

PPQ Deputy's Safeguarding Award Submission Form

1. Name, Address, Organization and Job Title, and Phone Number of Nominee (if a group is being submitted, provide the contact information for the entire group)

USDA-APHIS-PPQ-CPHST Molecular Diagnostics and Biotechnology National Program

- Pat Shiel – National Program Staff Scientist (Interim Program Administrator) (919-855-7416)
- Phil Berger – CPHST Director (919-855-7414)
- Don Seaver – CPHST TQAU (919-855-7448)

USDA-APHIS-PPQ-CPHST National Plant Germplasm and Biotechnology Laboratory (NPGBL).

- Vessela Mavrodieva – Research Associate (Proficiency Test Manager) (301-504-7100)
- Sarika Negi – CPHST NPGBL Agriculturist (301-504-7100)
- Laurene Levy – CPHST NPGBL Lab Director (301-504-7100)
- Renee DeVries-Paterson – CPHST NPGBL Plant Pathologist (301-504-7100)

Note: The current functions of the National Plant Protection Laboratory Approval Program (NPPLAP) were developed and runs as an active and combined effort of the CPHST National Program and the CPHST NPGBL.

2. Describe the action that enhanced safeguarding.

Creation and functions of the National Plant Protection Laboratory Approval Program

This project was initiated to fulfill an urgent need for reliable diagnostics in the current *Phytophthora ramorum* Emergency Program. The need to perform complex regulatory molecular procedures to make reliable determinations for the SOD program until 2004 could only be accomplished by PPQ in Beltsville, MD. However, several labs in partnership with PPQ, including State Department of Agriculture labs and labs within the newly organized National Plant Diagnostic Network, had capable expertise and equipment to fulfill this function that if engaged and certified could increase the diagnostic capacity and also begin to build a strong dispersed network of qualified diagnosticians to aid PPQ programs beyond SOD. In fact now that the program has been in place since 2004 for SOD, it was been expanded to include HLB in FY 2008.

NPPLAP is designed to evaluate laboratories and their diagnosticians to gain a reasonable assurance that the labs have the capabilities to make accurate and timely diagnostic determinations. The process includes a site visit by a CPHST-coordinated team of scientists with hands-on expertise of the validated PPQ molecular based diagnostics to inspect and further evaluate the lab facilities using checklists that examine the labs equipment, personnel, chain of custody, facility infrastructure, and maintenance. After successful completion of the inspection phase, a blind DNA Proficiency Test Panel is sent by the NPGBL Proficiency Testing Section to

each Diagnostician within approved labs. This test not only evaluates and verifies the proficiency of the Diagnostician's technical skills in the lab, but it also can measure the overall capabilities of the lab and its personnel to interpret and accurately report proficiency test data. The Proficiency Panel was designed to mimic the samples received by the national lab for final determinations. Each Diagnostician must process the samples and analyze the results in accordance with PPQ protocols and provide a timely determination for evaluation by NPPLAP. The panel results are returned to the NPGBL and evaluated for accuracy and rigor in the processing and reporting of determinations. The Proficiency Panel component of the process is the KEY STEP for determining the diagnostic capabilities of a Diagnostician. The Proficiency Panel is passed on a yearly basis and is designed to include the introduction of new diagnostic protocols and advances in the understanding of the biology of this pathogen.

3. How did the action enhance safeguarding?

NPPLAP serves as a blueprint for future programs where molecular diagnostics are needed on a large scale. Engaging the CSREES NPDN and state departments of agriculture laboratories in this process affords PPQ a unique opportunity to increase the diagnostic capacity and proficiency in a dispersed laboratory network to be in a state of readiness when needed by PPQ for engagement in emergency situations.

A system is now in place to partner with labs outside PPQ in the use of molecular diagnostics for emergency (and other) programs. These kinds of partnerships have demonstrated the ability to rapidly respond to the diagnostic needs of PPQ in a timely and efficacious manner. What was initially in 2004 to 2006 a unique and experimental program within plant pathogen diagnostics to develop lab capacity with a high level of technical sophistication, has emerged in 2007/2008 as a robust system that is accepted and is gathering interest from international counterparts.

In addition, this program provides PPQ and APHIS with a partial inventory of U.S. molecular capabilities for plant pest detection that is useful in any future program, including a general agricultural emergency or bio-threat. It also allows PPQ to quickly assess diagnostic capabilities and provides the needed factual basis for a meaningful gap analysis. If technical gaps are identified through proficiency testing they are quickly closed by an extensive hands-on training system provided by the NPGBL for NPPLAP.

4. How does it demonstrate innovation or initiative?

Several innovations were tested, resolved and continue to be refined in order for this program to be successful. Many of the improvements to the program have been as a result of stakeholder comments and suggestions. The development of NPPLAP was a new concept for regulatory plant pathology that was initiated and developed to engage labs outside the USDA system to provide meaningful results from a molecular biology based diagnostic for the PPQ programs. Although unique for plant pests, this program has successfully adapted some components of similar programs in APHIS NSVL system, which can be used to open the door to harmonization and standardization of programs within APHIS.

This program not only investigated protocols to develop, validate, stabilize, and deploy

proficiency tests initially from DNA only and in FY2008 from infected plant tissues, it developed protocols to fairly and reasonably evaluate the proficiency of Diagnosticians in labs outside of PPQ, and within PPQ (NPGBL, Regional Identifiers, and recently PHP MDL). Evaluation of PPQ Diagnosticians was necessary to demonstrate to PPQ customers that this process holds PPQ to the same (actually higher) standards as those who participate in NPPLAP, and to document the proficiency of Diagnosticians within PPQ. The Proficiency Panel testing developed for *P. ramorum* from FY2004 -2008, and in FY2008 for HLB is (to our knowledge) the first deployments of a quality assurance system used for molecular diagnostics in PPQ and one of the few in the field of plant pathology.

5. Which of the four areas of the Safeguarding Review does the activity support? Check one:

- [1]X Pest Detection and Response (**primary**)
- [2]X Exclusion (**secondary**)
- [3]Gathering and use of international information about pests/pathways
- [4]Permits (managing the movement of pests through permit systems)

6. What recommendation or safeguarding principle does the action support? Cite a specific recommendation from the review or the principle reflected in a recommendation or series of recommendations.

The most specific recommendation covered by the National Plant Board Safeguarding Review are parts of **Recommendation 47** under 'Pest Detection Tools' subheading (c) and (d), which recommends that PPQ 'Establish specific goals for technology transfer of new discoveries for ultimate application in emergency response programs.', and 'Continue to explore the use of biotechnology in improving detection and response systems'. **Recommendations I-31** (Take concrete measures to foster a strong sense of collegiality between and among Area Identifiers and taxonomists/systematists in other organizations) and **I-33** (Examine the needs of Area Identifiers and specialists with respect to instrumentation and equipment and correct all deficiencies) also apply these principles. This program also directly addresses **Recommendation D-42**, which is to 'Develop molecular diagnostic tools for frequently introduced or difficult to identify species groups via partnerships with USDA-ARS or external researchers', and **Recommendation E-91**: 'Develop rapid generalized testing for target species'.

In addition, there are several sections in the Safeguarding Report that encourage the development of standards for pest programs and to gain ascendancy as a world leader in these efforts. These include **Recommendation 4**: 'Set an international example through a commitment to continually improve the safeguarding system, providing a leadership precedent for other countries', and **Recommendation 43**: 'Develop cooperation between agencies within USDA, other Federal agencies, academic institutions, and industry research organizations to discuss the research priorities established by the Agency and determine the best course of action to meet the needs.'

In addition to meeting several recommendations of the Safeguarding review, the NPPLAP also addresses several Homeland Security Presidential Directives, specifically **HSPD9**.

7. Provide any information that demonstrates the outcome/success of the activity.

The NPPLAP provides blind Proficiency Test (PT) Panels to each diagnostician in the program annually. This allows the program to gauge the proficiency and compliance to standards needed for valid diagnostic determinations. Using this PT results as a measure, the NPPLAP process has shown a continuous increase in participating labs and certified analysts for the *Phytophthora ramorum* Regulatory Program. In 2005 when the program began, 14 diagnosticians from 9 participating laboratories were certified to make molecular diagnostic determinations for USDA regulatory programs. In 2006, a total of 25 diagnosticians from 11 participating labs were certified, and in 2007, a total of 31 diagnosticians from 18 participating labs were certified. The 2008 PT tests are currently underway.

Beginning in 2007, the NPPLAP expanded its capacity by addition of molecular diagnostic tests for the devastating Huanglongbing (Citrus Greening) pathogen, *Candidatus Liberibacter asiaticus*. The Real-time PCR diagnostics for this Select Agent pathogen and the two related pathogens of Citrus Greening were developed and validated by the CPHST National Plant Germplasm and Biotechnology Laboratory in Beltsville, MD. To date, there are 11 participating laboratories for this diagnostic, with 9 diagnosticians from 5 of the labs certified so far.

Implementation of the NPPLAP has had a direct benefit to PPQ by increasing the quality of samples that are forwarded for federal confirmation that results in a higher percentage of true positive samples being forwarded. A reduction in false positives in field laboratories has been realized. In addition, Stakeholders are pleased that their laboratories can complete samples that are non-PASS increasing local sample turn-around times.

NPPLAP serves as an objective template when PPQ engages any outside laboratories for any procedure that uses molecular diagnostics for regulatory pests. The program is not only applicable to plant pathogens, but also to any insect, arachnid, mollusk, or noxious weed pests where a molecular approach will facilitate diagnostics. This program provides a cost effective and reliable service for several PPQ programs and projects PPQ as a leader in the development and promoter of technical competence in advanced molecular diagnostics.