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Animal and
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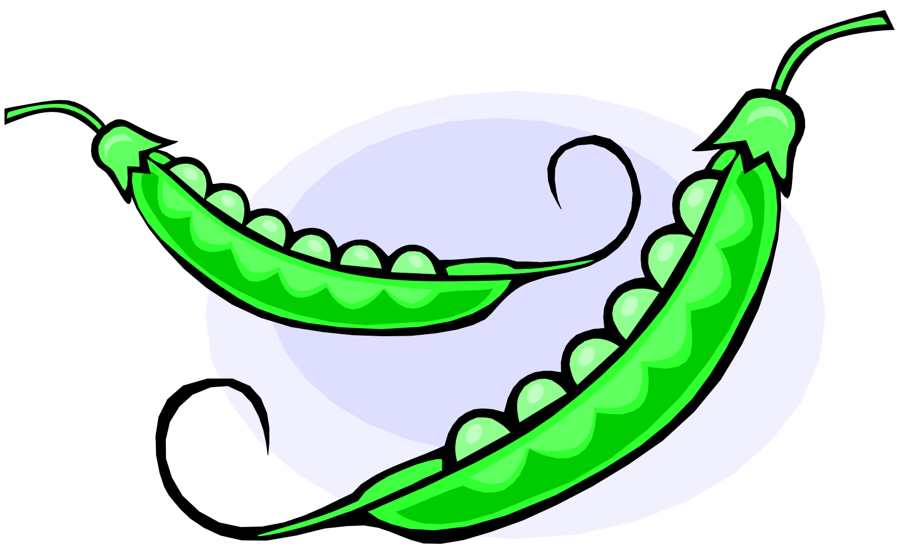
Plant Protection
and Quarantine

Guidelines for Plant Pest Risk Assessment of Imported Fruit & Vegetable Commodities



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Introduction & Framework

Introduction

In this document, we provide guidance for conducting commodity pest risk assessments in the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ). The purpose of commodity pest risk assessment is to determine

1. the plant pest risk associated with fruit and vegetable commodities imported into the United States for consumption and
2. the phytosanitary measures that may be used to mitigate the risk.

Risk assessments are conducted by PPQ under the regulatory authority provided in Title IV—Plant Protection Act of 2000 (7 U.S.C. § 7701-7786, 2000) and in conformity with PPQ's responsibilities as the national plant protection organization (NPPO) for the United States under Article IV.2.f of the International Plant Protection Convention (IPPC).

Pest risk analysis (PRA) is the process used by NPPOs as the technical justification for phytosanitary measures. PRA is defined by the IPPC as "the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it." The process requires a risk assessment to characterize the risk and risk management to determine appropriate measures.

In this document, we provide guidelines for PPQ risk analysts conducting commodity import pest risk assessments, as well as for stakeholders and trading partners interested in understanding our methodology and rationale. The process we describe here is used to inform risk management, but does not include the risk management analysis.

This document supersedes *Guidelines for Pathway-Initiated Pest Risk Assessments, Version 5.02* (PPQ, 2000). Information covered here includes

- an overview of pest risk analysis as outlined by the IPPC,
- the legal framework for conducting pest risk analysis, and
- specific guidelines for conducting commodity import pest risk assessments for APHIS-PPQ.

These Guidelines are based on a qualitative methodology for assessing the likelihood and consequences of pest introduction and spread. Conclusions are expressed as relative rankings based on scientific, technical, and operational evidence and uncertainty. Basic information required by the USDA for initiating the process is found in the Prerequisite Rule (7 CFR § 319.5, *Requirements for submitting requests to change the regulations*).

These Guidelines will be updated as needed to incorporate corrections and improvements. All changes will be logged in Supplement No. 5.

Pest Risk Analysis Framework

Pest risk analysis (PRA) is "the process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it" (IPPC, 2012).

PPQ's risk assessment procedures are consistent with the International Standards for Phytosanitary Measures (ISPMs) adopted by IPPC as follows:

- No. 1, *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*
- No. 2, *Framework for pest risk analysis*
- No. 11, *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, and supplements

The use of biological and phytosanitary terms in these guidelines conforms to ISPM No. 5, *Glossary of Phytosanitary Terms* (IPPC, 2012). We discuss these standards in more detail in the IPPC Standards related to risk analysis section.

Stages of pest risk analysis

The IPPC describes three stages of pest risk analysis in ISPMs No. 2 and 11: initiation, risk assessment, and risk management.

Initiation

The first stage of pest risk analysis, initiation, involves defining the hazards by identifying the pest(s) and conditions that are of concern and should be considered for risk analysis.

Initiation points include:

- **Identification of pathway(s).** A pathway, often an imported commodity, is identified as a means for the introduction and/or spread of pests. A pathway other than commodity import could be identified (natural spread, packing material, mail, garbage, compost, passenger baggage, etc.).

- **Identification of pests.** A specific pest requires evaluation. For example, this may be the result of a pest detection or interception, because a pest is being imported (e.g., biocontrol organism), because the organism previously was not known to be a pest, or because there was a change in the status or incidence of a pest in the PRA area. The results of initiation are clearly identified hazards (pests, pathways, or conditions), which become the focus for risk assessment.
- **Review of policies.** Regulatory policies or operations require evaluation, for example, to revise regulations or requirements; to prioritize risk management activities; if a new system, process, or procedure is introduced; if new information is made available that could influence a previous decision; or if an international dispute on phytosanitary measures arises.

Pest risk assessment

Stage 2 of pest risk analysis is pest risk assessment: the evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences (IPPC, 2012).

Risk assessment begins by first determining which pests to assess and then evaluating these pests for the likelihood and consequences of their introduction and/or spread. Risk assessment is composed of two distinct phases:

- **Pest categorization.** A preliminary screening of individual pests to determine whether or not the pests meet the defining criteria for a quarantine pest or regulated non-quarantine pest.
- **Risk assessment**. The examination and analysis of biological and economic information to estimate the potential for introduction and spread and the potential economic impact of the pests

Pest risk management

Stage 3, pest risk management, is the evaluation and selection of options to reduce the risk of the introduction and spread of a pest (IPPC, 2012). It results in a summary of options, including recommendations for the selection of preferred options. Options are assessed based on information about their efficacy, feasibility, and impacts.

The procedure in this stage is to identify and evaluate mitigation measures that may be used to reduce the risk. These may be existing measures or measures developed specifically for the conditions under consideration.

The Legal Framework for PRA

In this section of the guidelines, we provide an overview of the international and national legal framework for pest risk analysis. This framework provides the basis for why and how we conduct pest risk analysis, and creates a system of accountability for the conduct of pest risk analysis. In this section, we address

- The World Trade Organization and the IPPC,
- Relationship of the IPPC to the SPS,
- IPPC Standards related to risk analysis,
- The appropriate level of protection and the acceptable level of risk,
- Provisional and emergency measures,
- Precaution under the IPPC and SPS,
- Rational relationship,
- Probable versus possible,
- International guidelines for considering economic impacts in PRA
- National legislative framework for PRA,
- Climate change in PRA, and
- Relationship of the PPA to the WTO-IPPC framework.

The World Trade Organization and the IPPC

The World Trade Organization (WTO) is the international organization responsible for establishing rules of trade. The rules are legally binding for its member nations. WTO agreements are the result of negotiations between WTO Members. Agreements are implemented by Members toward the objective of a non-discriminatory trading system based on agreed rights and obligations. Each Member can expect that its exports will be treated fairly and consistently in other Member countries and each Member country agrees to do the same for imports into its own country. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement; SPS WTO, 1995) covers requirements for food safety and the life and health of animals and plants. The SPS Agreement requires that restrictions be based on international standards or scientific principles and evidence, that they be applied only to the extent necessary to protect health, and that they do not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail. To achieve its objective, the SPS Agreement encourages Members to use international standards, guidelines, and recommendations where they exist, and identifies standard-setting bodies for food safety, animal health, and plant health. Members may adopt SPS measures that result in higher levels of health protection—or measures for health concerns for which international standards do not exist—provided that they are technically justified. Technical justification is accomplished by an assessment of risk taking into account scientific principles and evidence (technically justified). Article 2 of the SPS Agreement (*Basic Rights and Obligations*) and Article 5 (*Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection*) describe the central concepts. The IPPC is a multilateral treaty for international cooperation in plant protection, and is identified in the SPS Agreement as the standard-setting body for plant health. The Convention makes provisions for the application of measures by governments to protect their plant resources from harmful pests (phytosanitary measures) that may be introduced through international trade. The IPPC complements the SPS Agreement by providing the international standards recognized by the WTO to ensure that phytosanitary measures have a scientific basis for their placement and strength and are not used as unjustified barriers to international trade.

Article 5.1 of the SPS Agreement states that WTO Members “shall” ensure that phytosanitary measures are based on an assessment of risk. The agreement defines risk assessment as “The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential adverse effects on human or animal health arising from the presence of additives, contaminants, toxins, or disease-causing organisms in food, beverages or feedstuffs.”

Slightly different terminology is used in the IPPC (1997) and associated standards (e.g., ISPMs No. 2, 5, 11, and 21) to reflect the same concepts and obligations. Two terms that are particularly important are found in Article II (*Use of terms*):

- **Technically justified.** Justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information.
- **Pest risk analysis.** The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it (IPPC, 2012).

Despite the subtle differences in terminology, the SPS Agreement and the IPPC are clear that a systematic process for gathering, evaluating, and documenting scientific and other information is required to provide the basis for phytosanitary measures affecting trade. This involves consideration of economic as well as biological aspects of pest risk for plant health and life.

Relationship of the IPPC to the SPS

These requirements of the SPS Agreement create a direct relationship between risk assessment and international standards, which are established by the relevant international organizations. The SPS Agreement states that a risk assessment is not required where measures are based on international standards. This is because the risk basis for the standard is already internationally agreed upon. Where standards do not exist or are deemed inappropriate, risk assessment is needed to provide the justification for measures. Another part of the relationship involves the standards developed for performing risk assessment. In both cases, the standard setting organizations play a significant role in providing governments with the means to justify their SPS measures.

At this time, only a few specific phytosanitary standards can be used to directly support national measures in lieu of risk assessment. Therefore, where phytosanitary measures are concerned, WTO Member governments are largely forced to base their decisions on risk assessments. This means that the process used for phytosanitary risk assessment becomes extremely important to all countries.

IPPC Standards related to risk analysis

ISPM No. 2, *Framework for Pest Risk Analysis* (IPPC, 2007), was originally adopted by the IPPC in 1995 as *Guidelines for Pest Risk Analysis* and was revised in 2007. This standard has served for more than a decade as the primary conceptual and procedural reference for phytosanitary risk analyses. This standard provides basic background regarding risk analysis for phytosanitary purposes and outlines a three-stage process for conducting risk analysis. ISPM No. 2 has been widely used by NPPOs throughout the world as a reference outline for developing their phytosanitary risk analysis systems and processes.

ISPM No. 11, *Pest Risk Analysis for Quarantine Pests*, was adopted in 2001. In 2003, the Interim Commission on Phytosanitary Measures (now the Commission on Phytosanitary Measures), the governing body of the IPPC, adopted a supplement on environmental risks, and in 2004, a supplement on genetically modified organisms was added (IPPC, 2004a).

In 2004, ISPM No. 21, *Pest Risk Analysis for Regulated Non-Quarantine Pests* (IPPC, 2004b), became part of the family of standards devoted to pest risk analysis. All of these standards provide significant detail regarding the concepts and practice of risk analysis.

The appropriate level of protection and the acceptable level of risk

The SPS Agreement discusses the acceptable level of risk in terms of the appropriate level of protection. In phytosanitary terminology, the terms “negligible pest risk” and “quarantine security” are also commonly used. Other terms, such as insignificant risk, no significant risk, *de minimus* risk, and safety are also encountered occasionally in documents and discussions related to the same or similar concepts.

It is the sovereign right of an importing country to establish its appropriate level of phytosanitary protection. The appropriate level of protection (or acceptable level of risk) is not determined by the individual risk analyst but is instead determined by broader policy.

In general terms the degree of risk[1] accepted is commensurate with the benefits and costs of an alternative. This means that although the absolute risk of a particular pest might be significant, it may still fall within an acceptable level of risk (or alternatively, there may be an appropriate level of protection) if, for example, one of the following applies:

- The benefits associated with accepting the risk are greater than any associated costs.

1 Risk in this context refers to the likelihood of pest introduction with unacceptable consequences.

- The risk mitigation costs are affordable.
- The risk is below what is considered normal or allowable compared to existing risks that are being accepted.
- The risk is unchangeable and therefore must be accepted.

The acceptable level of risk is not necessarily a "bright-line concept" and should not be expected to be static. The strength of the measures applied in response to the risk should be linked to sound and open criteria and the measures should be consistent, to the extent possible, with the strength of measures for similar situations.

Provisional and emergency measures

The SPS Agreement (SPS WTO, 1995) and the IPPC (1997) include concepts and terms for provisional and emergency measures that may not be well understood or aligned. Other instruments and organizations also refer to so-called "precautionary measures" that are variously understood and generally linked to the application of the "precautionary approach" (also sometimes known as the "precautionary principle").

Emergency measures are not explicit in the SPS Agreement but extend from Annex B paragraph 6 (urgent problems) and the resulting Emergency Notification format adopted by the SPS Committee (G/SPS/7 Rev 1). Article VII.6 of the IPPC is explicit about "emergency action" based only on the detection of a pest, indicating that such action will be evaluated (implying a PRA) as soon as possible to ensure that it is justified. The IPPC's Principle 14 (ISPM No. 1; IPPC, 2006) refers to emergency actions for new or unexpected phytosanitary situations based on a preliminary PRA and indicating that such measures "shall" be temporary and the subject of a detailed PRA as soon as possible.

Provisional measures are referenced in Article 5.7 of the SPS Agreement. Based on the text of the SPS Agreement and relevant jurisprudence to date, such measures have the following characteristics:

- They are taken in the absence of sufficient scientific evidence.
- They are based on the available pertinent information (i.e., Members must search for and consider available evidence), including information provided by relevant international organizations (e.g., the IPPC), and information about measures applied by others.
- They require that the Member imposing the measure actively pursue the information required for a more objective assessment of the risk and review of the measure within a reasonable period of time.

Precaution under the IPPC and SPS

The term “precautionary measures” is not explicitly used or described in either the IPPC or the SPS Agreement, although SPS jurisprudence indicates that provisional measures may “reflect precaution.” It may be argued, however, that phytosanitary measures are by their nature more or less precautionary depending on the influence of uncertainty in the judgment regarding acceptable risk. The concept of precaution based on uncertainty is therefore implicit in the application of proper risk analysis.

Uncertainty and precaution have a direct relationship: the higher the uncertainty, the greater the need for additional precaution. A properly done risk analysis provides decision makers and stakeholders with a clear understanding of the information that may be lacking, the variability and possible error in the information used, and the significance of this uncertainty to the conclusions drawn.

Two key points in understanding that the precautionary provisions for agricultural and environmental protection are in harmony must be made here. First, the precautionary approach, as described in the Rio Declaration, the Convention on Biological Diversity, and the Cartagena Protocol, is not necessarily incompatible with the IPPC or the SPS Agreement. The second important point is that these environmental agreements do not explicitly associate the application of the precautionary approach with the “failure” of risk analysis. Indeed, they are rather explicit about risk analysis as the basis for evaluating the available information.

The question is whether a determination regarding the adequacy of information is made before risk analysis is undertaken or completed, or whether the risk analysis is completed and becomes the basis for identifying the uncertainty. This question also points to risk analysis as the starting point for dialogue on the issue and also the starting point for harmonization based on the realization of mutual goals for the protection of plant and environmental health from harmful pest invasion.

Rational relationship

A key principle of risk analysis (although not described as such in either the IPPC or the SPS Agreement) is the concept of rational relationship. This concept has been a central issue in many SPS disputes and is rooted in the linkages between evidence and conclusions that are made implicitly or explicitly in both risk assessment and risk management. The concept has two components: (1) demonstrating an actual cause and effect relationship and (2) demonstrating that the magnitude of the response is reasonable. For example, there is no basis for assuming that root pests will be associated with fruit; therefore, any risk assigned to fruit for root pests or any measures that may be required would have no rational relationship from a cause and effect standpoint. The second element of rational relationship follows the idea that the strength of measures is proportional to the risk. The concept here is that the magnitude of the risk and the strength of measures applied to mitigate risk are on sliding scales. Higher risks correspond with stronger measures and vice versa. Measures do not have a rational relationship with the risk when they are misaligned based on other effective options that may be available. A simple example: a treatment designed for internally feeding arthropods may be overly rigorous for external feeders and contaminating pests.

Probable versus possible

SPS jurisprudence has made an important distinction between the concepts of probable and possible. Numerous possible scenarios have been put forward in PRAs as the basis for events that represent risks without credible evidence that such events occur other than expert opinion and assumptions that they are possible. The results of disputes on this point clearly and consistently support the position that events that are relevant to risk analysis under the SPS Agreement must have a demonstrated probability and cannot only be possible.

International guidelines for considering economic impacts in PRA

Guidance found in international agreements and standards is somewhat ambiguous regarding how consequences of introduction should be evaluated, which can result in different interpretations by different countries.

Economic analysis guidance in the SPS Agreement

The SPS Agreement explicitly endorses consideration of risk-related costs (e.g., potential production or sales losses or control and eradication costs) in both assessing risks and managing risks through the choice of an SPS measure to protect animal or plant health. The language in the Agreement suggests that consideration of producer impacts alone would be sufficient to comply with the letter of the SPS Agreement, and that choice of an SPS measure is not required to be justified by an analysis of the effects on producers, consumers, taxpayers, and industries that use the regulated product as an input.

Article 5.3 of the Agreement states:

"In assessing *the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk*, Members shall take into account as relevant economic factors: the potential damage in terms of *loss of production or sales* in the event of the entry, establishment or spread of a pest or disease; *the costs of control or eradication* in the territory of the importing Member; and the relative *cost-effectiveness of alternative approaches to limiting risks*."

In addition, Article 5.6 states that Members must ensure that their measures are not more trade restrictive than necessary to achieve their appropriate level of protection; however, what is meant by "not more trade restrictive than necessary" and whether this term has implications for economic consequence analysis in PRA is a matter of interpretation.

IPPC guidance to economic consequence analysis in PRA

Several ISPMs (e.g., ISPMs No. 2, 5, and 11) either reference economic considerations or provide guidance that is applicable to economic analysis in a pest risk assessment. The overall importance of economic considerations in phytosanitary decision-making is suggested by the number of key phytosanitary concepts that reference economic terms. In ISPM No. 5, *Glossary of phytosanitary terms* (IPPC, 2012), the phrases "economic impacts" and "economic consequences" are explicitly mentioned in definitions of several important phytosanitary terms such as "pest risk," "pest risk assessment," "phytosanitary measure," and "phytosanitary regulation." "Economic importance" and "economically important losses" are explicitly mentioned in the definitions of other terms, including the definition for the key phytosanitary concept of "quarantine pest." The glossary does not include a definition for any of the terms related to economic impacts or economic importance but does contain a supplement that provides guidelines for understanding them (IPPC, 2012, Supplement 2).

Supplement No. 2 to ISPM No. 5 (IPPC, 2012). The scope and purpose of the supplement is to provide clarification to ensure that economic terms are clearly understood and consistently applied and to illustrate certain economic principles as they relate to the IPPC's objectives, in particular but not limited to environmental considerations. The supplement clearly states that the IPPC can account for environmental concerns in economic terms using monetary or non-monetary estimates and that market impacts are not the sole indicator of pest consequences.

Section 4 of the supplement to the glossary, *Economic Considerations in PRA*, discusses types of economic effects and costs and benefits. It describes a relatively inclusive approach to economic considerations in PRA, indicating that all economic effects (not just market related), both costs and benefits, and both direct and indirect effects, should be considered in PRA. It affirms the cost-benefit criteria for decision making, whereby policies should be pursued if benefits are at least as large as costs, and indicates that judgments about the preferred distribution of costs and benefits are a policy choice to be made outside the context of the economic analysis.

ISPM No. 2, Framework for pest risk analysis (2007a). ISPM No. 2 does not give specific guidance on how economic impacts should be conceptualized or measured, but describes the stages in a pest risk assessment and indicates where it is appropriate to consider economic factors:

- Pest categorization: to determine whether a pest is "of potential economic importance."
- Pest risk assessment: to assess potential economic impacts
- Pest risk management: to determine whether or not appropriate phytosanitary measures to reduce pest risk to an acceptable level are available, cost-effective, and feasible. In addition, the ISPM indicates that PRA documentation should include *evidence of economic impact* [emphasis supplied], and evaluation of risk management options.

ISPM No. 11, Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms (2004a). ISPM No. 11 Section 2.3, *Assessment of potential economic consequences*, contains the most fully elaborated description of the process for assessing economic consequences in the pest categorization stage of a risk assessment, but contains such broad guidance that it leaves many questions unanswered about what should be measured and how it should be measured.

The guidelines discuss situations in which a detailed analysis of economic consequences may or may not be necessary. If it is widely agreed that pest introduction will have unacceptable consequences, detailed analysis may not be necessary. On the other hand, it may be necessary to examine economic factors in greater detail when the level of consequences is in question, or when consequences are needed to evaluate the strength of measures, or to assess the relative benefits of exclusion versus control.

The guidelines indicate that both direct and indirect effects of the pest should be identified and analyzed. In evaluating direct effects, which include effects of the pest on the potential host or the environment, the guidelines specify that the total crop area and/or potentially endangered area should be identified. Examples of direct effects on cultivated hosts could include crop losses, control measures, and effects on production practices. Direct effects of the pest on the environment could include reduction of keystone species or endangered native plants. Examples of indirect effects of the pest in the PRA area include effects that are not host-specific, such as effects on domestic and export markets (i.e., loss of export markets), changes to demand because of quality changes in the commodity, and social or other effects.

Summary SPS Agreement and ISPM guidance on economic consequences

The SPS Agreement describes a more limited set of factors to be considered in economic assessments than do the ISPMs. This distinction is important because different approaches described in the SPS agreement and the ISPMs (i.e., estimating negative impacts to producers as opposed to estimating both costs and benefits) will affect what is measured, how results are interpreted, and could support different conclusions regarding risk management by decision makers.

The SPS Agreement explicitly endorses consideration of risk-related impacts to producers in the importing country. The ISPMs describe a very broad range of approaches to economic consequence analysis in PRA, with ISPM No. 11 emphasizing the inclusion of environmental impacts and endorsing a continuum of approaches ranging from “no detailed analysis” if consequences are widely viewed to be unacceptable, to qualitative analysis, to various approaches of quantitative analysis, which include consideration of relevant impacts on consumers, producers, and domestic and foreign markets.

Based on available guidance in the SPS Agreement and the ISPMs, and in the absence of any clarifying WTO jurisprudence or case law, it may be concluded that risk assessment practitioners have considerable latitude in determining how to approach economic consequence analysis in PRA. This latitude would be subject to the conditions that any phytosanitary measures based on a risk assessment and economic consequence analysis should not violate the consistency provisions of the SPS Agreement by arbitrarily or unjustifiably discriminating between Members and should not be applied in such a way as to constitute a disguised restriction to trade.

National legislative framework for PRA

The Plant Protection Act (PPA; 7 U.S.C. § 7701-7786, 2000) became law in June 2000 as part of the Agricultural Risk Protection Act. The PPA consolidates all or part of 10 USDA plant health laws into one comprehensive law, including the authority to regulate plants, plant products, certain biological control organisms, noxious weeds, and plant pests. The Plant Quarantine Act, the Federal Pest Act, and the Federal Noxious Weed Act are among the 10 statutes the new Act replaces. The PPA is necessary because of the major impact plant pests currently have and could have on the agriculture, environment, economy, and commerce of the United States.

The following provisions of the PPA are important in relation to pest risk analysis associated with importations of plants and plant products:

"…the Secretary shall publish for public comment a notice describing the procedures and standards that govern the consideration of import requests. The notice shall—

1. specify how public input will be sought in advance of and during the process of promulgating regulations necessitating a risk assessment in order to ensure a fully transparent and publicly accessible process; and
2. include consideration of the following:
   - ❖ Public announcement of import requests that will necessitate a risk assessment.
   - ❖ A process for assigning major/non-routine or minor/routine status to such requests based on current state of supporting scientific information.
   - ❖ A process for assigning priority to requests.
   - ❖ Guidelines for seeking relevant scientific and economic information in advance of initiating informal rulemaking.
   - ❖ Guidelines for ensuring availability and transparency of assumptions and uncertainties in the risk assessment process including applicable risk mitigation measures relied upon individually or as components of a system of mitigative measures proposed consistent with the purposes of this title."

Relationship of the PPA to the WTO-IPPC framework

From a legal standpoint, there is an important distinction to understand regarding differences between the Plant Protection Act (PPA)–our national authority for the implementation of plant protection programs and actions–and the WTO-IPPC framework, including all of the obligations, responsibilities, and guidance relevant to NPPOs such as PPQ. The legal ramifications for PRA are not the same and the terminology and concepts are not entirely consistent on many important points.

One key difference regards the lack of consistency between the PPA concept of regulated pests and the WTO-IPPC concept of the same. The PPA provides the Secretary of Agriculture (APHIS by delegation) the authority to regulate any pest deemed to be harmful whether or not it meets the defining criteria of the IPPC. This authority is necessary for the USDA to implement programs for domestic pests (whether exotic, naturalized, or native). For example, the PPA does not link noxious weeds to quarantine pests in order to provide USDA with the flexibility to implement programs for domestic weeds. As a result, referring to “noxious weeds” in a PRA for imported articles represents a shift from the IPPC concept of a regulated pest (a quarantine pest or regulated non-quarantine pest) to the PPA concept, which may include the IPPC concept but is not limited to it.

Another area where the WTO-IPPC framework must be interpreted against national policies is in the determination of pest status for purposes of pest listing in the PRA. The list of pests requiring analysis in the PRA should include all organisms for which the current national policy is to require phytosanitary measures (actionable pests). This includes organisms that meet the IPPC definition of a quarantine pest, but it also extends to other types of pests, including those that are established in the United States but are under consideration for official control and other pest taxa that for policy reasons are considered to require quarantine action. For example, taxonomic groups that are commonly intercepted in immature form and cannot be identified to species level may require action for the entire taxa (usually genus) because one or more species in that genus are quarantine pests.

The reverse may also be true. Pests that meet the defining criteria for a regulated pest may not require action in all circumstances. For example, the current policy for armored scales that meet the internationally agreed criteria for a quarantine pest is to require action if associated with propagative material but not on fruit for consumption, because fruit is considered to be a negligible risk for introduction whereas plants are an excellent pathway.

Other such differences exist that make it important for analysts to pay close attention to concepts and terminology in the PRA process. One way to do this is to think about the analysis from the standpoint of potential legal challenges.

A point that might be challenged in a U.S. court will be reviewed, argued, and ultimately judged against the authority of the PPA. A U.S. judge will have little interest in arguments based on the IPPC/WTO framework. Likewise, a challenge raised by a trading partner will be judged against the IPPC and the WTO, especially the SPS Agreement, where our domestic legal situation may have some bearing on the background but the central issue will ultimately be decided against the relevant international authority.

Climate change in PRA

Climate change affects the ability of a plant pest to enter, establish, and spread in new environments. There are some challenges in making specific predictions about the effect of climate change on pest behavior. Members of the North American Plant Protection Organization's (NAPPO's) Pest Risk Analysis and Invasive Species Panels developed a discussion paper, C*limate Change and Pest Risk Analysis* (NAPPO, 2012), in which they considered issues related to climate change in PRA and identified several challenges.

The biggest challenge to effectively addressing climate change in PRA relates to the time horizon for climate change and the length of time for which a PRA is considered valid. Climate change models are generally based on projections of at least 20 years (Hellman et al., 2008), while PRAs often focus on a shorter time frame and may be updated when new information becomes available. Pest risk analyses represent the knowledge available at the time they were conducted—they are a "snapshot in time." Consideration of future events and impacts is also limited to relatively short projections in time; however, the specific length of time that a given PRA is valid is not precisely defined. The time horizon for routine commodity PRAs is understood to be less than 20 years, which is the time horizon for seeing effects of climate change. Therefore, it is beyond the scope of these Guidelines to attempt assessing the effect of climate change on pest behavior.

Furthermore, models used in PRA for predicting climate change and simulating the impact of climate change on species distributions may increase uncertainty to the point of compromising their utility. Climate change models usually address information at a global scale and may not be fine-tuned for predictions at the local or regional levels needed for most PRAs.

In addition to the scientific challenges involved in considering climate change in PRAs, the SPS Agreement requires that measures be based on evidence and least trade restrictive. A risk assessment is intended to provide sufficient evidence that a chosen measure(s) is not arbitrary, unjustified, or a disguised barrier to trade. Therefore, climate change projections within a PRA must be sufficiently robust to meet these requirements. Specifically, sufficient scientific evidence is required to show a causal link between climate change and the risk being assessed.

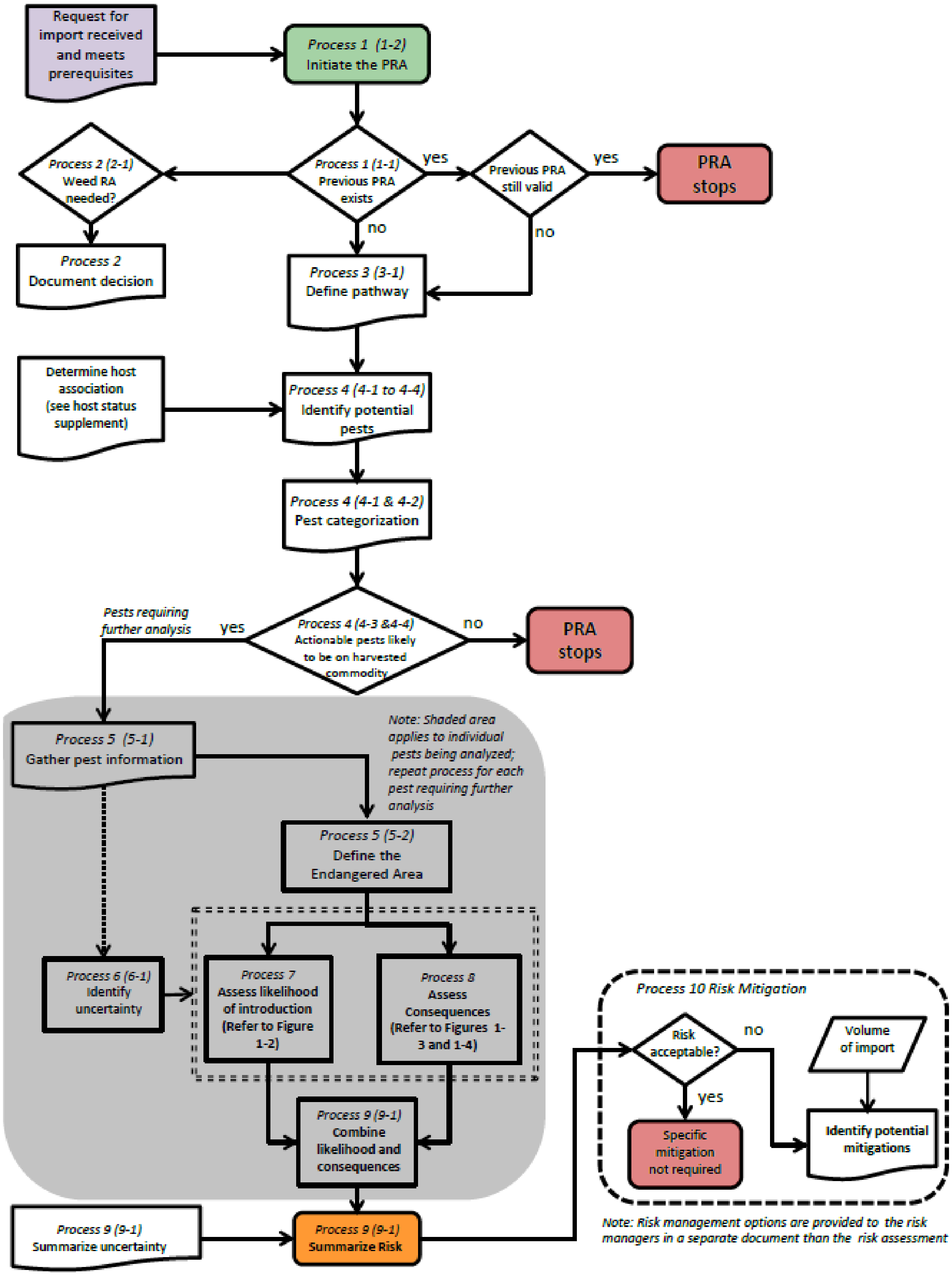
The interaction of climate change with changes in trade patterns will increase the need for new PRAs and for revision of existing ones to take into account changes in pest distribution and the likelihood of their associations with pathways (EFSA, 2007). However, the decision about whether or not to consider climate change scenarios or incorporate complex models into a PRA will depend on feasibility, goals, and the rigor of the available scientific support. Climate modeling can be complex, time-consuming, and resourceintense, and it may not be necessary to answer the question at hand.

Overview of the PPQ Risk Assessment Model for Commodity Imports for Consumption

Overview of the model

Risk is a product of the likelihood of an adverse event—in this case, a pest introduction—and the magnitude of the consequences. We separately rate the uncertainty during each process in the risk assessment and provide a summary of the uncertainties associated with the overall risk rating. In Figure 1-1, we depict the conceptual model for the process.

Figure 1-1. Processes overview. Procedures are in parentheses.



Volume of consignments consideration

In these Guidelines, we do not include volume as an element to be rated. Although we recognize that volume can affect the level of risk (e.g., increased volume has the potential to increase risk), it is difficult, if not impossible, to accurately predict or control the volume of importations or the effect on risk. Following are some of the factors related to volume that can affect risk:

- Seasonal timing of consignments (e.g., winter vs. summer).
- Frequency and volume over time (e.g., a few large consignments vs. multiple small consignments).
- Changes to the proposed frequency and volume of exports (both increases and decreases).
- Proposed destinations for export markets.

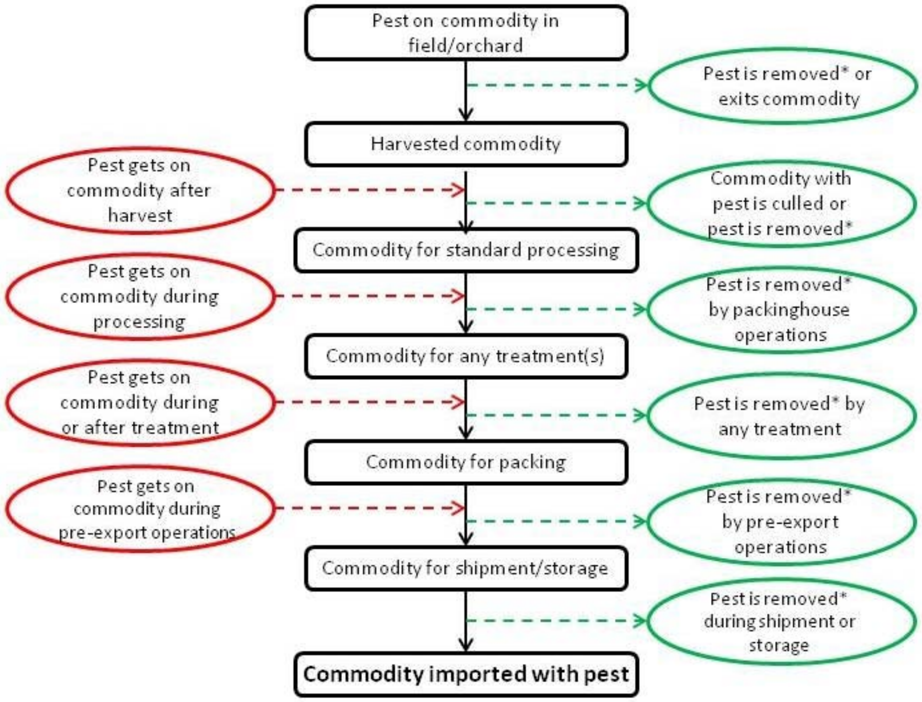
Therefore, for the purposes of these Guidelines, we will use the volume proposed in the prerequisite information and assume that any proposal to export a commodity for commercial purposes will represent a significant enough volume of trade to affect risk. If the analyst judges, based on evidence, that changes in the initially proposed volume of trade will significantly affect risk, this will be noted in relation to risk management. This is particularly important if inspections are key to risk management.

Pathway considerations

Agricultural commodities move through different steps in international trade, from the field and packinghouses at the farm, through export-import brokers, to retailers and, finally, to consumers, and perhaps into the environment. While most pests may first become associated with the commodity (pathway) at the farm, pests may also enter or exit the pathway at any stage until arrival in the importing country or area (Figure 1-2). The risk of escape into a new environment does not begin until the commodity has arrived in the PRA area. This may be problematic when the pest treatment facility is located in the PRA area (as can be the case, for instance, with irradiation), before the risk is adequately mitigated. Most pests associated with commodities for consumption have a low likelihood for establishment.

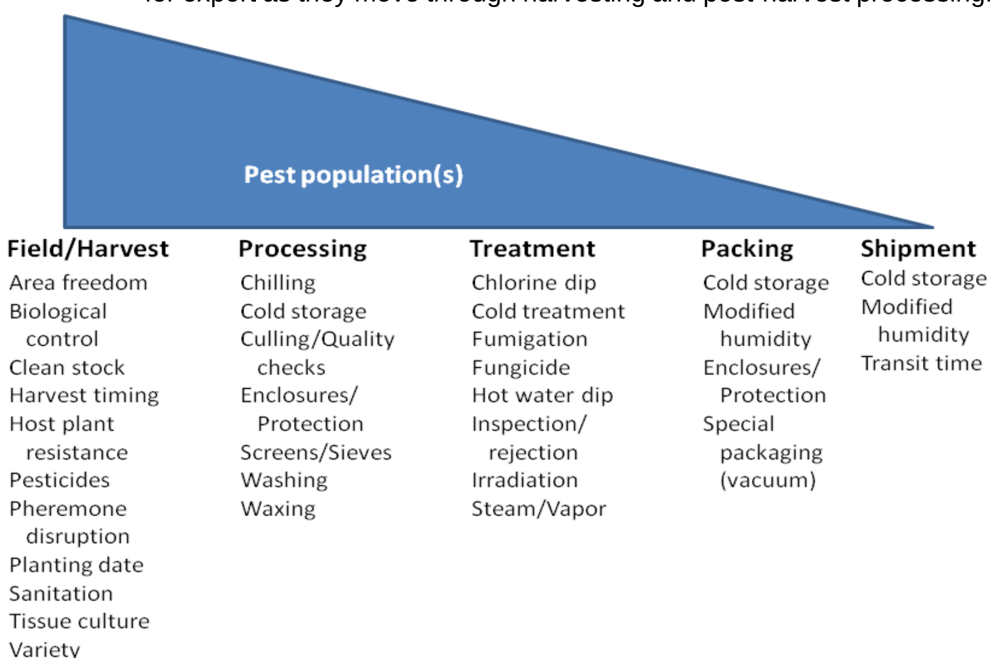
Pest populations on agricultural commodities will generally decrease as commodities move through the process, particularly with effective post-harvest processing measures (Figure 1-3). Increases in pest population size are rare and most likely would be associated with re-infestation or conditions conducive to the organisms' growth and development during storage and shipping (e.g., pathogens, arthropods reproducing parthenogenetically).

Figure 1-2. Pest presence on agricultural commodities can change as a result of harvest and post-harvest processing measures from harvest through shipping. This figure represents general harvest and post-harvest processes and is not intended to be comprehensive.



* Removed means physically separated, killed, or otherwise made unviable

Figure 1-3. An example of anticipated decrease in pest populations on commodities for export as they move through harvesting and post-harvest processing.



The endangered area

The area within the PRA area that has the identified biotic and abiotic conditions favorable for a pest's establishment is identified as the "endangered area." We define the area endangered by each pest by determining the portion of the PRA area where suitable hosts for that pest occur overlaid with portion of the PRA area where suitable environmental conditions also occur. Once a pest has entered the PRA area, it must be able to establish and subsequently spread in order for there to be consequences. The likelihood that a pest will establish (i.e., be able to survive, reproduce and/or perpetuate itself into the foreseeable future) is dependent on the pest overcoming biotic and abiotic resistance in a new area. Another way of stating that is that the pest must find suitable conditions in the PRA area to establish. Those conditions include biotic factors (availability of host material, presence or absence of natural enemies, etc.) and abiotic factors (e.g., temperature, season, humidity, rainfall or other environmental conditions that affect the ability of the pest to survive and reproduce).

Likelihood of introduction

We qualitatively assess the likelihood of introduction as Negligible, Low, Medium, or High. The likelihood of introduction is based on the likelihoods of entry and establishment. The likelihood of entry depends on the pest being associated with the commodity and surviving or remaining with the commodity throughout the entire post-harvest and shipping processes. The likelihood of establishment depends on characteristics of the pest and suitability of the PRA area. The risk factors comprising the model for likelihood of introduction are interdependent and the relationship is therefore multiplicative. Thus, if any risk factor is rated as Negligible, then the overall likelihood will be Negligible.

Potential consequences of introduction

We determine if the pest is likely to cause unacceptable impacts in the PRA area upon introduction by considering the potential direct and indirect impacts in relation to a hypothetical situation where the pest is supposed to have been introduced and to be fully expressing its potential economic consequences throughout the endangered area. This evaluation is made by obtaining information on the types of impacts currently being caused by the pest in areas where the pest occurs naturally or has been introduced. Spread potential is evaluated as a component of potential consequences because the expression of potential economic consequences depends on the rate and manner of spread in the PRA area. Our analysis of spread potential focuses on determining whether the pest is likely to be able to spread throughout the endangered area quickly enough to result in economically important losses.

Pests that are unlikely to cause unacceptable impacts are called “non-threshold pests” because their total impacts are not expected to reach the threshold of damage that would warrant additional phytosanitary measures within a reasonable period of time.

Uncertainty analysis

Estimating pest risk involves many uncertainties, in large part because assessors have to extrapolate from the current situation of the pest to a novel situation in the PRA area. Two major types of uncertainty in analyzing risk are (according to Merrick and van Dorp, 2006)

- the randomness of the system itself, including natural variability (aleatory uncertainty) and
- the lack of knowledge about the system (epistemic uncertainty).

Uncertainty due to variability among individuals is inherent in biological systems and should be measured or described. New or additional information will not usually reduce uncertainty arising from variability. Uncertainty due to lack of knowledge may be reduced by further study and data collection. In reality, the clear distinction between variability and uncertainty from lack of knowledge is not always possible to make and may be dependent on the context. Furthermore, most risk assessments deal with both types of uncertainty concurrently. The distinction between two types of uncertainty is, however, important when explaining model results to decision makers or the public and when expending resources for data collection.

Common sources of uncertainty include

- old/dated information,
- conflicting information,
- absence of information,
- extrapolation of information available for congeneric organisms,
- reliance on expert judgment and conflicting or vague opinions from experts, and
- incorrect assumptions or models.

Documenting the degrees and types of uncertainty in the assessment and indicating where expert judgment has been used is important. This increases transparency and may help identify and prioritize research needs.

Separating the uncertainty that arises due to lack of knowledge from the ratings of risk elements is important; ratings should be based only on the available evidence, not the uncertainty associated with the evidence. For instance, a given risk element should not be rated higher if there is a lot of uncertainty; rather, the rating should be assigned based on available evidence and the high level of uncertainty should be noted. At the same time, we recognize that a given risk element may be assigned a rating that may more or less accurately reflect the actual probability associated with that risk element, depending on the level of uncertainty. Higher levels of uncertainty could mean a given rating may be over- or under-estimating probability by one or more levels (e.g., a low rating with high uncertainty would truly be medium or high if we had more evidence on which to base our judgment). In cases with a high degree of variability, the analyst will typically make a conservative judgment resulting in a higher risk rating. This underscores the importance of describing uncertainty—including sources and magnitude—while at the same time maintaining judgments that are based on available evidence.

The feasibility of reducing uncertainty sources depends on the type of uncertainty, the possibility of gaining further data, and applying more reliable assessment methods. The application of quantitative uncertainty assessment (tiers 2 and 3 in EFSA, 2006) is generally recommended after the qualitative uncertainty assessment has been performed in order to point out the uncertainty sources for addressing later in the quantitative evaluation and for considering those uncertainties that cannot be quantified (Colyvan, 2008; EFSA, 2006).

Overall risk rating

The concerns of the public and most decision makers focus on events with dire consequences, even if these events have low probabilities of occurring. Yet, models have been helping to mask the criticality of catastrophic events by adhering to the expected value of risk, which intrinsically can equate a low probability of high-consequence events with a high probability of low-consequence events. The reliance on this commonly used metric, when it is used as the sole measure of risk, can confuse the decision makers, leading to bad choices. The problem is that the expected value of risk is an operation that essentially multiplies the consequences of each event by its probability of occurrence and adds all these products over the entire probability range (Haimes, 2009). Transparency resulting from separating estimates of overall risk due to impact and due to likelihood allows implementation of mitigation measures that are most appropriate for each of the risks.

The overall pest risk is presented as a table depicting, for each individual pest, the specific risk rating for the likelihood of introduction, the determination of whether or not the pest is likely to cause unacceptable impacts, and the uncertainties associated with the ratings (see Process 9: Summarizing the final risk ratings and uncertainty for more detail).

Risk mitigation documentation

Throughout the analysis, the analyst will collect information on both the pathway (e.g., the commodity being exported) and the pests. Much of the information gathered during risk assessment is also useful to risk management. Moreover, the risk assessment should inform and guide risk management (rather than simply act as a trigger), and the risk analyst is in the best position to provide information relevant to the development of risk management options. In Process 10: Risk mitigation notes, we provide more detailed guidance on the types of information gathered during risk assessment that are particularly relevant to risk management. We also provide a template and an example for communicating that information to risk managers.

Summary of processes

In Table 1-1, we summarize the main processes in the PPQ pest risk assessment model for commodity imports. Each process will be discussed in more detail in Conducting Pest Risk Assessment in PPQ.

Process 7: Assessing the likelihood of introduction and Process 8: Assessing potential consequences of introduction can be performed in either order, as appropriate. Pests that have a Negligible likelihood of being introduced do not usually need to be assessed for consequences; similarly, pests that are unlikely to cause unacceptable economic consequences do not need to be analyzed for likelihood of introduction. Describing uncertainty is an important part of every process, but is explicitly assessed in terms of the risk ratings determined in Processes 7 and 8.

Table 1-1. Summary of the processes that comprise PPQ's risk assessment model for commodity imports for consumption.

Stage 1. Initiation
Process 1: Documenting the initiating event and scope. Describe the reason(s) for conducting the risk assessment and some of the background information regarding the proposed importation.
Process 2: Determining if a weed risk assessment for the commodity is needed.
Process 3: Defining the pathway. Describe the pathway based on information about the commodity, information provided by the exporting country regarding production practices, and processing of the commodity; state any assumptions.
Process 4: Creating the pest list and pest categorization. Compile a comprehensive list of all potential pests known to occur in the exporting country or region that are known to be associated with the host plant from anywhere in the world. Identify pests meeting criteria for further analysis.
Stage 2. Pest Risk Assessment
Process 5: Collecting information and defining the endangered area. Gather the information necessary to complete the risk assessment (Processes 7 and 8). Based on available information, determine whether Process 7 or 8 should be completed first.
Process 6: Assessing uncertainty for risk elements.
Process 7: Assessing the likelihood of introduction. Estimate the likelihood of introduction (entry and establishment). Entry and establishment are evaluated as Risk Elements A and B, respectively. Pests that are rated Negligible at any stage do not need to be evaluated further.

Table 1-1. Summary of the processes that comprise PPQ's risk assessment model for commodity imports for consumption.

Stage 1. Initiation
Process 8: Assessing potential consequences of introduction. Determine if the pest is likely to cause unacceptable economic consequences. Direct impacts are evaluated as Risk Element C, and trade impacts are evaluated in Risk Element D.
Process 9: Summarizing the final risk ratings and uncertainty.
Stage 3. Risk Management
Process 10: Risk mitigation notes. Provide important information on pest biology, pathway, and uncertainty relevant to risk management.

Section 2

Conducting Pest Risk Assessment in PPQ

Stage 1: Initiation

Initiation is the first stage of pest risk analysis and consists of defining the specific scope of the analysis and identifying the pests of concern that will be analyzed in the risk assessment. In PPQ commodity import risk assessment, the Initiation stage is completed using the following four processes (as outlined in the previous section in Table 1-1 on page 1-25):

- Process 1: Documenting the initiating event and scope
- Process 2: Determining if a weed risk assessment for the commodity is needed
- Process 3: Defining the pathway
- Process 4: Creating the pest list and pest categorization

NOTE

As outlined in ISPMs No. 2 and 11, pest categorization is actually a part of pest risk assessment (Stage 2); however, for practical purposes the first part of pest categorization, determining whether pests are actionable, occurs as the pest list is developed (see Process 4: Creating the pest list and pest categorization on page 2-9).

Process 1: Documenting the initiating event and scope

In Process 1, we document why the risk assessment was initiated and describe its scope. In most cases, a risk assessment is initiated to evaluate the pest risk associated with a new importation request. Additional possible initiating events are listed in ISPMs No. 2 (IPPC, 2007) and 11 (IPPC, 2004a). The initiating event of the risk assessment must be documented, but before we initiate a risk assessment, we need to determine if the risk assessment is actually needed. If a previous risk assessment exists and adequately addresses the risks posed by the proposed commodity importation into the PRA area from the export area in question, the current risk assessment process may stop at this point.

Scoping is the process step during which the risk analysts and PPQ headquarters staff, usually during a conference call, determine the scope of the risk assessment. The scope of a risk assessment includes the commodity(ies) to be imported, export area(s), PRA area, field and/or harvest procedures to be considered when assessing pest risk, and other details that provide the basis for the risk assessment and all other subsequent decisions.

Procedure 1-1. Determining if a new or revised risk assessment is needed

Follow steps 1-3 to determine if a new or revised risk assessment is needed for the commodity.	
Step 1	Determine whether any previous risk assessments have been completed for the requested or a sufficiently similar (neighboring country; close relative of plant species) commodity/country combination. If an assessment already exists, go to Step 2. If a new assessment is needed, go to Step 3.
Step 2	If a risk assessment already exists, determine whether it adequately addresses the current risks in question. Consider the following: ◆ Is the pest list complete? ◆ Have pest distributions or information on biology changed since that original risk assessment was completed? ◆ Have phytosanitary policies and/or regulations changed since that risk assessment was completed? If the existing risk assessment adequately addresses the risks posed by the proposed importation of the commodity, no new risk assessment needs to be initiated. If a revised assessment is needed, go to Step 3.
Step 3	In the “Initiating Event” section of the risk assessment, briefly state the reason why a new or revised risk assessment is needed.
If a new or revised risk assessment is needed, continue to Procedure 1-2: Documenting the initiating event.	

Procedure 1-2. Documenting the initiating event

State the following in the "Initiating Event" section of the risk assessment.
Name and affiliation of the requestor
Of the plant species to be imported: ◆ the valid scientific name and common synonyms ◆ common name(s) ◆ cultivar/variety/race/etc. (if applicable) ◆ plant part(s) to be imported (e.g., root, fruit, leaf) ◆ condition of the plant parts to be imported (fresh, dried, processed, etc.) ◆ seasonality of imports (if applicable)
The export and PRA areas
The reason why the risk assessment is needed (see Procedure 1-1: Determining if a new or revised risk assessment is needed). For example: ◆ The requested commodity importation into the requested PRA area is currently not authorized. ◆ The commodity is currently permitted into a portion of the United States, but requestor wishes to expand the market (importing area). ◆ The commodity is currently permitted from a portion of the exporting country, but requestor wishes to expand the exporting area. ◆ Importation of the commodity with additional plant parts is requested. ◆ The pest risk associated with the commodity has changed or is expected to change. For example: ❖ New mitigation measures for the commodity are proposed or implemented (e.g., irradiation) ❖ There is reason to believe (based on scientific studies or port-of-entry interceptions) that a new pest associated with the commodity has become established in the exporting area. ◆ New information indicates that a pest is likely to be more damaging in the PRA area than originally determined.
Continue to Process 2: Determining if a weed risk assessment for the commodity is needed on page 2-4.

Process 2: Determining if a weed risk assessment for the commodity is needed

In some cases, the imported commodity may have the potential to propagate and become invasive in the PRA area. The likelihood that this may happen is evaluated in a weed risk assessment, conducted separately from the commodity pathway risk assessment. A weed risk assessment need only be conducted under certain conditions. The project lead of the commodity pathway risk assessment is responsible for determining whether or not a weed risk assessment may be required and referring the plant for further analysis.

Procedure 2-1. Determining if a weed risk assessment for the commodity is needed

Follow steps 1-4 to determine whether a weed risk assessment is necessary. Because not all plant parts of every commodity are capable of propagation, consider not only the *species* proposed for import, but also the *form* in which the commodity will be imported.

	IF	THEN
Step 1	The commodity is **already enterable** into the PRA area from other countries.	**A weed risk assessment is not needed.** In the "Determination of the necessity of a weed risk assessment for the commodity" section of the risk assessment, state that an assessment of weed risk potential is not required because the commodity is already enterable from other countries. Provide references. Continue to Process 3: Defining the pathway on page 2-6.
	The commodity is **not enterable i**nto the PRA area from other countries.	Go to Step 2.
Step 2	The plant species is **widely established** (native or naturalized) in the PRA area. (If questionable, consult the weed team.)	**A weed risk assessment is not needed.** In the "Determination of the necessity of a weed risk assessment for the commodity" section of the risk assessment, state that an assessment of weed risk potential is not required because the commodity is already widely established in the PRA area. Provide references. Continue to Process 3: Defining the pathway on page 2-6.
	The plant species is **not widely established** (native or naturalized) in the PRA area. (If questionable, consult the weed team.)	Go to Step 3.
Step 3	Any part of the imported commodity **can easily propagate** or be propagated.	Go to Step 4.
	The imported commodity **cannot easily propagate** or be propagated.	**A weed risk assessment is not needed.** In the "Determination of the necessity of a weed risk assessment for the commodity" section of the risk assessment, state that an assessment of weed risk potential is not required because the plant parts to be imported cannot be propagated. Provide references. Continue to Process 3: Defining the pathway on page 2-6.

Procedure 2-1. Determining if a weed risk assessment for the commodity is needed

Follow steps 1-4 to determine whether a weed risk assessment is necessary. Because not all plant parts of every commodity are capable of propagation, consider not only the ***species*** proposed for import, but also the ***form*** in which the commodity will be imported.		
	IF	**THEN**
Step 4	A weed risk assessment **has already been completed** for this species.	**A weed risk assessment is not needed.** In the "Determination of the necessity of a weed risk assessment for the commodity" section of the risk assessment, state that an assessment of weed risk potential has already been completed. State the conclusions of the assessment and provide references. Continue to Process 3: Defining the pathway on page 2-6.
	A weed risk assessment **has not already been completed** for this species.	**A weed risk assessment may be required.** Notify the weed team and in the "Determination of the necessity of a weed risk assessment for the commodity" section of the risk assessment, state "Because the commodity has the potential to be propagated, an assessment of weed potential may be required before importation of the commodity plant species is authorized. If required, the weed potential will be analyzed separately and will not be included in this document." Continue to Process 3: Defining the pathway on page 2-6.

Process 3: Defining the pathway

The IPPC (2012) defines a pathway as "any means that allows the entry or spread of a pest." In the context of commodity pest risk assessments, the pathway is the commodity to be imported, together with all the processes it undergoes from production to importation and distribution in the PRA area that may have an impact on pest risk.

A detailed description of the pathway, including the morphological and physiological characteristics of the commodity, provides the necessary foundation for the risk assessment.

> ***NOTE***
>
> All components of the pathway, as they are described in the risk assessment, become mandatory conditions for importation of the commodity. Therefore, the pathway description should ultimately only include those components of the pathway that will actually be used the risk assessment as a basis for identifying the potential pests associated with the commodity and evaluating their risk.

Procedure 3-1. Defining the pathway

Based on the scope of the risk assessment, provide a detailed description of the pathway that includes the information listed in this procedure. All components of the pathway used in the risk assessment as a basis for evaluating pest risk become mandatory conditions for importation of the commodity.

The commodity to be imported, including

- plant part(s) to be imported (e.g., root, fruit, leaf) and inclusion/exclusion of specific other plant parts (e.g., stems, calyces, husks).
- condition at the time of entry (e.g., fresh, dried, processed).
- cultivar, variety, race, colors, variability, grade, size, restrictions (e.g., kosher), or other pertinent information.
- expected end-use (e.g., consumption, milling, etc.).
- stage of maturity at time of harvest.
- stage of maturity at time of import.

Production and harvest procedures in the exporting area that will be explicitly considered during the risk assessment. Examples include

- growing conditions (e.g., greenhouse, overhead irrigation).
- specific pest control or exclusion practices such as area freedom, biological control, pheromone disruption, routine pesticide application (including target pests of the treatments).
- planted crop (e.g., clean stock, host-resistance). If the planted crop is to be from certified seed or nursery stock, indicate the origin of the stock or seed (country, state).
- cultural practices such as sanitation, planting date, harvest timing, crop rotation, etc.
- method of harvesting (e.g., manual, clipped, machine-harvested, selective harvesting).

Post-harvest procedures in the exporting area that will be explicitly considered during the assessment. Examples include

- processing procedures such as chipping, washing, brushing, waxing, sieves.
- quality procedures such as culling, quality inspections.
- pest exclusion practices such as enclosures, screens.
- treatments (including target pests) such as dips, cold treatment/refrigeration, fumigation, irradiation, fungicide applications, hot water vapor treatments.
- packing, boxing, and wrapping methods including special enclosures/protections, packaging, etc.

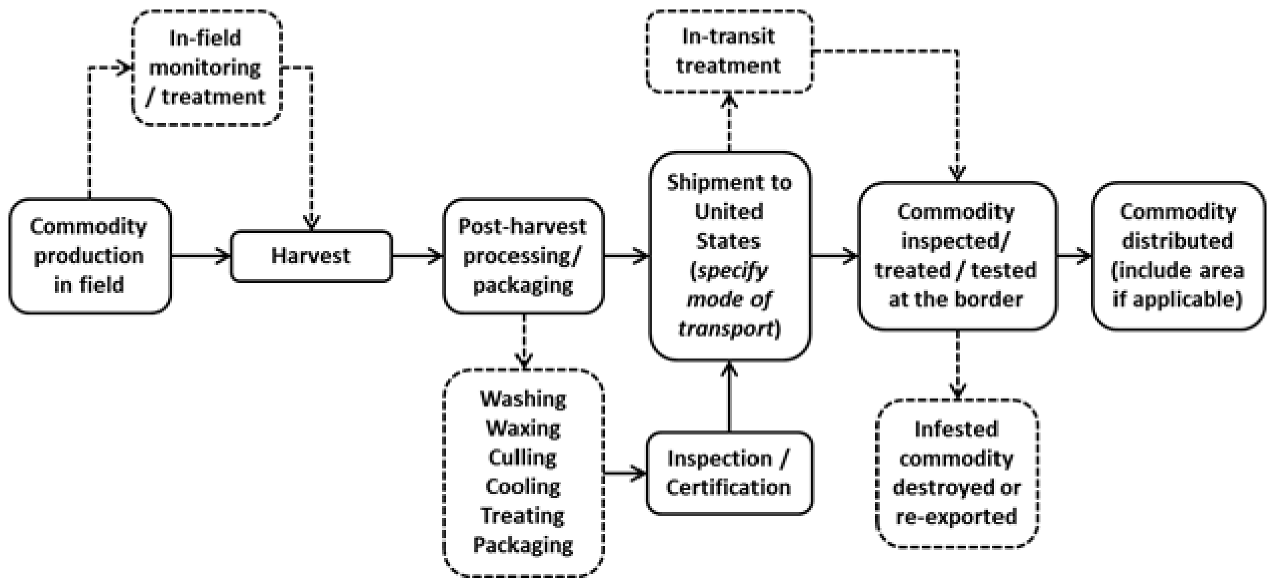
Shipping and storage conditions that will be explicitly considered during the assessment. Examples include

- storage duration and conditions (e.g., cold storage, modified humidity).
- shipping methods (e.g., truck, cargo).
- transit time.
- timing of consignments (season).

A visual depiction of the pathway. Figure 2-1 provides a generic depiction, but the specific details and the level of detail will vary from case to case.

Continue to Process 4: Creating the pest list and pest categorization on page 2-9.

Figure 2-1. A generic graphic representation of a commodity pathway.



Process 4: Creating the pest list and pest categorization

In this process, we identify the plant pests that could become established in the PRA area as a result of the importation of the commodity and determine which of these pests meet the criteria for further analysis. The pests selected for further analysis are those whose association with the commodity pose a specific hazard to the PRA area because they are of regulatory significance and have a reasonable likelihood of being associated with the harvested commodity.

Identifying pests for the pest list

The process begins when we develop a list of pests in the export area that are known to be associated with the commodity anywhere in the world and to be of regulatory significance to the PRA area. Pests are considered to be of regulatory significance if they are "actionable" at U.S. ports of entry. Actionable pests include quarantine pests, regulated non-quarantine pests, pests considered for or under official control, and pests that require evaluation for regulatory action. Refer to National legislative framework for PRA on page 1-14 for more details regarding national policies determining pest status for the purpose of pest listing in the risk assessment. Non-actionable pests that are present in the exporting area and known to be associated with the commodity are not placed on the pest list. Instead, these pests are recorded in a separate table along with supporting evidence in an appendix to the risk assessment.

In general, we do not include pests on the pest list if the only evidence of presence in the exporting area is weak or dubious (e.g., very few interceptions in permit cargo, only interceptions in baggage from the exporting country, other evidence refutes any reports of pest presence in the host country). We list any pests with a doubtful distribution in the export area before the pest list in the "Pests considered but not included on the pest list" section.

Similarly, we only list pests for which the commodity is a Type 1 host (natural host) or Type 2 host (conditional host) (refer to Supplement 3: Host Status on page 3-10 for an explanation of host types). If the evidence of host association is insufficient to conclude that the commodity is a Type 1 or Type 2 host, we do not list such pests. Instead, we list them in the "Pests considered but not included on the pest list" section. If there is evidence of a non-actionable vector in the exporting area that transmits an actionable pest, we list the actionable pest in the pest list and analyze it if appropriate; if we determine the actionable pest is a candidate for risk management, relevant information about the vector is included in the risk mitigation notes. Type 4 hosts (fomites) are included on the list if there is clear evidence that the commodity is a common pathway for the movement of the pest.

In general, we do not include organisms identified only to the genus level in the pest list, as the taxonomic unit for pests selected for evaluation beyond the pest categorization stage is usually the species (ISPM No. 11: IPPC, 2004b). Instead, we list pests identified only to the genus level in the “Pests considered but not included on the pest list” section, and we prepare genus-level datasheets for those that have actionable regulatory status and have a reasonable likelihood of being associated with the harvested commodity.

Developing the pest list and selecting pests for further analysis

Pest categorization continues by determining which of the pests identified as actionable have a reasonable likelihood of being associated with the harvested commodity. Pests that are associated with the specific plant part(s) to be imported and are likely to remain viable with the plant part(s) throughout the harvesting process are generally considered to have a reasonable likelihood of being associated with the harvested commodity. These pests are analyzed further in Process 7: Assessing the likelihood of introduction on page 2-35 and/or Process 8: Assessing potential consequences of introduction on page 2-50.

Some plant pests may be of concern but are not selected for further analysis for a variety of reasons, such as

- The pest is not associated with the harvested plant part(s) or is associated with those parts at an earlier stage but not at harvest.
- The pest is mobile and will be eliminated while commodity is harvested.
- The commodity is a conditional host, and there is high certainty the conditions for non-host status are met, etc.

If no actionable pests are likely to be associated with the harvested commodity, the risk assessment stops here.

Organisms identified only to the genus level

Organisms identified only to the genus level are difficult to assess, because pertinent biological information (pest status, hosts, distribution, behavior) usually differs sufficiently between species that a general conclusion for the genus is not possible. Also, if the genus in question is reported in the PRA area, we often cannot know if the unidentified species occurs in the PRA area and, consequently, whether or not it has actionable regulatory status for the PRA area. We therefore usually do not include organisms identified only to the genus level on the pest list, and we do not assess them using Process 7: Assessing the likelihood of introduction or Process 8: Assessing potential consequences of introduction.

However, because genus-level organisms may still pose a risk to the PRA area, it is not justifiable to simply ignore them. Instead, we usually address them by following Procedure 4-5: Handling organisms identified only to genus level. According to this procedure, unless there is a PPQ policy decision to the contrary, if the genus is not present in the PRA area, the U.S. regulatory status of the "*Genus* sp." organism is "actionable," whereas if the genus is present in the PRA area, the status is either "non-actionable" or "undetermined." For any "*Genus* sp." organisms with actionable regulatory status that could be on the harvested commodity plant part(s), we prepare a genus-level datasheet to be used by risk managers as a basis for determining if measures beyond those intended to mitigate fully identified pests are warranted. Often, however, the development of detailed assessments for known pests that inhabit a variety of ecological niches, such as internal fruit feeders or foliage pests, allows effective mitigation measures to eliminate the known organisms as well as similar but incompletely identified organisms that inhabit the same niche.

It is important to note that there may be situations when it is appropriate not to follow Procedure 4-5: Handling organisms identified only to genus level. In particular, if there is sound evidence that the species in question (though identified only to genus) is different from any species of that genus known to occur in the PRA area (e.g., broader areas of establishment or host range), it should be listed as an "actionable" pest. Also, there may be situations when a full analysis using Process 7: Assessing the likelihood of introduction and/or Process 8: Assessing potential consequences of introduction, instead of a genus-level datasheet, is warranted, such as when there is sufficient biological information on the unidentified organism to allow for proper analysis of its likelihood and consequences of introduction. If a full analysis is prepared, the pest should be included on the pest list.

Procedure 4-1. Identifying potential pests for the pest list

Follow steps 1-6 to identify potential pests for the pest list.	
Step 1	Identify pests associated with the commodity plant anywhere in the world. In this case, "association" includes any instance where you have evidence that links a pest to the commodity. Note that the actual host status (or strength of the association) will be evaluated in a subsequent procedure. Go to Step 2.
Step 2	Determine whether the pests identified in Step 1 are found in the exporting area. Go to Step 3.
Step 3	For organisms identified only to the genus level, go to Procedure 4-5: Handling organisms identified only to genus level.
	For organisms identified to the species level or lower (e.g., biotypes, strains, race), go to Step 4.

Procedure 4-1. Identifying potential pests for the pest list

Follow steps 1-6 to identify potential pests for the pest list.	
Step 4	Determine whether each pest is actionable at U.S. ports of entry on commodities for consumption. Actionable pests include quarantine pests, regulated non-quarantine pests, pests considered for or under official control, and pests that require evaluation for regulatory action. Go to Step 5. Procedure 4-2: Optional: Determining whether a pest is actionable may be useful in determining whether a pest is actionable, but in some cases, you may need to consult other sources to make a determination.
Step 5	Place pests with a non-actionable regulatory status in a separate table in an appendix to the risk assessment (PRA Template: Appendix A). You should provide supporting references in this appendix, including PPQ policy on non-actionable status, if relevant. See the PRA Template for more details. For actionable pests associated with the commodity and found in the export area, go to Procedure 4-3: Determining whether to include an actionable pest on the list.

Procedure 4-2. Optional: Determining whether a pest is actionable

This procedure applies to pests identified to the species level or lower. For organisms identified only to the genus level, continue to Procedure 4-5: Handling organisms identified only to genus level. This procedure is applicable for most pests, but in some cases, you may need to consult other sources to determine whether a pest is actionable. It is not necessary, or in some cases appropriate, to use this procedure in instances where the PPQ policy for the pest is already known (e.g., armored scales, which are non-reportable on commodities for consumption; some citrus pathogens where fruit is not a pathway for introduction, etc.). Treat pests listed as "reportable" in PestID as actionable, unless a specific note in PestID or other PPQ port policy indicates otherwise. It also may be useful to consult previous PRAs in which the pest is listed, check domestic Emergency Action Notifications (EANs) for any evidence of domestic regulation, or seek information from DEEP (Deregulation Evaluation for Established Pests) or NPAG (New Pest Advisory Group) to clarify pest status.

Follow the steps of this procedure to determine whether a pest is actionable.		
	IF	**THEN**
Step 1	The pest's genus **is listed** in PestID.	Go to Step 2.
	The pest's genus i**s not listed** in PestID.	Go to Step 6.
Step 2	The entire genus (i.e., "*Genus* spp.") **is listed** as "non-reportable."	**The pest is non-actionable.** Refer back to Step 5 of Procedure 4-1: Identifying potential pests for the pest list.
	The entire genus (i.e., "*Genus* spp.") **is not listed** as "non-reportable."	Go to Step 3.

Follow the steps of this procedure to determine whether a pest is actionable.		
	IF	**THEN**
Step 3	The pest species (or sub-species, if applicable) **is listed** in PestID.	Go to Step 4.
	The pest species (or sub-species, if applicable) **is not listed** in PestID.	Go to Step 6.
Step 4	The pest **is listed** as "non-reportable" (either for all commodities or for commodities for consumption).	**The pest is non-actionable.** Refer back to Step 5 of Procedure 4-1: Identifying potential pests for the pest list.
	The pest **is not listed** as "non-reportable."	Go to Step 5.
Step 5	The pest **is listed** as "reportable" (either for all commodities or for commodities for consumption).	**Assume the pest is actionable.** Continue to Procedure 4-3: Determining whether to include an actionable pest on the list.
	The pest **is not listed** as "reportable."	**Seek further guidance** from National Identification Services or another regulatory expert.
Step 6	There **is evidence** that the pest **is present** in the PRA area.	Go to Step 7.
	There **is no evidence** that the pest **is present** in the PRA area.	**Assume the pest is actionable.** Continue to Procedure 4-3: Determining whether to include an actionable pest on the list.
Step 7	There **is a PPQ program or restriction policy** in place for the pest--for example, the pest is under PPQ official control.	**Assume the pest is actionable.** Continue to Procedure 4-3: Determining whether to include an actionable pest on the list.
	There **is not a PPQ program or restriction policy** in place for the pest.	**Assume the pest is non-actionable.** Refer back to Step 5 of Procedure 4-1: Identifying potential pests for the pest list.

Procedure 4-3. Determining whether to include an actionable pest on the list

Follow the steps of this procedure to determine whether to include an actionable pest on the list.		
	IF	**THEN**
Step 1	The available **evidence indicates** that the pest is associated with the commodity plant species (anywhere in the world).	Go to Step 2.
	The available **evidence does not indicate** that the pest is associated with the commodity.	**Do not include the pest on the pest list.** Explain your rationale in the "Pests considered but not included on the pest list" section of the risk assessment.
Step 2	The available **evidence indicates the pest occurs** in the export area.	Go to Step 3.
	The available evidence **does not indicate the pest occurs** in the export area.	**Do not include the pest on the pest list.** Explain your rationale in the "Pests considered but not included on the pest list" section of the risk assessment.

Procedure 4-3. Determining whether to include an actionable pest on the list

Follow the steps of this procedure to determine whether to include an actionable pest on the list.		
	IF	**THEN**
Step 3	The commodity plant species is a **Type 1 host (natural host)** for the pest, based on the pest's association with the host species in any country of the world.	**Include the pest on the pest list.** Continue to Procedure 4-4: Completing the pest list table.
	The commodity plant species is a **Type 2 host (conditional host)** for the pest, based on the pest's association with the host species in any country of the world.	**Include the pest on the pest list.** Continue to Procedure 4-4: Completing the pest list table.
	The commodity plant species is a **Type 3 host (natural non-host)** for the pest, based on the pest's association with the host species in any country of the world.	**Do not include the pest on the pest list.** Explain your rationale in the "Pests considered but not included on the pest list" section of the risk assessment.
	The commodity plant species is a **Type 4 host (fomite)** for the pest, based on the pest's association with the host species in any country of the world.	**Include the pest on the pest list if there is clear evidence that the commodity is a common pathway for movement of the pest.** Explain your rationale in the "Remarks" section of the pest list or in the "Notes on pests identified in the pest list" section. Continue to Procedure 4-4: Completing the pest list table. **Otherwise, do not include the pest on the pest list.** Explain your rationale in the "Pests considered but not included on the pest list" section of the risk assessment.

Procedure 4-4. Completing the pest list table

For each step in this procedure, document supporting information in the pest list or in the body of the risk assessment. Where applicable, indicate sources of uncertainty, but do not use uncertainty codes. Be specific and clearly link appropriate evidence to relevant citation(s). If you have text that is too long to reasonably fit in this pest list table, put this text in section 2.3 “Notes on pests identified in the pest list” of the PRA Template and state in the pest list table “see additional discussion below in section 2.3.”

The pest list should be presented using the format shown in Table 2-1. Arthropods should be listed alphabetically by order and then family. Pathogens should be divided by type. They should be listed after the arthropods and proceed as follows: 1) Nematodes, 2) Fungi and Chromistans, 3) Bacteria and Phytoplasmas, 4) Viruses and Viroids, and 5) Pathogens of Unknown Etiology (biotic factors only). Other non-traditional entries, such as algae or protozoans, are to be listed in categories of their own as well. Pathogens should be listed alphabetically under each type (“type” meaning: nematodes, etc.). Organization like the arthropods (separated by order and family) is not an efficient or stable way to present the pathogens due to the continuous revisions in pathogen taxonomy. These revisions are based on new evidence, and, with the growing application of molecular tools for identification, additional revisions are anticipated.

Follow the steps of this procedure to complete the pest list table.	
Step 1	Fill out each column on the pest list as follows, then go to Step 2.
	Pest name: ◆ List the current scientific name of the pest, including the authority. ◆ List valid synonyms if needed to support information provided in the pest list. ◆ In some cases, it might be appropriate to identify the organism below the species level (e.g., biotypes, race, or strains); consult the appropriate authority for guidance. If listing an organism below the species level, clearly document the rationale for doing so. The rationale “should include evidence demonstrating that factors such as differences in virulence, host range or vector relationships are significant enough to affect phytosanitary status” (ISPM No. 11: IPPC, 2004b). ◆ If only a common name is known, list it as such and incorporate the uncertainty level associated with a common name.
	Evidence of presence in export area: ◆ Identify the evidence that the pest is found in the export area. ◆ Describe uncertainty regarding distribution and, if relevant, regulatory status in the exporting country (e.g., limited distribution and under official control).

Follow the steps of this procedure to complete the pest list table.	
	Host status: ◆ State the host status of the commodity plant species for the pest (see Supplement 3: Host Status on page 3-10). ◆ Base your conclusions on evidence of the pest's association with the imported plant species in any country of the world. ◆ If the commodity plant species is a Type 2 (conditional) host for the pest, provide information on the specific conditions under which it is a host and provide an explanation of the evidence and your uncertainty. If strong evidence indicates the commodity is a Type 2b host (i.e., non-host), still include the pest on the pest list, and include information regarding non-host status under "On harvested plant part(s)?". ◆ If the commodity is a Type 4 host (fomite), provide evidence that the commodity is a common pathway for movement of the pest.
	Plant part(s) association: ◆ Identify the part or parts of the plant with which the pest is physically associated. Ideally, evidence should refer to the actual plant species to be imported and the actual pest species under analysis. However, in some cases, we may extrapolate from evidence referring to other plant species or closely related pest species. In these cases, provide information on your logic, assumptions for extrapolation, and uncertainty.
	On harvested plant part(s)?: ◆ Indicate if the pest has a reasonable likelihood of being on and remaining with the plant part(s), in viable form, throughout the harvesting process. Consider all plant parts present after harvest but prior to post-harvest processing. Do not consider post-harvest practices, such as washing, dipping, etc., at this step even when they are routine. ◆ Answer "Yes" or "No" and, if appropriate, cite and/or discuss evidence for your decision. Note: "Yes" indicates simply that the pest has a reasonable likelihood of being associated with the harvested commodity; the level of pest prevalence on the harvested commodity (low, medium, or high) is qualitatively assessed in Risk Element A1: Pest prevalence on the harvested plant part(s) as part of Process 7: Assessing the likelihood of introduction. ❖ **Answer yes if:** ❖ The commodity plant species is a Type 1 host (natural host) for the pest, and the pest is reasonably likely to be associated with the commodity plant part(s) to be imported following harvesting from the field and prior to any post-harvest processing. ❖ The commodity plant species is a Type 2 host (conditional host) for the pest, and conditions in the exporting area are such that there is a reasonable likelihood that the pest will be associated with the commodity plant part(s) to be imported following harvesting from the field and prior to any post-harvest processing. ❖ **Answer no if:** ❖ Characteristics of the pest, commodity, or harvesting process are such that it is unlikely the pest will be on the commodity after it is harvested. ❖ The commodity plant species is a Type 2 host (conditional host) for the pest, and there is a reasonably high level of certainty that the conditions for non-host status (Type 2b host) are met (e.g., specific varieties used for export known to be a non-host, specific timing of harvest, only evidence of host association under experimental conditions), and the status is supported by sufficient evidence. Keep the pest in the pest list table, and explain the conditions and evidence for the Type 2b status. Those pests for which the answer was yes, continue to Process 5: Collecting information and defining the endangered area on page 2-22. If there are no pests for which the answer is yes, the risk assessment stops here.

Follow the steps of this procedure to complete the pest list table.	
	Remarks: Use this section for information pertinent to the pest list, but that does not fall under the previous columns. For example: ◆ For pests that have a limited distribution in the United States but are included on the pest list because they are actionable pests: list the pest's distribution in the PRA area and provide references, including PestID or agency correspondence. ◆ Overarching assumptions and/or uncertainty.
Step 2	Summarize the following information in sub-sections placed after the pest list table in the risk assessment: ◆ "Notes on pests identified in the pest list": Summarize information that is too lengthy to fit in the main pest list table. This sub-section can also include a summary of actionable pests not selected for further analysis, including the justification for why they were not selected (e.g., the organism is not likely to be associated with the harvested plant part(s), the commodity meets the criteria for a Type 2b host for a pest, existing PPQ policy does not require analysis of those pests). ◆ "Pests selected for further analysis": List those pests on the pest list for which the answer to "On harvested plant part(s)?" is "Yes".
If you have completed your pest list, continue to Process 5: Collecting information and defining the endangered area on page 2-22.	

Table 2-1. Actionable pests reported on [species name of plant to be imported] (in any country) and present in [export area] (on any host).

Pest name	Evidence of presence in the export area	Host status	Plant part(s) association	On the harvested plant part(s)?	Remarks
Genus species Authority	REF Describe any uncertainty regarding distribution and, if relevant, regulatory status in the exporting country (REF)	Type 1, 2, or 4 (REF) If applicable, provide brief justification for judgments and conclusions (REF) For Type 4 hosts, provide additional justification for inclusion on pest list (REF)	Indicate the part(s) of the plant with which the pest is associated (i.e., fruit, flowers, stems, leaves, roots). Consider association on the actual imported plant species Describe uncertainty regarding plant part association including any extrapolations or assumptions (REF)	Yes or No Provide brief justification for judgments and conclusions (REF)	**If pest is present in the United States:** "Present in [List States]" (REF) **Optional:** Include a brief explanation of any additional information you feel is necessary to capture in the pest list

Procedure 4-5. Handling organisms identified only to genus level

Refer to the following notes when completing this procedure.

- **Note 1.** An organism identified to the genus level should only be included in the risk assessment if it is reported simultaneously on the commodity and in the export area in the same reference [e.g., "Genus sp. attacks Commodity X in Country X (Anonymous, 2010)"].
- **Note 2.** Treat pests listed as "reportable" in PestID as "actionable," unless a specific note in PestID or other PPQ port policy indicates otherwise.
- **Note 3.** There may be situations when it is appropriate not to follow this procedure (see Organisms identified only to the genus level on page 2-10). If this is the case, clearly document the evidence and associated uncertainty for this decision in the risk assessment.

Follow the steps in this procedure to determine how to handle organisms identified only to genus level.		
	IF	**THEN**
Step 1	The genus (i.e., "*Genus* sp.") **is listed** in PestID.	Go to Step 2.
	The genus (i.e., "*Genus* sp.") **is not listed** in PestID.	Go to Step 3.
Step 2	The whole genus (i.e., "*Genus* sp.") is listed as **"reportable"** in PestID in the PRA area.	**The pest either has actionable or undetermined regulatory status.** Go to Step 3.
	The whole genus (i.e., "*Genus* sp.") is listed as **"non-reportable"** in PestID in the PRA area.	**The pest is non-actionable.** Refer back to Step 5 of Procedure 4-1: Identifying potential pests for the pest list.
Step 3	There is **adequate evidence that the pest occurs** on the commodity in the export area.	Add the pest to Table 1 in the "Organisms identified only to genus level" section of the risk assessment. Go to Step 4.
	There is **not adequate evidence that the pest occurs** on the commodity in the export area.	Add the pest to the "Pests with weak evidence for association with the commodity or for presence in the export area" section of the risk assessment.
Step 4	Any species in the **genus is present** in the PRA area.	In Table 1 of the "Organisms identified only to genus level" section of the risk assessment, indicate that the genus is present in the PRA area and that the regulatory status is undetermined. Go to Step 5.
	The **genus is not present** in the PRA area.	In Table 1 of the "Organisms identified only to genus level" section of the risk assessment, indicate that the genus is not present in the PRA area and that the regulatory status is actionable. Go to Step 5.
Step 5	The pest **could be associated** with the harvested commodity plant parts.	In Table 1 of the "Organisms identified only to genus level" section of the risk assessment, indicate that the pest could be associated the harvested plant parts. Go to Step 6.

Follow the steps in this procedure to determine how to handle organisms identified only to genus level.

	IF	THEN
	The pest **could not be associated** with the harvested commodity plant parts.	In Table 1 of the “Organisms identified only to genus level” section of the risk assessment, indicate that the pest could not be associated with the harvested plant parts.
Step 6	The pest has **undetermined regulatory status**.	In the risk mitigation notes document, state that the level of risk of the congeners (if any are to be analyzed in the risk assessment) may or may not be similar to that of the organism in question, and that in general, there is high uncertainty regarding efficacy of risk mitigation measures when applied to organisms identified only to the genus level.
	The pest has **actionable status**.	For each pest, create a genus-level datasheet. (Note: Do not create a datasheet for pests with undetermined regulatory status). The datasheet should include the following primary elements: ◆ absence of the genus in the PRA area and regulatory status of some species belonging to it (if information is available). ◆ distribution of species from the genus in the world and potential for establishment in PRA area. ◆ known host range (plant species and families) of different species within this genus. ◆ biology contributing to dispersal (fecundity, number of generations, ability for active dispersal on its own or through human activities) and possibility of spread in PRA area. ◆ potential for economic and environmental consequences in the PRA area. The following factors should be considered when assessing significance of the genus. ❖ previous history of successful establishment in new areas. ❖ phytopathogenic or phytophagous characteristics. ❖ observations of causing injury to plants, beneficial organisms, etc. ❖ being reported as pests. ❖ ability to act as a vector for known pests. ❖ adverse effects on non-target organisms beneficial to plants (such as pollinators or predators of plant pests). ❖ interception records. Include the genus level datasheet as an appendix to the main risk assessment document. Summarize the information from the datasheet after Table 1 in section 2.1.3. “Organisms identified only to the genus level” of the risk assessment. In the risk mitigation notes document, state that the level of risk of the congeners (if any are analyzed in the risk assessment) may or may not be similar to that of the organism in question, and that in general there is high uncertainty regarding efficacy of risk mitigation measures when applied to organisms identified only to the genus level.

Continue to Process 5: Collecting information and defining the endangered area on page 2-22.

Stage 2: Pest Risk Assessment

Stage 2 of pest risk analysis is composed of two distinct phases: pest categorization and risk assessment. In PPQ commodity import risk assessments, the first phase, pest categorization, begins as the pest list is built in Process 4: Creating the pest list and pest categorization and continues in Process 5: Collecting information and defining the endangered area when we define the area endangered by the pest. The second phase, risk assessment, is the heart of Stage 2 and involves analyzing biological and economic information about the pests selected for further analysis in order to estimate their likelihood of being introduced into the PRA area (via the commodity) and identifying the potential economic and environmental impacts that would result from their introduction.

Processes in PPQ commodity import risk assessment

In PPQ, pest risk assessment is divided into five processes:

- Process 5: Collecting information and defining the endangered area
- Process 6: Assessing uncertainty for risk elements
- Process 7: Assessing the likelihood of introduction
- Process 8: Assessing potential consequences of introduction
- Process 9: Summarizing the final risk ratings and uncertainty

> ***NOTE***
>
> Pest risk assessment is not linear; although the processes of Stage 2 are numbered and described individually for convenience, they are not necessarily completed sequentially. Each process provides the framework and specific instructions for conducting various individual aspects of commodity import risk assessment, but analysts have flexibility in approaching each process and determining the best order in which to complete the assessment.

Risk elements evaluated in PPQ commodity import risk assessment

The likelihood that a pest will be introduced into the PRA area via the commodity is analyzed in Process 7: Assessing the likelihood of introduction. By definition (ISPM No. 5: IPPC, 2012), this likelihood includes both the likelihood of the pest entry in the PRA area and the likelihood of its establishment in the PRA area upon entry. We determine the likelihood of introduction by evaluating the following risk elements (described in detail in Process 7).

Risk Element A: Likelihood of entry
◆ Risk Element A1: Pest prevalence on the harvested plant part(s)
◆ Risk Element A2: Likelihood of surviving post-harvest processing before shipment
◆ Risk Element A3: Likelihood of surviving transport and storage conditions of the consign-ment
Determining the likelihood of establishment (Risk Element B)
◆ Risk Element B1: Likelihood of coming into contact with host material in the endangered area
◆ Risk Element B2: Likelihood of arriving in the endangered area

The potential impacts of a pest introduction in the PRA area are evaluated in Process 8: Assessing potential consequences of introduction. Once a pest has entered the PRA area, it must be able to establish and subsequently spread in order for there to be consequences. The consequences of introduction are determined by evaluating the following risk elements (described in detail in Process 8).

Risk Element C: Determining the potential direct impacts
◆ Risk Element C1: Damage potential in the endangered area
◆ Risk Element C2: Spread potential
Risk Element D: Determining potential trade impacts
◆ Risk Element D1: Determining export markets at risk
◆ Risk Element D2: Likelihood of trading partners imposing additional phytosantiary requirements

NOTE
We evaluate spread potential as a part of the potential consequences of introduction because it relates to how quickly the pest will be able to cause full impacts in the PRA area.

Process 5: Collecting information and defining the endangered area

The purpose of this process is to gather and organize the biological, environmental, and economic information necessary for evaluating each of the risk elements and to determine the logical order in which they should be evaluated. Before beginning this process, analysts should first determine whether an assessment or other standard text (e.g., Pest Notes) has already been developed for the pest that could be relevant for the commodity pathway being assessed.

In general, assessment of the likelihood of entry involves evaluating the biology of the pest in terms of how the pest relates to the conditions of the pathway and the characteristics of the commodity that were described in Process 3: Defining the pathway. Assessing the likelihood of establishment, spread, and the subsequent potential impacts of the pest in the PRA area involves evaluating the biology of the pest in relation to the suitability of conditions in the PRA area. Those conditions include biotic factors (e.g., availability of host material, presence or absence of natural enemies) and abiotic factors (e.g., temperature, season, humidity, rainfall, or other environmental conditions that affect the ability of the pest to survive and reproduce).

Gathering information and identifying sources of uncertainty

The first part of Process 5 involves gathering the necessary information to complete Process 7: Assessing the likelihood of introduction and Process 8: Assessing potential consequences of introduction. Analysts can and should consult many different sources of information in this process, such as the scientific literature, databases, compendia, information provided by the exporting country, and subject matter experts. As much as possible, the information obtained should relate to the specific pest and how it behaves on hosts and in environmental conditions similar to those present the PRA area. When such information is unavailable, analysts may need to extrapolate from other related pests and situations. Analysts should explicitly note when collected data are based on extrapolations as it is an important factor in evaluating uncertainty. The type of information needed to complete Process 7: Assessing the likelihood of introduction and Process 8: Assessing potential consequences of introduction includes the following.

Information about the export area
◆ prevalence of a pest or disease agent in the exporting area
◆ geographic and environmental characteristics
◆ standard industry practices and procedures in the export area
◆ surveillance system(s)
◆ effectiveness of mitigation measures an treatments in the areas where (and if) controlled

◆ previous risk assessments (including those of foreign countries) of the commodity and related commodities from the same origin
Information about the commodity
◆ type or class of commodity
◆ nature of raw material used to produce the commodity
◆ intended use of the product
◆ pest or disease agent survival in transit
◆ interception data
Pest-specific information
◆ potential host range of the pest in the PRA area
◆ symptoms expected to be caused by the pest on important potential hosts in the PRA area and plant parts affected
❖ type and degree of damage caused
❖ secondary damage that may occur as a result of the pest
◆ life history of the pest
❖ life stages (including duration)
❖ reproductive strategies (sexual, parthenogenetic, etc.)
❖ adaptive characteristics (dormancy, increased fecundity, number of generations, known expansion of host range, etc.)
◆ climatic/environmental constraints of the pest
❖ temperature/humidity requirements
❖ current geographic distribution
◆ ease of detection/inspection
◆ on commodity (e.g., size, ability to hide, signs of damage, latency, distinctiveness of symptoms)
◆ in the environment (e.g., methods of detection, including trapping mechanisms, signs of damage/presence)
◆ ease of identification
❖ similarity to other species
❖ methods of identification/diagnostics
❖ ease of identification of various life stages
◆ ease of removal of the pest from infested/infected commodity during standard packing-house practices (e.g., washing, brushing, waxing)
◆ means of dispersal
❖ natural mobility of life stages (adult flight, larval silk ballooning, etc.)
❖ vectors (and presence of vectors in the PRA area)
❖ other mechanisms required for successful dispersal (wind, rain, soil, etc.)
❖ other requirements necessary for dispersal (e.g., the availability of a particular phenological stage of the host)
◆ prevention and control strategies used for the pest anywhere in the world
❖ field control
❖ phytosanitary measures
❖ possible effect of standard industry practices on survival of the pest

❖ existing export protocol requirements where host commodities are currently enterable
Information about the PRA area
◆ After clearly defining the PRA area for the particular risk assessment (e.g., continental United States, all 50 U.S. states, U.S. territories only), analysts should consider information regarding
❖ distribution of the commodity
❖ availability of susceptible hosts and/or competent vectors
❖ geography and environment
❖ control and production practices
❖ presence of similar pests

In addition to considering the type of information available, analysts should be aware that the quality of the information will vary based on the source. Both the quality and applicability of available information will impact the certainty of the resulting risk rating. Supplement 4: Evaluation of Evidence on page 3-29 provides general guidance on how analysts can relate both the quality and applicability of evidence to their level of uncertainty (Process 6: Assessing uncertainty for risk elements on page 2-33). Analysts should identify gaps in knowledge and possible areas for future research in the mitigation notes (Process 10: Risk mitigation notes on page 2-67).

When gathering information, analysts should keep in mind the scope of the analysis and the description of the pathway. In some cases it may be unnecessary to gather detailed information on the biology of the pest or on the environmental conditions in the PRA area, particularly when it is clear that the rating for a particular risk element is likely to be negligible. For example, if the scope of the analysis explicitly includes evaluating a post-harvest treatment such as irradiation or fumigation that will, with a high degree of certainty, remove the pest from the pathway (or render it inviable), the likelihood of entry of the pest will be negligible and it would be unnecessary to gather additional information about this pest.

Determining the order of analysis

When the endangered area is defined and it is determined that at least some part of the PRA area could be endangered by the pest, an analyst should commence the risk assessment phase. As previously mentioned, Process 7: Assessing the likelihood of introduction and Process 8: Assessing potential consequences of introduction can be conducted in either order. If it is determined that the risk associated with either the likelihood or consequences of introduction is Negligible, it may be unnecessary to complete the other processes. Further, within Process 7, the analysis of the individual risk elements can be completed in any order. In other words, in most cases, an analyst can start an assessment with any one of the following procedures.

Procedure 7-1: Assessing the likelihood of entry (Risk Element A)
Procedure 7-2: Determining the likelihood of establishment (Risk Element B)
◆ Risk Element B1: Likelihood of coming into contact with host material in the endangered area OR
◆ Risk Element B2: Likelihood of arriving in the endangered area
Procedure 8-1: Determining the potential direct impacts (Risk Element C)

In deciding the best order to proceed with the assessment, analysts should first consider whether the risk ratings for one or more of the elements are likely to be negligible. An element that is likely to have a negligible risk rating should generally be evaluated first, in order to avoid needless research and analysis. Next, analysts should consider the availability, quality, and applicability of information necessary for evaluating each of the risk elements (see Supplement 4: Evaluation of Evidence on page 3-29). As a general principle, it is more efficient to first evaluate the risk elements for which there is the greatest amount of reliable evidence available.

With experience, analysts will be able to decide which risk elements to evaluate first.

Defining the endangered area

While the PRA area is the area for which the risk assessment is intended, the endangered area is defined as the portion of the PRA area where ecological factors favor the establishment of the pest and where the presence of the pest will result in economically important losses. In some cases, the area endangered by the pest may be as large as the entire PRA area, but in other cases, when the pest is restricted by climate or hosts, the endangered area may only constitute a small portion of the PRA area.

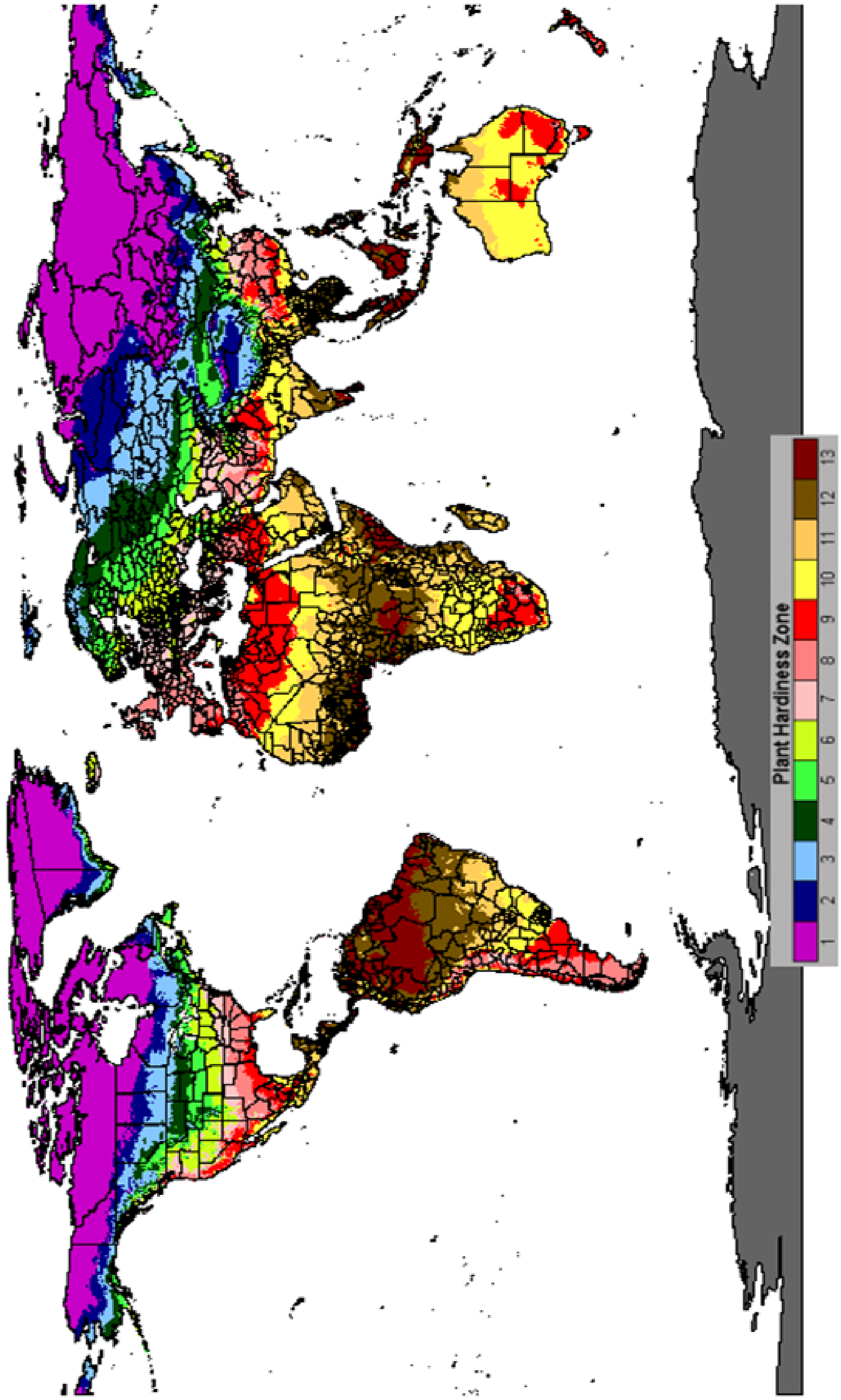
There are two important parts to determining the endangered area. First we identify the portion of the PRA area where the organism is likely to be able to establish. Then, we determine whether the pest has the potential to damage economically important plants in that area.

Identifying the portion of the PRA area where the pest can actually survive and cause negative impacts is a crucial precursor to determining the potential risk of the pest in terms of its likelihood of establishment and associated consequences. Based on the biology of the pest and the identified biotic and abiotic conditions of the PRA area, analysts determine the area endangered by the pest (i.e., the endangered area) by identifying the portion of the PRA area where the pest can likely establish and cause economically important consequences. Important factors that influence where the organism can survive include abiotic factors such as temperatures (minimum/maximum), humidity, and rainfall, and biotic factors such as the availability of suitable host material. Host material suitable for survival might include uncultivated, unmanaged plants, or even weeds, that are not economically important. However, for the purposes of these Guidelines, we will be considering as pest hosts only economically important plants that occur in the areas of suitable climatic conditions. As a result, we assume that the area potentially suitable for a pest establishment is the same as the endangered area.

In many cases, we do not have detailed information on the abiotic requirements of the pest or on the abiotic conditions of the PRA area. The global plant hardiness zone map developed by Magarey et al (2008) groups regions that have the same average annual extreme minimum temperature into distinct zones (Figure 2-2), allowing for easy comparison and matching of the temperature suitability in the areas of the pest's current distribution elsewhere in the world to that of the PRA area. Because temperature, particularly low winter temperature, is often a critical factor determining the geographical range of many organisms (especially insects) (Worner, 1998; Bale et al., 2002), the area endangered by a pest can often be described in terms of average minimum temperature zones by "plant hardiness zone matching." It is important to note that when we use this method to define the portion of the PRA area climatically suitable for pest establishment, we are making two implicit assumptions: 1) that cold tolerance is the major limiting factor of the pest's current distribution, and 2) that cold tolerance is likely to be the major restriction in the PRA area.

If analysts have specific information that can narrow this area or otherwise provide more precision, the endangered area may be described by other relevant means, so long as the boundaries (such as states or counties) are clearly identified (see Procedure 5-2: Defining the endangered area). In any case, regardless of how the endangered area of the pest is defined, it must have both a suitable climate and available hosts.

Figure 2-2. Temperature zones (aka "plant hardiness zones") for defining the endangered area (Magarey et al., 2008).



Procedure 5-1. Determining the order of analysis

Follow the steps below to determine the order of analysis.		
	IF	**THEN**
Step 1	**An analysis or other standard text has already been developed** for the pest that is relevant for the commodity pathway being assessed. (Check Pest Notes and/or the PRA library.)	If appropriate, use the analysis in your assessment and continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63. Otherwise, go to Step 2.
	No analysis or other standard text has developed for the commodity pathway being assessed.	Go to Step 2.
Step 2	Based on the scoping call, the defined pathway **explicitly includes treatments** (such as irradiation or fumigation) that would likely lead to the pest having a negligible likelihood of entry.	Continue to Procedure 7-1: Assessing the likelihood of entry (Risk Element A).
	Based on the scoping call, the defined pathway **does not include any treatments** (such as irradiation or fumigation) that would likely lead to the pest having a negligible likelihood of entry.	Go to Step 3.
Step 3	Conduct a preliminary search for information on the pest (see Gathering information and identifying sources of uncertainty). Consider the availability, quality, and applicability of information necessary for evaluating each of the risk elements and then determine your order of analysis. As a general principle, it is more efficient to first evaluate the risk elements for which there is the greatest amount of reliable evidence available. In determining the order of analysis, keep in mind that the pest analysis can stop if: ◆ The Likelihood of Entry is rated Negligible. ◆ There is no endangered area (Procedure 5-2: Defining the endangered area). ◆ The pest is determined to be a non-threshold pest (Process 8: Assessing potential consequences of introduction on page 2-50) ◆ Either Risk Element B1 or Risk Element B2 (under Likelihood of Establishment) is rated Negligible.	

Procedure 5-2. Defining the endangered area

NOTE
This procedure is unnecessary when Risk Element A: Likelihood of entry is rated Negligible. It may also be unnecessary if the pest is highly unlikely to transfer from the commodity to a new host on its own (see Step 1 of Risk Element B1: Likelihood of coming into contact with host material in the endangered area).

Determine the area endangered by the pest by following the steps in this procedure. In some cases, Step 1 and Step 2 may be combined (for example, if you use a model in Step 1 that considered both climate and host availability).	
Step 1	Using plant hardiness zone matching or another method, identify the portion of the PRA area that has climatic conditions suitable for the pest's survival based on its current global geographic distribution and any biological characteristics that may limit its ability to survive in the PRA area (such as temperature tolerance, humidity requirements, etc.). If you determine that suitable environmental conditions do not exist in the PRA area, or exist in protected areas only (e.g. glasshouses), state this in the risk assessment and conclude that the endangered area is Negligible. The assessment of the pest can stop at this point. Otherwise, proceed to Step 2.
	Plant hardiness zone matching. In this method you will use the global plant hardiness zone map developed by Magarey et al. (2008) to match the plant hardiness zones where the pest currently is found to the corresponding zones in the PRA area. 1. Determine the current distribution of the pest through the world. 2. Using the map developed by Magarey et al. (2008), identify the plant hardiness zones in which the pest is currently distributed. If a pest is recorded in a country with several plant hardiness zones and there are no data on specific areas of its distribution, consider all hardiness zones in that country (if it is reasonable to do so). 3. Identify the corresponding plant hardiness zones in the PRA area.
	Other methods. If you have specific information that can identify the climate requirements with more precision than hardiness zones, you may use this information to either refine the boundaries of the temperature zones identified using plant hardiness zone matching, or you can use another method of climate matching (e.g., NAPPFAST model, degree-day model, precipitation analysis, etc.). Regardless of the method you use, you must clearly identify the geographic area you have determined is likely to be climatically suitable for the pest by either providing a map or by clearly describing the boundaries of the area.
Step 2	Determine the distribution of Type 1 hosts of the pest in the portion of the PRA area identified in Step 1 (i.e., in the area where climatic conditions are suitable for the pest's establishment). Determine the distribution of Type 2 hosts in this area if there is a reasonably high level of certainty that the conditions for host status would be met there. If you determine that no suitable host material is found in the portion of the PRA area identified in Step 1 (except in protected areas, such as glasshouses), state this in the risk assessment and conclude that the endangered area for the pest is Negligible. The assessment of the pest can stop at this point. Otherwise, go to Step 3.

<table>
<tr><th colspan="2">Determine the area endangered by the pest by following the steps in this procedure. In some cases, Step 1 and Step 2 may be combined (for example, if you use a model in Step 1 that considered both climate and host availability).</th></tr>
<tr><td>Step 3</td><td>Determine if any of the hosts present in the area of concern (identified in step 2) are of economic importance. As defined by ISPM No. 11, Supplement 2 (IPPC, 2004b), “economically” important hosts refers to both commercial and non-market (environmental) plants such as
◆ agricultural crops
◆ horticultural crops, ornamentals, nursery plants
◆ timber
◆ environmentally important non-commercial hosts such as threatened and endangered species, plants important to aesthetics of natural areas, ecologically important species, etc.
◆ plant species with a particular social importance, such as those to Native Americans
If you determine that none of the hosts plants identified in Step 2 are of economic importance, state this in the risk assessment and conclude that the endangered area for the pest is Negligible. The assessment of the pest can stop at this point.
Otherwise, go to Step 4 on page 2-31.</td></tr>
</table>

<table>
<tr><th colspan="2">Determine the area endangered by the pest by following the steps in this procedure. In some cases, Step 1 and Step 2 may be combined (for example, if you use a model in Step 1 that considered both climate and host availability).</th></tr>
<tr><td>Step 4</td><td>Based on the behavior and symptoms of the pest in the areas where it is currently distributed, determine whether the pest has the potential to impact the specific plant host species identified in step 3 by answering the questions below.

Where the symptoms and/or the degree of damage caused by the pest vary throughout the pest's distribution, you should place emphasis on the symptoms and damage the pest causes in regions most climatically similar to the area of concern (identified in Step 1) and on plant identified in Step 3.

1. In its current area of distribution, is the organism a known pest (or vector of a pest) of any of the hosts identified in Step 3?
◆ For example:
❖ Has the organism been described in the literature as a pest on one or more of the hosts identified in Step 3?
❖ Do control programs for the pest exist on one or more hosts identified in Step 3?
❖ Has the pest been documented to cause reductions in plant density, or impact ecological fitness of at least one of the non-commercial hosts identified in Step 3 (anywhere in the world)?
❖ Has the pest been documented to cause yield losses in commercial production of at least one host identified in Step 3? Consider both pre-harvest and post-harvest losses (losses due to unmarketable commodity).
2. Based on the type of damage caused by the pest in its current distribution, could the pest (acting by itself or as a vector) cause damage to the hosts identified in Step 3?
◆ For example:
❖ Is the type of damage or symptoms caused by the pest likely to result in pre-harvest losses of any commercially produced hosts identified in Step 3 (e.g., plant mortality, premature fruit drop, prevention of fruit set, dieback)?
❖ Is the type of damage or symptoms caused by the pest on any of the commercially produced commodities identified in Step 3 likely to result in post-harvest production losses (due to unmarketable commodity)?
❖ Is the type of damage or symptoms caused by the pest on any of the commercially produced commodities identified in Step 3 likely to result revenue losses resulting from a reduction in the value of the commodity (e.g., yellow/damaged leaves on a horticulture plant resulting in a lower market price; damaged fruit diverted from fresh market to juice market)?
❖ Is the type of damage caused by the pest likely to impact any of the environmentally or socially important plants identified in Step 3?

If you answered yes to either Question 1 or 2, go to Step 5.

If neither of the questions above could be answered yes, state in the risk assessment that the pest potential on economic hosts at risk is Negligible and conclude that the endangered area for the pest is Negligible. The assessment of the pest can stop at this point.</td></tr>
</table>

Determine the area endangered by the pest by following the steps in this procedure. In some cases, Step 1 and Step 2 may be combined (for example, if you use a model in Step 1 that considered both climate and host availability).	
Step 5	Describe the endangered area. In most cases, you can describe the endangered area in terms of the Magarey et al. (2008) plant hardiness zones. As mentioned above, these zones provide a convenient method for bounding the endangered area because they divide the PRA area into distinct regions that have similar climates (in terms of average minimum winter temperatures) and, in many cases, hosts. To define the endangered area, simply identify the zones that have both suitable climate (as identified in Step 1) and available hosts (as identified in Step 2). In the risk assessment, state that the endangered area of the pest is considered to be within the identified zones, and explain your rationale and any uncertainty. If you have used methods in Step 1 and Step 2 that more precisely identify the area of concern, you may define the endangered area in other terms; however, you must clearly describe the boundaries of this area (e.g., by state or county) and provide a map, if applicable. The identified area must have both suitable climate (Step 1) and economically important hosts at risk (Step 3 and Step 4). In the risk assessment, be sure to clearly explain your rationale and any uncertainty.

Process 6: Assessing uncertainty for risk elements

Separating the uncertainty that arises due to lack of knowledge from the ratings of risk elements is important; ratings are made based only on the available evidence, not the uncertainty associated with the evidence. For instance, a given risk element should not be rated higher if there is a lot of uncertainty; rather, the rating should be assigned based on available evidence and the high level of uncertainty should be noted. At the same time, we recognize that a given risk element may be assigned a rating that may more or less accurately reflect the actual probability associated with that risk element, depending on the level of uncertainty. Higher levels of uncertainty could mean a given rating may be over- or under-estimating probability by one or more levels (e.g., a low rating with high uncertainty would truly be medium or high if we had more evidence on which to base our judgment).

For some risk elements and where information is available, variability might be included in the rating; such situations should be documented in the text of the analysis. In cases with a high degree of variability, the analyst will typically make a conservative judgment resulting in a higher risk rating. This underscores the importance of describing uncertainty—including sources and magnitude—while at the same time maintaining judgments that are based on available evidence.

We assess the uncertainty associated with each risk rating under likelihood of introduction (Process 7: Assessing the likelihood of introduction) and potential consequences of introduction (Process 8: Assessing potential consequences of introduction). Procedure 6-1: Assessing uncertainty for each risk element is a guide for assigning uncertainty ratings to each risk rating based on available evidence (modified after Andrews et al., 2004). Where appropriate, analysts should provide written explanations about the level of certainty associated with each rating. Gaps in knowledge should be specifically discussed, and possible areas of future research should be identified, as appropriate.

Analysts should consult Supplement 4: Evaluation of Evidence on page 3-29 when assessing and assigning ratings of uncertainty. The supplement provides guidance on relating both the quality and quantity of evidence to the level of uncertainty.

Procedure 6-1. Assessing uncertainty for each risk element

For each risk rating, assign an uncertainty rating based on the guidance in this procedure.	
Uncertainty rating	**Description**
Certain (C)	**Additional or better information is very unlikely to change the rating.** This rating requires that: ◆ The risk rating is based on well-documented evidence (e.g., original research paper published in peer reviewed journal, or a survey conducted by an NPPO with an approved methodology). ◆ Area- or species-specific data are available. ◆ Scientific consensus exists on methodological approach, or our agency has much experience with the pest.
Moderately certain (MC)	**Additional or better information probably will not change rating.** Example justifications for this rating: ◆ Published articles or other documentation consists of review article of several original research studies. ◆ Research or survey results are available but without detailed methodology.
Moderately uncertain (MU)	**Additional or better information may or may not change rating.** Example justifications for this rating: ◆ Some area- or species-specific data are used, but most of the data were approximated or extrapolated from similar situations (i.e., research conducted in the areas of comparable climate, on a related host, or with a congeneric pest species).
Uncertain (U)	**Reliable information is not available.** Example justifications for this rating: ◆ The risk rating is based on poorly documented methodology and results. ◆ No area- or pest-specific data are available and no close approximations were used. ◆ No reliable identification of the organism is available. ◆ The pest biology, association with the host, or field prevalence are unknown.

Process 7: Assessing the likelihood of introduction

We assess the likelihood of introduction by assigning High, Medium, Low, or Negligible ratings, as determined below in Risk Elements A and B. We note that in these risk elements we define "surviving" to mean avoiding mortality, remaining reproductively viable, and remaining with the commodity; this can include pests and pathogens that can remain dormant, live endophytically or remain latent in the host without showing signs or symptoms of infection.

In Risk Element A: Likelihood of entry, we assess the likelihood of entry of the pest into the PRA area. We assess this likelihood by determining a baseline risk rating [Risk Element A1: Pest prevalence on the harvested plant part(s)] based on the likely pest prevalence or population on the harvested commodity. From that point, we determine if the pest prevalence will increase, decrease, or remain the same as the pest moves along the pathway. We specifically examine the likelihood that post-harvest processing before shipment (Risk Element A2: Likelihood of surviving post-harvest processing before shipment), as well as transport and shipping conditions will affect pest prevalence and thus entry potential (Risk Element A3: Likelihood of surviving transport and storage conditions of the consignment). We note that, in some cases, pest prevalence may increase after harvest. If we have evidence that this is likely to occur, we will specifically address this in the risk elements below. Additionally, although the volume of commodity entering the PRA area also impacts the entry potential of each pest, unless otherwise noted, we assume that the volume of commodity entering the country will be of a sufficient amount that entry and establishment is probable.

In Risk Element B: Likelihood of establishment, we assess the likelihood that the pest will establish in the PRA area upon entry. Specific sub-elements include Risk Element B1: Likelihood of coming into contact with host material in the endangered area and Risk Element B2: Likelihood of arriving in the endangered area.

We combine the likelihoods of entry and establishment to give an overall likelihood of introduction. We define the different categories of the overall likelihood of introduction as follows:

- **High.** Pest introduction is highly likely to occur.
- **Medium**. Pest introduction can occur, but for that to happen the exact combination of required events described needs to occur.
- **Low**. Pest introduction is unlikely to occur because one or more of the required events is unlikely to happen, or the full combination of required events is unlikely to align properly in time and space.

- **Negligible**. Pest introduction is highly unlikely to occur given the exact combination of events required for successful introduction.

> ***NOTE***
>
> The risk factors comprising the model for likelihood of introduction are interdependent and therefore the model is multiplicative rather than additive. Therefore, if any of the risk ratings in this section are Negligible for a certain pest, the overall likelihood of introduction for that pest becomes Negligible and the assessment for may stop.

Procedure 7-1. Assessing the likelihood of entry (Risk Element A)

Risk Element A: Likelihood of entry

Risk Element A1: Pest prevalence on the harvested plant part(s). Provide a qualitative rating for the size of the pest population that may be associated with the harvested plant part(s). This will be the baseline rating for likelihood of entry. For the baseline risk level, assume that the commodity was not subjected to any post-harvest treatments, including those that are usually associated with good industry practices, such as washing for mango. Determine the baseline risk ranking by deciding which of the criteria in Risk Element A1: Pest prevalence on the harvested plant part(s) best apply to the pest you are analyzing. Rate your uncertainty (Process 6: Assessing uncertainty for risk elements) and provide a narrative explanation for your decision.

> ***NOTE***
>
> A Negligible rating is not possible for Risk Element A1: Pest prevalence on the harvested plant part(s) because only pests associated with the harvested commodity were selected for further analysis in Process 4: Creating the pest list and pest categorization. If a pest-free area was being considered as a part of the defined pathway, that pest would already have been removed from the pathway in the previous process.

> ***NOTE***
>
> Type 2b hosts (conditional non-hosts) would have been included in the pest list (Procedure 4-3: Determining whether to include an actionable pest on the list) but not subject to further analysis if there was sufficient evidence and a reasonable level of certainty that the commodity met Type 2b host criteria (e.g., a non-host). Therefore, in this procedure, you should consider conditional hosts to be Type 2a hosts (that is, the commodity can serve as a host under specified conditions). Consult Supplement 3: Host Status on page 3-10 for more details on designating host status.

Risk Element A1: Pest prevalence on the harvested plant part(s)		
	IF	**THEN**
Step 1	Any of the following statements apply: ◆ Evidence indicates that this organism always has a low association with the harvested plant parts. ◆ The export area is recognized as an area of low pest prevalence (ALPP) for the pest in question. ◆ The commodity is a Type 2 host and the specific conditions required for it to serve as a host are unlikely to occur at any given time (e.g., for a Type 2a host, conditions generally are such that the pest can only rarely successfully attack the host, seasonality).	**The baseline risk rating (A1) is Low.** Continue to Step 2.
	Any of the following conditions apply: ◆ Effective standard industry practices exist in the field and are applied before commodity is harvested. ◆ The commodity is not a preferred feeding (infection) site for the pest (e.g., the pest is occasionally associated with fruit, but generally feeds only on leaves). ◆ The commodity is a Type 2 host under specific environmental conditions, and those conditions occur sometimes but not constantly (e.g., for a Type 2a host, the conditions are such that the pest may successfully attack or infect the commodity at least some of the time, seasonality).	**The baseline risk rating (A1) is Medium.** Continue to Step 2.
	Both of the following statements apply: ◆ The plant species to be imported is 1) a host and 2) the part(s) to be imported is a preferred feeding site of the pest. (For Type 2 hosts, the commodity is a Type 2a host under specific environmental conditions, and those conditions frequently or always occur). ◆ No standard industry field practices beyond minimal handling during harvest are being considered.	**The baseline risk rating (A1) is High.** Continue to Step 2.

Risk Element A2: Likelihood of surviving post-harvest processing before shipment. Assess the likelihood of the pest surviving through post-harvest processing, packing, and preparing the commodity for shipping. For this risk element, consider the post-harvest practices defined for the pathway in Process 3 and how they affect the likelihood that the pest will remain with the commodity. Do not give a separate rating for the likelihood that the pest will survive post-harvest processing before shipment. Rather, depending on the likelihood, you should adjust the rating from Risk Element A1: Pest prevalence on the harvested plant part(s) (the baseline risk rating) up or down as appropriate, or keep it the same.

Consider the following:

- The ease of detection of infested/infected commodity during packinghouse practices described in Process 3: Defining the pathway.

- The ease of removal of the pest from infested/infected commodity during standard packinghouse practices, e.g., washing, brushing, waxing.
- The quality standards and their possible effect on the pest's association with the commodity.

Risk Element A2: Likelihood of surviving post-harvest processing before shipment		
	IF	**THEN**
Step 2	Evidence indicates that **the entire pest population is highly likely to be killed** or rendered inviable during processing (e.g., PPQ-approved irradiation treatment).	**The rating is Negligible.** Stop the risk assessment for the pest here. Summarize your findings and uncertainty. Continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63.
	Evidence **does not indicate that the entire pest population is highly likely to be killed** or rendered inviable during processing.	Go to Step 3.
Determine which of the situations in Step 3 best applies to the pest you are analyzing. Provide your rating, rate your uncertainty, and provide a narrative explanation for your decision.		
Step 3	Reliable efficacy data or comparable evidence, provided by the NPPO of the exporting country or a comparable source, indicate that processing measures are likely to significantly reduce pest prevalence in the commodity (e.g., surface pests eliminated during washing, pathogens mitigated by washing with bleach). Do not automatically assume the efficacy of measures. Evidence needs to be specific and credible, and should be provided by the NPPO of the exporting country or other comparable source.	**Decrease the baseline risk rating (A1) by one level.** **A1** | **becomes** | **A2** H → M M → L L → Negl.* *A change in the rating from Low to Negligible should be based on reliable evidence that the post-harvest processes described in the Process 3: Defining the pathwayare highly likely to kill or render inviable the pest population remaining from the previous step. If this is the case, the risk assessment process can stop here. Continue to Process 9: Summarizing the final risk ratings and uncertainty.
	The pest is neither eliminated from the commodity nor does the population increase. In other words, you expect the pest prevalence in the commodity to remain more or less constant on the commodity through the post-harvest process.	**The baseline risk rating does not change.** The rating for A2 stays the same as the rating for A1.
	Either of the following apply: ◆ Evidence indicates that the prevalence of the pest can significantly increase in the period after harvest and before shipping. ◆ Safeguards for the commodity are absent, and this seems likely to lead to re-infestation (e.g., no insect-proof screens on field boxes or in the packinghouse). In other words, you expect the pest prevalence in the commodity to increase during the post-harvest process.	**Increase the baseline risk rating (A2) by one level.** **A1** | **becomes** | **A2** H → H M → H L → M
Continue to Risk Element A3: Likelihood of surviving transport and storage conditions of the consignment.		

Risk Element A3: Likelihood of surviving transport and storage conditions of the consignment. Here we assess the likelihood of the pest remaining with the commodity from packing through arrival. For this element, we consider the duration and conditions of transport and storage in the defined pathway, and the effects of these on pest survival. We also give the description of uncertainty associated with this rating.

Examples of factors you should consider include:

- Duration of the life cycle of the pest in relation to time in transport and standard shipping conditions. For example, if transport is by air, the risk is likely to be high for most of the organisms because of the short duration of transport.
- Vulnerability of the life stages during transport or storage. Some conditions (combination of temperature and storage time) could be close to the limits of cold tolerance for certain life stages.
- Standard industry practices and their possible effect on the survival of the pest, if any.

NOTE

Do not give a separate rating for Risk Element A3: Likelihood of surviving transport and storage conditions of the consignment. Rather, depending on this likelihood, adjust the rating from Risk Element A2: Likelihood of surviving post-harvest processing before shipment up or down one level, or not at all, as appropriate.

<table>
<tr><th colspan="3">Risk Element A3: Likelihood of surviving transport and storage conditions of the consignment</th></tr>
<tr><th></th><th>IF</th><th>THEN</th></tr>
<tr><td>Step 4</td><td>Either of the following apply:
◆ Conditions in transit or storage are equivalent in duration and temperature to an approved APHIS treatment against the same pest on the same commodity.
◆ Evidence indicates that the entire pest population is highly likely to be killed or rendered inviable during transportation or storage.</td><td>The rating is Negligible. Stop the risk assessment for the pest here. Summarize your finding and uncertainty.
Continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63.</td></tr>
<tr><td></td><td>Neither of the above apply.</td><td>Go to Step 5.</td></tr>
<tr><th colspan="3">Determine which of the situations in Step 5 best applies to your pest, provide your rating, rate your uncertainty, and provide a narrative explanation for your decision. Then go to Procedure 7-2: Determining the likelihood of establishment (Risk Element B).</th></tr>
<tr><td>Step 5</td><td>Evidence indicates that the conditions of transport or storage in the defined pathway would significantly reduce the pest population with the commodity.</td><td>Decrease the risk rating for A2 by one level.
<table>
<tr><th>A2</th><th>becomes</th><th>A3</th></tr>
<tr><td>H</td><td>→</td><td>M</td></tr>
<tr><td>M</td><td>→</td><td>L</td></tr>
<tr><td>L</td><td>→</td><td>Negl.*</td></tr>
</table>
*A change in the rating from Low to Negligible should be based on reliable evidence that the post-harvest processes described in the Process 3: Defining the pathway are highly likely to kill or render inviable the pest population remaining from the previous step. If this is the case, the risk assessment process can stop here. Continue to Process 9: Summarizing the final risk ratings and uncertainty.</td></tr>
<tr><td></td><td>The transport and storage conditions in the defined pathway have no effect on the pest population.</td><td>The risk rating does not change. The rating for A3 stays the same as the rating for A2.</td></tr>
<tr><td></td><td>Either of the following apply:
◆ Evidence indicates that the prevalence of the pest can significantly increase during shipping (specify conditions)
◆ Safeguards for the commodity are absent and this can lead to re-infestation</td><td>Decrease the risk rating for A2 by one level.
<table>
<tr><th>A2</th><th>becomes</th><th>A3</th></tr>
<tr><td>H</td><td>→</td><td>H</td></tr>
<tr><td>M</td><td>→</td><td>H</td></tr>
<tr><td>L</td><td>→</td><td>M</td></tr>
</table></td></tr>
</table>

Procedure 7-2. Determining the likelihood of establishment (Risk Element B)

Risk Element B: Likelihood of establishment

In this risk element, we assess the pest opportunity for establishment based on availability of host and suitable climate. It consists of two independent risk elements, Risk Element B1: Likelihood of coming into contact with host material in the endangered area and Risk Element B2: Likelihood of arriving in the endangered area, which can be analyzed in either order. If the risk rating for either element is Negligible, the analysis of the pest can stop at that point.

Risk Element B1: Likelihood of coming into contact with host material in the endangered area. First, we assess how likely the pest is to come into contact with a suitable host. To do this, consider the following:

- The endangered area identified in Process 5: Collecting information and defining the endangered area.
- Distribution of hosts in the endangered area. If applicable, consider if the pest requires alternate hosts to complete its life cycle, and if those hosts are present in the endangered area (e.g., the developmental cycle of some aphids).
- The pest life stage(s) present on the imported commodity and information relating the likelihood of it coming into contact with a host and attacking/ infecting it. For example:
    - known dispersal mechanisms (e.g., active or passive dispersal mode).
    - vectors needed for its dispersal and their presence in the endangered area.
    - proportion of survivors within a certain time period after leaving the commodity.
    - ability to complete development and/or reproduce on the commodity before or after arrival in the endangered area.

NOTE
It is essential to follow the order of steps when rating this risk element.

Risk Element B1: Likelihood of coming into contact with host material in the endangered area Use the following guidance to determine the risk rating for Risk Element B1. Provide your rating, rate your uncertainty, and provide a narrative explanation for your decision.		
	IF	**THEN**
Step 1	Any of the conditions listed below apply to the pest situation you are assessing. ◆ The phenological stage of available hosts in the endangered area is unsuitable for pest establishment during the importation season, and the pest cannot survive until the host becomes suitable. ◆ A vector or other agent required for contact with the host to occur is absent in the endangered area or present but cannot acquire or transmit the pest (i.e., does not feed on the discarded plant part). ◆ The pest life stage present is highly unlikely to move on its own from the commodity to a new host and ❖ is highly unlikely to develop into a dispersing life stage, OR ❖ the dispersing life stage of the pest is very short-lived and very susceptible to different mortality factors (e.g., exposure to elements, natural enemies, etc.).	**The rating for Risk Element B1 is Negligible.** Stop the risk assessment for the pest here. Summarize your finding and uncertainty. Continue to Process 9: Summarizing the final risk ratings and uncertainty.
	None of the above conditions apply.	Go to Step 2.
Step 2	Any of the conditions listed below apply to the pest situation you are assessing. ◆ Conditions necessary for the pest's transmission to the host are seldom met (e.g., temperature, moisture). ◆ Few natural hosts exist in the endangered area. For example: ❖ very low host density in the stands or their populations are sparsely distributed through the endangered area. ❖ hosts are tropical/subtropical plants only and not commercially produced. ❖ pest has a restricted host range. ◆ Vector or other dispersal agent is present (if required), but with low prevalence. ◆ Dispersing life stage of the pest has limited ability to disperse naturally.	**The rating for Risk Element B1 is Low.**
	None of the above conditions apply.	Go to Step 3.

Risk Element B1: Likelihood of coming into contact with host material in the endangered area **Use the following guidance to determine the risk rating for Risk Element B1. Provide your rating, rate your uncertainty, and provide a narrative explanation for your decision.**		
	IF	**THEN**
Step 3	Given that the pest is capable of dispersing on its own or through a widely prevalent vector, any of the conditions listed below apply to the pest situation you are assessing. ◆ Suitable hosts are widely established in only a limited portion of the endangered area (e.g. commercially-produced warm climate crops when the endangered area includes both temperate and warm climate areas). ◆ Suitable hosts are not continuously distributed throughout the endangered area (e.g., botanical gardens). ◆ The commodity may arrive in the endangered area at times when phenology of the host is not suitable. ◆ The environmental requirements necessary for the pest's successful transfer to and establishment on new hosts in the endangered area are met only under certain conditions (e.g., season, temperature, humidity, etc.).	**The rating for Risk Element B1 is Medium.**
	None of the above conditions apply.	Go to Step 4.
Step 4	Given that the pest is capable of dispersing on its own or through a widely prevalent vector, the following conditions should apply to the pest you are assessing. ◆ Suitable hosts are widely and regularly distributed throughout the entire endangered area. ◆ Suitable hosts in the endangered area are available regardless of season. ◆ No alternate hosts are needed to complete development or, if needed, are widely available. ◆ All environmental requirements are usually met for the pest's transfer to a suitable host in the endangered area (e.g., wind, water, temperature).	**The rating for Risk Element B1 is High.**

Risk Element B2: Likelihood of arriving in the endangered area. In most cases, we have little information about commodity movement in the PRA area. For this reason, in the absence of specific evidence, we assume that commodities move throughout the PRA area in proportion to consumer population size, with more populous areas getting more of the commodity than less populous areas. This assumption implies that larger volumes of the commodity will be moved to more populated areas, thus increasing the risk of pests entering those areas. We, however, are not taking into account the actual volumes of the commodities arriving in different areas as such information is not readily available and is prone to market fluctuations.

If specific information exists about where the commodity is most likely to move, its shipping frequency, or seasonality, this information can be used to determine more precisely the likelihood of the pest finding a suitable climate. For example, if we have evidence that a commodity would be imported only to an area where certain ethnic markets are located, and this region is outside the endangered area, or that the commodity is intended for specific seasons (e.g., holidays), such information can be used to lower the rating (see Step 2).

If the endangered area described in Process 5: Collecting information and defining the endangered area is defined in terms of temperature or plant hardiness zones, we may use Supplement 2: Plant Hardiness Zones Area and Population Analysis to easily find the percentage of the U.S. population that occurs within the zones corresponding to the endangered area. If the endangered area is defined in another way, we use the latest U.S. census to calculate the total population in the PRA area and in the endangered area. We calculate the proportion of the population in the endangered area relative to the population in the PRA area.

NOTE
A rating of Negligible is not possible for Risk Element B2, because an endangered area has been identified within the PRA area, and we assume that any commercial trade volume is significant enough for there to be some risk.

<table>
<tr><th colspan="3">Risk Element B2: Likelihood of arriving in the endangered area
Determine the base rating for this element using the criteria below.</th></tr>
<tr><th></th><th>IF</th><th>THEN</th></tr>
<tr><td>Step 1</td><td>Less than 10 percent of the population lives within the endangered area.</td><td>The rating for Risk Element B2 is Low. Go to Step 2.</td></tr>
<tr><td></td><td>Between 10 and 25 percent of the population lives within the endangered area.</td><td>The rating for Risk Element B2 is Medium. Go to Step 2.</td></tr>
<tr><td></td><td>Greater than 25% of the population lives within the endangered area.</td><td>The rating for Risk Element B2 is High. Go to Step 2.</td></tr>
<tr><th colspan="3">Based on the criteria in Step 2, adjust the rating from Step 1 up or down as appropriate. Then go to Procedure 7-3: Determining the combined likelihood of establishment.</th></tr>
<tr><td>Step 2</td><td>You do not have specific information about the distribution of the commodity (including its destination, shipping season, frequency, etc.), or what is known about its distribution is unlikely to change the risk.</td><td>Your analysis of Risk Element B can stop here. Continue to Procedure 7-3: Determining the combined likelihood of establishment.</td></tr>
<tr><td></td><td>At least one of the following statements applies:
◆ The commodity is likely to solely be distributed in specialty markets outside of the endangered area.
◆ The commodity has a very short shipping season (e.g. 1 month or less)
◆ The commodity will only be imported infrequently (e.g., less than 5 times) in small quantities during times of year that would prevent pest establishment (e.g., winter months).</td><td>Decrease the risk rating for B2 by one level.<table><tr><th>B2</th><th>becomes</th><th>B2’</th></tr><tr><td>H</td><td>→</td><td>M</td></tr><tr><td>M</td><td>→</td><td>L</td></tr><tr><td>L</td><td>→</td><td>Negl.*</td></tr></table>*Requires a high degree of uncertainty (i.e., a rating of C or MC); otherwise, leave as Low.</td></tr>
<tr><td></td><td>Either of the following statements apply:
◆ The commodity is likely to be distributed mainly to markets within the endangered area throughout the year, including seasons that are favorable for pest establishment.
◆ Either high volumes or frequency of imports justify increasing the risk rating.</td><td>Increase the risk rating for B2 by one level.<table><tr><th>B2</th><th>becomes</th><th>B2’</th></tr><tr><td>H</td><td>→</td><td>H</td></tr><tr><td>M</td><td>→</td><td>H</td></tr><tr><td>L</td><td>→</td><td>M</td></tr></table></td></tr>
</table>

Procedure 7-3. Determining the combined likelihood of establishment

Risk Element B: Combined likelihood of establishment

The matrix in this procedure is used to combine Risk Element B1: Likelihood of coming into contact with host material in the endangered area and Risk Element B2: Likelihood of arriving in the endangered area in order to determine the overall likelihood of the pest becoming established in the endangered area via the specific commodity import pathway. If Risk Element B1 is Negligible, the overall likelihood of establishment (Risk Element B) is Negligible and no further analysis is needed. This is shown as “no analysis” in the matrix below. The other values for the Likelihood of Establishment are found as the intersection in the matrix for the ratings of Risk Elements B1 and B2.

Risk Elements B1 and B2 will be rated High when the pest is likely to come in contact with suitable hosts in the endangered area (during times favorable for pest establishment) and it coincides with a large consumer presence in the area. If either risk element is not ranked High, then Risk Element B1: Likelihood of coming into contact with host material in the endangered area is the “weighting” factor for the likelihood of establishment (e.g., a combination of High and Medium ratings becomes High). The assumption is that pest’s ability to come in contact with hosts is an intrinsic factor for that pest-commodity association and remains stable regardless of the area of the commodity’s distribution. Distribution of the commodity is more likely to be affected by changes in market demands or in demographics.

Risk Element B: Combined likelihood of establishment

Combine Risk Elements B1 and B2 using the matrix in this procedure to determine the rating for Risk Element B. In the risk assessment, state the rating, rate your uncertainty, and provide a narrative explanation for your decision.

		Risk Element B1: Likelihood of coming into contact with host material in the endangered area			
		Negligible	**Low**	**Medium**	**High**
Risk Element B2: Likelihood of arriving in the endangered area	**High**	**no analysis**	**M**	**M**	**H**
	Medium		**L**	**M**	**H**
	Low		**L**	**M**	**M**

Determining the overall likelihood of introduction

If the overall likelihood of introduction is High, this implies possible continuous entries of sizable pest populations (Risk Element A: Likelihood of entry is High or Medium) and high likelihood of the commodity being moved to parts of the Endangered Area with the High consumer population and of the pest’s High ability to transfer to a new host (Risk Element B: Likelihood of establishment is High). If the likelihood of pest entry (Risk Element A: Likelihood of entry) is Low and the likelihood of establishment in the endangered area (Risk Element B: Likelihood of establishment) is High, the overall rating will be Medium. Similarly, if the likelihood of introduction is Low, this implies possible irregular entries of smaller pest populations (Risk Element A: Likelihood of entry is Low or Medium) and limited opportunity for the pest to be moved to areas with high consumer populations and/or limited ability of the pest to come into contact with host material (Risk Element B: Likelihood of establishment is Low).

Procedure 7-4. Determining the overall likelihood of introduction

The rating for overall Likelihood of Introduction is weighted towards pest establishment because this element is more important. If the pest cannot establish then the likelihood of entry becomes irrelevant. Once a pest has entered, we are most concerned with its establishment potential.

Risk Element B: Combined likelihood of establishment

Combine the ratings for the likelihoods of entry (Risk Element A) and establishment (Risk Element B) into a rating for the overall likelihood of introduction according to the matrix below. If either entry (Risk Element A) or establishment (Risk Element B) is rated Negligible, the overall likelihood of introduction is Negligible and no further analysis is needed.

		Risk Element B: Likelihood of Establishment		
		Low	Medium	High
Risk Element A: Likelihood of Entry	High	M	M	H
	Medium	L	M	H
	Low	L	M	M

Process 8: Assessing potential consequences of introduction

The purpose of this process is to determine whether the introduction of the pest would result in unacceptable economic consequences in terms of the potential agricultural, environmental, and social impacts that could result from the pest establishing in the endangered area. We evaluate the consequences of introduction without respect to the pathway of introduction by assuming a hypothetical situation where the pest is introduced and fully expressing its potential economic consequences in the endangered area.

We evaluate both direct impacts (i.e., impacts resulting from pest damage to host plants) and trade impacts. In general, we do not identify or evaluate indirect impacts beyond potential trade impacts, even though we acknowledge that such impacts are often unacceptable. However, it is not the purpose of this analysis to estimate the magnitude of the total impacts, but instead only to determine whether a given pest is likely to cause unacceptable economic consequences. Therefore, it is sufficient to limit our evaluation of potential consequences to the direct pest effects and the potential impacts to trade. Any other unacceptable impacts would likely occur as a result of one or more direct or trade impacts.

Similarly, although in practice the total consequences of introduction of a pest would be dependent on the rate and manner of spread in the PRA area, because, again, we are not estimating the magnitude of the total consequences, it is sufficient for the purposes of this analysis to simply determine if the spread potential of the pest is significant enough that it would be likely to spread throughout the endangered area within a reasonable period of time. Pests that have a Low or Negligible spread potential are not likely to cause unacceptable impacts unless the damage potential of the pest is High.

Pests that are likely to cause unacceptable consequences are termed “threshold pests”; those that are not likely to cause unacceptable consequences are termed “non-threshold pests.” By using this approach we explicitly acknowledge that non-threshold pests may cause some damage in the PRA area; however, that level of damage is expected to be low enough that routine port-of-entry inspection will be sufficient to mitigate the risk associated with their possible entry. Threshold pests, on the other hand, are expected to cause a level of damage that may warrant additional phytosanitary measures beyond routine port-of-entry inspection (to reduce their likelihood of entry) in order to meet the acceptable level of risk.

A pest is not likely to cause unacceptable direct impacts in the endangered area if any of the following criteria applies:

- The pest is not likely to cause significant losses to commercial or non-commercial plants as a result of mitigating conditions in endangered area.

- Should the pest become established in any portion of the endangered area, its ability to move beyond its initial point of introduction is very limited, so that spread in the endangered area is likely to be very slow or negligible, limiting any potential damage to a localized area.

A pest is not likely to cause unacceptable trade impacts if hosts of the pest are not exported, if the pest already occurs in countries importing commodities from the endangered area that are likely to be pathways for moving the pest, or if the countries already require phytosanitary measures for the exported commodity that will be effective against the pest.

In determining whether a pest will cause unacceptable damages to the PRA area, we evaluate how the pest is behaving in its current area of distribution. When the evidence suggests that a given pest is behaving differently in different parts of its distribution, we place emphasis on how the pest behaves in the parts of the distribution most similar to the endangered area. In many cases, there is little evidence to predict how a pest will behave in the endangered area. In these circumstances, our uncertainty rating may be high, and such pests should be explicitly identified in the notes to the risk managers.

Once it can be shown that the consequences of the pest's establishment in the PRA area will likely exceed a certain threshold of damage, the pest is determined to be a threshold pest. It is beyond the scope of this analysis to attempt to quantify, estimate, or predict the magnitude of potential pest effects. It is important to understand, therefore, that the analysis of a particular pest will not necessarily identify all of the potential impacts that would likely result from its introduction. This approach is consistent with ISPM No. 11 (2004b), which acknowledges that detailed analysis of the consequences of introduction is not necessary when it is widely agreed that pest introduction will have unacceptable consequences. The approach is sufficient for most pests analyzed in commodity import assessments., but a more detailed economic analysis of potential consequences can be conducted separately, if needed.

Procedure 8-1. Determining the potential direct impacts (Risk Element C)

Risk Element C: Determining the potential direct impacts

Risk Element C1: Damage potential in the endangered area. Consider the climate and cultural conditions that exist in the endangered area and decide whether the introduction of the pest in the endangered area will result in unacceptable economic (including environmental and social) damage or loss to plants in the endangered area. Assume a hypothetical situation where the pest is introduced throughout the endangered area and fully expressing its potential economic consequences. In general, you should consider only evidence related to plants identified in Step 3 of Procedure 5-2: Defining the endangered area. Do not consider symptoms/damage on unrelated plants, unless they are very similar.

<table>
<tr><th colspan="2">Risk Element C1: Damage potential in the endangered area</th></tr>
<tr><td>Step 1</td><td>Identify the climatic and cultural conditions in the endangered area that are likely to impact the damage potential of the pest.

Consider:
◆ climatic conditions that would affect pest population and/or virulence.
◆ host distribution (including amount of production of cultivated hosts and abundance of environmental hosts) in the endangered area.
◆ conditions that would affect the status of conditional hosts.
◆ current standard production practices of the cultivated hosts at risk (including any organic production). Note any practices that would likely mitigate the consequences of establishment of the pest. Examples of such practices include:
❖ pesticides routinely applied for other pests that would also control the pest being assessed.
❖ cultural control practices such as field sanitation, crop rotation, etc.
❖ planting of host-resistant varieties and/or clean stock.
◆ the presence and distribution of similar pests in the endangered area, including natural areas. Note the impact these pests currently cause in the endangered area. Consider questions such as
❖ how would the damage caused by this pest compare?
❖ how are similar pests in the endangered area being controlled (including natural controls), if at all?
❖ if control practices are in place, would they also mitigate this pest?

Continue to Step 2.</td></tr>
<tr><td>Step 2</td><td>With respect to the conditions in Step 1, estimate the damage potential of the pest in the endangered area in terms of percent losses. Then go to Step 3.

Factors to consider:
◆ how widespread each condition is in the endangered area (for example, consider standard production practices of commercial hosts vs. organic production, presence and density of environmental/wild hosts, etc.).
◆ host preference and status.
◆ type of damage caused by the pest on hosts present in the endangered area (see Step 4 of Procedure 5-2: Defining the endangered area).
◆ ease of control. Are pesticides/treatments for the pest readily available?
◆ ease of detection (affects surveillance and monitoring costs).
◆ is pest likely to be mitigated/controlled by any of the conditions in the endangered area?</td></tr>
</table>

Risk Element C1(a): Damage potential to commercial hosts		
	IF	**THEN**
Step 3	Either of the following statements apply. ◆ The introduction of the pest in the endangered area would likely result in 10 percent or greater yield losses in at least one commercially cultivated host. ◆ The introduction of the pest would likely result in a significant increases in costs of production beyond normal annual fluctuations. For example, consider increased costs to producers due to the implementation of additional control practices (or regimes) in the endangered area (beyond those already in place for the control of similar pests) and/or costs associated with surveillance and monitoring.	**Potential damage in the endangered area is significant.** In the risk assessment, indicate that the pest meets the criteria for having the potential to cause unacceptable damage in the endangered area. Rate your uncertainty, summarize the evidence, and then proceed to Step 5.
	Neither of the above statements apply.	Go to Step 4.

Risk Element C1(b): Damage potential to non-commercial hosts		
	IF	**THEN**
Step 4	Either of the following statements apply. ◆ The type of damage or symptoms caused by the pest in the endangered area would likely result in population reduction (beyond normal fluctuations) of threatened and endangered, or socially and other environmentally important plants. Do not consider "quality" losses. Do not consider host congeners unless you have evidence the pest damages multiple congeners. ◆ The introduction of the pest in the endangered area would likely result in significant reductions of amenity values (due to obviously and visibly damaged plants) beyond normal annual fluctuations.	**Potential damage in the endangered area is significant.** In the risk assessment, indicate that the pest meets the criteria for having the potential to cause unacceptable damage in the endangered area. Rate your uncertainty, summarize the evidence, and then proceed to Step 5.
	Neither of the above statements apply.	**Potential damage in the endangered area is not significant.** In the risk assessment, indicate that the pest does not meet the criteria for having the potential to cause unacceptable damage in the endangered area, rate your uncertainty, and summarize the evidence. Continue to Procedure 8-4: Determining potential trade impacts.

Risk Element C2: Spread potential

In this risk element, you will determine the likelihood that the pest will spread beyond its initial point of introduction within a reasonable amount of time. Pests that have a Low or Negligible spread potential are not likely to cause unacceptable impacts unless the damage potential is High.

Risk Element C2: Spread potential	
Step 5	Consider the following factors: ◆ current distribution and spread patterns of the pest. For example, is the pest spreading rapidly around the world? How quickly is the distribution of the pest expanding, particularly in areas it has been introduced that are climatically similar to the endangered area? ◆ abundance and continuity of natural hosts in the areas in endangered area. If applicable, consider if the pest requires alternate hosts to complete its life cycle. ◆ dispersal potential ❖ natural dispersal mechanisms (flight, vectors, rain/wind, etc.) and availability of such mechanisms in the endangered area. ❖ intentional or unintentional movement of infected or infested plants or plant products (for example, a pathogen infecting only leaves may not likely be moved by humans if the leaves are not part of the commodity). ❖ intentional movement of the organism. ❖ ability of the organism to hitchhike on conveyances. ◆ relevant life history of the pest. ❖ life stages (including duration). ❖ reproductive strategies (fecundity, parthenogenesis, alternating generations, etc.). ❖ adaptive characteristics (dormancy, expansion of a host range, climatic tolerance, i.e., supercooling, etc.). ❖ ease of detection. ◆ control or mitigation practices in the endangered area that would limit spread.
Continue to Step 6.	

	IF	THEN
Step 6	The pest is **already present** in some portion of the endangered area.	Go to Step 7.
	The pest is **not already present** in the endangered area.	Go to Step 8.
Step 7	The pest has been present in the endangered area for **more than 10 years** and is not part of an official program for eradication, containment, or area-wide control.	**Spread potential is not significant.** In the risk assessment, indicate that the pest does not have a significant spread potential, rate your uncertainty, and summarize the evidence. Continue to Procedure 8-3: Additional analysis for pests with undetermined trade impact.
	The pest has been present in the endangered area for **fewer than 10 years**.	Go to Step 8.
Step 8	**Evidence indicates that the pest is spreading or has spread** in other parts of the world—that is, the distribution of the pest is expanding, particularly in areas where it has been introduced that are climatically similar to the endangered area.	**Spread potential is significant.** In the risk assessment, indicate that the pest has a significant spread potential, rate your uncertainty, and summarize the evidence. Continue to Procedure 8-2: Determining if the pest is likely to cause unacceptable direct economic impacts.
	There is **no evidence that the pest is spreading or has spread** in other parts of the world.	Go to Step 9.

	IF	THEN
Step 9	Any of the following statements apply. ◆ The pest requires specific vectors for dispersal that are not present in the endangered area. ◆ The pest has limited natural dispersal potential and is unlikely to be moved by humans. Consider the likelihood of humans moving the pest from an area of establishment in the endangered area to another portion of the endangered area (e.g., purposeful movement, accidental movement on plant parts in domestic trade, movement on fomites, etc.). Do not consider interception records. ◆ The dispersal abilities of the pest would not allow it to access the available hosts (e.g., hosts are patchy/non-continuously distributed, separated by geographic barriers, non-persistent vectors). ◆ The dispersal stage requires a specific combination of conditions which rarely occur together (e.g., wind-rain event at a particular life stage).	**Spread potential is not significant.** In the risk assessment, indicate that the pest does not have a significant spread potential, rate your uncertainty, and summarize the evidence. Procedure 8-3: Additional analysis for pests with undetermined trade impact.
	None of the above statements apply.	**Spread potential is significant.** In the risk assessment, indicate that the pest has a significant spread potential, rate your uncertainty, and summarize the evidence. Go to Procedure 8-2: Determining if the pest is likely to cause unacceptable direct economic impacts.

Procedure 8-2. Determining if the pest is likely to cause unacceptable direct economic impacts

Determine the likelihood of the pest to cause unacceptable direct economic impacts by combining the ratings for the damage potential (Risk Element C1) and spread potential (Risk Element C2) according to this procedure.

IF	AND	THEN
The damage potential (C1) was not significant.	→	**The pest is not likely to cause unacceptable direct impacts in the endangered area.** Go to Procedure 8-4: Determining potential trade impacts.
The damage potential (C1) was significant.	The spread potential (C2) was significant.	**The pest is likely to cause unacceptable direct economic impacts in the endangered area.** To analyze trade impacts (only necessary upon special request), go to Procedure 8-4: Determining potential trade impacts. Otherwise, continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63 if the likelihood of introduction has already been completed for this pest, or to Process 7: Assessing the likelihood of introduction on page 2-35 if the likelihood of introduction has not been completed.
The damage potential (C1) was significant.	The spread potential (C2) was not significant.	**The likelihood of the pest causing unacceptable direct economic impacts cannot be determined at this point.** Continue to Procedure 8-3: Additional analysis for pests with undetermined trade impact.

Procedure 8-3. Additional analysis for pests with undetermined trade impact

Pests that have a significant damage potential but do not have a significant spread potential may or may not meet the criteria for causing unacceptable direct impacts. Follow this procedure to determine the likelihood of causing unacceptable direct economic impacts for a pest whose likelihood of causing unacceptable direct economic impacts could not be determined using Procedure 8-2: Determining if the pest is likely to cause unacceptable direct economic impacts.

IF	THEN
Evidence suggests that the pest is capable of causing major damage (i.e., 50 percent field losses) and it meets one of the following criteria: ◆ Most of the commercial production of one or more of the pest's hosts occurs within a small area, such as a single hardiness zone, county, or other defined region. ◆ The pest is associated with a threatened or endangered species found in the endangered area.	**Consider the pest to meet the threshold of causing unacceptable direct economic impacts in the endangered area.**
The above does not apply.	**Consider the pest to not be likely to cause unacceptable direct economic impacts in the endangered area** and analyze the trade impacts using Procedure 8-4: Determining potential trade impacts. If potential trade impacts have already been analyzed and they are not likely to significant, conclude that the pest does not meet the threshold for causing unacceptable economic impacts.

Procedure 8-4. Determining potential trade impacts

Risk Element D: Determining potential trade impacts

Based on the total market for the host commodities at risk (identified in Step 3 of Procedure 5-2: Defining the endangered area), determine if introduction of the pest in the endangered area would likely result in unacceptable trade impacts to the PRA area, in terms of losses of existing export markets.

NOTE

Trade impacts are analyzed for the entire PRA area, not just the endangered area, because the entire PRA area may be impacted if the pest is able to establish in any portion of it. For example, trading partners may impose provisional measures until it can be demonstrated that the pest will not establish outside of the defined endangered area. Should the pest become established in the PRA area, there may be costs associated with demonstrating and maintaining pest-free areas (e.g., costs associated with surveys).

Risk Element D1: Determining export markets at risk.

Risk Element D1: Export markets at risk			
		IF	**THEN**
Step 1	Determine whether plant products potentially affected by the pest have been exported from the PRA area in the past five years. Consider the specific plant part(s) being exported, and the pest association with these parts.	No host commodities are currently being exported.	**The pest is not a threshold pest.** The analysis of potential trade impacts can stop here. Continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63.
		Host commodities are currently being exported.	Go to Step 2.
Step 2	Identify the export markets of the host commodities identified in step 1 from the PRA area and determine which of these markets are currently free from the pest or consider the pest to be of quarantine significance.	No export market is currently free from the pest (i.e., the pest is currently distributed everywhere that host commodities are currently being exported from the PRA area).	**The pest is not a threshold pest.** The analysis of potential trade impacts can stop here. Continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63.
		At least one export market for at least one host commodity is currently free from the pest.	Go to Step 3.

Risk Element D1: Export markets at risk			
		IF	**THEN**
Step 3	Determine the export value of host commodities that are typically exported to countries free from the pest or to countries where the pest is considered to be of quarantine significance. In general, you should start with major export commodities	The value of any commodity exported to countries free from the pest is greater than 10 percent of the total export value of that commodity.	Go to Step 4.
		The export value of every commodity exported to countries free from the pest is less than 10 percent of the total export value of that commodity.	**The pest is not a threshold pest.** The analysis of potential trade impacts can stop here. Continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63.

Risk Element D2: Likelihood of trading partners imposing additional phytosantiary requirements. In completing Step 4, consider factors such as:

- degree to which the exported commodity is processed. For example, is the exported commodity processed in such a way that the pest has a negligible likelihood of being moved with the commodity?
- current phytosanitary requirements already in place for the commodity. For example, do trading partners already require phytosanitary measures (for other pests) that would also mitigate this pest? (PCIT/EXCERPT)
- likelihood of taking action against the pest. For example, do trading partners currently maintain regulations for the pest? Do they currently take action on similar pests? Are they unlikely to take action against the pest because it is unlikely to establish in the country? (PCIT/EXCERPT; Trade director)
- importance of domestic production in the trading countries. For example, do trading partners have significant domestic production of any hosts associated with the pest? (FAO Stats). Do they export significant amounts of host commodities to countries that are free of the pest? (GTIS for trade; CABI, etc. for pest freedom)
- trade with other countries where the pest is currently distributed. For example, are trading partners currently importing host commodities from other countries where the pest is distributed? Under what conditions? What kinds of phytosanitary measures are required?

Risk Element D2: Likelihood of trading partners imposing additional phytosanitary requirements		
	IF	**THEN**
Step 4	Trading partners that are currently free from the pest would be likely to impose an export ban on host commodities, or require the implementation of additional phytosanitary measures on them as a condition of export.	**The pest is a threshold pest.** If you've already completed the likelihood of introduction for this pest, continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63. Otherwise, go to Process 7: Assessing the likelihood of introduction on page 2-35.
	The above does not apply.	**The pest is not a threshold pest.** The analysis of potential trade impacts can stop here. Continue to Process 9: Summarizing the final risk ratings and uncertainty on page 2-63.

Process 9: Summarizing the final risk ratings and uncertainty

For this process, we briefly summarize the results for the pests analyzed in Process 7: Assessing the likelihood of introduction and Process 8: Assessing potential consequences of introduction. For each pest, we separately present the overall result or rating for the likelihood of introduction assessment and the overall result for the consequences assessment.

NOTE
The results for likelihood and consequences of introduction are not combined to give one overall risk rating. We use these overall results to determine which of the analyzed pests are candidates for risk management and which are not. If warranted, we also provide a summary of the uncertainty associated with each pest analysis.

The final result of the qualitative uncertainty assessment should be the identification of most relevant sources of uncertainty and technical means for reducing them, as well as the evaluation of the overall effect of uncertainty sources on the risk estimate.

Procedure 9-1. Summarizing the final risk ratings and uncertainty

Follow the steps of this procedure to summarize the final risk ratings and uncertainty.	
IF	**THEN**
The pest meets at least one of the following criteria: ◆ no portion of the PRA area is likely to be endangered by the pest (i.e., the area endangered by the pest is Negligible). ◆ does not meet the threshold to likely cause unacceptable consequences of introduction. ◆ received a Negligible overall risk rating for likelihood of introduction.	**The pest is not a candidate for risk management.** In the "Summary and Conclusions" section of the risk assessment, summarize this list of pests in a table that contains, for each pest, the reason the pest is not a candidate for risk management. For each pest, if warranted, provide an uncertainty statement in the table; this statement should focus on identification of the most relevant sources of uncertainty and technical means for reducing them, as well as the evaluation of the overall effect of uncertainty sources on the risk estimate.
The pest meets the following criteria: ◆ meets the threshold to likely cause unacceptable consequences of introduction. ◆ received an overall risk rating for likelihood of introduction above Negligible.	**The pest is a candidate for risk management.** In the "Summary and Conclusions" section of the risk assessment, summarize this list of pests in a table that contains, for each pest, the likelihood of introduction overall rating (i.e., High, Medium, or Low). Note that the results of the consequences of introduction assessment do not need to be included in this table, as all these pests meet the threshold for unacceptable consequences. For each pest, if warranted, provide an uncertainty statement in the table; this statement should focus on identification of the most relevant sources of uncertainty and technical means for reducing them, as well as the evaluation of the overall effect of uncertainty sources on the risk estimate. Continue to Process 10: Risk mitigation notes on page 2-67.

Stage 3: Risk Management

Risk Management in pest risk analysis

The core elements of pest risk analysis are risk assessment and risk management. Pest risk management is defined by the IPPC as the “evaluation and selection of options to reduce the risk of introduction and spread of a pest” (ISPM No. 5: IPPC, 2012). This means that mitigations may be applied at any point in the production chain to reduce likelihood of entry (e.g., pre-border); or to reduce likelihood of establishment or spread (e.g., post-border).

There are three general aspects to risk management that should be considered: policy, analytical and operational. The policy aspect is that part of risk management where overall policy is considered, including the appropriate level of protection/acceptable level of risk. Several key principles of the SPS and IPPC apply to the policy aspects of risk management, including in particular the

- application of the appropriate level of protection (ALOP),
- principle of least trade restrictive measures (minimal impact),
- principle of non-discrimination (including national treatment),
- principle of managed risk, and
- principle of equivalence.

Non-technical factors (e.g., social and political concerns) may be considered under the policy component of risk management, or for instance, priorities for risk management may be decided by broader policy issues. Since zero-risk is not a reasonable option, risk management should focus on reduction of risk that can be justified and is feasible within the limits of available options and resources. In any case, the overarching policy of the NPPO, together with any country/commodity-specific policies, is usually the main driver in the ultimate decision-making stages for risk management. Usually the policy aspects of risk management are beyond the purview of the individual risk analyst—these decisions are carried out by decision-makers that are not involved in the risk assessment stage of PRA.

The analytical aspect of risk management is the component that considers and weighs various options for mitigating risk. Options are usually analyzed for efficacy and feasibility, and to some extent costs associated with various options. The analysis of options in pest risk management necessitates a close linkage with the pest risk assessment part of PRA. The risk assessment should provide relevant information and analysis regarding a particular pathway(s), control points, uncertainties identified in the assessment, pests likely to be in a pathway, and important information about the biology of the pest that may factor into the selection of risk management options (e.g., feeding strategies, host status, etc.). Risk management is therefore dependent on the risk assessment to provide information about what mitigation options may be useful, and how various mitigation options will affect overall risk.

The operational aspect of risk management is the selection and application of mitigation options that are decided upon based on the policy and analytical components of pest risk management. For imported commodities, this may be the designation of a specific work plan between trading partners, or the implementation of a preclearance program. Work plans will outline the activities that must be undertaken for the commodity to be imported (e.g., specified areas for export, packing conditions, treatments, etc.). Depending on the commodity, the pests and the level of risk involved, the operational component may be fairly simple (a single phytosanitary treatment like fumigation) to highly complex (a large-scale systems approach for managing several pests).

The IPPC has produced several standards that provide general guidance on pest risk management, as well as some standards that provide specific guidance on particular aspects of pest risk management—for instance, standards that address pest-free areas, specific pests like fruit flies or specific types of phytosanitary treatments. The ISPMs particularly relevant to pest risk management, and which may be consulted in identifying options, are shown in Table 2-2.

Table 2-2. ISPMs with special relevance for pest risk management.

ISPM No.	Title
1	*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*
4	*Requirements for the establishment of pest free areas*
10	*Requirements for the establishment of pest free places of production and pest free production sites*
14	*The use of integrated measures in a systems approach for pest risk management*
18	*Guidelines for the use of irradiation as a phytosanitary measure*
22	*Requirements for the establishment of areas of low pest prevalence*
23	*Guidelines for inspection*
24	*Guidelines for the determination and recognition of equivalence of phytosanitary measures*
26	*Establishment of pest free areas for fruit flies (Tephritidae)*
28	*Phytosanitary treatments for regulated pests*
29	*Recognition of pest free areas and areas of low pest prevalence*
30	*Establishment of areas of low pest prevalence for fruit flies (Tephritidae)*
32	*Categorization of commodities according to their pest risk*

Uncertainty in risk management

The primary purpose for identifying and communicating uncertainty is to provide the decision maker with as complete and objective a view of the risk as possible. Carefully noting and considering uncertainty in PRA also helps governments to identify priority research needs and highlights for trading partners the points where the provision of more or better information may improve a decision. The uncertainty noted in the assessments of economic consequences and likelihood of introduction should also be considered and included in the analysis of risk management options.

Where there is significant uncertainty, a conservative approach may be adopted as a temporary measure. However, the measures selected must nevertheless be based on a risk assessment that takes into account the available scientific information. In these circumstances the measures should be accepted as provisional and reviewed as soon as additional information becomes available.

The overall approach to dealing with uncertainty is addressed as a policy question, but it is the responsibility of the risk analyst to highlight uncertainty in the analysis and the potential effects of uncertainty during the risk management stage.

Process 10: Risk mitigation notes

In APHIS-PPQ, the processes of risk assessment and risk management for commodity imports are conducted separately and by two different groups within PPQ. Although individual risk analysts are not ultimately involved in developing the risk management for document for commodity imports, the analyst(s) that conducts the assessment is in the best position to provide analytical information that will inform the decisions being made about risk management. This information is placed in an internal document called "risk mitigation notes" to be shared with the risk managers to ensure that important information that would be of potential use in risk management is not lost. Preparing the risk mitigation notes is an informal process that will vary from analysis to analysis, but general guidance is on preparing this document is provided here.

Guidance for preparing risk mitigation notes

Step 1: Identify possible options

General options. Traditionally, measures applied to imported commodities have relied on high-efficacy (e.g., probit-9 mortality) phytosanitary treatments aimed at reducing the presence of a particular pest (e.g., a species of fruit fly) on a given commodity. For example, phytosanitary treatments may include fumigations, cold treatments, heat treatments, or irradiation. However, a wide array of measures may be applied to mitigate risk (either singly or in combination), in addition to traditional phytosanitary treatments. The measures listed below are examples of those that are most commonly applied to traded commodities. The available measures can be classified into broad categories. These include measures (ISPM No. 11: IPPC, 2004a):

- applied to the commodity post-harvest (e.g., brushing, washing, waxing, treatments),
- applied to prevent or reduce original infestation of the commodity by a pest(s) (e.g., integrated pest management (IPM) programs, bagging, safeguarding, sanitation, etc.),
- applied to ensure the area or place of production of the consignment is free from the hazard (e.g. pest free areas or areas of low pest prevalence), and
- concerning the prohibition of commodities (in the absence of any other feasible options).

Specific options. In Table 2-3, we summarize many of the risk management options commonly applied pre- and post-harvest to commodities to reduce, prevent or eliminate quarantine pests (IPPC, 2002). In some cases, a single measure may be sufficient to manage risk (e.g., a high mortality treatment); however, in many cases, additional measures are needed to reduce risk to an acceptable level.

Table 2-3. Measures that can be applied to manage pest risk^ (IPPC, 2002; Jang and Moffit, 1994).

Pre-harvest	Pest-free areas or areas of low pest prevalence Resistant cultivars Healthy planting material Pest mating or development disruption Sanitation and cultural controls Certification schemes Testing Protected conditions*
Harvest	Harvesting at specific times or specific stages of ripeness Culling infested products Field sanitation Harvest technique In-field chemical treatments Field surveillance Tarping* Sanitation*
Post-harvest handling	Post-harvest treatments (chemical, heat, waxing, washing brushing, etc.) Testing Culling Packinghouse inspection Processing (degree and type) Method of packing* Screening* Sanitation*
Shipping	Treatment in transit (e.g., cold treatment) Speed and type of transport Pre-shipment inspection Testing Sanitation* Type of packaging*

Table 2-3. Measures that can be applied to manage pest risk^ (IPPC, 2002; Jang and Moffit, 1994).

Distribution	Restrictions on ports of entry Restrictions on time of year Post-entry quarantine Post-entry Inspection Post-entry treatment Packaging*
End use	Restrictions on end-use Post entry processing Packaging*

*Indicates a safeguarding measure (see section on Systems Approaches).

^This table is not inclusive of all potential measures; it lists the most common measures used on imported commodities.

Systems approaches and control points. "Systems approach" is defined as "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" (IPPC, 2012). Systems approaches may be applied in cases where a single measure, such as a phytosanitary treatment, is either not available or is not likely to achieve the appropriate level of phytosanitary protection or in cases where the only other alternative is prohibition. The cumulative effect of combining independent measures can provide the necessary level of phytosanitary protection where no other alternatives are available.

Systems approaches include independent measures, redundancy, and safeguarding. Combining measures that act independently of each other has the advantage that if any one measure fails, the overall system maintains a high level of efficacy. Similarly, including redundant (or overlapping) measures means that if one measure applied at a particular point in the production chain fails, another measure directed at that same point will assure that mitigation of risk still occurs. Lastly, measures that do not necessarily reduce pest prevalence, but that are aimed at preventing any new risk from being introduced into the system are called "safeguards" (IPPC, 1999; Follett and Neven, 2006).

The types of measures that are applied in a systems approach can occur anywhere in a production chain, from pre-planting and pre-harvest through distribution and final end-use of the commodity (Table 2-3). Thus, the main advantage of systems approaches is that the risk is managed beginning at origin, thereby reducing the level of risk for the importing country. Systems approaches can also be used to mitigate the risk of pests that are not normally associated with the commodity (hitchhikers or contaminating pests), or pests that are not accounted for in the PRA process (unknown pests) (MAF, 2008).

In general, the use of a systems approach requires a relatively good knowledge of the production practices, the biology of the pest(s), and its relationship to the host(s) and post-harvest practices. In many cases, a systems approach can be highly flexible in the number and type of measures applied (as long as at least two measures act independently), even if specific data on efficacy is lacking. The number and types of measures combined in a systems approaches can range from very simple combinations (e.g., two independent measures such as low pest prevalence combined with fumigation) to highly complex, “control point” systems (IPPC, 1999; IPPC, 2002). This is dependent on the

- level of risk involved;
- cost, feasibility, and efficacy of possible measures;
- suitability of any given management option for managing that risk;
- availability of information for the pest(s) and associated commodity;
- the level of uncertainty; and
- the appropriate level of protection (or acceptable level of risk).

The role of control points in risk management and systems approaches. For the purposes of this discussion, it is useful to make a distinction between “control points” and “critical control points.” Control points are points where controls can be applied in the production chain, and the controls are expected to have some effect on the system (i.e., a reduction in risk). We may or may not be able to measure the exact effect of the control, but we would expect that the control would have some (perhaps undefined) level of efficacy. An example of a control point that may be difficult to measure would be field sanitation and the removal of fallen fruit from orchards to manage risks associated with fruit flies. We know that sanitation would reduce risk, but the exact level of efficacy would be difficult to measure. In addition, certain measures or conditions exist or are included to compensate for uncertainty. These may not be monitored as independent procedures (e.g., packinghouse sorting), or may be monitored but not controlled (e.g., host preference/susceptibility).

In other cases, the control points may be well defined, and the level of efficacy of that control can be measured, quantified, monitored, and verified. In addition, such points in the system may be points where controls must be applied in order to reduce risk sufficiently. These would be regarded as critical control points. For some commodities, most or all of the specific points in the production chain can be well defined, the hazards and mitigations can be measured, each point can be controlled, and the efficacy of each mitigation step can be verified and documented. In these cases, a "critical control point" system can be applied—this being the most rigid type of systems approach used for phytosanitary risk management (IPPC, 1999).

The use of a control point system for phytosanitary purposes does not imply or prescribe that application of controls is necessary to all control points. These are addressed by risk management procedures whose contribution to the efficacy of the system can be measured and controlled.

Even if a critical control point system is not used in risk management, the analysis of control points and critical control points may be useful to identify and analyze hazards as well as the points in a pathway where risks can be reduced and monitored and adjustments made where necessary.

Step 2: Identify information and option for risk management

The risk analyst is uniquely positioned to provide relevant information for the formulation of risk management options and plans. Throughout the analysis, the risk analyst should have documented information relevant to risk management for

- quarantine pests likely to follow the pathway,
- the pathway itself (see Process 3: Defining the pathway on page 2-6) and potential control points (and critical control points),
- potential effects of mitigations, and
- any uncertainty associated with the pest(s) and the pathway.

Table 2-4 and Table 2-5 provide examples of how and what type of information can be presented on both the pathway and the pests. It includes information on the pathway (described in the risk assessment) and information on pests gathered during the analysis that is particularly relevant to risk management. Figure 2-6 and Figure 2-7 are examples of a completed template using the fruit fly *Dacus ciliates* (pest) on Jordan beans (pathway).

Information presented to the risk manager should highlight potential mitigations for the pest(s) and the pathway, the anticipated effects of mitigations, and the level and source of uncertainty (if applicable). Note that analyzing the pathway for specific control points, as highlighted in the previous section may assist the analyst in determining whether mitigations applied at control points will have a significant effect on the overall risk (e.g., critical control points). The information provided to the risk manager should include particularly critical details from the analysis (including relevant uncertainty) that will aid in decision-making and in the determination of which measures will be most effective, feasible and justified.

Table 2-4. Examples of the type of pathway information useful for risk managers.

Information relevant to risk mitigation	Potential mitigations	Anticipated effect or impact	Uncertainty (level and source)
Pathway/commodity: include information on pathway/commodity/processing relevant to risk management. Information may come from exporting country or from technical sources.			
Production areas	Protected cultivation, pest-free areas, or areas of low pest prevalence	Prevention of infestation	Lack of specific data Conflicting data Variable data Variability of commodity Availability of technology Suitability of technology Effects on or of commodity Need for monitoring Efficacy of inspection Unintended use Volumes may not be tracked
Planting and harvest times	Pest-free time periods/reduced host susceptibility	Reduce or prevent infestation	
Cultivar selection	Host status/resistance	Reduce or prevent infestation	
Post-harvest handling	Washing, waxing, brushing, bathing, culling, etc.	Reduce or prevent infestation	
Processing	Peeling, baling, heating, cooling, cooking, milling, etc.	Reduce or prevent infestation	
Packing and safeguarding	Prevention of re-infestation	Prevention of re-infestation	
Treatments	Commodity tolerates various treatments	High mortality	
Shipment	Mode of shipments includes treatment potential (e.g., cold treat in transit)	Potential mortality	
Inspection	Commodity is easily inspect/tested	Detect infestation	
Intended use	Devitalization	Prevent establishment	
Volume of exports** (proposed by exporting country)	Note whether or not increased volumes beyond originally requested volume will affect overall risk	Potentially increase risk**	

Table 2-5. Examples of the type of pest information useful for risk managers.

Information relevant to risk mitigation	Potential mitigations	Anticipated effect or impact	Uncertainty (level and source)
Pest: include a section for each actionable pest or group pests as appropriate			
Pest biology (feeding, reproduction, development)	In-field pest management practices	Reduce or prevent infestation	Lack of specific data Conflicting data Variable data Variability of pest (e.g., biotype or strain differences) Availability of technology Suitability of technology Use of proxy species for treatments Efficacy of detection Unknown organisms
Seasonality	Time of harvest or shipping (e.g., when the pest is not active)	Reduce or prevent infestation	
Host specificity	Resistant cultivars, non-host status	Reduce or prevent infestation	
Susceptibility (or resistance) to treatments	Pre-shipment, in-transit, or post-entry treatments	Reduce or eliminate infestation	
Distribution (geographic, temporal)	Restrictions on time of year or destinations of imports	Prevent establishment	
Climate suitability	Restrictions on time of year or destinations of imports	Prevent establishment	
Environmental resistance or susceptibility	Various types of shipping conditions or post-harvest handling	Reduce infestation	
Detectable/testable	Field trapping, reliability of pre- or post-entry inspection	Detect infestation	
Presence of hitchhikers	Inspection	Detect infestation	
Role of vectors	Determine presence or absence of vectors in the United States by surveillance	Reduce establishment	

Table 2-6. Example reporting for the pathway/commodity combination of Jordan bean.

Relevant section of risk assessment	Information relevant to risk mitigation	Potential mitigation	Anticipated effect or efficacy	Uncertainty (level and source)
Scope, Risk Element A1	Production areas	Field management of pests in that country usually implements IPM programs, which includes biological control.	Some reduction in pest prevalence, particularly external feeders.	Medium high uncertainty, since specific controls are not listed.
Scope, Risk Element A1	Planting and harvest times	n/a	n/a	n/a
Scope, Risk Element A1	Cultivar selection	n/a	n/a	n/a
Scope, Risk Element A2	Post-harvest handling	Beans need to be intact, fresh appearance, clean (in particular free from any impurity or any visible chemical trace), free from foreign smell or taste, free from all abnormal external moisture, and sufficient size. The state of the product must be such as to enable it to withstand transport and handling.	Some removal of external pests; anticipate a medium level of efficacy for this measure, but it would be insufficient alone.	Medium high certainty that this measure is effective for removing most external pests.
Scope, Risk Element A2	Processing	n/a	n/a	n/a
Scope, Risk Element A2	Packing and safeguarding	Standard packinghouse procedures: 1) The contents of each package must be uniform and contain only beans of the same origin, variety, and quality. 2) Packaging must be of such a kind as to ensure that the beans are properly protected; any paper or other material used inside the package must be new and harmless to human food; and when printed matter is used the printing must be on the outside only so as not to come into contact with the product. Each package must be legibly and indelibly marked on the outside with data for 1) Packer and dispatcher identification: name, address or code mark; 2) Nature of the product description: type (fresh beans, runner beans, and fine beans) or variety; 3) Product origin: district or national, regional or local, and trader name; 4) Commercial specification description: class, sizing, and classification; and 5) Official control mark.	Protection against re-infestation post-packaging—generally highly effective at preventing an increase in risk.	Medium high certainty that this measure is effective for preventing re-infestation by pests.
Scope, Risk Element A3	Shipment	n/a	n/a	n/a

Table 2-6. Example reporting for the pathway/commodity combination of Jordan bean.

Relevant section of risk assessment	Information relevant to risk mitigation	Potential mitigation	Anticipated effect or efficacy	Uncertainty (level and source)
Scope, Risk Element B2	Import timing	n/a	n/a	n/a
Scope	Treatments	n/a	n/a	n/a
Scope	Intended use	Beans are intended for consumption. It is possible, however, that beans could be used for planting.	Low increase in risk possible if beans were to be planted and are viable.	High uncertainty—data to support or refute potential risk are not available.
Scope	Volume of exports**	n/a	n/a	n/a
Variable	Inspection	n/a	n/a	n/a
Variable	Other	n/a	n/a	n/a

Table 2-7. Example reporting for the pest *Dacus ciliates* (Tephritidae).

Relevant section of risk assessment	Information relevant to risk mitigation	Potential mitigation	Anticipated effect or efficacy	Uncertainty (level and source)
Risk Elements A1, A2, A3	Pest biology	n/a	n/a	n/a
Risk Elements A1, A2, A3, B2	Seasonality	**See climate suitability.	n/a	n/a
Risk Element A1	Host specificity	This species of fruit fly is primarily associated with cucurbits. Beans may only be a conditional host for this species—i.e., given high population pressure and proximity to cucurbit hosts. This may reduce the prevalence of the pest in the commodity.	Reduced prevalence of the pest in the commodity—in combination with a treatment, low prevalence is likely to be sufficient to manage risk for this pest.	Medium low—further information on host status (e.g., experimental and field data on whether beans are a natural host for this species would reduce uncertainty.

Table 2-7. Example reporting for the pest *Dacus ciliates* (Tephritidae).

Relevant section of risk assessment	Information relevant to risk mitigation	Potential mitigation	Anticipated effect or efficacy	Uncertainty (level and source)
Risk Element B1	Distribution	In combination with host status, the prevalence of this pest may be low in commercial bean production (depending on proximity to other host material and other environmental conditions). Surveillance records may inform as to whether this pest is present in sufficient numbers to present a risk in commercially produced beans.	Surveillance to demonstrate the prevalence of the pest will not reduce risk in itself but will provide supporting evidence in making determinations of host status (e.g., conditional host status) and will indicate if the population is low enough to be effectively treated with treatments such as cold treatment.	n/a
Risk Element B2	Climate suitability	Importation of beans from Jordan during winter months would reduce survivability of this pest if infested beans were imported.	Reduce likelihood of establishment since this species is a subtropical pest.	Medium low.
Risk Elements B1, B2	Environmental resistance or susceptibility	n/a	n/a	n/a
Scope	Presence of hitchhikers	n/a	n/a	n/a
Variable	Detectable/ testable	n/a	n/a	n/a
Variable	Susceptibility or resistance to treatments	Fruit flies in the family Tephritidae are susceptible to many types of treatments including cold treatment and irradiation. In combination with conditional host status, a treatment would be sufficient to manage risk associated with this pest.	Reduce risk to an acceptable level for this pest.	Medium low uncertainty--specific treatments for this pest may not exist, in which case proxy treatments may be necessary.
Variable	Role of vectors	n/a	n/a	n/a
Variable	Other	n/a	n/a	n/a

Section 3

Supplements and References

Supplement 1: WTO Disputes

The SPS Agreement contains provisions for settling disputes between Members in cases where Members contend that another's measures are not consistent with the Agreement. To date, there have been six dispute settlement cases related to the SPS Agreement, and in each case, risk analysis has played a prominent role. The cases are:

- The Variety Testing Case (the United States vs. Japan)
- The Hormones Case (the United States and Canada vs. the European Communities)
- The Salmon Case (Canada vs. Australia)
- The Fire Blight Dispute (the United States vs. Japan)
- The Fire Blight Dispute (New Zealand vs. Australia)

- The GMOs Case (the United States and Canada vs. the European Communities)

This section provides a brief summary of five of those cases, including a description of key SPS principles relevant to each case.

The Variety Testing Case (the United States vs. Japan)

Measure at issue. Japan's requirement to test each variety of certain agricultural products (apples, cherries, peaches, walnuts, apricots, pears, plums, and quinces) for the efficacy of treatment against codling moths. The United States claimed that it was not necessary to test each variety of a fruit for the efficacy of the treatment.

In this case, the issue of scientific justification was the key SPS principle being tested. Members have two options to show that their measures are based on science. They may either:

- base their measures on international standards or
- base their measures on scientific risk assessment.

Panel findings. The variety testing requirement violated Article 2.2 since there was no rational relationship between the scientific evidence submitted by Japan and the measure.

The exception provided in Article 5.7 did not apply. Japan invoked this article, which allows Members to take provisional measures where scientific information is insufficient. However, the Panel found no evidence that Japan had actively sought to obtain additional information in order to review its measure within a reasonable period of time, as required by Article 5.7.

The variety testing requirement violated Article 5.6 since it was more trade-restrictive than required to achieve Japan's appropriate level of protection. The Panel was unable to rule on product-by-product testing, an alternative proposed by the United States, since it did not have sufficient evidence to decide whether this method achieved Japan's appropriate level of protection. But the Panel considered another testing method related to sorption levels as a less trade-restrictive alternative.

The measure violated Article 7 and Annex B. The Panel found the variety testing requirement should have been published although the requirement was not mandatory.

Appellate body findings. Upheld the Panel's finding on Article 2.2 that the measure was not based on science.

Upheld the Panel's finding on Article 5.7, and noted that the length of the "reasonable period of time" had to be established on a case-by-case basis.

Reversed the Panel's finding on Article 5.6 regarding determination of sorption levels. The alternative measure had not been proposed by the United States, which had the burden of proof.

Upheld the Panel's finding on Article 7 and Annex B, agreeing that the measure should have been published.

The Hormones Case (the United States and Canada vs. the European Communities)

Measure at issue. An EC (European Communities) ban on imports of beef from cows treated with hormones [oestradiol 17ß, progesterone and testosterone, trenbolone acetate (TBA), zeranol, and melengestrol acetate] for growth-promotion purposes. The EC claimed the ban was necessary for food safety; the United States and Canada claimed there was no evidence of harm to human health.

In this case, the key principles being tested were “harmonization” (basing measures on international standards) and/or technically justifying measures which deviate from standards (through risk assessment).

It is important to note that the encouragement to use international standards does not mean that these constitute a floor or a ceiling on national standards. National measures do not violate the SPS Agreement simply because they differ from international norms. According to Article 3 and Article 5 of the SPS Agreement, Members are permitted to adopt SPS measures that are more stringent than the relevant international standards or adopt SPS measures when international standards do not exist, provided the measures are

- based on scientific risk assessment,
- consistently applied, and
- not more trade restrictive than necessary.

Panel findings. The EC measure violated Article 3 on harmonization. Although international standards existed for five of the six hormones in question, the EC measure was not based on these standards; it reflected a higher level of protection and was not justified by a risk assessment, as required by Article 3.3.

The EC ban was not based on a risk assessment, and violated Article 5.1. The EC’s scientific studies on five of the hormones did not support the ban on hormone-treated meat.

The EC measure violated Article 5.5, because the level of protection sought for hormone-treated meat was higher than required in comparable situations; these differences were arbitrary or unjustifiable, and resulted in discrimination or a disguised restriction on trade. In particular, in contrast to the ban on hormones for growth-promoting purposes, the EC permitted higher levels of the same naturally occurring hormones in untreated meat and other foods; the use of the same hormones for therapeutic and herd management purposes; and the use of other growth promoters (such as the anti-microbial carbadox and olaquindox, known to be carcinogenic) in swine production.

The EC had not invoked Article 5.7, which allows precautionary measures to be taken on a provisional basis, but rather the “precautionary principle” in general. The Panel found that invoking the “precautionary principle” did not override a country’s obligations under the SPS Agreement.

Appellate body findings. Agreed with the Panel’s finding that since the EC measure reflected a higher level of protection than the international standard and was not justified by a risk assessment, it violated Article 3.

Confirmed the Panel’s finding on Article 5.1 that there was no rational relationship between the measure and the scientific evidence submitted on five of the hormones, and found that there was no risk assessment at all for the sixth hormone (melengestrol acetate).

Reversed the Panel’s findings on Article 5.5. The Appellate Body considered that there was a fundamental difference between added hormones and naturally-occurring hormones in meat and other foods, and that the therapeutic use of hormones involved closer supervision and control. Although the Appellate Body agreed that the difference between a ban on hormone-treated beef and the use of growth promoters in swine production was arbitrary, it did not consider that this resulted in discrimination or a disguised restriction on trade.

Upheld the Panel’s finding on the use of precaution and its relationship with Article 5.7.

Implementation/“retaliation”. When the EC was unable to implement by the May 13, 1999 deadline, the United States and Canada sought the right to retaliate against the EC in the amount of US$202 million per year and CDN$75 million per year. The arbitrators found the appropriate level to be US$116 million and CDN$11.3 million per year, respectively.

The Salmon Case (Canada vs. Australia)

Measure at issue. Australia's ban on importation of fresh chilled or frozen salmon, allegedly to protect the domestic salmon population from a number of diseases. Canada claimed that salmon imported for human consumption was very unlikely to lead to the introduction of these diseases.

In this case, the key principles being tested were "harmonization" (basing measures on international standards) and or technically justifying measures which deviate from standards (through risk assessment).

Panel findings. The import ban violated Article 5.1, because it was not based on a risk assessment. Australia had carried out a risk assessment for ocean-caught Pacific salmon, but the Panel found no rational relationship between the measure and the risk assessment. For the other types of salmon, no risk assessment had been carried out. The Panel considered that the measure prohibiting imports of fresh chilled and frozen salmon could also be described as a requirement that the salmon be heat-treated.

The Australian measure violated Article 5.5, because the level of protection sought for salmon was much higher than in comparable situations; these differences were arbitrary or unjustifiable, and resulted in discrimination or a disguised restriction on trade. In particular, there were no restrictions on imports of frozen herring for bait; and there were few restrictions on imports of live ornamental fish.

The ban on salmon was more trade-restrictive than required to achieve Australia's appropriate level of protection, and therefore violated Article 5.6.

Appellate body findings. Reversed the Panel's finding that the ban on the other types of salmon was not based on a risk assessment, because the Panel made the finding based on the heat-treatment requirement. It found, however, that Australia's risk assessment on ocean-caught Pacific salmon was not a proper risk assessment in the sense of the SPS Agreement, and the ban therefore violated Article 5.1. It upheld the finding that no risk assessment had been carried out for other types of salmon.

Upheld the Panel's finding on Article 5.5, that the higher level of protection on salmon resulted in discrimination or a disguised restriction on international trade.

Reversed the Panel's findings on Article 5.6 because it was based on the heat-treatment requirement, and not on the import ban.

Article 21.5 (Compliance) Panel findings. Australia had failed to comply by the deadline set by the arbitrator because its new measure on salmon took effect on July 19, 1999, and new measures on other fish (to comply with the consistency requirement) were phased in at later dates.

The requirement that salmon be in a particular consumer-ready form was not based on a risk assessment, and violated Article 5.1.

The definition of consumer-ready product was more trade-restrictive than required, and thus violated Article 5.6.

The Fire Blight Dispute (the United States vs. Japan)

Measure at issue. Japan's set of requirements on apples from the United States, including that they come from an orchard free of fire blight, surrounded by a buffer zone, undergo at least three annual inspections, chlorine treatment, etc. in order to prevent the entry of *Erwinia amylovora*, the bacteria that causes fire blight, into Japan. The United States claimed that there was no evidence that mature, symptomless apples could serve as a pathway for the disease.

In this case, the key principles being tested were “harmonization” (basing measures on international standards) and or technically justifying measures which deviate from standards (through risk assessment).

Panel findings. Japan's measure, the set of requirements taken as a whole, violated Article 2.2 because it was maintained without sufficient scientific evidence that apple fruit could serve as a pathway for the entry, establishment or spread of fire blight. The Panel considered the risk from mature, symptomless apples, the U.S. export product, and the risk that something other than mature, symptomless apples might be inadvertently or illegally shipped.

The exception provided in Article 5.7 did not apply. This was not a situation in which sufficient scientific evidence did not exist, rather, there was a wealth of scientific evidence regarding fire blight but it did not support Japan's measure.

Japan's measure violated Article 5.1 because it was not based on a risk assessment appropriate to the circumstances. Japan's pest risk assessment was not sufficiently specific regarding the risks of entry, spread or establishment through imported apples as opposed to other possible pathways, nor did the risk assessment evaluate the likelihood of entry, establishment or spread through apples. Furthermore, Japan's risk assessment failed to evaluate the risk according to the SPS measures which might be applied, but rather considered only the existing measures.

The Panel exercised judicial economy and did not rule on an alleged claim that the measure was more trade restrictive than necessary in violation of Article 5.6. The Panel found that the United States had failed to make a prima facie argument that the measure had not been notified and was in violation of Article 7 and Annex B.

Appellate body findings. The Appellate Body upheld the Panel's findings with respect to violations of Article 2.2 and 5.1, as well as with regard to the inapplicability of Article 5.7 in this situation. The Panel's findings on Article 7 and Annex B were not appealed.

In addition, the Appellate Body ruled that the Panel had the authority to make findings and draw conclusions with respect to all apple fruit from the United States, and not just with respect to mature, symptomless apples as the United States claimed.

The Appellate Body furthermore rejected an argument that the Panel had failed to objectively assess the evidence before it regarding the likelihood of completion of the last stage of the pathway.

Article 21.5 (Compliance) Panel findings. Japan breached Article 2.2 of the SPS Agreement by maintaining the compliance measure at issue without sufficient scientific evidence.

Japan violated Article 5.1 of the SPS Agreement because the phytosanitary measure was not “based on an assessment, as appropriate to the circumstances, of the risk to [...] plant life or health” in Japan because Japan relied on uncorroborated new studies that do not support the conclusion that imported apples could spread fire blight.

If the United States only exported mature, symptomless apples, the alternative measure proposed by the United States would meet the requirements of Article 5.6 as a substitute to Japan's current measure.

The GMOs Case (the United States and Canada vs. the European Communities)

Measure at issue. Alleged general EC moratorium on approvals of biotech products, EC measures allegedly affecting the approval of specific biotech products, and EC member State safeguard measures prohibiting the import/marketing of specific biotech products within the territories of these member States.

In this case, the issues of scientific justification, transparency, equivalence, and approval procedures were the key SPS principles being tested.

In 2003, the United States requested the establishment of a Panel to examine the EC's 1998 alleged moratorium on the approval of biotech products, which the United States claimed was restricting trade on food and agricultural products and was inconsistent with the SPS Agreement's Articles 2, 5, 7, and 8. The United States alleged that there existed a moratorium on the approval of biotech products, which since 1998 had limited the number of products receiving approval in EC states. Additionally, so-called "safeguard measures" were in place in six EC Member states, prohibiting certain biotech products that had already been approved at the EC level.

General EC moratorium. The Panel found that a general de facto moratorium on approvals of biotech products was in effect on the date of panel establishment, i.e., August 2003. It was general in that it applied to all applications for approval pending in August 2003 under the relevant EC legislation, and de facto because it had not been formally adopted. Approvals were prevented through actions/omissions by a group of five EC member States and/or the European Commission.

SPS Articles 5.1 and 2.2: The Panel found that the EC decision to apply a general moratorium was a decision concerning the application/operation of approval procedures, i.e., a procedural decision to delay final substantive approval decisions. It was not applied for achieving the EC level of sanitary or phytosanitary protection and, hence, was not an "SPS measure" subject to Articles 5.1 or 2.2.

SPS Annex C(1)(a) and Article 8: The Panel found that the general moratorium led to undue delay in the completion of the EC approval procedure conducted in respect of at least one biotech product at issue and thereby to the European Communities acting inconsistently with Annex C(1)(a) and, by implication, Article 8.

Product-specific measures. SPS Annex C(1)(a) and Article 8: The Panel found that in 24 of the 27 product-specific approval procedures it examined, the procedure had not been completed without undue delay. In respect of these procedures, the European Communities had, therefore, acted inconsistently with Annex C(1)(a) and, by implication, Article 8.

EC Member State safeguard measures. SPS Article 5.1, 2.2 and 5.7: According to the Panel, the record did not indicate that there was insufficient evidence to conduct a risk assessment within the meaning of Article 5.1 and Annex A(4) for the biotech products subject to safeguard measures. As a result, Arts. 5.1 and 2.2 were applicable. In this regard, the Panel found that none of the safeguard measures at issue were based on a risk assessment as required under Art. 5.1 and defined in Annex A(4). By maintaining measures contrary to Article 5.1, the European Communities had, by implication, also acted inconsistently with Article 2.2.

Figure 3-1. Relevant findings of SPS disputes.

SPS Disputes: Relevant Findings			
Dispute	**Related Articles**	**Panel Findings**	**Apellate Findings**
Australia Salmon	5.1(Must be based on appropriate risk assesment)	5.1	5.1
	2.2(Must be applied only to extent necessary)	2.2	2.2
	5.5(Arbitrary or unjustifiable distinctions)	5.5	5.5
	2.3(Scientific justification)	2.3	2.3
	5.6(Not more trade restrictive than necessary)	5.6	
Japan Varietals	2.2(Must be applied only to extent necessary)	2.2	2.2
	5.7(Provisional measures)	5.6	5.7
	5.6(Not more trade restrictive than necessary)	5.7	5.6
	5.1(Must be based on appropriate risk assesment)	Annex B	5.1
		7	
Japan Fire Blight	2.2(Must be applied only to extent necessary)	2.2	2.2
	2.3(Arbitrary or unjustifiable discriminations between Members)	5.7	5.7
	5.1(Must be based on appropriate risk assesment)	5.1	5.1
	5.2(Relevant scientific evidence and processes)		
	5.3(Relevant economic factors)		
	5.6(Not more trade restrictive than necessary)		
	6.1(Regional adaptation)		
	6.2(Pest or disease free areas; or areas of low prevelance)		
	7(Transparency in measures)		
	Annex B(Transparency of regulations)		
EC Biotech	2(Basic rights and obligations)	Annex C	N/A
	5(Risk assesment, appropriate level of protection)	8	
	7(Transparency in measures)	5.1	
	8(Control, inspection and approval procedures)	2.2	
EC Hormones	2(Basic rights and obligations)	3.1	3.3
	3(Harminization)	3.3	5.1
	5(Risk assesment, appropriate level of protection)	5.1	
		5.5	

Supplement 2: Plant Hardiness Zones Area and Population Analysis

Plant hardiness zones represent areas of average annual minimum temperatures, illustrating where it is safe to plant plants without frequent cold damage. They are a component of phytosanitary risk analysis and are a useful tool for estimating potential area of impact for plant pests. Using Geographic Information Systems (GIS), it is possible to determine the approximate area and population of the United States covered by each hardiness zone, which allows for a more accurate risk estimate.

Global plant hardiness zones were created by ZedX Inc. for the North Carolina State University APHIS Plant Pest Forecast System (NAPPFAST) using methods described in Magarey et al. (2008). The zones were created at a grid resolution of 10 km using monthly data from the Climate Research Unit (CRU) and station data from the Daily Global Historical Climatology Network (GHCN). Individual hardiness zone grid files for zones 1-13 were transferred into ArcInfo 9.2. The geo-tiff grid files were converted to polygons and the area in square miles was calculated using the edit and summarize function. To estimate population by hardiness zone, county data containing 2005 census data was utilized from the ESRI US County Area Shapefile. Counties were manually assigned to a hardiness zone when they were estimated to be covered by 50 percent or more of that zone. Population information from the assigned counties was obtained using the summarize function. Area was estimated for zones 12 and 13, which are present in Hawaii, but population for those zones was included in zone 11 using the previously described methodology.

The plant hardiness zones for Puerto Rico, a commonwealth of the United States, were also analyzed using zone coverage of county areas to estimate area. Eight percent of the island was determined to be in Zone 11 and 92 percent in Zone 12 (Figure 3-2). The population of Puerto Rico, estimated to be 3.944,249 in 2007, was obtained from the CIA World Factbook (CIA, 2008). Area and population values for Puerto Rico were not included in the estimates for the United States.

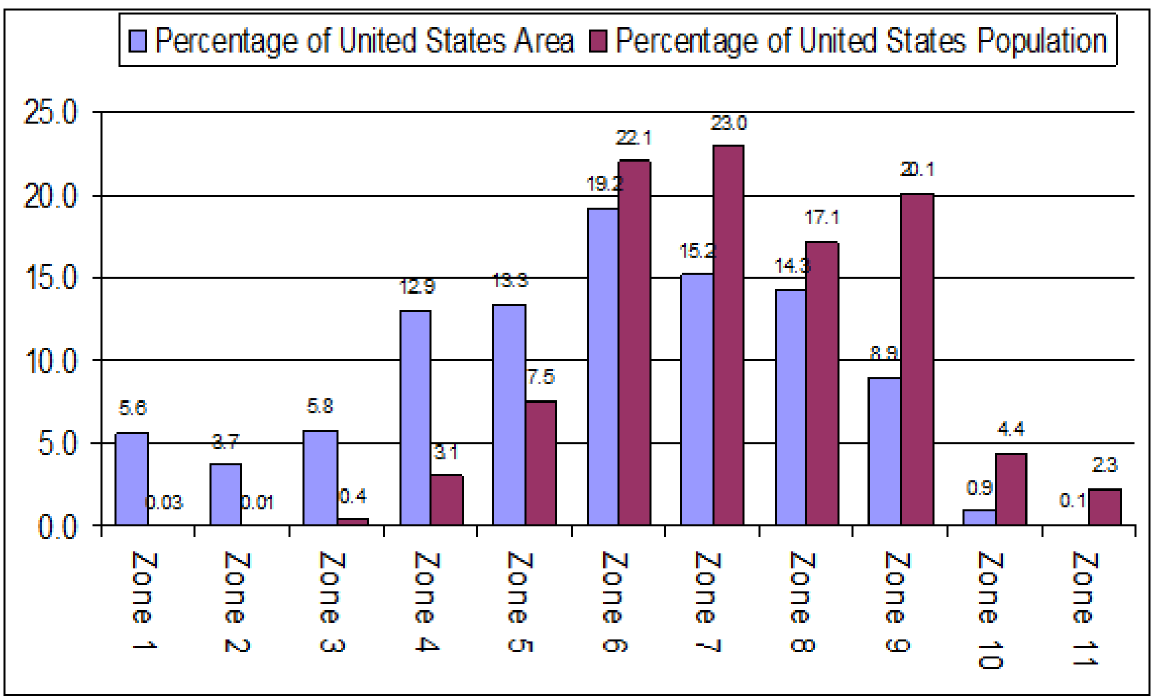
Table 3-1. Estimated percentage of area and population of the United States by plant hardiness zones. Hardiness zones were generated using data from 1997-2006 (Magarey et al., 2008); population estimates were derived from 2005 census data at county level.

Plant hardiness zone	Estimated area in square miles	Percentage of U.S. area	Population from 2005 census	Percentage of U.S. population
1	199,053	5.6	94,942	0.03
2	130,616	3.7	15,490	0.01
3	206,116	5.8	1,172,840	0.04

Table 3-1. Estimated percentage of area and population of the United States by plant hardiness zones. Hardiness zones were generated using data from 1997-2006 (Magarey et al., 2008); population estimates were derived from 2005 census data at county level.

Plant hardiness zone	Estimated area in square miles	Percentage of U.S. area	Population from 2005 census	Percentage of U.S. population
4	456,289	12.9	9,142,737	3.1
5	470,679	13.3	22,520,330	7.5
6	677,225	19.2	65,924,988	22.1
7	536,148	15.2	68,715,477	23.0
8	505,586	14.3	51,178,543	17.1
9	315,856	8.9	59,946,996	20.1
10	31,993	0.9	13,257,280	4.4
11	4,712	0.1	6,734,768	2.3
12	1,119	0.03	Included in 11	n/a
13	1,319	0.04	Included in 11	n/a
Totals	3,536,711	100	298,720,176	100

Figure 3-2. Estimated percentage of area and population of the United States by plant hardiness zones. Hardiness zones were generated using data from 1997-2006 (Magarey et al., 2006); population estimates were derived from 2005 census data at county level.



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Supplement 3: Host Status

Host status issues in PRAs

Pests can be associated with host plants in different ways, depending on the biology of the host and pest, and the environment in which pests and hosts interact. The nature of the relationship that a pest has to a host can impact the ability of the host commodity to be a source of viable propagules of the pest that can lead to its entry and establishment in the PRA area. This supplement is meant to provide a conceptual framework for analyzing host status and a decision tool to evaluate not only host status as an intrinsic biological property of a pest as it interacts with a host, but also attempts to account in part for the likelihood of the pest to move on the commodity in a form and manner that would allow its introduction. Or more simply put, analysts are encouraged to look carefully at host status, and also determine whether or not the infested/ infected commodity will be a source of the pest, enabling it to become established. This guide attempts to increase the transparency of the process of evaluating host status for new risk analysts and our stakeholders, as well to improve the consistency of our risk assessments.

Scope and purpose

Determining the status of hosts with respect to pests is one of the central pieces of information needed to conduct PRA. The determination of host status can have major impacts on phytosanitary measures required for importing and exporting commodities, as well as domestic level decisions and actions (e.g., eradication programs, surveys, etc.). In commodity- based PRAs (e.g., Q56 PRAs for importation of fruits and vegetables for consumption), the issue of host status influences the PRA in four key places:

- qualitative likelihood or probability the pest will follow the pathway for entry on the host,
- qualitative likelihood or probability the pest will find suitable hosts after entry and establishment,
- qualitative likelihood or probability that the pest can spread, and

- the extent of economic impact (on hosts in the importing country) that the pest is likely to have.

Because host status can affect the estimated level of risk for a pest (through the four likelihoods identified above), it is critical that host status be defined as accurately as possible in the PRA.

There are many diverse sources of information available that provide lists of hosts for pests. Some of these sources simply associate the pest with a host(s) in a very general sense, while other sources of information provide a detailed description of the relationship of the pest to the host(s). Likewise, information sources may describe different types of hosts, according to the status of that host to the pest. This terminology is not harmonized and can be interpreted in many different ways. The diverse terminology and the diversity of descriptions of host- pest interactions may be extremely difficult to interpret when conducting PRA.

This paper provides guidelines for interpreting information regarding pest-host interactions for the purpose of PRA, and furthermore provides suggested terminology that should be used to describe the status of host(s) with respect to pests, or in defining the host-pest interactions.

Key issues

Host status is, in many cases, very clear for well-documented pests for which there is agreement in the scientific literature. However, there can sometimes be considerable controversy in interpreting information, even for pests that are well understood. Host status requires regular review for several reasons:

- errors in the literature or in databases and compendia (e.g. inaccuracy due to incorrect citations, incorrect interpretations). See Appendix A: Recommendation for Prunus persica varieties to be considered non-hosts for Bactrocera cucurbitae on page 3-27 for an example of this issue.
- host status of a commodity may be variable depending on host and pest biology (e.g., imprecision due to changes in host status depending on season, ripeness, variety, geographic area, population density). See Appendix A: Recommendation for Prunus persica varieties to be considered non-hosts for Bactrocera cucurbitae on page 3-27 for examples.
- host status is unclear (lack of data in the literature, conflicting information, or only experimental hosts are described but lacking field data). See Appendix A: Recommendation for Prunus persica varieties to be considered non-hosts for Bactrocera cucurbitae on page 3-27 for examples.

- cases where a pest is associated with a commodity but may not be feeding on that commodity (e.g., snails on tile, hitchhikers or contaminating pests; alfalfa weevil on pomegranate).

Terminology

Background

An array of terminology describes host-pest interactions in the scientific literature, but the terms are not used consistently nor are they harmonized and is difficult to interpret with regard to the level of risk the specified interaction may present. Examples of terms found in the literature include, but are not limited to, those found below.

EXAMPLE	host	experimental host	non-host
	field host	laboratory host	host of unknown significance
	natural host	secondary host	alternate host
	primary host	non-preferred host	latent host
	preferred host	wild host	indicator host
	commercial host	occasional host	local lesion host
	regulated host	minor host	diagnostic host
	reproductive host	poor host	associated host
	conditional host	rare host	
	conditional non-host	natural non-host	

These different terms imply information about the relationship of the pest to the host, and therefore, correspondingly, the level of risk associated with the host status but do not define the exact parameters for any of such relationship. For instance, terms such as natural, field, preferred, and primary host imply that the pest can be found on the host plant in the field (or other production system) and that the pest can survive and perpetuate itself under natural growing conditions for the host. Most work on host status has been done on fruit flies (Tephritidae), but host status concerns also occur with other groups of pests (including other arthropods and plant pathogens).

For example, ISPM No. 11 (IPPC, 2004a) talks about hosts that are capable of sustaining pests “under natural conditions.” This would not generally include laboratory or experimental hosts. Under certain conditions or circumstances, plants that are susceptible to a given pest in the laboratory may remain free from infestation or infection under natural conditions. Plants may be susceptible only at a certain life stage (fruiting, flowering, etc.) when the pest is not present and active. Physical features of the plant, such as hairs or wax layers, may prevent vectors or water droplets containing inoculum from contacting the plant surface. Experimental or laboratory inoculation or infestation methods can allow infestations or infections to occur that do not occur in nature (e.g., mechanical inoculation, or dodder infection of a plant with a virus or phytoplasma normally vectored by an insect that does not feed on that plant; insect pests feeding on plants when lacking another food source).

National, regional, and international organizations have recognized the need to harmonize methods for determination of, and terminology related to, host status. This is important in conducting PRA, proposing risk mitigation options, communicating to domestic and foreign stakeholders, and in developing regulations and strategies to address pests. Two regional organizations (Asia Pacific Plant Protection Organization or APPPC, and North American Plant Protection Organization or NAPPO) have developed regional standards on host status, and the IPPC has a produced a draft standard on host status for fruit flies based largely on the two regional standards. The standards provide guidance to countries on how to determine host status, and further define categories of host status.

Recommendation 1: Host status terminology

Consistent with the NAPPO RSPM No. 30 [*Guidelines for the Determination and Designation of Host Status of a Fruit or Vegetable for Fruit Flies (Diptera: Tephritidae)*] (NAPPO, 2008), the following terms should be used for hosts with regard to pests that feed on or infect hosts.

Type 1 host (natural host). A plant species that becomes infested or infected by a plant pest in nature under natural conditions (e.g., natural, cultivated and/or unmanaged plants) and the plant pest is sustained on that plant species. No other trials are necessary to confirm host status.

Type 2 host (conditional host). A plant species that is only a host or a non-host under defined narrow range of conditions, respectively (e.g., host variety, stage of host maturity, other physiological conditions of the host, environmental, ecological or other physical conditions).

Type 2 Hosts can be considered:

- **Type 2a.** A non-host becomes a host (example: lemons become a fruit fly host under heavy population pressure and drought; artificially inoculated laboratory hosts for some plant viruses, viroids, or phytoplasmas).
- **Type 2b.** A host becomes a non-host (example: avocados are generally a fruit fly host, but ‘Hass’ avocados are a non-host for some species of fruit flies).

Type 3 host (natural non-host). A plant species that does not become infested or infected by a plant pest under natural conditions (e.g., natural, cultivated and/or unmanaged plants) and the plant pest is not sustained on the plant species, nor can the pest survive, perpetuate itself or spread.

Type 4 host (fomite). An object or material (including a harvested plant part) that may be contaminated with a pest and that could transmit that pest from one place to another.

For the purposes of this document, a Type 2 host (conditional host) can also be used to describe hosts that have been experimentally infested (or infected) but for which field data or other evidence is lacking. The above terms may apply in one or more areas within the range of the pest, which should be specified.

In some cases, pests may be associated with a host or other material, but not actually feeding on or infecting the host material. Examples of such associations include:

- snails that adhere to tiles.
- pupae in packing boxes.
- pests that attack parts of the host plant other than fruit, but that “hitchhike” with the fruit.

In these cases, the host material is not a food source, but may serve as a substrate for the pest to move in trade. The most applicable term for such materials (including fruit, boxes, or other material where the pest is present but is not feeding / infesting the fruit or vegetable) is “fomite” (Type 4 host).

Evidence and information sources

Background

There are many sources of information for host status, including original refereed scientific literature, various types of compendia, scientific reviews, interception records, NPPO records, and technical reports, as well as other sources that are less reliable (e.g., websites, news articles, etc.). Host records from reputable refereed scientific publications are considered to be the most reliable. Whenever possible, the original source of information should be checked and referenced for any host record, even for pests that are well understood. In some cases, this may involve going back in the literature a hundred years or more. In cases where the original reference(s) cannot be obtained, the analyst should trace back the information as far as possible.

Various types of compendia are often available and very useful sources of information. However, care should be taken in interpreting information in such compendia, particularly with regard to host status (as well as geographic distribution). The problem arises because original evidence is sometimes misinterpreted when it gets added to different compendia, but once a reference is established, it becomes ingrained in the literature and is rarely questioned or validated.

Interception records are also common sources of information for associating a pest with a host. In cases where there are repeated interceptions, these records can provide a useful basis for judging host status. However, single or a few interception records, especially those on baggage (vs. commercial fruit) should be interpreted with caution. In the absence of any other corroborating information, single interception records are generally not indicative of a host-pest association.

Figure 3-2 provides a discussion of the types of evidence that is used for determining host status, and the corresponding (relative) level of reliability. In general, information from well-known, peer-reviewed scientific journals and identifications done by taxonomic specialists are viewed to be the highest in reliability and should be considered accordingly. For pathogens in particular, Koch's postulates should also be considered in determining host status of the plant species. When a pathogen is associated with a diseased plant, proof of its role as the cause of the disease may be established by completing several steps known as Koch's Postulates (after the 19th century bacteriologist, Robert Koch).

Koch's Postulates to prove pathogenicity are (definitions adapted from Shurtleff and Averre, 1997; Falkow, 2004)

1. **Consistent association.** Consistent association of a suspected causal agent with a disease.
2. **Isolation.** Isolation of the pathogenic agent and its growth in pure culture. This may be difficult with some kinds of pathogens, e.g., obligate parasites, non-culturable organisms, but specialized methodologies, transmission studies, or consistent association with other isolated molecular markers can contribute to identifying and characterizing non-culturable pathogens. For example, some plant viruses can be isolated by means of transmission to experimental hosts or cells by insect vectors, parasitic plants or grafting, then used to re-infect healthy plants of the original host species. Re-inoculation: Inoculation of healthy plants with prospective pathogen must produce the same symptoms as the initial disease described. Re-isolation: The pathogen must be re-isolated from the inoculated, diseased plant and identified as being identical to the original pathogen.

Recommendation 2: Interpretation and evaluation of evidence related to host status

Table 3-2. Reliability of evidence. Criteria for evaluating the reliability of evidence from most reliable (1) to least reliable (8). Table adapted from M. Hennessey, unpublished, and *ISPM No. 8, Determination of pest status in an area* (IPPC, 1998). A=arthropod; P=Pathogen.

Relative level of reliability of evidence	Type of evidence					
		Host status determination method	How recorded	Pest/ plant collector	Pest/ plant identifier	Location and date precision
1	A	Reproductively viable adult reared out of natural infestation on plant or from commercial or commercial grade consignment in trade (if origin traceable).	NPPO record (e.g.,, many interception records); refereed publication	Taxonomic specialist	Discriminating biochemical, serological, or molecular diagnosis	Delimiting or detection survey
	P	Koch's postulates completed with cultures/isolates from natural infection on plant or from commercial or commercial grade consignment in trade (if origin traceable).				
2	A	Viable adults from forced field infestation of green or commercial harvestable grade plant.	Refereed scientific or technical journal	Professional specialist	Specimen maintained in an official collection; taxonomic description by specialist	Other field or production survey
	P	Koch's postulates have not been completed, but the pathogen can be grown in pure culture and successful inoculations made with, for example, single spore isolates (or equivalent for organisms other than fungi), resulting in development of the same symptoms.				

Table 3-2. Reliability of evidence. Criteria for evaluating the reliability of evidence from most reliable (1) to least reliable (8). Table adapted from M. Hennessey, unpublished, and *ISPM No. 8, Determination of pest status in an area* (IPPC, 1998). A=arthropod; P=Pathogen.

Relative level of reliability of evidence		Type of evidence: Host status determination method	How recorded	Pest/ plant collector	Pest/ plant identifier	Location and date precision
3	A	Viable adults from lab infestation (choice or non-choice) of green or commercial harvestable grade plant.	Official historical record; State Extension Service Bulletin; plant disease clinic report; a few interception records	Scientist	Specimen in a general collection	Casual or incidental field observations, possible with no defined location or date.
	P	Pathogen cannot be grown in culture, but successful inoculations can be made, for example by insect vectors, graft transmission, or parasitic plants (dodder) from naturally infected plant material to healthy plants, resulting in development of the same symptoms. The pathogen is consistently associated with the disease in the host.				
4	A	Lab infestation of ground or non-commercial grade plant.	Non-refereed scientific or technical journal or publication	Technician	Description and photo	Observation with/ in products or by-products; interception
	P	Successful laboratory inoculations are made, for example, by mechanical transmission, but only to experimental hosts, no evidence that the pathogen infects plants in nature, in cultivation, or production systems.				
5	A	Reproductively viable adult reared from ground, damaged, or non-commercial grade plant.	Specialist amateur publication	Expert amateur	Visual description only	Precise location/ date unknown
	P					
6	A	Oviposition observed but no viable adults, pupae, larvae, or eggs in plant.	Unpublished scientific or technical document	Non-specialist	Non specialist	
	P	Plants produce symptoms characteristic of infection with specific pathogen, without any confirmation of the organism causing the disease.				
7	A P	Plants produce general symptoms of a disease or infestation.	Non-technical publication; periodical or newspaper			
8	A P	Host status determination unknown.	Unpublished personal communication	Collector unknown	Method of identification unknown	Location and date unknown

Interpreting evidence to determine host status

Background

There are two levels in determining host status. The first level is collecting evidence on actual experiments or data to establish host status. The second level is in interpreting the published data or other evidence to make a judgment as to what the host status is. As mentioned previously, numerous terms can be found in the scientific literature to describe host status, but for the purposes of PRAs done for commodities, the terms Type 1, 2, 3 and 4 hosts (natural host, conditional host, natural non-host, and fomite, respectively) should be used. Table 2 provides a list of terms used to describe host status and identifies, using the above terminology, how other terms found in the literature may be interpreted.

Guidance to researchers on determining host status is available, at least for fruit flies, in the two regional standards and in the draft IPPC standard identified previously. These documents outline the experimental designs that should be used in determining host status. They also provide guidance on how to interpret results of various types of tests (e.g., laboratory testing, field samples, cage testing). When host status testing follows such protocols, it is relatively simple for risk analysts and regulators to make a determination on host status. However, in many cases, the available literature is based on experiments that have not followed specific protocols but that nonetheless identify the host status of plants. Furthermore, because the available evidence can be highly variable in quality, experimental design, and numerous other factors, risk analysts must make certain judgments about host status based on the available evidence.

The categories for natural host and natural non-host are often relatively clear and easy to interpret from the literature. In cases where a pest can complete its life cycle and/or a population can be naturally sustained on that plant, or in other words, the pest can survive, multiply, and spread via an infected or infested plant part, then the host may be regarded as a “natural host.” In contrast, if a pest cannot complete its life cycle, and/or a population cannot be naturally sustained on a plant, then that plant is considered a natural non-host.

Not surprisingly however, “conditional hosts” are the most difficult to understand or interpret, particularly with regard to the level of risk they may pose. A conditional host may be either a natural host that can be a non-host under specific conditions, or it may be a natural non-host that can be a host under specific conditions. The conditions that affect whether a plant may be a host or not include:

- host variety,

- physiological state of the host (including ripeness, life stage of pest on specific plant parts),
- barriers to transmission of the pest (host to vectors, and vice versa),
- geographic variations in pests (including strains or races) or hosts, and
- environmental conditions (including seasonality, drought, or other conditions).

The risk analyst must make a judgment about the host status based on the quality of evidence and the type of evidence provided (e.g., field studies, laboratory studies, etc. See Recommendation 2), especially for Type 2 hosts. For Type 2 hosts, there must be specific evidence describing the exact conditions under which a plant becomes a host or non-host. Table 3-3 provides recommendations for host status descriptions.

Recommendation 3: Procedure for identifying host status in PRAs

Use Table 3-3 to determine whether a plant is a Type 1, 2 or 3 host. The first row shows the harmonized terminology that should be used. Subsequent rows show terms that may be occur in the literature and suggest how those terms should typically be interpreted. In examining evidence, Recommendation 2 should also be followed. Figure 3-3 provides a flow chart to aid in examining evidence and making a judgment as to host status.

Table 3-3. Recommended classification of definitions found in the literature for host status according to terminology for Type 1, 2, and 3 hosts; level of host associations and uncertainty expected for the type of host status. For both association and uncertainty, these levels are estimated and generalized, and are intended for description purposes only. There maybe be cases where either association or uncertainty differ from what is listed here.

Continuum of host status from natural host to natural non-host →											
Type 1 host: natural host			Type 2 host: conditional host 2a: host			Type 2 host: conditional host 2b: non-host			Type 3 host: natural non-host		
Term	**Level of associa-tion with the host**	**Expecte d uncer-tainty**	**Term**	**Level of associa-tion with the host**	**Expecte d uncer-tainty**	**Term**	**Level of associa-tion with the host**	**Expecte d uncer-tainty**	**Term**	**Level of associa-tion with the host**	**Expecte d uncer-tainty**
Host	H, M	C, MC	Condi-tional host	H, M	C, MC, MU	Condi-tional non-host	L, N	C, MC	Non-host	N	C, MC
Field host	H, M	C, MC	Experi-mental host	M, L	MU, U	Experi-mental host	M, L	MU, U			
Primary host	H, M	C, MC	Labora-tory host	M, L	MU, U	Labora-tory host	M, L	MU, U			
Pre-ferred host	H, M	C, MC	Occa-sional host	M	MC, MU	Poor host	L	MU, U			
Com-mercial host	H, M	C, MC	Second-ary host	H, M, L	(MC), MU	Unusual host	L	MU, U			
Wild host	H, M	C, MC	Minor host	M, L	C, MC, MU	Rare host	L	MU, U			
			Non-pre-ferred host	M, L	MC, MU						

In the case of fomites, there should be documented evidence that a pest is associated with the material in question. This evidence can come from the scientific literature, NPPO reports, or other technical documents. One of the most common sources of evidence for pest association with a fomite is port interception records. Examples of fomites or pest association with fomites include:

EXAMPLE

Commodity of plant origin: pest feeds on or infects plant, but not exported plant part; pest associated with plant but does not feed on or infect plant or exported plant part; pest intercepted with commodity, but no other documentation available (e.g., a true hitchhiker)

Commodity of non-plant origin: tiles/stone; vehicles/machinery

Material associated with the commodity: boxes containing plant parts; wrapping materials; packing materials or containers

Containers/conveyances: shipping containers; railway cars; ships and other vehicles

Other: soil; growing media; leaves, twigs, or other prohibited materials

Relationship of host status to risk

The level of pest association and uncertainty for Type 4 hosts (fomites) is variable, and depends on the type of pest, the type of association of the pest with the fomite, the potential for moving in trade or other means, the potential for mitigation (e.g., cleaning, removal of pests, treatments), and other factors. Therefore, fomites can only be addressed on a case by case basis and general guidance on the level of risk posed by fomites is not possible.

For Type 1 hosts (natural hosts), the expected level of association of the pest with the host (i.e., that the pest is associated with the plant part of a particular species) will in most cases be high or at least medium, and the level of uncertainty will be relatively low (i.e., certain, moderately certain). Likewise, for natural non-hosts, the level of association of a pest with the host will be negligible, with low uncertainty (i.e., certain, moderately certain).

There may be greater uncertainty when determining whether a Type 2 host (conditional host) can be a host or non-host. However, the determination that a Type 2 host is a non-host (e.g., Type 2b or a non-host under specific conditions) should only be made when there is low uncertainty (i.e., certain or moderately certain). If uncertainty is judged to be moderate or more than moderate, then a conservative interpretation of the data should be made and the host status should be determined to be a Type 1 host.

In all cases, the determination of host status can be accompanied by both a specified level of likelihood of association (using the recommended terminology) and uncertainty. The specified level of likelihood of association and the uncertainty are useful for making judgments in PRAs as to whether a pest may be expected to follow a particular pathway.

Examples, exceptions, and uncertainty

Analysts should be aware that there are always exceptions or unusual circumstances that can affect host status. Perhaps one of the most well-known examples is that of lemons serving as a host of Medfly (the Mediterranean fruit fly). It was commonly understood that lemons were not a host of Medfly, until Medfly was intercepted in imported lemons. In reviewing the evidence, it was determined that during an exceptionally dry year, and a year with an exceptionally high Medfly population, the pests were able to overcome the natural resistance of lemon fruit to Medfly, and populations were able to successfully develop on lemons. This situation, therefore, proved to be an exception to the conventional wisdom concerning the host status of lemons. Following are some additional examples of pests and types of hosts.

EXAMPLE

Plum pox virus

Natural host range (Type 1 hosts): *Prunus armeniaca, P. cerasifera, P. domestica, P. glandulosa, P. persica, P. insititia, P. spinosa, P. salicina, P. cerasus, P. avium, Juglans regia*

Experimental hosts (Type 2 hosts): *Capsella bursa-pastoris, Celosia argentea,Chenopodium capitatum, C. ambrosioides, C. foetidum, C. foliosum, C. murale, C. quinoa, Cyamopsis tetragonoloba, Emilia sagittata, Gomphrena globosa, Humulus lupulus, Hyoscyamus niger, Lupinus albus , Lycopersicon esculentum, Melilotus albus, M. officinalis, Nicandra physalodes, Nicotiana acuminata, N. benthamiana, N. bigelovii, N. clevelandii, N. debneyi, N. glutinosa, N. megalosiphon, N. occidentalis, N. rustica, N. sylvestris, N. tabacum, Petunia × hybrida, Physalis floridana, P. peruviana, Pisum sativum, Ranunculus arvensis, R. sardous, Senecio vulgaris, Sesbania exaltata, Sorbus domestica, Stellaria media, Trifolium pratense, T. repens, Vicia sativa, V. villosa, Zinnia elegans*

EXAMPLE

***Anastrepha distincta* (Peru citrus)**

Literature (Norrbom and Kim, 1988) lists only laboratory and questionable reports of *A. distincta* on citrus.

Based on this evidence, it was determined that this fruit fly species is not likely to be associated with commercial citrus for export (Type 3 host).

EXAMPLE

Monilinia fructigena in the United States

Guignardia citricarpa in Peru

Interception can be valuable in establishing potential pathways, but data should be scrutinized carefully and used cautiously.

EXAMPLE

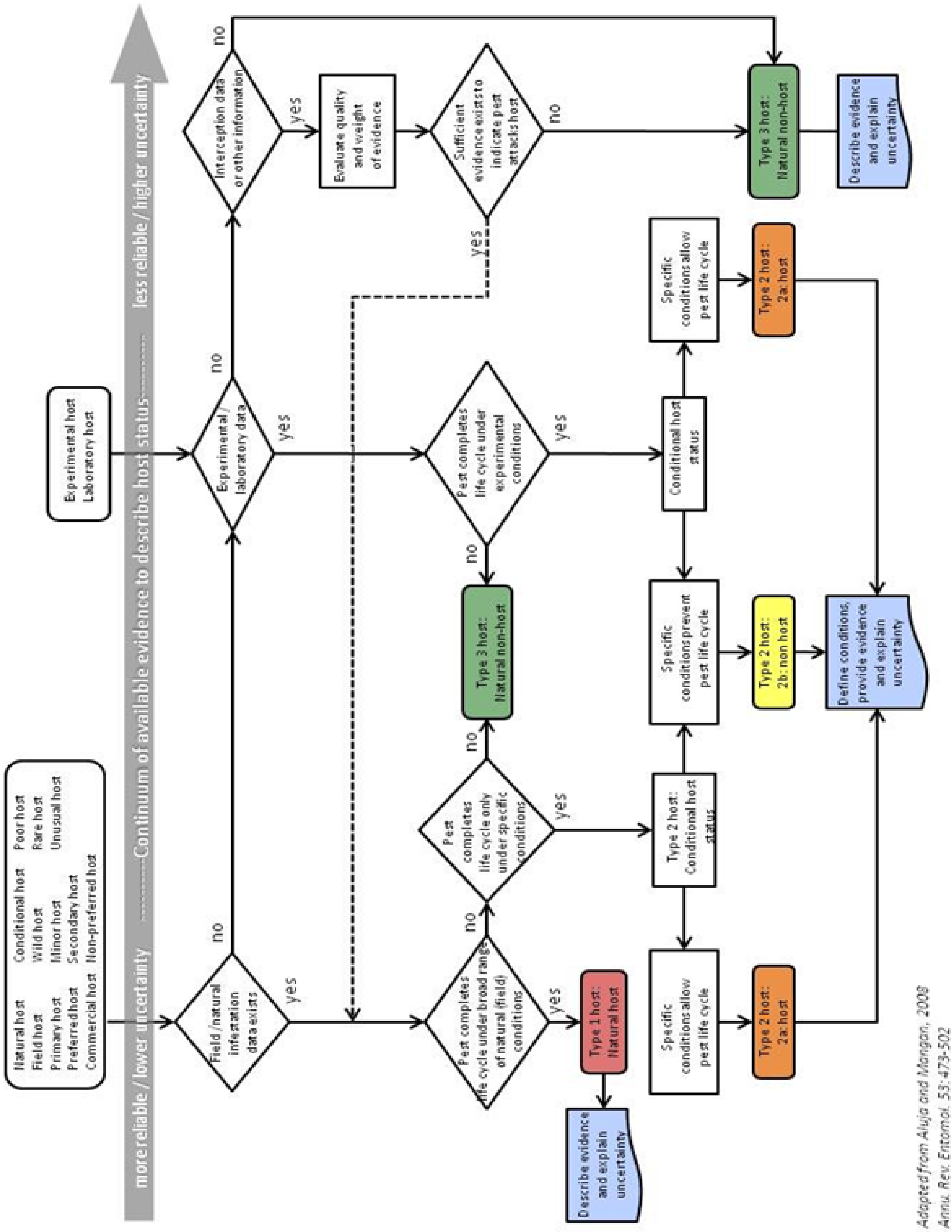
Sweet orange scab (*Elsinoë australis*)

Quarantine pest that has been intercepted on citrus from Peru by APHIS on multiple occasions.

All interceptions were made from passenger baggage and ship's stores or quarters. As such, the true origin of the fruit is difficult to determine.

The disease has been reported from surrounding countries and flights from some of these countries to the United States connect through Peru.

Figure 3-3. Determination of host status for PRA based on scientific evidence.



Appendix A: Recommendation for *Prunus persica* varieties to be considered non-hosts for *Bactrocera cucurbitae*

Current regulatory status. Peach (*Prunus persica*) is currently regulated domestically and internationally as a host of *Bactrocera cucurbitae* (melon fruit fly or MFF); however, nectarine (also *P. persica*) is not regulated as a host of MFF. Peach and nectarine are the same species; the only difference is that nectarines are a smoothed-skinned variety of *Prunus persica* lacking the typical velvety skin found on peaches.

Taxonomy of MMF. This species has been described previously as *Chaetodacus cucurbitae* (Coquillet), *Dacus cucurbitae* Coquillet, *Strumeta cucurbitae* (Coquillet), and *Zeugodacus cucurbitae* (Coquillet). The current accepted name is *Bactrocera cucurbitae* (Coquillet).

Status of MMF in the continental United States. Although MFF has been long established in Hawaii, it is not established in the continental United States. It is periodically introduced and eradicated in California. It primarily occurs in parts of Asia and the Pacific region, and sporadically in Africa.

Hosts of MFF. MFF primarily attacks plants in the family Cucurbitaceae (pumpkins, squash, gourds, cucumbers, melons and related species). It can attack fruits and flowers, as well as occasionally stems and roots. There are numerous unconfirmed records on non-cucurbit hosts and non-cucurbit hosts are considered to be uncommon.

Host status of *Prunus persica* varieties for MFF. There are very few reliable records of MFF infesting peach and no records of MFF infesting nectarines. White and Elson-Harris (1992) provide the following information "Other Hawaiian records are….peach (*Prunus persica*)…(Harris et al., 1986b; Maehler, 1951; Nakagawa et al. 1968)" (pg 265).

When the original references are checked, neither Maehler (1951) nor Nakagawa et al. (1968) actually mention peach as a host of MFF. Harris et al. (1986) mentions that peaches were collected in Hawaii to look for adult emergence; however, no adult MFF emerged from peach in any of the collections over a two-year period of the study. In the original Harris article, peach is listed as a "rare host" even though no flies have ever been collected from peach.

In White and Elson Harris (1992) in the "Useful plants and their associated tephritids" section, *Prunus perscia* is listed as an "unusual host" (pg. 473).

Back and Pemberton (1917) reared a single fly from peach in 1914. This is the only reliable record of MFF being associated with peach.

According to a review by Liquido et al. (unpublished), MFF has never been collected from peach in any records between 1949 and 1991 in Hawaii. There are no other reliable records or scientific publications that conclusively show peach (or nectarine) serves as a host for melon fruit fly.

Recommendation. Based on the available scientific evidence, it is recommended that neither peach nor nectarine (e.g., any variety of *Prunus persica*) be regulated domestically or internationally for melon fruit fly (*Bactrocera cucurbitae*).

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Supplement 4: Evaluation of Evidence

Separating uncertainty arising from the lack of knowledge from ratings is important; ratings are made based only on the available evidence, not the uncertainty associated with the evidence. For instance, a given element should not be rated higher if there is a lot of uncertainty; rather the rating should be assigned based on available evidence, but the high level of uncertainty should be noted.

The uncertainty associated with the available evidence should be evaluating in terms of both its reliability and its applicability (Table 3-4).

Reliability refers to how reliable the source of the information is in terms of the quality of the source, age of the source, the methodology used, and the degree of consensus. The quantity of information available can also be used in evaluating resources. For example, many resources from lower quality sources that have the same conclusion may be more powerful in terms of certainty than a single reference from a higher quality publication source.

Applicability refers to how applicable the information is to your situation. In most cases, the risk rating should be based on evidence on how the pest is currently behaving in the situations that correspond to the PRA area. Since this information is not always available, we must extrapolate and make assumptions, but emphasis should always be placed on how the pest behaves in the parts of the distribution most similar to the PRA area.

Table 3-4. Reliability of sources of information from low to high.

	Publication source	Reliability	Examples
1	Well-known/respected peer-reviewed journal (English language or translated into English	Low	None
		ML	Few or no original research papers; any found do not describe methodology OR methodology used is not widely accepted.
		MH	At least one original research paper with detailed description of methodological approach. Several original research papers without specified methodology. Multiple published review articles; articles cite independent (separate) sources of information.
		High	Multiple original research papers with detailed description of the methodological approach(es) used; approaches are widely accepted.

Table 3-4. Reliability of sources of information from low to high.

	Publication source	Reliability	Examples
2	Obscure or less-well known/respected peer-reviewed journals (English language or translated into English)	Low	No original research. Few or no review or summary articles.
		ML	Few or no original research papers; methodology may or may not be described. Multiple published review articles which may or may not cite independent (separate) sources of information.
		MH	Multiple original research papers (with specified methodology).
		High	Many original research papers (by multiple authors) that include a detailed description of the methodological approach(es) used; approaches are widely accepted; supported by other evidence.
3	Foreign language peer-reviewed journals (abstract in English)	Low	Few or no review or summary articles. No supporting evidence found.
		ML	Multiple review articles research papers (which may or may not cite independent (separate) sources of information.
		MH	Multiple original research papers (methodology specified in abstract).
		High	n/a
4	Other reputable sources (e.g., universities, experts, scientific societies)	Low	Few or no reports; those that are found may or may not be based on independent (different) information sources. No supporting evidence found.
		ML	Several articles and reports that may or may not have each been based on independent (different) information sources.
		MH	Many articles and reports; each article/reports is based on independent information; methodology is described.
		High	n/a
5	Information from trading partner	Low	Evidence not well-documented or inconsistent with other sources; methodology not verified or it is not widely accepted.
		ML	Evidence well-documented and consistent with other sources; methodology has either not been verified or it is not widely accepted.
		MH	Well-documented evidence that is generally consistent with other information; methodology verified and widely accepted.
		High	Well-documented evidence; methodology verified and widely accepted; supported several other sources.

Table 3-4. Reliability of sources of information from low to high.

	Publication source	Reliability	Examples
6	Scientific consensus	Low	May or may not have scientific consensus. Methodology may or may not be generally accepted. NPPO may or may not have experience with pest; if so, the evidence is may or may not be consistent with NPPO experience.
		ML	May or may not have scientific consensus. Any methodology described may or may not be generally accepted. NPPO may or may not have experience with pest; if so, the evidence is generally consistent with NPPO experience.
		MH	General consensus in scientific literature and other sources (but may include a few contradictory reports). Methodological approaches used are generally accepted. Evidence consistent with NPPO experience w/ pest.
		High	High consensus in scientific literature and other sources (no or practically no contradictory evidence found). Methodological approaches are widely accepted. Evidence generally consistent with NPPO experience w/ pest.

Table 3-5. Applicability of sources of information from low to high.

	Publication information	Applicability	Examples
1	Species-specific data	Low	Species-specific data were limited; most of the species data were approximated or extrapolated from congeneric species, or other similar species.
		ML	Species-specific data were used; some of the species data were approximated or extrapolated from congeneric (or other) species known to behave similarly.
		MH	Species-specific data were used.
		High	Data for both species were used.
2	Environment-specific data	Low	Environment-specific data were limited; no close proxy data was available; extrapolations were based on situations that may or may not be applicable.
		ML	Some environmental-specific data were used, but most were approximated or extrapolated from similar situations (i.e., research conducted in the areas of comparable climate, on a closely related host).
		MH	Some environment-specific data were used, but at least some data were approximated or extrapolated from similar situations (i.e., research conducted in the areas of comparable climate, on a closely related host).
		High	Environment-specific data were used.

Figure 3-4. Combining applicability and reliability of information to obtain a certainty rating.

		Reliability			
		Low	Moderately Low	Moderately High	High
Applicability	High	**Moderately Uncertain**	**Moderately Certain**	**CERTAIN**	**CERTAIN**
	Mod. High	**Moderately Uncertain**	**Moderately Certain**	**Moderately Certain**	**CERTAIN**
	Mod. Low	**UNCERTAIN**	**Moderately Uncertain**	**Moderately Certain**	**Moderately Certain**
	Low	**UNCERTAIN**	**UNCERTAIN**	**Moderately Uncertain**	**Moderately Uncertain**

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