

Peer Review Report of the Procedures and Standards that Govern the Consideration of Import and Export Requests Under the Plant Protection Act

A Report Presented by the National Plant Board
to the Secretary of Agriculture
and the US Congress

July 2006



Executive Summary

This review was undertaken to fulfill the requirement of Section 402 of the Specialty Crop Competitiveness Act of 2004. This Act required the Secretary of Agriculture to enter into an agreement with the National Plant Board to obtain a peer review of the procedures and standards that govern the consideration of import and export requests under section 412 of the Plant Protection Act (PPA). These procedures and standards fall under the jurisdiction of Plant Protection and Quarantine (PPQ), a program of the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) which is the National Plant Protection Organization (NPPO) of the United States.

PPQ's external stakeholders include state plant regulatory agencies, domestic agricultural producers, importers, and exporters as well as consumers and the general public. The interests of these diverse stakeholders are often in competition. Different values and legitimate differences of opinion over PPQ decisions related to import and export requests have led some stakeholders to believe that the current procedures do not serve them well. It is the Peer Review Committee's belief that the agency's import and export processes will best, and most impartially, serve its stakeholders if it can effectively fulfill its mission to safeguard America's agriculture and natural resources, as this in turn will strengthen the marketability of US agricultural products.

But PPQ will not be able to do this unless its import systems, in particular, are supported by a regulatory structure that is based on risk so that it can prioritize its resources accordingly. PPQ's current regulatory structure and priority setting process dictate allocation of too many resources to relatively low risk pathways and too few resources to relatively high risk pathways. Because of the construct of its federal import regulations, risk analysis resources must be chiefly devoted to low risk routine fruits and vegetable import requests at the expense of the higher risk plant pest introduction pathways associated with nursery stock and noxious weeds. As a result, there is still an unacceptable level of introductions of nonindigenous plant pests.

PPQ's import request responsibilities are clearly delineated under the PPA and the agency is currently developing and implementing a number of enhancements to its processes for consideration of import requests. In 2001 PPQ published a notice and request for comments in the Federal Register that described the procedures and standards that govern import requests. PPQ is continuing to work towards being respon-

sive to the relevant issues raised in response to that notice as well as the recommendations found within the 1999 Safeguarding Review Report. Many, but not all of the measures taken to realize these objectives or outcomes have been fully executed. Those remaining can be characterized as "work in progress". These initiatives are intended to improve data quality as well as bring more consistency, rigor and transparency to its import processes.

In contrast, the agency's export responsibilities are not similarly legislatively mandated. Indeed, most export processes are not under the agency's control but are dictated by the importing country for which market access and/or retention is sought. Yet there are clearly export facilitation functions that PPQ is uniquely entrusted to undertake. Where the agency has control, the current processes governing export requests are good ones but lack adequate resources.

PPQ's risk analysis process, which consists of the elements of risk assessment, risk management and risk communication, has many strong points. PPQ led the world in the development of phytosanitary risk assessment. PPQ's risk assessments are readily available and, in general, understandable to informed and interested parties. The process and findings of its assessments are reasonably transparent and sound.

However, a key finding of the Committee's review is that in order for PPQ to be most effective, it must complete its transition from a focus on risk assessment to a more comprehensive risk analysis agency by developing its own risk management framework and standard operating procedures. Currently, the risk management element is suffering from the fragmented and dispersed nature of the risk management function within the agency. Risk management decisions do not always appear to be tied to the evidence within the overall analysis in a manner that is transparent to stakeholders. Risk communication within the agency is largely overlooked, under valued, and is not consultative.

The Committee believes that peer review of PPQ's risk analysis is a desirable thing and can improve the quality of the agency's scientific products and its decision-making process while promoting public confidence in the agency's integrity. But it must be emphasized that peer review is not a means of arbitrating policy decisions. Peer review cannot be used to determine whether or not the data and analysis are adequate for regulatory decision-making.

Recommendations

Based on its findings and conclusions, the Peer Review Committee offers the following prioritized recommendations for improvement of PPQ's import and export processes:

- A much higher priority and adequate resources must be allocated now to the revision of the federal foreign nursery stock quarantine and the noxious weed regulation even while the agency works towards revising its foreign fruits and vegetables quarantine regulation.
 - Pest risk analyses for nursery stock and noxious weed regulations should be housed within PPQ's Plant Epidemiology and Risk Analysis Laboratory (PERAL).
 - PPQ should immediately begin the development of a weediness screen to predict potential invasiveness of plants introduced into new environments.
 - PPQ should develop a means to evaluate plant taxa, in the field, for potential weediness prior to introduction into the ornamental trade.
- Development and publication of a strategic risk management framework for PPQ that will function, more or less, as a flexible standard operating procedure for the agency. This should include:
 - A risk management process that identifies the outcomes expected from measures analyzed.
 - A process to monitor and evaluate the efficacy of risk mitigation measures chosen then a means to modify these as necessary.
 - Development and publication of a risk communication strategy that is more interactive than the current one that includes input from its stakeholders prior to rulemaking.
 - Immediate clarification of its risk related terminology and development of a means to use terms consistently. Examples include: risk analysis, risk assessment, risk management, risk mitigation, and risk communication.
- The risk analysis program is not yet adequately funded, including risk analyses needed in support of export requests. As current regulatory initiatives are realized, resources should be allocated to the risk analysis function.
 - Field experience, such as site visits, must be part of the training of risk analysts to ensure that mitigation measures chosen are operationally feasible, thus ensuring the utility and credibility of the risk analysis.
- Adequate resources must be made available for risk analyses developed in support of export requests to minimize the need to redirect resources away from other risk analysis activities.
- PPQ should develop and publish general guidelines for processes that are associated with the development of PRAs and related technical or scientific information in support of export programs, one that includes the role of stakeholders.
- Implementation of peer review for risk analysis must include:
 - Augmentation of the pool of peer review experts by means of a general call for qualified people who would like to make themselves available. Suggestions from the public could be included in the recruitment strategy. All potential reviewers should be pre-screened for conflict of interest, and no nominee should be self-limited to any one specific assessment review. Areas of expertise of potential reviewers should be inventorized for relevance to PPQ needs.
 - Inclusion of relevant international obligations that are applicable to pest risk analyses in its peer review plans to provide context and guidance to the reviewers.
 - Material that goes to peer review should include not just the scientific content (pest lists and biological information), but also the potential mitigations which are being considered. PPQ should also use Methods Development scientists to review this part of the risk analysis documents.
 - Development of a clear set of criteria for determining which pest risk analyses qualify as "influential" or "highly influential" under the OMB guidelines.
- PPQ must continue its commitment to be a world leader in risk analysis by way of a commitment to continuous improvement of its risk analysis protocols and guidelines and active participation in international and regional standard development.
- Another independent review should be conducted in three years' time to look at the effectiveness of both PPQ's current import and export initiatives in progress and the status of the implementation of these recommendations.

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Introduction and Methodology

Signed into law by the President in December 2004, Section 402 of the Specialty Crops Competitiveness Act of 2004 requires the Secretary of Agriculture to do the following:

SEC. 402. IMPORT AND EXPORT REGULATION REVIEW.

(a) Peer Review- The Secretary of Agriculture shall enter into an agreement with the National Plant Board to obtain a peer review of the procedures and standards that govern the consideration of import and export requests under Section 412 of the Plant Protection Act (7 U.S.C. 7712). The peer review shall be consistent with the guidance by the Office of Management and Budget pertaining to peer review and information quality.

(b) Elements of Review- The peer review required by subsection (a) shall address, at a minimum--

- (1) The preparation of risk assessments; and
- (2) The sufficiency, type, and quality of data that should be submitted to the Secretary of Agriculture.

(c) Submission of Results- The results of the peer review conducted under subsection (a) shall be submitted to the Secretary and Congress not later than 180 days after the date of the enactment of this Act.

To fulfill this charge, the National Plant Board (NPB) appointed a steering committee which in turn appointed a Peer Review Committee to conduct the review. To assist the Peer Review Committee, the steering committee developed the following questions:

1. Does the current process for the consideration of import and export requests serve agency stakeholders well? If yes, how? If not, why not, and what changes are needed?
2. Does the current risk analysis process and its associated documents effectively support proposed phytosanitary measures identified by APHIS? If yes, how? If not, why not, and what changes are needed?
3. What role should the peer review process play to ensure that the best science has been considered in the risk analysis process? How would this best be accomplished?
4. Are PPQ's risk analyses readily understandable and transparent to its stakeholders? Do these risk analyses provide enough information to justify the actions taken by PPQ? If yes, how? If not, why not and what changes are needed?

At its first meeting, the Peer Review Committee adopted the following mission: To produce a report for submission to the Secretary of Agriculture and the US Congress that provides a meaningful analysis of the current US import and export procedures with particular attention to the role and quality of its

risk analysis capabilities within the framework of its mission to protect plant health and life.

The Committee met several times with PPQ, and other appropriate USDA staff. It was provided with documents and briefings on relevant agency activities. A draft version of this review was submitted to the steering committee which in turn sent it out for an external stakeholder review. Stakeholder comments received were provided to the Peer Review Committee. Relevant comments and recommendations have been incorporated into this final document.

Authorities

The US Department of Agriculture's Animal and Plant Health Inspection Service's (APHIS) Plant Protection and Quarantine's (PPQ) consideration of import and export requests are subject to the agency's statutory authorities under the Plant Protection Act (PPA), the Information Quality Act, and relevant international treaties. The following is a summary of the authorities germane to the Peer Review Committee's work.

Plant Protection Act

Under Section 412 (7 USC 7712) of the Plant Protection Act, the Secretary of Agriculture may prohibit or restrict the import, entry, export, or interstate movement in commerce of any plant or plant product if it is determined that such action is necessary to prevent the introduction of plant pests into, or their spread within, the US. The PPA requires that the processes used in developing regulations promulgated under the PPA are transparent, accessible and based on sound science.

Section 412 also provides PPQ authority to regulate the movement of plants, plant products, biological control organisms, noxious weeds, articles, and their means of conveyance, but it only addresses import requests—it does not address export requests. Within Section 402 of the PPA, Congress does indeed find that it is the responsibility of the Secretary to facilitate exports, as well as imports and interstate commerce. However, while congressional findings are useful in construing legislative intent, they do not make substantive law. The PPA is otherwise silent with respect to export requests and PPQ's responsibilities are ambiguous with respect to providing technical support in response to export requests from domestic interests to modify or remove current phytosanitary restrictions in a foreign country.

Information Quality Act

The Information Quality Act (IQA), also known as the Data Quality Act, was enacted in 2001 to require the Executive Office of the President's (EOP) Office of Management and

Budget (OMB) to issue guidance to federal agencies designed to ensure the “quality, objectivity, utility, and integrity” of information disseminated to the public. To assure that scientific information released to the public meets these criteria, in December 2004, OMB released a final bulletin to guide federal agencies on the conduct of peer reviews. This Bulletin established minimum standards for when peer review should be required for scientific information and the types of peer review that should be considered by agencies under different circumstances.

On January 9, 2006, OMB published a “Proposed Risk Assessment Bulletin” for comment by June 15, 2006. In general, this proposal seems to establish criteria that are consistent with the procedures and standards PPQ has established for risk assessment. But PPQ’s response to this proposal will not be developed in time for the Peer Review Committee to take it into consideration for its report.

Applicable International Treaties

The World Trade Organization’s (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures”, commonly known as the SPS Agreement, is a treaty established to promote international trade by ensuring that members’ sanitary and phytosanitary measures are not a disguised barrier to trade while continuing to recognize a member’s sovereign right to determine its own appropriate level of phytosanitary protection. For phytosanitary issues, the SPS Agreement identifies the organization operating under the International Plant Protection Convention (IPPC) as the party responsible for providing international standards to facilitate harmonization of plant health measures.

The IPPC is also a multilateral treaty deposited with the Director General of the Food and Agriculture Organization (FAO) of the United Nations. Its purpose is to foster international cooperation in the control of pests of plants and plant products and prevent their spread between countries. This Convention, originally adopted by FAO in 1951, was revised in 1997 to reflect the role of the IPPC in relation to the SPS Agreement. In addition, a Secretariat was created which in turn established the Commission on Phytosanitary Measures to address phytosanitary issues.

Countries which adhere to IPPC standards are presumed to meet their obligations under the SPS Agreement and therefore are considered safe from challenges under the Agreement regarding scientific justification, although they may still be challenged domestically. If a country chooses not to base its phytosanitary measures on relevant international standards or in cases where an applicable standard does not exist, that country is required to base its phytosanitary measures on an assessment, as appropriate to the circumstances, of the risks to plant life and health.

Findings and Recommendations

Terminology

Risk analysis is a decision support tool utilized in many discipline areas outside of the phytosanitary arena. It has evolved rapidly over the last few decades. In the process it has spawned an extremely varied and often confusing professional jargon. Initial applications of risk analysis techniques to phytosanitary issues focused principally on risk assessment. APHIS was an early national and international leader in applying risk assessment techniques to support decision-making as well as an active participant in the development of international standards for risk analysis. PPQ has defined risk analysis to be, “the process that includes risk assessment, risk management and risk communication.” This is consistent within the plant health risk arena.

Section 402 of the Specialty Crops Competitiveness Act of 2004 uses the term “risk assessment”. The workplan developed by the steering committee noted that the terms risk assessment and risk analysis are often used interchangeably and “that the Congress and the public would be better served if the study to be conducted by the National Plant Board focused not merely on “risk assessments” but on the broader process of “risk analysis” which includes risk assessment.”

Paragraph 4 of Annex A of the SPS Agreement provides the following definition for risk assessment:

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

The SPS Agreement does not refer to risk management per se, although the concept is implicit in that the theme of the Agreement is “measures” which result from risk-based decisions.

To align itself more closely with the SPS Agreement, the IPPC, in its 1997 revision, incorporated various concepts from the SPS Agreement, including those of transparency and pest risk. But whereas the SPS Agreement uses the term “risk assessment”, the IPPC uses the term “pest risk analysis” (PRA). In particular, it states that a member’s phytosanitary measures must be “technically justified” by way of PRA:

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 evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it.

The IPPC's definition states that the core elements of pest risk analysis are "risk assessment" and "risk management." The term "risk assessment" is used to describe a process contained within risk analysis; i.e. the characterization of risk based on an identification of pests of concern and an evaluation of the evidence to estimate the likelihood and consequences of an adverse event. In the case of plant health, the "adverse event" is normally the introduction or spread of a harmful pest.¹ The term "risk management" is used to refer to the analytical process used to identify risk mitigation options and evaluate these for efficacy, feasibility and impacts in order to decide or recommend the most appropriate means to mitigate risks that are found to be unacceptable as a result of risk assessment.

Although the mix of terms and emphasis may seem to obfuscate the meaning and role of risk assessment and risk analysis, there exists in practice a very strong consistency in the understanding and use of the concepts represented by the terms within the phytosanitary community. To this end, the IPPC works to promote harmonization in the interpretation and application of risk analysis concepts by way of its glossary, the fifth international standard for phytosanitary measures (ISPM 5). ISPM 5 is updated almost annually and the most recent version is now titled – Consolidated Glossary of Phytosanitary Terms – 2005. This document will serve as the source for terminology used within this report. The acronym PRA will be used to refer to pest risk analysis.

Another element variously considered to be part of PRA, but as yet not officially defined is "risk communication". Historically, the IPPC has not viewed risk communication as an "analytical" element so it has been given a low priority for standard-setting. Nonetheless, the ability for a national plant protection organization (NPPO) to communicate risk to its stakeholders, and the way it intends to manage it, must be a high national priority.

Simple communication about risk within PPQ has been hindered by terminology, definitions and interpretation. For example, risk analysis and risk assessment, as well as risk mitigation and risk management, are sometimes used interchangeably even though they are defined differently within the international phytosanitary community.

PPQ in essence parses risk management into two distinct functions using the terms "risk mitigation" and "risk management". Risk mitigation is the term used to describe the identification and evaluation of measures to reduce risks while risk management is used to describe the negotiation and decision-making process. The persistent use of this terminology separates the agency linguistically from most other organizations using risk analysis and greatly hinders its risk communication capability.

¹ Griffin, R. Module 11, RiskAnalysis and the IPPC. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and Agreement on Technical Barriers to Trade (TBT). Multilateral Trade Negotiations on Agriculture – A Resource Manual. Food and Agriculture Organization of the United Nations. Rome 2000.

Confusion in the use of terminology is not entirely the fault of PPQ. It is duly noted that the SPS Agreement, IPPC, OMB, and others all use the language to suit their own purposes. Nonetheless the proliferation and persistence of an imprecise use of terms often means that what the agency is trying to communicate is not what is being heard by its stakeholders. This has resulted in stakeholder frustration with the agency's communications, especially about risk management decisions. It would be useful for the agency to articulate publicly for itself and others what it means by risk analysis and its various tasks. The Committee strongly advises APHIS to consider the language of the relevant international communities when defining terms, especially if it intends to continue being a leader in international standard development.

Recommendation: PPQ must immediately clarify its risk related terminology and develop a means to use terms consistently. Examples include: risk analysis, risk assessment, risk management, risk mitigation and risk communication.

Priority Setting

PPQ's agenda is crowded with import and export requests and myriad other demands on agency resources. These legitimate yet often competing demands originate from within APHIS and USDA, Congress, the Executive Office of the President, other federal agencies, states, agricultural producers, exporters and importers, processors and distributors, the environmental community, academia, and the general public. The agency has limited discretion in setting its agenda and is regularly confronted with the inevitable tradeoffs that result from limited resources and conflicting values. The manner in which agency priorities are set is an area in need of improvement, recognizing that the agency has only a limited control over the priorities it is assigned.

Many offices are involved in the risk analysis process and each office has its own responsibilities and priorities. Consequently, PPQ's risk analysts are pressured by differing priorities from Phytosanitary Issues Management (PIM), the trade support team (TST), and the US Trade Representative (USTR). There are currently too many conflicting priorities getting in the way of the most efficient and effective allocation of PPQ's risk analysis resources. To complicate matters many of these priorities appear suddenly, move quickly and change rapidly.

PPQ recognizes the need to address the issues associated with its priority setting process and is attempting to craft a solution. Priorities from trade negotiations do have a justified role; however, these priorities need to be consolidated and ranked by all the trade players before submission to PERAL. At the present time, top priority is given to all export issues and those phytosanitary import issues identified by the Secretary. All other work is now being prioritized via quarterly meetings between PHP and PERAL. This quarterly leadership meeting is held with persons from the Office of the Administrator, Office of the Deputy Administrator, the Trade Support Team, and Policy and Program Development to review and establish the priorities.

Regulatory Structure

Even more problematic, PPQ's regulatory structure is outdated and currently it is not based on risk so that the agency can prioritize its resources appropriately. PPQ's current regulatory structure dictates allocation of too many resources to relatively low risk pathways and too few resources to relatively high risk pathways. As a result, there is still an unacceptable level of introductions of nonindigenous plant pests.

A primary example of the suboptimal allocation of resources is seen in the amount of risk analysis resources currently devoted to the federal foreign fruits and vegetables quarantine (7 CFR 319.56, or Q56) versus the federal foreign nursery stock quarantine (7 CFR 319.37, or Q37) and the noxious weed regulation. A majority of the Q56 requests are routine or low risk while plant pest introduction pathways associated with Q37 and noxious weeds present much greater risks. The 1999 safeguarding review identified plants for planting (nursery stock) as a greater concern than the comparatively well protected movement of consumable fruits and vegetables.

The Safeguarding Review found that "there is a need to update and harmonize plant quarantine regulations to assure their adequacy to effectively address current and emerging invasive plant pest introduction pressures" It also agreed with the internationally held view that the risk of plant pest introduction is higher for plants for planting (nursery stock) than with commodities intended for consumption (fruits and vegetables). It recommended that the agency review each of its quarantines and revise these where appropriate.

The following PPQ initiatives address these recommendations and additional initiatives which are underway go further to streamline as well as bringing more consistency, rigor and transparency to its import processes:

- Docket 02-132-2: Strengthen requirements regarding request for changes in phytosanitary regulations – final rule published May 30 and effective June 29, 2006
- Docket 03-068-1: Streamlining Q56, revision of fruit and vegetable regulations – proposed rule published on April 27, 2006
- Docket 03-069-4, Revision of nursery stock regulations

The current federal foreign nursery stock regulations (Q37) do not require completion of a PRA prior to the importation of new plant taxa or prior to the importation of taxa from a new origin, except for plants in growing media. Most plants may be imported with a phytosanitary certificate and visual inspection upon entry. The noxious weed regulation merely restricts the interstate movement of listed plant taxa. These regulations are sorely outdated and constitute a wide open pathway for the entry of both plant pests and pest plants. PPQ has only just begun the process of updating these regulations.

PPQ's regulatory structure is outdated and currently it is not based on risk so that the agency can prioritize its resources appropriately. PPQ's current regulatory structure dictates allocation of too many resources to relatively low risk pathways and too few resources to relatively high risk pathways. As a result, there is still an unacceptable level of introductions of nonindigenous plant pests.

Recommendations:

- **A much higher priority and adequate resources must be allocated now to the revision of the federal foreign nursery stock quarantine and the noxious weed regulation even while the agency works towards revising its foreign fruits and vegetables quarantine regulation.**
- **Pest risk analyses for nursery stock and noxious weed regulations should be housed within PERAL.**
- **PPQ should immediately begin the development of a weediness screen to predict potential invasiveness of plants introduced into new environments.**
- **PPQ should develop a means to evaluate plant taxa, in the field, for potential weediness prior to introduction into the ornamental trade.**

Import and Export Procedures and Standards

With the passage of the PPA, along with new trade obligations and a global marketplace, the mission of the agency has changed; it is no longer simply plant protection. Its revised mission statement:

PPQ's Mission Statement: PPQ safeguards agriculture and natural resources from the risks associated with the entry, establishment, or spread of animal and plant pests and noxious weeds. Fulfillment of its safeguarding role ensures an abundant, high-quality, and varied food supply, strengthens the marketability of U.S. agriculture in domestic and international commerce, and contributes to the preservation of the global environment.

PPQ's Vision: PPQ will provide world leadership, excellence, and innovation in safeguarding agriculture and natural resources.

PPQ's import request responsibilities are clearly delineated and well-established policies govern the processing of phytosanitary certificates. The agency's export responsibilities are ambiguous, especially with respect to providing technical support in response to domestic interests to modify or remove current phytosanitary restrictions in a foreign country.

PPQ bears sole responsibility and accountability for the information and analyses developed in support of the agency's regulatory decisions regarding import requests. In contrast, other agencies, academia, and other nongovernmental entities such as trade associations, and private consultants may provide some applied research, data acquisition, analytical, and other technical services in support of export requests for currently restricted or prohibited products. For such products, however, there are clearly export facilitation functions that PPQ is uniquely entrusted to undertake. Finally, while PPQ is the official liaison to foreign NPPOs, the political, administrative, and legal processes and outcomes in other countries are not subject to the agency's control. For example, market access apparently gained by negotiation later may be denied through legal challenge brought by private parties in the importing country.

Stakeholder Considerations

The 1999 safeguarding review² defined "stakeholder" as "those with a "stake" in the primary mission of the organization, the protection of America's plant resources. PPQ has internal, as well as external, stakeholders. The Office of Risk and Cost Benefit Analysis (ORACBA), Policy and Program Development, and other program staff are examples of internal stakeholders. To meet the needs of internal stakeholders, PPQ's work products must be timely enough for use in trade discussions/negotiations; and, these must provide a sufficient level of technical/scientific information to support US policy decisions.

PPQ's external stakeholders include state plant regulatory agencies, domestic agricultural producers, importers, and exporters as well as consumers and the general public. The interests of these diverse stakeholders are often in competition. The Committee presumes a process serves stakeholders well if it (is):

- Based on science
- Transparent
- Acknowledges and explains relevant uncertainties
- Inclusive of stakeholder input and feedback
- Clear, concise and comprehensive
- Timely
- Responsive to internal and external stakeholder needs
- Iteratively provides for interaction between parties

The Committee finds stakeholders generally well served by the quality of PPQ's scientific work conducted in support of its import and export processes.

Different values and legitimate differences of opinion over PPQ decisions related to import and export risks have led some stakeholders to believe current procedures do not serve them well. Conversely, of course, other stakeholders feel well served by the process when it produces agreeable outcomes. The Committee finds stakeholders generally well served by the quality of PPQ's scientific work conducted in support of its import and export processes as noted elsewhere in this report. It also finds room for improvement among the other qualities listed above.

Creation of the Plant Epidemiology and Risk Analysis Laboratory (PERAL)

Prior to 2001, the responsibility for the production of risk assessments and the administration of risk analysis resided within Plant Health Programs and there were fewer than six risk analysts. In October 2001, a decision was made to relocate the risk assessment function to the newly-formed Center for Plant Health Science and Technology, resulting in the creation of the Plant Epidemiology and Risk Analysis Laboratory (PERAL). PERAL currently has 44 employees of which about 35 are scientists who specialize in risk analysis. This represents a considerable increase in personnel resources devoted to phytosanitary risk analyses. One purpose for this change was to insulate risk analysis from the policy aspect of the agency and to focus more closely on the scientific dimension of trade issues.

The mission of PERAL is to apply state-of-the-art research and science-based processes to develop analyses supporting risk-based decision-making for PPQ programs. The vision of PERAL is to apply risk analysis methodologies to safeguard natural biological systems and agriculture; to lead the world in pathway and other risk analysis as it becomes the leading risk analysis and methods development and applications center.

The workload of the PERAL risk analysts is currently allotted to key activities:

23 percent	Q56 (fruits and vegetables)
12 percent	Pest introduction pathway analysis
9 percent	Q37 (plants for planting)
9 percent	Export PRAs and other technical information or analyses
9 percent	Organism PRAs

² National Plant Board, Safeguarding American Plant Resources, A Stakeholder Review of the APHIS-PPQ Safeguarding System. July 1999.

9 percent	New Pest Advisory Group (NPAG)
9 percent	Geographic information systems (GIS), modeling and mapping
3 percent	Global Pest and Disease Database (GPDD)
5 percent	Capacity building (internal and external training such as workshops seminars, mentoring visitors)
12 percent	Management (the Director and Team Leaders also contribute significantly to the technical work)

These percentages illustrate that resources are allocated according to where the greatest demand is for PRAs. Some additional notes about PERAL personnel resources:

- Eight Foreign Service nationals from the Colombia Center for Phytosanitary Excellence were recently hired by PPQ as scientists/analysts. These new personnel are in the process of being integrated with CPHST work, including in particular PRA. They are expected to become integral members of PERAL but will also provide support across the spectrum of CPHST-related work.
- Five new risk analyst positions have been recently authorized for PERAL. This will provide additional resources that will initially be directed to Q56. The number of Q56 PRAs would be expected to increase to more than 60/year.
- A new information management position was recently authorized for PERAL. This position will provide much needed oversight and coordination to information collection, storage and dispersion resources and activities.

The analyses produced by the PERAL are used to support PPQ's risk-based regulatory policy decisions for export and import initiatives, as well as domestic pest management programs. The work of the staff is also important for identifying and assessing new pest threats, monitoring the effectiveness of existing programs, and helping to prioritize available resources to maximize protection capabilities. The PERAL group has rapidly developed as a key support function for regulatory plant protection in the US and serves as a global benchmark for phytosanitary risk analysis.

The rapid growth of PERAL's risk analysis staff ensures they are experientially "young." It has been observed during this review that PERAL staff lacks peripheral vision concerning the "big picture" of risk analysis because the vast majority of this staff is relatively new and inexperienced. Most staff members lack operational or field experience with the chain of events that moves product from the point of production to final consumption or intended use. There is an especially dire lack of experience with and knowledge of the operational feasibility and efficacy of risk mitigation measures. This is not a criticism, merely an observation that is reasonable considering recent years' ramping up of the program. The Committee finds it in the agency's interest to provide training

opportunities through field experience, site visits and the like and to develop staff retention strategies to provide the much needed in-house capability to conduct good risk analysis.

Recommendation: Field experience, such as site visits, must be part of the training of risk analysts to ensure that mitigation measures chosen are operationally feasible, thus ensuring the utility and credibility of the risk analysis.

Import Procedures

In 1999, recognizing the need to enhance the effectiveness of its safeguarding system, the agency sought input from stakeholders through a formal review process. Under a cooperative agreement with PPQ, the National Plant Board assembled a panel of external stakeholders to review PPQ's safeguarding system. The Safeguarding Review Report, *Safeguarding America's Plant Resources*, was delivered to the agency in July 1999 with high expectations among stakeholders and within the program for its implementation. The report contained over 300 recommendations of which the first recommendation was to urge the agency to work with Congress and stakeholders toward enactment of the Plant Protection Act during the current congressional session. The Plant Protection Act was passed and signed into law in 2000 after 17 years of negotiation.

Section 412 (d) of the PPA required the Secretary to publish for public comment a notice describing the procedures and standards that govern the consideration of import requests. To carry out this mandate in 2001 PPQ published a notice and request for comments in the Federal Register. PPQ continues to work towards being responsive to the relevant issues raised by stakeholders in response to the safeguarding review and the notice it published in 2001. Not all of the measures taken to realize these objectives or outcomes have been fully met; some can be characterized as a "work in progress". The following actions taken by the agency are either accomplished or in process:

- Organizational changes: creation of CPHST and the Commodity Import Analysis and Operation (CIAO) program
- Approval for increased risk analyst and risk management staffing
- Development of the Regulatory Project Management System
- Publication of non-routine PRAs for public comment
- Implementation of the OMB peer review process

Operationally, CIAO officially came into being during the first quarter of 2005 to bring a focus and greater visibility to import issues by creating a dedicated staff for the purpose of analyzing import requests, managing associated rulemaking proceedings, and selecting and negotiating necessary phytosanitary measures. By forming CIAO, PPQ's Plant Health

Programs is seeking to improve the way import requests are managed through the use of import specialists that also function as regulatory project managers for rulemaking proceedings.

The following PPQ initiatives which are underway go further to streamline as well as bringing more consistency, rigor and transparency to its import processes:

- PPQ will expedite the processing of import requests through the streamlining of its fruit and vegetable regulations in 7 CFR 319.56 for risk analyses which are deemed to be “routine”;
- Import requests will have to contain the minimum data elements called for in a new regulation (proposed 7 CFR 319.5) before they are deemed to be complete and ready for processing;
- A discussion of the efficacy of risk management options will now appear in its risk analyses;
- Assumptions and uncertainties pertaining to risk management options will be clearly stated;
- All non-routine risk assessments will be scrutinized to determine if they would be deemed “influential” or “highly influential” and if so, peer reviewed consistent with the OMB guidelines;
- PPQ will seek to explain in its import policy documents the rationale for the selection of risk management options.
- PPQ will communicate with its trading partners, state co-operators, and stakeholders in a clear and timely manner when unanticipated events occur associated with the importation of a commodity.

Publication is anticipated soon of a final rule to require specific information on an import permit application to ensure that PPQ is provided with the information it needs to prepare a risk and/or other analyses. At this time, provision of this information, always needed to process the import request, is optional and very few importers make this information available. So, PPQ has elected to make the submission of such data a mandatory requirement and a pre-requisite for the agency to consider an import request. Streamlining the process should help facilitate trade of both imports and exports. It is the delay in collection of this data that is currently one of the major delays in the processing of import requests. Although it is likely that US trading partners will ask that PPQ submit similar information on behalf of US exporters seeking market access abroad, such basic information should be readily available to our risk assessors and trade directors.

A Regulatory Project Management System (RPMS), currently under development, is intended to be a “real time” tracking system to bring greater accountability and efficiency to the rulemaking process as it pertains to import requests. The RPMS will catalogue the location of all relevant supporting documents and it will provide the document preparers with timely prompts indicating when an action is required to move the document on to the “next step”. RPMS should improve the management of both resources and regulatory actions.

Export Procedures

To facilitate the export of US products, PPQ acts as an intermediary between US exporters and the plant health government agencies of the importing country. PPQ negotiates the risk mitigation and import requirements of another country and certifies that the export product meets those requirements. Other governmental agencies, academia and other nongovernmental entities such as trade associations and private consultants may provide some applied research, data acquisition, analytical, and other technical services in support of export requests. For such products, however, there are clearly export facilitation functions that PPQ is uniquely entrusted to undertake as the US national plant protection organization – including certification that exports meet the phytosanitary requirements of the other country. PPQ is well positioned to serve as the liaison to other federal agencies involved in facilitating exports of US plants and plant products and as the counterpart to other national plant protection organizations.

Where the agency has control, the processes governing export requests are good ones but suffer from a lack of adequate resources. But, most of the export processes are not under the agency’s control. These are dictated and controlled by the country for which market access or retention is sought. PPQ’s role for exports is to provide the evidence and technical justification that it can to meet the other country’s appropriate level of protection and to validate the appropriateness of their demands.

PPQ stresses that there is no backlog of export risk analysis work and that all export issues are considered a high priority and are dealt with immediately wherever possible. Delays occur while waiting for action to be taken by the importing country and it is these delays that contribute to the perception of a backlog. Where necessary resources are reallocated within the PERAL to cover export needs. This work, however, is not usually as extensive as it is for imports.

The PERAL workload allocation reflects the current level of export risk analysis work, not a prioritization of the work. Most requests involve creation of a pest list to share with a trading partner or providing scientific evidence regarding pest status or pest risk for a particular country. “Export PRAs” are rarely undertaken, but are expected to become more common in the future, in particular to expedite trade negotiations for countries where the infrastructure for PRA is less well-developed. If so, both the agency and its stakeholders would benefit from the development of a general guideline, or protocol, on the process that will be followed, including the role of the requesting industry.

PPQ believes that its stakeholders would be better served if information was made publicly available for export-related services and procedures relating to plants and plant products. For this reason, the agency published a Federal Register notice on June 29, 2006 that explains in detail the services offered by PPQ pertaining to the export of plant related commodities. This notice will provide information concerning

trade-related international agreements and details PPQ's role in facilitating the export of plant-related commodities.

In addition, on May 1, 2006, the agency published a notice to provide background information and solicit public comment on the use of bilateral workplans. Bilateral workplans are signed written agreements between PPQ and officials of the importing national plant protection organization that specify the phytosanitary measures agreed to by each party. Bilateral workplans designate how specific phytosanitary issues are to be addressed. This notice is being published for the specific purpose of making PPQ's processes relating to trade more transparent.

An ongoing peripheral export support service is the agency's participation in negotiation and development of international and regional phytosanitary standards. PPQ was an early leader in development of such standards, including those for risk analysis. Development of standards facilitates harmonization of measures and member adherence to regional and international phytosanitary obligations, and downstream can help in the removal of barriers to market access. PPQ has been very influential in the development of international phytosanitary standards and guidelines that facilitate trade through harmonization. The agency also provides international leadership by taking seriously its obligations under international agreements to avoid the development or maintenance of disguised trade barriers.

Four SPS disputes, three of which have been brought by the US, have been resolved under the WTO's dispute settlement process. While underscoring a country's right to determine the level of protection it deems appropriate (also referred to as "acceptable risk"), these cases have also provided valuable juris prudence regarding the purpose and conduct of risk assessments.

- The purpose of a risk assessment is to ensure that measures are applied only to the extent necessary and are not maintained without sufficient scientific evidence resulting in a disguised barrier to trade. This is referred to as the "rational relationship" that must exist between measures chosen and the risk assessment. This finding was made in three of the four disputes.
- A proper risk assessment must include the following elements:
 1. identify the target organism(s) as well as the potential biological and economic consequences associated with entry or spread,
 2. evaluate the likelihood of entry, spread, and,
 3. evaluate the likelihood of entry, spread according to the SPS measures which might be applied.
- In applying element three, a proper risk assessment must evaluate all the measures that might be applied, not just measures which have been applied so that this evaluation does not become "an exercise tailored to and carried out for the purpose of justifying decisions ex post facto".

US success in reinforcing the role of risk analysis, while ensuring that its risk analyses are beyond reproach in the international arena, assists in bilateral negotiations. The agency needs to continue to be a leader in risk analysis by way of a commitment to continuous improvement of its risk analysis protocols and guidelines and participation in international risk analysis fora and standard setting.

Recommendations:

- **PPQ must continue its commitment to be a world leader in risk analysis by way of a commitment to continuous improvement of its risk analysis protocols and guidelines and active participation in international and regional standard development.**
- **Adequate resources must be made available for risk analyses developed in support of export requests to minimize the need to redirect resources away from other risk analysis activities.**
- **PPQ should develop and publish general guidelines for processes that are associated with the development of PRAs and related technical or scientific information in support of export programs, one that includes the role of stakeholders.**

Risk Analysis

PPQ has defined risk analysis to be "the process that includes risk assessment, risk management and risk communication." This is consistent with the so-called plant health risk analysis community. The Committee has given risk analysis as practiced by PPQ, and the broader plant health community, considerable consideration. This section summarizes the observations and findings of the Committee on the topic of the risk analysis paradigm.

Risk analysis has evolved to the point where it has become more than a technique to be taken down off the shelf and applied in specific situations. It has become more of a paradigm, a new approach to solving problems. Risk analysis is becoming the approach that many organizations take to making decisions and solving problems. Unable to "prove" safety, many organizations now are oriented to identifying and managing risks. In best practice the risk analysis paradigm is a way of conducting business in situations of uncertainty and it is driven and led by the risk management framework, i.e., in this instance, the mitigation measures developed and implemented to accomplish the PPQ mission as plant pest issues emerge and threaten the US.

PPQ developed the following vision for risk analysis for the Peer Review Committee:

- All risk analyses are based on scientific methods and evidence and provide a factual basis for decision making;
- Assumptions and the type and degree of uncertainty are characterized in each assessment;

- Risk analyses in support of import decisions are timely, transparent, and include risk mitigation options, and the basis for decisions based on these assessments is well documented;
- A peer review process is used for highly significant and controversial analyses to assure that they are founded on the relevant scientific information and have properly characterized the level of uncertainty;
- PPQ will find innovations to bring greater efficiency, especially to more routine assessments;
- Assessments provide a basis for effective risk communication.

In best practice the risk analysis paradigm is a way of conducting business in situations of uncertainty and it is driven and led by the risk management framework

The risk analysis process and its associated documents in use at the time of the Committee's review did not realize the vision articulated above. The agency was quite candid about the fact that it understood that its stakeholders sometimes have difficulty understanding and relating to agency decisions relative to its risk management decisions. The vision above represents the articulation of an evolving process. To the extent that PPQ realizes this vision, the risk analysis process will more effectively support proposed phytosanitary measures identified by PPQ.

Several issues identified during this review, such as setting program and organizational priorities, allocating resources proportionate to the risk associated with the different pathways (e.g., Q37), identifying a focal point for the management of phytosanitary risks, establishing a risk communication function, etc. can all be addressed within the risk analysis paradigm. Consequently, the Committee encourages PPQ to complete its transition from an agency with a risk assessment focus to a more comprehensive risk analysis agency. As noted in other recommendations, this means the agency must refine and develop its own risk management framework and standard operating procedures for risk assessment, risk management, and risk communication in support of the PPQ mission.

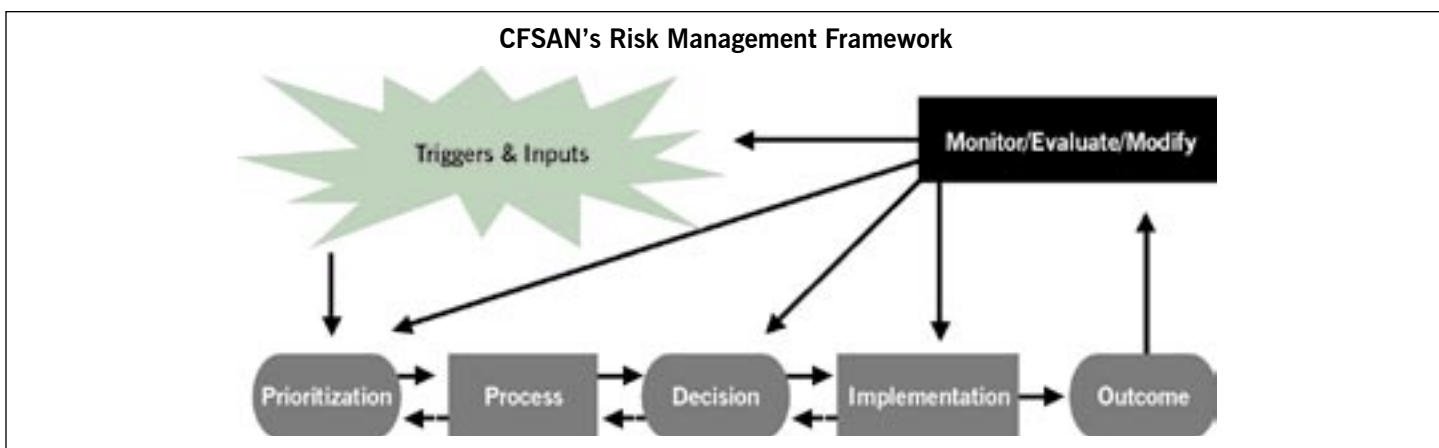
If risk analysis is to be the paradigm for conducting business, a position the Committee favors, then it is helpful to consider the activities (e.g., setting priorities, allocating resources,

performing PRAs, identifying mitigation measures, monitoring the effectiveness of solutions and the like) of such an agency as all being part of the risk management framework. This entails expanding the agency's current view of what constitutes risk management.

To illustrate this expanded view of an agency driven by risk management principles, an example is offered. The example below is taken from a federal agency with food safety responsibilities to present evidence of the pragmatic and timely nature of this approach to managing risks. A sample risk management framework is presented in the following graphic³ from the Center for Food Safety and Applied Nutrition (CFSAN)'s Risk Management Framework Training Manual to illustrate the idea of a risk management framework. The Committee makes no specific recommendation of this model but presents it as an example of what is meant by a risk management framework.

With reference to the above model, PPQ's current pest risk analysis process may be triggered, for example, by the presence of a new pest, a request from a trading partner or individual importer to import a new commodity or a commodity from a new region, or to modify the entry requirements for a commodity already authorized for entry under specific conditions. A trigger is anything that initiates any kind of risk analysis activity.

At any one time PPQ must ascertain which of these triggers needs immediate attention. Those items with the highest priority are addressed by the initiation of an appropriate agency process. There is an internal process, described below, that often but not always includes a risk assessment. There is also an external process that includes risk communi-



³ Center for Food Safety and Applied Nutrition, Food and Drug Administration, US Department of Health and Human Services. CFSAN's Risk Management Framework Training Manual. December 2004.

cation and any formal public participation requirements that bind the agency. Every risk management activity, whether it involves a risk assessment or not, is assumed to review the scientific state of knowledge, analyze available evidence and then interpret this evidence in terms of its meaning for phytosanitary security.

The internal process of a risk management activity should include a review of the effectiveness of risk management options that mitigate identified pests or other risks germane to the mission of the agency. The scientific and other evidence applicable to these risk mitigation alternatives should be presented in the risk assessment when one is done. The PRA by itself constitutes neither a final recommendation nor a decision. A decision is made on the basis of the scientific and other information generated by both the internal and external processes. Implementation may require regulatory action, bilateral trade negotiations or other processes.

In the evolving risk analysis paradigm, best practice risk management identifies the desired outcome of the implemented risk management measures. These outcomes are monitored (measured) as are the state of the science and changing stakeholder values to evaluate the effectiveness of the risk management measures. Those measures that fail to achieve the desired outcomes are modified to assure they will do so. The framework can be seen to underlie a dynamic cycle in which past regulatory decisions are re-evaluated and the validity of a regulation is periodically reviewed.

In contrast to this conceptual model, the PPQ risk analysis process seems to have evolved incrementally, rather than strategically, as an approach to solve problems and resolve issues. It appears to have evolved out of the risk assessment task, with an assessment orientation and a stunted view of the role of risk management in the risk analysis process. There is no sense that regulatory decisions are expected to be validated by monitoring of their results, and routinely reexamined for their continued usefulness.

Now is a good time for PPQ to step back from this evolutionary path and to redirect it with a more formal structural commitment to the broadly construed risk management tasks. Risk management means a great deal more than the steps taken to mitigate the risk of introduction of a pest of concern. A strategic approach to making decisions using the

A strategic approach to making decisions using the risk analysis paradigm, driven and lead by a risk management framework, offers PPQ the opportunity to address many of the issues raised during the course of this review.

Terminology

The following definitions are offered to illuminate, rather than to prescribe, the basic meaning of the three risk analysis tasks as these relate to PPQ:

Risk assessment is a systematic science-based process for quantifying and describing the nature, likelihood and magnitude of risk associated with the potential introduction of pests and diseases associated with export and import decisions. It is to explicitly include consideration of relevant uncertainties.

Risk management is the most important process. It is an ongoing process of identifying and prioritizing the work to be done by PPQ. It includes the process of weighing policy alternatives and implementing appropriate control options, including rule making. It also includes procedures for monitoring and re-evaluating outcomes of the decisions.

Risk communication is the open, two-way exchange of information and opinion about risk leading to a better understanding of the risks and better risk management decisions. It provides a forum for both the internal and external interchange of information with all concerned about the nature of the hazards, the risks, the risk assessments, and how risks should be managed. The internal communications involve risk managers, risk analysts, and other relevant agency personnel. External communications include the risk analysis team, consumers, industry, the academic community and other interested parties.

risk analysis paradigm, driven and lead by a risk management framework, offers PPQ the opportunity to address many of the issues raised during the course of this review.

An additional significant concern that has arisen repeatedly is the transparency of the risk analysis process in general and with the basis for the risk management decision in particular. It is the opinion of the Committee that the outcome of a risk management activity, e.g., the risk manager's decision, should be stated unambiguously and the underlying rationale and basis for the decision should be made explicit. Currently, the decision is provided within a proposed rule but the rationale, or supporting documentation, is largely absent. The Committee observed that the current PPQ risk management function is ill-defined and a formal or structured risk communication function is largely non-existent.

A transparent risk analysis is one that is sufficiently documented to be independently reproduced by qualified analysts. The decision of the risk managers should be directly tied to the evidence presented in the documentation of the risk analysis. A risk communication process that provides meaningful opportunities for input and feedback by all

stakeholders is an important component of a meaningful and transparent risk analysis process. Best practice transparency requires accessibility. State-of-the-art access to information, including innovative and effective use of the internet, and an ISO (International Organization for Standards) system for managing this is dynamic and still evolving. Development of the pest list is based on a thorough search of the available scientific literature, but the other elements of the pest risk analysis, including consequences, are typically categorized qualitatively.

Risk Assessment

PPQ has a relatively long history of doing good risk assessment. It also prepares the most comprehensive pests lists possible using the most comprehensive scientific databases available worldwide. The risk assessments routinely use the best scientific evidence available and assessments are clearly tied to that evidence. PPQ's risk assessments are readily available and, in general, understandable to informed and interested parties. The process and findings of their assessments are reasonably transparent and sound.

One of the more difficult tasks in evaluating a completed assessment is to locate and extract appropriate data for use in the process. The deficiencies, in this regard, noted during this review are due to regulatory and administrative processes, rather than the assessment process itself. We find the general risk assessment process as practiced by PPQ to be appropriate. The manner in which it is and is not used, however, was troubling to the Committee.

The Q56 risk assessment process and supporting documents are well done and will continue to be so as long as there is an agency commitment to continuous improvement of the process. The lack of current risk assessment guidelines for quarantines other than Q56, especially Q37 and the noxious weed regulation, is a major concern of the Committee and an area in need of improvement. Although PERAL is working on the development of global risk assessment procedure for Q37, there is a need for a weediness, or invasiveness, screen to predict when plants may become pests themselves when introduced into a new environment. There is also a need for a means to evaluate plant taxa, in the field, for potential weediness prior to introduction into the ornamental trade.

The current feedback process relies on port of entry inspection and passive surveillance as the primary mechanisms to verify the sufficiency of the phytosanitary measures in place. Active monitoring and surveillance would strengthen the feedback, providing information about the efficacy of individual risk reduction measures and systems of measures under operational conditions. However, PPQ cannot measure everything, everywhere, all the time. Resources available for monitoring and surveillance are scarce, requiring careful consideration of priorities.

The scarce resources of an agency committed to the management of risks need to be allocated with explicit consideration

to areas at greatest risk for new pest introduction. It has been noted by the Committee that the risk analysis process could be enhanced in some circumstances by expanding the range of impacts considered when assessing the risks of an introduced organism, i.e., risks to non-agricultural interests and hosts other than the particular commodity assessed, a consideration of cumulative risk.

Risk Management

Risk management as defined by PPQ and presented elsewhere in this report as risk mitigation and risk management is too narrowly defined. A good risk management process requires a formal framework such as the example model above. Risk management, broadly defined, comprises at least the following tasks:

- Identifying problems on the agency's agenda
- Setting priorities
- Allocating resources to these priorities
- Managing the risk assessment process (e.g. assigning responsibility and deadlines, allocating resources, ensuring appropriate review)
- Evaluating the risks assessed (e.g., economic, environmental, legal or other studies)
- Identifying and evaluating measures to reduce risks
- Overseeing the risk communication process
- Negotiating and making decisions
- Identifying outcomes to monitor
- Monitoring and evaluating the outcomes of the implemented risk management measure(s)
- Modifying the measures as needed
- Documenting the process
- Directing and managing the entire risk analysis process

It should be noted that risk managers need not perform all of these tasks but should be responsible for seeing that they are performed satisfactorily.

The most glaring deficiency is that the risk mitigation decision is not always tied to the evidence in a manner that is transparent to its stakeholders. Good risk analysis requires a logical and rational relationship between the risk assessment and the risk managers' decision. Critics have suggested such a relationship does not always exist in PPQ's decisions. There is a sense in some quarters that if the scientists of PPQ can identify a problem a solution can always be negotiated. The basis for that negotiation is not always found in the risk analysis rendering the process opaque to all those not involved in the negotiated settlement.

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There is currently no formal or comprehensive risk management process the Committee could succinctly identify. In fact, different views of risk management responsibilities between PHP and PERAL appear to the Committee to have left the risk management process in a state of disarray.

PPQ has made a distinction between risk mitigation and risk management in order to clarify the respective functions of PERAL risk analysts and Plant Health Program (PHP) risk managers. The major responsibility for risk mitigation, i.e., finding mitigation options, is housed in PHP. PHP has the principal responsibility for "risk management," the operational actions taken by field personnel to reduce risk. Because of the dispersed responsibility for the bulleted tasks above throughout the agency, the Deputy Administrator of PPQ is the lowest level party with an overall responsibility for the many risk management functions. This is much too high in the organizational structure. The risk management tasks require more effective integration within the risk analysis process. Overall responsibility for the tasks above should be as close to the analysis and activity as possible. Someone needs to be in charge of the sum total of the risk management functions for any given problem and that person should not be at the Deputy Administrator level.

The Committee sees a need for PPQ to articulate and adopt a formal risk management framework for the agency. It bears repeating that the evaluation of risk mitigation measures is not a well defined task and it appears to be a major weak-

The Committee sees a need for PPQ to articulate and adopt a formal risk management framework for the agency. It bears repeating that the evaluation of risk mitigation measures is not a well defined task and it appears to be a major weakness in the overall analysis process.

ness in the overall analysis process. A concern has been raised during this review that at times the agency is in rule-making before the efficacy of the mitigation measures chosen have been analyzed.

The agency appears to be somewhat aware of this ill-defined risk management function and the need to address it. The PPQ Executive Team is aware that roles and responsibilities between PHP and PERAL need to be clarified, and has begun to take action to ensure that specific program responsibilities are clearly delineated. In 2006 a team approach consisting of the PERAL risk analyst, a PHP import specialist, PIM trade director, and CIAO and/or Risk Analysis Systems (RAS) risk manager was implemented to identify potential risk mitigation options to include in the draft risk assessment by PERAL. The risk mitigation options that are identified through this process include those proposed by the exporting country, and risk mitigations applied to the same commodity imported from other countries into the US or from the exporting country into other countries.

Recommendation: Development and publication of a strategic risk management framework for PPQ that will function, more or less, as a flexible standard operating procedure for the agency. This should include:

- **A risk management process that identifies the outcomes expected from measures analyzed, and,**
- **A process to monitor and evaluate the efficacy of risk mitigation measures chosen then a means to modify these as necessary.**

Risk Communication

Risk communication within APHIS seems to be the weakest link in all its risk analysis processes. At present, the role of risk communication within the agency is undefined, although there is a public participation process. Yet, effective risk communication is essential to good risk assessment and risk management. Risk communication must be an ongoing interactive process conducted within the agency and with its external stakeholders; it is more than public participation.

Although good risk communication begins with commonly understood terminology, it is often frustrated in the US by the lack of a two-way communication process. PPQ has expressed frustration with its stakeholders' reluctance to accept agency assurances of its dedication to holding risks down to an acceptable level. This may be due, in part, to not devoting enough effort to learning the specific concerns of stakeholders. There is a need to provide meaningful opportunities for stakeholder involvement throughout the process; this includes opportunities for input, not just feedback. The agency is beginning to make some efforts to dialog with its stakeholders. Its stakeholder meeting regarding Spanish clementines was just such a beginning. But these meetings need to become the norm, not the exception.

Effective risk communication is essential to good risk assessment and risk management. Risk communication must be an ongoing interactive process conducted within the agency and with its external stakeholders.

Failure to involve stakeholders early in the process causes mistrust which in turn generally puts the agency on the defensive. Stakeholders who are not consulted during the decision-making process are more likely to oppose or misunderstand agency decisions. Waiting too long to release information can and does cause issues to be eclipsed by stakeholder anger with the process. The agency must communicate its legal mandates during the risk communication process so all understand the limitations on the agency and stakeholder roles during the process.

It is the quality of the agency's risk communication efforts that will assure its stakeholders of the agency's commitment to the fulfillment of its safeguarding mission. Its ability to effectively communicate risks associated with import requests continues to improve. But efforts to communicate its commitment and means to bring these risks to an acceptable level are hindered by an opaque decision-making process. This continues to produce mistrust of the agency's risk reduction capability by its stakeholders; mistrust that has, at times, led stakeholders to seek legal and legislative remedy. One could argue that the mandate for this review is just such an example.

Historically, the agency has largely relied on formal public meetings/hearings as its means to interact with its stakeholders. Such public meetings and hearings are not often the most appropriate forum for effective and meaningful risk communication. To have a meaningful dialogue about risk, the agency must look beyond traditional and mandated approaches. There is a rich literature on risk communication techniques that build trust and confidence in agency/stakeholder relationships. The key is to provide settings and opportunities that allow the agency to consider and react to concerns and questions when they can still influence the decision-making process.

Risk communication has variously been characterized as consisting of three elements: informing, persuading, and consulting. Risk communication, even done well, will not resolve all conflict. But, risk communication, done poorly, will almost certainly lead to a failure of government to effectively manage risk.

Recommendation: Development and publication of a risk communication strategy that is more interactive than the current one that includes input from its stakeholders prior to rulemaking.

Role of Peer Review

The Committee believes that peer review is desirable and can improve the quality of government science while promoting public confidence in the integrity of the government's scientific products and its decision-making process. Peer review can serve an important quality control function, and there are strong arguments for PPQ to submit the scientific basis for all major regulatory decisions to independent review.

But the Committee wants it clearly understood that peer review is not a means of arbitrating policy decisions. Peer review, where it is conducted at the end of the regulatory development process, adds value primarily by preventing unintended errors or omissions. The anticipated scrutiny also may cause the agency to be more diligent. In addition, the review contributes to an iterative, institutional learning process. However, in many cases, end-of-the-line peer review cannot repair mistakes or omissions made early in the regulatory development process or fill data gaps. Back-end inspection may be able to identify scientific uncertainties, but rarely can it reduce them.

Peer review was considered by the Committee to be one of several types. These include

- External review under OMB guidelines, by experts specifically recruited to carry out this task. Such reviews would be carried out for analyses which are classed by PPQ "nonroutine" and meet OMB's criteria of either "influential" or "highly influential".
- Informal external review by other USDA staff or members of other government or university departments.
- Internal review by other members of PERAL or by other USDA or APHIS staff.
- USDA clearance, in part, prior to document release.

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The choice of reviewers should be as unbiased as possible, given the small size of the pool of expertise available. The OMB guidelines include conflict of interest guidelines which may be difficult to apply unless a larger field of experts can be accessed. It is recommended that PPQ attempt to increase the number of available experts by means of a general call for qualified people who would like to make themselves available. Suggestions from the public could be included in the recruitment strategy. All potential reviewers should be pre-screened for conflict of interest, and no nominee should be self limited to any one specific assessment review.

Timing of reviews may vary depending on the type of review. Internal reviews and informal external reviews may be carried out on a late draft of the analysis. It may be useful to carry out OMB reviews concurrently with the public comment period or to begin the OMB review prior to the public review period.

It is not yet clear how the PPQ criteria for determining which analyses should be externally reviewed relate to the OMB categories. It would be valuable to its stakeholders to have PPQ articulate the relationships among the terms, so that the congruence is consistent. Those asked to carry out a peer review should be made aware of how widely the review will be made available. If it is intended that the individual reviews will be accredited to authors, or a summary report will be created, that should be made clear prior to their agreement.

Internal review is a normal practice in PERAL and data quality is highly valued. A formal peer review process in PPQ is still evolving but there are several practical problems that confront peer review. These are:

- Is the best peer review methodology being used?
- There are relatively few persons or organizations in a good position to do such review.
- The possibility of review and the quality of review vary depending on the availability and willingness of appropriate experts to provide input.
- Availability and willingness of experts to review is a big variable.
- Quality control, consistency, and timeliness are serious challenges.

For the purposes of this review, peer review is considered to be a formal/documented independent review by equivalent scientists beyond the influence of the authors and the major stakeholders that could be used 1) as an impartial means to validate the science, 2) inspire trust, credibility and 3) provide transparency in the risk analyses performed. PPQ has similarly defined peer review as a scientific review of a PRA document that is conducted by individuals competent in the area of risk analysis and in phytosanitary matters and that focuses, among other things, on the careful evaluation

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of scientific evidence used, its comprehensiveness, the appropriateness of analyses and interpretations of the evidence and uncertainty, and the validity of conclusions.

PERAL's *internal* review; and PPQ's clearance processes consist of the following steps:

1. A commodity risk analysis is assigned to a scientist in PERAL and after a first draft is completed, the document is subjected to internal review. This internal review is conducted by scientific peers within PPQ, usually (but not always) within PERAL. Guidelines for this review process are part of PERAL's ISO 9001/2000 certification.
2. Certain analyses are sent to USDA's Agricultural Research Service (ARS) for technical review (currently averaging approximately ten per year). The review focuses on the risk analysis for the commodity but may extend to review of the underlying evidence. The number and nature of analyses submitted for ARS review depends on the availability of resources in ARS to support this work, the type of expertise needed for review, and the time available. The document may also be distributed to academic and other scientific counterparts in universities or independent international groups. Scientific staff (professors) at accredited universities may be considered appropriate reviewers.
3. Routine (non-significant) analyses are forwarded to the relevant PPQ program staff after internal PERAL review and external review that may have been possible. By previous policy directive and for all "significant" rules or those that are expected to receive this designation or for items that appear to be controversial, the risk analysis is reviewed by the Policy and Program Development Staff (PPD, an independent group within APHIS). Concerns or issues raised by PPD are communicated back to PPQ and the document is revised, as appropriate. Once PPD clears the document, it is submitted to the relevant PPQ program.

4. PPQ programs receive the document from PERAL (routine) or PPD (significant) and may make adjustments as necessary for policy purposes before making the document public through a Federal Register notice. During the public comment period, PPQ may also send copies of the risk analysis documents to known experts requesting review and comment.
5. After the PRA goes through public comment, all input is evaluated and the document is revised, as appropriate. For significant rules, the revised PRA may go through PPD once more, and PPD forwards the document for interagency review. If the proposed rule is estimated to have an annual economic impact of \$100,000,000 (in 1994 dollars), ORACBA is required to review the risk assessment and cost-benefit analysis. The Office of General Counsel (OGC) is responsible for reviewing proposed and final rules for legal sufficiency, which is integral to regulatory review but distinct from scientific peer review.
6. If a decision is made (considering the risk analysis and other supporting documents) to proceed with a rule, the Administrative Procedure Act requirements are followed. This includes a second round of review, as part of the public comment period on the rule itself. If the rule survives stakeholder and agency review, it is then signed and becomes effective, usually within 30 days of signature.
7. If the risk analysis document concerned movement of a commodity, a permit will be available immediately once the rule is effective and will have a validity of five years. However, changes in pest dynamics or updates to the risk analysis document may affect the validity of a permit depending on the nature of new risk factors.

Implementation of the OMB Guidelines

PPQ currently classifies risk analyses as being either “routine” or “non-routine”. Non-routine risk analyses are published for public comment for 60 days prior to the publication of a proposed rule. Generally speaking, PPQ will seek to have any risk analysis deemed “non-routine” to be a candidate for peer review under the OMB guidelines. The OMB guidelines require agencies to categorize scientific analyses as being either “highly influential” or “influential”; those classified as such are subject to peer review. Currently there are five such risk analyses that are candidates for peer review.

Risk analyses identified as non-routine will then be screened to determine if they would be deemed to be influential or highly influential. Peer reviewers shall likely be asked to commence their review at the same time a risk analysis is made available for a 60-day public comment period and announced in the Federal Register. Peer reviewers will be asked to complete their review within a 60-day comment period that runs simultaneously with the public comment period. In some cases peer reviewers will be asked to review public comments. The author of the risk analysis will then have two sets of comments to address: those from the general public and those from the peer reviewers.

It is PPQ’s intent to make this process as transparent as possible by summarizing the comments received from the public and peer reviewers and providing PPQ responses to the comments submitted, including the reasoning as to why a comment was accepted or rejected. The comments and PPQ’s responses to the comments will appear in an addendum to the risk analysis. The revised risk analysis will also be made available for public scrutiny a second time when a proposed rule is published based on the risk analysis which has been both previously peer and publicly reviewed. PPQ believes that the peer review process will make such documents more robust and less susceptible to scientific or legal challenges.

At this time the greatest challenge will be finding qualified peer reviewers; this universe is exceedingly small. There is a need for more collaborators with differing skills and knowledge (mitigation, evaluations, economics, cost/benefit analyses, modeling, etc.) rather than simply reviewers. Information voids and uncertainties can be illuminated by review but it cannot fill them. It may be a challenge to develop a meaningful peer review process and still be in compliance with Federal Advisory Committee Act (FACA) depending on the peer review and transparency mechanisms chosen.

Currently, PPQ has no formal relationship with experts, institutions, or agencies that may be asked to assist with external peer review, thus such reviews are agreed on a voluntary and ad hoc basis and most likely with minimal compensation for the required resources (primarily expert time). As a result, PPQ has no possibility to prescribe the time required for such reviews or specify the quality of the products.

Recommendations: Implementation of peer review for risk analysis must include:

- **Augmentation of the pool of peer review experts by means of a general call for qualified people who would like to make themselves available. Suggestions from the public could be included in the recruitment strategy. All potential reviewers should be pre-screened for conflict of interest, and no nominee should be self-limited to any one specific assessment review. Areas of expertise of potential reviewers should be inventorized for relevance to PPQ needs.**
- **Inclusion of relevant international obligations that are applicable to pest risk analyses in its peer review plans to provide context and guidance to the reviewers.**
- **Material that goes to peer review should include not just the scientific content (pest lists and biological information), but also the potential mitigations which are being considered. PPQ should use Methods Development scientists to review this part of the risk analysis documents,**
- **Development of a clear set of criteria for determining which pest risk analyses qualify as “influential” or “highly influential” under the OMB guidelines.**

Conclusions

PPQ's external stakeholders include domestic agricultural producers, importers, and exporters as well as consumers and the general public. The interests of these diverse stakeholders are often in competition. Different values and legitimate differences of opinion over PPQ decisions related to import and export risks have led some stakeholders to believe the current procedures do not serve them well. It is the Peer Review Committee's belief PPQ can best serve its stakeholders by effectively accomplishing its mission. But PPQ will not be able to do this unless its import and export systems are supported by a regulatory structure that is based on risk, i.e., one that will enable it to prioritize its resources based on risk.

A major finding of the Committee's review is that PPQ should complete its transition from a focus on risk assessment to become a risk analysis agency. This means the agency will need to develop its own risk management framework and standard operating procedures for risk management, risk assessment and risk communication in support of the PPQ mission. To the extent that PPQ realizes its risk analysis vision, the risk analysis process will more effectively support its proposed phytosanitary measures.

The Committee believes that peer review is a desirable thing that can improve the quality of government science while promoting public confidence in the integrity of the government's scientific products and its decision-making process. But it must be understood that peer review is not a means of arbitrating policy decisions. Peer review cannot be used to determine whether or not the data and analysis are adequate for regulatory decision-making.

Recommendation: PPQ should request another independent review in three years' time to look at the effectiveness of both PPQ's current import and export initiatives in progress and the status of the implementation of the recommendations found within this report.

Peer Review and Steering Committee Members

Peer Review Committee

Ms. Dorteza Zadig, Peer Review Committee Chair. Ms. Zadig is a Program Supervisor with the Plant Health and Pest Prevention Services division of the California Department of Food and Agriculture. She is responsible for the development and review of risk analyses and various other scientific and technical support activities. In addition, she is a member of the North American Plant Protection Organization's panels for pest risk analysis and plants for planting. She was a member of the Safeguarding Review Panel and chair of its Pest Exclusion Committee.

Mr. Richard Orr is the Assistant Director for International Policy and Prevention, National Invasive Species Council, US Department of the Interior. Mr. Orr has an MS in Entomology from Brigham Young University and a BS in Biology from Southern Oregon University. He has been with the National Invasive Species Council since 2003. Mr. Orr was previously employed as a Senior Entomologist with USDA/APHIS for 22 years. For the final ten years with APHIS, Richard was involved in the development and design of risk assessments, risk management projects, and interagency and interdepartmental projects dealing with various invasive alien species. Before joining USDA/APHIS, Richard conducted international and domestic entomological research, including a two-year natural history study of West African timber pests for the Smithsonian Institute. Over the past 20 years, he has been actively involved with ecological and distributional research involving dragonflies and damselflies for the US Fish and Wildlife Service, National Park Service, Nature Conservancy, and Maryland's Department of Natural Resources.

Dr. Mark R. Powell is a Risk Scientist with the USDA Office of Risk Assessment and Cost Benefit Analysis (ORACBA), where he focuses primarily on sanitary and phytosanitary issues. Dr. Powell received his Ph.D. in Ecology from Rutgers University. Prior to coming to ORACBA, he was a risk assessment team leader at the USDA Food Safety and Inspection Service. He was formerly a Fellow at the Resources for the Future Center for Risk Management, where he published Science at EPA: Information in the Regulatory Process in 1999.

Mr. Thomas Sim IV served the Kansas Department of Agriculture from 1975 to 2005 first as the agency's plant pathologist and later as the Kansas state plant regulatory official to the Central and National Plant Boards. In November 2005, Mr. Sim became the Director of Regulatory Operations for USDA-APHIS Biotechnology Regulatory Services.

Dr. Ken Vick has been the USDA/Agricultural Research Service's (ARS) National Program Leader for post-harvest entomology since 1991 and Senior National Program Leader since 1997. As such he oversees the ARS research program dealing with plant quarantine issues, both import and export. He also leads the ARS research program for alternatives to methyl bromide. He has worked with APHIS on many quarantine assignments including bilateral negotiations and at the World Trade Organization. He serves on the Montreal Protocol Methyl Bromide Technical Options Committee and the Quarantine/Preshipment Taskforce.

Dr. Doreen Watler has a background in Entomology, with a Ph.D. from the University of Alberta, Canada. She has worked in the Canadian Plant Health Program for nearly 25 years, initially as a risk assessor in Agriculture and Agrifood Canada, and currently as the National Manager of the Plant Health Risk Assessment Unit, in the Science Branch of the Canadian Food Inspection Agency, which comprises a team of entomologists, plant pathologists and botanists providing risk assessments and technical information and advice to the Plant Health Division of the same agency. The Plant Health Survey Unit is also under her management.

Dr. Charles Yoe is a Professor of Economics at the College of Notre Dame of Maryland and Adjunct Professor in the Department of Nutrition and Food Science at the University of Maryland. Risk analysis is his current area of primary research. Dr. Yoe developed and has taught courses in risk assessment and risk management for several agencies of the U.S. federal government in a wide variety of risk analysis applications. His applied risk assessment work includes participation in over 75 projects, one of which won the Secretary's Award for the US Department of Agriculture 2000. He has also received the Food and Drug Administration Director's Special Citation Award and the FDA CFSAN Director's Special Citation Award in 2004 for work in risk analysis. He has served on several FAO/World Health Organization Expert Consultations, has done methodological research to support the development of a revised microbial risk assessment framework for the Risk Assessment Consortium and Environmental Protection Agency, was the principle author of a risk analysis overview manual for FAO, and has participated in a series of on-site risk analysis training seminars in Africa and Eastern Europe for USDA's Foreign Agricultural Service.

Steering Committee

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Terms of Reference and Abbreviations

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CGPT - 2005	Consolidated Glossary of Phytosanitary Terms – 2005; contains the Glossary 2004 and terms approved in 2005, prepared by the IPPC Secretariat, July 2005
CIAO	Commodity Import Analysis and Operations
CPHST	Center for Plant Health Science and Technology
FAO	Food and Agriculture Organization of the United Nations
IPPC	International Plant Protection Convention as deposited with FAO in Rome in 1951 and as subsequently amended (CGPT - 2005)
IQA	Information Quality Act, Section 515 of Public Law 106-554, 2000
ISPM	International Standard for Phytosanitary Measures, an international standard adopted by the Conference of FAO, the Interim Commission on phytosanitary measures or the Commission on phytosanitary measures, established under the IPPC
NPB	National Plant Board
NPPO	National Plant Protection Organization
OMB	Office of Management and Budget
ORACBA	Office of Risk and Cost Benefit Analysis
PERAL	Plant Epidemiology and Risk Analysis Laboratory
Pest risk analysis	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 (CGPT - 2005)
Pest risk assessment	For quarantine pests: Evaluation of the probability of the introduction and spread of a pest and of the associated potential economic consequences (CGPT - 2005)
Pest risk management	For quarantine pests: Evaluation and selection of options to reduce the risk of introduction and spread of a pest (CGPT - 2005)
PHP	Plant Health Programs
PIM	Phytosanitary Issues Management
PPA	Plant Protection Act
PPD	Policy and Program Development
PPQ	Plant Protection and Quarantine
PRA	Pest risk analysis (CGPT - 2005)
Quality	An encompassing term comprising utility, objectivity, and integrity. The guidelines sometimes refer to these four statutory terms, collectively, as “quality”. (OMB IQA Guidelines, 2002)

Risk assessment	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 biological and economic consequences.... (Annex A, paragraph 4, SPS Agreement)
RPMS	Regulatory Project Management System - Intended to be a “real time” tracking system to bring greater accountability and efficiency to the rulemaking process as it pertains to import requests.
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 (CGPT - 2005)
Transparency	The principle of making available, at the international level, phytosanitary measures and their rationale (CGPT - 2005)
TST	Trade Support Team
USTR	US Trade Representative
WTO-SPS	World Trade Organization - Agreement on the Application of Sanitary and Phytosanitary Measures

