

Minutes  
Plant Variety Protection Board Meeting  
May 26, 2004

George Washington Carver Center  
Beltsville, Maryland 20705 USA

Board Members attending (with affiliation):

Peter Bretting, USDA, Agricultural Research Service  
Leticia Cabrera, University of Texas at Brownsville  
Harry Collins, Delta and Pine Land Company  
Bruce Hunter, Syngenta Seeds (retired) and American Seed Trade Association  
Sharan Lanini, Consultant  
Virginia Lehman, Blue Moon Farm, LLC  
Salomon Montano, New Mexico farmer  
Bruce Morrissey, Dupont de Nemours Co.  
Hector Quemada, Crop Technology Consulting, Inc.  
Renee Rockwell, Pioneer Hi-Bred International, Inc. (via teleconference)  
Jodie Smith, Fort Peck Community College  
Margaret Smith, Cornell University  
Walter Wiles, Southern University

USDA and AMS staff:

Charles (Chuck) Lambert, Deputy Under Secretary for Marketing and Regulatory Programs  
A.J. Yates, 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  
Michael Feil, Chief Statistics Branch  
Annette White, USDA/AMS/Administrative Officer's Office  
Yvette Waul, Program Assistant

Plant Variety Protection staff:

Gwen Adams, PVP Analyst  
Paula Armstead, Contract Clerk  
Alan Atchley, Examiner  
Kunal Bose, PVP Assistant  
Robin Davis, Examiner  
Mark Hermeling, Quality Assurance Examiner  
James Mantoath, Associate Examiner  
Thomas Salt, Examiner  
Janice Strachan, Examiner  
Jeffrey Strachan, Examiner  
Bernadette Thomas, Information Technology Specialist

Beretha Thornton, Associate Examiner  
Leigh Wiltison, PVP Assistant  
Paul Zankowski, Commissioner

Visitors:

Sign Language Interpreters : Cathy Rader and Yvonne Robinson

Opening remarks were made by Paul Zankowski, Robert Epstein, A.J. Yates, and Chuck Lambert. The meeting agenda was adopted. The Board approved the minutes of the March 2003 meeting.

**Reports:**

**PVP Accomplishments from March 2003 to May 2004.** Paul Zankowski. The PVP Office has 13 full time positions, two of which were filled within the past year, the office also has a contract secretary. Since March 2003, an examiner was promoted to a Quality Assurance examiner, the PVP secretary departed, one program assistant was reassigned from the Seed Regulatory and Testing Branch and one program assistant was directly hired.

A breakdown was provided of which examiner handles each of the major crops, and what their current workload is. In FY2003, 350 new applications were received by the office, mostly agricultural crops. Four hundred thirty nine applications were issued, abandoned, withdrawn or otherwise disposed of during FY2003. Since March 2003, the PVP Office has reduced the backlog of undecided applications by approximately 100 with a current approximate backlog of 736.

In FY 2003, \$1,143,000 was expended from the trust fund and \$1,246,000 was budgeted. The trust fund balance increased from \$1,193,000 to \$1,281,000 during the fiscal year 2003. A 35% fee increase went into effect in FY 2003 which reduced the budget deficit but did not affect the rate of incoming applications. In Fiscal Year 2004, \$1,487,000 in expenditures and overhead was budgeted.

The office reorganized the Quality Assurance (QA) program and transferred these duties to an Examiner. This program's main goal is to harmonize the processing of applications among the examiners. The PVPO staff attended various stakeholders meetings in the past 13 months in order to address their concerns and to update them of the PVPO activities and status. The PVPO conducted international training in Michigan (July 2003) and at Beltsville for 4 days with the Vietnam PVPO (August 2003) and ½ day with the Japan PVPO (December 2003). The Vietnam training was part of an ongoing cooperation with the Foreign Agricultural Service to provide training in the US form of plant breeder's rights.

The PVPO has made 29 exhibit C forms (objective variety description) for the most frequently filed crop kinds available as pdf files on the office website. Expired PVP certificates were scanned and converted to pdf format in 2002. A web based interface is being developed to make these certificates freely available to the public by late 2004. A merchant credit card account was received by the PVPO that will allow applicants to pay for filing and examination fees with 4 major cards. The PVPO staff will work with the AMS Information Technology staff to develop the web based software to allow the processing of these transactions.

The PVP database conversion from STAR to Microsoft SQL was discussed with the goals of 1) migrating data from a hierarchical to a relational database, 2) to develop the required business systems to meet information or operational needs, 3) improve database management and security, and 4) to provide a platform to allow a better transition to e-business. During the first phase of the conversion a contractor was selected who conducted interviews with the PVPO to develop a Requirements document. An Options document was prepared from these database requirements so that the contractor can develop a Design document that specifies how the new database will function.

The Commissioner traveled to the National Center for Genetic Resources Preservation in August 2003 to discuss potato clonal storage fees, phytosanitary requirements, seed replenishment, direct seed shipment procedures, identification and storage of Genetically Engineered Organism (GEO) seed, and the fate of inbred seed after PVP certificate expiration.

The legislation extending the protection for Marshall ryegrass was discussed and the Board met during lunch to propose a statement from the Board regarding this law.

**PVP Filing Statistics.** Jeff Strachan. In fiscal year 2003, the PVPO received 350 new applications. So far in fiscal year 2004, the PVPO has received 225 new applications, this was 86% of the cumulative average of incoming applications for the period 1990-2004.

**PVP Financial Summary.** Annette White. In FY2003 the PVPO was funded by \$1,173,000 of the trust money supplemented by additional funds to support departmental related biotechnology and international standards related programs. During FY2003, the PVPO expended \$1,143,441 (\$1,246,000 was budgeted) and incoming revenue was \$1,302,708, this resulted in increasing the trust fund balance from \$1,193,000 to \$1,281,267.

For FY2004, the planned budget is \$1,487,000 with salary/benefits, rent/utilities, and contracts the largest line items. Other sources of 2004 funding include \$145,000 in alternate funding for biotechnology and international standards projects.

A fee analysis was presented, based on current fees, with revenue remaining fixed at \$1,271,000 through 2007 and obligations increasing from \$1,143,000 in FY2003 to \$1,572,000 in FY2007. This scenario would result in the trust fund being depleted each year through 2007 by approximately \$200,000 to \$300,000 per year. If the current fees were not changed, the trust fund balance would be approximately \$310,000 at the end of FY2007.

The effects of a 10% and 20% fee increase on the trust fund balance were presented. If a 10% fee increase was instituted in FY2005, incoming annual revenue would be approximately \$1,384,000 and a 20% fee increase would result in \$1,510,000 annual revenue. The 20% fee increase would stabilize the trust fund through FY2007. Based on these scenarios, Annette recommended at least a 20% fee increase. The Board wanted to study a proposed fee increase and respond to this recommendation later in the meeting.

**PVP Quality Assurance (QA) Program.** Mark Hermeling. Every other application recommended for issuance is checked to determine if all the quality criteria are met. If an application fails the QA process, then all of that examiner's applications are reviewed until one passes the QA process. This fiscal year 45 of 146 applications have been returned to examiner

for further work. On the application form, the standards include having a valid signature, evidence that the variety is new, and the variety name has been cleared. The Exhibit A needs to trace the pedigree back to public or commercial lines, then describe the breeding methods and selection criteria used, finish by showing evidence that the variety is uniform and stable, and explicitly discuss variants. Variants and off-types were defined following industry standards. The Exhibit B must provide the names of comparison varieties, and establish and support clear differences. The Exhibit C must provide an adequate variety description. Data in the Exhibit D should not contradict information presented elsewhere in the application. The Exhibit E must properly establish ownership and eligibility for PVP.

**PVP Office Site Update.** Alan Atchley. The administration of the NAL Building plans to install sprinklers on the PVPO floor in August 2004. Due to the requirement of the PVPO to move to another floor within the NAL building during the sprinkler installation and then back to the present floor, the PVPO has contacted a USDA realty specialist and commercial office realtors to inquire about the availability of commercial office space outside of the NAL building. Two suitable office locations that are approximately 6,000 square feet and would accommodate 16 offices/rooms plus a conference room were identified within 12 miles of the current office location. The PVPO and S&T administration will be considering whether this commercial office space is affordable, safe, secure, and can provide a more efficient office environment than the current location.

**PVP E-Business and Database Migration Plans.** Bernadette Thomas. PVP is continuing with five projects related to computer technology and databases.

The first project is the database migration, which would migrate the current database into a relational database in order to meet new information/operational needs, create a more efficient user environment, and improve database management/security. A contract for the project was awarded to CNSI who conducted interviews with the PVP staff to draft a Requirements Specification Document, followed by a System Alternatives Analysis Document, which resulted in a recommended database design document. The contractor will deliver a system design document and test plan on how the database should run. Subsequent phases of the project will be the conversion of data, development of a maintenance plan, evaluation and implementation of system enhancements, and the development of end user manuals and training. The database conversion project is being funded by appropriated biotechnology money, but may require trust fund money in order to complete.

The second project involved making electronic forms accessible through the internet. Twenty nine objective variety description forms have been made web available, in addition to the S&T-470 application form. In the future these forms may be able to be filled in online and submitted electronically.

The third project was the scanning and electronic conversion of all expired and issued PVP certificates. All expired certificates and certificate inserts that were issued from 1973 to 1983 have been converted. The pdf files for these certificates should be web accessible by August 2004. (Note: These pdf files are now available on the PVP website.) The goal is to have all the expired and issued certificates available as pdf files within the next 1-2 years.

The last project is to allow payment of some fees by credit card. The PVPO has received a merchant credit card account that will allow for the payment of the filing, search, certificate

issuance, and copies of records fees. The PVPO will work with the AMS Information Technology group to develop the web interface. The office will continue to accept checks and money orders for payments.

Finally the PVP web page has been re-designed to be consistent with the agency's design. The new version breaks the information into separate pages, with links to take users to the desired pages more quickly.

**Domestic and International PVP Training.** Robin Davis, Tom Salt, Janice Strachan. The PVPO has been asked by the seed industry to conduct domestic training. The PVPO would like to develop this training either on site at the PVPO or at seed industry related meetings. For on site meetings, the PVPO would need to coordinate hotel/transportation arrangements, lunches/breaks, and determine how to effectively charge for training. If the training were conducted as a workshop proceeding or following industry meetings, then interactive time with the PVP trainers continues after the workshop and the responsible society would make all the arrangements and pay the PVPO at the conclusion of the meetings.

During ASTA sponsored training, ASTA could make all the training arrangements, PVP trainers would be hired as "teachers" and the PVPO would be paid for their services.

Several different venues were discussed for the off-site training including society meetings, private sector regional meetings, university and experiment station sites, and other government agencies. The PVPO will work with societies such as ASTA to determine how, when, and where to conduct the domestic training.

The PVPO has been conducting international PVP training in conjunction with FAS, ASTA, various governments, and university programs and through Cochran fellowships. Fourteen countries have been trained on the US PVP systems and these countries have joined UPOV. Additionally, 12 countries have been trained but are not currently UPOV members and several countries and regions of interest have been contacted regarding US PVP training.

The international training is arranged through the USDA FAS with the PVP examiners hired as teachers and paid travel, per diem, salary and benefits plus lost productivity time up to \$89 per hour.

**Update on Process Improvement Plan (Six Sigma).** Janice Strachan. The Six Sigma philosophy was summarized. The PVPO had previously focused on reducing the time to certificate issuance and improved application processing which were relatively easy to measure. The progress made due to this improvement included a reduction in the time to issuance in FY 2001 and 2002 and a continued reduction in the application backlog by disposing of more applications than are received.

Other areas that can affect the customer's experience with the office include obtaining information and forms, preparing/filing applications, the examination/search process, certificate issuance, adverse actions, and ancillary processes/services. Possible improvements for the customer may be achieved by expanding quality assurance to cover customer service and clerical work, maintain the same expected standards for examiners in all years, and re-define the rules, regulations, and procedures that customers can expect.

It was proposed that the PVP Regulations and Rules be completely re-written so that it can become an office manual. Improvements include: the use of plain English, grouping related sections, adding sections on voucher seed samples and obligations of the certificate holder

during the term of protection, and removing sections that are no longer valid due to past amendments.

**Topics Brought Forward by Board Members and Other Issues** Paul Zankowski. The recent Canadian Supreme Court ruling against a farmer and in favor of Monsanto was discussed in relation to public perception of intellectual property, patents, and PVP.

A Board member brought up the topic of the burden of seed replenishment for issued PVP varieties. Multiple replenishment requests were sometimes made, for deposits which were less than 1 year old. The requests often related to inadequate warm germination despite the fact that the seed was tested by the owner prior to submission and found suitable. There were questions on how the seed was temporarily stored by the PVPO, why treated seed could not be submitted (in contrast to seed storage at the American Type Culture Collection), and why the PVPO did not implement the March 2003 Board recommendation for direct seed shipment. It was again recommended that seed not be handled by the PVPO and that it be sent directly to NCGRP, as was done at the March 2003 Board meeting.

The PVPO explained that the NCGRP requested seed replacement for 1,160 samples either because the germination had deteriorated to less than 85% or the seed number fell below 2,100 seed (both NCGRP criteria for replacement).

It was suggested by Board members that the PVPO quickly get the regulations changed so that direct seed shipment to NCGRP can be accomplished and that PVP owners send in more than 2,500 seed in order to avoid the NCGRP low seed condition. The NCGRP wants a PVP number assigned to a variety before it accepts seed from direct shipment. The PVP regulations will need to be changed so that a complete PVP application does require seed before a PVP number can be assigned. The representative from the Office of General Counsel (OGC) indicated that this regulation change may be able to be incorporated into the current supplemental fee increase.

The NCGRP would like the variety owner to fill out a seed / tissue culture deposit form that would contain a question pertaining to the Genetically Engineered Organism (GEO) status of the variety. The nature of this GEO question is being worked on at the Secretary of Agriculture level. The PVPO is working with the NCGRP to inform them which varieties are believed to be GEO as determined by information present in the PVP application – this is in response to an Office of Inspector General (OIG) concern regarding a potential for unintended release of unidentified GEO seed. The PVPO will provide the NCGRP with an updated list of varieties which are thought to be GEO at least every six months.

The issue of the fate of NCGRP stored inbred seed of a PVP hybrid variety was discussed. The OGC representative stated that the cost to obtain a PVP on a hybrid variety is that the inbred parent's seeds will be turned over to the National Germplasm program after the PVP expiration of the hybrid variety.

The proposed increased clonal storage fee for potato at the NCGRP was presented. The fee will increase from a one time payment of \$625 to 4 payments of \$925, \$525, \$525, and \$525 payable every 5 years. For each payment interval, \$25 will be retained by the PVPO to cover the cost of fee processing. The PVPO will be acting as the intermediary for the processing of the clonal storage fee that is charged by NCGRP. The NCGRP found that the \$600 currently charged does not cover the cost of labor, supplies, and energy to maintain clonal storage as mini-tubers,

slow growth in vitro cultures, and cryogenic shoot tip storage. They indicated that private facilities typically charge \$2,000 to \$4,500 for 20 years of clonal storage. This fee change will go into effect on July 1, 2004. The Board did not present any opposition to the clonal storage fee increase.

The Board took up the discussion of another general fee increase in addition to the pending supplemental and 20% general fee increase that were recommended in 2001 and 2003, respectively. The financial analyst recommended at least a 20% fee increase to stabilize the PVPO trust fund into 2007. The Board members discussed whether a 20% fee increase was really necessary on top of the forthcoming two fee increases. There was discussion from the Office of the Deputy Administrator (ODA) that it takes approximately 18 months for a proposed fee increase to be processed and go into effect. The last fee increase made up for many years without fee increases. Over the coming years, the PVP Office will incur cost of living salary increases, increased rent and supply costs, and possible loss of biotechnology and global market money. The PVPO is required to complete the processing of all applications that have already been filed. Although we try to anticipate future needs, we are always behind. The Board would not approve a 20% fee increase because they felt there has not been enough time to evaluate the effects of the forthcoming supplemental and 20% fee increases.

Following this discussion, the Board approved a 10% annual fee increase which should be re-visited every year so as to determine if it is necessary. They felt that this 10% per year increase should stabilize the trust fund at least in the short term. The Board also felt that the PVP examining staff needs to make themselves available by traveling to various meetings to better promote the office and to answer customer questions.

The Board discussed the issue concerning the Marshall ryegrass law and in relation to the passage of this law the Board passed the following motion by a 13:0 vote:

*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.*

**Future Program Activities of the PVP.** Paul Zankowski. Forthcoming activities and issues for the PVPO were discussed including the supplemental fees, potential legislative issues following the Marshall ryegrass law, and domestic training. The supplemental and general fee increases with their impact on the PVPO finances were discussed. The PVPO is continuing to monitor any other legislation that might be similar to the Marshall ryegrass law and which may extend or revive the period of protection for a variety.

In the area of e-business, the PVPO intends to proceed first with developing the interface for expired certificate web publication and then to publish pdf files of expired certificates by the end of August 2004 (Note: This has been accomplished by June 2004). The un-scanned expired

PVP certificates will next be scanned and converted to pdf files and, lastly, issued PVP certificates will be scanned and converted for future web publication. The office will be working with the AMS IT group to develop the web interface for credit card fee payment.

The productivity goals for the PVP are to finish approximately 400 applications this year, either by issuance of the certificate, denial of the application, or by applicant abandonments or withdrawals. This should bring the number of undecided applications to fewer than 700 by fiscal year 2005.

The PVPO will offer international training as long as the cost of training and lost productivity can be recovered. The PVPO will work with the seed industry and other users to develop a forum for domestic PVP training.

The relocation of the PVPO out of the NAL building will most likely occur in August 2004. The PVPO is evaluating several bids from private office buildings.

Meeting adjourned.

#### **Summary List of Recommendations by the Board:**

1. The Board would like the PVPO to move ahead on the direct shipment of seed to the NCGRP by modifying the Rules and Regulations of the Plant Variety Protection Act as necessary.
2. The Board recommends that PVPO and the Secretary of Agriculture communicate their concerns to Congressional authorities regarding the Marshall ryegrass issue and its impact on research innovation and future commercial investment opportunities.
3. The Board recommends a 10% annual fee increase which should be re-visited every year so as to determine if it is necessary depending on the PVPO finances.