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INTERIM COMMISSION ON PHYTOSANITARY MEASURES

Fifth Session

Rome, 7-11 April 2003

Adoption of International Standards

Agenda Item 5 of the Provisional Agenda

Introduction

1. Five documents, given in Annexes I-V are submitted to the ICPM for consideration. It is noted that two of these documents represent new ISPMs:

- *Guidelines for the use of irradiation as a phytosanitary measure*; and
- *Guidelines for regulated pest lists*.

Included also are proposed amendments to the *Glossary of Phytosanitary Terms* and two draft supplements:

- Supplement to ISPM No. 11: *Analysis of environmental risks*; and
- Glossary Supplement No. 2: *Guidelines on the understanding* of potential economic importance *and related terms including reference to environmental considerations*.

Amendments to the Glossary of phytosanitary terms (Annex I)

2. The Interim Standards Committee (ISC), at its Fourth Meeting in November 2001 requested that the Glossary Working Group to:

- reconsider the term *growing period* as it is related to *growing season;*
- consider the terms *transience*, *incursion*, and *outbreak* with regard to their relevance, relationship and appropriate distinctions that may need to be made in their definitions;
- review the relationship and relevance of the terms *premises* and *place of production*; and
- consider whether the term *safeguards* should be defined and included in the Glossary.

3. In addition, the Glossary Working Group was asked by the Secretariat to review terms in the draft ISPM Guidelines for the use of irradiation as a phytosanitary measure, and in the draft supplements *Risk analysis for the environmental hazards of plant pests* and *Guidelines on the*

understanding of potential economic importance *and related terms*. The Secretariat also raised concerns associated with the dual meaning of spread and variations in the interpretation and use of the terms detection and interception. The lack of consistency with conventional capitalization practices was also noted.

4. The Glossary Group met February 2002, hosted by the European and Mediterranean Plant Protection Organization in Paris, France. The recommendations of the working group on amendments to the Glossary were referred to the First Meeting of the Standards Committee (SC) in May 2002. Draft amendments approved by the SC were distributed to governments for consultation in June 2002. Comments from the consultation process were considered by the SC at their Second Meeting in November 2002. New and revised terms and definitions approved by the SC for submission to the ICPM are indicated in Annex 1.

Glossary Supplement No. 2: Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations (Annex II)

5. The Third Session of the ICPM (April 2001) recommended that the term *potential economic importance* be defined and it suggested that this may be done through a supplement to the *Glossary of phytosanitary terms*. The Secretariat added the topic to the agenda of the Glossary Working Group which met February 2002 in Paris, France. In this instance, the working group was complemented by invited experts from the United States and the United Kingdom who assisted the understanding of concepts and terminology associated with economic analyses.

6. The Glossary Working Group prepared a draft supplement which was referred to the First Meeting of the Standards Committee in May 2002. The SC approved a modified draft that was distributed to governments for consultation in June 2002. Comments from the consultation process were considered by the SC at their Second Meeting in November 2002. The draft was revised by the SC based on comments from governments before being approved for submission to the ICPM as Annex II.

Supplement to ISPM No. 11: Analysis of environmental risks (Annex III)

7. The Third Session of the ICPM (April 2001) recommended that a standard be elaborated on the application of pest risk analysis for environmental hazards, including in particular the concept of invasive species as understood from the Convention on Biological Diversity (CBD).

8. The Secretariat, in collaboration with EPPO, organized an expert working group that met August 2001 in Vienna, Austria to address the topic. The working group prepared a draft that followed ISPM No. 11: *Pest risk analysis for quarantine pests*. The draft was designed as a supplement to ISPM No. 11 based on the view of the experts that the process is essentially identical but certain additional guidance is required to highlight key points for the application of the process to environmental risks. The working group strongly recommended that the supplement be combined with ISPM No. 11 in any future revision of ISPM. No. 11.

9. The draft supplement prepared by the expert working group was referred to the First Meeting of the Standards Committee in May 2002. The SC approved a slightly modified draft that was distributed to governments for consultation in June 2002. Comments from the consultation process were considered by the SC at their Second Meeting in November 2002. The draft was revised by the SC based on comments from governments before being approved for submission to the ICPM as Annex III.

Guidelines for the use of irradiation as a phytosanitary measure (Annex IV)

10. The Third Session of the ICPM (April 2001) agreed that the Secretariat should elaborate a standard providing guidelines on the use of irradiation as a phytosanitary measure. The ICPM stated that this work would be dependent on the availability of extra-budgetary resources. It was indicated at the time that the Joint FAO-IAEA Division of Nuclear Techniques in Food and Agriculture was in a position to assist with funding and technical support.

11. An expert working group met November 2001 in Mexico City, Mexico to prepare the first draft of the standard. All costs for this meeting were covered by funds provided through the Joint FAO-IAEA Division. The draft prepared by the meeting was developed further over the following months until it was submitted to the First Meeting of the Standards Committee in May 2002. The SC reviewed and approved the draft for distribution to governments for consultation in June 2002. Comments from the consultation process were considered by the SC at their Second Meeting in November 2002. The draft was revised by the SC based on comments from governments before being approved for submission to the ICPM as Annex IV.

Guidelines for regulated pest lists (Annex V)

12. The Second Session of the ICPM (October 1999) placed a high priority on the completion of a standard providing guidelines for the listing of regulated pests according to the obligations of the IPPC. An expert working group was organized by the Secretariat in Pretoria, South Africa in January, 2000 to prepare the first draft of the standard. The draft was submitted to the First Meeting of the Interim Standards Committee in May 2000. The ISC amended the draft and approved it for distribution to governments for consultation in June 2000.

13. Comments collected by the Secretariat indicated that there were irreconcilable differences regarding the application of the standard to listing non-regulated pests. As a result, the draft was given a lower priority in later meetings of the Interim Standards Committee and subsequently the Standards Committee in order to ensure that other drafts were not delayed. In the meantime, the Secretariat shared the summary of comments with the Interim Standards Committee and undertook to identify options for further consideration by governments with differing views. Comments and options were reconsidered by the SC at their Second Meeting in November 2002, resulting in a revised draft that the SC approved for submission to the ICPM as Annex V.

14. The ICPM is invited to:

1. *Adopt* the amendments to the *Glossary of phytosanitary terms* in Annex I, noting that terms and definitions adopted in new standards will also become amendments to the Glossary.
2. *Note* that the Glossary has been updated to reflect conventional capitalization practices.
3. *Adopt* as Glossary Supplement No. 2: *Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations* in Annex II.
4. *Adopt* as a supplement to ISPM No. 11: *Analysis of environmental risks* in Annex III.
5. *Note* that the expert working group has strongly recommended that the supplement be integrated with ISPM No. 11 and *recommend* whether this should be undertaken.
6. *Adopt* as ISPM No. 18: *Guidelines for the use of irradiation as a phytosanitary measure* in Annex IV and *express its gratitude* to the FAO-IAEA Joint Division for its support.
7. *Adopt* as ISPM No. 19: *Guidelines for regulated pest lists* in Annex V.

STANDARDS COMMITTEE DRAFT
November 2002

AMENDMENTS TO THE GLOSSARY OF PHYTOSANITARY TERMS

New and Revised Terms and Definitions

growing period (of a plant species)	Time period of active growth during a growing season
growing season	Period or periods of the year when plants actively grow in an area, place of production or production site
incursion	An isolated population of a pest recently detected in an area, not known to be established, but expected to survive for the immediate future
outbreak	A recently detected pest population, including an incursion, or a sudden significant increase of an established pest population in an area

Glossary of phytosanitary terms, Supplement N° 2

GUIDELINES ON THE UNDERSTANDING OF *POTENTIAL ECONOMIC IMPORTANCE* AND RELATED TERMS INCLUDING REFERENCE TO ENVIRONMENTAL CONSIDERATIONS

1. Purpose and Scope

These guidelines provide the background and other relevant information to clarify *potential economic importance* and related terms, so that such terms are clearly understood and their application is consistent with the International Plant Protection Convention (IPPC) and the International Standards for Phytosanitary Measures (ISPM). These guidelines also show the application of certain economic principles as they relate to the IPPC's objectives, in particular in protecting uncultivated/unmanaged plant species, wild flora, habitats and ecosystems with respect to invasive alien species that are plant pests.

These guidelines clarify that the IPPC:

- can account for environmental concerns in economic terms using monetary or non-monetary values;
- does **not** assert that market impacts are the sole measure of pest consequences;
- 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 an area.

The scope of the IPPC extends to the protection of cultivated plants in agriculture (including horticulture or forestry), uncultivated/unmanaged plant species, wild flora, habitats and ecosystems.

2. Background

The IPPC has historically maintained that the adverse consequences of plant pests, including those concerning uncultivated/unmanaged plant species, wild flora, habitats and ecosystems, are measured in economic terms. References to the terms *economic, economic effects, economic impacts, potential economic importance* and *economically unacceptable impact* and the use of the word *economic* in the IPPC and in ISPMs has resulted in some misunderstanding of the application of such terms and of the focus of the IPPC.

The scope of the Convention applies to the protection of wild flora resulting in an important contribution to the conservation of biological diversity. However, it has been misinterpreted that the IPPC is only commercially focused and limited in scope. It has not been clearly understood that the IPPC can account for ecological or environmental concerns in economic terms. This has created issues of harmonization with other agreements, including the Convention on Biological Diversity and the Montreal Protocol on Substances that Deplete the Ozone Layer.

3. Economic Terms and Environmental Scope of the IPPC and ISPMs

The economic terms found in the IPPC and ISPMs may be categorized as follows.

Terms requiring judgement to support policy decisions:

- *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 related to evidence that supports the above judgements:

- *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. Section 2.2.3 includes many items demonstrating the broad scope of economic impacts that is intended to be covered.

ISPM Pub. No. 11 notes in section 2.1.1.5 with respect to pest categorization, 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 2.3 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 2.3.2.2 addresses analysis of commercial consequences. Section 2.3.2.4 provides guidance on the assessment of the non-commercial and environmental consequences of pest introduction. It acknowledges that certain types of effects may not apply to 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. Where a risk is found to be unacceptable, Section 3.4 provides guidance on the selection of risk management options, including measurements of cost-effectiveness, feasibility and least trade restrictiveness.

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 covers the protection of cultivated plants in agriculture (including horticulture and forestry), uncultivated/unmanaged plant species, wild flora, habitats and ecosystems.

4. Economic Considerations in PRA

4.1 Types of economic effect

In PRA, economic effects should not be interpreted to be only market effects. Goods and services not sold in commercial markets can have economic value and economic analysis encompasses much more than the study of market goods and services. The use of the term *economic effects* provides a framework in which a wide variety of effects (including environmental and social effects) may be analysed. Economic analysis uses a monetary value as a measure to allow policy makers to 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.

4.2 Costs and benefits

A general economic test for any policy is to pursue the policy if its benefit is at least as large as its cost. Costs and benefits are broadly understood to include both market and non-market aspects. Costs and benefits can include both quantifiable measurements and qualitative measurements of costs and benefits. Measurement of non-market goods and services may be difficult to quantify but nevertheless are essential to consider.

Economic analysis for phytosanitary purposes can only provide information with regard to costs and benefits but does not judge if one distribution is necessarily better than another distribution of costs and benefits of a specific policy. In principle, costs and benefits should be measured regardless to whom they occur. Given that judgments about the preferred distribution of costs and benefits are policy choices, these should have a rational relationship to phytosanitary considerations.

Costs and benefits 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. Costs and benefits associated with indirect consequences of pest introductions may be less certain than costs and benefits associated with direct consequences. Often, there is no monetary information about the cost of any loss that may result from pests introduced into natural environments. Any analysis should identify and explain uncertainties involved in estimating costs and benefits and assumptions should be clearly stated.

5. Application

The following three criteria should be met before a plant pest is deemed to have *potential economic importance*:

- a potential for introduction in the PRA area;
- the potential to spread after establishment; and
- a potential harmful impact on:
    - plant health, for example crop loss; or
    - the environment, for example damage to ecosystems, habitats, or species; or
    - some other specified value, for example recreation, tourism, aesthetics.

Environmental damage, arising from the introduction of a plant pest, is one of the types of damage recognized by the IPPC. Contracting parties to the IPPC have the right to adopt

phytosanitary measures with respect to a pest that has the potential for environmental damage alone. Such action should be based upon a Pest Risk Analysis that includes the consideration of evidence of potential environmental damage. 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.

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*).

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, 2002. 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.

APPENDIX

This appendix provides additional clarification of some terms used in this supplement:

Economic analysis: It primarily uses monetary values as a measure to allow policy makers to compare costs and benefits from different types of goods and services. It encompasses more than the study of market goods and services. Economic analysis does not prevent the use of other measures that do not use a monetary value; for example, qualitative or environmental analysis.

Economic effects: This includes market effects as well as non-market effects, such as environmental and social considerations. Measurement of the economic value of environmental effects or social effects may be difficult to establish. For example, the survival and well being of another species or the value of the aesthetics of a forest or a jungle. Both qualitative and quantitative worth may be considered in measuring economic effects.

Economic impacts of plant pests: This includes both market measures as well as those consequences that may not be easy to measure in direct economic terms, but which represent a loss or damage to cultivated plants, uncultivated plants or plant products.

Economic value: This is the basis for measuring the cost of the effect of changes (e.g. in biodiversity, ecosystems, managed resources or natural resources) on human welfare. Goods and services not sold in commercial markets can have economic value. Determining economic value does not prevent ethical or altruistic concerns for the survival and well-being of other species based on cooperative behavior.

Qualitative measurement: This is the valuation of qualities or characteristics in other than monetary or numeric terms.

Quantitative measurement: This is the valuation of qualities or characteristics in monetary or other numeric terms/values.

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

SCOPE

This supplement to ISPM Pub. No. 11 (*Pest Risk Analysis for quarantine pests*) provides details regarding the analysis of risks of plant pests to the environment and biological diversity, including those risks affecting uncultivated/unmanaged plant species, wild flora, habitats and ecosystems contained in the PRA area.

This supplement does not include consideration of:

- vertebrates;
- marine environments;
- the intentional introduction of biological control agents (separately covered under the IPPC by ISPM Pub. No. 3 (*Code of conduct for the import and release of exotic biological control agents*); and
- living modified organisms (dealt with in separate ICPM guidelines).

PURPOSE

This supplement provides more detailed guidance on the analysis of the consequences for the environment and biological diversity of the introduction of quarantine pests, as part of the assessment of potential economic consequences described 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 therefore they have been less likely to be evaluated, regulated and/or placed under official control. An example of this type of pest is Dutch elm disease (*Ophiostoma novo-ulmi*).

- *indirectly affect plants*

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

- *indirectly affect plants through effects on other organisms*

Specific guidance is needed on pests that primarily affect other organisms, but thereby cause deleterious effects on plant species, or plant health in habitats or ecosystems. Examples are tracheal

mites (*Acarapis woodi*) and the Varroa mite (*Varroa destructor*). These pests destroy bees and interfere with the pollination of plants.

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

This supplement should only be used in conjunction with ISPM Pub. No. 11. It is not a stand-alone document. The elements it describes are relevant to any PRA for quarantine pests. The supplement does not describe an independent PRA process.

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.

Environmental consequences are included in 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. In addition, many organisms indirectly affecting plants also satisfy this definition (such as weeds/invasive plants). The fact that they are injurious to plants can be based on evidence obtained in an area where they occur. In the case of organisms where there is insufficient evidence that they affect plants indirectly, it may nevertheless be appropriate to assess on the basis of available pertinent information, whether they are potentially injurious in the PRA area by using a clearly documented,

consistently applied and transparent system. This is particularly important for plant species or cultivars that are imported for planting.

1.1.1 PRA initiated by the identification of a pathway

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

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

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

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 (see ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1 on official control).

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.

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

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, wherever a reference is made to a host or a host range, this should be understood to refer instead to a suitable habitat[*] in the PRA area.

In the case of imported plants, the concepts of entry, establishment and spread have to be considered differently. An imported plant for planting 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 unintended habitats within the PRA area, and then establish in those habitats. Accordingly, section 2.2.3 may be considered before section 2.2.2. Unintended habitats may occur in the vicinity of the intended habitat in the PRA area.

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

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

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 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 imported plants, establishment concerns the unintended habitats.

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 imported plants, spread takes place from the intended habitat or place of intended use to an unintended habitat, where the pest may establish. Further spread may then occur to other unintended habitats.

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

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

2.2.4 Conclusion on the probability of introduction and spread

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

2.2.4.1 Conclusion regarding endangered areas

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

2.3 Assessment of potential economic consequences

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

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

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/invasive plants; and
- pests affecting plants through effects on other organisms.

Specific evidence is needed of direct and indirect environmental effects.

In the case of plants which are imported for planting, the consequences for the intended habitat should be included in addition to those for the unintended habitats. Planting may affect further use or have a harmful effect on the intended habitat.

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

2.3.1.1 Direct pest effects

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

- known or potential host plants (in the field, under protected cultivation, or in the wild)
- types, amount and frequency of damage
- crop losses, in yield and quality
- biotic factors (e.g. adaptability and virulence of the pest) affecting damage and losses
- abiotic factors (e.g. climate) affecting damage and losses
- rate of spread

- rate of reproduction
- control measures (including existing measures), their efficacy and cost
- effect on existing production practices
- environmental effects.

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

Examples of direct pest effects on plants and/or their environmental consequences include:

- reduction of keystone plant species;
- reduction of plant species that are major components of ecosystems (in terms of abundance or size), and endangered plant 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 or environmentally significant, non-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 pest effects on plants and/or their environmental consequences include:

- significant 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, erosion, water table changes, increased fire hazard, nutrient cycling, etc.);
- effects on human use (e.g. water quality, recreational uses, tourism, animal grazing, hunting, fishing); and
- costs of environmental restoration.

As noted above, the effects on human and animal health (e.g. toxicity, allergenicity) may be considered, as appropriate, by other agencies/authorities.

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

Whether the element of the environment is being assessed in terms of use or non-use values, methods exist for their valuation, such as market-based approaches, surrogate markets, simulated markets, and benefit transfer. 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.

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

2.3.2.1 Time and place factors

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

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

2.3.2.2 Analysis of commercial consequences

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

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

2.3.2.3 Analytical techniques

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

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

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

2.3.2.4 Non-commercial and environmental consequences

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

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.

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

2.5 Conclusion of the pest risk assessment stage

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

3. Stage 3: Pest Risk Management

In relation to the opening paragraph of Stage 3, it should be stressed that the purpose of phytosanitary measures is to reduce phytosanitary risks. All these measures are intended to account for uncertainty and should be designed in proportion to the risk. Regardless of the degree of uncertainty in the assessment of economic consequences and probability of introduction, pest risk management should be addressed.

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 processs 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 and the concept of official control also apply to:

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

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

The 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 import of 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 imported plants, it may be decided not to take phytosanitary measures at import, but only to apply surveillance or other procedures 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 should, as appropriate, be notified to relevant competent authorities responsible for national biodiversity policies, strategies and action plans.

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

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.

STANDARDS COMMITTEE DRAFT (Publication No. 18)
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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 specific procedures for the application of ionizing radiation as a phytosanitary treatment for regulated pests or articles. This does not include 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.
Principles of plant quarantine as related to international trade, 1995. ISPM Pub. No. 1, 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[1]

absorbed dose*	Quantity of radiation energy (in **Gray**) absorbed per unit of mass of a specified target [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]

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

[1] 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.]

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, inactivation or removal of pests, or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM Pub. No. 15, 2002; ISPM Pub. No. *(Ir), 2003]

OUTLINE OF REQUIREMENTS

Treatment with ionizing radiation (irradiation) may be used for pest risk management. NPPOs should be assured that the efficacy of the treatment is 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. It should be demonstrated to the NPPO that facilities are appropriately designed for phytosanitary treatments. Procedures should be in place to ensure that the treatment can be conducted properly and commodity lots are handled, stored and identified to ensure that phytosanitary security is maintained. 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 between facility operator and the NPPO 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. To the extent necessary, it is the NPPO's responsibility to cooperate with other national and international regulatory agencies concerned with the development, approval, safety and application of irradiation, or the distribution, use or consumption of irradiated products. Their respective responsibilities should be identified to avoid overlapping, conflicting, inconsistent or unjustified requirements.

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 (e.g. non-emergence of adults);
- inability to reproduce (e.g. sterility); or
- inactivation.

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

2.1 Efficacy

The required 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 an appropriate response for pest(s) that are not vectors and remain on or in the commodity.

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 required 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 radioactive 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) (limits set by Codex Alimentarius). The unit of measurement for absorbed dose should be Gray (Gy).

Variables to consider when implementing 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 should also ensure that the minimum absorbed dose (Dmin) is fully attained throughout the commodity to provide the prescribed level of efficacy. Owing to the differences in the configuration of treatment lots, higher doses than 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.

Because mortality will rarely be technically justified as the required response, live target pests may be found. Therefore it is essential that the irradiation treatment ensures they are unable to reproduce. In addition, it is preferable that such pest(s) are unable to emerge from the commodity unless they can be practically distinguished from non-irradiated pest(s).

3.1 Application

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 point of entry;
- a designated location in a third country;
- a designated location within the country of final destination.

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

Annex 1 lists the doses for specific approved treatments as part of this ISPM. Appendix 1, which is attached for information only, provides some published information on absorbed dose ranges for certain pest groups.

According to the pest risks to be addressed and the available options for pest risk management, irradiation can be used as a single treatment or combined with other treatments as part of a systems approach to meet the level of efficacy required (see ISPM Pub. No. 14: *The use of integrated measures in a systems approach for pest risk management*).

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 such that the dosimeter response covers the entire range of doses likely to be received by the product. In addition, the dosimetry system should be calibrated in accordance with international standards or appropriate national standards (e.g. Standard ISO/ASTM 51261 *Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing*).

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 each geometric packing configuration, arrangement and product density that will be used during routine treatments should be required by the NPPO prior to the approval of a facility for the treatment application. 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 the 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, location and frequency of these measurements should be prescribed based on the specific equipment, processes, commodities, relevant standards and phytosanitary requirements.

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 in the country where the facility is located 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 2).

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

6. Phytosanitary System Integrity

Confidence in the adequacy of an irradiation treatment is primarily based on assurance that the treatment is effective against the pest(s) of concern under specific conditions and the treatment has been properly applied and the commodity adequately safeguarded. The NPPO of the country where the facility is located is responsible for ensuring system integrity, so that treatments meet the phytosanitary requirements of the importing country.

Efficacy research and dosimetry provide assurance that only effective 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 at the treatment facility

Because it is not possible to visually distinguish irradiated from non-irradiated products, treated commodities should be adequately segregated, clearly identified, and handled under conditions that will safeguard against contamination and/or infestation, or misidentification.

A secure means of moving the commodity from receiving areas to treatment areas without misidentification 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 afterwards.

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 Labelling

Packages should be labelled 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 location, 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.

A verification agreement should be concluded between the facility and the NPPO of the country where the facility is located. Such an agreement may include the following elements:

- approval of the facility by the NPPO of the country where the facility is located;
- the monitoring programme as administered by the NPPO of the country where treatments are conducted;
- audit provisions including for unannounced visits;
- free access to documentation and records of the treatment facility; and
- corrective action to be taken in cases of non-compliance.

7. Documentation by the Treatment Facility

The NPPO of the country where the facility is located is responsible for monitoring recordkeeping and documentation by the treatment facility and ensuring that records are available to concerned parties. As in the case of any phytosanitary treatment, trace-back capability is essential.

7.1 Documentation of procedures

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;
- labelling, recordkeeping, and documentation requirements.

7.2 Facility records and traceability

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

Calibration and quality control programmes should be documented by the facility operator. Appropriate treatment records for phytosanitary purposes should be kept by the irradiation facility for at least one year to ensure traceability of treated lots. 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 regulated 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 doses – target and measured;
- date of treatment;
- any observed deviation from treatment specification.

8. Inspection and Phytosanitary Certification by the NPPO

8.1 Export inspection

Inspection to ensure the consignment meets the phytosanitary requirements of the importing country should include:

- documentation verification, and
- examination for non-target pests.

Documentation is checked for completeness and accuracy as the basis for certifying the treatment. Inspection is done to detect any non-target pests. This inspection may be done before or after the treatment. Where non-target pests are found, the NPPO should verify whether these are regulated by the importing country.

Live target pests may be found after treatment but should not result in the certification being refused. Where mortality is required, live target pests may be found during the period immediately following the treatment application depending on the specification for efficacy (see section 2.1). Moreover, when mortality is not the required response, it is more likely that live target pests may persist in the treated consignment. This should also not result in the certification being refused. Audit checks, including laboratory analyses may be undertaken to ensure that the required response is achieved. Such checks may be part of the normal verification programme.

8.2 Phytosanitary certification

Certification in accordance with the IPPC validates the successful completion of a treatment when required by the importing country. The Phytosanitary Certificate or its associated documentation should at least specifically identify the treated lot(s), date of treatment, 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 that additional phytosanitary requirements have also been met (see ISPM No. 7: *Export certification system* and ISPM No.12: *Guidelines for Phytosanitary Certificates*).

8.3 Import inspection

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 import inspection should not be considered to represent treatment failure resulting in non-compliance 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. Where mortality is required, live target pests may be found when transport times are short, but should not result in the consignment being refused.

The detection of pests other than target pest(s) on import should be assessed for the risk posed and appropriate measures taken, considering in particular the effect the treatment may have had on the non-target pest(s). The consignment may be detained and any other appropriate action may be taken by the NPPO of the importing country. NPPOs should clearly identify the contingency actions to be taken if live pests are found:

- target pests—no action to be taken unless the required response was not achieved;
- non-target regulated pests:
  - no action if the treatment is believed to have been effective;
  - action if there is insufficient data on efficacy or the treatment is not known to be effective;
- non-target non-regulated pests—no action, or emergency action for new pests.

In case of non-compliance or emergency action, the NPPO of the importing country should notify the NPPO of the exporting country as soon as possible (see ISPM Pub. No. 13: *Guidelines for the notification of non-compliance and emergency action*).

8.4 Administration and documentation by the NPPO

The NPPO should have the ability and resources to evaluate, monitor, 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 monitoring, certification, accreditation and approval of facilities for phytosanitary treatments is normally undertaken by the NPPO where the facility is located, but by cooperative agreement may be undertaken by:

- the NPPO of the importing country;
- the NPPO of the exporting country; or
- other national authorities.

Memoranda of Understanding (MOUs), compliance agreements, or similar documented agreements between the NPPO 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. Similarly, the NPPO of the importing country may establish cooperative approval and audit procedures with the NPPO of the exporting country to verify requirements.

All NPPO procedures should be appropriately documented and records, including those of monitoring inspections made and Phytosanitary Certificates issued, should be maintained for at least one year. In cases of non-compliance or new or unexpected phytosanitary situations, documentation should be made available as described in ISPM Pub. No. 13: *Guidelines for the notification of non-compliance and emergency action.*

9. Research

Appendix 2 provides guidance on undertaking research for the irradiation of regulated pests.

ANNEX 1

SPECIFIC APPROVED TREATMENTS

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

ANNEX 2

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. There is a physical separation between incoming and outgoing holding areas where required		

Criteria	Yes	No
4. Irradiation treatment		
Facility is able to perform required treatments in conformity with a 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 using calibrated dosimetry. Dosimetry records are kept and made available to the NPPO as needed		
5. Packaging and labelling		
Commodity is packaged (if necessary) using materials suitable to the product and process		
Treated consignments and/or lots are adequately identified or labelled (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 1

This appendix is for reference purposes only. The list is not exhaustive and should be adapted to specific circumstances. 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 [1]

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.

To ensure the minimum absorbed dose is achieved for phytosanitary purposes, it is recommended to seek information about the Dmin for a particular target species and also to take into consideration the note in Appendix 2.

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 (Nematoda)	Sterilize actively reproducing adult	~4,000

References

International Atomic Energy Agency. 2002. Global database on irradiation efficacy research <http://www.ididas.iaea.org>.

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.

http://www.iaea.org/icgfi is also a useful site for technical information on food irradiation.

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

APPENDIX 2

RESEARCH PROTOCOL[2]

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 unless preliminary testing indicates that results from in vitro treatments are no different than in situ.

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.

International ISO Guidelines are available for conducting dosimetry research on food and agricultural products (see Standard ISO/ASTM 51261 *Guide for Selection and Claibration of Dosimetry Systems for Radiation Processing*).

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 at least five (5) dose levels and a control for each developmental stage, with a minimum of 50 individuals where possible 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.

[2] Based primarily on insect pest treatment research.

- During the period of post-treatment observation of 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 controls must develop and/or reproduce normally for a given replicate for the experiment to be valid. Any study where the control or check mortalities are high indicates that the organisms were held and handled under sub-optimal conditions. These organisms may give misleading results if their treatment mortality is used to predict an optimum treatment dose. In general, mortality in the control or check should not exceed 10%.

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 upon request be presented to interested parties, for example the NPPO of the importing country, for consideration in establishing an agreed commodity treatment.

STANDARDS COMMITTEE DRAFT (Publication No. 19)
November 2002

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

GUIDELINES FOR REGULATED PEST LISTS

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

INTRODUCTION

SCOPE

This standard describes the procedures to prepare, maintain and make available lists of regulated pests.

REFERENCES

Determination of pests status in an area, 1998. ISPM Pub. No. 8, 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.
Guidelines for Phytosanitary Certificates, 2001. ISPM Pub. No. 12, FAO, Rome.
Guidelines for surveillance, 1998. ISPM Pub. No. 6, FAO, Rome.
Guidelines for the notification of non-compliance and emergency action, 2001. ISPM Pub. No. 13, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest Risk Analysis for quarantine pests, 2001. ISPM Pub. No. 11, FAO, Rome.

DEFINITIONS AND ABBREVIATIONS

certificate	An official document which attests to the phytosanitary status of any consignment affected by phytosanitary regulations [FAO, 1990]
commodity	A type of plant, plant product, or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001]
NPPO	National Plant Protection Organization [FAO, 1990; ICPM, 2001]
official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]
official control	The active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests (see Glossary Supplement N° 1) [ICPM, 2001]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]
Pest Risk Analysis	The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it [FAO, 1995; revised IPPC, 1997]

pest status (in an area)	Presence or absence, at the present time, of a pest in an area, including where appropriate its distribution, as officially determined using expert judgement on the basis of current and historical pest records and other information [CEPM, 1997; revised ICPM, 1998]
phytosanitary action	An official operation, such as inspection, testing, surveillance or treatment, undertaken to implement phytosanitary regulations or procedures [ICPM, 2001]
Phytosanitary Certificate	Certificate patterned after the model certificates of the IPPC [FAO, 1990]
phytosanitary 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).

phytosanitary procedure	Any officially prescribed method for implementing phytosanitary regulations including the performance of inspections, tests, surveillance or treatments in connection with regulated pests [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
phytosanitary regulation	Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM, 2001]
quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC 1997]
regulated article	Any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved [FAO, 1990; revised FAO, 1995; IPPC, 1997]
regulated non-quarantine pest	A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party [IPPC, 1997]
regulated pest	A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]

OUTLINE OF REQUIREMENTS

The International Plant Protection Convention (IPPC) requires contracting parties to the best of their abilities to establish, update and make available lists of regulated pests.

Lists of regulated pests are established by the NPPO of an importing contracting party to specify all regulated pests for which phytosanitary action may be taken. Specific lists of regulated pests are a subset of these lists. Specific lists are provided on request to the NPPOs of exporting contracting parties as the means to specify regulated pests for the certification of particular commodities.

Quarantine pests, including those subject to provisional or emergency measures, and regulated non-quarantine pests should be listed. Required information associated with the listing includes the pest's scientific name, the pest category and any commodity or other article that is regulated for the pest. Supplementary information may be provided such as synonyms and references to data sheets and pertinent legislation. Updating of the lists is required when pests are added or deleted or when required information or supplementary information changes.

Lists should be made available to the IPPC Secretariat, to RPPOs of which the contracting party is a member and, on request, to other contracting parties. This may be done electronically and should be in an FAO language. Requests should be as specific as possible.

REQUIREMENTS

1. Basis for Lists of Regulated Pests

Article VII.2i of the IPPC (1997) states:

> *Contracting parties shall, to the best of their ability, establish and update lists of regulated pests, using scientific names, and make such lists available to the Secretary, to regional plant protection organizations of which they are members and, on request, to other contracting parties.*

Therefore, contracting parties to the IPPC have the explicit obligation to prepare and make available, to the best of their abilities, lists of regulated pests. This is closely associated with other provisions of Article VII regarding the provision of phytosanitary requirements, restrictions and prohibitions (VII.2b) and the provision of the rationale for phytosanitary requirements (VII.2c).

In addition, the certifying statement of the Model Phytosanitary Certificate annexed to the Convention implies that lists of regulated pests are necessary by referring to:

- quarantine pests specified by the importing contracting party;
- phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests.

The availability of lists of regulated pests assists exporting contracting parties to correctly issue Phytosanitary Certificates. In instances where a list of regulated pests is not supplied by the importing contracting party, the exporting contracting party can only certify for pests it believes to be of regulatory concern (see ISPM Pub. No. 12: *Guidelines for Phytosanitary Certificates*, section 2.1).

The justification for regulating pests corresponds to the provisions of the IPPC requiring that:

- pests meet the defining criteria for quarantine or regulated non-quarantine pests to be regulated (Article II – "regulated pest");
- only regulated pests are eligible for phytosanitary measures, (Article VI.2);
- phytosanitary measures are technically justified, (Article VI.1b); and
- PRA provides the basis for technical justification, (Article II – "technically justified").

2. Purpose of Lists of Regulated Pests

The importing contracting party establishes and updates lists of regulated pests in order to assist it in preventing the introduction and/or spread of harmful pests and to facilitate safe trade by enhancing transparency. These lists identify those pests that have been determined by the contracting party to be quarantine pests or regulated non-quarantine pests.

A specific list of regulated pests, which should be a subset of those lists, may be provided by the importing contracting party to the exporting contracting party as the means to make known to the exporting contracting party those pests for which inspection, testing or other specific procedures are required for particular imported commodities, including phytosanitary certification.

Lists of regulated pests may also be useful as the basis for harmonization of phytosanitary measures where several contracting parties with similar and shared phytosanitary concerns

agree on pests that should be regulated by a group of countries or a region. This may be done through regional plant protection organizations.

In developing lists of regulated pests, some contracting parties identify non-regulated pests. There is no obligation for listing such pests. The provision, however, of this information may be useful, for example for facilitating inspection.

3. Listing of Regulated Pests

Lists of regulated pests are established and maintained by the NPPO of the contracting party. The pests to be listed are those that have been determined by the NPPO to require phytosanitary measures:

- quarantine pests, including pests which are the subject of provisional or emergency measures; or
- regulated non-quarantine pests.

A list of regulated pests may include pests for which measures are required only in certain circumstances.

4. Information on Listed Pests

4.1 Required information

The required information to be associated with listed pests includes:

Name of pest – The scientific name of the pest is used for listing purposes, at the taxonomic level which has been justified by PRA (see also ISPM Pub. No. 11: *Pest Risk Analysis for quarantine pests*). The scientific name should include the authority (where appropriate) and be complemented by a common term for the relevant taxonomic group (e.g. insect, mollusk, virus, fungus, nematode, etc.).

Categories of regulated pests – These are quarantine pest, not present; quarantine pest, present but not widely distributed and under official control; or regulated non-quarantine pest. Pest lists may be organized using these categories.

Association with regulated article(s) – The host commodities or other articles that are regulated for the listed pest(s).

Where codes are used for any of the above, the NPPO responsible for the list should also make available appropriate information for its proper understanding and use.

4.2 Supplementary information

Information that may be provided where appropriate includes:

- synonyms;
- reference to pertinent legislation, regulations, or requirements;
- reference to a pest data sheet or PRA;
- reference to provisional or emergency measures.

4.3 NPPO responsibilities

The NPPO is responsible for procedures to establish lists of regulated pests and to produce specific lists of regulated pests. However, information used for necessary PRA and subsequent listing may come from various sources within or outside the NPPO including other agencies of the contracting party, other NPPOs (in particular

where the NPPO of the exporting contracting party requests specific lists for certification purposes), regional plant protection organizations, scientific academia, scientific researchers and other sources.

5. Maintenance of Lists of Regulated Pests

The NPPO is responsible for the maintenance of pest lists. This involves updating lists and appropriate recordkeeping.

Lists of regulated pests require updating when pests are added or deleted, or the category of listed pests changes, or when information is added or changed for listed pests. The following are some of the more common reasons for updating these lists:

- changes to prohibitions, restrictions or requirements;
- change in pest status (see ISPM Pub. No. 8: *Determination of pest status in an area*);
- result of a new or revised PRA;
- change in taxonomy.

The updating of pest lists should be done as soon as the need for modifications is identified. Formal changes in legal instruments, where appropriate, should be adopted as quickly as possible.

It is desirable for NPPOs to keep appropriate records of changes in pest lists over time (e.g. rationale for change, date of change) for reference and to facilitate response to inquiries that may be related to disputes.

6. Availability of Lists of Regulated Pests

Lists may be included in legislation, regulations, requirements or administrative decisions. Contracting parties should create operational mechanisms for establishing, maintaining and making available lists in a responsive manner.

The IPPC makes provision for the official availability of lists and languages to be used.

6.1 Official availability

The IPPC requires that contracting parties make lists of regulated pests available to the IPPC Secretariat and regional plant protection organizations to which they are members. They are further obliged to provide such lists to other NPPOs upon request (Article VII.2i).

Lists of regulated pests should be made available officially to the IPPC Secretariat. This may be done in written or electronic form, including the Internet.

The means for making pest lists available to regional plant protection organizations is decided within each organization.

6.2 Requests for lists of regulated pests

NPPOs may request lists of regulated pests or specific lists of regulated pests from other NPPOs. In general, requests should be as specific as possible to the pests, commodities, and circumstances of concern to the contracting party.

Requests may be for:

- clarification of the regulatory status for particular pests;
- specification of quarantine pests for certification purposes;
- obtaining regulated pest lists for particular commodities;
- information concerning regulated pests not associated with any particular commodity;
- updating previously provided pest list(s).

Pest lists should be provided by NPPOs in a timely manner, with highest priority given to requests for lists necessary for phytosanitary certification or to facilitate the movement of commodities in trade. Copies of regulations may be provided where pest lists included in these regulations are considered adequate.

Both requests and responses for pest lists should be through official contact points. Pest lists may be provided by the IPPC Secretariat when available, but such provision is unofficial.

6.3 Format and language

Lists of regulated pests made available to the IPPC Secretariat, and in response to requests from contracting parties, should be provided in one of the five official languages of FAO (required under Article XIX.3c of the IPPC).

Pest lists may be provided electronically or by access to an appropriately structured Internet website where contracting parties have indicated this is possible and the corresponding organization have the capability for such access and have indicated willingness to use this form of transmittal.