Public Policy Update

Establishing a Supercontainment Facility: A USDA, APHIS-PPQ Pilot Program

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The objective of the USDA, Animal and Plant Health Inspection Service (APHIS) is to protect the health and value of American agriculture and natural resources. APHIS uses its umbrella of protection to assure its customers and stakeholders that it is rigorously monitoring against the introduction or re-emergence of both animal and plant pests and diseases that could limit production and damage export markets. Plant pests and pathogens are monitored and regulated by APHIS through the use of plant protection and quarantine (PPQ) permits and facility inspections. The current multistep process of receiving a permit for importation or interstate movement of plant pathogens or infected plant tissue or soil can take from one to three months, depending on the risk level of the pathogen and the availability of federal and state inspectors and requires the following steps: 1) researcher development of a standard operating procedure (SOP) for working with the requested pathogen and application submission; 2) APHIS-PPQ review of application for completeness and evaluation of pest risk; 3) APHIS inspection of facilities to be used for containment and mitigation of risk; 4) state department of agriculture consultation, inspection, and response; 5) development of permit conditions and agreement to permit conditions by permittee; and 6) issue of final permit. This process is required for all permit requests and by all persons requesting a permit. In departments and facilities where several plant pathologists are each working with a number of permitted organisms, the inspection process can quickly become repetitive, with multiple facility inspections within a very short period of time.

In the spring of 2010, in collaboration with **Michael Kenney**, biocontainment scientist, USDA-APHIS-PPQ, the Department of Plant Pathology at The Ohio State University (OSU) Ohio Agricultural Research and Development Center (OARDC) participated in a year-long pilot program aimed at streamlining the federal and state facility-inspection process. The objective of the pilot program was to improve the efficiency of the inspection process through the use of a risk-assessment process. In short, the goal was to establish a supercontainment facility for working with plant pathogens. At the start of the program, the entire facility, including labs, greenhouses, growth chambers, and surrounding environments, was assessed by both federal and state inspectors for potential risk factors that could lead to the release of a permitted plant pathogen into the environment. Following the assessment, the inspectors identified areas and procedures within and surrounding the facility that were potential risk factors. In collaboration with departmental and OARDC administration, corrective measures were taken to reduce any identified risks. The second step in the pilot program was to develop a manual that included departmental general operating procedures (GOPs) and SOPs for the various types of pathogens, plant products, and insect vectors that are studied in the department. The manual also contains facility infrastructure maps and color images of structures or equipment specific to the containment facility. A copy of the manual can be downloaded from the OSU Department of Plant Pathology's website at go.osu.edu/D7c. The final step in the pilot program was to establish a containment director position and a training program within the department. The containment director's responsibilities include monitoring the containment facilities, maintaining copies of all APHIS-PPQ permits held within the department, providing copies of the department manual to new students and employees, and organizing and recording annual training sessions. The purpose of the training sessions is to ensure that all employees are familiar with the procedures required to work with permitted organisms and to update employees with changes associated with working with permitted organisms. Once all of these steps were completed, the facility was re-inspected by a local APHIS plant health safeguarding specialist to ensure compliance with recommended changes.

From our perspective, the supercontainment facility pilot program was a success. Some of the benefits to our department are listed below.

1. Recommendations on infrastructure and procedures that improved the overall security and functionality of our facility.
2. Elimination of multiple re-inspections for the permits applied for during the period of the pilot program, resulting in less time required to issue permits.
3. Improved communication between permit holders and federal and state inspectors.
4. Development of a comprehensive and dynamic manual that allows for efficient documentation of minor changes and/or additions to our facility, thereby eliminating the need for additional on-site visits from APHIS personnel.

In addition to these benefits, we took this opportunity to coordinate our institutional inspections with the APHIS-PPQ inspection. Before the start of the pilot program the OARDC Environmental Health and Safety Office had no official guidelines for inspecting facilities using permitted plant pathogens or insect vectors. The OARDC inspection team worked with us and the local APHIS plant health safeguarding specialist to develop guidelines that were suitable to the unique requirements for containing plant pathogens and vectors. We are currently working to coordinate our annual institutional inspection with the APHIS-PPQ inspection. Lastly, an unforeseen benefit of the pilot program was a rapid emergency response to a tornado that hit our campus in the fall of 2010. Because of the pilot program, the federal and state inspectors were very familiar with our containment greenhouse facilities, knew what permits were associated with our facilities, and understood our emergency response procedure. As a result, we were able to rapidly satisfy the regulatory agencies and ourselves that no accidental release of permitted pathogens had occurred. The relationship also facilitated the re-opening of our containment greenhouses within two short months of the tornado. It is our hope that this program will continue, and we encourage USDA-APHIS to proceed with what we see as a highly successful program in the future. ■

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