

USDA Plant Variety Protection Office (PVPO)  
Room 3543, USDA South Building  
1400 Independence Ave. S.W.  
Washington, DC 20250

Board Members attending (with affiliation):

Charles Brown; Brownseed Genetics, LLC  
Jianli Chen; University of Idaho  
Joonhyung Cho; University of North Carolina at Chapel Hill  
Danielle Conway; University of Maine  
Eloy Corona; Bayer Crop Science LP  
Jose Costa; USDA/ARS  
Emily Dierking; Indiana Crop Improvement Association  
John Duesing; DuPont Pioneer  
Elizabeth Lee; University of Guelph  
Stevan Madjarac; Monsanto Company  
Jose Re; RiceTec, Inc.  
Wendell Shauman; Shauman Farms  
Bernice Slutsky; American Seed Trade Association  
Katherine White; Wayne State University  
Alternate: David Burns, Burns' Farms, Inc.  
Alternate: James Sutton, Georgia Department of Agriculture

USDA and AMS staff:

Ruihong Guo, Deputy Administrator, USDA/AMS/Science and Technology  
Douglas Keeler, Associate Deputy Administrator, USDA/AMS/Science and  
Technology  
Paul Zankowski; Commissioner PVPO  
Jeff Haynes, Deputy Commissioner, PVPO

Others Attending:

Marymar Butruille, Monsanto  
Paul Nelson, Monsanto  
Rachel Pilloff, Lowe Hauptman & Ham, LLP  
Kitisri Sukhapinda, U.S. Patent and Trademark Office

Call to Order and Introduction

The meeting agenda was adopted. The 2015-2017 Board consists of 14 members and 2 alternates with 4 members continuing from the 2013-2015 Board and 2 who were

members of earlier Boards. The three main functions of the Board were discussed – 1) advising the Secretary regarding the Plant Variety Protection Office's (PVPO) Rules and Regulations, 2) making advisory decisions on all appeals to the Secretary, and 3) advising the Secretary on all questions regarding public usage of the varieties. The PVPO has also used the Board's assistance by asking for their advice on PVPO procedural matters.

### PVPO Update Report

A briefing report was provided to the Board prior to the teleconference that highlighted the PVPO's achievements since December 2015. During this time the PVPO examined and processed 322 applications year to date (compared to 397 processed last year to date). The processing goal for this fiscal year was reduced to allow the PVPO staff to focus on testing the electronic PVP (ePVP) application system. Even with reduced examining, the average application processing time dropped to 1.4 years compared to the 2.8 years in 2013. The PVPO received 304 new applications year to date compared to 361 in FY2015. The Office anticipates receiving 100-150 more applications by the end of September to finish up FY2016. Thirty three different crop kinds were received this year. The current unprocessed application inventory was 305 compared to 307 for last year. The PVPO issued 467 PVP certificates year to date.

The PVPO improved the public's understanding of U.S. PVP concepts by publishing a newsletter that provided information on the PVPO website and explained PVP criteria: novelty, distinctness, uniformity, and stability in simple terms. Future newsletter issues will discuss variety naming, look into the difference between PVP and patents, and provide tips on conducting DUS trials. To extend international outreach the PVPO met with 4 different foreign delegations to discuss the U.S. PVP process and its benefits. The PVPO has increased its outreach to the U.S. public sector by planning webinars and presentations with the Association of University Technology Managers (AUTM) and the University and Industry Consortium (UIC) to expand PVP knowledge to as many universities as possible. The PVPO has also been targeting the potato sector by meeting with the National Potato Council and by also touring potato trials to interact with growers and breeders.

The PVPO staff visited wheat and sorghum field trials to improve their observation competency. The PVPO also plans to provide training to the staff on the analysis and use of molecular markers once the methods related to PVP applications are better determined.

The PVPO participated in several International Union for the Protection of New Varieties of Plants (UPOV) meetings including the general sessions held in Geneva where a proposed international system for cooperation is being discussed. The PVPO worked with UPOV to have soybean added to the developing Electronic Application System. The Office participated in the UPOV Biomolecular Technique (BMT) meeting to discuss the U.S. role in molecular technology development related to PVP. The Board asked if any policy issues were discussed at the BMT. The PVPO indicated that the U.S. presentation of a molecular marker threshold model had a lot of discussion but that most BMT discussions focused on the use of molecular technology for variety identification, PVP enforcement, and the management of reference collections.

#### Electric PVP (ePVP) application Update

The ePVP system has two components – 1) the web based outward facing Portal which is used by applicants for filing, application updates, and bidirectional application communication and by the PVPO staff to enter/modify paper based applications and 2) CRM (= Customer Relationship Management) which is internal only and is used by the PVPO staff for application examination and management. The system operates with 1) the portal governing applications entry, 2) an interface that connects the portal to the SQL database through a Dot Net application, and 3) CRM connecting to SQL for internal PVPO operations.

The PVPO is fully examining soybean, pepper, and peanut applications using ePVP. These crops are entered into the ePVP System from the portal and examined in CRM. All three crops have been moved from the legacy STAR database to the ePVP System. The Portal access is currently limited and only used by PVPO staff until the software is fully rolled out.

The PVPO is currently reconciling ePVP Portal and CRM errors to allow the entry of additional crops into the system. The next steps will be 1) provide the entry of non-PVP (reference or similar) varieties for distinctness comparison and 2) bulk upload of applications. Following the addition of the bulk upload feature, additional crops will be added to the system including corn, wheat, barley and oat in early 2017. An ePVP demonstration is planned for the December 2016 PVP Board meeting.

The Board asked if users could conduct distinctness searches that would allow the comparison their variety against other PVP varieties in the system. This feature is not currently available because some data for PVP-pending varieties is confidential. In the future it may be possible to allow users to conduct distinctness searches lacking confidential data.

The Board asked if the ePVP searches might be copyrighted or if the ePVP system and data can be licensed to others for a fee. The PVPO responded that the ePVP software might be available to other on a fee-for service basis.

The Board asked if ePVP would contain data for utility patented varieties. The system could use publicly available issued patent data however it was mentioned that utility patent data may not correlate to the PVP criteria - distinct, uniform, and stable.

#### Molecular Marker (MM) Subcommittee/Working Group Update

The PVPO provided an update on the MM Joint Working Group (The Board's MM subcommittee combined with the ASTA Group in 2014 to form the Joint Working Group (WG)). Initially the Joint WG focused on a MM Reference Distance model but then switched emphasis to a Pairwise model in 2015.

Currently no crops are distinguished solely on MM differences at the PVPO. In December 2014 the Board recommended that MM could be used to break ties in cases where a new variety is facing a phenotypic tie with existing PVP varieties (i.e. Pairwise Model). At this time the Office is not in a position to use MM data to distinguish varieties or to break phenotypic ties of similar varieties. Historically the PVPO has been able to work with its applicants to obtain additional data that resolved a phenotypic tie.

The Office explained that it follows UPOV guidelines for PVP examination and the DUS determination. In the past some applicants have submitted MM data voluntarily as additional data or as a means of distinguishing their new variety from their claimed most similar variety; however the PVPO does not use this data in its determination of distinctness. The PVPO does retain MM data for future reference. It was explained that some PVP exhibit C forms have data fields for MM data but that the PVPO is considering removing these MM fields to eliminate confusion about what type of data is required.

In 2016 the Joint WG planned to provide crop specific threshold and minimum distance criteria; however as of yet a recommendation has not been made to the Board. The PVPO is waiting for the Board's MM recommendations before 1) developing policy on MM data use, 2) developing MM administrative procedures for incorporating data into applications, and 3) determining how to examine MM data.

A technical action plan from the Joint WG explained that the members are working together, using the shared dataset (6K soy, 3072 corn) to develop models for arriving at a minimum distance threshold. Each WG member validates the model with their own

datasets (markers and/or germplasm) to determine if they are confident with the approach. This technical group is scheduling meetings every 3 weeks to discuss problems, progress, and ideas. Their goal is to define a difference/similarity threshold and minimum distance criteria for the soybean and/or corn by October.

The Joint WG's future plan is to 1) provide a recommendation to the ASTA Intellectual Property Rights Committee, 2) provide a recommendation to the PVP Board, 3) Publish a paper(s) on the MM process, 4) present the procedure to UPOV at the Technical Committee, TWA, and BMT meetings, and 5) gain UPOV's understanding for the U.S. PVP MM approach. The Board asked about gaining UPOV's recognition be it the pairwise or reference model. This would not be a formal UPOV endorsement but rather information sharing that this is the U.S. PVP MM approach. The Board asked how this recommendation would be brought forward – for instance “\_\_\_\_\_ is how a MM threshold would be used in the PVP process” and “\_\_\_\_\_ is the information that should be conveyed to the PVPO to make a distinctness determination”.

#### International Treaty for Plant Genetic Resources for Food and Agriculture

The reason that the Treaty was developed derives from the fact that 70% of the food that is grown and eaten comes from crops that are not native to the U.S. For example the wheat developed by Norman Bourlag, father of the green revolution, is based on a germplasm from the U.S., Japan, and Mexico. No country is self-sufficient with regard to germplasm availability and plant breeding.

Before the Treaty access to germplasm was being restricted prompting discussions from countries about giving something back to the country which provided the genetic resource. The Treaty established international rules and standards around germplasm access and benefit sharing using a Standard Material Transfer Agreement (sMTA) and a multi-lateral system covering 64 crops. Currently the Treaty has 139 contracting parties. The U.S. participated in negotiating the Treaty and signed it in 2002, however the Senate has not yet ratified it.

The sMTA is supposed to provide a standard means to access germplasm while giving back (benefit sharing) to the source country. However there are problems with the sMTA and it is being reviewed. The U.S. has been attending the sMTA meetings but cannot fully participate since the U.S. is not a contracting party.

The Treaty is very important to U.S. breeders because it is becoming increasingly difficult to internationally access plant germplasm for the development of new varieties. The concept of access and benefit sharing is better suited under the Treaty as

compared to the Nagoya Protocol under the Convention on Biological Diversity. The Nagoya Protocol establishes a parallel access and benefit sharing system which is bilateral, more cumbersome, more expensive, and is not focused on agriculture. In summary the Treaty is a much better option for plant breeder's germplasm access than the Nagoya Protocol. Recently the Senate passed the Treaty through the Foreign Relations committee with the hope for a floor vote; however, this did not occur before the summer recess. A Senate floor vote for ratification may occur in September. Because the Treaty is very technical some parts of it are misunderstood. UPOV also plans to have a symposium in October 2016 about the interconnectedness of the Treaty and UPOV

#### December 2016 PVP Board Meeting

The December 2016 PVP Board meeting will occur at ASTA's Corn, Sorghum, and Soybean Research Conference (the conference occurs December 5-9) at the Hyatt Hotel on East Wacker Dr., Chicago, IL. The meeting will occur over 2 days December 5, 2016 - 1:00-5:00 PM and December 6, 2016 - 8:00 AM - 3:00 PM. The meeting agenda will include updates on PVPO accomplishments, MM Working Group, UPOV / SAA meetings, ePVP and activities on PVP cooperation with other countries. There are also plans for a presentation from Peter Button, UPOV's Vice Secretary General, on the UPOV system, development of the UPOV Electronic Application System, and an update on the International System of Cooperation. A presentation from Kees van Ettehoven, Head of the Netherland (Naktuinbouw) Variety Registration Department, is planned about the Netherlands PVP process and UPOV's BMT perspective on MM. The Joint MM Technical Group will also meet on December 5 in the morning and the ASTA IP Committee will meet on the morning of December 7.

#### 2017-2019 PVP Board

The Charter of the current Board expires on February 5, 2017; the PVPO is in the process of renewing the Charter. A non-expired Charter must be in place in order to hold a Board meeting. The term of the current 2015-2017 Board expires on May 26, 2017. The PVPO will be soliciting nominations for 2017-2019 Board starting in December 2016.

#### Suggestions/Recommendations

The PVPO should actively seek advice from the Board by directing it and by going into more detail on certain topics. For example it may be necessary to have a separate Board teleconference on the MM findings and proposed recommendations. The PVPO

suggested seeking more guidance on outreach. The Board also mentioned discussing the vulnerability of the PVPO's revenue which is dependent on 2 crops and possible options for the PVPO has when revenue drops. The Board suggested re-visiting the brainstorming topics that were developed in December 2015 and prioritizing which would have the greatest impact. The Board also brought up re-examining payment options for PVP applications – looking into annual maintenance fees and different fees depending on the applicant size.

The Board meeting was adjourned.