

Plant Variety Protection (PVP) Board Meeting Minutes
April 25-26, 2012

USDA Plant Variety Protection Office
Room 4-2223
USDA George Washington Carver Center
5601 Sunnyside Avenue
Beltsville, Maryland 20705

Board Members attending (with affiliation):

June Blalock; USDA, ARS, Office of Technology Transfer
Robert Bowman; Iowa Farmer
Kent Bradford, University of California, Davis
Leticia Cabrera; Iowa Western Community College and Northwest Missouri State University
Steven Callistein; Pioneer Hi-Bred International, Inc.
Jonathan Egilla; Lincoln University of Missouri
John Gardner; Washington State University
Patrick Kole; Idaho Potato Commission
Kristine Mantey; ArborGen
Corinne Marshall; Sakata Seed America, Inc.
Salomon Montano; New Mexico farmer
John Nelsen; RiceTec, Inc.
Katherine White; Wayne State University

USDA and AMS staff:

David Shipman, AMS Administrator, USDA/AMS
Robert Epstein, Deputy Administrator, USDA/AMS/Science and Technology
Alan Post, Associate Deputy Administrator, USDA/AMS/Science and Technology
Robert Ertman, USDA/Office of the General Counsel
Jeff Haynes, Acting Deputy Commissioner, PVP Office
Paul Zankowski, Commissioner, PVP Office
Roger Simonds, Lab Manager, National Science Laboratory
Doug Bailey, AMS Chief Information Officer
Chris Apagwu, Information Technology Specialist
Bernadette Thomas, Information Technology Specialist
Francesca Abii, Information Technology Specialist

Visitors:

John Gaudet, USDA, ARS, Office of Technology Transfer
Marion Ravelonandro, USDA, ARS, Office of Technology Transfer

PVP Board Meeting Minutes - April 25-26, 2012

Opening remarks were made by Paul Zankowski, Robert Epstein, and David Shipman regarding the Agenda, 2011 Board minutes and Appeal to the Secretary. The PVP Board members introduced themselves and discussed what outcomes the group would like to see from the two-day Board meeting. The meeting agenda was adopted and the recommendations of the May 2011 PVP Board Meeting were reviewed.

PVP Office Update. Paul Zankowski. The PVP Office structure was discussed – The Office is currently staffed by: 1 Commissioner, 1 Deputy Commissioner, 6 PVP Examiners, 3 Associate PVP Examiners, 2 Information Technology Specialists, and 3 PVP Program Analysts. One of these PVP Examiners is located at an APHIS/AMS Office facility in Minneapolis MN.

The PVP application processing workload is distributed among the six Examiners. Over the past four fiscal years the PVP application backlog has increased from 745 to 1208 with 598 application incoming in fiscal year 2010 and 530 incoming in 2011.

The Office staff participated in domestic and international outreach as well as PVP training meetings during the 2011 fiscal year. For example in September 2011 the Office (PVPO) hosted 2 Chinese PVP Examiners that worked alongside the PVP staff to learn the U.S. system for PVP processing. PVP staff also participated in the UPOV Technical Working Party for Vegetables (TWV) held in Monterey, Calif. in July 2011 and in the Geneva UPOV session in October 2011. Due to budget restrictions, the Commissioner was unable to attend any UPOV Technical Working Party meetings outside of the United States.

The Business Process Re-engineering (BPR) project and the PVP application processing workflow were discussed. The Board noted that application processing productivity did not increase directly since the BPR recommendations were adopted in April 2011.

The Office efforts to upgrade the current PVP database software and electronic PVP application filing were also discussed. The new system would not directly help with the current application backlog, but would make future application processing more efficient. It was explained that the Examiner's distinctness database searches are easily accomplished with relative confidence on distinctiveness; however, striving for absoluteness in the defining distinctiveness requires an unreasonable commitment of Examiner's time and impacts the efficiency of the Office's operation.. The Board was concerned that the batch application processing goal for the new system might delay its development. The Office has participated in the American Seed Trade Association

(ASTA) Electronic PVP Working group in order to receive input on criteria for the new software system.

The Board made the recommendation that the PVPO continue to expand its interaction with the ASTA Electronic PVP Working group.

The Board recommended that the PVPO look at the U.S. Patent and Trademark Office (PTO) electronic application systems since they converted from paper to electronic application processing and they might provide insight into the process. It was mentioned that utility patents can be filed electronically, but plant patents cannot due to complication with accurate rendition of color photographs. It was also recommended that the office look to other UPOV countries to see how they developed their electronic systems and databases. It was noted that most other UPOV member PVP offices are funded by appropriated funds and therefore have the financial capability to develop new electronic application systems and databases.

The PVPO noted that all PVP certificates that have ever been issued were converted to electronic pdf files with the assistance of temporary contract staff hired September 2011 to January 2012 – most of these are now posted on the PVP website. The temporary staff also scanned many paper applications and correspondences in order to provide the PVPO a virtual office structure.

AMS National Science Laboratory (NSL) Varietal Differentiation Capabilities.

Roger Simonds. The National Science Laboratory provides chemical, microbiological and bio-molecular testing services on a wide variety of agricultural products supporting the Agency's commodity program areas with centralized scientific expertise. The NSL developed/validated microsatellite (SSR) based methodology as part of a biotechnology enforcement program for tomatoes, and avocados – this test enables inspectors to verify a specific variety and to differentiate it from lower quality produce. The NSL also has a program for Genetically Engineered Organism (GEO) detection.

Appeals to the Secretary of Agriculture and Overview of 2011 Appeal Decision.

Paul Zankowski and Bob Ertman. The 2011 Appeal to the Secretary was reviewed. In summary the Appeal asked if the PVPO could apply the “postmark rule” as equivalent to “arrived in the office” for responses from applicants. During the May 2011 PVP Board meeting the Board recommended that it should be within the Commissioner’s discretion to apply a “mailbox rule” to revive an abandoned application. The USDA Judicial Officer concluded that the Commissioner has the discretion to apply the “mailbox rule” to an applicant’s request to revive an abandoned application. Therefore, the Commissioner

revived the potato application #200500232 and the variety was determined to be new, distinct, uniform, and stable.

The PVPO has subsequently changed its policy and will consider applicant's responses as the "arrived in the office" date being equivalent to the postmark date. The PVPO has also changed template letters for applicant's responses to "All requested information must be postmarked or in the Plant Variety Protection Office on or before MMM-DD-YYYY, or this application will be deemed abandoned." The postmark rule will be applied to any response required from an applicant except the initial PVP application filing. In order to receive a filing date the complete PVP application and fees must be in the office.

The Board suggested that it was the applicant's burden to prove the postmark date and not the PVPO's. Office of General Counsel (OGC) commented that if something is received before the due date, then the PVPO doesn't need to keep the postmark/envelope. The Board suggested that the PVPO should only accept the US mail postmark, thereby indicating that the government has the response to the PVPO. It was commented that most agencies use the mailbox rule but limit it to the US Mail.

Issue of PVP Expiration and transgenic events in seed. Paul Zankowski and Bob Ertman. The issues surrounding the public release of seeds by National Center for Genetic Resources Preservation (NCGRP) was discussed. NCGRP is concerned about releasing the seeds of expired PVP varieties when that seed may be the subject of a patent, contain transgenic events, or may be regulated by another Federal agency (such as the case of transgenes that expresses insecticidal proteins - the Environmental Protection Agency also regulates these plants).

Currently, the Office tries to obtain transgenic information regarding the new plant variety from block 18 of the ST470 (PVP Application form) with the optional question "DOES THE VARIETY CONTAIN ANY TRANSGENES? Y/N, IF SO, PLEASE GIVE THE ASSIGNED USDA-APHIS REFERENCE NUMBER FOR THE APPROVED PETITION TO DEREGULATE THE GENETICALLY MODIFIED PLANT FOR COMMERCIALIZATION" and in block 4 of the ST472 (Seed Deposit form) with the optional question "Genetically Engineered Organism? Y/N".

Also, block 24 of the ST470 form requests information on other forms of intellectual property protection that maybe in effect at the time of filing the new plant variety application. The question that is asked is as follows: "IS THE VARIETY OR ANY COMPONENT OF THE VARIETY PROTECTED BY INTELLECTUAL PROPERTY RIGHT (PLANT BREEDER'S RIGHT OR PATENT)? Y/N. IF YES, PLEASE GIVE

COUNTRY, DATE OF FILING OR ISSUANCE AND ASSIGNED REFERENCE NUMBER.” and in block 5 of ST472 with the question “Patented Material? Y/N, If Yes, provide the patent application number or the Patent Number”.

The new proposed forms would have the word “optional” removed from the transgene or Genetically Engineered Organism blocks, additionally form ST472 would ask several more questions under blocks 4 and 5 as follows:

Block 4: Genetically Engineered Organism (GEO)? YES/NO

1. Name of Transgene(s):
2. Organization for Economic Co-operation and Development (OECD) Event(s) designation(s)
3. Has this Event(s) been deregulated by the USDA Animal Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS)? YES/ NO (If YES, provide the approved APHIS BRS petition number(s) to de-regulate this event:
4. Does the GEO contain or produce a Plant Incorporated Protectant(s) (PIP)? YES/NO, if YES provide the EPA registration number(s).

Block 5: Patented Material(s)? YES/NO, if YES provide Patent Number(s):
Patent application(s) applied for? YES/NO, if YES provide Patent Application Number(s):

If yes for either block 4 or 5 questions the PVP owner may be contacted 2 years prior to expiration of PVP to request information on patent status (patent number(s) and expiration date(s)) as well status of PIP registration (if applicable).

The Board provided the following general comments:

1. Regardless of the information provided in the seed deposit form or PVP application, the conduct of the NCGRP must be consistent with PVP Regulation 97.7,
2. To minimize the burden on the applicants, both forms should request essentially the same information using consistent terminology,
3. The requested information must be specific enough to allow timely and accurate completion consistent with the OMB burden statements associated with these revised sections,
4. Regarding the patent information requested:
 - a. An applicant may not know the requested information, and
 - b. The patent information requested will, in all likelihood, not be accurate at the time the PVP certificate expires

5. The language cannot be worded in a way that would suggest a representation or warranty that no unintended transgenes (i.e. Adventitious Presence abbreviated as AP) are present in the variety or the voucher specimen.

The Board was advised of an urgent timeline of 1-2 weeks for the finalization of this language.

The Board expressed a number of concerns regarding the wording used to request transgenic event and patent information. For example, the Board indicated that some current transgenic events will fall outside the scope of BRS since they do not contain the pathogenic components that require APHIS regulation (BRS derives its authority to regulate transgenic events that may pose a pest risk from the Plant Protection Act. The definition of a regulated article is found at 7 CFR § 340.1). In this case, NCGRP's objective of being informed of material subject to external regulation (such as a foreign regulatory authority) would not be achieved.

The Board suggested that the issue of unintended AP would need to be addressed so that the statements in ST470 and ST472 would not be taken as a representation that no AP was present. The PVPO provided guidance on where to obtain the USDA-APHIS reference number (http://www.aphis.usda.gov/biotechnology/not_reg.html). The Board requested that the PVPO also provide similar guidance on the form for where to obtain the EPA registration number and OECD event designation.

The Board asked why the patent information on the seed deposit form was necessary since there is nothing in the Patent Law that prevents the distribution of patented material. It was indicated that NCGRP's policy is to not release patented germplasm and that no seed increases are made by NCGRP until the PVP expires. The Board asked whether a refusal to release expired or abandoned seed deposits on the part of the NCGRP was consistent with the obligations for a depository provided under PVP Regulation 97.7. OGC was to research this question and report back to the Board.

The Board wanted to know how the patent and PVP information currently requested as part of the PVP application, such as on question 24 of the PVP form, was used by the PVPO. The PVPO responded that it wasn't used for examination because it was so broadly worded that it resulted in different interpretations by applicants. The Board and PVPO observed that applicants do not currently answer the question to the extent of its full scope. Furthermore, that it is well beyond any information needed for the examination process and encompasses the full international patent portfolios for transgenic events with multiple patented components. The Board suggested that the

question be revised to limit the request to patents and PVP information that is relevant to the examination of the application. Some possible wording was discussed.

In view of the urgent timeline, the Board discussed changing block 18 of the ST470 to “DOES THE VOUCHER SPECIMEN OF THIS VARIETY DEPOSITED IN SUPPORT OF THE APPLICATION CONTAIN ANY TRANSGENIC EVENT(S)?” or “DOES THE VOUCHER SPECIMEN OF THE VARIETY CONTAIN ANY TRANSGENIC EVENTS?” and remove the “(OPTIONAL)”. The Board was also concerned about the issue of essentially derived varieties in the context of the questions asked on these forms. OGC stated that the PVPO is not concerned with essential derivation.

The Board was concerned about the timeframe that the PVPO had for submitting these forms to OMB for renewal; they suggested that the PVPO communicate these deadlines to the Board and ASTA Seed Deposit Working Group (the PVPO has participated in this group to help refine these 2 forms).

The Board was also concerned about whether it was possible to exhaustively list all requested patent and PVP information requested on the PVP application and seed deposit forms, which is international in scope and encompasses IP of all types, and noted that to compile such a list would greatly exceed the OMB burden statement allocated for completion of the form. It was suggested that it might be better for the NCGRP to request patent information closer to the time of PVP expiration, rather than at the time of the PVP application, because the information would not be complete or correct at the time of PVP expiration approximately 20 years later. The Board recommended that the NCGRP consider a letter to the applicant that requested this information in a voluntary manner at a time near PVP expiration. The Board noted that while the issue of PVP expiration and transgenic events in seed was one that needed to be addressed by NCGRP and its counsel, however, the language could be worded to protect NCGRP, such as:

In accordance with PVP Regulation 97.7(h), all PVP restrictions on the availability to the public of the deposited material have been irrevocably removed upon the abandonment, cancellation, expiration, or withdrawal of the PVP certificate. However, the recipient is hereby informed that other restrictions on the deposit or use of the deposit may apply, including but not limited to restrictions resulting from regulatory requirements, other intellectual property rights (e.g. patents and/or trademarks), and seed laws. Recipient accepts all liability for the deposit and its use and hereby agrees to indemnify ARS for....

The Board suggested that the questions being asked on both the ST470 and ST472 forms regarding transgenic events, patent and PVP information be consistent.

The Board wanted to know why the PVPO does not solicit all this information on one form, and the PVPO responded that the ST470 information is needed for filing the information, while the ST472 form is sent to NCGRP along with deposited seed.

The Board asked if the NCGRP has the right not to release seeds because of intellectual property or transgenic regulatory issues. The Board suggested the PIP question be modified to simply ask "is it EPA regulated – Y/N" The Board also suggested that the PVPO's OGC review these issues and then discuss them with its stakeholders.

Following this discussion, the Board was informed that the deadline was not until June, and then further informed that there was no deadline and that the revisions could be submitted and approved by OMB at any time.

The Board and PVPO agreed that there were many significant issues that needed to be addressed and that the Seed Deposit Working Group organized by the ASTA should develop revisions to these sections of the PVP application and seed deposit form in consultation with several Board members and make a recommendation to the Board and PVPO.

PVP Finances Obligations versus Revenue – revisit PVP fee schedule versus value to stakeholders. Robert Epstein. The current total fees to obtain PVP are \$5,150, with no fee increase having occurred since October 2005. The top expenses over the past several years have been salary, rent-utilities-communication, overhead, and contracts. For FY2011 revenue was \$2.701 million and obligations were \$2.502 million resulting in an end of year Trust fund balance of \$3.753 million. The minimum operating expense of the Trust fund must be at least 4 months of operating reserve or approximately \$800,000. If the PVPO receives 350 applications for FY12 the estimated deficit would be \$867,000 versus a projected \$163,000 surplus if the PVPO receives 550 applications.

The Board wanted to know how it could assist on the PVPO's financing issue. It was indicated that the PVPO needs more than user fees to fulfill its mission. The Board wanted to know if the PVPO receives appropriations or if the Administration has requested funding from the executive budget. The Board felt that the Secretaries of Commerce, Agriculture, and USTR could make a compelling case for PVPO funding.

The Board indicated that they could not advocate for the PVPO unless they understand PVPO future projections under a range of outcomes. The Board requested several times the financial information on the cost of implementing the new data base in order to provide sound recommendations to the office. The Board suggested there is a need for futuristic thinking such as combining services with the PTO. It was stated that the U.S. Patent and Trademark Office (PTO) laws recently changed after more than 60 years, so change is possible; change at the PVPO can be packaged under need for modernization, harmonization, and innovation initiatives. A Board member suggested as an alternative to appropriation perhaps the ASTA could ask its members to pay an extra fee to the PVPO for computer upgrades. The Board suggested that the PVPO develops a five-year plan to update its systems and achieve its objective without focusing on money; however, the office does maintain both a fiscal year business and long range strategic plans. The plans are used to establish program priorities for reducing the application backlog and provide a financial base to allow reinvestment in office infrastructure.

The Board requested financial projections from the PVPO showing financial information based on a range of projections that was provided the subsequent day. The PVPO predicted between 400-420 applications in FY2012 (a revised estimate in June 2012 predicts the possibility of 450 application for FY 2012). It was observed by the PVPO and Board that a \$350-500K expenditure on phase 1 (design phase assessment) for a computer database study would have a significant impact on the office budget. Significant concern was expressed by the Board about entering into a second planning process for a database and electronic system without a clear plan for how to finance implementation.

Business Process Reengineering (BPR) Project: Successes and Shortcomings - Review of BPR compliance report. Paul Zankowski, Jeff Haynes, Bernadette Thomas. The top objectives for the BPR were 1) Improve PVPO operations, efficiencies, and controls; 2) improve the quality and timeliness of PVP examinations; 3) standardize PVPO business and management processes; and 4) reduce the application backlog. The application backlog has continued to grow since 2004 and peaked at over 1,200 applications in 2011. The backlog reduction was one of the primary objectives for the BPR when the BPR procedures were put in place in April 2011.

The BPR divided the application processing into 1) Program Analysts - receiving the PVP applications/funds and processing the preliminary applicant information; 2) Associate Examiners – conducting the preliminary review of New, Distinct, Uniform, Stable and writing the preliminary searches; 3) Examiners – conducting in-depth analyses of distinctness and confirming New, Uniform, & Stable criteria; 4) Deputy

Commissioner & Commissioner - performing QA review of applications, recommending for PVP, reviewing the final DUS assessment and making the final PVP recommendation; and 5) Program Analysts – processing the certificate fees and certificate printing /signature processing.

Prior to the BPR - GS13 Examiner had 80 applications per year disposal goal and GS12 Examiner's goal was 60. The BPR assessment deduced that Examiners could theoretically dispose of 2 applications per day. However, in FY2012 the disposal goal for Examiners was set to 100 applications for the year with the overall office goal of about 600 applications.

Historically the PVP overall application disposal has been 438 in 2008, 377 in 2009, 352 in 2010, and 424 in 2011. For FY12 the current midyear overall disposal was 202 and it's estimated that overall 450 applications would be disposed by year's end. This would have the effect of reducing the backlog to about 1,150 if 350 applications came in during the year.

In order to get a better picture of where application were in the processing stream the current 1,200 application backlog was analyzed using the new BPR system. Approximately 94 applications were at the first Program Analyst step, 240 at the Associate Examiner stage, 906 at the Examiner step, 17 at the QA/Deputy Commissioner/Commissioner step, and 315 were in the Program Analyst certificate processing level (these 315 are not considered part of the backlog). The PVPO directed the Board to slide 9 of the presentation, and pointed out that PVP Application Disposal by Examiner since FY2008 displayed large variations between Examiners with one Examiner having consistently low annual disposals versus another Examiner with high annual disposals.

The Board commented that the PVPO needs to do good quality work, but not perfection, keeping in mind the PVP will be enforced by the courts. It was noted that individuals function at the tactical, operational, and strategic levels within an organization but it appears that Examiners are trying to operate at the operational instead of the tactical level. The Board supported the idea of an application review by Associate Examiners without subsequent "in-depth" examination by the non-associate Examiner. The Board suggested establishing guidelines to direct Examiners on how much time to spend on an application that has already been reviewed by an Associate Examiner.

The BPR contractor (Paradigm Inc.) conducted a review in the summer of 2011 to determine how well the PVP staff was complying with the BPR and the Standard Operating Procedures (SOPs). The study found that none of the Examiners were able

to meet biweekly goals and that some of the Examiners had no applications disposed. This study also found that some Examiners avoided the SOPs by writing letters to applicants before the request for information protocol was established or by requesting certificate fees without having the final PVP recommendations.

Topics brought forward by Board Members. Paul Zankowski. The Board had 3 topics to bring forward – 1) payment of certificate fees within 30 days, 2) making African countries aware of PVP services, and 3) level of US government involvement in November 2012 UPOV symposium and other UPOV meetings.

The Board wanted the PVPO to consider revising the late fee required for certificate fee payments received after 30 days. Section 81 (a) and (b) of the Plant Variety Protection Act indicates that the certificate fee must be paid within one month and if the payment is not timely an applicant can pay the certificate fee within nine months of the due date with an additional late fee (\$41). The Board recommended that the certificate fee be paid up to 90 days after the PVPO communication without a late fee payment. OGC said they would review this recommendation and determine if it were legally acceptable. The PVPO will inform the Board of whatever decision is made regarding this issue and would inform the public via the website if the policy changes.

The Board wanted to consider an approach to make African countries aware of US PVP services. It was mentioned that the Global Diversity Trust and ASTA funding through the USDA Foreign Agricultural Service could be an approach to this issue.

The Board wanted to ensure that the US government and especially the PVPO participates in the UPOV symposium “*Benefits of Plant Variety Protection for Farmers and Growers*” as well as other UPOV meetings such as the Technical Working Parties (TWP). It was indicated that the PVPO will attend the October/November 2012 meeting.

The Board stressed the importance of the PVPO's participation in UPOV TWPs so the U.S. can be more involved at the inception stage of ideas/controversies rather than at the veto stage in Geneva. The Board indicated that the U.S. involvement in the UPOV TWPs could have an influence on developing country's intellectual property (IP) issues. The Board reiterated that it's more robust to have a pro-active versus veto power stance. The Board suggested that the PTO deputy director might be able to make funds available for the PVPO to travel to UPOV TWPs. The Board indicated that it would also be useful to have more involvement from the USDA Agricultural Research Service (ARS) especially at the UPOV Biochemical and Molecular Techniques and DNA Profiling in Particular Working Party (BMT).

Procedural Changes to PVP. Paul Zankowski. The PVPO presented several proposed office procedural changes to the Board including 1) the Postmark Rule, 2) Acceptable Seed Repositories, 3) the PVP Seed Deposit Form and Transgenic Varieties, 4) time to reply for certificate fee payment, and 5) fee collection for Potato Tissue Culture Deposit.

The postmark rule resulting from the 2011 Appeal to the Secretary was put in effect on January 27, 2012 and all communications requiring a response now indicate "All requested information must be postmarked or in the Plant Variety Protection Office on or before MMM-DD-YYYY, or this application will be deemed abandoned."

An issue of acceptable PVP seed deposit repositories was resolved for seven wheat, oat, and barley varieties stored at the Small Grain Collection in Aberdeen, Idaho. Even though this location is part of the ARS National Germplasm Collection this site was deemed unacceptable by both NCGRP and Aberdeen because of storage conditions and security; therefore the seven varieties will be transferred to NCGRP.

The changes to both the PVP application form (ST470) block 18 and 24 and the Seed Deposit form block 4 are still under review as was discussed previously in the minutes.

The Board wanted the PVPO to consider revising the late fee requirement for certificate fee payments received after 30 days. The PVPO will inform the Board of whatever decision is made regarding this issue and would inform the public via the website of the policy changes.

The PVPO collects fees for the NCGRP tissue culture storage of PVP potato varieties. The total fees collected are \$2,500 – and are comprised of \$925 collected to prepare the tissue culture deposit and pay for storage at NCGRP from years 0 to 5, and three subsequent payments of \$525 each at years 6, 11, and 16. . NCGRP collects \$2,400 and PVPO collects \$25 processing fee (\$100 total) with each of these four payments.

The PVPO is proposing to collect a onetime fee of \$2,500 for all 20 years of potato storage. This onetime fee would reduce the PVPO's accounting fee collection burden which currently has the effect of a "maintenance fee" for only potato. The Board considered collecting a lump sum for 20 years of storage as too expensive. OGC indicated that an approved potato variety gets 20 years of protection and therefore 20 years of storage should be paid. The Board thought it was outrageous to ask for 20 years of payment, especially if someone drops PVP after 5 years. It was recommended that the PVPO discuss this with NCGRP since their funding restrictions might require them to spend all the money in the year that they receive it. The Board recommended that the storage fee be left as is and advised the PVPO not to collect the \$2500 up front.

Update on PVP database conversion and electronic PVP applications. Doug Bailey. The PVPO is proposing to upgrade its database and to provide an electronic PVP filing system. These upgrades are needed to allow the office to become automated for every aspect of a PVP application. Currently all applications and responses are electronically scanned but data is manually entered into the current databases.

The current PVP database (Cuadra STAR) is a flat file structure that uses a cryptic query language, and has limited software support. The database is used for PVP accounting, PVP distinctness searches, and to monitor PVP staff's workflow.

The new software should have a SQL structure to handle the database needs for crops, accounting, and work progress monitoring and provide a user environment that is easy to learn and navigate. In addition the new software should allow for web-based application submission with these capabilities: 1) direct download of applicant PVP information without any re-keying, 2) electronic filing for every component of a PVP application, 3) generation of an electronic filing receipts confirming the application submission, 4) attachment of digital image files, data tables, or any other description information files, 5) batch uploading many applications, and 6) providing automated responses for common letters and forms. Ideally the new system should provide an electronic payment system with secure and user-friendly web-based payment application that allows users to pay fees while the application is in process. Other characteristics of the software should include operating under the USDA Electronic Credentialing System; compatibility with other UPOV member filing systems; and a capability to evolve and incorporate future molecular data for distinctness comparison.

Under Phase 1 of the software development plan a vendor would define and develop business requirements, system requirements, data requirements, and detailed system / database design specification. In Phase 2 a different vendor would successfully migrate data from STAR to SQL. Under Phase 3 a vendor would develop the PVP electronic application. Phase 4 and 5 would involve system deployment and support/maintenance, respectively.

The Board asked when the PVPO first started using STAR – the information technology (IT) staff responded in 1984. The Board was concerned about how much time the PVP staff will spend to provide operational requirements and to test the new system. The Board suggested the migration of all data and providing reasons why it can be done versus not doing it. The Board wanted to know how the transition would occur from STAR to the new system. IT responded that STAR's usage would be gradually reduced until it is phased out.

The Board was concerned about getting Phase 1 done right; if it isn't then time and money will be wasted. IT indicated that a vendor that does Phase 1 is not allowed to bid on Phases 2 to 5. The Board question why the Phase 1 contractor couldn't bid on Phases 2 to 5. IT indicated that the Phase 1 vendor must be different from the vendor for phase 2-5 (based on current USDA procurement policy) and must be CMI certified. IT said that Phase 1 would describe what needs to be done but not how to do it. The Phase 1 vendor may subcontract with another vendor for Phases 2 to 5. The Board did not think the exclusion of Phase 1 vendors from bidding on Phase 2 to 5 was provided in federal procurement law and suggested that the Phase 1 vendor not be barred from bidding on Phase 2 to 5 if permitted by the USDA.

PVP Board General Discussion. PVP Board Members

The PVP Board was concerned about 1) the extreme importance PVP to US agriculture and the inability of the PVPO to perform its basic function of reviewing applications for new plant varieties efficiently; 2) the PVPO backlog and organizational efficiency ; and 3) that the PVP Board is not being utilized very well.

The Board would like agendas, meeting materials, and finance information and models to be delivered within a reasonable time previous to the meeting so the Board could study them better. It was noted that the Board did not receive an agenda for the Board meeting in advance.

The Board indicated that it is difficult to advocate for the PVPO without financial transparency additionally they want the PVPO to set global PVP standards. The Board wanted their comments included in the minutes and in a letter to the Secretary. The Board wanted the PVPO dysfunction rectified; members were worried that the database technology project is on the wrong path and could drain the PVPO of resources without sufficient funds to adequately complete the project. They suggested that the PVPO consider technology implemented by the European and Canadian PVP/PBR offices.

There was a unanimous desire from the Board for the Office to "Lead" IPR for PVP globally via the presence of the Office at international meetings and the frequent and repeated sharing of ideas and concepts for data collection and application reviews with other PVP offices around the world. The Board strongly suggested that the Office envision these objectives without focusing on financing issues to present a vision of what the Office could do globally. These objectives could subsequently be prioritized for presentation to the administration as the "PVPO pathway to success".

The Board was concerned about the new database plan and the lack of PVP application review progress; better cooperation with other PVPOs; better work on e-filing and databases. The Board expects PVPO synergy with the PTO which currently uses no e-filing for Plant Patents for a better understanding of the best approaches to database management. The Board suggested that the PVPO needs an attitude of what it can do instead of what it can't do.

The Board suggested more interaction with the PTO and ARS Genetic Resource Information Network (GRIN) to synergize their systems.

The Board commented that the US has tried to be a leader in intellectual property rights and that the US system needs to be a model for other nations. The Board reiterated that the PVPO needs to be more forward thinking than its current situation; but perhaps the PVPO is not aligned well with AMS nor is it placed well within the USDA and that collaboration with other agencies, such as the USPTO, should be considered. The Board remarked that there is a systematic inability to make progress at the PVPO; the PVPO is not getting the recognition within the USDA that it should get; and this should be referenced in the letter to the Secretary with a list of the urgency options.

The Board indicated that there is a lot of reach and desire from within the Board but members need relevant and timely financial information from the PVPO in order to provide assistance. The Board expressed a strong willingness to support the PVPO, and noted that to do so it needs the PVPO to put together clear goals and tactics for achieving its objective so that the Board members can provide assistance to the PVPO.

The Board emphasized that it is very important for the PVPO to complete its core function of examination and certificate issuance. The Board said that the office needs to prioritize its database wish list and should evaluate the UPOV database to see what it can provide to the PVPO.

UPOV Activities and PVP Harmonization Activities with China. Paul Zankowski.

The PVPO participated in the UPOV Technical Working Party for Vegetables (TWV) meeting held in Monterey, CA in July 2011 and in the UPOV meeting / symposium held in Geneva October 2011. The PVPO also hosted 2 Chinese PVP Examiners to work alongside the PVP staff from October to December 2011. These Examiners first toured the US seed industry during September 2011 to gain a better understanding of US agriculture and seed technologies.

While the Chinese Examiners visited the US PVPO they wanted to comprehend the Intellectual Property laws of the USA, understand US PVP examination methods using

breeder provided data instead of government run field tests, work on live US PVP applications, understand the examination procedure for asexually reproduced varieties (at the US PTO), and learn how the US moved from UPOV1978 to UPOV 1991. The overall goal for both countries was to allow the U.S. and China to better harmonize their PVP examination processes. The PVPO provided interactive training for these Examiners by having them work on pending PVP applications from three seed companies that waived confidentially for this specific timeframe. The Chinese Examiners were shown the specifics of PVP examination for corn, soybean, cotton, potato, wheat, lettuce, and canola. They also spent a week working with the PTO staff to better understand the procedures for Utility and Plant Patents.

PVP staffing – roles of the Program Analysts, Associate Examiners, and Examiners and Deputy Commissioner. Jeff Haynes and Paul Zankowski. The roles of each of the PVP staff were discussed in combination with the new Standard Operating Procedures (SOPs) and PVP Office Operations Manual.

Program Analysts are responsible for 1) receiving and processing incoming applications; 2) preparing electronic and hardcopy folders; 3) entering application data into the STAR database; 4) developing and sending filing letters/communications; 5) processing fees paid by credit card or check; 6) processing certificates for issued PVP; 7) processing certificate fees paid; and 8) following up on due dates and late fees.

Associate Examiners are responsible for 1) the preliminary reviewing of application for new, distinct, uniform and stable criteria; 2) variety information data entry into STAR; 3) searching for the initial most similar variety; 4) tracking of seed and tissue deposit dates and fees; 5) general correspondence with the applicant for minor missing information; and 6) in the future - processing Requests for Information (RFI).

Examiners are responsible for 1) conducting in-depth analysis of PVP applications for new, distinct, uniform and stable criteria; 2) refining the most similar variety database search if needed; 3) justifying any requests for information from applicants and seeking approval by the Commissioner; 4) corresponding with applicants; 5) creating the final summary report and recommendations for protection.

The Deputy Commissioner is responsible for 1) the Quality Assurance (QA) review of applications / approval of PVP recommendations; 2) being the management representative on Change Control Committee; 3) updating the Standard Operating Procedures and Office Operating Manual; 4) chairing crop team review meetings and 5) developing crop team backups.

The Commissioner is responsible for 1) the crop distribution/re-distribution; 2) acting as the backup QA review; 3) approving RFI justifications; 4) making the final determination of applications recommended for PVP that have been reviewed by QA; 5) attesting to PVP certification in conjunction with the Secretary; 6) being the USDA representative to UPOV; 6) acting as the liaison between PVP staff and USDA/AMS administration, USPTO, UPOV, seed industry, etc..

Some of the new processes that have been implemented in conjunction with or after the BPR include; 1) justifying why an RFI (Request for Information) is necessary before communicating with PVP applicants (letters, e-mails, faxes, phone calls etc.) – this is reviewed and approved by the Commissioner and was implemented in April 2011; 2) meeting with Crop Teams quarterly to ensure all members are aware of duties and to discuss progress and was implemented in fall 2011; 3) meet with Examiners biweekly to ask them to describe the significant problems delaying the processing of their 10 closest applications and to offer quick solutions - implemented in April 2012; 4) having Associate Examiners process applications and pass directly to the QA process – implemented May 2012; 5) planning to distribute high volume crops (corn and soybean) among several Examiners and Associate Examiners (at planning stage); and 6) holding listening sessions with top soybean, corn, cotton applicants – work with them to explain and correct discrepancies that prevent their applications from moving forward - (at planning stage).

PVP Board's Recommendations:

1. The PVPO should continue to interact with the ASTA Electronic PVP Application working group in order to gather information from PVP users to determine the requirements for electronic PVP applications and the new PVP database.
2. The PVPO should change the wording of questions 18 and 24 of the PVP application form (ST470) and blocks #4 and #5 of the Seed Deposit Form based on recommendations from the ASTA Seed Disposition Working Group, input by ARS and by the Board's final edit of the PVP Board minutes. The Board requested that the PVPO provide guidance on the form for where to obtain the EPA registration number and OECD event designation, similar to what it provides for the USDA-APHIS reference number. OGC for the PVPO should provide an opinion regarding PVP Regulation 97.7 and under what conditions the NCGRP may or may not refuse to release a seed deposit for which the PVP certificate has expired or is abandoned.
3. The Board supported the idea of a thorough application review by Associate Examiners without subsequent "in-depth" examination by an Examiner.
4. The Board noted the failure of the PVPO to meet objectives stated in previous minutes (for example, see the 5-year strategic plan for 2007-2012 in the November

2007 Board minutes) and recommended that a letter be drafted to the Commissioner to highlight this issue and to suggest opportunities to utilize the Board to assist in achieving PVPO strategic objectives. These objectives include optimizing PVP certificate quality and timeliness, achieving organizational excellence, and improving plant breeder's rights and enforcement domestically and abroad.

5. The Board recommended the PVPO waive the requirement for applicants to pay the certificate fee within one month and not to collect late fees until after 90 days.

[Subsequent to the meeting, the Board was notified that the Deputy Assistant General Counsel has advised the PVPO that the PVP Office cannot waive or extend the payment of the certificate issuance fee until after 90 days as recommended by the Board, 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 current \$41 late fee.]

6. The Board recommended that the PVPO 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.