Plant Variety Protection (PVP) Board Meeting Minutes - July 31, 2013

USDA Plant Variety Protection Office (PVPO) Room 4530-S USDA South Building 1400 Independence Ave. S.W. Washington, DC 20250

Board Members attending (with affiliation):

June Blalock; USDA, ARS, Office of Technology Transfer

Leticia Cabrera; Iowa Western Community College

Joonhyung Cho; University of North Carolina at Chapel Hill

Harry Collins; Mississippi Farmer

Danielle Conway; University of Hawaii at Manoa Jonathan Egilla; Lincoln University in Missouri

Hezekiah Gibson; United Farmers USA/Gibson Farm

Patrick Kole; Idaho Potato Commission Stevan Madjarac; Monsanto Company Salomon Montano; New Mexico Farmer; Corinne Marshall; Sakata Seed America, Inc.

Dana Rewoldt

Wendell Shauman; Farmer;

Larry Teuber; University of California, Davis

USDA and AMS staff:

Ruihong Guo, Acting Deputy Administrator, USDA/AMS/Science and Technology

Sharlene Deskins, Attorney, Office of General Counsel (OGC)

Paul Zankowski; Commissioner PVPO

Jeff Haynes, Acting Deputy Commissioner, PVPO

Others Attending:

Stephen Smith, Dupont Pioneer

David Dierig, ARS National Center for Genetic Resources Preservation (NCGRP)

Jennifer Klemens, ARS Office of Technology Transfer (OTT)

Aurelia Skipwith, ARS OTT

Gail Poulos, ARS OTT

Sharon Roberts, ARS OTT

Introductions

Opening welcoming remarks were made by Paul Zankowski and Ruihong Guo regarding the Agenda, 2012 Board minutes and Appeals to the Secretary. The meeting agenda was adopted.

Review of Recommendations from the April 2012 PVP Board Meeting
The recommendations of the April 2012 Board meeting were reviewed and the actions of the PVPO (in italics) toward these were presented.

- 1. Continue Interaction with the American Seed Trade Association (ASTA) Electronic PVP Application working group. The PVPO met with the group in October 2012 and is planning to meet with them again in the fall of 2013. The working group was impressed by the ongoing and planned activity towards an ePVP system and new database.
- 2. Change the wording of questions 18 and 24 of PVP application form (ST470) and blocks #4 and #5 of the Seed Deposit Form these questions dealt with other intellectual property for the PVP variety and the Genetically Engineered Organism (GEO) status. In order to submit the PVP forms to the Office of Management and Budget (OMB) for on time renewal the forms were left as is and were approved by OMB. This topic and the legal consequences of changing these forms will be discussed at a future PVP Board meeting.

The Board indicated that ASTA is very interested in the continuation of form modification. The Board also suggested that the PVPO consider coordinating new variety applications with the Association of Official Seed Certifying Agencies (AOSCA) and other seed certificating agencies in order to remove potential impediments.

- 3. Support Associate Examiner (AE) application processing without subsequent" indepth" examination by an Examiner. The PVPO developed a two track PVP application examination procedure (discussed later). This procedure has resulted in 206 additional PVP applications disposed as of July 23, 2013.
- 4. The Board noting the failure of the PVPO to meet previously stated objectives including optimizing PVP certificate quality and timeliness, achieving organizational excellence, and improving plant breeder's rights. The PVPO has taken actions to meet the objectives by further refining the Business Process Reengineering (BPR) procedures, examining staff personnel changes, process streamlining to eliminate bottlenecks, and the establishment of challenging goals for the examining staff. The PVPO has developed a strategy to further organizational excellence and improve plant breeder's rights through an outreach plan that focuses on 1) Enhancing the value of the PVP certificates by increasing their acceptance by other countries, 2) Increasing the number of PVP applications by demonstrating the benefits of PVP and encouraging the

development of new varieties, and 3) Providing Strong Global Leadership in the PVP field. The PVPO will sponsor a booth at the ASTA Corn, Sorghum and Soybean conference to be held in Chicago, IL - December 10-13, 2013. The booth will be staffed with PVP Examiners to address questions and further outreach for U.S. PVP. The PVPO will be preparing a new strategic plan that encompass these outreach ideas.

- 5. Waive the requirement for applicants to pay the certificate fee within one month and not to collect late fees until after 90 days. The preceding Board was notified about the Deputy Assistant General Counsel's advice that the PVPO cannot waive or extend the payment of the certificate issuance fee until after 90 days, and that this fee must be paid within one month (and up to nine months after the due date) as indicated in the PVP Act (Section 81) or it is late and requires the payment of the \$41 late fee. The PVPO took no further action on this.
- 6. Do not change the collection of the ARS potato tissue culture storage fee from four payments totaling \$2,500 over 15 years to one payment of \$2,500 due at the time of PVP certificate issuance. The PVPO did not change the payment options, but is requesting a higher fee to allow the PVPO to recover its billing/collection costs. More discussion about the ARS and PVPO fees is presented in the "Potato Tissue Culture Fee collection" section of these minutes.

PVPO Major Activities

The PVPO presented the major activities that have taken place since the April 2012 Board meeting including 1) office relocation, 2) implementation of two track application processing, 3) application disposal / PVPO productivity, and 4) the plan for the ePVP system / database.

Relocation

The PVPO relocated from the National Agricultural Library (NAL) in Beltsville, MD to the USDA South Building in Washington, DC in November 2012. This move is saving the PVPO over \$150,000 per year, and provides the staff with additional research, networking and training resources. The new address is USDA, AMS, S&T, Plant Variety Protection Office, 1400 Independence Ave., S.W., Rm. 4512-South Bldg., Mail Stop 0274, Washington, DC 20250-0274; (202) 260-8983 (Tel.) and (202) 260-8976 (Fax). The Board suggested that the PVPO make key PVPO staff Vcard information available to Board members to improve electronic communication and access.

Two Track Application Processing

The PVPO implemented a two–track application processing system where Examiners focus on the old cases and the Associate Examiners (AE) work on new incoming cases. The goal is to reduce the old inventory and to prevent new cases from becoming old. As Examiners deplete their old cases, they receive new cases to maintain a working pool of applications. This change resulted in 206 additional applications processed as of July 23, 2013. The Board was very impressed by the PVPO's accomplishments and wanted information on the oldest applications (there are 9 applications from 2009). The Board wanted clarification on the role of the Examiners versus the AEs – it was explained that previously the AEs had more of an assistance role but under this new system, they are empowered to fully process applications. It was clarified that an application goes through either one of the tracks and not both. The Board asked for a clearer view of the two–track system at the next meeting.

Application Disposal / PVPO Productivity

The PVPO started FY2013 with an application inventory of 1,109 and received 433 new applications, for a total of 1542 applications. 703 applications were recommended for certificate issuance and 35 were abandoned, leaving 804 applications in its inventory. The Board inquired about incoming applications variability over the past few years: 598 in 2010, 530 - 2011, 491- 2012, and 433 so far for 2013. The PVPO indicated that it will be looking to the seed industry and applicants for help on forecasting future incoming applications. The PVPO will reach a point where inventory reduction is less of a challenge than receiving more applications, making outreach the next priority. The Board suggested that the ASTA Future Seed Executives (FuSE) be a good venue for PVP outreach and training.

The PVPO has set a goal of an inventory below 600 applications, with none of the applications more than 2 years old. Based on the current processing rate it is expected that the inventory will drop below 600 by the end of fiscal year 2014. The Board indicated that the PVPO should have a broader perspective regarding PVP examination and should look to coordination among the major seed organizations (ASTA, Organisation for Economic Co-operation and Development (OECD), AOSCA, etc.) with different but complimentary roles.

ePVP System / Database

The PVPO reviewed the status of the new electronic PVP (ePVP) system and database that will be completed in three phases. Phase I encompassed the assessment of all crop and tracking data transfer to the new system. This phase started on August 23, 2012 and was completed on June 28, 2013 with a total cost of \$480,000. Phase II is the full development of the internal and external user systems that includes crop

examination, application tracking, electronic payments, quality assurance, administrative tools and full Web functionality. This phase will be done in 19 sprints (three–week mini projects) that will enable the PVPO staff to test each sprint component and provide feedback. Phase II started on July 18, 2013 with a targeted completion date of May 1, 2014 and an estimated cost of \$1.1 million. Phase III is training and maintenance with an estimated cost of less than \$200,000. The PVPO anticipates that both phases II and III will be less than budgeted.

The Board is eager to participate in testing the internal and external parts of the new ePVP system. The Board had several comments (addressed below) about the new ePVP system – the PVPO response is in italics:

- Availability of crop data since crop databases contain pending/confidential application data - this information would not be publically available.
- Relationship between the USDA Germplasm Resources Information Network (GRIN) system, public availability of data, and the new ePVP system this will be assessed during phase II ePVP development.
- Details of customer/user levels within the ePVP system ePVP will have a multilevel matrix of customers; these levels will be accessed through the e-authentication process so that a breeder may have access to different parts of the system versus a lawyer versus a finance specialist.
- Confidentiality of data during the internal ePVP testing process nongovernment users that test the internal ePVP would only have access to public data from issued PVP applications.
- Importance of thorough ePVP testing and evaluation by different user roles the PVPO will involve testing at all user levels for internal testing this would include PVPO Program Analysts, Examiners, Associate Examiners, Board Members, etc. and for external Breeders, Lawyers, Finance Specialists, Board Members, etc.
- Prioritizing ePVP system components / wish lists during development components will be prioritized during Phase II development; additional software upgrades, and component additions will be done by the USDA Information Technology Staff because the software will be fully compatible with the existing USDA software.

The PVPO indicated that the ePVP development is the first test of the 'Agile' software development method in the Agricultural Marketing Service (AMS) and will be used as a model system for the future processes. The Board requested updates of the ePVP program/ wish list 2-3 times during the year in order to provide guidance and assistance – the PVPO will provide the Board with update throughout development.

Molecular Markers for PVP

The PVPO often receives applications with molecular marker data that distinguishes an applicant's variety from other varieties. Applicants and former PVP Board members brought up the issue of the PVPO needing a better system to utilize molecular markers. The PVPO currently has no method to receive applications with only molecular marker data.

The current PVPO policy for the submission of molecular marker data (developed at the March 2007 PVP Board Meeting) was discussed. The 2007 Board developed the policy in conjunction with the PVPO and OGC during that meeting. The Board asked if these markers were generic or specific and whether they were linked to a phenotype – it was suggested that a marker be linked to a phenotype. The Board indicated that two different committees are working on molecular markers policies within in the International Union for the Protection of New Varieties of Plants (UPOV) Biochemical and Molecular Techniques and DNA Profiling in Particular Working Party (BMT) and ASTA – and that it may be more efficient for the PVPO to work with these groups. It was further discussed that these groups may exclude discussions with the public sector and since this Board represents a diverse sector – a subcommittee of the Board would be a better venue for this discussion.

The PVPO explained that under the Federal Advisory Committee Act (FACA) - a subcommittee could include a wide range of molecular technology experts – not exclusively Board members. The Board recommended that the PVPO initiate a technical subcommittee composed of volunteers to review the use of molecular markers for PVP. This subcommittee would be governed from within and would report its findings to the Board. Volunteers wanting to become subcommittee members can email Paul Zankowski (paul.zankowski@ams.usda.gov). The Board continued with deliberations on the use of molecular markers for PVP including 1) basing PVP solely on molecular differences, 2) lack of access to molecular technology by applicants, and 3) molecular differences not linked to phenotype. The Board cautioned about moving exclusively to molecular differences – the PVPO responded that changes in the technology are challenging the Office to look deeper into this issue.

Potato Tissue Culture Fee collection

Potato PVP owners must deposit a voucher specimen of their germplasm in a public depository. Most potato tissue culture specimens are stored at the National Center for Genetic Resources Preservation (NCGRP) in Ft. Collins, CO. The NCGRP charges the PVP owner \$2,400 to recover tissue culture storage and maintenance expenses for the 20–year life of a PVP certificate. The PVPO currently charges \$100 for transaction handling on behalf of the NCGRP - with the payment either as a lump sum of \$100 or as

4 incremental payments of \$25 at year 1, 6, 11 and 16 (NCGRP receives \$900, \$500, \$500, and \$500). The PVPO explained that the current \$25 processing fee is not enough to recover actual costs and proposed that it collect \$205 each time the fee is processed on behalf of the NCGRP.

Under this new scenario if a potato PVP holder pays the NCGRP fee as a lump sum they would pay \$2,605 (with \$2,400 going to NCGRP and \$205 to the PVPO). If a potato certificate holder pays in four installments they would pay \$1,105 at year 1, \$705 at year 6, \$705 at year 11, and \$705 at year 16, for a total of \$3,220 over 16 years.

The PVPO has issued 193 potato PVP certificates – the specimens for 187 of these are stored at the NCGRP and 6 are stored at North Dakota State Seed Department (NDSSD; which only accept their own varieties). The PVPO outlined the requirements for an acceptable depository according to the rules of the § 97.7 of the PVP's Regulations and Rules of Practice.

The Board suggested that NCGRP collect money directly from PVP applicants – a NCGRP representative responded that 1) they were unsure if PVP applicants can work directly with NCGRP, and 2) if the current \$2400 is enough to cover the 20 years of storage. NCGRP indicated that they will 1) better present the actual cost of potato storage during the December 2013 PVP Board meeting and 2) determine if direct NCGRP-PVP applicant billing would be possible.

The Board asked why NCGRP couldn't invoice PVP owners directly – NCGRP explained that they don't operate under a fee for service authority and have no mechanism for billing. The Board stated that the PVPO has the authority to collect the potato storage money and pay it incrementally to the NCGRP. NCGRP plans to review the cooperative agreement between the NCGRP and PVPO to determine if this procedure can be changed. The Board was interested in alternative depositories in the potato–growing region (University of Idaho, Oregon State University, etc.). NCGRP cautioned about the appropriateness of alternate depositories and the costs of the tissue culture procedure, cryopreservation facilities, and personnel. The Board inquired if the NCGRP payment process can be automated under the new ePVP system. The Board recommended that this discussion be tabled until the December 2013 PVP Board meeting – the PVPO agreed. The Board indicated that the new PVPO charge of \$205 seemed reasonable but other depository options need to be determined.

The PVPO discussed the next PVP Board meeting that will be held in Chicago, IL on December 9 and 10, 2013. This meeting will include an in-depth discussion on international PVP harmonization and recognition.

Board Recommendations

- 1) The PVPO initiates a subcommittee of volunteers to review the use of molecular markers for PVP –this subcommittee will report back to the PVP Board.
- 2) The potato tissue culture storage and PVP handling fee issue should be discussed in greater depth at the December 2013 Board meeting.