



NAPPO

North American Plant Protection Organization
Organización Norteamericana de Protección a las Plantas
MEXICO - USA - CANADA

NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM 31 General Guidelines for Pathway Risk Analysis

The Secretariat of the North American Plant Protection Organization
1431 Merivale Road, 3rd Floor, Room 140
Ottawa, Ontario, Canada, K1A 0Y9
July 23, 2012

Contents

Review	3
Approval.....	3
Implementation	3
Amendment Record.....	3
Distribution.....	3
Introduction.....	4
Scope	4
References	4
Definitions, Abbreviations and Acronyms.....	5
Outline of Requirements	5
1. Background	5
1.1 Pathways.....	5
1.2 Pathway risk analysis.....	7
1.3 Reasons for pathway risk analysis	7
1.4 Relationship to other types of pest risk analyses.....	8
1.5 Diversity and variation in pathway risk analysis	9
2. Requirements.....	11
2.1 Initiation phase (stage 1).....	12
2.2 Pathway analysis (stage 2).....	13
2.3 Pathway risk assessment (stage 3)	14
2.4 Pathway risk management (stage 4)	18

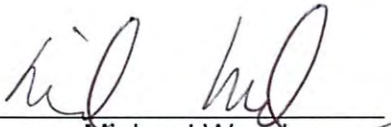
Review

NAPPO Regional Standards for Phytosanitary Measures are subject to periodic review and amendment. The next review date for this NAPPO standard is 2017. A review of any NAPPO Standard may be initiated at any time upon the request of a NAPPO member country.

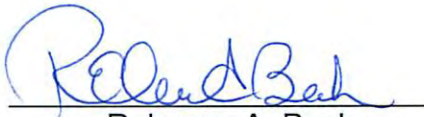
Approval

This Standard was approved by the North American Plant Protection Organization (NAPPO) Executive Committee on July 23, 2012 and is effective immediately.

Signed by:



Michael Wood
Executive Committee Member
Canada



Rebecca A. Bech
Executive Committee Member
United States



Javier Trujillo Arriaga
Executive Committee Member
Mexico

Implementation

See the attached implementation plans.

Amendment Record

Amendments to this Standard will be dated and filed with the NAPPO Secretariat.

Distribution

This standard is distributed by the NAPPO Secretariat, to the Industry Advisory Group (IAG) and Sustaining Associate Members (SAM), the International Plant Protection Convention (IPCC) Secretariat, and to other Regional Plant Protection Organizations (RPPOs).

Introduction

Pathway risk analysis, a type of pest risk analysis (PRA), is consistent with the obligations and rights of sovereign nations as described in the International Plant Protection Convention (1997). In particular, Article 1 states that:

“Where appropriate, the provisions of the Convention may be deemed by contracting parties to extend, in addition to plants and plant products, to storage places, packaging, conveyances, containers, soil and any other organism, object or material capable of harbouring or spreading plant pests, particularly where international transportation is involved.”

Current international standards (e.g. ISPM 2: 2007, ISPM 11: 2004, ISPM 21: 2004) which focus on evaluating pest risk provide very little specific guidance for conducting pathway risk analysis. In addition to traditional commodities being considered as pathways, there are many other types of pathways that may result in pest introduction and spread. The IPPC Glossary identifies a pathway as “Any means that allows the entry or spread of a pest” (ISPM 5). This standard builds upon guidance in existing international standards for phytosanitary measures (e.g., ISPM 2: 2007, ISPM 11: 2004, ISPM 21: 2004). It offers some conceptual and general guidance for conducting pathway risk analysis.

Scope

This standard provides general guidelines for undertaking pathway risk analysis. It complements existing standards (e.g. ISPM 2: 2007; ISPM 11: 2004; RSPM 32: 2009) that address pest and commodity PRAs.

References

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 5. (updated annually). *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 systems approach for pest risk management*. Rome, IPPC, FAO.

RSPM 5. (updated annually). *NAPPO glossary of phytosanitary terms*. Ottawa, NAPPO.

RSPM 7. 2008. *Guidelines for Petition for First Release of Non-indigenous Phytophagous Biological Control Agents*. Ottawa, NAPPO.

RSPM 12. 2008. *Guidelines for Petition for First Release of Non-indigenous Entomophagous Biological Control Agents*. Ottawa, NAPPO.

RSPM 20. 2011. *Guidelines for the Establishment, Maintenance and Verification of Areas of Low Pest Prevalence for Insects*. Ottawa, NAPPO.

RSPM 22. 2011. *Guidelines for Construction and Operation of a Containment Facility for Insects and Mites used as Biological Control Agents*. Ottawa, NAPPO.

RSPM 33. 2009. *Guidelines for regulating the movement of ships and cargo from areas infested with Asian Gypsy Moth*. Ottawa, NAPPO.

Definitions, Abbreviations and Acronyms

Definitions and terms used in the present standard can be found in ISPM 5 and NAPPO RSPM 5.

Outline of Requirements

Pathway risk analysis is a process for evaluating the pest risk and risk management options associated with one or more pathways for the introduction or spread of pests. It may be used for a variety of purposes; for example, to identify potential pathways for the introduction and spread of pests, to assess the likelihood and consequences of the introduction or spread of pests along a pathway, to compare and rank multiple pests and pathways according to their level of risk, and to identify risk management options and evaluate their efficacy. The policies and responses to pathway risks relevant to two or more national plant protection organizations (NPPOs) may be harmonized by sharing or developing regional pathway risk analyses.

Pathway risk analysis is used to evaluate how conditions and events associated with a pathway affect pest prevalence and ultimately pest risk. The analytical process can be broken down into four stages: initiation, pathway description and categorization, pathway risk assessment and pathway risk management. Because pathway risk analyses may be conducted for any number of reasons, they may end at any of these stages.

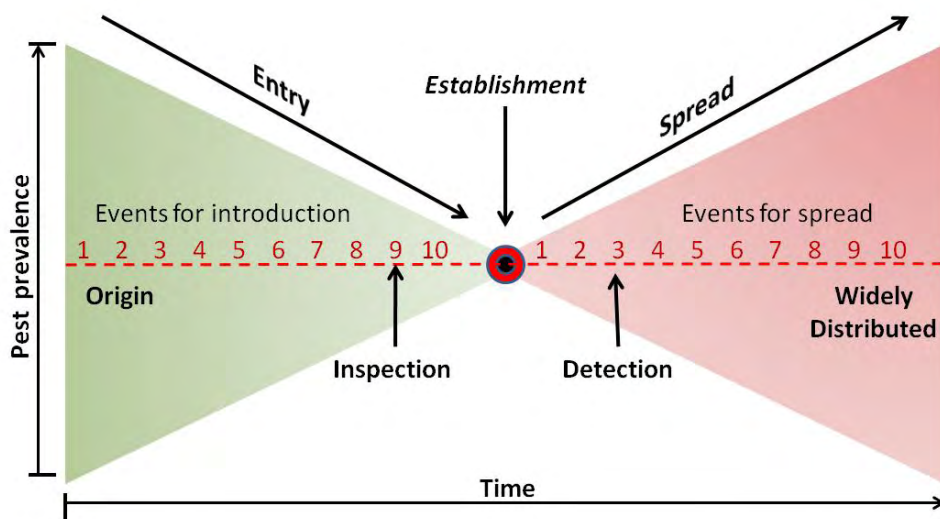
1 Background

1.1 Pathways

Pathways are defined as “any means that allows the entry or spread of a pest” (ISPM 5). Pathways may be natural, as in the case of a pest spreading via wind currents, or human-assisted as in the case of pests spreading with wood packaging material or plants for planting. Regulatory officials usually focus on human-assisted pathways, but recognizing and understanding natural spread can be an important factor when comparing pest risks and prioritizing the application of phytosanitary measures to pathways.

Many NPPOs consider pest risk in relation to the importation of commodities. This is the focus of several of the IPPC's phytosanitary standards. However, some plant pests, depending on their biology, do not have to be associated with a host plant in order to be introduced to a new area. For example, night time flying insects can easily be drawn into cargo containers if they are loaded at night under bright lights. Weed seeds may become attached to clothing or get lodged in the intake grills of refrigerated containers. Snails have been known to be intercepted in containers of tiles. Plant pests can also be introduced or spread through pathways not directly associated with trade in plants and plant products. For example, military equipment and personnel returning from overseas can spread pests if soil and plant debris is not cleaned off equipment. This pathway was responsible for the introduction of golden nematode to Long Island, New York, following World War I. Other means, including roadways, waterways, and other corridors, can act as pathways for the natural or human mediated introduction and spread of pests both within and between areas (see for example, RSPM 33: 2009).

Pathways represent a broad continuum, from pest association with the pathway at the region of origin, through entry, establishment, and finally to spread within the region at risk. Of particular concern to risk assessors are the conditions and events that occur along these pathways which either reduce or increase pest risk. Figure 1 provides a conceptual model of the relationship between pathways, events, and pest prevalence. Once these factors are known and understood, risk managers may identify either single or multiple risk management options to reduce pest risks associated with the pathway to acceptable levels (for example, ISPM 14: 2002 describes the systems approach).



Source: Robert Griffin,
USDA-PPQ-CPHST-PERAL

Figure 1: A pathway continuum model which relates change in pest prevalence in a pathway to events (and conditions) along the pathway. This generic model for a pathway begins at the origin where a pest becomes associated with the pathways, proceeds to entry into a new region, establishment, and subsequent spread. A pathway risk analysis can evaluate any set of events along this continuum.

1.2 Pathway risk analysis

Pathway risk analysis is the process of evaluating how the set of conditions and events in a pathway affect the likelihood of pest introduction and/or spread, and what options there may be to manage those risks. The conditions associated with each pathway and the specific set of events that happen along it affect the ability of a pest to enter, establish, and spread. Pathway risk analysis integrates information about pathway events and conditions with information about pest biology. This synthesis can then be used to identify options and strategies that mitigate pest risks associated with the pathway.

The risk associated with any pathway is characterized by the likelihood and the consequences of the introduction and spread of pests. For commodity import trade requests this represents the likelihood and consequences of pest introduction. However, for a pathway risk analysis of pest spread within an area (e.g., country, region), this represents the likelihood and consequences associated with an increase in the distribution of a pest. Likelihood and consequences are an inherent part of any risk analysis. However, the focus of a pathway risk analysis is typically on how the pathway affects the likelihood of introduction and/or spread. In some cases, the consequences of introduction are already well known or assumed from prior risk analyses and therefore not included. In other cases the consequences may need to be explained or assessed, particularly if they are poorly understood. Guidelines for assessing the consequences of pest introduction and spread are described in ISPM 11: 2004 and will not be discussed in detail in this standard.

The complexity of pathway risk analysis is dependent on the nature of the pathway, the scope of the analysis, the diversity of pests involved, and whether any individual PRAs are included in the analysis. The likelihood of pest introduction and/or spread via a pathway(s), and the possibilities for reducing risk are estimated based on the available evidence and information which may be collected specifically for purposes of pathway risk analysis. As with PRA, a key element of pathway risk analysis is describing assumptions and uncertainties associated with each stage of the analysis, including risk management options.

1.3 Reasons for pathway risk analysis

Pathway risk analyses may be initiated for a variety of reasons, including the following:

- Preparing detailed analysis of a high risk pathway
- Ranking and comparing the risk associated with multiple pathways
- Reviewing potential or previously unassessed risks
- Evaluating the impact of data variability and uncertainty on the likelihood of introduction/spread
- Evaluating risk to help prioritize and ensure cost effective use of finite resources
- Analyzing pest risks associated with transportation and other conveyances, beyond that posed by trade of commodities

- Developing and evaluating systems approaches to pest risk management along a pathway
- Review of existing policies.

1.4 Relationship to other types of pest risk analyses

1.4.1 Individual pest risk analyses

The PRA process described in ISPM 11: 2004 focuses on the risk associated with a particular pest moving along one or more pathways. A PRA evaluates the likelihood and consequences of introduction and/or spread for the organisms that meet the defining criteria for a quarantine pest and are found to have the potential for introduction via the pathway. By contrast, pathway risk analysis focuses on a pathway to:

- Understand how the chain of events associated with the pathway affect pest prevalence, the likelihood of pest introduction/spread, and ultimately the pest risks associated with that pathway;
- Evaluate how pathway events can be influenced to mitigate pest risk;
- Identify other pathways which may be assessed and compared (i.e., ranked); or
- Understand the combined risk of various pathways for one or multiple pests.

Pathway risk analysis may be more data-intensive and quantitative than other types of PRAs, requiring more detailed information on volume, frequency, distribution, and other details associated with the pathway. Pathway risk analyses may use models to describe the dynamic relationship between pests, pathway events and conditions, and uncertainty. Flowcharts, maps, tables and other graphically-oriented elements of analysis may be used where they facilitate the understanding of critical relationships. Finally, while PRAs often follow a fairly standard structure and process, pathway risk analyses are much more diverse due to variation in their initiating events, scope of analysis and analytical approach.

The PRA process is integral to pathway risk analysis as it establishes the background principles for analysis and provides the mechanism for assessing each pest in a particular pathway. Furthermore, for pathways where the consequences of particular pests are poorly known, pest risk analysis allows the estimation of this component of risk. Thus PRAs can be integrated into pathway risk analyses to enhance and complement them.

1.4.2 Commodity pest risk analysis

Commodity pest risk analyses that NPPOs routinely conduct are a type of pathway risk analysis in that they are pathway-initiated and they consider pest risk associated with that pathway. Commodity based pest risk analyses represent a special type of pathway risk analysis since the pathways are more clearly defined. Furthermore, they may also describe some aspects of the host and pathway that are relevant to pest risk. However, functionally, these analyses are a collection of individual pest risk analyses grouped together based on a single commodity.

PRAs consider factors about introduction and spread at the level of individual species but may not provide a dynamic and holistic view of how the chain of events along a pathway affects pest prevalence and risk, as a pathway risk analysis would. Finally, typical commodity based PRAs evaluate consequences, while pathway risk analyses may not.

1.5 Diversity and variation in pathway risk analysis

Pathway risk analyses are highly variable. Analyses are inherently unique due to differences in objectives, scope of analysis, data availability, and analytical approach. Furthermore, they may stop at different stages (see below), depending on the objectives of the analysis. As such, this standard is inherently broad to account for the diverse set of ways a pathway risk analysis may be conducted.

1.5.1 Objectives

Section 1.3 listed possible reasons for initiating a pathway risk analysis. Behind these reasons are specific objectives that will ultimately determine how the analysis is conducted and the type of data needed. Pathway risk analyses typically evaluate events contributing to either the likelihood of introduction or the likelihood of spread. They do not necessarily consider the entire pathway from pest association with the pathway to spread throughout a region (see Figure 1). In fact, an analysis may focus on any range of events along the pathway continuum (Figure 1), even if it is just two or three steps. It is important in any analysis to be explicit about the objectives and limits of the analysis with respect to the pathway continuum and any assumptions relating to risk factors beyond the part of the pathway that is evaluated (see section 1.2). Below are some examples of objectives of pathway risk analyses:

- Evaluate container loading practices at a packing facility to determine how they affect the likelihood of contaminating pests.
- Describe and categorize potential pathways for pest introduction from a certain region through a port receiving high volumes of cargo.
- Compare the risk of pest introduction associated with direct and indirect passenger flights between two cities in different countries.
- Calculate the probability of wood boring pests spreading from the transport of infested material to landfills.
- Compare whether a wind-borne plant pathogen is more likely to spread to other regions naturally or via human-mediated transport of infected material.
- Evaluate the most likely pathway by which a newly detected pest became established (e.g., traceback).
- Estimate the change in the risk of pest introduction should one of the risk mitigation measures in a systems approach fail.
- Identify the relative risk of a number of different commodity pathways, in order to prioritize inspection efforts at ports.
- Evaluate a pest newly found in association with one or more pathways that may require phytosanitary measures.
- Analyze previously unassessed pathways, including those not directly related to trade (e.g., movement of military vehicles, disaster relief support, construction of a new road or waterway).

- Review a regulatory policy pertaining to pests or pathways that appear to pose unacceptably high phytosanitary risks.
- Evaluate operational procedures and priorities.
- Identify and evaluate risk management options for a pathway.
- Evaluate the impact of natural disasters on the long-distance spread of pests.
- Evaluate and quantify the impact of human and animal migration on pest introduction and spread.

1.5.2 Types of pathway risk analysis

The type of pathway risk analysis refers to whether the analysis considers one or multiple pests, and one or multiple pathways. Variation in these two factors results in four types of pathway risk analyses:

- Single pathway, single pest, (e.g., marble tile transporting a snail species)
- Multiple pathways, single pest, (e.g., trade, tourism, and military equipment enabling the movement of a pest between regions)
- Single pathway, multiple pests, (e.g., commodity from one location with a number of associated pests)
- Multiple pathways, multiple pests, (e.g., air and sea cargo from another country carrying multiple pests; two country border analysis).

At times, the difference between a pathway risk analysis and another type of pest risk analysis (discussed in section 1.4) may not be obvious because they share somewhat similar objectives and methodologies. For example, single pathway - single pest analyses will sometimes resemble pest risk analyses, particularly when they include detailed consequences of introduction/spread. Also, single pathway - multiple pest analyses will sometimes resemble commodity-initiated pest risk analyses when the pathway is a commodity that is the pest host. In these cases, classification of the risk analysis as a pathway risk analysis or some other type of phytosanitary analysis is perhaps more of an academic exercise that has no bearing on the development or use of the analysis itself. However, per the definition and discussion above, a risk analysis can be considered a pathway risk analysis if the emphasis of the analysis is on the likelihood of introduction or spread.

It is important to realize that the specific objectives and context of the risk analysis will determine whether the analysis considers a single pathway or multiple pathways. For example, in a comparative study, apples from Canada and cherries from Canada are two separate pathways that are evaluated. However, these two pathways and all other fruit pathways from Canada could be combined into a single, yet broad pathway if it were relevant to the study's objectives.

1.5.3 Scope: narrow vs. broad

The scope of a pathway risk analysis is related entirely to the particular objectives of the analysis. The scope may range from specific and narrow (e.g., an imported fruit from a particular country) to general and broad (e.g., wooden handicrafts from China – many types of articles with different pests, as any item could be composed of wood from several plant species).

The scope of the analysis will affect how the analysis is conducted and the type of data needed. For example, a pathway risk analysis of a specific commodity will likely require a considerable amount of detailed information about the conditions and events related to the pathway (e.g., frequency, quantity, field growing, harvest and storage conditions, etc.) in order to evaluate how the pathway affects the likelihood of pest introduction. An analysis of this type may include individual PRAs for the quarantine pests. However, a broader analysis, such as a comparison of the relative risk of pest introduction between commodities for consumption and plants for planting, may not necessarily require a great deal of pathway- or pest-specific information. It may not even focus on individual pests. Instead the analysis may compare the relevant differences between these two types of pathways in order to estimate their relative risk.

Pathway risk analyses with a broad scope may evaluate (via PRA) representative pests in order to characterize the pest risks associated with the pathway. Such approaches are advantageous when a large number of potentially regulated pests are associated with the pathway, or when the pests associated with the pathway are not well known.

2 Requirements

This section describes the four stages in pathway risk analysis. These stages are roughly analogous to the steps and stages of pest risk analysis described in ISPM 2: 2007 and ISPM 11: 2004: the initiation, pathway description, risk assessment and risk management.

In Stage 1, the detailed scope and specific objectives of the analysis are provided. In Stage 2, the pathway is described along with relevant pest-specific information, if available. Assumptions about the analysis or about events and conditions beyond the limits of the analysis are also given. In Stage 3, the pathway(s) are analyzed in detail to evaluate the chain of events inherent to the pathway and its effects on pest prevalence and risk. The overall pest risks associated with the pathway are analyzed in terms of the likelihood of pest introduction and/or spread. Separate pest-specific PRAs may be incorporated here. In Stage 4, risk management options are evaluated and recommended for their efficacy in reducing pest risks associated with the pathway. The four stages are sequential and build upon each other. However, because a pathway risk analysis may be conducted for any number of reasons, it may end at any of the above described stages.

By necessity, requirements in this standard provide general guidance for pathway risk analysis. Requirements are intended to be broad, flexible and non-prescriptive to reflect the diversity of pathway risk analyses. The entire process from initiation to risk management should be documented in a risk analysis to the extent that if a review or a dispute arises, the sources of information and rationale used in reaching the management decision can be clearly demonstrated.

Other aspects of documentation are discussed in ISPM 11: 2004.

An important aspect of all risk analyses is the description of uncertainty (ISPM 2: 2007). Sources of uncertainty within a particular analysis may include: missing, incomplete, inconsistent or conflicting data; natural variability of biological systems; subjectivity of analysis; and/or sampling error.

The nature and degree of uncertainty in the analysis should be documented and communicated, and the use of expert judgment or opinion indicated. If adding or strengthening of phytosanitary measures is recommended to compensate for uncertainty, as may be done in a systems approach (ISPM 14: 2002), it should be documented. Documentation of uncertainty not only contributes to transparency, it may also be useful for identifying research needs and priorities. In cases where pathway risk analyses are more quantitative than other types of PRA (e.g. sensitivity analysis, probabilistic scenario analysis, probabilistic modeling, etc.) there may also be opportunities to apply more mathematical or complex modeling principles to quantify the consequences of uncertainty on risk. Specific approaches for this are discussed elsewhere and are not further elaborated in this standard.

2.1 Initiation phase (Stage 1)

Because pathway risk analysis may be used for many purposes, the initiation phase is particularly important. In this stage, all relevant information concerning the reason for initiation of the analysis, which pathways are of concern, and the scope and objectives of the analysis are described. This is not only important for the end users of the analysis but also for the risk analysts and requestors who need to ensure the analysis addresses the intent of the request.

Below are four critical elements that should be included in the initiation stage of pathway risk analyses, though not necessarily in the order presented.

2.1.1 Identification of the pathway and pests of concern

The pathway of concern must be clearly identified, whether it is related to a commodity, conveyance, or natural pathway. If the intent is to compare multiple pathways, then all relevant pathways need to be identified. If relevant, spatial or temporal factors should also be described. For example, the analysis may only be for movement of a commodity at a certain time of the year (e.g., Canadian Christmas trees to Puerto Rico in November). If the objective of the pathway risk analysis is to *identify* potential pathways of regulatory concern, then the scope of the investigation becomes important and needs to be clearly stated in the initiation stage (e.g., “this pathway risk analysis identifies the natural pathways through which weed seeds may enter the country”).

The phytosanitary risk or the potential for risk associated with each pathway should be identified and linked to the pathway. In some cases, a specific pest or group of pests of regulatory concern might already be identified as associated with the pathway. In other cases, the specific set of pests associated with the pathway may be unknown, but it is reasonable to expect that some pests have potential to be associated with the pathway based on other data. If a risk or a potential risk of concern cannot be reasonably identified for the pathway(s), then the pathway risk analysis stops at this stage.

2.1.2 Identification of the area of analysis

The area in relation to which the pathway risk analysis is conducted should be defined as precisely as possible. This area is analogous to the PRA area as stated in ISPM 11: 2004.

2.1.3 Background information

Any background information that could be used to help frame and guide the analysis should also be provided in the initiation phase. This information includes the reason why the analysis was requested, who requested it, and whether the analysis should follow a certain approach. Information on how the analysis will be used and who the intended audience is likely to be should be included. If the pathway risk analysis is to focus on the likelihood of introduction, then sufficient information regarding the consequences of introduction should be provided or referenced in the initiation stage. Standard terminology should be used (e.g., ISPM 5 and RSPM 5).

2.1.4 Scope and objectives of the analysis

The scope of the analysis and its specific objectives are important components of the initiation stage. The scope identifies the limits of the analysis with respect to the pathway continuum shown in Figure 1. As stated in the background section, pathway risk analysis may evaluate the entire pathway continuum from introduction to spread. More often, however, it focuses on one or the other, or on a small section of the continuum, or even on a single point along the pathway (e.g., a political border). The objectives of the analysis must be clear and explicit for both developers and end users. Clearly identified objectives will help determine data needs and analytical approaches.

2.1.5 Conclusion of initiation

At the end of Stage 1, the initiation point, the pathways of concern and the PRA area will have been identified. Relevant background information has been collected and pathways have been identified as possible candidates for phytosanitary measures. If a risk or a potential risk of concern cannot be reasonably identified for the pathway(s), then this should be documented and the pathway risk analysis stops at this stage. Factors which could lead to re-examination should also be documented. In the absence of sufficient information the uncertainties should be identified and the process should continue.

2.2 Pathway description (Stage 2)

In this stage, more detailed information is gathered about the pathway(s) of concern, and pathways are described and characterized. Each pathway to be assessed should be clearly described to the level of specificity required for the analysis, to ensure that risk is being assessed for the elements of the pathway, and that information used in the assessment is relevant to the pathway in question. The following are examples of factors that may be considered in pathway description:

- Origin and destinations
- Relevant events and conditions associated with the pathway
- Limits of the analysis with respect to the pathway continuum (Figure 1)
- Modes , conduits and vectors of transport or movement
- Intentional or unintentional introduction of organisms
- Routes for arrival at points of entry and distribution within the country

- Transit countries or regions
- Contamination / secondary infestation
- Temporal aspects of the pathway
- Relevant events and conditions associated with the pathway
- Standard industry practices
- Frequency, size and volume
- Composition, diversity, and abundance of the pests of concern
- Assumptions about the conditions beyond the scope of the analysis
- Other assumptions and uncertainties.

2.2.1 Conclusion of pathway description

At the end of Stage 2, the pathway(s) of concern have been described and characterized. The content and structure of this stage will vary depending on the objectives of the analysis. If the objective of the analysis is simply a detailed description of the potential pathways through which a pest or group of pests could enter or spread between regions, then the analysis may stop at this stage. However, in other cases, a short and simple description of the pathways may be sufficient before continuing with further pathway risk analysis as described in Stages 3 and 4.

2.3 Pathway risk assessment (Stage 3)

In this stage a detailed assessment of risk is undertaken to estimate how the chain of events and conditions along the pathways may affect pest prevalence and risk of pest introduction and /or spread. Pest specific risk assessments may be included here as well as discussion of the relative importance of events, thereby establishing the potential for the pathway(s) to transport a pest.

Some or all of the following steps may be applied within a pathway risk analysis, although it is not necessary to follow them in order presented. The pathway risk assessment will be as complex as the technical requirements of each particular set of circumstances.

2.3.1 Pathway categorization

Pathway categorization is the process of determining whether a pathway is of regulatory or phytosanitary significance and should continue with the subsequent stages of pathway risk analysis. The rationale for pathway categorization is analogous to that for pest categorization (ISPM 11: 2004), which is the process for determining whether a pest is a quarantine or regulated non-quarantine pest. If a pathway or group of pathways is not of regulatory or phytosanitary significance, then the pathway risk analysis may end at this stage. A pathway may be of regulatory or phytosanitary significance if it contains or has the potential to transport regulated pests.

2.3.2 Pathway mapping and modeling

Pathway mapping is a useful tool for identifying key aspects of the pathway and their significance. A map may take the form of a list or table but usually appears as a flowchart identifying events, conditions, and locations in a pathway. Thus, it can help to guide or frame the risk assessment.

Depending on the level of analysis required and the nature of the data, pathway maps may be written as mathematical models that describe the effect pathway events and conditions on pest prevalence.

These models can be designed to simulate all or parts of the pathway, and incorporate uncertainty. Pathway mapping can also help in summarizing complex data in a visual way by providing information about the pathway over space and through time. This can provide perspective and context to data and other information which is linked to conclusions and recommendations that are associated with a part or parts of the pathway. In all cases a pathway map/model should:

- Identify origin(s), events and endpoints
- Identify locations and conditions
- Identify control points
- Describe pest prevalence and any associated changes over time.

The general objective of pathway mapping and modeling should be to understand ‘how’, ‘where’, and ‘how much’ pest prevalence increases or decreases over the course of the pathway, and how this affects the probability of introduction or spread. A key piece of information will be a quantitative or qualitative estimate or assumption regarding pest prevalence at the outset. While the pest presence and prevalence may be assumed, the scenario (series of critical events in a pathway) should not be assumed.

2.3.3 Pests of concern

In pathway risk assessment, all quarantine pests or potential quarantine pests should be identified. If the scope of the analysis is very broad, specific pests representative of groups of pests may be chosen on the basis of taxonomic, ecological, or life-history similarity. Rationale and assumptions for grouping pests should be clearly stated.

2.3.4 Assessment of pathway events related to the introduction and spread of pests

The structure of a pathway risk assessment should correspond to the series of events along the pathway. The assessment may be quantitative or qualitative or both, depending on the nature of the analysis and available data. All scenarios that are to be ranked or compared should be treated equivalently in their analysis.

The assessment follows the series of events and conditions that influence the probability of pest presence, transport, survival, entry, escape, establishment and spread to arrive at some conclusion for an unmitigated scenario. The probabilities for each of these events are then used to understand the overall likelihood of pest entry, establishment, or spread.

Factors that may be considered include (but are not limited to):

Pathway magnitude

- Diversity of pests transported
- Number of individuals per species transported
- Frequency of known entry of pests

- Frequency of transit
- Size/volume of incoming material
- Number of potential entry points along pathway

Pathway factors affecting survivability of pests

- Speed/duration of pathway
- Potential for maintaining pest viability in transit or storage (consider conditions during transloading, commercial procedures applied in transit such as refrigeration, sealed packaging)
- In-transit contamination, co-mingling of shipments
- Suitability of season for survival of organisms
- Pest interactions

Detection of pests along pathway

- Ease of inspection
- Ease of detection of pests
- Required inspection expertise
- Required diagnostic expertise
- Degree of detection resources required

Environmental compatibility

- Proximity of entry, transit and destination points to hospitable environments for establishment (i.e. suitable climate, hosts, habitats)
- Suitable areas for establishment crossed by pathway
- Proximity to areas of low pest prevalence or pest free areas
- Potential introduction of generalist organisms (i.e. organisms with little environmental specificity)
- Intended use of commodity

Biological characteristics affecting pest establishment

- Pest life stage at the time of arrival in the new environment
- Availability / suitability of hosts
- Potential for reproduction
- Availability / density of mating partners
- Minimum number of propagules required to establish a self-sustaining population.

The magnitude of the pathway should be considered in terms of frequency, volume, and exposure to a significant number and variety of pests. For the time in transit, the survivability of pests in relation to environmental conditions, as well as opportunities for contamination and cross-contamination, should be taken into account.

The potential for the pathway to facilitate the movement of pests need only be considered in relation to the pests of concern.

Control points along the pathway (points where phytosanitary measures are or could be applied or where the pest status of the consignment could be monitored) should be identified. Any commodities, conveyances, packing materials and handling/treatment protocols involved in the pathway should be considered in the pathway risk assessment.

The assessment of the risk associated with a pathway should consider existing practices or conditions that have a mitigating effect on pest prevalence in a pathway. For instance, the routine selection, culling and cleaning process which is a normal industry practice in a packing house would be expected to reduce pest prevalence.

The analyst may assume this process will occur and include it as a factor in evaluating the unmitigated risk, or the analyst could remove the assumption from the beginning of the analysis and then look at the efficacy of the packing process as a mitigating measure.

Depending on the objectives of the analysis, if there are multiple pests of concern it may be necessary to conduct the pathway assessment separately for each pest or group of related pests. This is because pests may respond differently to pathway events and conditions. After evaluating each pest separately in the pathway, the cumulative risk of all pests in the pathway may be considered.

2.3.5 Consequences of pest introduction and spread

An analysis of the consequences of introduction or brief summaries of the consequences with supporting citations should be given for all pests of concern likely to follow the pathway. Guidelines for the analysis of consequences of pest introduction are available in other international and regional standards (ISPM 2: 2007, ISPM 11: 2004, RSPM 7: 2008, RSPM 12: 2008, RSPM 20: 2011, RSPM 22: 2011, RSPM 33: 2009). Consequences may include impacts to plant industries, human infrastructure, domestic and international trade, natural resources. The analysis of consequences should consider both market and non-market impacts, and direct as well as indirect impacts as described in ISPM 11: 2004. Individual PRAs can be either included in the body of the text or grouped in an appendix.

2.3.6 Pathway comparison

Pathway risks for separate pathways may be ranked or compared relative to each other, or rated on a scale that allows comparisons and ranking from different analyses using the same criteria and scale. The establishment of rankings provides supporting rationale for policy decisions regarding the prioritization of pathways and helps to identify areas where resources may be focused. Comparison of pathway risks is straightforward when the analyses focus on the same pest or groups of pests. However, with multiple pests or different groups of pests, it becomes more complex because the sum or total risk represented for all pests must first be determined for each pathway. For a multiple-pest pathway, it may be necessary to consider the significance of the risk posed by several lower-risk pests on one pathway as compared to that of one higher-risk pest on another pathway. Methodologies for comparison should be stated and clearly described, whether they are qualitative or quantitative in approach.

2.3.7 Conclusion of the pathway risk assessment

At the end of Stage 3, the pest risk associated with the pathway(s) of concern has been evaluated, and uncertainties have been identified. If it has been determined that a pathway has the potential to serve as a means for the entry or spread of at least one potential regulated pest, the pathway risk analysis should continue.

If a pathway does not fulfill this criterion, the risk analysis process for that pathway may stop. In the absence of sufficient information, the uncertainties should be identified and the assessment process should continue.

2.4 Pathway risk management (Stage 4)

Pathway risk management is the process of identifying, evaluating, and selecting mitigation options along the pathway to reduce the likelihood of introduction and spread of pests.

General guidance for pest risk management is provided in ISPM 11: 2004, much of which is relevant to pest risks associated with pathways. It includes, for example, guidance on determining acceptable level of risk, and lists of mitigation options for consignments and other types of pathways, of options for preventing or reducing infestation in crops, and ways of establishing and maintaining pest-free areas.

The remainder of this section builds on ISPM 11: 2004 and discusses risk management issues that are particularly applicable to pathway risk analysis. Pathway risk management options will follow from the pathway risk assessment and will therefore tend to focus on events rather than pests themselves. Pathway risk management will identify and evaluate mitigation measures that alter pathway conditions and events which will in turn decrease pest prevalence and the resultant risk.

The first decision to be made in pathway risk management is to determine whether measures need to be put in place to mitigate risk or if the risks identified are deemed to be acceptable. For example, industry practices or other risk mitigation measures that are already in place along the pathway may reduce pest risk to acceptable levels. In such cases this should be documented and the pathway risk analysis can be concluded. Each country will need to determine its own acceptable level of risk according to the principle of managed risk (ISPM 1: 2006).

If the level of risk is deemed unacceptable, risk management will proceed. Management options may focus on the pathway identified as posing the greatest risk or on a single event or process within a pathway that has been identified as the highest risk.

2.4.1 Control points

Pathway risk analysis may identify control points along a pathway that may provide opportunities for risk management. Management measures could focus on evaluating the control points associated with pathways or pathway events representing the highest risk and continuing to develop and evaluate measures until an acceptable level of risk has been achieved. Measures may be identified in addition to industry practices or may be adapted or adopted from industry practices alone or in a systems approach. Each control point can be assessed to determine if risk management options can be applied and to estimate the effectiveness of these management options. Where necessary, multiple phytosanitary measures may be applied at one or multiple control points in order to minimize the risk to an acceptable level.

2.4.2 Systems approach

In some cases, managing the phytosanitary risks associated with a pathway may be best accomplished through the use of a systems approach (ISPM 14: 2002) which involves the integration of two or more independent measures to reduce pest risk. These measures can be applied to events or processes such as post-harvest treatment, storage, loading, unloading, trans-shipment and points of destination. As mentioned previously, pathway risk management may include both general and pest specific measures and should include considerations of standard practices that occur along the pathway that may mitigate risk. Pathway risk management using a systems approach, with multiple control points to mitigate the risks associated with multiple pests, may provide multiplicative risk reduction at each step. This approach to risk management has further benefits including:

- i) A risk mitigation failure at one point along the chain of measures will not result in a total lack of protection.
- ii) Risk management measures aimed at a number of pests associated with a pathway may incidentally protect against as yet unknown pest risks.
- iii) Cost saving measures may be found. Pathway risk management may be used to mitigate multiple pests along multiple pathways. There may be instances where this may be done with minimal extra effort and cost.
- iv) Because the entire chain of events has been assessed, pathway risk management may be able to evaluate not only the control point where measures are applied but also how measures applied at one control point may impact pest risks further along or throughout the rest of the chain

2.4.3 Uncertainty in risk management

Where effectiveness of mitigating measures is reasonably certain, the minimum number of measures required to reduce the risk to an acceptable level should be identified. Following IPPC principles, required measures should not be more stringent than necessary.

In cases where there is uncertainty that the mitigation measures will achieve an appropriate level of protection, additional measures may be required. The level of uncertainty combined with the estimated level of risk will dictate the level of additional measures adopted to mitigate risk. As new evidence is gathered and uncertainty is reduced, mitigation measures may be re-evaluated as necessary.

2.4.4 Natural dispersal and impact

Regulation of natural dispersal pathways is generally ineffective in the absence of natural barriers, and in such cases managers may seek to reduce the likelihood of establishment. The management options for natural dispersal may include foresight activity and may be used to direct research and development opportunities. An analysis of natural dispersal mechanisms may lead to management options including weather monitoring and forecasting to develop control measures.

2.4.5 Monitoring effectiveness

The effectiveness of pathway risk management strategies may be monitored using suitable performance measures, such as the number of pests intercepted at the end of, or along the pathway, either prior or subsequent to the application of risk mitigation measures. Monitoring of effectiveness may be especially advisable where risk mitigation measures are not based on empirical evidence.

2.4.6 Conclusion of risk management

At the end of Stage 4, risk management options will have been identified and evaluated, and applied where necessary. Pathway risk analysis may also be a trigger for additional risk analyses. While pathway risk analysis may identify individual pests of concern, pest or commodity-specific PRAs may also need to be conducted to develop management options for individual pests.

Not all pathway risk analyses will have management as a focus. Risk management options will depend on the scope of the pathway risk analysis and the risks identified. Pathway analyses that do not have risk management or phytosanitary regulation as objectives, may be used to identify information gaps and needs in data collection.