REPORT

Rome,
Italy,
13-17 May
2002

Standards Committee
First meeting

Meeting Report
AGP/2002

REPORT OF THE FIRST MEETING OF THE STANDARDS COMMITTEE

Rome, Italy: 13 – 17 May 2002

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2002

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1. OPENING OF THE MEETING

The meeting was opened by Mr Canale, Chairperson of the Interim Commission on Phytosanitary Measures. Mr Canale reviewed the history of the development of the Standards Committee (SC), noting that the committee was established with a view to ensuring both adequate regional representation and technical expertise. He noted that the SC had two main objectives for its first session, to elect the Chair, Vice-chair and the SC-7 and to review draft standards that will be sent for country consultation.

Mr Van der Graaff welcomed the members of the SC. He noted that some members of the Standards Committee had participated in the Committee of Experts on Phytosanitary Measures and the Interim Standards Committee and could provide experience to the new SC, while at the same time noting that the new SC needs to establish how it will best accomplish its objectives.

2. WELCOME ADDRESS

Mr Alex Thiermann was invited by the Secretariat of the IPPC to provide a welcome address. Mr Thiermann discussed his long-time interest in the IPPC. Previously, he had been a delegate for Codex Alimentarius, Chair of the SPS Committee, participated in negotiations on the revision of the IPPC (1997), and is currently serving as Chair of the Codes Commission for the Office Internationale des Epizooties (OIE). Mr Thiermann noted the importance of the work that the new Standards Committee would be undertaking during this meeting.

Mr Thiermann noted that the heightened profile of international standards developed by standard-setting organizations, including the IPPC, is a result of the entry into force of the SPS Agreement. He remarked on the importance of ensuring the scientific and technical integrity of international standards, especially in light of the potential political pressures that can arise from some high profile issues. Furthermore, he mentioned the importance of the participation of developing countries in the three standard-setting bodies, as well as their respective standard-setting processes. Mr Thiermann also described the procedures that OIE follows in developing international standards, and discussed parallel processes in the IPPC.

Mr Thiermann expressed his appreciation for the invitation to provide this welcome address. He extended an invitation to the IPPC to participate in OIE meetings, especially in areas of mutual concern, such as the application of the concept of equivalence. Mr Griffin, Coordinator of the Secretariat of the IPPC, thanked Mr Thiermann for providing the welcome address to the First Meeting of the Standards Committee.

3. ELECTION OF CHAIRPERSON, VICE-CHAIRPERSON AND SC-7

Mr Canale requested the members of the SC to nominate a Chair and Vice-Chair of the SC. The SC agreed that the Chair should be selected from within the membership of the SC and that it would be desirable for the Chair to be familiar with the activities of previous standards committees (i.e. the ISC and CEPM). Mr Hedley nominated Mr Vereecke (European Commission), noting Mr Vereecke's previous accomplishments as Chair of the Interim Standards Committee. Mr Vereecke accepted to Chair the SC. Mr Sosa (Belize) was invited and agreed to serve as Vice-Chair.

4. ADOPTION OF REPORT OF THE FOURTH INTERIM STANDARDS COMMITTEE

The meeting agreed that the report of the Fourth Meeting of the Interim Standards Committee (ISC) could not be adopted by the SC because it is a different committee. The SC therefore agreed to leave the report of the Fourth Meeting of the ISC to be amended as necessary by the Secretariat based on comments from members of the 4th ISC.

5. STANDARDS COMMITTEE PROCEDURES

The meeting discussed the terms of reference and rules of procedure for the SC. With regard to regular meetings, the SC agreed that full meetings of the SC would normally be held once per year in November, and the SC-7 could meet once per year in spring. The meeting also agreed that the Chair of the SC should provide a report of the activities of the SC to the ICPM.

The SC also discussed how comments on draft standards or specifications should be handled in the future. The SC agreed that the Secretariat should be required to provide the rationale for accepting or rejecting proposals upon request. It was noted that handling comments, both by the Secretariat and the SC, is very important to ensure transparency, but is also extremely time-consuming.

The SC agreed that the SC-7 should be composed of technical experts, but concern was expressed over the need to ensure adequate representation of all regions and developing countries. It was stressed that the members of the SC-7 would need to be able to devote a significant amount of time and effort to perform the required activities of the committee. The SC agreed that one representative of each region, agreed amongst the SC members of that region, would serve on the SC-7.

The regions nominated the following representatives to serve on the SC-7: Mr W. Songa (Africa); Ms A. B. Othman (Asia); Mr M. Bader (Near East); Mr A. Pemberton (Europe); Mr Ribiero e Silva (Latin America and the Caribbean); Mr C. Hood (South Pacific); Mr N. Klag (North America). The SC accepted the nominations and established the SC-7 on this basis.

6. AMENDMENTS TO THE GLOSSARY OF PHYTOSANITARY TERMS

The SC considered amendments to the *Glossary of phytosanitary terms* proposed by the Glossary Working Group. The SC was informed that the Glossary Working Group has historically included a Spanish speaker, a French speaker, representatives of NAPPO and EPPO, the Coordinator of the IPPC, and Mr Hedley, former Chair of the ICPM.

The terms *growing period* and *growing season* were considered by the SC. Both of the these terms had been considered in the Fourth Meeting of the Interim Standards Committee (ISC-4), at which time it was agreed to retain both terms in the Glossary, but to refer the definition of *growing period* back to the Glossary Working Group. The SC accepted the definitions proposed by the Glossary Working Group with minor modifications.

The meeting discussed the use of the terms *incursion, outbreak* and *detection.* The terms *incursion* and *outbreak* had also been considered by ISC-4 in reviewing the draft standard *Pest reporting*. At that time, it was agreed to refer both terms back to the Glossary Working Group since the two terms were both necessary, but distinct concepts. Although the term *outbreak* was adopted when the draft standard *Pest reporting* (adopted as ISPM Pub. No. 17) was adopted in the Fourth Session of the ICPM; the term was modified by the Glossary

Working Group. A definition was proposed by the SC for the new term *incursion*. The term *outbreak* was modified to refer to a *significant sudden* increase in a pest population and the definition proposed for the term *incursion* was accepted by the SC. A new definition for the term *detection* was also accepted by the SC.

The SC also considered the terms *premises, safeguards* and *spread.* It was agreed in each of these cases that defining these terms in the *Glossary of phytosanitary terms* was not necessary. For the term *spread*, it was noted that there are two interpretations of the term: spread from one *area* to another, and spread within an *area.* In the cases of *premises* and *safeguards* it was agreed that normal dictionary definitions of these terms are sufficient and therefore no special distinction was necessary in the *Glossary of phytosanitary terms.*

7. GLOSSARY SUPPLEMENT NO. 2: GUIDELINES ON THE INTERPRETATION AND APPLICATION OF *POTENTIAL ECONOMIC IMPORTANCE* AND RELATED TERMS INCLUDING REFERENCE TO ENVIRONMENTAL CONSIDERATIONS

The SC discussed the proposal for the supplement to the *Glossary of phytosanitary terms* on "potential economic importance ". This term is part of the definition of *quarantine pest* and it has been recommended that the term be expanded upon in a supplement to the *Glossary*, in particular to provide guidance on how to interpret economic importance in conducting pest risk analyses.

It was suggested that the role of impacts on the environment be made more explicit in the supplement. The SC agreed to change the title to include specific reference to the environment, although the SC also agreed that the supplement went beyond environmental concerns. In order to make this more explicit, it was agreed to add in the *Purpose and scope* section language from Article 8(h) of the Convention on Biological Diversity, stating that the objective of the IPPC also applies to protecting ecosystems, habitats or species with respect to invasive alien species that are plant pests. It was also suggested that the ICPM should consider providing guidance on methodologies to assess economic impacts.

The SC discussed whether to include the term *uncertainty* in the document where benefits and costs are addressed. It was noted that the term referred mostly to uncertainty in association with indirect consequences, and that the use of the term in the title of the section could be confusing. It was agreed to delete the term from the title of the section.

The meeting discussed how this supplement would apply to regulated non-quarantine pests, with respect to direct or indirect damage. It was agreed that the document should refer to ISPM Pub. No. 16 *Regulated non-quarantine pests: concept and application* directly, rather than discuss this point in the text. The meeting also agreed to include a references section at the end of the supplement referring specifically to the Report of the Third Session of the ICPM, and to Appendix XIII of the report (Statements of the ICPM Exploratory Open-ended Working Group on Phytosanitary Aspects of GMOs, Biosafety and Invasive Species).

Minor modifications to the draft supplement were agreed by the SC, and the document was approved for country consultation.

8. SUPPLEMENT TO ISPM PUB. NO. 11 (PEST RISK ANALYSIS FOR QUARANTINE PESTS): ANALYSIS OF ENVIRONMENTAL RISKS

Mr Griffin introduced the draft supplement to ISPM Pub. No. 11, *Analysis of environmental risks.* He noted that the supplement was organized following the sections of ISPM Pub. No. 11 and that the supplement should be read in tandem with the standard. Mr Smith, observer

from EPPO, had submitted a copy of the supplement aligned with relevant sections of the ISPM to assist with reviewing the draft.

The SC considered the best way to present the draft supplement to countries for consultation, noting the need for ISPM Pub. No. 11 to be followed closely. One suggestion was to format the document in two columns, as submitted by Mr Smith. Another suggestion was to incorporate the new draft text directly into the standard. There was a concern that countries might comment of the already adopted text of ISPM Pub. No. 11, so it was suggested that the new text be highlighted in the document. It was also suggested that an explanatory note be made for countries so that it is understood that the text of ISPM Pub. No. 11 was not up for review or comment.

In reviewing the draft supplement to ISPM Pub. No. 11 (*Pest risk analysis for quarantine pests*) *Analysis of environmental risks,* the SC noted that the terms "hazard" and "risk" should be used appropriately. It was decided that the title of the standard should refer to "risks" rather than hazards. With respect to terminology, one member of the SC expressed a concern over the use of terms such as *wild, natural, unnatural, cultivated, un-cultivated, ecosystems, habitat, unintended habitat* and other related terms and expressed the need for greater clarity in the application of such terms. It was agreed that the SC should not endeavor to define these terms, but to leave the possibility open for there to be further study of these terms, allow countries to comment of these terms, and to decide later how they should be handled in the standard.

The meeting discussed concerns regarding the initiation stage for PRAs with respect to intentionally imported plants, if there is a concern that those plants could be pests. It was felt that there could be problems if all intentionally imported plants (including nursery stock) were subject to full PRAs, and that the system would need to be transparent and consistently applied.

The meeting considered whether weeds can be considered to be distinct from invasive plant species, if weeds are a subset of invasive plants, or if invasive plants are a subset of weeds. It was agreed that the document would refer primarily to weeds, as this term was viewed to be more inclusive, and to refer to invasive plant species in the context of weeds.

With respect to *unintended habitat*, the meeting discussed using terms such as spread or establishment when referring to the presence of a pest in an area. The SC noted that if a pest is already in an area, the correct term to use is spread, whereas if the pest has moved to a new area, the correct term to use is establishment. The meeting then discussed how the concept of a PRA area should be understood in this standard. It was agreed to delete reference to entry, establishment and spread for intentionally imported plants to unintended habitats, and to state instead that for intentionally imported plants, establishment concerns the unintended habitat.

The meeting discussed the use of the wording "consignment of pests" in the draft supplement. It was noted that although the wording may seem awkward, the exact wording comes from ISPM Pub. No. 11 and should not be considered for changes. The SC made minor modifications to the draft supplement and approved the document for country consultation.

9. GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY MEASURE

Mr Griffin introduced the draft standard on irradiation. He informed the SC that this standard, like the ISPM for wood packaging material, was directly relevant to future discussions on efficacy of measures, and that this point in particular was considered by the working group in drafting the standard. He mentioned that the working group, in considering the need for

guidance on efficacy of measures tried to lay the groundwork for a future standard on the topic, while at the same time not limiting potential applications of terms or concepts applicable specifically to irradiation and efficacy in general.

The SC considered the use of the terms *irradiation* and *ionizing radiation*. The SC agreed that the term irradiation refers to the phytosanitary treatment, while the term ionizing radiation refers specifically to the type of radiation used in an irradiation treatment. The SC also agreed that the title of the standard should refer to the use of irradiation as a phytosanitary measure, rather than a phytosanitary treatment.

The SC noted that in addition to plant protection organizations, other international, regional, national or sub-national bodies may regulate the use of nuclear technologies. The SC stated that it is important that it is made clear that the standard should be applied solely to evaluating the efficacy of irradiation as a phytosanitary treatment and avoid discussion of other issues such as food safety or commodity tolerance of irradiation. At the same time, the SC acknowledged that it may be useful to provide general references on the use of irradiation in food, and it was agreed that this information could be furnished in a reference section as an appendix. Concerns over the use of irradiation as a phytosanitary treatment as opposed to use for food safety arose in other parts of the standard, including the use of certain terms such as *devitalization.*

One concern of the SC was how to provide guidance in the standard regarding the detection of live pests in irradiated commodities. The working group that drafted the standard was explicit in noting that mortality is not always technically justified as a condition for import. It is agreed that these pests, in principle, pose minimal risk providing the irradiation treatment is effective. However, one member of the SC was concerned that inspectors at ports of entry may not be able to properly distinguish between consignments that have been irradiated or not. The SC agreed to maintain the text as it is and allow countries to comment if necessary.

Mr Griffin pointed out that Annex 2 to the document (Specific approved treatments) was at this time still blank, in anticipation that data can be evaluated and treatments approved at a later date. The SC also agreed that a table depicting minimum doses for certain pests should be included in the document, but as an appendix noting that the table is for reference purposes only, (based on the position that an annex is part of the standard while an appendix is not necessarily part of the standard).

The SC approved the draft standard with minor modifications to be distributed for country consultation.

10. GUIDELINES FOR IMPORT REGULATORY SYSTEMS

The SC did not have time to fully consider this draft standard and deferred it to a later date. One member of the SC who had participated in the early drafting of the standard noted that the current document bore little resemblance to the original draft. It was suggested that, when the SC has time to review the draft, the original early draft also be examined with the most current draft as it was thought by some to provide useful guidance on import regulatory systems, in particular for developing countries.

11. SPECIFICATIONS FOR ISPMS

The SC reviewed two new specifications for ISPMs: one on efficacy of measures and another on PRA for RNQPs. The meeting discussed the scope of the ISPM for efficacy of measures,

and debated whether the standard should be limited to phytosanitary treatments, or if it should also address other phytosanitary measures besides treatments. One concern is that if the standard is to apply to measures, the scope may be too wide, and impossible for a working group to adequately cover. At the same time, the SC recognized that, especially in light of new obligations under the SPS Agreement and the IPPC for least trade restrictive measures, countries would need guidance on how to evaluate measures other than treatments, including systems approaches. It was agreed that the standard would address measures, rather than only treatments. The SC also requested that the working group should provide a report to the SC as soon as possible after the meeting and before the next SC meeting.

The meeting also noted that this standard would be produced to provide guidance to the ICPM as well as countries on evaluating the efficacy of measures. This is noteworthy in the sense that standards have not previously been directed towards the ICPM specifically, but have been applied by countries.

Mr Hood suggested that Mr Hedley could act as steward for this standard owing to his experience with the previous standards committees. Mr Hedley accepted to act as steward with assistance from Mr Hood. Finally, Mr Pemberton suggested that the host country (United Kingdom) government be invited to participate in the working group for the meeting since it is to be held at Imperial College, UK at the invitation of the Chair of GISP (Global Invasive Species Programme).

The meeting then discussed the specification for the standard for PRA for RNQPs. Mr Canale agreed to act as a steward for the standard.

12. OTHER BUSINESS

In discussing the draft standards for irradiation and for environmental risks, the SC discussed the relevance and usefulness of including examples in the text. The SC was informed that historically, examples have not typically been used in standards, but this did not preclude the possibility of including examples in future standards. It was noted that both the irradiation standard and that standard on environmental risks include numerous examples. The meeting agreed that in some cases, examples can be helpful in understanding particular points in a standard. Some examples were maintained in the drafts and others were deleted where they appeared unnecessary.

In discussing the irradiation standard, it was noted that there were appendices recommending specific treatment rates, and that these appendices would need to be periodically reviewed and updated. Mr Griffin informed the SC that this was also the case for the wood packaging standard adopted at the 4th Session of the ICPM, and would probably be the same for the upcoming standard on efficacy of measures. The meeting discussed the need for the ICPM to develop a mechanism or framework to address the need to update standards. The meeting was informed that in Codex Alimentarius and in the OIE, there are expert committees that meet annually to review new data, and it was suggested that this system could be proposed to the ICPM for its consideration.

One member of the SC requested clarification of the standards development process. The Secretariat developed a flowchart diagram to help add transparency to the standard-setting process.

13. DATE AND VENUE OF THE SECOND STANDARDS COMMITTEE MEETING

The meeting agreed that the next meeting of the SC would take place in Rome from 4-8 November 2002. It was also agreed that the SC-7 would meet the week immediately prior to the SC from 28 October - 1 November 2002.

14. CLOSURE

The Chairperson closed the meeting by expressing his appreciation for the SC's hard work during the week. He noted that the new SC had made progress in learning how to function most efficiently to accomplish its work programme, and expressed his hope that the SC could continue the excellent work of the preceding committees. The Chairperson thanked the Secretariat and the meeting was closed.

ANNEX I

STANDARDS COMMITTEE

FIRST SESSION

13-17 May 2002 -- Rome

AGENDA

1. Opening of the Session

2. Welcome Address

3. Election of the Chairperson

4. Adoption of Agenda

5. Matters Arising from the Previous Meeting

6. Standards Committee procedures
    - Review of rules of procedure and suggestions for modifications
    - Establishment of the working group

7. Approval of Draft Standards for Country Consultation
    - Glossary of phytosanitary terms
    - Economic impacts and related terms
    - Supplement to ISPM 11 on environmental hazards
    - Irradiation as a phytosanitary treatment
    - Import regulatory systems

8. Specifications for new ISPMs

9. Other Business

10. Closure

Note: Changes made here to the Terms of Reference and Rules of Procedure reflect suggested changes that may be recommended to ICPM-5 after discussions in the November meeting of the SC.

Terms of Reference for the Standards Committee

1. Establishment of the Standards Committee
The Standards Committee (SC) was established by the Third Interim Commission on Phytosanitary Measures.

2. Scope of the Standards Committee
The Standards Committee manages the standard-setting process and assists in the development of International Standards for Phytosanitary Measures (ISPM) which have been identified by the ICPM as priority standards.

3. Objective
The main objective of the Standards Committee is to prepare draft ISPMs according to the standard-setting procedures in the most expeditious manner for adoption by the ICPM.

4. Structure of the Standards Committee
The Standards Committee consists of 20 members, including three members drawn from each the FAO Regions, and two from North America. The distribution for each region will be:

- Africa (3)
- Asia (3)
- Europe (3)
- Latin America and the Caribbean (3)
- Near East (3)
- North America (2)
- Southwest Pacific (3)

An expert group of seven members, the Standards Committee Working Group (SC-7) is selected by the Standards Committee from its membership.

The functions of the SC-7 are determined by the Standards Committee and include the review and revision of specifications, working group drafts and drafts from the consultation process. Temporary or permanent working groups and drafting groups may be established by the Standards Committee as required to assist the SC-7.

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;
- designation of membership of working groups 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[1]; and
- other functions related to standard setting as directed by the ICPM.

6. IPPC Secretariat

The Secretariat provides administrative, technical and editorial support as required by the Standards Committee. The Secretariat is responsible for reporting and record keeping regarding the standard.

Rules of Procedure for the Standards Committee

Rule 1. Membership
Members should be senior officials designated by governments and have qualifications in a scientific biological discipline (or equivalent) in plant protection, and experience and skills particularly in the:

- practical operation of a national or international phytosanitary system;
- administration of a national or international phytosanitary system; and
- application of phytosanitary measures related to international trade.

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Each FAO Region may devise its own procedures for selecting its members of the Standards Committee. The Secretariat is notified of the selections that are submitted to the ICPM for confirmation.

The Standards Committee is responsible for selecting the SC-7 members from within its membership for confirmation by FAO. Members selected for the SC-7 will meet the above-mentioned qualifications and experience.

Rule 2. Period of Membership
Members of the Standards Committee shall serve for two years, with a maximum of six years. Only seven members are replaced every 2 years to ensure continuity.

Membership of SC-7 lapses with membership of the Standards Committee or upon resignation.
Replacements to the Standards Committee are decided by the FAO Region concerned.
Replacements to the SC-7 are selected by the Standards Committee.

Rule 3. Chair
The Chairperson and Vice-Chairperson of the Standards Committee are elected by the Standards Committee **from its membership** and serve for two years, with a possibility of re-election for an additional term of two years.

The Chair of the SC-7 is elected by members of the SC-7. The term is for 2 years with the possibility of re-election.

Rule 4. Sessions
Meetings of the Standards Committee are normally held at FAO-Headquarters in Rome.

[1] The assigning of stewardship involves designating an individual to be responsible for managing the development of a particular standard from its inception to its completion according to the specifications for the standard and any additional directions provided by the SC and IPPC Secretariat.

The Standards Committee meets at least **once** per year primarily to facilitate the approval procedures within the standard setting process.
Regular sessions:
Unless otherwise decided by the ICPM, meetings **of the Standards Committee shall** be held in **November**. The Standards Committee may authorize the SC-7 or special-purpose groups to meet more frequently than the Standards Committee within the limits of available resources.

Extraordinary sessions:
The Standards Committee, in consultation with the Bureau of the ICPM may call an extraordinary session of the Standards Committee within the limits of available resources.
A majority of the Standards Committee shall constitute a quorum.

Rule 5. Approval
Approvals relating to specifications or draft standards are sought by consensus. Final drafts of ISPMs which have been approved by the Standards Committee are submitted to the ICPM without undue delay.

Rule 6. Observers
For observer status, Rule 7 of the Rules of Procedure of the ICPM will apply.

Rule 7. Reports
Standards Committee meeting records shall be kept by the Secretariat. The report of the meetings shall include:

- approval of draft specifications for ISPMs;
- finalization of specifications with a detailed explanation including reasons for changes; and
- reasons why a draft standard has not been approved.

The Secretariat shall **endeavor to** provide to ICPM Members **upon request** the rationale of the Standards Committee for accepting or not accepting proposals for modifications to specifications or draft standards.

A report on the activities of the Standards Committee shall be made by the Chairperson of the Standards Committee to the annual session of the ICPM.

Reports shall be adopted by the Standards Committee before they are made available to Members of the ICPM and RPPOs.

Rule 8. Language
The business of the Standards Committee shall be conducted in the English language.

Rule 9. Amendments
Amendments to the Rules of Procedures and the Terms of Reference may be promulgated by the ICPM as required.

Standards Committee Draft
May 2002

AMENDMENTS TO THE GLOSSARY OF PHYTOSANITARY TERMS

1. New and Revised Terms and Definitions

detection	Finding an organism in an area, consignment or regulated article
growing period (of a plant species)	Time in the cycle of vegetation when plants actively grow in an area
growing season	Period or periods of the year when plants actively grow in an area
incursion	An isolated population of a pest, new to an area, recently detected and expected to survive for the immediate future
outbreak	A recently detected pest population or a sudden significant increase of an established pest population in an area

Glossary of phytosanitary terms
Supplement No. 2
GUIDELINES ON THE INTERPRETATION AND APPLICATION OF *POTENTIAL ECONOMIC IMPORTANCE* AND RELATED TERMS INCLUDING REFERENCE TO ENVIRONMENTAL CONSIDERATIONS

1. Purpose and Scope

The purpose of this guideline is to provide background and other relevant information concerning the term *economic* as used in the IPPC and ISPMs, and to ensure a harmonized interpretation and application of the term *economic importance* and related terms consistent with the objectives of the IPPC in protecting ecosystems, habitats or species with respect to invasive alien species that are plant pests.

2. Background

The IPPC has historically maintained that the adverse consequences of plant pests are measured in economic terms. This is qualified by the understanding that economic impacts are broadly interpreted to include those consequences that may be less easily quantified in direct economic terms but nonetheless represent a cost in loss or damage to plants and plant products, including both cultivated and non-cultivated plants.

A quarantine pest is defined by the Glossary as: "*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.*" The Glossary defines a regulated non-quarantine pest as: "*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 country."* (emphasis added)

The references to *economic importance* and *economically unacceptable impact* in these definitions and the use of the word *economic* in various terms in other IPPC documents has resulted in questions being raised regarding whether the IPPC (1997) maintains the right of members to adopt phytosanitary measures with respect to pests that do not necessarily cause quantifiable economic damage to plants, plant products or ecosystems within its territory. Some of the confusion persists due to the fact that *economic effects* are interpreted to be only *market effects*. It is important to begin by recognizing that goods and services not sold in commercial markets can have economic value and that economic analysis has come to encompass much more than the study of market goods and services. The use of the term *economic effects* provides a framework for analyzing a wide variety of public policy choices (e.g. environmental and social effects).

The basis for measuring the economic value of changes in managed resources, natural resources, ecosystems or biodiversity is their effect on human welfare. This anthropocentric focus of economic valuation does not preclude a concern for the survival and well being of other species. The survival of other species can be desirable not only because of the uses people make of them, but also because of altruistic or ethical concerns.

While non-market goods and services have economic value, their benefits and costs are difficult to quantify or measure in monetary terms. Costs and benefits are to be understood to

include both quantifiable measures (to the extent that these can be usefully estimated) and qualitative measures of the costs and benefits that are difficult to quantify, but nevertheless essential to consider. Furthermore, in choosing among alternative regulatory approaches, it may be advisable for countries to consider those that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity).

While all costs and benefits are not easily measured in monetary terms, economic analysis uses a monetary value as a convenient measure to allow policy makers to meaningfully compare costs and benefits from different types of goods and services. This does not preclude the use of other tools such as qualitative and environmental analyses that may not use monetary terms.

3. Interpretation of Economic Terms in the IPPC and ISPMs

The terms related to *potential economic importance* found in the IPPC and ISPMs are categorized as follows:

Terms requiring judgement :

- *potential economic importance* (in the definition for *quarantine pest*)
- *economically unacceptable impact* (in the definition for *regulated non-quarantine pest*)
- *economically important loss* **(**in the definition for *endangered area*)

Terms requiring evidence:

- *limit the economic impact* (in the definition for *phytosanitary regulation* and the agreed interpretation of *phytosanitary measure*)
- *economic evidence* (in the definition for *pest risk analysis*)
- *cause economic damage* (in Article VII.3 of the IPPC [1997])
- *direct and indirect economic impacts* (in ISPM Pub. No. 11 and ISPM Pub. No. 16)
- *economic consequences and potential economic consequences* (in ISPM Pub. No.11)
- *commercial and non-commercial consequences* (in ISPM Pub. No. 11)

ISPM Pub. No. 2 refers to *environmental damage* as a factor to consider in the assessment of potential economic importance. Items such as s*ocial costs* and *crop losses* are also included in this listing, demonstrating the broad scope of economic impacts that is intended to be covered.

ISPM Pub. No. 11 notes that there should be a clear indication that the pest is likely to have an unacceptable economic impact, which may include environmental impact, in the PRA area (section 2.1.1.5). Section 2.3 of the standard describes the procedure for assessing potential economic consequences of an introduction of a pest. Effects may be considered to be direct or indirect. Section 2.3.2.4 provides guidance towards assessing the non-commercial and environmental consequences of pest introduction. It acknowledges that certain types of effects may not have an existing market that can be easily identified, but it goes on to state that the impacts could be approximated with an appropriate non-market valuation method. This section notes that if a quantitative measurement is not feasible, then this part of the assessment should at least include a qualitative analysis and an explanation of how the information is used in the risk analysis. *Environmental or other undesirable effects of control measures* are covered in section 2.3.1.2 (Indirect effects) as part of the analysis of economic consequences.

There is a perception, largely by persons outside of the phytosanitary sector, that the IPPC is commercially focused and limited in scope by the emphasis in practice on market impacts as the sole measure of pest consequences. This has created issues of harmonization with other agreements, including the Convention on Biological Diversity and the Montreal Protocol. In particular, the IPPC has been seen by some to not explicitly account for ecological or environmental concerns in other than economic terms. However, in April 2001 the ICPM recognized that under the IPPC's existing mandate, to take account of environmental concerns, further clarification should include consideration of the following five proposed points relating to potential environmental risks of plant pests:

- reduction or elimination of endangered (or threatened) native plant species;
- reduction or elimination of a keystone plant species (a species which plays a major role in the maintenance of an ecosystem);
- reduction or elimination of a plant species which is a major component of a native ecosystem;
- causing a change to plant biological diversity in such as way as to result in ecosystem destabilization;
- resulting in control, eradication or management programs that would be needed if a quarantine pest was introduced, and impacts of such programs (e.g. pesticides or the release of non-indigenous predators or parasites) on biological diversity.

Thus it is clear that the scope of the IPPC extends to the protection of cultivated plants in agricultural or horticultural production environments, non-cultivated plants in managed or semi-managed environments, and plants in non-cultivated or non-managed environments.

4. Benefits and Costs

In general, an economic test for any policy is that it should be pursued if its benefit is at least as large as its cost. Benefits and costs are broadly understood to include both market and non-market aspects. As noted above, costs and benefits include both quantifiable measures and qualitative measure of costs and benefits. These measures are difficult to quantify, but nevertheless are essential to consider. Benefits and costs should be measured regardless to whom they occur. Judgements about the preferred distribution of benefits and costs are policy choices; that is, economic analysis for phytosanitary purposes cannot judge if one distribution is necessarily better than another distribution of costs and benefits of a specific policy. Benefits and costs must be counted whether they occur as a direct or indirect result of a pest introduction or if a chain of causation is required before the costs are incurred or the benefits realized.

Benefits and costs associated with indirect consequences of pest introductions may be less certain than benefits and costs associated with direct consequences because there is often a lack of fully quantified data regarding potential losses from introduced pests that affect natural environments. Any analysis should identify and explain uncertainties involved in estimating benefits and costs and assumptions should be clearly stated.

5. Application

Environmental damage, arising from the introduction of a plant pest, is one of the types of damage recognized by the IPPC. The IPPC preserves the right of Members to adopt phytosanitary measures with respect to a pest that has the potential for environmental damage alone, without a quantifiable damage component. Such action must be based upon a Pest Risk

Analysis, which may include the consideration of evidence of potential environmental damage.

Three criteria should be met before a pest is deemed to have *potential economic importance*. The pest must have:

- a potential for introduction in the PRA area;
- the potential to spread after establishment; and
- a potential impact on plant health resulting in crop loss; damage to ecosystems, habitats, or species; or, an impairment or loss of some other specified value (e.g. recreation, tourism, aesthetics).

In the case of regulated non-quarantine pests, because such pest populations are already established, introduction in an area of concern and environmental effects are not relevant criteria in the consideration of *economically unacceptable impacts* (see ISPM Pub. No. 16: *Regulated non-quarantine pests: concept and application*).

When indicating the direct and indirect impact of pests on the environment, the nature of the harm or losses arising from a pest introduction should be specified in Pest Risk Analysis.

REFERENCES

International Plant Protection Convention, 1997. FAO, Rome.
Glossary of phytosanitary terms, 2002. ISPM Pub. No. 5, FAO, Rome.
Guidelines for Pest Risk Analysis, 1996. ISPM Pub. No. 2, FAO, Rome.
Pest Risk Analysis for quarantine pests, 2001. ISPM Pub. No. 11, FAO, Rome.
Regulated non-quarantine pests: concept and application, ISPM Pub. No. 16, FAO, Rome.
Report of the Third Session of the Interim Commission on Phytosanitary Measures (includes the working group document in Appendix XII), 2001. FAO, Rome.

Pest Risk Analysis for quarantine pests
Supplement to ISPM Pub. No. 11
ANALYSIS OF ENVIRONMENTAL RISKS

SCOPE

This supplement to ISPM Pub. No. 11 provides details regarding the analysis of environmental risks of plant pests, including those affecting uncultivated/unmanaged plant species, wild flora, habitats and ecosystems contained in the PRA area. This supplement does not include consideration of vertebrates and of marine environments. Biological control agents are separately covered under the IPPC by ISPM Pub. No. 3 (*Code of conduct for the import and release of exotic biological control agents*).

PURPOSE

This supplement provides more detailed guidance on the analysis of the environmental consequences of the introduction of quarantine pests, as part of the assessment of potential economic consequences in ISPM Pub. No. 11: *Pest Risk Analysis for quarantine pests*. It also provides additional information, to allow ISPM Pub. No. 11 to address the full range of pests covered by the IPPC.

The full range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. According to recommendation C34/1 of ICPM-3, "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 they are less likely to be evaluated, and less likely to be regulated and/or placed under official control.
(e.g. *Ophiostoma novo ulmi* [Dutch elm disease])*indirectly affect plants (e.g. weeds*)
In addition to pests that directly affect host plants, there are those, like weeds/invasive plants, which affect plants primarily by other processes, such as competition.
(e.g. for cultivated plants: *Reynoutria japonica* [competitor in natural and semi-natural habitats] or for uncultivated/unmanaged plants: *Cyperus esculentes* [weed of agricultural crops])

- *indirectly affect plants through effects on other organisms*

Specific guidance is needed on pests that primarily affect other organisms, but thereby cause deleterious effects on plants or plant health in ecosystems.

Analysis of environmental risks is essential in a PRA, to protect the environment, ecosystems and wild flora can be protected without creating disguised barriers to trade.

This supplement should only be used in conjunction with ISPM Pub. No. 11. It is not a stand-alone document. The processes it describes are relevant to any PRA for quarantine pests. The supplement does not describe an independent PRA process. The supplemental text for country consultation is outlined with a border, while the text of ISPM Pub. No. 11 has been reduced in size and font to distinguish it from the supplement.

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.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Glossary of phytosanitary terms, 1999. ISPM Pub. No. 5, FAO, Rome.
Guidelines for pest risk analysis, 1996. ISPM Pub. No. 2, FAO, Rome.
Guidelines for surveillance, 1998. ISPM Pub. No. 6, FAO, Rome.
International Plant Protection Convention, 1992. FAO, Rome.
New Revised Text of the International Plant Protection Convention, 1997. FAO, Rome.
Principles of plant quarantine as related to international trade, 1995. ISPM Pub. No. 1, FAO, Rome.
Export Certification System, 1997. ISPM Pub. No. 7, FAO, Rome
Requirements for the establishment of pest free areas, 1996. ISPM Pub. No. 4, FAO, Rome.
Determination of pest status in an area, 1998. ISPM Pub. No. 8, FAO, Rome.
Requirements for the establishment of pest free places of production and pest-free production sites, 1999. ISPM Pub. No. 10, 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 Pub. 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 Pub. 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 Pub. 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 Pub. 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]

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.

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.

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 defined in ISPM Pub. No. 11 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 plants as pests, it is important to note that the plants concerned should satisfy this definition. Pests directly affecting plants satisfy this definition, and many organisms indirectly affecting plants also do so (such as weeds/invasive plants), since 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 no evidence that they are known to affect plants indirectly, it may be possible to assess whether they are potentially injurious in the PRA area by using a clearly documented, consistently applied and transparent system. This is particularly important in the case of plant species or cultivars that are intentionally imported for planting.

1.1.1 PRA initiated by the identification of a pathway

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

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

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

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.

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).

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

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.

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 Pub. No. 1: *Principles of plant quarantine as related to international trade* (FAO, 1995).

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.

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.

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 (cf. Glossary Supplement no. 1).

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.

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.

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.

With respect to a plant being assessed as a pest with indirect effects throughout Section 2.2, wherever a reference is made to a host or a host range, this should be understood to refer instead to a suitable habitat[2] in the PRA area.

In the case of intentionally imported plants, the concepts of entry, establishment and spread have to be considered differently. An intentionally imported plant will in any case enter, and will 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 an unintended habitat within the PRA area, and then establish in that habitat. Accordingly,

[2] In the case of organisms that affect plants indirectly, through effects on other organisms, this will extend also to those other organisms.

section 2.2.3 may be considered before section 2.2.2. According to the management of the organism concerned, unintended habitats may occur in the vicinity of the intended habitat in the PRA area.

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.

2.2.1 Probability of entry of a pest

In the case of intentionally imported plants, this section does not apply.

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.

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.

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.

2.2.2 Probability of establishment

In the case of intentionally imported plants, establishment concerns the unintended habitat.

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 Pub. 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).

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.

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.

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 intentionally imported plants, spread takes place from the intended habitat 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 manifest 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.

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 (section 2.3.1) also applies to pests affecting uncultivated/unmanaged plants, weeds, and pests affecting plants through effects on other organisms. Specific evidence is needed of direct and indirect environmental effects.

The indirect environmental consequences considered should result from effects on plants. These consequences on plants, however, may be less significant than those that affect other organisms or systems which is beyond the scope of this supplement.

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.

Examples of direct consequences of pest effects on plants include:

- reduction of keystone species (i.e. species that have a disproportionate effect relative to their biomass on ecosystem structure or processes);
- reduction of species that are major components of ecosystems (in terms of abundance or size), and endangered species (including effects below species level where there is evidence of such effects being significant);
- significant reduction, displacement or elimination of other native 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).

Examples of indirect consequences of pest effects on plants include:

- indirect effects on plant communities (species richness, biodiversity);
- significant effects on designated environmentally sensitive areas;
- significant change in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species);
- effects on man's use (clean water, tourism, grazing, hunting, fishing);
- costs of environmental restoration; and
- effects on human and animal health (toxicity, allergenicity)[3].

2.3.2 Analysis of economic consequences

Section 2.3.2.4 states that some effects concern "some type of value, but not have an existing market which can be easily identified" and that "these impacts could be approximated with an appropriate non-market valuation method", or that "qualitative information about the consequences may be provided". Section 2.3.3 allows, along with assessment in monetary value, that "economic consequences can also be expressed qualitatively or using quantitative measures without monetary terms".

Application of ISPM Pub. No. 11 to environmental hazards requires clear categorization of environmental values and how they can be assessed. The environment can be valued economically in terms of its "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 values" (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. Such methods should be used in consultation with experts in economics. 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 qualitative 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.

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:

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[3] Often requires the involvement of other agencies/authorities.

- *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.

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.

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.

Assessment of the probability and consequences of environmental hazards often involves greater uncertainty than for pests of cultivated or managed plants, 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

In relation to the opening paragraph of Stage 3, it should be stressed that the purpose of phytosanitary measures is to reduce the future probability and consequences of phytosanitary risks. All these measures are thus precautionary in nature and are designed in proportion to the risk. Lack of certainty in the assessments of economic consequences and probability of introduction is not a reason not to address 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.

3.1 Level of risk

The principle of "managed risk" (ISPM Pub. 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.

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 Pub. 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 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 principle of non-discrimination applies also to pests affecting uncultivated/unmanaged plants, weeds, and pests affecting plants through effects on other organisms. If any of these become established in the PRA area, official control should be applied, and the phytosanitary measures at import should not be more stringent than the official control measures.

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 extended to the intentional import of exotic plants considered to be pests. These consignments may be restricted to species or varieties posing less risk.

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.

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 Pub. 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 Pub. 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.

Where there is a high level of uncertainty regarding pest risk from intentionally imported plants, it may be decided not to take phytosanitary measures at import, but to apply surveillance after entry (Art IV 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 Pub. No. 7: *Export certification system*). The issuance of phytosanitary certificates (see ISPM Pub. 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.

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.

Phytosanitary measures taken in relation to environmental hazards may be integrated into 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.

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

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

The main elements of documentation are:

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

ANNEX VI

STANDARDS COMMITTEE DRAFT
COUNTRY CONSULTATION
MAY 2002

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY MEASURE

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

INTRODUCTION

SCOPE

This standard provides technical guidance on the application of ionizing radiation as a phytosanitary treatment for regulated pests. This does not include irradiation treatments used for:

- the production of sterile organisms for pest control;
- sanitary treatments (food safety and animal health);
- the preservation or improvement of commodity quality (e.g. shelf life extension); or
- inducing mutagenesis.

REFERENCES

Export certification system, 1997. ISPM Pub. No. 7, FAO, Rome.
Guidelines for phytosanitary certificates, 2001. ISPM Pub. No. 12, FAO, Rome.
Glossary of phytosanitary terms, 2002. ISPM Pub. No. 5, FAO, Rome.
Guidelines for Pest Risk Analysis, 1996. ISPM Pub. No. 2, FAO, Rome.
International Plant Protection Convention, 1992. FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest Risk Analysis for quarantine pests, 2001. ISPM Pub. No. 11, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM Pub. No. 14, FAO, Rome.

DEFINITIONS AND ABBREVIATIONS[4]

absorbed dose*	Quantity of radiation energy (in **gray**) absorbed per unit of mass of a specified material [ISPM Pub. No. *(Ir), 2003]
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**]
Commodity	A type of **plant**, **plant product**, or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
Dmin*	The localized minimum absorbed dose within the process load [ISPM Pub. No. *(Ir), 2003]
devitalization	A procedure rendering **plants** or **plant products** incapable of germination, growth or further reproduction [ICPM, 2001]

[4] The references listed in brackets refer to the definition or revision of the term. Please see the most recent version of the Glossary of phytosanitary terms for the most up-to-date reference.

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

dose mapping*	Measurement of the absorbed dose distribution within a process load through the use of dosimeters placed at specific locations within the process load [ISPM Pub. No. *(Ir), 2003]
dosimeter*	A device that, when irradiated, exhibits a quantifiable change in some property of the device which can be related to absorbed dose in a given material using appropriate analytical instrumentation and techniques [ISPM Pub. No. *(Ir), 2003]
dosimetry*	A system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use [ISPM Pub. No. *(Ir), 2003]
efficacy (treatment)*	A defined, measurable, and reproducible effect on pests by a prescribed treatment [ISPM Pub. No. *(Ir), 2003]
gray (Gy)*	Unit of absorbed dose where 1 Gy is equivalent to the absorption of 1 joule per kilogram 1 Gy = 1 $J.kg^{-1}$ Formerly, the special unit for absorbed dose was the rad 1 rad = 10^{-2} $J.kg^{-1}$ = 10^{-2} Gy [ISPM Pub. No. *(Ir), 2003]
inactivation*	Rendering micro-organisms incapable of development [ISPM Pub. No. *(Ir), 2003]
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**]
ionizing radiation	Charged particles and electromagnetic waves that as a result of physical interaction, creates ions by either primary or secondary processes [ISPM Pub. No. *(Ir), 2003]
irradiation*	Treatment with any type of ionizing radiation [ISPM Pub. No. *(Ir), 2003]
NPPO	National Plant Protection Organization [FAO, 1990; ICPM, 2001]
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to **plants** or **plant products** [FAO, 1990; revised FAO, 1995; IPPC, 1997]

phytosanitary certification	Use of **phytosanitary procedures** leading to the issue of a **Phytosanitary Certificate** [FAO, 1990]
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; ISC, 2001]

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

PRA	**Pest Risk Analysis** [FAO, 1995; revised ICPM, 2001]
process load*	A volume of material with a specified loading configuration and treated as a single entity [ISPM Pub. No. *(Ir), 2003]
regulated pest	A **quarantine pest** or a **regulated non-quarantine pest** [IPPC, 1997]
required response*	A specified level of effect for a treatment [ISPM Pub. No. *(Ir), 2003]
treatment	**Officially** authorized procedure for the killing or removal of pests or rendering **pests** infertile [FAO, 1990, revised FAO, 1995; ISPM Pub. No. 15, 2002]

OUTLINE OF REQUIREMENTS

Treatment with ionizing radiation (irradiation) may be used for pest risk management. The adoption of irradiation by NPPOs requires that the efficacy of the treatment be scientifically demonstrated for the regulated pest(s) of concern and the required response. Application of the treatment requires dosimetry and dose mapping to ensure that the treatment is effective in particular facilities and with specific commodity configurations. The NPPO should verify that facilities are appropriately designed and procedures are in place to ensure that the treatment can be conducted properly and commodity lots are handled, stored and identified to ensure their phytosanitary integrity. Recordkeeping by the treatment facility and documentation requirements for the facility and NPPO are also important aspects of irradiation treatment and should include a compliance agreement stipulating in particular the specific requirements for phytosanitary measures.

GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY MEASURE

1. Authority

The NPPO is responsible for the phytosanitary aspects of evaluation, adoption, and use of irradiation as a phytosanitary measure where the technology is authorized by the country in question. To the extent necessary, the NPPO should cooperate with other national and international regulatory agencies to avoid overlapping, conflicting, inconsistent or unfair requirements and their respective responsibilities should be identified. This includes phytosanitary authorities as well as regulatory bodies concerned with the development, approval, safety, and application of irradiation or the distribution, use, or consumption of irradiated products.

2. Treatment Objective

The objective of using irradiation as a phytosanitary measure is to prevent the introduction or spread of regulated pests. This may be realized by achieving certain responses in the targeted pest(s) such as:

- mortality;
- preventing successful development of pests (e.g. non-emergence of adults);
- the inability of the pest(s) to reproduce (e.g. sterility); or
- inactivation (failure of microorganisms causing plant disease to develop).

Phytosanitary uses of irradiation also include the devitalization of plants (failure of plants, including seeds, to grow or reproduce: e.g. seeds may germinate but seedlings do not grow; or tubers, bulbs or cuttings do not sprout).

2.1 Efficacy

The treatment efficacy should be specifically defined by the importing NPPO. It consists of two distinct components:

- a precise description of required response;
- the statistical level of response required.

It is not sufficient to only specify a response without also describing how this is to be measured.

The choice of a required response is based on the risk as assessed through PRA, considering in particular the biological factors leading to establishment and taking into account the principle of minimal impact. A response such as mortality may be appropriate where the treatment is for the vector of a pathogen, whereas sterility may be the most appropriate response for pest(s) that are not vectors and remain on or in the commodity.

The level to which the required response is achieved should also be specified.

If the response is mortality, time limits for the effect of the treatment should be established.

A range of specific options may be specified where the expected response is the inability to reproduce. These include:

- complete sterility;
- limited fertility of only one sex;
- egg laying and/or hatching without further development;
- altered behaviour; and
- sterility of F_1 generation.

3. Treatment

Ionizing radiation may be provided by isotopes (gamma rays from cobalt-60 or cesium-137), electrons generated from machine sources up to 10MeV, or by x-rays up to 5 MeV. The unit of measurement for absorbed dose should be gray (Gy).

Variables to consider when implementing irradiation treatments include the dose rate, treatment time, temperature, humidity, ventilation and modified atmospheres that may be compatible with treatment effectiveness. Modified atmospheres may reduce treatment efficacy at a prescribed dose. Treatment procedures ensure that the minimum absorbed dose (Dmin) is fully attained throughout the commodity to provide the prescribed level of efficacy. Because of the differences in the configuration of treatment lots, doses of at least three times the Dmin may be required to ensure that the Dmin is achieved throughout the configured consignment or lot. The intended end use of the product should not be jeopardized by the irradiation treatment.

3.1 Application

Irradiation treatments may be single treatments or combined with other treatments, or part of a systems approach (see ISPM Pub. No. 14: *The use of integrated measures in a systems approach for pest risk management*). Irradiation can be applied:

- as an integral part of packing operations;
- to bulk unpackaged commodities (such as grain moving over a belt);
- at centralized locations such as the port of embarkation.

When safeguards are adequate and transit movement of the untreated commodity is operationally feasible, treatment may also be performed:

- at the port of entry;
- at a designated location in a third country;
- in the country of final destination.

Treated commodities should only be certified and released only after dosimetry measurements confirm that the Dmin was met. The appropriate re-treatment of consignments may be allowed.

Annex 1 lists the doses for specific approved treatments. The Appendix provides guidance on absorbed dose ranges for certain pest groups.

4. Dosimetry

Dosimetry ensures that the required Dmin for a particular commodity was delivered to all parts of the consignment. The selection of the dosimetry system should be within the range of

the Dmin and calibrated in accordance with international standards or appropriate national standards.

Dosimeters should be appropriate for the treatment conditions. Dosimeters should be evaluated for stability against the effects of variables such as light, temperature, humidity, storage time, and the type and timing of analyses required.

Dosimetry should consider variations due to density and composition of the material treated, variations in shape and size, variations in orientation of the product, stacking, volume, and packaging. Dose mapping of the product in every geometric packing configuration, arrangement, and product density that will be used during routine treatments should be required prior to the approval of a facility by the NPPO. Only the configurations approved by the NPPO should be used for actual treatments.

4.1 Calibration of components of the dosimetry system

All components of the dosimetry system should be calibrated according to documented standard operating procedures. An independent organization recognized by the NPPO should assess performance of the dosimetry system.

4.2 Dose mapping

Dose mapping studies should be conducted to fully characterize the dose distribution within the irradiation chambers and commodity and demonstrate that the treatment consistently meets prescribed requirements under defined and controlled conditions. Dose mapping should be done in accordance with documented standard operating procedures. The information from the dose mapping studies is used in the selection of locations for dosimeters during routine processing.

Independent dose mapping for incomplete (partially-filled) as well as first and last process loads is required to determine if the absorbed-dose distribution is significantly different from a routine load and to adjust the treatment accordingly.

4.3 Routine dosimetry

An accurate measurement of absorbed dose in a consignment is critical for determining and monitoring efficacy and is part of the verification process. The required number and frequency of these measurements should be prescribed based on the specific equipment, processes, commodities, and relevant standards.

5. Approval of Facilities

Treatment facilities should be approved by relevant nuclear regulatory authorities where appropriate. Treatment facilities should also be subject to approval (qualification, certification, or accreditation) by the NPPO prior to applying phytosanitary treatments. Phytosanitary approval should be based on a common set of criteria plus those specific to the site and commodity programmes (see Annex 3).

Phytosanitary re-approval should be done on an annual basis or following repairs, modifications, or adjustments in equipment or processes that affect the absorbed dose.

6. System Integrity

Confidence in the adequacy of irradiation treatment is primarily based on assurance that the treatment is efficacious against the pest(s) of concern under specific conditions and the treatment has been properly conducted and the commodity adequately safeguarded.

Efficacy research and dosimetry provide assurance that only efficacious treatments are used. Well-designed and closely monitored systems for treatment delivery and safeguarding assure that treatments are properly conducted and consignments protected from infestation, reinfestation or loss of integrity.

6.1 Phytosanitary security measures

Treated commodities should be adequately segregated, clearly identified and handled under conditions that will safeguard against contamination and/or infestation or mistaken identity.

A fail-safe means of moving the commodity from receiving areas to treatment areas without mistaken identity or risk of cross-contamination and/or infestation is essential. Appropriate procedures specific to each facility and commodity treatment programme should be agreed upon in advance. Commodities that are unpackaged or exposed in packaging require safeguarding immediately following treatment to ensure that they are not subject to infestation, reinfestation or contamination afterward.

Packaging prior to irradiation may be useful to prevent reinfestation if irradiation is done prior to export, or to prevent the accidental escape of target pest(s) if treatment is done at the destination.

6.2 Labeling

Packages should be labeled with treatment lot numbers and other identifying features allowing the identification of treatment lots and trace-back (i.e. packing and treatment facility identification and locations, dates of packing and treatment).

6.3 Verification

The adequacy of treatment facilities and processes should be verified through monitoring and audit of facility treatment records that include, as necessary, direct treatment oversight. Direct, continuous supervision of treatments should not be necessary provided treatment programmes are properly designed to ensure a high degree of system integrity for the facility, process, and commodity in question. This level of oversight should be sufficient to detect and correct deficiencies promptly.

The degree of verification required for a facility is determined by:

- approval of the facility by NPPOs of both the importing and exporting countries;
- the monitoring and certification programme as administered by the NPPO of the country where treatments are conducted;
- agreement on a document procedure including provisions for unannounced monitoring and free access to treatment records;
- the degree of compliance with national and international regulations and standards for irradiation processing;

- the maintenance and history of the facility.

7. Documentation and Monitoring

Appropriate treatment records should be kept by the irradiation facility for at least one year to ensure traceability of treated lots. As in the case of any phytosanitary treatment, trace-back capability is essential if pests other than the target pests are detected.

7.1 Identification and traceability

Documented procedures help to ensure that commodities are consistently treated as required. Process controls and operational parameters are usually established to provide the operational details necessary for a specific authorization and/or facility. At a minimum, an agreed written procedure should address the following:

- consignment handling procedures before, during, and after treatment;
- orientation and configuration of the commodity during treatment;
- critical process parameters and the means for their monitoring;
- dosimetry;
- contingency plans and corrective actions to be taken in the event of treatment failure or problems with critical treatment processes;
- procedures for handling rejected lots;
- labeling, recordkeeping and documentation requirements.

7.2 Facilities

Packers and treatment facility operators should be required to keep records. These records should be available to the NPPO for review especially when a trace-back is necessary.

Calibration and quality control programmes should be documented by the facility operator. The facility operator should keep all records for every treatment. Dosimetry records must be kept by the treatment facility for at least one full year after treatment. In most cases, these records are required under other authorities, but these records should also be available to the NPPO for review. Other information that may be required to be recorded includes:

- identification of facility and responsible parties;
- identity of commodities treated;
- purpose of treatment;
- target quarantine pest(s);
- packer, grower and identification of the place of production of the commodity;
- lot size, volume, and identification, including number of articles or packages;
- identifying markings or characteristics;
- quantity in lot;
- absorbed dose – target and measured
- date of treatment

7.3 Inspection

Inspection at export should ensure that quarantine pests are absent, other than the pest(s) being targeted by the irradiation treatment. The detection of other than target pest(s) on import should be assessed for the risk and appropriate measures taken, considering in particular the effect the irradiation treatment may have had on the non-target pest(s).

For quarantine purposes it is essential that pest(s) surviving irradiation treatment are rendered unable to reproduce and it is desirable for pest(s) to be unable to emerge from the commodity unless they can be practically distinguished from non-irradiated pest(s). As the application of irradiation treatments for quarantine purposes may not result in the target pest(s) mortality, the detection of live stages of target pests in either import or export inspection should not be considered to represent treatment failure unless evidence exists to indicate that the integrity of the treatment system was inadequate. Laboratory or other analyses may be performed on surviving target pest(s) to verify treatment efficacy. Such analyses should only be required infrequently as part of monitoring unless there is evidence to indicate problems in the treatment process.

The NPPO of the importing country should not consider the detection of live target pests, or other pests as appropriate, a treatment failure unless mortality was the required response when determining contingencies for the interception of live quarantine pests on consignments that have been subject to irradiation treatment and certified by the NPPO of the exporting countries.

7.4 Certification

Phytosanitary certification in accordance with the IPPC validate the successful completion of an irradiation treatment when required by the importing country. Certification should specifically identify the treated lot(s) and record the target minimum dose and the verified Dmin.

The NPPO may issue Phytosanitary Certificates based on treatment information provided to it by an entity approved by the NPPO. It should be recognized that the Phytosanitary Certificate may require other information supplied to verify additional phytosanitary requirements have also been met (see ISPM No. 7: *Export certification system* and ISPM No.12: *Guidelines for phytosanitary certificates*).

8. Administration

The NPPO should have the ability and resources to evaluate, adopt and authorize irradiation undertaken for phytosanitary purposes. Policies, procedures, and requirements developed for irradiation should be consistent with those associated with other phytosanitary measures, except where the use of irradiation requires a different approach because of unique circumstances.

The NPPO in the importing country or the exporting country may, by cooperative agreement, defer to the other NPPO or other agreed upon national authorities for the monitoring, certification, accreditation and approval of facilities for phytosanitary treatments.

Memorandums of Understanding (MOUs), compliance agreements, or similar documented agreements between NPPOs and the treatment applicator/facility should be used to outline process requirements and assure that responsibilities, liabilities, and the consequences of non-compliance are clearly understood. Such documents also strengthen the enforcement capability of the NPPO if corrective action may be necessary.

9. Research

Research into all phytosanitary treatments shares common steps. However, irradiation is unique because acute mortality rarely is justified as the required response. Greater skill is required to keep the pests in good condition post treatment in order to evaluate responses.

It is the responsibility of the NPPO to ensure that prescribed treatments are efficacious against phytosanitary pests. The equipment, processes, and dosimetry for treatment research should be well documented and standardized whenever possible. Details concerning the condition of commodities both before and after treatments, as well as the condition and viability of the pests and survivors, should be reported.

Annex 2 provides further guidance on undertaking research for the irradiation of quarantine pests.

10. Commodity tolerance

The research and commercial sectors share responsibility to ensure that phytosanitary treatments also are practical for commercial use. Phytotoxic effects are not usually addressed by NPPO officials of the exporting or importing countries, but this aspect is important from a practical standpoint and should be considered because it affects the commercial quality of the commodity and therefore the feasibility of the treatment. In addition, data addressing the commercial feasibility of treatments, including phytotoxicity and issues of quality can be useful to the NPPO in prioritizing the resources devoted to treatment approval.

Experiments prior to confirmatory tests determine the tolerance of commodities to irradiation doses up to three times that demonstrated by research to be efficacious. Normal commercial practice is that a dose of at least three times the Dmin is applied to ensure that the Dmin is achieved throughout the configured consignment or lot. Irradiated commodities should not have significant loss of quality or shelf life. For some fresh produce, a slightly later harvest date than usual may be desirable where it is known that irradiation treatment interferes with ripening and extends the shelf life.

ANNEX 1

SPECIFIC APPROVED TREATMENTS

The purpose of this annex is to list irradiation treatments that are globally approved for specified applications. [Treatment schedules to be added as agreed in future].

ANNEX 2

RESEARCH PROTOCOL[5]

Research materials

It is recommended to archive samples of the different developmental stages of the pests studied in order to, among other reasons, resolve possible future disputes on identification. The commodity to be used should be of normal commercial condition.

To perform treatment research to control quarantine pests it is necessary to know its basic biology as well as define how the pests used in the research will be obtained. The experiments with irradiation should be carried out on the commodity infested naturally in the field and/or with laboratory-reared pests that are used to infest the commodity preferably in a natural form. The method of rearing and feeding should be carefully detailed.

Note: Studies done with pests *in vitro* are not recommended because the results could be different from those obtained when irradiating the pests in commodities.

Dosimetry

The dosimetry system should be calibrated, certified, and used according to recognized international standards. The minimum and maximum doses absorbed by the irradiated product should be determined striving for dose uniformity. Routine dosimetry should be conducted periodically.

Estimation and confirmation of minimum absorbed dose for treatment

Preliminary Tests
The following steps should be carried out to estimate the dose required to ensure quarantine security:

- Radiosensitivity of the different stages of development of the pest in question that may be present in the commodity that is marketed must be established with the purpose of determining the most resistant stage. The most resistant stage, even if it is not the most common one occurring in the commodity, is the stage for which the quarantine treatment dose is established.
- The minimum absorbed dose will be determined experimentally. If pertinent data do not already exist, it is recommended to use five (5) dose levels and a control for each developmental stage, with a minimum of 50 individuals for each of the doses and a minimum of three (3) replicates. The relationship between dose and response for each stage will be determined to identify the most resistant stage. The optimum dose to interrupt the development of the most resistant stage and/or to avoid the reproduction of the pests needs to be determined. The remainder of the research will be conducted on the most radiotolerant stage.
- During the period of post-treatment observation the commodities and associated pests, both treated and control, must remain under favorable conditions for survival, development, and reproduction of the pests so that these parameters can be measured. The untreated

[5] Based primarily on insect pest treatment research.

controls must develop and/or reproduce normally for a given replicate for the experiment to be valid.

Large Scale (Confirmatory) Tests

- To confirm if the estimated minimum dose to provide quarantine security is valid, it is necessary to treat a large number of the most resistant stage while achieving the desired result, be it lack of pest development or sterility. The number treated will depend on the requirement of the importing country. The level of efficacy of the treatment should be established between the exporting and importing countries and be technically justifiable.
- Because the maximum dose measured during the confirmatory part of the research will be the minimum dose required for the approved treatment, it is recommended to keep the maximum-minimum dose ratio as low as possible.

Recordkeeping

Test records and data need to be kept to validate the data requirements and should be presented to the importing country for consideration in establishing the agreed commodity treatment.

ANNEX 3

CHECKLIST FOR FACILITY APPROVAL

The following checklist is intended to assist persons inspecting or monitoring facilities seeking to establish/maintain facility approval and certification of irradiated commodities for international trade. The failure to receive an affirmative response to any item should result in the refusal to establish or the termination of an existing approval or certification.

Criteria	**Yes**	**No**
1. Premises		
Irradiation facility meets the approval of the NPPO as regards phytosanitary requirements. The NPPO has reasonable access to the facility and appropriate records as necessary to validate phytosanitary treatments		
Facility buildings are designed and built to be suitable in size, materials, and placement of equipment to facilitate proper maintenance and operations for the lots to be treated		
Appropriate means, integral to the facility design, are available to maintain non-irradiated consignments and/or lots separate from treated consignments and/or lots		
Appropriate facilities are available for perishable commodities before and after treatment		
Buildings, equipment, and other physical facilities are maintained in a sanitary condition and in repair sufficient to prevent contamination of the consignments and/or lots being treated		
Effective measures are in place to prevent pests from being introduced into processing areas and to protect against the contamination or infestation of consignments and/or lots being stored or processed		
Adequate measures are in place to handle breakage, spills, or the loss of lot integrity		
Adequate systems are in place to dispose of commodities or consignments that are improperly treated or unsuitable for treatment		
Adequate systems are in place to control non-compliant consignments and/or lots and when necessary to suspend facility approval		
2. Personnel		
The facility is adequately staffed with trained, competent personnel		
Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes		
3. Product handling, storage and segregation		
Commodities are inspected upon receipt to ensure that they are suitable for irradiation treatment		
Commodities are handled in an environment that does not increase the risk of contamination from physical, chemical, or biological hazards		
Commodities are appropriately stored and adequately identified. Procedures and facilities are in place to ensure the segregation of treated and untreated consignments and/or lots		
4. Irradiation treatment		
Facility is able to perform required treatments in conformity with a		

Criteria	Yes	No
scheduled process. A process control system is in place providing criteria to assess irradiation efficacy		
Proper process parameters are established for each type of commodity or consignment to be treated. Written procedures have been submitted to the NPPO and are well known to appropriate treatment facility personnel		
Absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices. Dosimetry records are kept and made available to the NPPO as needed		
5. Packaging and labeling		
Commodity is packaged (if necessary) using materials suitable to the product and process		
Treated consignments and/or lots are adequately identified or labeled (if required) and adequately documented		
Each consignments and/or lot carries an identification number or other code to distinguish it from all other lots		
6. Documentation		
All records about each consignment and/or lot irradiated are retained at the facility for the period of time specified by relevant authorities and are available for inspection by the NPPO as needed		
The NPPO has a written compliance agreement with the facility		

APPENDIX

This listing is for reference purposes only. The references here are widely available, easily accessible and generally recognized as authoritative. The list is not comprehensive or static; nor is it endorsed as a standard under this ISPM.

ESTIMATED MINIMUM ABSORBED DOSES FOR CERTAIN RESPONSES FOR SELECTED PEST GROUPS[6]

The following table identifies ranges of minimum absorbed dose for pest groups based on treatment research reported in the scientific literature. Minimum doses are taken from many publications that are in the references listed below. Confirmatory testing should be done before adopting the minimum dose for a specific pest treatment.

Pest group	Required response	Minimum Dose Range (Gy)
Aphids and whiteflies (Homoptera)	Sterilize actively reproducing adult	50-100
Seed weevils (Bruchidae)	Sterilize actively reproducing adult	70-100
Scarab beetles (Scarabidae)	Sterilize actively reproducing adult	50-150
Fruit flies (Tephritidae)	Prevent adult emergence from 3rd instar	50-150
Weevils (Curculionidae)	Sterilize actively reproducing adult	80-165
Borers (Lepidoptera)	Prevent adult development from late larva	100-280
Thrips (Thysanoptera)	Sterilize actively reproducing adult	150-250
Borers (Lepidoptera)	Sterilize late pupa	200-350
Spider Mites (Acaridae)	Sterilize actively reproducing adult	200-350
Stored product beetles (Coleoptera)	Sterilize actively reproducing adult	50-400
Stored product moths (Lepidoptera)	Sterilize actively reproducing adult	100-1,000
Nematodes (Nematocera)	Sterilize actively reproducing adult	~4,000

References

[IAEA] International Atomic Energy Agency. 2002. Global database on irradiation efficacy research <http://www.adidas.iaea.org>. (not yet published on-line).

Hallman, G. J. 2001. Irradiation as a quarantine treatment. In: Molins, R.A. (ed.) Food Irradiation Principles and Applications. New York: J. Wiley & Sons. p. 113-130.

Hallman, G. J. 2000. Expanding radiation quarantine treatments beyond fruit flies. J Agric. and Forest Entomol. 2:85-95.

[6] Not conclusively demonstrated with large scale testing. Based on literature review by Hallman, 2001

Standards Committee
May 2002

International Plant Protection Convention
International Standards for Phytosanitary Measures

SPECIFICATIONS FOR STANDARDS

Specification No. 8: EFFICACY OF MEASURES: CONCEPT AND APPLICATION

Description of the purpose of the standard
This standard is to provide technical guidance for a framework for measuring and evaluating the efficacy of phytosanitary measures. It should provide the basis for a procedure for the ICPM for the evaluation of measures approved in standards and also provide the fundamental elements to be elaborated in greater detail in supporting documents (e.g. supplemental standards).

Scope
This should be a concept standard on the evaluation of efficacy of phytosanitary measures, linked to the risk management aspects of PRA and also relevant aspects of other standards (and draft standards) associated with risk management including treatments and surveillance. The standard should make provision for supplemental standards dealing with practical aspects of specific measures and methodologies.

Tasks
Review existing standard(s), draft standards, discussion and reference papers and other technical information available on measuring and evaluating the efficacy of measures. Formulate a standard that describes fundamental principles and concepts and identifies specific approaches and/or methodologies most useful for phytosanitary purposes. Note for the Standards Committee any points to be considered for the future development of related standards and identify those standards considered to be highest priority. Propose a framework and strategy for future supporting work, including the development of procedures by the ICPM for evaluating measures to be adopted in standards. Note also for the Standards Committee any problems or concerns anticipated by application of the standard in practice.

Provision of resources
Funded by the FAO Regular Programme for the IPPC Secretariat.

Proposed work programme
First Expert Working Group tentatively set for 1-5 July 2002 (it is anticipated that additional working groups will be required). Report-back to the SC with draft documents, reference material, and the draft report from the meeting as soon as available or no later than 15 September 2002.

Steward
John Hedley (New Zealand), with assistance from Christopher Hood (Australia)

Collaborator
Imperial College (UK) by invitation of GISP in cooperation with the NPPO of the UK as appropriate

Expertise
5-7 international phytosanitary experts having interest and expertise in the evaluation of efficacy of phytosanitary measures, linked to the risk management aspects of PRA and also relevant aspects of other standards (and draft standards) associated with risk management including treatments and surveillance.

Participants to be determined

Approval
First Session of the Standards Committee; May 2002

References to be determined

Specification No. 9: PEST RISK ANALYSIS FOR REGULATED NON-QUARANTINE PESTS

Description of the purpose of the standard
This standard is to complement ISPM Pub. No. 11: *Pest Risk Analysis for quarantine pests.* It will provide technical guidance specifically for the analysis of RNQP and the technical justification for measures for regulated non-quarantine pests (RNQP). It should be a stand-alone standard (similar to ISPM 11) but consistent with ISPM 11, and to the extent possible, ISPM 2 (*Guidelines for Pest Risk Analysis*), and ISPM 16 (*Regulated non-quarantine pests: concept and application*).

Scope
This standard should address the full process of PRA for RNQP (not only the aspects unique to RNQP). Particular emphasis should be placed on pest categorization and the evaluation of consequences owing to the critical nature of these aspects of PRA for RNQP. Relevant approaches or methodologies should be described in particular as regards the evaluation of economic impacts and criteria to consider when determining the acceptable level of risk.

Tasks
Review existing standard(s), draft standards, discussion and reference papers and other technical information available on RNQP. Formulate a standard that describes the full process of PRA for RNQP, including specific approaches and/or methodologies. Note for the Standards Committee any problems or concerns associated with the process of PRA for RNQP and any difficulties anticipated by application of the standard in practice.

Provision of resources
Funded by the FAO Regular Programme for the IPPC Secretariat

Proposed work programme
First Expert Working Group set for 9-13 September 2002 in Wageningen, Netherlands.

Steward
Felipe Canale (Chair of the ICPM)

Collaborator
EPPO and the Plant Protection Service of the Netherlands

Expertise
5-7 international phytosanitary experts, including experts having familiarity and interest in PRA and crop certification schemes, some of whom have been involved with previous discussions on the concept standard for RNQP.

Participants to be determined (including Bram de Hoope)

Approval
First Session of the Standards Committee; May 2002.

References to be determined

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