INTERNATIONAL STANDARD FOR PHYTOSANITARY MEASURES 14

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Protecting the world's plant resources from pests

ISPM 14

ENG

The use of integrated measures in a systems approach for pest risk management

Produced by the Secretariat of the
International Plant Protection Convention (IPPC)

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INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES

ISPM 14

The use of integrated measures in a systems approach for pest risk management

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This is not an official part of the standard

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2010-07 IPPC secretariat amended ISPM 14 by Ink amendments on CPM-5 (2010).

2014-01 IPPC secretariat noted that between 2002 and 2006 the Annex 1 was erroneously changed to Appendix. This error was corrected in 2011 when the standard was reformatted.

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CONTENTS

Adoption

This standard was adopted by the Fourth Session of the Interim Commission on Phytosanitary Measures in March 2002.

INTRODUCTION

Scope

This standard provides guidelines for the development and evaluation of integrated measures in a systems approach as an option for pest risk management under the relevant international standards for pest risk analysis (PRA) designed to meet phytosanitary import requirements for plants, plant products and other regulated articles.

References

The present standard refers to International Standards for Phytosanitary Measures (ISPMs). ISPMs are available on the International Phytosanitary Portal (IPP) at https://www.ippc.int/core-activities/standards-setting/ispms.

Codex Alimentarius. 2003. *Hazard analysis and critical control point (HACCP) system and guidelines for its application*. Annex to CAC/RCP 1-1969 (*General principles of food hygiene*) (Rev. 4 - 2003). Rome, Codex Alimentarius, FAO.

COSAVE. 1998. *Lineamientos para un sistema integrado de medidas para mitigación del riesgo de plagas (¨system approach¨)* [*Guidelines for an integrated system of measures to mitigate pest risk ("systems approach")*]. Estandar Regional en Proteccion Fitosanitaria 3.13, v. 1.2. Asunción, Paraguay, Comité de Sanidad Vegetal del Cono Sur.

IPPC. 1997. *International Plant Protection Convention*. Rome, IPPC, FAO.

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

Definitions

Definitions of phytosanitary terms used in the present standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

Outline of Requirements

ISPM 2 (*Framework for pest risk analysis*), ISPM 11 (*Pest risk analysis for quarantine pests*) and ISPM 21 (*Pest risk analysis for regulated non-quarantine pests*) provide general guidance on measures for pest risk management. Systems approaches, which integrate measures for pest risk management in a defined manner, could provide an alternative to single measures to meet the appropriate level of phytosanitary protection of an importing country. They can also be developed in situations where no single measure is available. A systems approach requires the integration of different measures, at least two of which act independently, with a cumulative effect.

Systems approaches range in complexity. The application of critical control points system in a systems approach may be useful to identify and evaluate points in a pathway where specified pest risks can be reduced and monitored. The development and evaluation of a systems approach may use quantitative or qualitative methods. Exporting and importing countries may consult and cooperate in the development and implementation of a systems approach. The decision regarding the acceptability of a systems approach lies with the importing country, subject to consideration of technical justification,

minimal impact, transparency, non-discrimination, equivalence, and operational feasibility. A systems approach is usually designed as an option that is equivalent to but less restrictive than other measures.

REQUIREMENTS

1. Purpose of Systems Approaches

Many of the elements and individual components of pest risk management are described in ISPM 2, ISPM 11 and ISPM 21. All phytosanitary measures must be technically justified according to Article VII.2(a) of the IPPC. A systems approach integrates measures to meet phytosanitary import requirements. Systems approaches provide, where appropriate, an equivalent alternative to procedures such as treatments or replace more restrictive measures like prohibition. This is achieved by considering the combined effect of different conditions and procedures. Systems approaches provide the opportunity to consider both pre- and post-harvest procedures that may contribute to the effective management of pest risk. It is important to consider systems approaches among pest risk management options because the integration of measures may be less trade restrictive than other risk management options (particularly where the alternative is prohibition).

2. Characteristics of Systems Approaches

A systems approach requires two or more measures that are independent of each other, and may include any number of measures that are dependent on each other. An advantage of the systems approach is the ability to address variability and uncertainty by modifying the number and strength of measures to meet phytosanitary import requirements.

Measures used in a systems approach may be applied pre- and/or post-harvest wherever national plant protection organizations (NPPOs) have the ability to oversee and ensure compliance with phytosanitary procedures. Thus a systems approach may include measures applied in the place of production, during the post-harvest period, at the packing house, or during shipment and distribution of the commodity.

Cultural practices, crop treatment, post-harvest disinfestation, inspection and other procedures may be integrated in a systems approach. Risk management measures designed to prevent contamination or re-infestation are generally included in a systems approach (e.g. maintaining the integrity of lots, requiring pest-proof packaging, screening packing areas, etc.). Likewise, procedures such as pest surveillance, trapping and sampling can also be components of a systems approach.

Measures that do not kill pests or reduce their prevalence but reduce their potential for entry or establishment (safeguards) can be included in a systems approach. Examples include designated harvest or shipping periods, restrictions on the maturity, colour, hardness, or other condition of the commodity, the use of resistant hosts, and limited distribution or restricted use at the destination.

3. Relationship with PRA and Available Pest Risk Management Options

The conclusions from pest risk assessment (Stage 2 of PRA) are used to decide whether pest risk management is required and the strength of measures to be used. Pest risk management, (Stage 3 of PRA), is the process of identifying ways to react to a perceived risk, evaluating the efficacy of these procedures, and recommending the most appropriate options.

A combination of phytosanitary measures in a systems approach is one of the options which may be selected as the basis for phytosanitary import requirements. As in the development of all pest risk management measures, these should take into account uncertainty of the risk. (see ISPM 11).

In principle, systems approaches should be composed of the combination of phytosanitary measures that are possible to implement within the exporting country. However, where the exporting country proposes measures that should be implemented within the territory of importing country and the

importing country agrees, measures within the importing country may be combined in systems approaches.

The following summarizes many of the options commonly used:

Pre-planting

- healthy planting material
- resistant or less susceptible cultivars
- pest free areas, pest free places of production or pest free production sites
- producer registration and training.

Pre-harvest

- field certification/management (e.g. inspection, pre-harvest treatments, pesticides, biological control etc.)
- protected conditions (e.g. glasshouse, fruit bagging etc.)
- pest mating disruption
- cultural controls (e.g. sanitation/weed control)
- low pest prevalence (continuous or at specific times)
- testing.

Harvest

- harvesting plants at a specific stage of development or time of year
- removal of infested products, inspection for selection
- stage of ripeness/maturity
- sanitation (e.g. removal of contaminants, "trash")
- harvest technique (e.g. handling).

Post-harvest treatment and handling

- treatment (e.g. fumigation, irradiation, cold storage, controlled atmosphere, washing, brushing, waxing, dipping, heat etc.)
- inspection and grading (including selection for certain maturity stages)
- sanitation (including removal of parts of the host plant)
- certification of packing facilities
- sampling
- testing
- method of packing
- screening of storage areas.

Transportation and distribution

- treatment or processing during transport
- treatment or processing on arrival
- restrictions on end use, distribution and points of entry
- restrictions on the period of import due to difference in seasons between origin and destination
- method of packing
- post-entry quarantine
- inspection and/or testing
- speed and type of transport
- sanitation (freedom from contamination of conveyances).

4. Independent and Dependent Measures

A systems approach may be composed of independent and dependent measures. By definition, a systems approach must have at least two independent measures. An independent measure may be composed of several dependent measures.

With dependent measures the probability of failure is approximately additive. All dependent measures are needed for the system to be effective.

Example:
A pest-free glasshouse where both double-door and screening of all openings is required is an example where dependent measures are combined to form an independent measure. If the probability that the screening fails is 0.1 and the probability that the double doors fail is 0.1, then the probability that the glasshouse will be infested is the approximate sum of the two values. Therefore the probability that at least one of the measures fails is the sum of both probabilities minus the probability that both fail at the same time. In this example the probability is 0.19 (0.1 + 0.1 − 0.01), since both the measures could fail at the same time.

Where measures are independent of each other, both measures must fail for the system to fail. With independent measures, the probability of failure is the product of all the independent measures.

Example:
If the inspection of a shipment has a 0.05 probability of failure and the limiting of movement to certain areas has a 0.05 probability of failure, then the probability of the system failing would be 0.0025 (0.05 × 0.05).

5. Circumstances for Use

Systems approaches may be considered when one or more of the following circumstances apply:

- individual measures are:
  - not adequate to meet phytosanitary import requirements
  - not available (or likely to become unavailable)
  - detrimental (to commodity, human health, environment)
  - not cost effective
  - overly trade restrictive
  - not feasible
- the pest and pest-host relationship is well known
- a systems approach has been demonstrated to be effective for a similar pest/commodity situation
- there is the possibility to assess the effectiveness of individual measures either qualitatively or quantitatively
- relevant growing, harvesting, packing, transportation and distribution practices are well-known and standardized
- individual measures can be monitored and corrected
- prevalence of the pest(s) is known and can be monitored
- a systems approach is cost effective (e.g. considering the value and/or volume of commodity).

6. Types of Systems Approaches

Systems approaches range in complexity and rigour from systems that simply combine independent measures known to be effective to more complex and precise systems such as critical control point systems (see Appendix 1).

Other systems based on a combination of measures that do not meet the requirements for a critical control point system may be considered effective. However, the application of the critical control point concept may be generally useful for the development of other systems approaches. For example, non-phytosanitary certification programmes may have elements that are also valuable for pest risk management and may be included in a systems approach provided the phytosanitary elements of the process are made mandatory and can be overseen and controlled by the NPPO.

The minimum requirements for a measure to be considered a required component for a systems approach are that the measure:

- is clearly defined
- is efficacious
- is officially required (mandatory)
- can be monitored and controlled by the responsible NPPO.

7. Efficacy of Measures

Systems approaches may be developed or evaluated in either a quantitative or qualitative manner or a combination of both. A quantitative approach may be more appropriate where suitable data are available, such as those usually associated with measuring the efficacy of treatments. A qualitative approach should be considered more appropriate where efficacy is estimated by expert judgement.

The efficacy of independent measures that may be used to reduce pest incidence can be expressed in different ways (e.g. mortality, reduction in incidence, host susceptibility). The overall efficacy of a systems approach is based on the combination of the efficacy of required independent measures. Wherever possible this should be expressed in quantitative terms with a confidence interval. For example, efficacy for a particular situation may be determined to be no more than five infested fruit from a total population of one million fruit with 95% confidence. Where such calculations are not possible or are not done, the efficacy may be expressed in qualitative terms such as high, medium, and low.

8. Developing Systems Approaches

The development of a systems approach may be undertaken by the importing country, or by the exporting country, or ideally through the cooperation of both countries. The process of developing systems approaches may include consultation with industry, the scientific community, and trading partner(s). However, the NPPO of the importing country decides the suitability of the systems approach in meeting its requirements, subject to consideration of technical justification, minimal impact, transparency, non-discrimination, equivalence and operational feasibility.

A systems approach may include measures that are added or strengthened to compensate for uncertainty due to data gaps, variability, or lack of experience is the application of procedures. The level of such compensation included in a systems approach should be commensurate with the level of uncertainty.

Experience and the provision of additional information may provide the basis for renewed consideration of the number and strength of measures with a view to modifying the systems approach accordingly.

The development of a systems approach involves:

- obtaining from a PRA the identity of the pest risk and the description of the pathway
- identifying where and when management measures occur or can be applied (control points)
- distinguishing between measures that are essential to the system and other factors or conditions

- identifying independent and dependent measures and options for the compensation for uncertainty
- assessing the individual and integrated efficacy of measures that are essential to the system
- assessing feasibility and trade restrictiveness
- consultation
- implementation with documentation and reporting
- review and modification as necessary.

9. Evaluating Systems Approaches

In the evaluation of systems approaches to meet phytosanitary import requirements, the evaluation of whether these are met or not should consider the following:

- considering the relevance of existing systems approaches for similar or the same pest(s) on other commodities
- considering the relevance of systems approaches for other pest(s) on the same commodity
- evaluating information provided on:
  - . efficacy of measures
  - . surveillance and interception, sampling data (incidence of pest)
  - . pest host relationship
  - . crop management practices
  - . verification procedures
  - . trade impacts and costs, including the time factor
- considering data against desired confidence levels and taking into account options for the compensation for uncertainty where appropriate.

9.1 Possible outcomes of evaluation

These may include determination that the systems approach is:

- acceptable
- unacceptable:
  - . efficacious but not feasible
  - . not sufficiently effective (requires an increase in the number or strength of measures)
  - . unnecessarily restrictive (requires a reduction of the number or strength of measures)
  - . not possible to evaluate due to insufficient data or unacceptably high uncertainty.

Where the systems approach has been found unacceptable, the rationale for this decision should be described in detail and made available to trading partners to facilitate the identification of possible improvements.

10. Responsibilities

Countries share the obligation to observe the principle of equivalence by considering pest risk management alternatives that will facilitate safe trade. Systems approaches provide significant opportunities to develop new and alternative pest risk management strategies, but their development and implementation requires consultation and cooperation. Depending on the number and nature of measures included in a systems approach, a significant amount of data may be required. Both exporting countries and importing countries should cooperate in the provision of sufficient data and the timely exchange of relevant information in all aspects of the development and implementation pest risk management measures, including systems approaches.

10.1 Importing country responsibilities

The importing country should provide specific information regarding its requirements. This includes specification of information and system requirements:

- identify pests of concern
- specify the phytosanitary import requirements
- describe types and level of assurance required (e.g. certification)
- identify points requiring verification.

Importing countries, in consultation with the exporting country where appropriate should select least trade restrictive measures where there are options.

Other responsibilities of the importing country may include to:

- propose improvements or alternative options
- audit (planned evaluation and verification of the systems approach)
- specify actions for non-compliance
- review and give feedback.

Where importing countries agree to accept the implementation of certain measures in their territories, importing countries are responsible for the implementation of those measures.

Agreed phytosanitary measures should be published (Article VII.2(b), IPPC).

10.2 Exporting country responsibilities

The exporting country should provide sufficient information to support evaluation and acceptance of the systems approach. This may include:

- commodity, place of production and expected volume and frequency of shipments
- relevant production, harvest, packing/handling, transport details
- pest-host relationship
- pest management measures proposed for a systems approach, and relevant efficacy data
- relevant references.

Other responsibilities of the exporting country include:

- monitoring/auditing and reporting on system effectiveness
- taking appropriate corrective actions
- maintaining appropriate records
- providing phytosanitary certification in accordance with requirements of the system.

This annex is a prescriptive part of the standard.

ANNEX 1: Critical control point system

A critical control point system would involve the following procedures:

(1) determine the hazards and the objectives for measures within a defined system

(2) identify independent procedures that can be monitored and controlled

(3) establish criteria or limits for the acceptance/failure of each independent procedure

(4) implement the system with monitoring as required for the desired level of confidence

(5) take corrective action when monitoring results indicate that criteria are not met

(6) review or test to validate system efficacy and confidence

(7) maintain adequate records and documentation.

An example of this type of system is practised in food safety and is termed a Hazard Analysis Critical Control Point (HACCP) system.

The application of a critical control point system for phytosanitary purposes may be useful to identify and evaluate hazards as well as the points in a pathway where risks can be reduced and monitored and adjustments made where necessary. The use of a critical control point system for phytosanitary purposes does not imply or prescribe that application of controls is necessary to all control points. However, critical control point systems only rely on specific independent procedures known as control points. These are addressed by risk management procedures whose contribution to the efficacy of the system can be measured and controlled.

Therefore, systems approaches for phytosanitary purposes may include components that do not need to be entirely consistent with critical control point concept because they are considered to be important elements in a systems approach for phytosanitary purposes. For example, certain measures or conditions exist or are included to compensate for uncertainty. These may not be monitored as independent procedures (e.g. packhouse sorting), or may be monitored but not controlled (e.g. host preference/susceptibility).

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IPPC

The International Plant Protection Convention (IPPC) is an international plant health agreement that aims to protect cultivated and wild plants by preventing the introduction and spread of pests. International travel and trade are greater than ever before. As people and commodities move around the world, organisms that present risks to plants travel with them.

Organization

- There are over 180 contracting parties to the IPPC.
- Each contracting party has a national plant protection organization (NPPO) and an Official IPPC contact point.
- Nine regional plant protection organizations (RPPOs) work to facilitate the implementation of the IPPC in countries.
- IPPC liaises with relevant international organizations to help build regional and national capacities.
- The Secretariat is provided by the Food and Agriculture Organization of the United Nations (FAO).

International Plant Protection Convention (IPPC)

Viale delle Terme di Caracalla, 00153 Rome, Italy
Tel: +39 06 5705 4812 - Fax: +39 06 5705 4819
Email: ippc@fao.org - Web: www.ippc.int