

ISPM 02 - Framework for Pest Risk Analysis (PRA)

Prepared as a knowledge product under the project:

“Strengthening Phytosanitary Compliance and Public Private Partnerships to Boost Seed Trade in the Asia-Pacific Region (STDF PG 755)”

What is PRA ?

Pest Risk Analysis (PRA) is a systematic process used to identify whether an organism is a pest, evaluate how likely it is to enter and spread, and understand its potential economic and environmental impacts in a defined geographical area.



Acceptable Level of Risk (ALOR)

Measures are applied only when the risk exceeds acceptable levels.

What is a Pest ?



Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products

Why PRA Matters ?



It ensures phytosanitary decisions are **science-based, transparent, harmonized, and justified**—protecting plants and enabling safe global trade.

The PRA process consists of three stages

STAGE 1: Initiation

Initiation Points:

- Identification of a **pest**
- Identification of a **pathway** (e.g. seeds, commodities)
- Review of existing **phytosanitary policies**
- Identification of an organism not previously known to be a pest

Steps:

- 1 Determination whether an organism is a pest
- 2 Defining the PRA area
- 3 Evaluating any previous PRA
- 4 Conclusion

STAGE 2: Pest Risk Assessment

Steps:

- 1 Pest categorization
- 2 Assessment of Introduction and spread
- 3 Assessment of economic and environmental impact
- 4 Conclusion

STAGE 3: Pest Risk Management

Steps:

- 1 Identification of phytosanitary measures
- 2 Evaluation of measures for effectiveness and feasibility
- 3 Selection of measures to reduce risk to an acceptable level

ISPM 11 - PRA for Quarantine Pests

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Example Scenario: Importation of Onion Seed from Thailand to the Philippines

Pest of Concern

Scientific name: *Xanthomonas axonopodis* pv. *allii*
Common name: Bacterial blight of onion

Pest Description

A seed-associated bacterial pathogen causing leaf blight, reduced bulb quality, and economic losses in onion production.



STAGE 1: Initiation

Initiation Point

This PRA is initiated by a **Pathway**

- Importation of onion seed (*Allium cepa*) for planting from Thailand into the Philippines

Identification of pest and pathway

Pest: *Xanthomonas axonopodis* pv. *allii*

Pathway: Onion seed for planting

PRA Area



The Philippines

Pest Categorization

The pest meets the criteria for a quarantine pest:

- Absent, or present with limited distribution and under official control in the PRA area
- Associated with the pathway (seed)
- Capable of establishment and spread
- Likely to cause economic consequences

CONCLUSION → The pest qualifies for further assessment

STAGE 2: Pest Risk Assessment

Probability of Entry



Seed - associated Pathogen

RISK LEVEL - HIGH

Probability of Establishment



Tropical Climate suitable

RISK LEVEL - HIGH

Probability of Spread



Irrigation, Contaminated tools, seedlings

RISK LEVEL - MODERATE-HIGH

Potential Consequences



Economic loss, Environmental consequences

RISK LEVEL - HIGH

OVERALL RISK CONCLUSION → HIGH → The pest qualifies as a Quarantine Pest

Final PRA Conclusion



Decision: Importation is permitted, subject to the implementation of specific phytosanitary measures to reduce risk to an acceptable level.

STAGE 3: Pest Risk Management

Risk Management Options

Measures to reduce risk to an acceptable level:

- Pest-free production places or sites
- Inspection and certification procedures
- Laboratory testing (validated diagnostic methods)
- Appropriate seed treatments
- Import restrictions (where necessary)
- Post-entry quarantine or inspection
- Least trade-restrictive / minimum necessary

Evaluation of Options

Measures are assessed based on:

- Effectiveness in reducing risk
- Technical feasibility
- Economic and operational considerations

Selected Measures

Recommended phytosanitary measures:

- Seeds originate from pest-free production sites
- Mandatory laboratory testing for the pest
- Application of approved seed treatment
- Phytosanitary certificate with additional declaration
- Post-entry inspection or quarantine, as appropriate

ISPM 02 and ISPM 11 - How They Work Together

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ISPM 02



ISPM 11



Purpose

Provides the overall framework for conducting Pest Risk Analysis (PRA)

Describe the process, principles and key elements

Provide detailed guidance for conducting PRA specifically for quarantine pests

Describe the methods for risk assessment and management



Scope

Applies to all pests and all PRA situations

Pests, pathways, policies and other initiatives

Applies to quarantine pests only

Including regulated non-quarantine pests



Focus

The “Big Picture”

Defines PRA, its purpose, principles and three stages

The “How”

- Pest categorization
- Assessment of entry, establishment and spread
- Assessment of potential impacts (economic and environmental)
- Risk estimation



Level of Detail

General and conceptual

Provides the structure and key requirements

Detailed and operational

Provides step-by-step methods, factors and examples for risk assessment and management.



Coverage of PRA stages

Describe the three stages of PRA

1. Initiation



2. Pest Risk Assessment



3. Pest Risk Management

Provides detailed guidance mainly for Stage 1 (Initiation) and high-level guidance for Stages 2 and 3.

Provides detailed guidance for Stage 2 (Pest Risk Assessment) and Stage 3 (Pest Risk Management), and also includes Initiation.

Focuses strongly on risk assessment (Stage 2)

HOW THEY WORK TOGETHER

ISPM 02 sets the foundation and overall structure for PRA



ISPM 11 provides the detailed “how-to” for assessing and managing risks from quarantine pests



Applied Together, they help NPPOs make science-based, transparent and justified phytosanitary decisions



ISPM 12 - Phytosanitary Certificates

Prepared as a knowledge product under the project:

"Strengthening Phytosanitary Compliance and Public Private Partnerships to Boost Seed Trade in the Asia-Pacific Region (STDF PG 755)"



ISPM 12 specifies the standardized format and content of phytosanitary certificates for the international movement of seeds, plants, plant products, and other regulated articles.



Purpose

The phytosanitary certificate provides an official declaration by the NPPO of the exporting country that a consignment meets the phytosanitary import requirements of the importing country.



Principles

- Issued only by the NPPO
- Based on inspection and/or other appropriate phytosanitary procedures
- Certifies phytosanitary facts, not commercial quality
- Valid only for the specific consignment
- Must be accurate, complete and verifiable



Types of PC

Export Certificate

Used when consignments are exported from the exporting country to importing country



Re-export certificate

Used when consignments are re-exported to a third country



Contents of PC

Phytosanitary Certificate

No. XXXXX

1.From: NPPO of exporting country			2.From: NPPO of importing country		
3.Declared name and address of exporter					
4.Declared name and address of consignee					
5.Place of origin			6.Declared means of conveyance		
7.Declared point of entry			8.Distinguishing marks		
9.Name of produce and quality declared			10.Botanical name of plants		
11.Additional declaration*			12.Additional official statement*		
13.Place of issue	14.Date	15.Name & Signature of authorized officer		16.official stamp of the NPPO	

**"Additional Declaration" and "Additional Official Statement" are included in the phytosanitary certificate prescribed by ISPM 12. Definitions of these terms are provided in ISPM 5 (Glossary of Phytosanitary Terms).*



Validity, Integrity & use

- The certificate is valid at the time of issuance.
- The integrity must be maintained during issuance and use.
- Measures may include secure paper, watermarks, seals, unique numbering and electronic security features.
- Any alteration invalidates the certificate.
- The certificate accompanies to the importing country.



Responsibilities of NPPOs

Exporting NPPO

- Ensures inspection and other phytosanitary actions are carried out
- Ensures the certificate is completed accurately
- Ensures the certificate is signed and stamped by an authorized officer
- Ensures the integrity and security of certificates.

Importing NPPO

- Establishes phytosanitary import requirements.
- Evaluate the certificate upon arrival
- Takes appropriate action if the seed certificate is missing, invalid or not in compliance



Key Messages

- A standardized certificate format promotes consistency and efficiency in international trade.
- Used correctly, the phytosanitary certificate strengthens biosecurity, and enables safe, reliable and sustainable trade.

ISPM 38 - International Movement of Seed

Prepared as a knowledge product under the project:

"Strengthening Phytosanitary Compliance and Public Private Partnerships to Boost Seed Trade in the Asia-Pacific Region (STDF PG 755)"

What is ISPM 38 ?

Provides guidance to for:

- Identifying and Managing seed-associated pest risks
- Establishing seed-specific phytosanitary import requirements



Applies To: Seeds for planting



Excludes: Grain and vegetable planting material

Why seeds need a separate standard ?



Produced in one country



Processed in another country



Stored for long period



Exported to multiple destinations



Frequently Re-exported



Import requirements may not be known when seed are produced



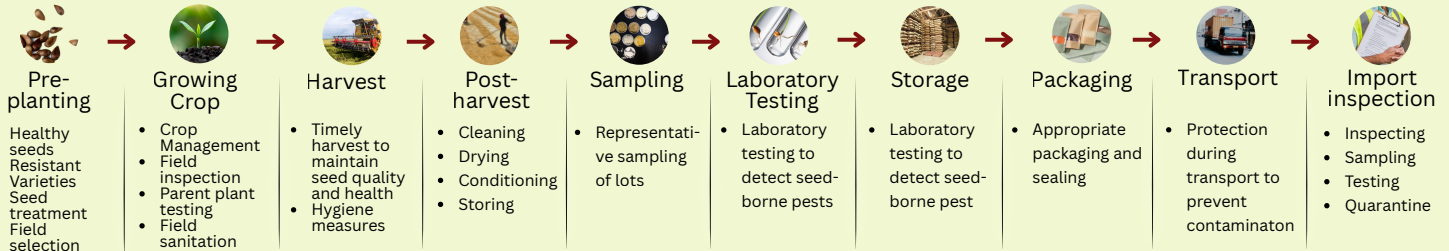
These unique characteristics create phytosanitary risks at multiple points along the seed movement. This is exactly why ISPM 38 was developed.

Purpose of imports determines risk

- Laboratory Testing**
(Seeds not intended for release)
LOWEST RISK
e.g., Diagnostic testing
Destructive Analysis
- Restricted Planting**
(Controlled conditions)
MEDIUM RISK
e.g., Germplasm
Breeding Material
- Field Planting**
(Open conditions)
HIGHEST RISK
e.g., Commercial Seed for cultivation

1 Risk level decides phytosanitary requirements

Phytosanitary measures along the seed production and seed movement



Some measures can be applied at one or more stages

Types of seed - associated pests

Seed transmitted pest

Pest that are persist on the seed and are transmitted to the plant growing from the seed

e.g., Bacteria, Virus, Fungi

Non seed transmitted (seed-borne) pest

Pest that are carried by the seed but are transferred to soil or water before infecting plants

e.g., Some fungi, Nematodes

Contaminating pests

Pest that are carried by the seed but are transferred to soil or water before infecting plants

e.g., Some fungi, Nematodes

Key Messages

- Seed are a unique pathway for pest movement
- Risk management must be applied throughout the seed production and movement process
- Seed specific phytosanitary measures, including inspection, sampling and testing are essential to manage risk.
- Safe seed trade depends on science-based, practical and consistent implementation.

Seed specific trade considerations

Mixing, blending and bulking

Lots may be mixed, blend or bulked. different approaches are needed to manage phytosanitary risk.

Record Keeping

Lots may be mixed, blend or bulked. different approaches are needed to manage phytosanitary risk.

Seed origin & traceability

The origin of seed lots traceable through all stages of production, handling, transport, and trade.

Re-export

Seed may be re-exported to other countries one or more times.

ISPM 45 - Requirements for NPPOs if Authorizing Entities to Perform Phytosanitary Actions

Prepared as a knowledge product under the project:

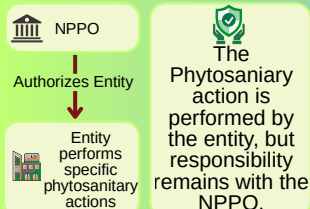
"Strengthening Phytosanitary Compliance and Public Private Partnerships to Boost Seed Trade in the Asia-Pacific Region (STDF PG 755)"

Scope

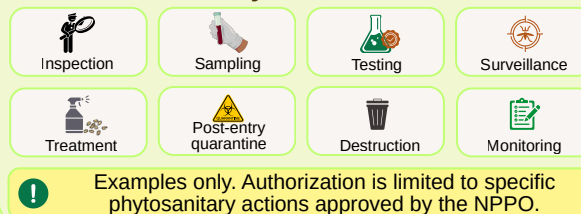
- ✓ **Provides requirements NPPOs:**
 - If they decide to authorize entities to perform specific phytosanitary actions on their behalf
- ✗ **Does Not Cover**
 - Issuance of phytosanitary certificates
 - Development and establishment of phytosanitary measures

! This distinguishes ISPM 45 from ISPM 12.

What is Authorization ?



What may be authorized ?



Authorization Programme



Eligibility Criteria

- ✓ Legal status
- ✓ Sufficient financial and human resources
- ✓ Competent personnel
- ✓ Documented procedures
- ✓ Equipment and infrastructure
- ✓ Ability to meet NPPO requirements
- ✓ Impartiality and independence
- ✓ Liability arrangements

! The NPPO assesses entities against these eligibility criteria.

Roles and Responsibilities

NPPO

- Assess entities against eligibility criteria
- Authorize entities to perform specific phytosanitary actions
- Define authorized phytosanitary actions and performance criteria
- Establish and implement the authorization programme
- Train NPPO personnel (and, where needed, entity personnel)
- Carry out audits and monitoring
- Maintain records and published lists of authorized entities
- Implement processes for suspension, revocation and reinstatement
- Ensure transparent communication
- Maintain impartiality and avoid conflicts of interest

Authorized Entity

- Provide required information to the NPPO
- Enter into a written authorization agreement
- Implement documented procedures
- Maintain competent and trained personnel
- Maintain infrastructure and resources
- Maintain records and documentation
- Notify the NPPO of significant changes or nonconformities
- Undergo audits and monitoring
- Comply with NPPO requirements
- Maintain confidentiality

Audits & Nonconformities

Audits

- Initial authorization audit
- Audits to maintain authorization
- Unscheduled audits (when needed)

Nonconformities

Critical

- Immediately impacts the integrity of the phytosanitary system
- Requires rapid corrective action
- May result in immediate suspension or revocation

Other

- Does not immediately affect system integrity
- Corrective action within the timeframe specified by the NPPO
- Repeated nonconformities may lead to suspension or revocation

Authorization Outcomes

Authorized → Suspend → Reinstated

Authorized → Revoked → New application

✗ Voluntary withdrawal

An entity may voluntarily withdraw from an authorization agreement

! Only the NPPO decides whether to authorize, suspend, revoke or reinstate authorization.