National Quality Assurance Program Review
Phytophthora ramorum

USDA, APHIS, PPQ
Quality Assurance Review Team

October 30, 2009

Executive Summary

From April - August 2009, a national review of the Phytophthora ramorum (*P. ramorum*) program was conducted as part of the PPQ National Quality Assurance Program at the direction of the National Plant Board and PPQ Executive Team. The primary goal of this review was to evaluate the programs business practices for strengths and weaknesses, and to identify areas in need of improvement. Program information was collected through three data gathering components. These components included: 1) site visits to California, Connecticut, North Carolina, Oregon and Washington; 2) focus group discussions at the Southern Plant Board meeting in Greenville, SC, and California Oak Mortality Task Force Symposium in Santa Cruz, CA; and 3) interviews and surveys of state and federal program officials.

Key issues were identified and are summarized in this report. Some of the key findings include the following:

- States visited recognized that further spread of *P. ramorum* cannot totally be prevented; however, without the program it would be widespread nationally in the nursery trade and would have spread further into the natural environment
- Best Management Practices (BMPs) afford significant reduction of risk in states where they are used
- The program has increased awareness of overall plant health in nurseries which has led to improved nursery management practices
- The *P. ramorum* program focuses on the infected host material (disease) and not the pathogen itself, which can also occur in soil and water. This is a point of major concern
- Trace work is resource intensive with limited benefits
- There are still many unknowns regarding environmental impacts, movement of the pathogen, and ability of the pathogen to cause disease

The review revealed several opportunities for program improvement. Some of the opportunities include the following:

- Clearly stated program goals and a set of program measures that serve as a true indicator of program success
- More options for treating *P. ramorum* in soil
- Review and revision of various APHIS protocols
- Greater application of BMPs to prevent further spread
- Improved program outreach – especially as it relates to BMPs
- Field diagnostic tools for rapid detection and screening
- More research in several areas including water contamination, causes of repeated infested nurseries, potential pathways, and pathogen movement

The final report of the National P. ramorum Quality Assurance Review contains thirty-two recommendations for improvement of the overall program.

Background:

Introduction

From April - August 2009, a national review of the Phytophthora ramorum (*P. ramorum*) program was conducted as part of the APHIS National Quality Assurance Program at the direction of the National Plant Board and PPQ Executive Team. The goal of this review was to identify program strengths, weaknesses, and areas for improvement. Due to the broad scope of the *P. ramorum* program, a Quality Assurance Coordination Team (QACT) was assembled to devise a plan to evaluate program components, and to identify necessary expertise and evaluation methodology. The QACT members were as follows:

Jeff Grode, Associate Director, Emergency and Domestic Programs, Riverdale, MD
Dominic Santoro, PPQ Eastern Region Quality Assurance (QA) Coordinator, Raleigh, NC
Jim Schoenholz, PPQ National QA Coordinator, Raleigh, NC
Carl Schulze, National Plant Board Representative, Trenton, NJ
Regan Thomas, PPQ Western Region QA Coordinator, Fort Collins, CO

Methodology

The program components of the *P. ramorum* program were reviewed using various methods. Operational components were reviewed through observation via site visits to California, Connecticut, North Carolina, Oregon and Washington. Other components were evaluated through two focus group discussions at the Southern Plant Board meeting in May, 2009, and the California Oak Mortality Task Force Symposium in June, 2009. In addition, 19 interviews/surveys of state and federal program personnel were conducted.

Site Visits

A review team was established for the site visit portion of the review. The team consisted of a cross section of eastern and western PPQ personnel that were knowledgeable of the program but did not have a specific stake in the results of the review. The review team members were as follows:

Clinton Campbell (Team Leader), PPQ, State Operations Support Officer (SOSO), Des Moines, WA
Jerry Levitt, PPQ, State Plant Health Director - Arizona (SPHD), Phoenix, AZ
Mary Mahaffey, PPQ, Plant Health Safeguarding Specialist (PHSS), Aurora, CO
Patrick Shiel, PPQ/Center for Plant Health Science and Technology (CPHST), Plant Pathologist, Raleigh, NC
Matt Travis, PPQ, State Plant Health Director - Maryland (SPHD), Baltimore, MD

Don Seaver (CPHST - Staff Scientist) and Terry Bourgoin (SPHD - Maine) filled in for Pat Sheil and Matt Travis respectively for site visits they were not able to attend. Dominic Santoro and Regan Thomas served as review coordinators in their respective regions.

Team members collected information through direct observations, interviews, and review of documents (e.g. correspondence, program records, analysis, and reports). Team members reviewed the information obtained during the visit in relation to effectiveness of

program delivery, efficiency of operations, and compliance with policies and regulations in achieving established goals. These site visits included observations and discussion with industry, state, and federal personnel regarding; 1) program operations and management oversight; 2) operations at nursery growers and retailers; and 3) operations at accredited and non-accredited state laboratories.

Focus Groups

Two facilitated focus group discussions were conducted at the Southern Plant Board (SPB) meeting in Greenville, SC in May and at the California Oak Mortality Task Force (COMTF) Symposium in Santa Cruz, CA in June. These focus group discussions were an open invitation to all meeting attendees. There were 16 participants at the SPB session and 11 at the COMTF session representing various industry, county, state, federal agencies and organizations.

Interviews

Interviews and surveys were conducted by the QACT to gather information regarding Program Management and Oversight; Laboratories and Diagnostics; and Survey activities including trace related surveys and the CAPS components. Those surveyed included National Laboratories at Kansas State University and Penn State University, and the USDA Laboratory in Beltsville, MD. Other targeted interviews/surveys included National and Regional Program Managers as well as State Operations Support Officers. State interviews/surveys conducted by Regional Program Managers included SPHDs and SPROs from Georgia, Mississippi, Louisiana, Texas, New Jersey, and Nevada.

Final Report

This report provides a comprehensive evaluation of the *P. ramorum* program based on information derived from a cross section of industry, state, and federal representatives across the United States. The observations in this report are broad in nature and focus on the program as a whole. Detailed information collected during the review is not part of the distribution for confidentiality purposes, but is being used by the *P. ramorum* program.

Findings and Recommendations:

SECTION 1: PROGRAM MANAGEMENT AND OVERSIGHT

A. General Program

1. Program Goals

Through discussions with program managers in all states visited, several program goals were stated. Examples of goals stated include the following: 1) maintain federal quarantine and enforcement, 2) serve the nursery and citizens, 3) protect the natural environment, 4) maintain trade, 5) eradicate and/or control the disease, and 6) mitigate the risk of spread. The stated goals of the program expressed by the interviewees were dependent on the level (local, state, or federal) of their involvement within the program. Of the goals stated, several reasons were given as to why the program was not meeting these goals. Reasons included: 1) limited financial and human resources, 2) industry and state pushback on regulations/policy, 3) lack of available science related to policy, and 4) slowness of the regulatory process. In these discussions it was also unclear to all involved as to what the primary purpose of the program was; therefore, this was stated as another reason why perceived national goals are not being met.

Recommendations

- Redesign national program goals to unify program stakeholders towards a common purpose.
- Develop a general purpose(s) statement that describes a strategy for reaching the stated goals.

2. Program Strengths

Stated program strengths were as follows:

- Good relationship between counties, states, and industry
- The program facilitates shipping/trade
- Some states identified having strong industry support
- Best Management Practices (BMP) in states that use them work well and have had positive impacts through improved nursery practices
- Program delivery has become more efficient over time
- Program helps industry see things differently and strive for a good plant health program
- Increased awareness of other *Phytophthoras* has helped develop the program infrastructure to better safeguard nursery production
- Good diagnostic laboratory support
- Field support at federal and state levels
- Support from different states/industry groups

Recommendation

- None

3. Program Weaknesses

Stated program weaknesses were as follows:

- Unclear and complicated regulations and protocols (continue to become more complicated and unclear)
- Underutilized BMPs by industry
- Inadequate outreach communication on the use of BMPs to educate industry on pathogen concerns
- Laboratory testing is good for after the fact detections, but is inadequate for a proactive disease monitoring system
- Traceback protocols are resource intensive with limited results
- Fungicide masking of symptoms makes it hard to detect the disease
- Lack of knowledge about the disease in the initial phases (getting better, but more is needed)
- Disease is a moving target (i.e. expanding host material, environmental, fungicides)
- Resource intensive program both in personnel and dollars
- Lack of applied science and methods (i.e. soil and soil treatments) for control and eradication
- Lack of understanding of the actual impacts of the pathogen (i.e. forest establishment; can it be eradicated?)
- Pushback from industry over stricter regulatory measures
- Nurseries for the most part look at the bottom line and do not go beyond the basic requirements
- Lack of detection tools (diagnostic tests) in the field
- Lack of a process for counties/states to be removed from a regulated area status

Recommendation

- Develop a program strategy to meet program goals and address identified program weaknesses.

4. Certification Program

Nursery certification programs geared towards *P. ramorum* management have been beneficial to nurseries in providing educational information and general practice guidelines regarding *P. ramorum* and other plant pest and disease issues. There are several good models to follow in developing a clean stock program. The more successful models emphasize county, state, federal, and industry collaboration.

Recommendation

- Develop an enhanced standard certification program to be available to states and counties in the regulated area. Enhanced certification goes beyond current nursery stock certification inspections; it involves production practices which are audited.

5. Best Management Practices (BMP)

Best Management Practices (BMP) in states that use them work well and have had positive impacts through improved nursery practices. Nurseries that have incorporated these practices are quick to recognize potential problems and address them immediately.

Recommendation

- Consider adopting the best available BMPs with a broad systems approach as the standard for phytosanitary certification in the regulated areas. These BMPs should be tied to all future outreach efforts and should be made mandatory as a prerequisite in the regulated areas.

6. Funding

Funding levels vary from state to state. Federal Cooperative Agreements in some states are the sole funding source for this program. States commented they do the most they can with the funding they receive and lack of funding can jeopardize program progress. It was also noted that a National *P. ramorum* survey has not been conducted in several years due to lack of funding. Compensation for plant removal was communicated as a means to provide incentives to nurseries to report potential problems or symptomatic plants. Other programs were cited for having this program component (i.e. citrus canker, plum pox) where *P. ramorum* does not.

Recommendation

- Investigate the feasibility of a compensation component to enhance program cooperation and provide incentives to report potential problems.

7. Political Pressures

There were no political pressures identified within the states that negatively impacted the ability to carry out provisions of the *P. ramorum* program. However, external political pressures between regulated and non-regulated states were cause for concern.

Recommendations

- None

8. Program Life Cycle

This program was viewed by review participants as a stable-ongoing program. It was noted that the review participants saw this program as a means to maintain trade and did not see an end strategy.

Recommendation

- The program purpose statement (recommended in Section A. 1, above) should include an exit strategy.

B. Organizational Structure and Staffing

This is a joint state and federal program (including counties); however, roles and responsibilities of federal, state and local personnel vary. In California the counties carry out the operational components of the program where CDFA and PPQ carry out the managerial components. In most other states, PPQ serves in the managerial role and states carry out the operational functions. Overall the management structure supports all necessary program functions.

Recommendation

- None

C. Training and Recruitment

States provided regulatory training and industry provided nursery employee training to meet their needs. Training in the regulatory area is provided by states regarding symptoms and survey techniques. Nursery employees are trained in detection and management practices. Overall training appeared to be adequate and readily available. Lack of funding in some states was a factor in not being able to provide as much training as they wanted. Turnover did not appear to hamper program progress or operations.

Recommendation

- None

D. Program Planning and Work Plans

Work plans are prepared as part of the Cooperative Agreements process and provide adequate program direction to states and counties.

Recommendation

- None

E. Performance Measures

Some targets or milestones are set by states to measure local accomplishments. The team did not identify any overarching set of program measures that would serve as a true indicator of program success. The most used measure of progress stated was the decline in the number of positive nursery detections. Industry communicated that APHIS should be able to tell them how well they are doing in regards to this program.

Recommendation

- Utilize national program measures that focus on revised program goals and outcomes.

F. Risk Analysis

Informally, risk has been analyzed at the local and industry level and the results are used in developing their management practices. On a larger scale, there have been limited risk studies regarding host material and potential pathways. This pathogen is considered by states and industry to be high risk for spread due to the broad range of host material. This pathogen is also considered high risk due to potential economic impacts on the nursery industry, and potential environmental and forest impacts. This is a necessary program based on science and risk.

Recommendation

- None

G. Program Operational Guidelines

PPQ writes and issues protocols for nursery survey, confirmed nurseries, and laboratory activities with input from states and industry; however, some states indicated the lack of opportunity for input. The protocols essentially drive the program's activities. There was great concern that the protocols were not always clear and needed to be interpreted by states before being distributed to industry. Time and resources were a stated concern in getting the protocols clear, concise, and current.

Recommendation

- Protocols need to be reviewed and revised by the National Program Manager to be more clear and concise with state input.
- Protocols need to be routinely reviewed and validated for applicability.

SECTION 2: OPERATIONS

A. Exclusion

The nursery exclusion function is focused on where nurseries obtain growing stock. Certified nurseries in the regulated area have increasingly moved to propagating their own stock in lieu of buying from outside sources. This has become a nursery level initiative.

P. ramorum is very difficult to detect on infected host material at port of entry Plant Inspection Stations due to several factors. Post entry quarantine is not required for entry of this plant material.

Recommendation

- Recommend that CPHST evaluate whether Q37 needs to be revised to include Rhododendrons, Pieris, Viburnum, Camellia, and Kalmia for post entry quarantine.
- Develop disease indexing and other testing protocols that can be implemented to verify and assure propagative material entering the U.S. is disease free.

B. Survey (CAPS) Pest Detection

CAPS funding is used in some states to conduct routine *P. ramorum* survey. Other states fund their own surveys through routine nursery inspections. It was indicated that inspectors are adequately trained and guidelines are followed. It was also indicated that funding was not available for a national CAPS survey for *P. ramorum*. The last national survey was conducted in 2005.

Recommendation

- Revisit the need to conduct another National CAPS Survey.

C. Survey (Trace)

The process to compile shipping records on the production end to provide trace information to regulatory officials is a very lengthy one. Regulatory officials on the receiving end indicated that they usually receive the trace information too late, since the plant material has already moved and nothing is left to inspect. Or, the plant material has already been in the state six months to one year before it has been traced. The overall trace

process is costly and resource intensive with questionable benefits. Timely notification is the key for trace work to be successful as plant material moves quickly in the nursery industry.

Recommendations

- Conduct an analysis of trace work to determine how successful trace work is in finding positive nurseries and the results of any follow-up surveys.
- Investigate the feasibility of providing shipping information to states receiving host plant material from regulated areas.

D. Sample Collection and Processing

The survey and sample collection process is solely dependent on the inspector's ability to find symptomatic plant material. The success of this process is based on many factors including environmental and use of fungicides. It is critical that more tools be made available during sample collection to help with detection at the field/nursery level.

Across the board, the sample collection and processing at all locations appeared to be in accordance with the protocols. The nursery sampling manual is followed. Sample tracking methods from the collection point to processing was adequate to ensure sample integrity. There was a general concern that the 40 sample minimum was not enough to detect *P. ramorum*. Several locations indicated that more samples were needed.

Recommendations

- Research the development of field diagnostic kits for quick screening and/or early *P. ramorum* detection.
- Evaluate the efficacy of the 40 sample minimum protocol to detect *P. ramorum*.

E. Regulatory Inspection (CFR)

Regulated states schedule regulatory inspections at times of year that are conducive to *P. ramorum* detection. Inspections are conducted annually in regulated counties and monthly in quarantine counties for certified nurseries that ship interstate. Inspection protocols were followed at all sites visited.

Recommendation

- None

F. Regulatory Compliance

Compliance agreements are a regulatory component of the program and used in regulated states to ensure compliance by nurseries and facilities shipping interstate. Inspections occur monthly for nurseries in quarantined counties and annually for nurseries in the regulated counties. The regulatory component of this program (including state and federal regulations) appears to effectively prevent the spread of the disease – to the extent possible. However, it was indicated from non-regulated states that the regulations did not go far enough in preventing the spread, since the current regulations allow the movement of known host material when similar programs do not allow this movement. It was stated

on several occasions that USDA regulates the infected host material (disease) and not the pathogen. There is a need for more focus on the pathogen and less on the symptoms.

It was pointed out that an Emergency Action Notification (EAN) cannot be issued to hold the potentially infested nursery stock until a determination has been made by the Beltsville laboratory. A few states questioned why they had to wait for federal laboratory confirmation to issue an EAN rather than rely on their own laboratory determination since they have been certified and proficiency tested.

It was also pointed out that there is no process/protocol for moving from a regulated status to a non-regulated status. Counties and states identified a need to establish a process that would allow them to move towards a non-regulated status.

Recommendations

- Recommend that the regulations be evaluated to include regulation of the *P. ramorum* pathogen in addition to the host material (disease).
- Develop a process for moving a geographic area (state/county) from a regulated status to a non-regulated status. This process should be supported by current science.

G. Treatments and Environmental Monitoring

Effectiveness of the Confirmed Nursery Protocol (CNP) is sketchy in regards to soil treatment, plant destruction blocks, and other mitigation measures. Soil treatment was mentioned multiple times as an area lacking the scientific support for adequate mitigation of the pathogen. There was disagreement among review participants as to the effectiveness of the size of the destruction block in relation to prevention of new infestations or contamination of other material in the nursery.

Recommendation

- There is a need to develop multiple efficacious soil treatment methods.

H. Sanitation/Cleaning and Disinfecting/Bio-Security

The program has a sanitation component. All sites visited were following sanitation protocols and taking necessary steps to prevent contamination through the movement of material onto the premises. Program personnel had necessary bio-security supplies and materials available in their vehicles. In California, BMPs contain good information regarding bio-security measures to prevent the movement of the pathogen. Nurseries are aware of sanitation methods.

Recommendation

- None

I. Laboratory

The proficiency testing is conducted annually at all certified laboratories. The process for this testing is time consuming and resource intensive. Many states felt this annual testing was beyond what was necessary for certification.

Many review participants stated the need to readily access the most current laboratory protocols. This was not always the case as the PPQ *P. ramorum* program website did not carry the most current information. The CPHST website is not directly updatable by personnel that post laboratory protocols. These protocol updates have to go to an Information Technology group in PHP to upload them, which creates a lag time in getting timely laboratory updates to the field locations.

It was communicated that the turnaround time for samples sent to the USDA Beltsville Laboratory was very good. There was some concern regarding the lag time from sending a sample to the local laboratory and getting results. The concern was that plants are not placed on hold and can move before results are completed. This was a concern during the seasonal peak of sample collection and getting results in the regulated and quarantined areas.

The implementation of real time PCR is a proven technique and works very well. Laboratories stated there was less contamination and this was a very reliable diagnostic tool.

There was concern among state laboratories regarding the length of the process for getting soil sample results in order to release the nursery. It was indicated that this process can take months.

Recommendations

- Allow CPHST access to the website to make timely laboratory protocol updates.
- Explore process improvements and other methods to expedite the *P. ramorum* proficiency testing to be less time consuming and resource intensive.
- Methods to detect *P. ramorum* in the soil need to be improved.

J. Pest Detection and Response

States are generally satisfied that the detection process is working through the quarantine and regulated county inspection program. Response from the Beltsville lab for final determination is good when samples are forwarded.

Recommendation

- None

K. Scientific Effectiveness (Methods)

It was stated on many occasions that more research on effective methods is needed. More importantly was the ability to integrate solutions into operational practices. Program areas most often cited for needed research included:

- Causes/pathways of repeated infested nurseries
- Soil contamination testing and mitigation measures
- Water contamination (i.e. genotyping of pathogen in water and nurseries)
- Potential movement of pathways into, and within, nurseries and environment
- Development of field diagnostic tools (field ID)

- Efficacy of the destruction lot size (CNP)
- Validation of block buffer distance to control pathogen movement

In regards to water detection, there was concern regarding water positives and the potential impacts on nurseries and environment. There was an expressed need to research this potential pathway.

Recommendations

- Continue to research the development of field diagnostic kits for quick screening and/or early *P. ramorum* detection.
- Review and research the relationship and/or distribution of the pathogen in water and soil and its potential to infect plant material in nurseries and the environment.
- Areas needing research as identified above should be forwarded to a Technical Working Group or Technical Review Team for further consideration.

L. Communication and Support

Overall program communication and support from all levels of PPQ was good. There was a desire by several review participants to resurrect the national conference call (including industry) to discuss new rules and clarify protocols.

Recommendation

- Consider resurrecting the national conference call to include industry to discuss new rules and clarify protocols.

SECTION 3: DATA MANAGEMENT

A. Data Management

All states had some form of data collection and reporting mechanism for the *P. ramorum* program. All states were able to retrieve program data at the operational level for analysis, reports, and decision making, and could provide information regarding program progress and accomplishment. No formal analysis is conducted at the state level; however, all states visited were able to provide necessary trend and statistical information. Appropriate data are entered into NAPIS however, it was stated that the data entry process was difficult. It was also stated that NAPIS was not user friendly when trying to get information out of the system. There is no national data collection system specific to *P. ramorum*. The National and Regional Program Managers must collect individual state data to compile specific reports and analyses.

Recommendation

- Investigate whether data collected is being used to the fullest extent possible to evaluate program progress towards established goals.

SECTION 4: COMMUNICATIONS

A. Interagency Cooperation

The program is conducted across multiple state and county jurisdictions. PPQ serves as the lead agency for program coordination and works closely with states and counties to execute program protocols. Overall, interagency cooperation and relationships were good. It was also stated that PPQ National and Regional Program Managers were providing good support.

Discussions during the focus group revealed a lack of forest involvement (i.e. Forest Service and State Departments of Natural Resources (DNR)) in the process. In some states, forestry is structured under DNR rather than Agriculture and in some cases left out of the loop regarding program participation and updates. There was a stated need for PPQ, states, and counties to be more aware of forest concerns when making program rules and decisions.

Recommendation

- Recommend including forest interests (i.e. in program discussions, working groups, rulemaking, etc.) in the process where appropriate.

B. Program Outreach and Public Affairs

The review revealed a need to conduct more outreach with industry regarding the use of the Best Management Practices (BMP). In the regulated states, most nurseries that ship interstate have implemented some form of BMPs to reduce the risk of infestation. Non-regulated states have not emphasized the use of BMPs to nurseries.

It was stated that the California Oak Mortality Task Force (COMTF) was a good model to bring experts together to serve in a research and advisory roll for *P. ramorum* or other regulatory incidents. COMTF is a good source of outreach information.

It was stated that it was difficult to find program information on the APHIS PPQ website and that the information was sometimes not accurate and/or current.

Recommendations

- Recommend including in the Cooperative Agreement Work Plans an outreach component that includes sharing validated BMPs with nursery establishments.
- Ensure the information on the APHIS PPQ website is current and meets the needs of internal and external customers.

C. Stakeholder Liaison

In most cases stakeholder groups are kept in the information loop regarding program activities and updates through meetings, conferences, and various communication methods. There was some indication that tribal jurisdictions may not always be kept in the loop.

Recommendation

- Ensure tribal jurisdictions are included in program communications.