

NATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

NSPM: 14

The use of integrated measures in a system approach for pest risk management 2013

(This standard is approved by (the NPPO and) the Quarantine Committee of Nepal, chaired by the secretary of the Ministry of Agriculture Development on 1st December 2013 and, is submitted by National Plant Quarantine Program to the National Notification Authority to be notified to the WTO member states)

Table of Contents

Abbreviations	i
1. Introduction.....	1
1.1 Scope	1
1.2 References	1
1.3 Definitions	2
1.4 Outline of requirements	2
2. Requirements.....	3
2.1 Purpose of systems approaches.....	3
2.2 Characteristics of systems approaches	3
2.3 Relationship with PRA and available pest risk management options	4
Pre-planting.....	4
Pre-harvest.....	4
Harvest.....	5
Post-harvest treatment and handling	5
Transportation and distribution.....	5
3. Independent and dependent measures	5
4. Circumstances for use	6
5. Types of systems approaches.....	7
6. Efficacy of measures	7
7. Developing systems approaches.....	8
8. Evaluating systems approaches	9
8.1 Possible outcomes of evaluation	9
9. Responsibilities.....	9
10.1 Importing country responsibilities	10

10.2 Exporting country responsibilities	10
Annex 1: Critical control point system.....	12
Annex 2: FAO/IAEA guidelines for implementing systems approaches for pest risk management	13

Abbreviations

CODEX	Codex Alimentarius
HACCP	Hazard Analysis Critical Control Point
FAO	Food and Agriculture Organization
IAEA	International Atomic Energy Commission
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
NPPO	National Plant Protection Organization
PRA	Pest Risk Analysis
SA	System Approach
SIT	Sterile Insect Technique
WTO	World trade organization

1. Introduction

1.1 Scope

This standard provides the guidelines for the development and evaluation of integrated measures in a systems approach for pest risk management under Plant Protection Acts 2007 and the Plant Protection Regulation 2010 for pest risk analysis (PRA) designed to meet phytosanitary import requirements for plants, plant products and other regulated articles. NSPM preparation based on guidelines and recommendations developed within the framework of the IPPC. This standard also adopted the principles, recommendations and format of ISPM to achieve international harmonization of phytosanitary measures with the aim to facilitate trade.

1.2 References

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.

IAEA2011. FAO/ IAEA Guidelines for Implementing system approach for pest risk management of Fruit flies (working Material). FAO/IAEA Division of Nuclear Techniques in FAO, Vienna, Austria, June 7-11, 2010, Reproduce by the IAEA Vienna, Austria

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

ISPM 1. 2006. Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade. Rome, IPPC, FAO.

ISPM 2. 2007. Framework for pest risk analysis. Rome, IPPC, FAO.

ISPM 4. 1995. Requirements for the establishment of pest free areas. Rome, IPPC, FAO.

ISPM 5. Glossary of phytosanitary terms. Rome, IPPC, FAO.

ISPM 11. 2004. Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms. Rome, IPPC, FAO.

ISPM 14. 2002. The use of integrated measures in a system approach for pest risk management. Rome, IPPC, FAO

ISPM 21. 2004. Pest risk analysis for regulated non-quarantine pests. Rome, IPPC, FAO.

Plant Protection Act 2007. National Plant Quarantine Program, Plant protection Directorate Ministry of Agriculture, Government of Nepal

The Plant Protection Regulation 2010. National Plant Quarantine Program, Plant protection Directorate Ministry of Agriculture, Government of Nepal

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

<http://www.naweb.iaea.org/nafa/ipc/public/ipc-systems-approach-2011.pdf>

1.3 Definitions

Definitions of phytosanitary terms used in the national standard can be found in ISPM 5 (*Glossary of phytosanitary terms*), Plant Protection Acts 2007 and the Plant Protection regulation 2010.

Systems approach(es): The integration of different risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of protection against regulated pests [NSPM: The use of integrated measure in a system approach for pest risk management)

1.4 Outline of requirements

It is necessary to minimize the pest risks associated with global trade. The standards “Frame work for pest risk analysis (NSPM), Pest risk analysis for quarantine pests including analysis of environmental risk and living modified organisms (NSPM) and Pest risk analysis of regulated non quarantine pests (NSPM)”, Plant Protection Act 2007, Chapter 5, Section 17 provide general guidance for National Plant Protection Organization (NPPO) on measures for pest risk management. Systems approaches should integrate measures for pest risk management in a defined manner, to obtain an alternative to single measures to meet the appropriate level of phytosanitary protection of an importing country. The NPPO Nepal shall establish a mechanism to develop workable measures. While developing a systems approach NPPO of Nepal requires the integration of different measures, at least two of which act independently, with a cumulative effect.

Systems approaches differ in types of obstructions. It is possible to use of critical control points system in a systems approach which will useful to identify and evaluate points in a pathway where specified pest risks can be reduced and monitored. NPPO can use quantitative or qualitative methods on the development and evaluation of a systems approach. Exporting and importing countries should consult and cooperate in the development and implementation of a systems approach. The decision regarding the acceptability of a systems approach lies with the NPPO of importing country, subject to consideration of technical justification, minimal impact, transparency, non-discrimination, equivalence, and operational feasibility. A systems approach is usually adopted as an option that is equivalent to but less restrictive than other measures.

2. Requirements

2.1 Purpose of systems approaches

A systems approach integrates measures to meet phytosanitary import requirements of the country. Systems approaches provide, where appropriate, an equivalent alternative to procedures such as treatments or replace more restrictive measures like prohibition. Many of the elements and individual components of pest risk management has been described in “NSPM: Frame work for pest risk analysis, NSPM: Pest risk analysis for quarantine pests including analysis of environmental risk and living modified organisms and NSPM: Pest risk analysis of regulated non quarantine pests. All phytosanitary measures must be technically justified according to Article VII.2 (a) of the IPPC. The systems approach integrates measures to develop new and alternative pest risk management strategies, which 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 contribute to the effective management of pest risk. It is important that the integration of measures may be less trade restrictive than other risk management options (particularly where the alternative is prohibition).

2.2 Characteristics of systems approaches

A systems approach of National Standard Phytosanitary Measures of Nepal requires two or more measures that are independent of each other, and can 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 of the country.

Measures used in a systems approach can be applied pre-and/or post-harvest where national plant protection organization have the ability to oversee and ensure compliance with phytosanitary procedures. Thus a systems approach can 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.

Systems approach can include cultural practices, crop treatment, post-harvest disinfestation, washing, cleaning, grading as per the commodities requirements and a final inspection 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 included components of a systems approach.

Adopted measures that do not kill pests or reduce their prevalence but help to 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, sucrose percentage or other condition of the commodity, the use of resistant hosts, and limited distribution or restricted use at the destination.

2.3 Relationship with PRA and available pest risk management options

The findings 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 should 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 NSPM: Pest risk analysis for quarantine pests including analysis of environmental risk and living modified organisms).

In principle, systems approaches can 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 should be combined in systems approaches. The following summarizes many of the options commonly used:

Pre-planting

- healthy planting (seed, cuttings, bulb, sets) materials of locally recommended variety

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

- weed control
- low pest prevalence (continuous or at specific times)
- testing.

Harvest

- harvesting plants at a specific growth 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, 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)
- inspection before packing
- certification of packing facilities
- sampling
- testing
- method of packing
- screening of storage areas.

Transportation and distribution

- treatment /sorting or processing during transport
- treatment /sorting 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
- means of transport
- sanitation (freedom from contamination of conveyances).

3. Independent and dependent measures

A systems approach should be composed of both independent and dependent measures. 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.

For an example

An example of Independent and Dependent measures

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). For detail see **Annex 2**.

4. Circumstances for use

In order to secure effective systems approaches there should be provision of 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 should be well known

- a systems approach has been demonstrated to be effective for a similar pest/commodity situation
- there should be the possibility to assess the effectiveness of individual measures either qualitatively or quantitatively
- relevant growing, harvesting, packing, transportation and distribution practices should be well-known and standardized
- individual measures should be monitored and corrected
- prevalence of the pest(s) should be known and can be monitored
- a systems approach should be cost effective (e.g. considering the value and/or volume of commodity).

5. 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 should 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 following measure for a system approach should be:

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

6. Efficacy of measures

Systems approaches should be developed or evaluated in either a quantitative or qualitative manner or a combination of both. Wherever possible this should be expressed in quantitative terms with a confidence interval. For example, efficacy (e.g. mortality, reduction in incidence, host susceptibility) for a particular situation should 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.

7. Developing systems approaches

The development of a systems approach should be done by the NPPO of the importing country, or by the exporting country, or ideally through the mutual cooperation of both countries. The process of developing systems approaches should 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 also 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 should 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.

8. 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.

8.1 Possible outcomes of evaluation

These should 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.

9. 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

There should be provision that 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
- commodity, place of production and expected volume and frequency of shipments
- 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 practiced 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).

Annex 2: FAO/IAEA guidelines for implementing systems approaches for pest risk management

Working material

FAO/IAEA Guidelines for implementing systems Approaches for pest risk management of fruit flies

Report and recommendations of the consultants group meeting organized by the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, Vienna, Austria, June 7-11 2010

Reproduced by the IAEA
Vienna, Austria 2011

NOTE

The material in this document has been supplied by the authors and has not been edited by the IAEA. The views expressed remain the responsibility of the authors and do not necessarily reflect those of the government(s) or the designating Member State(s). In particular, neither the IAEA nor any other organization or body sponsoring this meeting can be held responsible for any material reproduced in this document.

<http://www.naweb.iaea.org/nafa/ipc/public/ipc-systems-approach-2011.pdf>

1. Parts of a systems approach

By defining types of phytosanitary measures associated with SA with useful terms, we can better understand, develop, and modify SA. This will also allow us to better understand the requirements regarding independent and dependent measures within the SA.

1.1 Independent measures

We can define the large comprehensive phytosanitary measures as major components. These can be *poor host status, areas of low pest prevalence, pest exclusion structure, and less than probit-9 post-harvest commodity treatment among others*. These measures, by themselves, lower the risk of the pest and are thus independent measures for risk management. To be classed as a SA there must be two or more independent measures/major components working together in the pest risk management plan.

1.2 Dependent measures

Several measures, that by themselves would not significantly lower the risk, may be used in a combination to create an independent measure/major component. For instance, the *pest exclusion structure* (which is an independent measure) is made up of several dependent measures/elements, like *self-closing doors, screening, double doors*, etc. Individually, these can be classed as dependent measures or elements. Other dependent measures may be:

producer registration, training, trapping, field controls, etc. and many other similar elements that help support the independent measure/major component for risk management.

Other dependent measures/elements associated with SA are being employed as safeguards (safeguard measures). They can be actions required either in the exporting country such as *containment of the shipment* to protect from reinfestation and to maintain the integrity of the shipment or in the importing country to protect the importing country from an introduction of the pest when further mitigation is taking place. Safeguard measures may also be required in a shipment transiting third countries.

At least one of the dependent measures/elements is an action that verifies the effectiveness and or compliance of the independent measure/major component for risk management. These related elements include *trapping by the NPPO* (dependent) in an *area of low pest prevalence* (independent), *regular inspections by the NPPO* (dependent) of a *pest exclusion structures* (independent), and *monitoring of performance by the NPPO* (dependent) of a *less than probit-9 post-harvest treatment* (independent).

Certain specific dependent measures/elements used by the grower to support the independent measure/major component for risk management may not be required by the importing NPPO, but are actions commonly used to ensure compliance with a required component. An example of this is when a low level of pest population is required in a SA; the specific *field controls* used by the grower may be optional. This would be an outcome based requirement, as opposed to a prescriptive based requirement.

The dependent and independent measures that are integrated into a specific SA are agreed by the importing and exporting countries, or regions. These measures should be not only efficacious, but also technically and economically feasible.

Parts of a systems approach - an example

<i>Independent Measure or Major Component</i>
Area of low pest prevalence
<i>Dependent measures or elements</i>
<ul style="list-style-type: none"> o Quarantine controls o Trapping (verification element) o SIT o Sanitation o More, More, More

<i>Safeguard Measures</i>
Transport in pest proof sealed containers and more

Commonly used major components

Pre-harvest and harvest stage

<ul style="list-style-type: none">• Poor host status• Areas of low pest prevalence• Pest-free production site• Pest excluding structures• Field treatments
Post-harvest and shipment
<ul style="list-style-type: none">• Post-harvest treatment (Subprobit-9)• Shipment inspection
Entry and distribution
<ul style="list-style-type: none">• Seasonal windows• Limited distribution in importing country• Shipment inspection