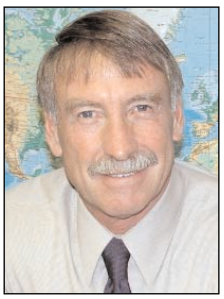
Public Policy Update

Issues Involving Movement of Plant Pathogens Discussed at APS Meeting in Anaheim

Jim Steadman, University of Nebraska, jsteadma@unlnotes.unl.edu



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At the APS Public Policy Board reporting session, **Sue Tolin** reviewed the permitting process for movement of plant pathogens and new issues that have arisen since September 11, 2001, as well as PPB activities to monitor these issues. The Agricultural Bioterrorism Protection Act (ABPA) of 2002 established a "select agent" list, required registration of these agents and notification of possession, specified biosafety/containment requirements for "select agents," and created severe penalties for noncompliance. One interpretation of the ABPA was that all select agents would require BL3-Ag containment. Because plant pathogens were not specifically excluded, application of this stringency even to select agents was viewed by APS members as inappropriate and unnecessarily costly. Additional concerns of plant pathologists regarding the select agent rules included unintended negative consequences, such as loss of microbial pathogen collections, fewer repositories of reference cultures, and loss of research programs and historical records. Overall heightened security in nonfederal institutions funded by USDA was recommended by an Office of Inspector General (OIG) audit report issued in September 2003. APHIS, in response to a separate OIG audit of permitting processes and in fulfillment of their responsibilities under the 2000 Plant Protection Act, has increased enforcement of labeling of foreign shipments to route through a PPQ inspection station, added a rule that foreign permit material can only be sent to the United States by bonded carriers, and added a signoff by permit recipients for compliance with all permit conditions and responsible safeguard of organisms for the duration of the permit.

The main issues raised by APS members were an increase in time needed for issuing permits, lack of standardized conditions imposed for approval of permits, the potential need for BL-3 safety containment for plant pathogens, loss of hand-carried importation, and impediments that the new climate imposes on research, training, and preparedness. In March 2004, the PPB met with the USDA to discuss the effect of the permitting process on plant pathology research. As a result, USDA APHIS will take the following steps to improve the permitting system: 1) a new electronic permit application process by April 2005; 2) pre-approval of "widely prevalent" pathogens, using APS-developed lists for expediting permits; 3) work with petitioners to deregulate specific pathogens; 4) improve efficiency and transparency of the system; and 5) work to standardize permit conditions for diagnostic labs using only non–high-risk plant pathogens.

A discussion session on the last day of the 2004 APS Annual Meeting in Anaheim, CA, was designed to address permitting for widely prevalent plant pathogens in the United States, as well as all permitting issues. **Mike Firko**, assistant director of plant health programs for APHIS, presented background on the 2000 Plant Protection Act and events that have led to changes in plant pest permit processes and regulations. Plant pest permits are required for all import and interstate movement of any plant pest or disease, including plant material and specimens being moved for the purpose of pest or disease diagnosis, as well as intrastate movement of plant pests if the pest was moved originally into a state under permit. Changes that affect plant pest permits include a signature agreeing to permit conditions, increased laboratory inspections, essential prohibition on "hand carry" for importations, and transit permits issued from the APHIS Permit Unit. Since October 2003, there have been around 60 transit permits issued per month. Firko then discussed the Agriculture Bioterrorism Protection Act of 2002; the "select agent" program, citing regulations published at 7 CFR 331; listing of 10 plant pathogens on PPQ webpages; and a 526 permit that is required for "select agents." In the discussion of plant pest permits, the following APHIS operating philosophies were listed: first in, first out; consistency; transparency; science-based; and risk-based. Firko also presented permit statistics on average numbers of permits and average time for issuance in days (41 for 2004 to date) and listed numbers of and reasons for pending permits. Finally, the steps that APHIS is taking to improve efficiency and response time were discussed, including ePermits, ISO 9000 certification, bar-coded shipping labels, and creation of a new permitting process for widely prevalent pathogens (WPP), but only for interstate movement of domestic isolates not intended for field studies. Permits for WPP can be expedited by generating lists of WPP agreed on by APS committees, PPQ review, and state concurrence. PPQ has some lists from APS committees

and is reviewing and editing them. There are issues of taxonomy and concurrence by State Plant Regulatory Officials (SPROs) before the time savings for the permit process can be realized. Although PPQ has never required a BSL-3 facility for permittees working with plant pathogens, PPQ was recently able to obtain agreement from USDA security officials that BSL-3 facilities were not needed for containment of plant pathogens.

Phyllis Himmel, director, worldwide pathology, Seminis Vegetable Seeds, compiled information from 10 companies on industry experiences with changes in the permitting process and regulations. Industry use of permits involves international and interstate movement of seeds, plant material, and pathogens; disease resistance research and testing and plant diagnostics. Permit issues include unclear permit processes and difficulty obtaining information needed on submitted permit applications, lack of complete information on greenhouse and laboratory containment facility requirements, inconsistency of customs agents interpreting permit guidelines, confidentiality of diagnostic reports, and no identification of permit owner for required condition signoff. The potential impacts of permitting changes and their implementation are moving plant pathology laboratories overseas, delaying and stopping research, delaying or losing plant samples for diagnostics, and increasing paperwork. Recommendations from industry include developing a clear permit application process, consistency in required information for permit applications, reducing the number of permits required through WPP identification and blanket permits for culture collections, allowing more than one name on a permit, treating diagnostics as confidential business information, allowing applicants to propose containment conditions for pathogenicity tests of diagnostic samples, allowing time for implementation of new regulations, allowing companies to operate while permit renewals are in process, and having an interactive website-based forum for exchange of information.

Rick Bennett, national program leader, plant health, USDA, ARS, obtained information from ARS scientists on the new permitting processes and regulations and had some concerns similar to those in industry regarding excessive time and lack of information on obtaining a permit and compliance regulations. There also was a disconnect found between science and permit regulations, especially overregulation of low-risk WPP. An APHIS website with clear information, electronic permit application, clear and relevant permit conditions, deregulation of low-risk WPP, and more efficient transparent process were recommended by ARS scientists.

Rosemary Loria, Cornell University and director of the Northeast Plant Diagnostic Network, commented on the effect that permitting issues are having on the National Plant Diagnostic Network (NPDN). Loria discussed the critical role that land-grant plant diagnostic labs have in protecting U.S. agriculture and the partnership of APHIS and NPDN labs. She then listed processes that would facilitate operation of the NPDN laboratory: online application and instructions, a customized form relevant to NPDN, an APHIS/PPQ hotline, and a risk-based pathogen list. There is a critical need to address the permitting issues identified by industry so NPDN laboratories have the tools they need to carry out their safeguarding mission.

In the final talk, **Anne Vidaver**, head of the Plant Pathology Department, University of Nebraska, gave a perspective on reinventing the permitting system. Points to consider included a system based on the best available current science; risk-based pathogen categories; oversight levels commensurate with risk of disease losses; recognition that plant pathogens are not all equal in severity (a concept recognized in categorizing human and animal pathogens); a transparent process; shorter responsive time (days not months); separation of permits by usage; recognition of pathogens across host kingdoms; and facilitation of movement of and research on WPP. Regular communication between APHIS-PPQ and stakeholders, including APS, is advocated. In 1999 the National Plant Board prepared "Safeguarding American Plant Resources. A Stakeholder Review of the APHIS-PPQ Safeguarding System." Most of the suggestions for reinventing the permitting system came from this document. The World Health Organization has categorized risk groups for human and zoonotic agents that the United States abides by and APHIS could use to categorize plant pathogens in a similar fashion. Impact of status quo: 1) inability of industry, academe, and government to conduct research needed by states and regulatory authorities, 2) lack of reference cultures for identity verification in pathogen-free certification programs, 3) independent replication in science jeopardized, 4) epidemiology and natural diversity studies at risk, and 5) slow design of diagnostic tools that require comparative studies with multiple strains and species to establish validity.

The Public Policy Board of APS plans to continue the dialogue with USDA-APHIS-PPQ to facilitate improvements in the permitting system. If you have comments or recommendations regarding the report on these sessions at the recent APS Annual Meeting or regarding permitting, please contact **Jim Steadman** (jsteadman1@unl.edu), Sue Tolin (stolin@vt.edu), or **John Sherwood** (sherwood@uga.edu). ■

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