

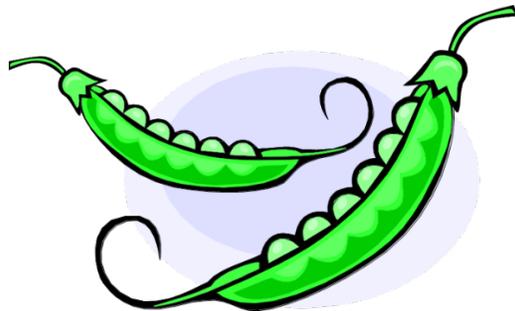


United States
Department
of Agriculture

Animal and
Plant
Health
Inspection
Service

Plant
Protection and
Quarantine

Imported Plant Commodity Pest Risk Assessment Framework



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WI E-522 Imported Plant Commodity Pest Risk Assessment Framework

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Introduction

The purpose of this document is to provide an overview of how the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ) conducts plant commodity import pest risk analyses. A pest risk analysis is used by USDA-APHIS-PPQ to determine:

1. The plant pests associated with plant commodities imported into the United States;
2. The risk associated with those pests;
3. The phytosanitary measures that may be used to mitigate the risk.

Risk analyses 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 taken against it.” Our process requires a risk assessment to characterize the risk associated with the introduction of a pest via a plant commodity pathway and a risk management analysis to identify appropriate phytosanitary measures.

In this framework, we provide guidance for stakeholders and trading partners interested in understanding our methodology and rationale for conducting PRA. The process we describe is used to inform risk management, but does not include the risk management analysis.

Information covered includes:

- An overview of PRA as outlined by the IPPC;
- The legal framework for conducting PRA;
- An overview of pest risk assessments as conducted by PPQ.

IPPC Pest Risk Analysis Framework

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

- No. 1, *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade* (IPPC, 2016c);
- No. 2, *Framework for pest risk analysis* (IPPC, 2016a);
- No. 11, *Pest risk analysis for quarantine pests* (IPPC, 2017b);
- No. 21, *Pest risk analysis for regulated non-quarantine pests* (IPPC, 2016b).

The use of biological and phytosanitary terms in this document conforms to ISPM No. 5, *Glossary of phytosanitary terms* (IPPC, 2017a). We discuss these standards in more detail in the section: IPPC Standards related to risk analysis.

Stages of pest risk analysis

The IPPC describes three stages of PRA in ISPM Nos. 2, 11, and 21; initiation, risk assessment, and risk management.

Initiation

The first stage, initiation, involves defining the hazards by identifying the pest(s) and conditions of concern that should be considered for PRA. Initiation points include:

- **Identification of pathway(s)** A pathway is defined as a means for the introduction and/or spread of pests. For the purposes of this document, the pathway of concern is the imported plant commodity for consumption or for propagation.
- **Identification of pest(s)** Pest species are evaluated because they were detected or intercepted; they are being imported (e.g., biocontrol organism); they were previously not known to be a pest; or there was a change in the status of a pest in the PRA area.
- **Review of policies** Regulatory policies or operations require evaluation to revise regulations or requirements; to prioritize risk management activities; when a new system, process, or procedure is introduced; when new information is made available that could influence a previous decision; or when an international dispute on phytosanitary measures arises.

Risk Assessment

Stage 2 is 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, 2017a).

Risk assessment begins by first determining which pests to assess and then evaluating these pests for the likelihood and consequences of their introduction and 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 definition of 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 pest(s).

Risk Management

Stage 3, risk management, is the evaluation and selection of options to reduce the risk of the introduction and spread of a pest (IPPC, 2017a). It provides a summary of mitigation measures that may be used to reduce risk and includes a recommendation for the preferred option. Options are assessed based on information about their efficacy, feasibility, and impacts, and may be existing measures or measures developed specifically for the conditions under consideration. Within PPQ, pest risk management is conducted separately from pest risk assessment.

Legal Bases for Pest Risk Analysis

This framework provides the international and national legal bases for why and how we conduct PRA as well as creating a system of accountability. In this section, we address:

- The World Trade Organization (WTO) 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;
- 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; its rules are legally binding for member nations. WTO agreements are the result of negotiations between WTO members and provide a non-discriminatory trading system between members based on agreed-upon 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; 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 protection for health concerns for which international standards do not exist provided they are technically justified. Technical justification is accomplished by an assessment of risk taking into account scientific principles and evidence. 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 that may be introduced through international trade (i.e., phytosanitary measures). 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 Agreements 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 country according 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 (IPPC, 1997) and associated standards (e.g., ISPM Nos. 2, 5, 11, and 21) to reflect the same concepts and obligations. Two terms that are particularly important are found in Article II:

- **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, where it should be regulated, and the strength of any phytosanitary measures to be taken against it (IPPC, 2017a).

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 considering economic as well as biological aspects of pest risk for plant health.

Relationship of the IPPC to the SPS

The requirements of the SPS Agreement create a direct relationship between risk assessment and international standards. The SPS Agreement states that a risk assessment is not required where measures are based upon already agreed to international standards, which are established for plants by the IPPC. Where standards do not exist or are deemed inappropriate, risk assessment is needed to provide justification for the measures. The IPPC also plays a significant role here by providing standards for performing PRA.

At this time, only a few specific phytosanitary standards can be used to directly support national measures in lieu of risk assessment. For most phytosanitary measures, WTO Members are largely dependent on risk assessments, making the PRA process extremely important to all countries.

IPPC Standards Related to Risk Analysis

ISPM No. 2, *Framework of Pest Risk Analysis* (IPPC, 2016a), was originally adopted by the IPPC in 1995 as *Guidelines for Pest Risk Analysis*. This standard has served as the primary conception and procedural reference for phytosanitary risk analyses. It provides basic background regarding PRA for phytosanitary purposes and outlines the three-stage process for PRA. ISPM No. 2 has been widely used by NPPOs throughout the world as a reference for developing their phytosanitary risk analysis systems and processes.

ISPM No. 11, *Pest Risk Analysis for Quarantine Pests* (IPPC, 2017b), was adopted in 2001. This standard provides details on how to conduct a PRA, including how to determine if pests are quarantine pests, assessing consequences, and risk management options.

ISPM No. 21, *Pest Risk Analysis for Regulated Non-Quarantine Pests* (IPPC, 2016b), was adopted in 2004. This standard applies to regulated non-quarantine pests associated with plants for planting and provides guidance on what pests meet this definition, how to evaluate their risk and, if appropriate, to identify risk management options to achieve a tolerance level.

Appropriate Level of Protection and 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; “insignificant risk”, “no significant risk”, “*de minimus* risk”, and “safety” may also be encountered.

An importing country has the sovereign right to establish its appropriate level of phytosanitary protection. The appropriate level of protection is not determined by the individual risk analyst but instead by broader policy.

In general terms, the acceptable level of risk¹ is commensurate with the benefits and costs of an alternative. While the absolute risk of a particular pest might be significant, it may still fall within an acceptable level of risk if one of the following applies:

- The benefits associated with accepting the risk are greater than any associated costs;
- 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 a static concept as the strength of phytosanitary measures applied depends on the most current information available. The measures should be consistent, to the extent possible, with the strength of measures for similar situations.

Provisional and Emergency Measures

The SPS Agreement (WTO, 1995) and the IPPC (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 “precautionary measures” that are variously understood and generally linked to the application of the “precautionary approach” (also 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 states “emergency action” will be based only on the detection of a pest, and that such action will be evaluated as soon as possible to ensure that it is justified. The IPPC’s Principle 14 (IPPC, 2016c) refers to emergency actions for new or unexpected phytosanitary situations based on a preliminary PRA and that such measures “shall” be temporary and subjected to 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, including information provided by relevant international organizations, and information about phytosanitary measures applied by others;

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

- They require that the Member imposing the measure actively pursue the information required for a more objective assessment of the risk and to review 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 SPS Agreement, although SPS jurisprudence indicates provisional measures may “reflect precaution”. Phytosanitary measures may be more or less precautionary depending on the influence of uncertainty on the acceptable level of risk. This makes the concept of precaution based on uncertainty implicit in the PRA.

Uncertainty and precaution have a direct relationship: the higher the uncertainty, the greater the need for precaution. The PRA provides decision makers and stakeholders with a clear understanding of the information that might be lacking, the variability and possible errors in the information used, and the significance of this uncertainty to the conclusions drawn.

The precautionary approach, as described in the Rio Declaration, the Convention on Biological Diversity, and the Cartagena Protocol, is compatible with the IPPC and the SPS Agreement as these environmental agreements are explicit about risk analysis being the basis for evaluating available information. This includes identifying sources of uncertainty affecting the analysis. Thus, the precautionary provisions for agricultural and environmental protection can operate in harmony as risk analysis is the basis for achieving the mutual goals of protecting of plant and environmental health from harmful pest invasions.

Rational Relationship

A key principle of risk analysis is the concept of rational relationship. The concept has two components: Demonstrating an actual cause and effect relationship, and demonstrating that the magnitude of the response is reasonable. For example, root pests would not be associated with fruit; therefore, any risk or measures assigned to fruit for root pests would have no rational relationship (i.e., no cause and effect). For the second component, the magnitude of the risk and the strength of measures applied to mitigate that risk are on sliding scales with higher risks corresponding 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. For example, requiring a treatment designed for internally feeding arthropods when the risk is from an external feeder has no rational relationship.

Probable Versus Possible

SPS jurisprudence has made an important distinction between the concepts of probable and possible. PRA that identified a risk without credible evidence that such an event had occurred (e.g., were based on expert opinion and assumptions that it was possible) have faced WTO challenges. The results of such disputes clearly conclude that events that are relevant for 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 ambiguous regarding how consequences of introduction should be evaluated. This can result in different interpretations by different countries.

Economic Analysis Guidance in the SPS Agreement

The SPS Agreement endorses considering risk-related costs (e.g., potential production or sales losses, control or eradication costs, et cetera) when assessing risks and identifying mitigation measures. Producer impacts alone are apparently sufficient to comply with the letter of the Agreement. Choice of a phytosanitary measure need not be justified by an analysis of its effect 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.

IPPC Guidance to Economic Consequence Analysis in PRA

Several ISPMs reference economic considerations or provide guidance that is applicable to economic analysis in a PRA. The overall importance of economic considerations in phytosanitary decision-making is shown by the number of key phytosanitary concepts that reference economic terms. In the *Glossary of phytosanitary terms* (ISPM No. 5, IPPC, 2017a), “economic impacts” and “economic consequences” are included in the 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 included in the definitions of other terms, including “quarantine pest”. The glossary does not include definitions for any terms related to economic impacts or economic importance, but does include a supplement that provides guidance for understanding them (IPPC, 2017a).

Supplement No. 2 to ISPM No. 5 (IPPC, 2017a)

The scope and purpose of the supplement is to provide clarification to ensure economic terms are clearly understood and consistently applied, illustrate certain economic principles as they relate to the IPPC’s objectives, and include environmental considerations. The supplement states that environmental concerns may be accounted for using monetary or non-monetary estimates and that market impacts are not the sole indicator of pest consequences.

Section 4 of this supplement, *Economic Considerations in PRA*, discusses types of economic effects and costs and benefits. It describes an inclusive approach to economic considerations in PRA, indicating that all economic effects (e.g., costs and benefits and 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 meet or exceed costs, and indicates that such decisions are a policy choice to be made outside the context of the economic analysis.

ISPM No. 2, Framework for Pest Risk Analysis (IPPC, 2016a)

ISPM No. 2 describes the stages in a PRA and indicates when it is appropriate to consider economic factors. However, it does not give specific guidance on how economic impacts should be conceptualized or measured. The stages are:

- **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 if appropriate phytosanitary measures to reduce pest risk to an acceptable level are available, cost-effective, and feasible. The ISPM also indicates that PRA documentation should include evidence of economic impact and evaluation of risk management options.

ISPM No. 11, Pest risk analysis for quarantine pests (IPPC, 2017b)

ISPM No. 11 Section 2.3, *Assessment of potential economic consequences*, contains a description of the process for assessing economic consequences in the pest categorization stage of a risk assessment, but provides such broad guidance that it leaves many questions unanswered about what and how such consequences should be measured.

This standard provides guidance for situations where a detailed analysis of economic consequences may be needed, such as when the level of consequences for a pest are in question, when the economic consequences are needed to determine the appropriate strength of measures, or when you need to assess the benefits of exclusion versus control. If it is widely agreed that pest introduction will have unacceptable consequences, detailed analysis may not be necessary.

The guidance states both direct and indirect effects of the pest should be identified and analyzed. For direct effects, the total crop area, potential endangered area or both should be identified. Examples of direct effects on cultivated hosts include crop losses, control measures, and effects on production practices. Direct effects on the environment may include reduction of keystone or endangered species. Indirect effects of the pest in the endangered area are not host-specific and include effects on domestic and export markets, changes in demand because of effects on commodity quality, and social or other indirect effects.

Summary of SPS Agreement and ISPM Guidance on Economic Consequences

The SPS Agreement describes a more limited set of factors to be considered in economic assessments as compared to the ISPMs. The different approaches described in the SPS agreement and the ISPMs may affect what is measured and how results are interpreted, which could lead to different conclusions regarding risk management by decision makers.

The SPS Agreement considers risk-related impacts to producers in the importing country, whereas the ISPMs describe a broad range of approaches to analyzing economic consequence. ISPM No. 11 emphasizes the inclusion of environmental impacts and endorses a continuum of approaches ranging from “no detailed analysis” if consequences are widely viewed to be unacceptable, to qualitative or quantitative analyses.

Based on available guidance in the SPS Agreement and the ISPMs, and in the absence of any clarifying WTO jurisprudence or case law, risk analysts have considerable latitude in determining how to analyze economic consequences in PRA. Regardless, phytosanitary measures based on the risk assessment and economic consequence analyses must still not violate the consistency provision of the SPS Agreement by discriminating between Members nor be applied in a manner that restricts trade.

National Legislative Framework for PRA

The Plant Protection Act (PPA; 7 CFR § 104, 2000) became law in June 2000, as part of the Agricultural

Risk Protection Act. The PPA includes the authority to regulate plants, plant products, certain biological control organisms, noxious weeds, and plant pests.

The following provisions of the PPA relate to PRA 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 are important differences between the Plant Protection Act (PPA) and the WTO-IPPC framework. The legal ramifications for PRA are not the same and the terminology and concepts are not consistent on many important points.

One key difference is between the concepts of regulated pests. 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 IPPC’s defining criteria. The USDA needs this authority to implement programs for domestic pests regardless of their origin (native, introduced, or naturalized). However, referring to such pests in PRA 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 when determining pest status for the purpose of pest listing in the risk assessment. The list of pests requiring analysis should include all organisms for which the current national policy is to require phytosanitary measures. This includes organisms that meet the IPPC definition of a quarantine pest or regulated non-quarantine pest, but also extends to pests that are established in the United States and are under official control or under consideration for official control, and to other pest taxa for which the policy is to require quarantine action. The reverse may also be true. Pests that meet the defining criteria for a quarantine pest may not require action in all circumstances.

Because there are fundamental differences between the PPA and the WTO-IPPC, it is important to pay attention to concepts and terminology in the PRA process. This is particularly true regarding legal challenges as a challenge in a U.S. court of law will be reviewed, argued, and judged against the authority of the PPA, whereas a challenge raised by a trading partner to the WTO will be judged against

the IPPC and SPS Agreement.

PPQ RISK ASSESSMENT MODEL

Risk is a product of the likelihood of an adverse event – in this case, a pest introduction – and the magnitude of its 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.

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, the environment or both. While most pests may first become associated with the commodity at the farm, pests may also enter or exit the pathway at any stage until arrival in the importing country or area (Figure 1). The risk of escape into a new environment does not begin until the commodity has arrived in the PRA area.

Pest populations on agricultural commodities will generally decrease as commodities move through the process, particularly with effective post-harvest processing measures (Figure 2). Increases in pest population size are rare and most likely would be associated with re-infestation or conditions conducive to the organism's growth and development during storage and shipping.

The volume of consignments can affect the level of risk. However, it is difficult to accurately predict the volume of importations and subsequent effect on risk. Therefore, in the PPQ PRA process, the volume proposed in the market access request is used to understand the magnitude of the pathway and we assume that any volume proposed will be significant enough to affect risk.

The Endangered Area

The “endangered area” represents the area within the PRA area that has biotic and abiotic conditions favorable for a pest's establishment. The likelihood that a pest will establish depends upon biotic factors such as availability of host material and presence or absence of natural enemies, and upon abiotic factors such as temperature, season, humidity, rainfall or other conditions that affect the pest's ability to survive and reproduce.

Once a pest has entered the endangered area, it must be able to establish and spread in order for there to be consequences. We use a “threshold” approach to assess those potential consequences. This approach assumes there are acceptable and unacceptable levels of risk. An “acceptable level of risk” means the amount of damage caused by the pest would be too small to justify requiring phytosanitary measures be put in place or action be taken at ports of entry (i.e., the cost of implementing any phytosanitary measures outweighs the benefits). We identify the host(s) at risk in the endangered area and then determine if the potential impacts resulting from pest establishment are likely to be unacceptable.

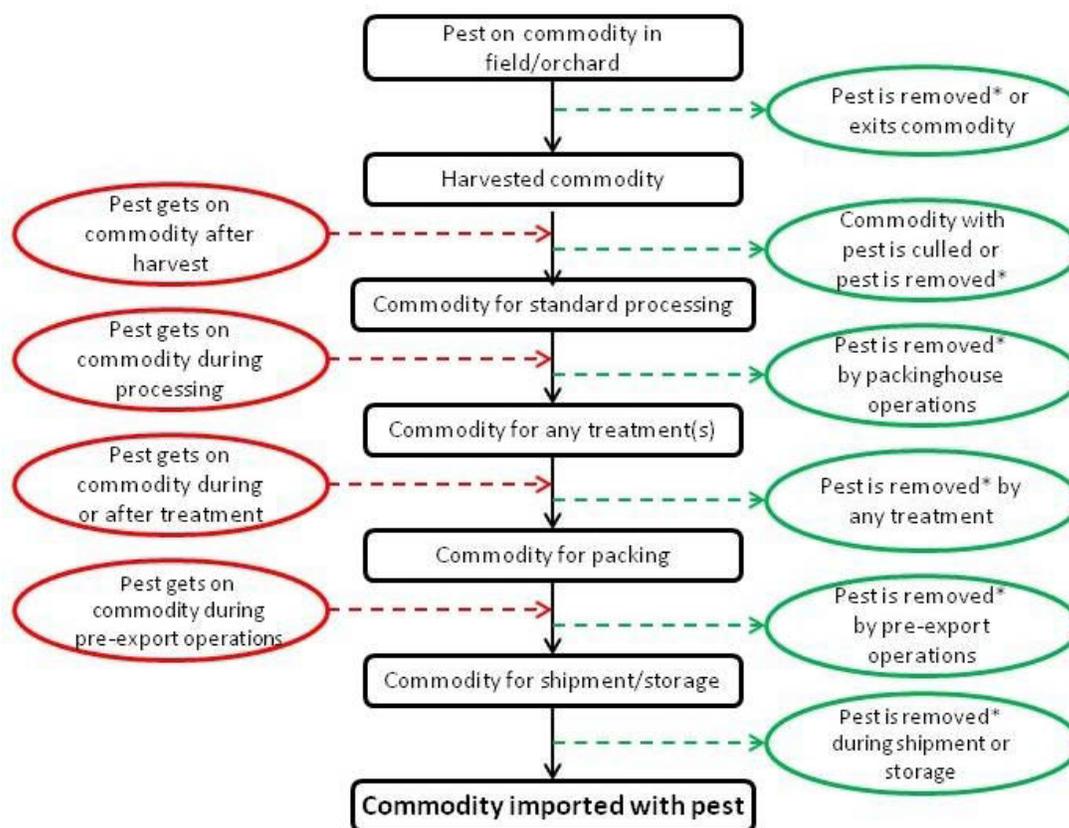
Likelihood of Introduction

For imported plant commodities, we qualitatively assess the likelihood of introduction as:

- **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;
- **Medium** Pest introduction can occur, but for that to happen the exact combination of required events must occur;
- **High** Pest introduction is highly likely to occur.

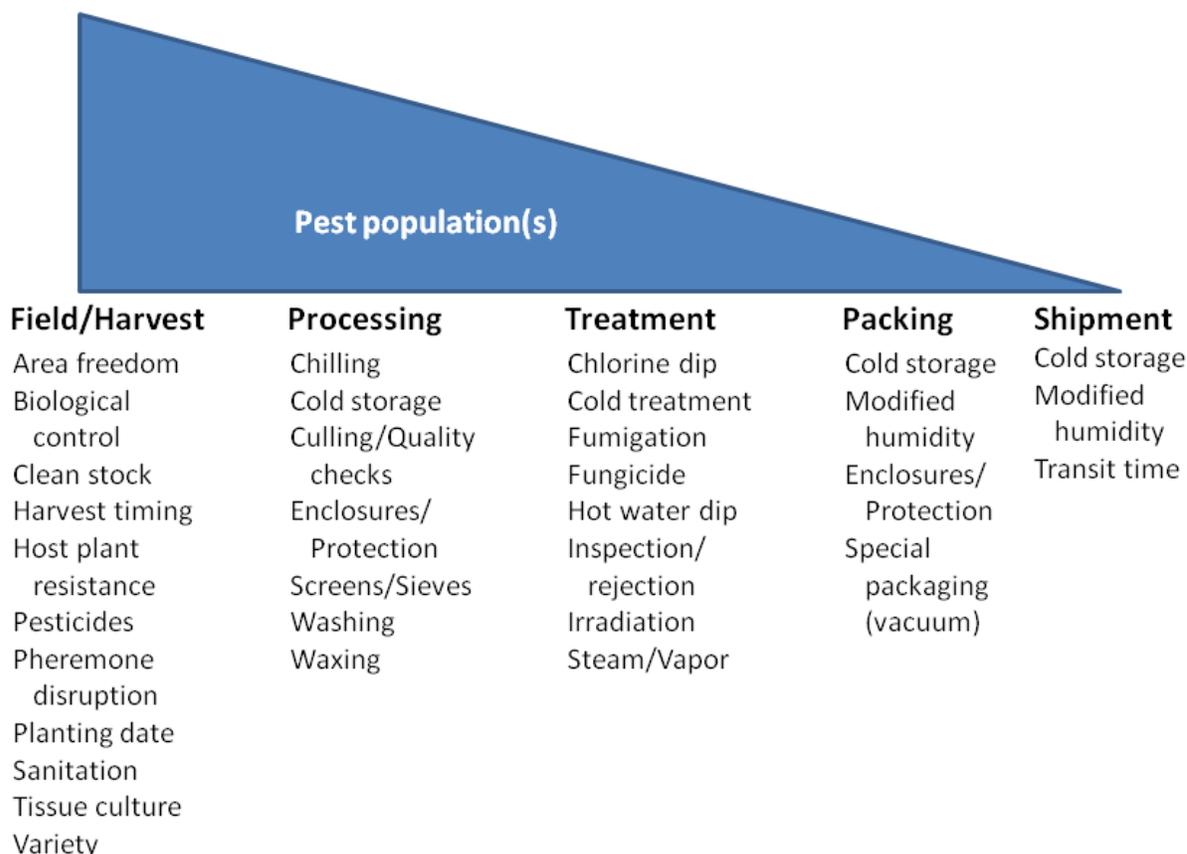
Figure 1. Pest presence on agricultural commodities can change as a result of harvest and post-harvest processing measures from harvest through shipping. This figure represents general harvest and post-harvest processes for commodities for consumption and is not intended to be comprehensive.



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

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 all post-harvest and shipping processes. The likelihood of establishment depends on characteristics of the pest and suitability of the endangered area. The risk elements comprising the model for likelihood of introduction are interdependent and multiplicative, with the final risk rating weighted towards establishment because we consider this risk element to be more important. Because of the interdependency of entry and establishment and the multiplicative nature of the model, if any risk factor rates as negligible, the overall likelihood will be negligible thereby stopping the analysis. We generally make note of such pests in the pest list.

Figure 2. An example of anticipated decrease in pest populations on fruit and vegetable commodities for consumption as they move through harvest and post-harvest processing.



Uncertainty Analysis

Separating the uncertainty that arises due to lack of knowledge about a pest from the risk element ratings is important because a higher level of uncertainty could mean a given rating may be over- or under-estimating the risk probability by one or more levels. In PPQ risk assessments, a given risk element will be assigned a rating based on the available evidence and the level of uncertainty about that evidence will be noted.

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, a conservative judgment may be justified resulting in a higher risk rating. Further contributing to uncertainty is how reliable the information is in terms of quality of the source, age of the source, methodology used, degree of scientific consensus, and applicability of the information available (i.e., how well does the situation described in the literature correspond to the endangered area).

This underscores the importance of describing uncertainty, including its sources and magnitude, while maintaining judgments that are based on available evidence. Explanations about the level of uncertainty associated with each rating is important, specifically identifying gaps in knowledge so that there is transparency in how the rating was determined.

Summary of PPQ's Risk Assessment Process

The purpose of PPQ's risk assessment process is to identify the pests that will follow an imported plant commodity pathway and to qualitatively determine the level of risk associated with those pests. We consider what is being imported and the condition of that commodity. However, unless directed otherwise, we do not consider any mitigations that may be employed by the exporting country in our risk assessment. We identify the areas within the United States that are at risk for each pest and determine the pest's potential to cause economic harm. We then assess the pest's likelihood of being introduced via the pathway, assigning it a qualitative rating of High, Medium, or Low. We also note any unknowns or uncertainty that may have influenced our rating.

PPQ's risk assessments are transparent and undergo a thorough internal review prior to posting for stakeholder consultation. All comments received from stakeholders must be evaluated, considered and, if needed, addressed before the risk assessment can move to the final stage of PRA, mitigation, which is conducted separately from the process described herein. Once the full PRA is completed, PPQ submits it for another round of public and stakeholder comment before making any policy decisions regarding the potential importation of the plant commodity.

Literature cited

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VERSION LOG

VERSION	DATE	SUMMARY OF CHANGES	AUTHORIZED BY
Original	Aug 1, 2012	Original entitled "Guidelines for plant pest risk assessment of imported fruit & vegetable commodities".	Griffin
01/2020-08	Jan 8, 2020	Updated to represent 2019 revisions to the commodity import PRA process.	Osterbauer/Kopper