

USDA Plant Variety Protection Office (PVPO)
Room 2068,
USDA South Building
1400 Independence Ave. S.W.
Washington, DC 20250

Board Members attending (with affiliation):

June Blalock;
Leticia Cabrera; Northwest Missouri State University
Joonhyung Cho; University of North Carolina at Chapel Hill
Harry Collins; Mississippi Farmer
Jonathan Egilla; Lincoln University in Missouri
Stevan Madjarac; Monsanto Company
Corinne Marshall; Sakata Seed America, Inc.
Salomon Montano; New Mexico Farmer;
Dana Rewoldt; Lawyer
Wendell Shauman; Farmer;

Absent: Danielle Conway, Hezekiah Gibson, Patrick Kole, Larry Teuber

USDA and AMS staff:

Ruihong Guo, Deputy Administrator, USDA/AMS/Science and Technology
Sharlene Deskins, Attorney, Office of General Counsel (OGC)
Brian Hill, Attorney, OGC
Paul Zankowski; Commissioner PVPO
Jeff Haynes, Deputy Commissioner, PVPO

Others Attending:

Bernice Slutsky, American Seed Trade Association (ASTA)

Call to Order and Opening Remarks

Opening welcoming remarks were made by Paul Zankowski and Ruihong Guo. The meeting agenda was adopted.

Follow-up on Recommendations from December 2013 PVP Board Meeting

The recommendations and PVPO actions were

1) The PVPO should add a paper processing fee surcharge once the ePVP system is fully functional.

The PVPO explained that this recommendation and #8 will be a part of the PVP regulation change package to be processed during fiscal year (FY) 2015.

- 2) The PVPO should develop a matrix for extension and late fees that considers the office request, the applicant's needs, and the incentive for a timely response.

The PVPO explained that only 10 extension requests occurred in the past year and that the need for these fees will be reduced under the ePVP system. The PVPO will create a matrix of extension and late fee issues. The PVPO explained that the fee may be changed from a flat fee to a time based fee (per month) and will be discussed at the next Board meeting.

- 3) PVPO should develop a blueprint for outreach and look at coordinating PVP certification with seed certifying agencies.

- 4) PVPO should develop a blueprint for harmonization of PVP grants with other countries.

The PVPO is working on blueprints for both recommendations 3 and 4 and will have these further developed by the next Board meeting.

- 5) PVPO will charge potato tissue culture certificate holders a \$107 processing fee each time a tissue culture fee is paid.

The PVPO implemented this fee on May 1, 2014 and changed its certificate fee request letter to incorporate the change. This fee can be charged in accordance with current PVPO regulations.

- 6) A subcommittee should be formed to define and design the GEO question on the ST470 and seed deposit forms.

This subcommittee has been formed and will meet in early June.

- 7) The PVP Board's marker subcommittee and the ASTA subcommittee should have a joint meeting.

The Molecular Marker subcommittee and the ASTA Corn Variety Identification Subcommittee (CVIS) held a joint teleconference on May 12, 2014 (outcome described later in the minutes)

- 8) The PVPO should adjust its regulations to handle postmarks, the change of PVPO address, fee changes, and electronic signatures.

- 9) The Board will consider Chicago and other cities for a 2014 physical meeting location and will hold a teleconference in May 2014.

The PVPO is considering holding the next physical meeting at either the ASTA Chicago in December 2014 or the ASTA Vegetable and Flower meeting held in Tampa, Florida in January 2015.

PVP Office Update – Staff, Productivity, Incoming Applications, Finances, and Fees

The PVPO is fully staffed at 13 employees. Program Analysts will continue to be needed to enter data from paper applications until the ePVP system is fully in place. The PVPO anticipates a need for more Associate Examiners with the possibility of Program Analysts moving into these positions.

The PVPO has had good productivity during the first 7 months of FY14 – with 496 applications processed and 309 new incoming applications resulting in an inventory of 455. The number of incoming applications varied over each of the past 7 months with a high of 60 in April and a low of 19 in December. For FY14 soybean, corn, potato, wheat and pea ranked as the top incoming species.

The PVPO revenue was \$1.34 million (M) and expenses were \$1.20 M resulting in a trust fund balance of \$3.15 M – which is equivalent to a 14.6 month operating reserve. This will be one of the first years when the PVPO added reserves to the trust fund. The breakeven point where incoming applications pay for all FY14 office expenses is approximately 420 applications; the PVPO is expected to exceed this. The Board asked if this reserve was high or low; the PVPO responded that the minimum reserve is 5 months and that the current reserve places the PVPO in very good standing.

The PVPO discussed possible future fee changes including 1) the sale of DUS (distinct, uniform, and stable) reports– the PVPO currently charges \$3.60 per page for a 20-40 page report while most other International Union for the Protection of New Varieties of Plants (UPOV) PVP Offices charge 350 Swiss francs (approximately \$395), 2) paper processing fee to be implemented about October 2015 when the ePVP system is fully in place, and 3) a per-month basis for the extension and late fees. The Board commented that the PVPO may want to consider a country by country fee; the PVPO responded that it would need to consult with its Office of General Counsel (OGC) about this proposal. The PVPO plans to present a full picture of fees at the next Board meeting.

ePVP System

The ePVP system version 2.0 will be released by May 16 for internal user testing; the final sprint is in process and will result in release 3.0 of the software for additional testing. The release version 4.0 will be available for domestic and international application testing including Board members. Board members will need to be level 2 e-authenticated by visiting a USDA facility with ID credentials. The ePVP system is an integrated application based on MS .NET MVC4 and MS Dynamics CRM 2013.

The costs for ePVP development has been \$602 thousand (K) for phase 1 (system plan and data migration scripts) and \$1,099 K for phase 2 (development using MS .NET Framework 4 for external portal and MS Dynamics CRM 2013 for internal portal). Phase 3 (support, maintenance, and upgrades) is estimated to cost \$100-200 K. The overall total ePVP system is estimated to cost \$1.9 M (less than the \$2.1 M estimate from 2012).

The only delays that have occurred involve migrating legacy STAR data to CRM. The soft ePVP release is anticipated on July 1, 2014 (= version 4.0). The current vendor will be available for software fixes and enhancements after the testing results have been compiled. Software support will transition to USDA Information Technology support after 6 months. Projected annual costs after the vendor is phased out would be \$50 K for IT support and \$24 K / year for software licensing.

The official ePVP release will be on October 1, 2014, the start of FY 2015. All future FY15 applications moving forward will be examined under the ePVP/CRM system. New FY15 hardcopy paper applications will be entered into the ePVP system by PVPO staff. All prior applications will be examined using the STAR system. The new ePVP software rollout will be announced using a Federal Register notice in mid-September. There will also be a user guide and webinar that presents the basics of entering an application into ePVP. A feature will be available for the bulk filing of applications outside of the ePVP system – so that bulk filers can email or upload application information. Eventually the bulk feature will be a component of the ePVP system.

The Board commented that a PVP regulation might need to be added to specify what the filing date would be if the ePVP system isn't working.

Outreach Activities

The PVPO met with the Community Plant Variety Office (CPVO) in Angers, France on April 4 to discuss increasing cooperation and developing ideas to harmonize the PVPO and EU systems.

Possible barriers that were identified during these meetings included:

1) Methods for growing out DUS trials, specifically 1) the official technical observation of the trials, 2) official designation of reference varieties used in the trials, and 3) differences between the CPVO technical questionnaire versus the US PVP exhibit C form.

2) US PVP Act definition of uniformity – in that variation is allowed as long as its describable, predictable, and commercially acceptable (the CPVO definition doesn't allow for this variation)

3) Process of variety denomination/registration – the CPVO has a formal system in place for naming and/or registering a variety whereas in the U.S. the variety name is regulated under the Federal Seed Act. In the U.S. the variety named using the name first used in interstate commerce (there is no registration system in the U.S.)

The Board commented that in the U.S. uniformity is better for functional varieties. The Board also asked why variety denomination is a barrier – the PVPO explained that in the US system a name becomes fixed when the variety is first sold whereas in the EU the name needs to be registered before the variety can be sold.

The U.S. and CPVO identified areas of common ground (areas where mutual collaboration and expertise can benefit both PVP systems) in 1) the use of electronic PVP application processing/databases and 2) the use of molecular markers. The CPVO was interested in the concept of using the U.S. database system to select better reference varieties for their DUS trials. Molecular markers could provide a common language between both the U.S. and CPVO for distinguishing varieties. The U.S. is also looking at its crop specific forms to see if they can be modified, streamlined, and better align with the CPVO forms – using lettuce as a pilot test. The CPVO was very interested in the U.S. accepting their DUS reports, but the PVPO needs to be assured that enough data is reported in the CPVO report to create a useful record for future database searches.

The Board wanted to know if agreement could be made on uniformity and stability – and then work toward the barrier of distinctness. The Board suggested that U.S. DUS trials could be monitored by experts trained by the PVPO and paid by applicants to review and qualify the trials.

The PVPO's discussions with the CPVO are a component of the US Trade Representative's (USTR) Transatlantic Trade and Investment Partnership (T-TIP). The discussions with the CPVO remain a very positive part of the T-TIP intellectual property rights (IPR) negotiations. The USTR IPR negotiations have focused on resolving differences between the U.S. and EU intellectual property systems.

During the April 2014 UPOV meetings the PVPO also met with Australia, Canada, Netherlands, and New Zealand PVP Offices to discuss outreach. Australia and Canada have PVP systems where the breeders conduct the DUS trials similar to the U.S. but officials from their offices evaluate the trials. The PVPO explained that Australia "deputizes" experts to review DUS reports/trials as qualified persons. The Board suggested that the PVPO could look into certifying technicians in coordination with the Canadian PVPO. The Board asked if Canada would be able to fully accept US DUS reports. The PVPO responded that we may consider a pilot system to certify the breeder based DUS trial to concur with the Canadian system. The Board asked if the USDA National Center for Genetic Resources Preservation (NCGRP) could be tasked with qualifying DUS trials – it was explained that NCGRP may not have adequate staff to evaluate trials.

The Board commented that some applicants only want U.S. PVP and not international PVP – so maybe a two tiered system would be better – 1) those requesting only U.S. PVP and 2) those requesting U.S. and foreign PVP. The Board commented that the Netherland PVPO will collect U.S. exhibit C PVP data for a fee. The Board also asked what would be the objective of a pilot study to have third party observers if the PVPO wasn't moving to the EU system. The PVPO commented that the ongoing pilot study with lettuce is comparing the U.S. exhibit C form with the CPVO lettuce form – to determine if the U.S. needs to ask for all that data – the PVPO is examining the exhibit C process to determine if everything is necessary – and can it be streamlined. The Board commented on the system of streamlining corn exhibit C data several years ago – and the impact of that streamlining.

The PVPO plans to target future outreach at two specific areas – seed certification and the Association of Official Seed Certifying Agencies (AOSCA). The PVPO also plans to conduct outreach at the National Association of Plant Breeders (NAPB) meeting in August 2014 and will have a booth.

UPOV Update

1. UPOV is moving forward in developing a centralized Electronic Application Filing system and the U.S. PVPO is planning a central role in our requirements within this system.
2. The U.S. plans to participate in the UPOV Biochemical and Molecular Techniques and DNA Profiling in Particular Working Party (BMT) to be held in Seoul, Korea in November 2014.
3. During the April 2014 meeting the UPOV Council approved the legislation of the African Regional Intellectual Property Organization (ARIPO) – this would create an organization similar to the CPVO and expand UPOV sanctioned intellectual property rights to ARIPO's 18 member countries.

Molecular Marker Subcommittee Update

The chair of the molecular marker subcommittee reported on their activities. The goal of the subcommittee is to help the PVPO and PVP applicants develop a consistent means to distinguish varieties using markers in conjunction with morphological/physiological characteristics. The subcommittee is looking at different models to incorporate molecular data into PVP applications so the PVPO can better use this data.

The subcommittee discussed a pilot study on corn where correlation between molecular data and PVP morphology data was evaluated. The study found the correlation wasn't as significant as desired; however the concept of using genetic distances relative to a

standard set of inbred varieties may be a useful means of characterizing a variety. The subcommittee held a joint meeting with the ASTA Corn Variety Identification Subcommittee (CVIS) to determine the best approach to analyze this data.

The concept of comparing a variety's genetic distance from standard inbred corn varieties was discussed. Using this genetic distance model the PVPO may be able to determine that a variety is distinct from others when morphology alone cannot. Under this system applicants would not be required to provide molecular data, but molecular data could be supplied as needed. The subcommittee is also trying to determine how this information can be stored in a database...

A summary of this model could be presented at the UPOV BMT meeting in November 2014 as a new concept to build confidence in the use of markers and morphological characteristics. The subcommittee is also looking at markers in soybeans, lettuce, and peas.

The Board commented that it may be useful to look at tomato molecular markers.

Other Issues

Non-deregulated events

The PVPO reported that some PVP applicants want to file PVP on varieties containing genetically engineered trait(s) not fully deregulated by USDA Animal and Plant Health Inspection Service Biotechnology Regulatory Services (BRS). Handling and storing seeds of these varieties would require BRS movement permits. PVP Regulation 97.7 part (d) allows a waiver for making the PVP seed deposit within 3 months for good cause. The PVPO decided 1) the issues of permits for these regulated varieties, 2) notifications for movement, and 3) storage / added complexity / exposure constituted good cause and granted a waiver so that seeds of non-deregulated events need not be shipped to NCGRP until deregulation occurs.

The Board wanted to know what would happen if BRS never deregulated the event - the PVPO would look into this issue. The Board commented that the PVPO might require extension fees until the seed is provided to the PVPO. The Board also commented that NCGRP could store seeds of a regulated event. The Board suggested that this topic be considered at the ASTA Seed Industry forum to provide the PVPO and applicants with a menu of possible options.

Marshall Ryegrass

The PVPO has received communications that a third extension for the PVP of 'Marshall' ryegrass might be forthcoming. The PVPO presented a summary of the PVP activity for this variety – this variety originally received PVP (certificate# 8200179) on June 29, 1984 after the office's examination and finding that the variety was new, distinct, uniform, and stable; the PVP certificate expired on June 29, 2002 (PVP was granted for an 18 year term under the PVP Act in place at the time of certification).

PVP certificate 200400094 for the 'Marshall' ryegrass variety was granted again on February 6, 2004 based on the Consolidated Appropriations Act of 2004 which specified

“That, in the case of the term of protection for the variety for which certificate number 8200179 was issued, on the date of enactment of this Act, the Secretary of Agriculture shall issue a new certificate for a term of protection of 10 years for the variety, except that the Secretary may terminate the certificate (at the end of any calendar year that is more than 5 years after the date of issuance of the certificate) if the Secretary determines that a new variety of seed (that is substantially based on the genetics of the variety for which the certificate was issued) is commercially viable and available in sufficient quantities to meet market demands.”

The ten year term for the second PVP grant expired on February 6, 2014. This was the only variety ever granted a second certificate and in effect a term extension by the PVPO.

During the PVP Board meeting of May 2004 the members issued this recommendation

The Plant Variety Protection Advisory Board expresses its grave concern over the Marshall ryegrass issue regarding the legislated private reissuance of a Plant Variety Protection certificate, after the original PVP certificate for this variety had expired. The Board believes this practice is contrary to Section 131 of the Plant Variety Protection Act and creates significant risk to innovation by undermining encouragement for research and investment by creating uncertainty of future commercial opportunities. The Board believes such a practice will greatly reduce the volume and diversity of available certified crop varieties, and unfairly increase the cost of seed to society. The Board suggests the PVP Office and the Secretary of Agriculture communicate these concerns to the appropriate Congressional authorities.

The Board commented that in 2004 there was a great deal of opposition from most of the seed industry. The Board felt that the 2004 extension set a bad precedent and that the foundation of intellectual property protection is that the developer of a new variety gets a fixed period of protection in exchange for making that variety publically available after the PVP expires. The Board commented that this variety was developed by Mississippi State University and that they were opposed to having the PVP extended in 2004 and is opposed to a 2014 extension. The 2004 extension (and possibly the 2014) extension) was promoted by the person with marketing rights for 'Marshall'. The Board was concerned that another extension may take the U.S. PVP out of compliance with UPOV. It was noted that ASTA and the NAPB have both sent letters to Capitol Hill regarding this issue.

The Board proposed the following recommendation:

The Plant Variety Protection Advisory Board expresses its grave concern over the Marshall ryegrass issue regarding the legislated private reissuance of a Plant Variety Protection certificate, for the second time in approximately ten years. The Board believes this practice is contrary to Section 131 of the Plant Variety Protection Act and creates significant risk to innovation by undermining encouragement for research and investment by creating uncertainty of future commercial opportunities. This legislation is also counter to the purpose and spirit of the PVP Act. The Board believes such a practice will greatly reduce the volume and diversity of available certified crop varieties, and unfairly increase the cost of seed to society. The Board proposes the PVP Office and the Secretary of Agriculture communicate these concerns to the appropriate Congressional authorities.

The Board unanimously voted for this recommendation.

The PVPO discussed the next physical meeting venue at either the ASTA December 2014 Chicago meeting or the ASTA January 2015 Vegetable and Flower Tampa meeting. The PVPO will get feedback from the Board on Chicago or Tampa.