

Plant Variety Protection (PVP) Board Meeting Minutes – December 9-10, 2013

USDA Plant Variety Protection Office (PVPO)
Water Tower Room of the Hyatt Regency Chicago Hotel
151 East Wacker Drive
Chicago, IL

Board Members attending (with affiliation):

June Blalock; USDA, ARS, Office of Technology Transfer
Leticia Cabrera; Iowa Western Community College
Joonhyung Cho; University of North Carolina at Chapel Hill
Harry Collins; Mississippi Farmer
Danielle Conway; University of Hawaii at Manoa
Jonathan Egilla; Lincoln University in Missouri
Hezekiah Gibson; United Farmers USA/Gibson Farm
Patrick Kole; Idaho Potato Commission
Stevan Madjarac; Monsanto Company
Salomon Montano; New Mexico Farmer;
Dana Rewoldt; Lawyer
Wendell Shauman; Farmer;
Larry Teuber; University of California, Davis

Absent: Corinne Marshall; Sakata Seed America, Inc.

USDA and AMS staff:

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

Others Attending:

Marymar Butruille, Monsanto
Bryan Savoy, Monsanto
Ron Ferris, Monsanto
Fawad Shah, AMS Seed Regulatory and Testing Branch
Stephen Smith, DuPont Pioneer

Call to Order, Introductions, and Opening Remarks

All those present gave a brief introduction and background. Opening remarks were made by Ruihong Guo and Anne Alonzo about the Board, the meeting's topics, and the advice desired from this Board. It was mentioned that the Plant Variety Protection

Office (PVPO) made great accomplishments in application processing and that AMS was looking for the Board to provide guidance on molecular marker use, harmonizing with other countries' PVP systems, and the electronic PVP application system. It was also commented that the current Board is extremely diverse, in respect to geography, ethnicity, and professional backgrounds - and could be considered as a model advisory committee for other USDA committees.

The meeting agenda was adopted.

The PVPO explained the function of the Board according to the PVP Act – 1) provide guidance on PVP regulations, 2) make advisory decisions on all appeals to the Secretary, and 3) advise the Secretary on questions regarding making varieties open for public use.

There were no appeals to the Secretary

Review of PVP Application Processing Procedures

The PVPO presented how PVP applications are processed:

- 1) PVP Program Analysts receive the application and funds, and process the preliminary application information.
- 2) PVP Examining staff confirms that the application variety is new, uniform, and stable and conducts/confirms the database distinctness search. The Examiners write an examination report that concisely summarizes this determination.
- 3) Deputy Commissioner and Commissioner perform the Quality Assurance reviews of the application and the examination report—and make the final assessment/recommendation for certification.
- 4) Program Analysts request the certificate fee and move the certificate through the printing/signature/mailing process.

PVP Finances, Trends, Projections, and Fees

The PVPO presented the revenue, expenses and profit/loss for the past 10 years – revenue ranged from \$1.3 to \$3.4 million and expenses were \$1.2 to \$3.1 million which resulted in a maximum fiscal year loss of \$332,000 to a fiscal year profit as great as \$1.3 million. The Board asked if expenses were reduced when the PVPO moved to DC - expenses were reduced by 1) \$150,000 annual rent savings and 2) PVP staff departures with no position backfilling. The losses in 2011 through 2013 were mostly due to the costs of the Business Process Re-engineering (BPR) project in 2011 and the electronic PVP (ePVP) application / database development in 2012/2013.

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A graph of revenue and expenses showed that the PVPO was profitable over the past 10 years with only minor losses. For the current year the highest expenses are salary/benefits and the ePVP system. A comparison of revenue and expenses for 2014 showed only a \$28,000 profit without much leeway for additional expenses. The Board asked about the cost of the ePVP system – it was explained that most charges for the system would be incurred in 2014 and that future costs would be less.

In 2014 - year to date the office received 62 applications (= \$272,000) and 215 certificate fees (= \$165,000). This revenue has covered the PVPO expenses to date. Major expenses in 2013 and 2014 were the ePVP costs and salary/benefits including awards to PVP staff. Expected revenue for 2014 would come from applications (\$1.97-\$2.23 million) and about \$500,000 from certificate fees. It was further explained that costs such as salary/benefits/within grade increases are fixed and are out of management's control. What-if scenarios were discussed with assumptions of the PVPO receiving 300 to 650 applications and issuing 700 to 900 certificates.

The PVPO explained that when applications are received most of the money is paid upfront without the work being completed; due to this the PVPO has banked money from received/uncompleted applications. The PVPO operates like a business by retaining extra money in its Trust fund and withdrawing money for special projects such as the BPR project and the ePVP system.

The current PVP fees were presented in order of occurrence - the application /examination and certificate issuance fees are the most common. The PVPO discussed ideas for changing some of the fees such as adding a time basis (per month) for both the extension and late fees. Currently the late fee is \$41 for a delayed response to an office action (the late fee is payable when a response is at least 1 month and up to 9 months late) and similarly an extension for an office response request is \$89 with typical extension of 6 months to 2 years. The PVPO proposes having both of these fees changed to a per month basis. The PVPO is also proposing a \$500 paper processing fee once the ePVP system is successfully working - as 1) an incentive to use ePVP and 2) in order to speed up application processing for both applicants and the PVPO. Currently application data is rekeyed by PVP staff into the STAR database system; the ePVP method would avoid PVPO data entry mistakes and reduce PVPO's labor needs.

The Board commented that the time based extension fee may need to be re-evaluated if an applicant needs to grow a variety for another year in order to provide information that is required by the PVPO. The Board also commented that the paper processing surcharge may need to have a 2-3 year sunset clause whereby paper applications are no longer accepted. The Board questioned the amount of the \$500 paper processing

fee – the PVPO responded that this was an estimate but it could be better calculated by looking at the time for PVP staff's data entry and processing. The Board commented that some applicants will never want to electronically file, but if the PVPO stops accepting paper applications those applicants will learn the electronic system. The Board also suggested that the PVPO raise the total application fee by \$500, but offer a \$500 discount for electronic filing. The PVPO commented that that it might be more difficult to raise the total application fee instead of adding a new fee. The Board asked if the paper surcharge would apply to other activities such as filing an extension by paper - the PVPO responded that it would need to look at all paper based responses and evaluate what responses might incur this fee.

The Board suggested that the time period for the extension and late fees might be per month or per quarter. The Board asked how long is the standard grace period for information requested by the PVPO – it's 90 days for the first office inquiry and 30 days for a second inquiry; however for the certificate fee request the grace period is one month but is payable up to 9 months late. The Board wanted to know why applicants request extensions – typical extension requests are for more time to 1) grow a variety and provide better descriptors, 2) better analyze a varieties data, and 3) finalize a variety name. The Board indicated for a month-based extension fee the PVPO needs to consider what the office needs versus what the applicant can provide—a time period basis may be appropriate if the applicant's justification for the extension is not reasonable. It may be best to develop a matrix for extension and late fees that considers the office's request, the applicant's needs, and the incentive for a timely response.

The Board considered different scenarios that would provide an incentive for applicants to respond including – 1) prepaying the certificate issuance fee with the application fee at a reduced rate instead of paying separately, 2) removing provisional protection if a timely response is not provided, 3) developing policy about restricting protection due to a lack of response, and 4) greater utilization of the revival fee for abandoned applications. It was suggested that the PVPO could better reach out to applicants who are non-responsive by e-mail and paper as well as by phoning.

It was concluded that there was support by the Board for the \$500 paper processing fee, but that more work was needed to justify the time based extension and late fees.

PVP 2013 Accomplishments

From 2008 to 2012 the PVP application inventory increased from 745 to up to 1,208. The inventory was reduced to 642 in 2013 by increased examining efficiency. Application processing was increased by using Associate Examiners and streamlining

processing methods. The examining staff was reduced by 2; for a total examining staff of 4 Examiners and 2 Associate Examiners. During 2013 over 900 applications were processed and more than 831 certificates were issued. The Board asked what the oldest species were in the current inventory – corn is the largest part of the oldest applications.

Also in 2013 the PVPO 1) developed an outreach plan that focuses on increasing PVP awareness, 2) completed phase 1 of the ePVP database project (assessment of all crop and tracking data for the new system), and 3) initiated ePVP phase 2 (fully functional system - scheduled to be completed in the summer of 2014).

The Board was impressed by the speed of PVP application processing and the accomplishments of 2013—they indicated US PVP efficiency is a good example to present to other countries to showcase what can be achieved.

PVP 2014 Business Plan

The PVPO presented its business plans for 2014 with five major categories – 1) Manage PVP Applications Actively; 2) Leverage the PVP Board's Technical Resources to Address Technical Challenges; 3) Promote the Plant Variety Protection Office as the Worldwide Leader on Protection of New Plant Varieties; 4) Increase Incoming PVP Applications; and 5) Launch the ePVP System.

For 2014 the PVPO reduced its processing goal to 700 applications in order to allow the staff to work on other projects including outreach and ePVP. In 2014 the PVPO plans to process all applications older than 2011 before the middle of FY2014 (=March 31). By 2015 the goal will be to process and issue applications within a year of filing.

The PVPO plans to increase outreach for vegetable and flower applications by participating in venues such as the American Seed Trade Association (ASTA) Vegetable and Flower and the National Association of Plant Breeders meetings. The Board also suggested that the PVPO look at meetings such as the American Society of Horticultural Science (ASHS) to promote PVP.

Brainstorming - How to Increase Awareness of PVP

The PVPO and Board brainstormed on ideas to increase the awareness of PVP as a means of increasing new applications.

The Board suggested that the PVPO consider producing a video (YouTube or other format) that presents the Office's mission, its objectives, and provides a PVP overview—this video could be displayed at meeting's attended by the PVP staff. The Board also

suggested looking to social media (Facebook or LinkedIn discussion groups) to promote PVP. Another avenue for outreach might be bringing members of the Plant Breeding Working Groups of the ASHS and the American Society of Agronomy (ASA) into the PVP Board either as members or as observers. It was also suggested that the PVP offer an online course or webinar on PVP that could be provided to universities and the public.

It was suggested that the PVP list reasons why a small/medium breeders might pursue getting PVP. i.e., what's in it for them, and how can they make their breeding efforts more attractive in the marketplace? If breeders obtains PVP certificate, then they have certain choices compared to when they do not. PVP Board members might also be able to present a PVP overview presentation to students or community members.

The Board commented that the concept of “why PVP” is more important than “PVP what” or “how to PVP”. The Board thought the issues of “what is a variety” from a genetic plant breeding standpoint needs to be clarified relative to its intellectual property protection along with the involvement of seed law and seed certification. The promotion of the entire seed system may be a good way to promote PVP. The Board questioned what determines a variety's distinctness versus what gives it legal protection and is there legitimacy for the process that proposes a variety. The Board thought that a PVP video may be a good method of promoting PVP to state seed associations. An observer suggested that an introduction on where food comes from may be an overall better introduction rather than how to protect your variety. In addition to where food comes from, topics on nutrition, environmental sustainability and health may be critical. The Board also considered reaching out to students and indigenous communities relative to section 44 of the PVP Act to declare a variety open to public use—indicating that no other country or intellectual property statute has as compelling avenue to make a variety available for the public good—or to promote awareness about PVP.

The Board suggested a system where small/medium size breeders could try the PVP system, perhaps at a reduced or graduated fee scale. The Board thought that the PVPO might consider a micro / small / medium / large entity fee scale such as the patent system—in order to better encourage all potential PVP customers.

The PVPO presented a summary of the most frequent PVP filers with DuPont/Pioneer and Monsanto at the top, as well as the USDA, Rutgers University, and University of Georgia—representing about 73% of applications filed in the past 10 years. The PVP application trend for ‘the most incoming crops’ was 25% corn, 23% soybean, 10% wheat, 5% potato, and 4.5% lettuce. The Board commented that it was interesting that

wheat ranked as number 3 – perhaps using PVP as the primary means of getting wheat seed certification.

The Board discussed a vision of PVP relative to seed certification. When a new variety is developed there are certain tasks including: 1) naming the variety, 2) be sure the breeders developed their variety, and 3) gathering characteristics of the variety for seed certification or for PVP application filing. Seed certification can happen through several different mechanisms: 1) Variety review boards, 2) state seed certification agencies, 3) PVP certification (but the certification agencies may need additional characteristics beyond PVP), and 4) OECD. A seed certified variety has no intellectual property protection– so that either PVP and/or a utility patent would be needed if protection is desired.

Seed quality is ensured by registered seed technologists working in certification agencies under the umbrella of Association of Official Seed Certifying Agencies (AOSCA) or the Society of Commercial Seed Technologists (SCST) in the U.S. and the International Seed Testing Association (ISTA) globally. These organizations verify seed germination percentages, that the variety is true to type (i.e., all the same species or variety) and is true to the characteristics of the variety. Seed certification agencies are private non-profits, state departments of agriculture, or crop improvement associations. Seed certification involves breeder seed, foundation seed, registered seed, certified seed—with all stages having specific certification standards. Farmers are interested in buying registered seed which they can plant under precise standards to produce certified seed, which is sold at a premium over uncertified seed. Certified seed sells at the premium price because of the standards under which it grew and its tracability. A Board member mentioned that for wheat—PVP may be an important avenue to seed certification (with intellectual property protection as a side benefit). The Board discussed the concept of title 5 of the Federal Seed Act (FSA) and the requirement that the variety be sold as certified seed with a specific name only. In conclusion seed certification is linked to PVP certification and may be an important alternate avenue for new PVP applications.

The Board also commented that the U.S. PVP system ultimately contributes to the public domain germplasm diversity pool. Whenever a PVP certificate expires its germplasm (and any parents used to produce it) becomes publicly available to use and propagate. The U.S. is one of the few countries to make this germplasm available at the end of the PVP process. The Board emphasized that the U.S. PVP system provides breeders with a limited period of protection in exchange for making that germplasm available to the public. The Board also commented that a PVP certificate has better value over utility patents in that it establishes a priority document for getting a variety protected internationally; which cannot be done with a utility patent.

The Board discussed the hostility that is occurring toward intellectual property rights in copyrights, trademarks, and within the courts. Intellectual property organizations have responded with public relation campaigns to explain why intellectual property matters, has value, and creates value—perhaps the PVPO could piggyback on these efforts. The Board commented that it may be useful to educate the public through an awareness campaign that focuses on PVP’s role in increasing public domain germplasm. An observer commented that the PVPO can also provide plant breeding education and show that most gains in plant yield comes from traditional breeding.

Blueprint Ideas for Outreach

1. Video showing PVPO’s mission and why PVP is important
2. Social media – Facebook, Twitter, LinkedIn
3. Webinar or online PVP course
4. Reduced fee depending on the applicant size
5. Linkage to seed certification process
6. Discuss “why obtain PVP” not “how to obtain PVP”
7. PVP’s place in world food security, sustainability and how varieties can be declared open for public use
8. PVP germplasm contributing to the public domain germplasm diversity pool (PVP germplasm is publically available upon PVP expiration)
9. Look to IP organizations public relations campaign as a way to promote PVP

International PVP Harmonization and Recognition

The PVPO discussed that the U.S. and many other countries separately examine new varieties for PVP eligibility and issue PVP. In order to obtain PVP rights an applicant must file in each country where protection is desired. The only exception is within the European Union (EU) where one application can be filed at the Community Plant Variety Office (CPVO) and one examination/grant of PVP rights would cover all the EU member countries. The PVPO is exploring whether the U.S. PVPO can enter into agreements with other countries whereby they accept/grant PVP based on the U.S. PVP examination and reciprocally the U.S. would accept/grant PVP rights based on another country’s PVP examination.

The Board asked the PVPO how far communications have progressed with other countries. The PVPO responded that discussions were at the concept stage, and focused on how the U.S. PVPO determines DUS (distinct, uniform, and stable). The Board commented that other country’s standards for uniformity and stability may be different from that in the U.S. The PVPO indicated that the standards for uniformity in the U.S. are based on section 42 of the PVP act which defines a variety as uniform “in

the sense that any variations are describable, predictable, and commercially acceptable.” This is very different from the way other countries define uniformity.

A global PVP harmonization system would potentially increase U.S. PVP application filings since applicants would save money and obtain protection in multiple countries through a single filing. This system could also reduce U.S. PVP filing with applicants migrating to whichever system is the least expensive and assures them the greatest likelihood of PVP issuance.

The Board asked if the PVP fees would remain the same under a system where another country did the PVP testing. The PVPO responded that it would need to consider what fees to charge when another country did the PVP testing. The Board also asked how other country’s testing could be incorporated into the PVP crop databases. The PVPO responded that the U.S. would accept another country’s PVP determination as equivalent to a U.S. determination and may not incorporate another country’s data into the U.S. databases. The Board commented that the seed industry may not be comfortable with U.S. PVP grant based solely on another country’s PVP determination.

The PVPO focused on 2 main questions: 1) is the industry comfortable with the U.S. accepting other country’s PVP system as equivalent to the U.S. PVP system and 2) what should be done with another country’s data – should this DUS data be incorporated into the U.S. PVP database?

The Board asked how the PVPO would manage variety naming since a variety may be marketed under different names in different countries. UPOV requires disclosure of all the names that a variety is sold under. The Board said that in potato a new variety might be marketed under an old variety’s name in order to main brand recognition—for example only 20% of ‘Yukon Gold’ marketed potatoes are really the ‘Yukon Gold’ potatoes—they may also include ‘Yukon Gem’ and other improved varieties.

The Board thought that PVP recognition may be accepted based on the DUS determination but that variety registration may not be accepted and would be required in each country.

When the PVPO asked if harmonization would be good for the U.S., the Board’s responses were mixed—with indications that harmonization may be beneficial for small individual public sector breeders who may save money if other countries accepted U.S. PVP grants. The Board explained that it is often expensive to file in multiple countries—some of which require an agent in that country to handle materials and quarantine. Additionally the Board emphasized that priority is an important benefit of harmonization.

The PVPO discussed the concept where PVP would be granted in the U.S. and no other fees would be required to get PVP in another country and likewise if PVP were granted by another country no other fees would be collected by the U.S. The Board responded that under all intellectual property protection system everyone pays regardless of who issues the grant. The Board suggested that the PVP fees could be reduced for a non U.S. PVP grant. The Board debated the justification and means for charging the filing and certificate fees.

The Board explained that PVP provides an intellectual property right to exclude others, and as such equivalence as occurs with organic regulatory standards doesn't necessarily apply. The legal right to exclude others must be granted in every country separately.

The Board reasoned that the focus of harmonization should not be on saving applicants money, but rather on saving applicants time. The Board commented that harmonization could also provide applicants with risk reduction and leveraged certainty in getting PVP grants. The Board suggested that quality controls could be incorporated into a harmonization agreement with a mechanism to check the quality of a country's PVP system.

The Board proposed that both country's application requirements and minimum standards (i.e., what is being asked from applicants) would be a key aspect of any harmonization negotiation. The PVPO suggested we approach this from the perspective of—we have X ways of examining but you have Y ways of examining—intellectually we agree that both methods get us to the same goal.

The Board introduced the concept of Patent Cooperation Treaty (PCT) filing, where a PCT application is filed in a receiving country's office (with applicant selection of the other countries where the patent rights are desired). Examination of the PCT application takes place within 30 months and an examination report is produced by the receiving country. This report is reviewed by the applicant's selected countries – each of these countries has the option of granting rights or asking for more information/examination. Under PCT there is a first fee for recognition and a priority date, but then a filing fee is charged in each separate country in order to reserve patent rights. PCT costs more than filing in each country separately – but is far less work.

The Board commented that UPOV has a means of purchasing DUS test results from other country's PVP offices—the PVPO indicated that the U.S. does this with Canada

and subsequently Canada reduces its applicant requirement for the years of DUS trials from 2 to 1 year.

In response to the board's concern that U.S. applicants would need to increase the number of traits provided, the PVPO explained that this was not the intention, but rather to get other countries to accept the U.S. PVP system. The PVPO explained that negotiation on the technical aspects will be very important; especially looking toward a state run grow-out system versus U.S.'s breeder based system. The PVPO stated that it worked on a side-by-side comparison of various PVP systems to see where the difference occurs. This comparison would be important to identify areas of technical difficulty and may need to be negotiated. The Board commented that the EU will probably insist on maintaining its variety registration system. The PVPO indicated that some parts of the negotiation may be out of scope such as the variety registration.

The Board commented that it will be important to know what is being asked for by each country before sharing data; the overall goal is to harmonize international standards and to facilitate trade. The Board also commented that some examination work, such as data entry into the U.S.PVP database would need to be done with a variety granted PVP by another country so that the variety doesn't disappear "under the radar".

Currently the PVPO has discussed harmonization with the CPVO, Australia, and Canada; both Australia and Canada have a breeder-based PVP testing system whereas the CPVO is a state-run testing authority. The PVPO discussed different levels of harmonization that range from sharing data, non-binding acceptance of examination results, binding acceptance of examination results, and full equivalent recognition. The U.S. PVP crops would coincide with about 25% of the crops examined for Australia and Canada - with their remaining 75% being asexually propagated plants that are protected by plant patents in the U.S. The CPVO was most interested in learning more about the U.S. database distinctness search—especially for managing their variety collections. The Australian PVP system follows the UPOV technical guidelines very closely and this may be a requirement for future harmonization. Crops for harmonization with Canada may include cereals (wheat, barley, oats, rye, triticale), oilseed (canola and soybean), potato, and pulses (lentils, dry beans, dry peas).

UPOV is working on a harmonized electronic application form that would enable applicants to file a UPOV form and indicate which countries they want to file in. Each of these countries would then receive a PVP application translated into their language. The initial UPOV form would involve lettuce, potato, rose and apple. The Board wanted to know if the U.S. Patent and Trademark Office (PTO) would be involved in the form testing, but the PVPO said no. The Board suggested that a higher level harmonization

might be needed with the PVPO and the PTO. Also the ISF has asked UPOV to look at a PCT like PVP system.

Harmonization Blueprint Ideas

1. Establish the minimum requirements for recognizing each PVP system.
2. Determine what is in-scope versus out-of-scope (variety registration).
3. Conduct a side-by-side comparison of the U.S. PVP versus harmonizing country.
4. Evaluate a PCT like system.

Potato Tissue Culture Storage and the PVP Fee Collection

The PVPO summarized the issue from the July 2012 PVP Board meeting, during which it was proposed that potato PVP owners must deposit a voucher specimen of their germplasm in a public depository. Most potato tissue culture specimens are stored at the NCGRP; applicants are charged \$2,400 by NCGRP during the life of the PVP certificate to recover tissue culture storage and maintenance expenses. NCGRP estimated that the true costs based on its expenses is \$2,571, with most of the costs incurred at year 1 and are due to labor. NCGRP explained that they could accept the full \$2,400 up front if the inflow of potato deposits was consistent each year so as to maintain a continual money stream.

The PVPO currently charges \$100 for NCGRP transaction handling—with the payment either as a lump sum of \$100 or as 4 incremental payments of \$25 at years 1, 6, 11 and 16 (NCGRP receives \$900, \$500, \$500, and \$500). The PVPO explained that the current \$25 processing fee is not enough to recover its actual costs and proposed to collect \$205 (calculated based on 2 hours of employee time) each time the fee is processed on behalf of the NCGRP. (A Board member looked at other possible potato depositories, but their costs may be similar to NCGRP). NCGRP explained that they would prefer receiving the \$2,400 up front since \$2,164 of the expense occurs at year 1, and if an applicant abandons their certificate at year 6, appropriations would actually subsidize the remaining \$1,264 of expenses due.

The Board commented that potato applicants should pay at least the actual NCGRP costs. The Board also commented that two hours of PVPO employee time to process the handling fee seemed too high and that with the ePVP system this labor would be reduced. The PVPO suggested that the \$205 fee per payment be reduced to \$107 per payment (this was based on section 97.175 of the Regulations and Rules of the Practice that allows \$107 per employee hour) for one hour of processing. The Board discussed this proposal and unanimously recommended that the PVPO charge \$107 each time the tissue culture fee is collected.

ePVP System

The electronic PVP (ePVP) system is being developed in 3 phases using the contractor: C3 Systems Inc. Phase 1 involved developing scripts to migrate data from the STAR database to MS SQL Server and was completed in 2013. Phase 2 is the development of the external user web portal and Customer Relationship Management (CRM) internal user management software; it is expected to be completed by summer 2014. Phase 3 is training and maintenance of the system.

ePVP will cover all the parts of the current paper PVP application via web based entry, and will provide users with real time notification of any submissions for an application or amendments. The system will provide interactive feedback as an applicant fills in the application form, and a preliminary finding of a variety's distinctness may be possible instantaneously when a critical amount of information has been provided.

The external user web portal will be used for electronic submission of a PVP application by the public. New users would need to be e-authenticated through the USDA system prior to submission of the first application or inquiry about existing applications. Once an account is created it is saved and can be used for subsequent access with a password.

The PVPO provided screenshots of the new ePVP system. The Board had questions on e-authentication—the PVPO responded that all users even non-applicants need to be e-authenticated to use this system. The role of a user (applicant, agent, payer, non-applicant) would be approved by the PVPO. A non-applicant would only have access to certain public information. The Board also asked if ePVP would replace the current system for finding information about the status and the content of PVP applications and certificates; and the PVPO responded that this system would be replaced sometime in the future.

Currently public searches are done using the ARS Germplasm Resources Information Network (GRIN). The Board suggested that the PVPO consider talking to the GRIN administrators about other PVP certificate information as they upgrade GRIN. The PVPO had some discussion with GRIN staff about providing exhibit C: descriptive information for all expired and issued PVP certificates.

The ePVP system will integrate into the 'pay.gov' system for processing credit cards and e-checks. The ePVP system will also allow bulk application filing when more than one application is filed by the same owner for multiple varieties. The system may also allow infrequent applicants to copy information from previous applications for new

filings. The Board suggested that the ePVP system be as technologically advanced as possible since it will jumpstart the PVPO's international leadership. The PVPO would like feedback from the Board when the first ePVP version is released.

The Board asked if a breeder could fill in part of an application while an administrator signs the application, and the payment comes from another person. The PVPO responded that these will be designated roles within ePVP to allow multiple people to work with an application—each having different access levels.

PVP Forms—Transgenic Seed & Other Intellectual Property Issues

When a PVP expires the seeds of the variety are made publicly available by the NCGRP. NCGRP would like to disclose to its seed recipients any information about the genetically engineered organism (GEO) status and issues of other intellectual property (IP) protection (utility patents, foreign PVP rights, etc.). Currently the PVPO find out information about the GEO (transgenic) and other IP status by asking applicants to respond to two questions on the ST-470 and seed deposit forms. A response to the GEO question is optional.

The April 2012 Board made recommendations that the wording to the GEO and IP questions be changed. The PVPO did not change either of these questions since both forms were undergoing Office of Management and Budget (OMB) approval.

NCGRP has resolved the issue of the IP question by enclosing the following disclaimer with all seeds that are distributed:

Intellectual Property Considerations

This order contains accessions that were originally deposited as a Plant Variety Protection Certificate (PVPC) voucher specimen. These accessions may be protected by intellectual property rights other than the expired PVPC. NPGS suggests that requestors may consult with the variety owner named on the issued PVPC.

(NPGS = National Plant Germplasm System)

NCGRP still needs assistance to obtain information about the GEO status and the transgene characteristics from PVP applicants.

Currently, the Office obtains transgenic information 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”.

The new proposed forms would have the word “optional” removed from the transgene or Genetically Engineered Organism blocks, additionally form ST472 may ask several more questions about the characteristics of the transgenes.

The Board asked: how are GEOs / transgenes being defined? The PVPO responded that it would need help defining those terms. NCGRP is most concerned with regulated transgenes that might be best defined by the USDA Animal and Plant Health Inspection Service Biotechnology Regulatory Services (APHIS-BRS). The Board commented that the definition of transgenes may be a liability for NCGRP. The Board recommended that a subcommittee be formed with the right expertise to address the terminology of how best to ask these questions. The Board also commented that level of transgenes and adventitious presence may need to be addressed.

The Board thought that better understanding of whom NCGRP is trying to protect (i.e. 1) the recipients of expired PVP seed, 2) NCGRP for distributing the seed, 3) the U.S. export market, 4) the PVP owner) would help formulate these questions. The Board asked if the PVP variety owner could be obligated to release the material to the public rather than NCGRP, and the OGC responded that this can only be done by changing the law. The Board commented that the subcommittee should focus on the requirements needed by NCGRP. The Board commented that the ramifications need to be considered if an applicant does not disclose GEO information that they know or should know. The Board suggested that ASTA could help set the options or conditions for these questions. Three members of the Board volunteered for the GEO question subcommittee.

Findings of the Subcommittee on Molecular Markers for PVP

The chair of the molecular marker subcommittee reported on their activities. The subcommittee is composed of eight experts on molecular marker technology.

The subcommittee has 4 goals:

1. Help the PVPO and PVP applicants develop a consistent means to use molecular markers.
2. Review the current PVPO, UPOV, and ASTA policies on the use of molecular markers
3. Consider assumptions regarding varieties of common knowledge and the need to distinguish a new PVP variety from all varieties of common knowledge.

4. How can the PVPO incorporate molecular marker data into its crop databases?

The first meeting focused on what UPOV and ASTA have already developed regarding policy or position papers. Three recommendations/comments resulted from the first meeting including:

- Ideas on how the PVPO could implement one or more of the 3 positive assessed UPOV marker concepts in a cost controlled manner.
- Gathering additional information on public markers that may be in use for maize and soybean.
- Looking to the seed industry to encourage PVP applicants to submit marker data with new applications as well as making existing marker data available to the Office for PVPed varieties.

During the second meeting the subcommittee had these recommendations/comments:

- The Office should provide the morphological data from its maize PVP database for the 92 expired PVP varieties that are assessed in the Nelson et al. paper (Molecular Characterization of Maize Inbreds with Expired U.S. Plant Variety Protection. *Crop Sci.* 48:1673–1685 (2008)).
 - PVPO data would be provided to the subcommittee.
 - Subcommittee members will compare the PVPO's morphological data with the marker data in the article and report their finding to the subcommittee.
 - If this proof of concept analysis proves useful then the subcommittee might suggest that a project be coordinated to profile more maize lines.
- The subcommittee will determine if any similar marker studies exist for lettuce, so that a similar markers-morphology comparison might be run.
- The subcommittee will also assess what marker data exists for pea PVP characteristics— when this data is gathered a determination of a proof of concept study will be reviewed.
- Project management for the initial proof of concept studies may be necessary and would require project coordination.

The subcommittee will try to do a proof-of-concept to determine if molecular data may be linked to morphological data for the 92 expired maize inbreds. The PVPO said it will release all the exhibit C data from the corn database and statements of distinctness for these 92 varieties. The subcommittee is recommending using existing published papers and existing markers to explore correlations to expired PVP maize as a proof-of-concept.

The Board asked if the subcommittee was looking at a means for using markers as the sole basis for distinctness, and the chair responded no. The subcommittee was hoping to determine if there was a super distinct threshold for markers, and secondly if there are criteria for markers to be used as a distinctness tie-breaker.

An observer mentioned that ASTA's Variety Identification subcommittee identified a set of 3,072 single nucleotide polymorphism (SNP) markers in corn to help identify essentially derived varieties. Another observer mentioned that the physical analysis to find correlation between SNP markers and PVP traits may be very difficult and that the assistance of technical statisticians would be necessary. An Observer also commented that the Board's marker subcommittee and the ASTA subcommittee should have a joint meeting. The Board agreed with the recommendation on having these two subcommittees convene a joint meeting.

PVP Regulations—Proposed Changes, Deletions, Additions

The PVPO is proposing the removal unneeded regulations and changing/adding regulations to the Regulations and Rules of Practice. One of the first regulations that needs to be added is the postmark rule to section 97.11. This is in response to a Judicial Officer ruling that the PVPO accept the postmark as the date for responses/fee payments (except for the original PVP application) instead of the 'arrived-in-office date.' The Board asked if other delivery service (FedEx, UPS etc.) receipts were acceptable instead of a US postmark. OGC and a Board member responded that the U.S. postmark is the only acceptable form.

The PVPO also stressed the need for applicant to have access to the PVP system during inadvertent government closures such as the shutdown. It was clarified that applicants can always access the PVP using <http://www.ams.usda.gov/PVPO>.

The PVPO will change section 97.5c to reflect the new DC address with any subsequent address changes posted in the federal register. The PVPO plans to add a change of owner/representative or change of owner/representative address fee (\$41) to section 97.175. Recordations (security interest, license, grant or conveyance; merger; revocation of assignment, security interest, license, grant, or conveyance) will remain at the \$41 fee. The PVPO will review the per-month extension and late fee, as well as the paper application processing surcharge to section 97.175, but these fees will be tabled until a later Board meeting. One Board member questioned the need for a change of address or owner/representative fee, and another Board member responded that this fee is not out of line with other IP systems such as the PTO. The PVPO responded that this fee would be reduced or eliminated under the ePVP system.

The PVPO proposed amending section 97.5(i) to accept copies of foreign PVP documentation of PVP rights granted using "copies of other country's grant can be used as evidence to support claims of uniformity and stability, these may be provided in the official language of the country of origin. An accurate English translation shall be

included”. Other changes proposed include changing “shall” to “should” in section 97.9 and changing section 97.12 “in the order” to “by the order”. The PVPO proposed changing section 97.19 regarding the Official Journal to “Information relating to pending applications shall be published periodically, as determined by the Commissioner to be necessary in the public interest”.

Other regulations that the PVPO recommended be changed include sections:

97.23(d) - be deleted

97.102, 97.152, 97.156, 97.201(a), 97.400 – add the phrase “and payment of the appropriate fee” at the end of these sections

97.151 – change to allow “attorneys, agents, or legal office representatives”

97.153 – delete – with the additions to 97.151

97.155 – change to allow for electronic signatures or scanned images/faxes of signatures

The Board commented and OGC agreed that section 97.151 “legal office representatives” language should not be included since anyone who works in an attorney’s office operates under the control of that attorney. The Board also commented that section 97.153 shouldn’t be deleted. The Board stated that in section 97.155 - electronic signatures can be designated by “S” “/” “typed name”. The Board recommended the regulation changes as presented.

Feedback from the Board, Recommendations & Meeting Summary

The Board commented that the current meeting was more productive than the April 2012 meeting. This meeting was considered fluid with a solid member base. The Board commented on the global perspective of IP protection and how this impacts the U.S. and developing countries. The Board asked if the PVPO will be involved in international IP activities with its reduced staff, and the PVPO responded that it’s office is coordinating with the U.S. PTO to get information about the U.S. PVP to other countries. The Board wanted to know if the PVPO will be participating in UPOV technical committees, and the PVPO responded that the most important upcoming technical committee meeting will be the UPOV Biochemical and Molecular Techniques and DNA Profiling in Particular Working Party (BMT) to be held in South Korea in November 2014.

The PVPO commented that UPOV is moving ahead with its electronic application system and the U.S. wants to show what it has done. The Board commented that the PVPO might consider licensing its ePVP system to other countries—at little or no cost to extend the U.S. point of view.

The Board wanted to know if the PVPO could consider recruiting other non-European or non-North American countries. The Board suggested that the PVPO consider new applications from other places once they know the benefits of the U.S. PVP system. The PVPO could be considered as a Center of Excellence and handle that country PVP applications.

The Board was impressed with the openness of the PVPO and stressed the importance of having face-to-face meetings. The Board commented that having a physical meeting in conjunction with an industry event is a good idea – if this meeting is held in Chicago in December 2014 – the Board wants to be able to participate more in the industry event. The PVPO responded that it will coordinate a future physical meeting better if it's held in conjunction with an industry event. The Board wanted to know what other ASTA meetings the PVPO attends, and the PVPO responded that it attends the ASTA Vegetable and Flower meeting and the ASTA Annual convention. The Board also thought the PVPO should consider Washington DC for a Board meeting.

The PVPO wanted the Board to consider locations for a future meeting. The PVPO is planning for one physical meeting each year, and perhaps several teleconferences – usually with special emphasis. It may be best to schedule a teleconference in early May. The Board also thought the PVPO should consider coordinating with the American Society of Agronomy and looking at the Independent Professional Seed Association and the California Seed Association as possible venues.

Board Recommendations

- 1) The PVPO should add a paper processing fee surcharge once the ePVP system is fully functional.
- 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.
- 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.
- 5) PVPO will charge potato tissue culture certificate holders a \$107 processing fee each time a tissue culture fee is paid.
- 6) A subcommittee should be formed to define and design the GEO question on the ST470 and seed deposit forms.
- 7) The PVP Board's marker subcommittee and the ASTA subcommittee should have a joint meeting.

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- 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.