

Public Policy Update

Permits and Movement of Plant Pathogens

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A special session on "Permitting and the Global Movement of Plant Pathogens" was held at the 2005 APS Annual Meeting in Austin, TX. This session was a follow-up to last year's discussion on U.S. permitting issues and expanded the discussion to North America and Europe. Perspectives on global movement of plant pathogens were presented by representatives of the European Plant Protection Organization, Canadian Food Inspection Agency, USDA-APHIS-PPQ, National Plant Diagnostic Network, and industry.

Mike Firko, director Permits, Registrations & Imports (PRI), USDA-APHIS, reviewed 17 types of permits issued by PRI and laws and regulations for possession, use, and transfer of plant pathogens. Plant pest permits are required for all import and interstate movement of any plant pest or disease, plant material, and specimens being moved for the purpose of pest or disease diagnosis, as well as intrastate movement of plant pests if moved originally into the state under permit. A permit is also required for viable lyophilized tissue, extracted DNA/RNA if it remains infective after extraction, and laminated disease samples if the material is viable and accessible. Inviolate and noninfective tissue, extracted DNA/RNA, and inaccessible laminate disease samples do not require a permit. In an effort to improve efficiency and response time, PRI is creating a new permitting process for widely prevalent pathogens (WPP). This expedited permit is only for interstate movement of domestic plant pathogen isolates and is not applicable for field studies, but it would save time by having state concurrence on movement into the state. In agreement with APS, lists of bacteria and viruses that will be expedited in 31 states are posted on APHIS web pages. Concerns such as pathogen synonyms, life stage, and host specificity have delayed implementing the WPP list for fungi.

The Plant Protection Act allows anyone to petition the Secretary of Agriculture to remove the requirement for a plant pest permit for specific taxa. Petitioners can facilitate consideration of their petition by submitting specific scientific information to APHIS (the list of information is available from either APS or APHIS). APHIS PPQ is planning to publish a proposed rule within the next few years to initiate permit user fees. These fees will be based on regulatory effort, i.e., cost recovery, and may range from \$100 to \$1,000. To simplify the process and decrease permit issuance time, an electronic permit issuance system (ePermits) is scheduled to be available for application, issuance, and signing of permits and conditions during January 2006. Electronic state review is scheduled to be available later in 2006. The Select Agent Program presently has eight plant pathogens listed on the PPQ Permits web pages. Firko listed the activities one might be involved in and whether a permit and/or registration would be needed. You would only need to register under the Select Agent Regulations if you send or receive known select agents (as opposed to diagnostic samples) or if you maintain viable cultures or spores of the select agent for diagnostic or research activities. The need for an interstate or intrastate permit depends on activity. A copy of the regulatory requirements can be obtained from the APHIS website (www.aphis.usda.gov/ppq/permits).

Jim Stack, regional director of the National Plant Diagnostic Network (NPDN), Kansas State University, discussed permitting, biosecurity, and NPDN. Biosecurity is a state of preparedness that in the case of plants ensures sustained productivity of plant resources and in the case of agriculture ensures a safe and constant supply of food, feed, and fiber. In a disease outbreak, rapid and accurate detection and diagnosis are needed to reduce impact. Individual diagnostic laboratories in the NPDN often need to send samples to other labs for confirmation or diagnostic assistance. It is difficult to predict the impact of new introductions of high consequence pathogens; however, continued introductions of high-consequence pathogens and pests are a certainty. In 2004 Customs & Border Protection intercepted 69,000 pathogens and pests.

There is no set of defining characteristics for pathogens, and thus, the ability to predict which species will be involved, the timing of an introduction, or the impact is limited. Agricultural biosecurity is an international issue, and international diagnostic and research networks are being developed. A process to facilitate research and education without compromising security and trade is needed. One model to consider is accreditation and certification. In this model, APHIS and USDA-CSREES would cooperatively establish an accreditation program for diagnostic laboratories. The permitting process would use the WPP list and assigned pathogen risk categories to grant laboratories broad permits to work with widely prevalent, low-risk pathogens. Imported and high-risk pathogens require laboratory inspections.

Bill Dolezal, Pioneer Hi-Bred International, gave an industry perspective on movement of live plant pathogens. Pathogen movement comes from international and interstate movement of seeds, plant materials, and pathogens for disease resistance research and testing of seeds, fungicides, and biocontrol agents. Plant diagnostics is a significant activity for industry, i.e., confirmation of pathogens in fields and race determination, that requires national and international pathogen movement. Industry can provide resources to collect pathogen data and address one of the APHIS strategic plans—reducing domestic threats through increased offshore threat assessment and risk-reduction activities. Through the plant pathology expertise found among the American Seed Testing Association membership and their international operations and testing locations, offshore monitoring can be done collaboratively with the USDA. APHIS also can inform industry of pests and pathogens that have been intercepted and their location. Industry can utilize their global networks to work with the USDA in training, testing new diagnostic methods, and conducting response research in developing countries. Monitoring Asian soybean rust is an example of this type of cooperation. Dolezal suggested that NPDN can play a key role in documenting WPP and that industry needs to link with NPDN. Industry should also be linked to the emergency response system within Homeland Security. In the event of a high-consequence pathogen introduction, company officials can supply specific seed source information, host genetic risk potential, and sources of resistance. Finally, he suggested that permits issued for pathogen sample collections in a country of trade can be used to document well-established pathogens that are not documented in the literature. This information could come from public or private pathogen collections and be helpful for commodity trade.

John McDonald, Center for Plant Quarantine Pests, Canadian Food Inspection Agency (CFIA), Ottawa, addressed regulations that affect the importation of plant pathogens into Canada. The Canadian government has established a Plant Protection Act that regulates the import and export of a pest and issuance of pest permits. Regulations dictate that importation of a pest, including plant pathogens, must be for such purposes as scientific research or education and that permit conditions must be adhered to. Canada is a signatory to the International Plant Protection Convention (IPPC) and thus phytosanitary measures should be technically justified, transparent, and not applied to arbitrarily restrict trade, while preventing introduction and/or spread of pests. No phytosanitary measures are required for nonregulated pests. A quarantine pest is one that is of potential economic importance to an area and not yet present or present but not widely distributed and that is being officially controlled. Currently there are no IPPC standards for international movement of plant pests and pathogens; thus, all imports are considered to be a quarantine category until determined otherwise. All plant pathogens imported require a CFIA permit. Applications for a permit undergo a scientific review, and conditions are set to mitigate risk to plant life and agricultural and forestry sectors. The permitting process in Canada is similar to the system that is in place in the United States. However, Canada is currently drafting guidelines for risk levels to assist in setting permit conditions. In the United States all permit conditions are for high-risk level pathogens. Although there is no Canadian equivalent of the U.S. Agricultural Bioterrorism Protection Act of 2002, the government is attempting closer scrutiny of permit applicants and stricter enforcement of regulations.

Anne-Sophie Roy, information officer for the European and Mediterranean Plant Protection Organization (EPPO), France, discussed European regulations for movement of live plant pathogens. EPPO makes regional standards (recommendations for its 47 member countries), and the EU makes phytosanitary regulations (compulsory tests for its 25 member states). The EU has a list of prohibited pathogens for unintentional introductions through trade, e.g., *Plum pox virus*, *Xylella fastidiosa*, and *Ceratocystis fagacearum*. The EU permit system is for import or internal movement of pathogens (normally prohibited) for scientific purposes. The process to obtain a letter of authority is similar to the permit required by APHIS for all pathogens (PPQ form 599). However, the EU makes no provisions for other pathogens that are not specifically prohibited. EPPO is in the process of providing guidelines for a system to authorize and manage import and containment of live pests and pathogens. This system will require minimum information to be provided to the National Plant Protection Organization (NPPO) that will allow NPPO to determine pest risk. Import is permitted when the pathogen is determined not to be a risk. No further application for permission to import should be necessary for pathogens that have been classed in this way. Import also may be permitted but only under specified conditions. Confinement and destruction conditions must be agreed on by NPPO. Consignment should be accompanied by an import authorization document issued by the NPPO of the importing country. Import is refused when risk and confinement conditions proposed are not acceptable. The EU system is compulsory but covers only regulated pests. The EPPO system is not compulsory; it relies on scientists to make recommendations and NPPOs to perform risk assessments.

All permitting systems in Europe and North America struggle with balancing biosecurity restrictions and allowing research and educational use of plant pathogens. ■