its administrative issues and strategies, making continual improvement to ensure its business practices are effective and efficient.

Goals	Timing	Priority	Means
5.1 Provision of an adequate budget for IPPC activities			
5.1.1 Establish strategies for increasing resources available to the IPPC	2004	High	ICPM, Bureau, Secretariat
5.1.2 Provide a transparent budget	Ongoing	High	Secretariat
5.1.3 Establish costing of Strategic Directions in Strategic Plan	2003	High	Secretariat
5.1.4 Identify the relationship of the IPPC Secretariat in the context of FAO	Ongoing	Low	ICPM
5.1.5 Increase Secretariat capacity through the use of FAO resources	Ongoing	High	ICPM, Bureau and Members
5.2 Implement planning, reporting and review mechanisms			
5.2.1 Review business plan annually	Ongoing	High	Bureau and Secretariat
5.2.2 Update strategic plan and operational programme annually	Ongoing	High	SPTA and ICPM
5.2.3 Report on activities of the Secretariat, including reporting by Secretariat on the implementation of the strategic plan	Ongoing	High	Secretariat
5.2.4 Establish procedures to identify issues where common action of the ICPM required	Ongoing	Low	ICPM

Strategic Direction No. 6: Promotion of IPPC and cooperation with relevant international organizations

This strategy direction recognizes the need to communicate IPPC issues, obligations, processes and interests to all concerned, including other bodies with similar or overlapping interests, and to encourage RPPOs to promote regionally the implementation of the IPPC.

Goals	Timing	Priority	Means
6.1 Promote the IPPC			
6.1.1 Encourage Members to deposit their instrument of acceptance for the New Revised Text (IPPC, 1997)	Ongoing	High	Members and Secretariat
6.1.2 Encourage non-contracting parties to adopt the IPPC	Ongoing	High	Members and Secretariat
6.1.3 Communicate IPPC issues, obligations, processes and interests to all concerned, including other bodies with similar or overlapping interests	Ongoing	High	Secretariat
6.1.4 Request RPPOs to promote regionally the implementation of the IPPC	Ongoing	High	ICPM
6.2 Strengthen cooperation with other international organizations			
6.2.1 Establish relations, identify areas of common interest, and where appropriate, develop coordinated activities and joint programmes with other relevant organizations including the CBD, OIE, Codex and WTO	Ongoing	High	Secretariat and Bureau
6.2.2 Strengthen cooperation and coordination with relevant organizations on technical assistance	Ongoing	Medium	ICPM and Secretariat
6.2.3 Develop a policy for linkages with research and education institutions.	2004	High	ICPM
6.3 Develop a plan of action for the provision of scientific and technical support for the IPPC			
6.3.1 Develop a plan of action for the provision of scientific and technical support for IPPC implementation	Ongoing	Medium	Bureau

IMPROVEMENT IN THE CURRENT STANDARD SETTING PROCESS

The following recommendations by the Informal Working Group on Strategic Planning and Technical Assistance to improve the current standard setting process are structured to correspond with the relevant chapters in the report of the Focus group on standard setting. Numbers in square brackets at the end of each heading identifies the corresponding section in the Focus Group report.

1. Recommendations for additional rounds of formal consultation [3.1.]

1. The Standards Committee (SC) should initiate a further round of consultation on standards that have undergone extensive changes as a result of formal country consultation. In such cases the SC should report to the ICPM their justification for sending a standard for a second round of consultation but could use its judgement in regard to this matter.
2. The SC should draw up criteria/guidance that it proposes to apply in determining the need for a further round of formal consultation on a draft standard.
3. In cases where a standard was submitted to the ICPM but not adopted the ICPM could decide if another round of consultation was needed.

2. Recommendations for the use of Technical Panels [3.2.]

1. The SC should establish Technical Panels in specific areas to assist the work of the SC.
2. These Technical Panels should work under general specifications established by the SC, according to Section 5 of the Terms of Reference of the SC, with membership according to current expert working group membership rules. Technical Panels should be groups responsible for the development of specific standards under the fast track system and also for providing advice at the request of the SC in their specific allocated subject area.
3. Under the direction of SC, Technical Panels should provide the SC with: draft technical standards under the fast track system, advice on draft technical standards, advice on country comments and advice on topics and priorities for technical standard development in their field of activity and other task as requested by SC. Technical Panels may draw on specialized expertise, the work of other working groups, other appropriate standards and the work of other relevant organizations in their work as appropriate. The chair of the Technical Panel should act as the steward for the subject area of the Technical Panel.
4. Potential areas for the formation of Technical Panels may include technical matters such as diagnostics, seed pathology, specific pest free areas, organism or commodity specific standards or treatments.
5. When the specific work of a Technical Panel is completed the SC should disestablish the group.

3. Recommendations on procedures for comments on standards at ICPM [3.3.]

1. Guidelines on the submission of comments at meetings of the ICPM should be drafted.
2. These guidelines should include the following points:
   a) Members should endeavour to provide only substantive comments at meetings of the ICPM.
   b) Members should endeavour to provide comments in writing to the Secretariat at least 14 days before the ICPM. The Secretariat will provide a copy of all comments received, in original form at the start of the ICPM.
   c) Members should indicate comments that are strictly editorial (do not change the substance) and could be incorporated by the Secretariat as considered appropriate and necessary.
   d) The Secretariat should provide a format/matrix for country comments. It would be preferable that comments be provided electronically using the standard format/matrix to allow comments to be collated.
   e) The same matrix should also be used for comments provided on standards during the

formal consultation period.

f) The matrix should be available on the IPP and the current guidance on comments on standards already present on the IPP should be modified to request that countries use the matrix.

4. Recommendations for regional technical assistance/consultation [3.4.]

1. As many as possible regional technical consultations on draft ISPMs should be conducted and the ICPM should investigate potential mechanisms to expand these consultations as well as seek to build opportunities for regional consultations through the trust fund or voluntary contributions.
2. The term "Regional Technical Consultation on Draft ISPMs" should be changed to "Regional Workshops on Draft ISPMs".
3. RPPOs should play a role, as appropriate, in such regional workshops within their region.

5. Recommendation for an expanded role of stewards [3.6.]

1. The SC should make greater use of stewards. Guidelines for the roles and responsibilities of a steward should be developed by the SC. Stewards should be invited to relevant SC meeting to assist the work of the SC on the standard that the steward is responsible for. The Secretariat should supply editorial expertise to assist stewards in carrying out their role.

6. Recommendations for an improved transparency to and from the SC [3.7.]

1. To improve the transparency:
   a) All country comments should be published in the IPP.
   b) The IPPC Secretariat should produce and make accessible a generic summary of SC reactions to classes of comments made in the country consultation.
   c) Members of the SC should report back to countries in their regions.
   d) Guidelines for members of the SC to be developed should incorporate guidance on this reporting function of SC members.

7. Recommendation on the use of modern communications [3.8.]

1. E-mail, teleconferencing and other modern communication methods should be used where possible to advance discussion on standards. However, face to face meetings of experts should be continued with e-mail communications used to supplement these meeting but not replace them.

8. Recommendations on the use of annexes [3.9.]

1. Technical annexes (such as treatment schedules, e.g. wood packaging) should be used as much as possible, where appropriate. Annexes should be open to revision separately to the main standard. Revision of annexes could be by a fast track procedure.
2. Annexes should only contain highly specific information that may need to be changed over time and that does not affect the principles incorporated in the primary standard.
3. Criteria for the formation and content of annexes should be developed by the SC.

9. Recommendations on guidelines for expert working group/technical panel members [3.10.]

1. A brief guideline for the operation of expert working groups/technical panels should be produced by the Secretariat in consultation with SC for approval by ICPM. This guideline should be provided to all expert working group/technical panel participants.
2. When each expert working group/technical panel is convened the chair spends time to discuss and explain the mode of operation and the roles and responsibilities of participants.

10. Recommendations on the length of the formal consultation period [3.11.]

1. The current 120 day formal consultation period should be reduced to 100 days to allow sufficient time for the SC and the Secretariat to deal with comments.
2. The distribution of draft standards should be improved and countries should be informed when draft standards for consultation are put on the IPP.

11. Recommendations on guidelines for Standards Committee members [3.12.]

1. A brief guideline on the role and responsibilities of SC members and the SC procedures should be produced by the Secretariat in consultation with SC for approval by ICPM. This should be provided to all SC members.

12. Recommendations for the adoption process of ISPMs at ICPM meetings

1. In cases where there were no substantial comments received on a draft standard, and therefore no substantial changes made to the draft by the Standards Committee, the Chairperson of the ICPM could propose that these standards be adopted without discussion.
2. The Chairperson of the ICPM should use this tool at their discretion.
3. Criteria for such a system should be developed.
4. That every member of the ICPM has the right to request the discussion of a standard proposed for adoption at the ICPM.

FAST-TRACK STANDARD SETTING PROCESS

The following recommendations by the Informal Working Group on Strategic Planning and Technical Assistance for a fast-track standard setting process are structured to correspond with the relevant chapters in the report of the Focus group on standard setting. Numbers in square brackets at the end of each heading identify the corresponding section in the Focus Group report.

1. Recommendations for criteria on the application of a fast track procedure [4.1.]

1. The fast track system should be used:
   a) Where specific technical material and resources are available or simple to develop.
   b) Where non-concept or technical standards of potential global interest that are approved by RPPOs or other organizations are available.
   c) Where technical annexes to concept and other existing standards are needed.
   d) For minor revisions to existing standards where these revisions are not of a conceptual nature.
   e) Where specifically authorized by ICPM.

2. Recommendation on the drafting of ISPMs [4.2.1.]

1. The Informal Working Group on Liaison with Research and Educational Organizations should investigate ways to coordinate and create linkages with relevant organizations that could assist in developing technical standards.

3. Recommendations for a fast track procedure [4.2.2.]

1. ICPM specifies subject areas for the fast track procedure (such as diagnostic, seed pathology, specific pest free areas, organism or commodity specific standards or treatments).
2. Technical panels are formed on the specific subject areas endorsed by the ICPM according to the rules endorsed for forming expert working groups.
3. SC sets specifications that provide general guidance on the technical standards required (e.g. format, type of information required, method of dealing with uncertainties etc.).
4. Technical panels work to the specifications set by SC.
5. Technical panel submits specific draft standards, via the Secretariat, to the SC at any time.
6. As far as possible SC clears these (check that they are in the correct format and that they meet the specifications) by email.
7. The Secretariat sends draft standards that have been cleared by the SC to all ICPM Members in appropriate official FAO languages.
8. If no formal objections are received after 100 days then the standard is included on the agenda for the next ICPM plenary session for adoption without discussion.
9. If objections to adoption are raised at ICPM then ICPM would need to decide to either try and resolve them in the current ICPM session or refer them back to the Secretariat and Standards Committee for further work.
10. If one or more formal objections are received during the 100 day consultation period, the Secretariat tries to resolve the issue(s) with the country(ies) concerned, and if these issues are resolved without change to the draft text, submits the standard to the ICPM for adoption without discussion.
11. If the issues cannot be resolved, the Secretariat requests the SC examine the comments and modify the standard if needed in consultation with the relevant technical panel.
12. The revised standard is placed on the agenda for the next ICPM meeting for discussion and adoption in the normal manner.

4. Recommendation on the definition of a formal objection

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.

PROPOSED CHANGES IN THE STANDARDS COMMITTEE TERMS OF REFERENCE (SECTION 5)

The following changes shown in *[italics in square brackets]* are proposed in the Standards Committee Terms of Reference Section 5 to allow for the establishment and disestablishment of technical panels.

5. Functions of the Standards Committee

The Standards Committee serves as a forum for:

- approval of draft specifications or amendment of specifications;
- finalization of specifications;
- designation of the members of the SC-7 and identify tasks of the group;
- *[establishment and disestablishment of working groups and technical panels as appropriate;]*
- designation of membership of working groups, *[technical panels]* and drafting groups as required;
- review of draft ISPMs;
- approval of draft standards to be submitted to ICPM Members for consultation;
- establishment of open-ended discussion groups where appropriate;
- revision of draft ISPMs in cooperation with the Secretariat taking into account comments of ICPM Members and RPPOs;
- approval of final drafts of ISPMs for submission to the ICPM;
- review of existing ISPMs and those requiring reconsideration;
- assigning stewardship for each ISPM; and
- other functions related to standard setting as directed by the ICPM.

TERMS OF REFERENCE FOR THE SUBSIDIARY BODY ON DISPUTE SETTLEMENT (SBDS)

(Note: Relevant provisions relating to length of membership and selection of Chair approved at ICPM-3 have been included for easy reference)

1. Establishment of the Subsidiary Body on Dispute Settlement

The Subsidiary Body on Dispute Settlement has been established by the Third Interim Commission on Phytosanitary Measures.

2. Scope of the Subsidiary Body on Dispute Settlement

The Subsidiary Body on Dispute Settlement manages the dispute settlement functions of the ICPM and provides assistance to the ICPM with regard to dispute settlement in the WTO and other organizations.

3. Objective

The main objective of the Subsidiary Body on Dispute Settlement is the oversight, administration and support of the IPPC dispute settlement procedures.

4. Structure of the Subsidiary Body on Dispute Settlement

The Subsidiary Body on Dispute Settlement consists of 7 members, one member drawn from each of the FAO Regions.

Members of the subsidiary body serve for a minimum of two years, and a maximum of six years (approved at ICPM-3).

The subsidiary body elects its Chairperson from among its membership (approved at ICPM-3).

5. Functions of the Subsidiary Body on Dispute Settlement

The Subsidiary Body on Dispute Settlement has the following functions:

1. Provide guidance to the Secretariat and disputing parties in selecting appropriate dispute resolution methods and may assist in conducting or administering consultation, good offices, mediation, or arbitration.
2. Propose nominations for independent experts using Expert Committee procedures (see the report of the second session of the ICPM, Appendix IX, Section 4 and the report of the third session of the ICPM, Appendix XI, Section H, paragraph 27b) where the disputing parties cannot agree on experts proposed by the Secretariat.
3. Approve reports of Expert Committees including verification of all points in Expert Committee procedures (see the report of the second session of the ICPM, Appendix IX, Section 4 and the report of the third session of the ICPM, Appendix XI, Section F); and
4. Undertake other functions as directed by the ICPM, which may include:
    a) assist the Secretariat with requests from WTO or other organizations;
    b) report on IPPC dispute settlement activities as well as dispute settlement activities undertaken or completed by other organizations that have implications for the phytosanitary community;
    c) assist in identifying appropriate experts (e.g. for WTO dispute settlement);
    d) assist in review and maintenance of expert rosters; and
    e) identify appropriate training opportunities.

6. IPPC Secretariat

The Secretariat provides administrative, technical and editorial support as required by the Subsidiary Body on Dispute Settlement. The Secretariat is responsible for reporting and record keeping regarding the dispute settlement activities.

PROVISIONAL CALENDAR FOR ICPM WORK PROGRAMME 2004-2005

2004	Standard setting	Other
Jan	ISPM 2 Revision	Information Exchange
Feb	• (9-13 Feb) Consignments in transit • (16-18 Feb) Glossary Working Group • (18-20 Feb) ISPM No. 1 Revision	• (17-19 Feb) International Forest Quarantine Research Group (IFQRG)
Mar	• (1-4 Mar) Inspection methodology	• (29 March-2 April) ICPM-6 • (30 March) Dispute Settlement Subsidiary Body
Apr	• (26-30 Apr) Standards Committee	
May	*(20 May) Drafts for country consultation posted on the IPP*	
June	*(21 June) Drafts for country consultation sent by mail* • Expert Working Group • Expert Working Group	• PCE Workshop - Far East
July	• Expert Working Group • Expert Working Group	• (5-7 July) Focus Group on SPTA • (8-9 July) Extended Focus Group on SPTA: role & functions of RPPOs
Aug	• Regional Workshops on draft ISPMs	• PCE Facilitators Workshop – Rome • (30 Aug- 3 Sept) 16th Technical Consultation among RPPOs, Kenya
Sept	• Regional Workshops on draft ISPMs • Expert Working Group *(30 Sept) Comments on draft standards submitted to Secretariat*	
Oct	*(1 Oct) Topics for new standards submitted to Secretariat.* • Expert Working Group	• (4-8 Oct) Strategic Planning and Technical Assistance
Nov	• Standards Committee Working Group • Standards Committee • Expert Working Group	
Dec	*Draft standards for ICPM-7 adoption will be posted on the IPP as they are finalized.* • Expert Working Group • Technical Panel	*Preparation of documents for ICPM-7, documents will be posted on the IPP as they are finalized.*

2005	Standard setting	Others
Jan 2005	• Expert Working Group • Expert Working Group • Technical Panel	• Informal Working Group on Technical Assistance • Information Exchange
Feb	• Technical Panel • (21-25 Feb) Technical Panel : Forest Quarantine • Expert Working Group • Glossary Working Group	• (15-17 Feb) IFQRG • Informal Working Group on Liaison with Research and Education Institutions
Mar	• Expert Working Group	
Apr	• (25-29 Apr) Standards Committee	• (4-8 Apr) ICPM-7 • (1 Apr) Dispute Settlement Subsidiary Body

Italics indicate important background activities.

In cases of additional funding, Expert Working Groups would be arranged according to priorities for standards. All dates are tentative and subject to change. The calendar will be posted on the International Phytosanitary Portal (IPP) (www.ippc.int) and any changes will be updated on the IPP.

MEMBERSHIP OF THE STANDARDS COMMITTEE

Nominations [Term ICPM-6 (2004) - ICPM-8 (2006)]

FAO Region	Country	Name	Status
Africa	Nigeria	Gabriel Olayiwola ADEJARE	
	Uganda	Robert KARYEIJA	
Asia	China	Wang FUXIANG	re-nomination
	India	Obbineni RAMALINGA REDDY	
	Malaysia	Asna BOOTY OTHMAN	re-nomination
Europe	EC	Marc VEREECKE	re-nomination
	Germany	Jens-Georg UNGER	
	Latvia	Ringolds ARNITIS	re-nomination
Latin American and Caribbean	Brazil	Odilson RIBEIRO E SILVA	re-nomination
	Costa Rica	Magda GONZÁLEZ ARROYO	
	Peru	Alicia DE LA ROSA BRACHOWICZ	
Near East	Jordan	Mohammad R. KATBEH BADER	re-nomination
	Kuwait	Hasan SHARAF	
North America	USA	Narcy KLAG	re-nomination
Southwest Pacific	Australia	David PORRITT	
	New Zealand	John HEDLEY	re-nomination
	Tonga	Sione FOLIAKI	re-nomination

Continuing members [Term ICPM-5 (2003) - ICPM-7 (2005)]

FAO Region	Country	Name
Africa	Morocco	Abdellah CHALLAOUI
Near East	Sudan	Ali Ibrahim KAMAL MAHGOUB
North America	Canada	Gregory WOLFF

MEMBERSHIP OF THE SUBSIDIARY BODY ON DISPUTE SETTLEMENT

[Term: ICPM-6 (2004) - ICPM-8 (2006)]

FAO Region	Country	Name	Status
Africa	Algeria	Mr Ali MOUMEN	re-nomination
Asia	Japan	Mr Motoi SAKAMURA	
Europe	Netherlands	Ms Mennie GERRITSEN	re-nomination
Latin America and Caribbean	Dominican Republic	Mr Pedro Julio JIMÉNEZ ROJAS	
Near East	Jordan	Mr Mohammad R. KATBEH-BADER	re-nomination
North American	USA	Mr John GREIFER	re-nomination
Southwest Pacific	New Zealand	Mr John HEDLEY	re-nomination

LIST OF DELEGATES AND OBSERVERS

Chairperson	:	Ralf LOPIAN (Finland)
Vice-Chairpersons	:	Felipe CANALE (Uruguay) Bulegeya KOMAYOMBI (Uganda)

MEMBERS - MEMBRES - MIEMBROS

ALGERIA - ALGÉRIE - ARGELIA

Représentant
Mme Fatiha BENDDINE
Sous-Directrice du contôle phytosanitaire
Direction de la protection des végétaux
Ministère de l'agriculture et du développement rural
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ANGOLA

Représentant
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Chef du departement
Direction nationale de l'agriculture, des forêts et de l'élevage
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Suppléant(s)
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