

National Genetic Resources Advisory Council (NGRAC)
MEETING SUMMARY
September 23-25, 2014
The Seed Science Center, Iowa State University, Ames, IA

Members Participating: Misra, Diver, Dillon, Moldenhauer, Smith, Snow, Williams, Worku (by phone).
Ex officio: Boyer, Bretting, Schloss (by phone), Pederson, Woteki (by phone).

Tuesday, September 23, 2014

Welcoming Comments and Introduction

Manjit Misra (chair, NGRAC) welcomed participants and asked them to introduce themselves. Joe Colletti (senior associate dean, School of Agriculture) welcomed participants on behalf of Iowa State University. Charles Boyer (representing the National Agricultural Research, Education and Extension [NAREE] Advisory Board) thanked the council for its past work and said that the Board was looking forward to further recommendations.

Response to AC21

Michael Schechtman (biotechnology coordinator, USDA) also thanked the council for its help in responding to the report of the Advisory Committee on Biotechnology & 21st Century Agriculture (AC21; November 2012), particularly with reference to coexistence of biotechnology with organic and traditional agriculture and the availability of organic and non-genetically engineered (non-GE) seeds. In response to NGRAC's recommendation that there be an educational effort, USDA has tasked NGRAC (in conjunction with USDA and industry) to conduct an ongoing evaluation of the availability of germplasm for developing GE, non-GE and organic seed, and to advise USDA on how to work with industry to address this issue. This will be particularly important in crops where there is a GE counterpart and where communications between industry and end-users is imperfect.

In particular, Schechtman suggested that NGRAC might do one or more of three things:

1. Work with the seed industry and USDA to develop a plan for ongoing evaluation of the pool of suitable available varieties;
2. Provide advice to USDA on how the Agency should work with industry; and/or
3. Work with the seed industry and USDA and participate in the evaluation of the pool of available varieties.

In the discussion that followed, members pointed out that the Council's resources are limited and its mandate focuses on sharing information and building bridges, not setting policy or standards. For this reason, the focused on item #2 above, rewording it as follows:

Provide guidance to USDA on how the Agency should work with stakeholders (to include public and private seed breeders, producers and distributors, as well as end-users and tribal governments) to ensure the ongoing availability of an adequate pool of appropriated germplasm for the breeding of organic, non-GE and GE crops.

Activities of the American Seed Trade Association, Organic Seed Committee

Charles Brown (chair, Organic Seed Committee, ASTA) said that for his members, the principal issues in germplasm are access and purity, with purity being by far the more controversial. In broad terms, the non-GE market represents about 10 percent of acres planted, while organic represents at best 250,000 acres. In crops such as corn, soy and cotton over 95 percent of acres are planted in GE varieties. In addition, most of the major seed companies in the United States are owned by chemical companies, many of them foreign; organic and non-GE growers are dependent six independent seed development programs, plus a handful of foundation companies that expand new seed varieties to marketable volumes.

In general, access to non-GE varieties is good, but there are a limited number of competitive hybrids per geographical and climatic zone. Access to organic seed needs improvement, especially in addressing barriers to evaluation and higher prices. Brown suggested several ways in which NGRAC could work with ASTA to address these needs:

- Support the National Plant Germplasm System (NPGS) and Germplasm Resources Information Network (GRIN) as the primary sources of germplasm and germplasm data, with adequate resources for collection, preservation, and distribution. Adequate resources will be increasingly important as NPGS and GRIN deal with an increasing volume of gene lines that are no longer sheltered by the Plant Variety Protection Act.
- Provide “freedom to operate” on new NPGS releases, including a third-party clearinghouse and legal expertise to deal with due diligence
- Support public breeding programs with a track record for line development, such as Cornell, North Carolina State, and North Dakota State University. In some cases these programs have aging investigators, and in many cases they have declining resources.

In the discussion that followed, participants suggested that the organic and non-GE sectors need protocols and resources for testing the purity of germplasm. More broadly, they need a central authority (like the crop germplasm committees for GE crops) to which they can take their problems and needs. Goss’ wilt and other fungal diseases are continuing threats for which there seems to be little inherent resistance, and climate change will bring a cascade of new disease and weather challenges.

Economic Issues Related to Organic Production

Catherine Greene (Economic Research Service, USDA) reported that, despite high demand for organic fruits, vegetables, dairy, and poultry, the adoption rates for organic corn and soybeans remains low, creating a crunch for organic feedstocks. The returns to organic corn exceed those for GE corn, and imports of organic soybeans are up significantly, so the barriers to adoption may be other than profitability. GE contamination appears to be a prominent concern, but growers have also cited their inability to acquire an adequate supply of non-GE seed and other

production inputs. Participants said that it would be useful to have similar data on crops other than corn and soy, and apparently ERS will begin collecting such data in 2015.

Wally Huffman (Iowa State University) suggested that there is insufficient data to inform policy on the coexistence of organic, non-GE and GE agriculture. In particular, data is lacking by crop on the distribution, frequency and cost of contamination, whether in the field or through “adventitious presence” of GE traits in non-GE seed. As a result, it is very difficult to assess the availability of appropriate geneplasm and very expensive to increase the purity of seed stock. In response, both the Organic Trade Association and the International Forum of World Organic Movements have been calling for stricter standards, including product- (rather than process-) based purity standards and a ban on protoplast fusion (which could force many organic producers out of the market).

There being no public comment, the meeting adjourned at 5:00 p.m. and participants took a tour of the ISU Seed Science Center.

Wednesday, September 22, 2014

NGRAC Response to AC21 Recommendations

In its initial discussion of responded to AC21 recommendations on availability and access, the Council adopted a systems approach that identified the principal players, problems, solutions, and recommendations at different stages of the seed development process:

- Uncharacterized geneplasm for breeding;
- Characterized geneplasm;
- New lines and hybrids in appropriate form;
- Seed for farmers; and
- Harvested products for processors and consumers.

Ideally, this approach should differentiate clearly between the needs of organic versus non-GE producers, and it should be reiterated for at least eight major crops:

1. Corn;
2. Soybeans;
3. Cotton;
4. Canola;
5. Alfalfa;
6. Sugar beets;
7. Papaya; and
8. Squash.

The attached matrix includes the major findings and conclusions that emerged from this discussion, but the following is a summary of additional ideas and recommendations that emerged.

[INSERT NGRAC MATRIX ABOUT HERE]

- The GRIN collection is not characterized and includes no proprietary lines. Characterization and evaluation are two areas where the USDA budget is stressed and might need to be increased.
- It is not within NGRAC's abilities to evaluate availability for USDA; rather, NGRAC's job is to advise USDA on where to concentrate its efforts, and which partners it might collaborate with.
- The NPGS collection is strong but not complete; are additional lines available through international collaborations? Granted that the NPGS collections are intended for researchers and major breeders, could they also make germplasm available to smaller breeders and "hobbyists" through a third-party clearinghouse?
- Lots of university breeding isn't strictly "public" but rather a public-private partnership, and the Bayh-Dole Act of 1980 may serve to shift the focus of this research toward large clients and regional needs. Large breeders have less incentive to address the needs of small clients, especially for organic and non-GE seed. The federal government retains march-in rights when a useful innovation isn't commercialized, but it's unclear if they've ever been used. *It may be time to assess the impact of Bayh-Dole on plant breeding.*
- Large germplasm collections should remain public domain. There appears to be broad dissatisfaction with the current structure of intellectual property and technology transfer, as well as the material transfer agreements that can prevent material in orphan collections from coming back into use. *USDA should facilitate public access to uncharacterized germplasm.*
- Native Americans may need help in characterizing and curating their plant resources, particularly since neglected varieties can become the source of vital traits in the future. Tribal attitudes should also be respected, including their desire for storage and qualified use of ceremonial varieties and their ability to buy land for cultural preservation as well as profit. Grants to organizations such as the Intertribal Agriculture Council and First Nation Seedkeepers would strengthen their capabilities in collection and improvement of wild and semidomesticated species. *NGRAC's report should include a paragraph on tribal needs.*

Remarks from the Research, Education, and Economics (REE) Mission Area

Catherine Woteki (under secretary for REE and Chief Scientist, USDA) addressed the meeting by videolink, updating participants on the implementation of the FY2014 Farm Bill. At the center of this effort is the creation of the Foundation for Food and Agricultural Research (FFAR), an independent nonprofit corporation that will seek private donations to fund research, matched by federal funds from a \$200 million "endowment" created by Congress. FFAR is currently setting up working committees to establish priorities and program areas.

Another initiative is the Global Alliance for Climate-Smart Agriculture, an international effort to develop better crop, livestock and aquaculture varieties that can tolerate extreme heat, drought and floods. Woteki noted that NGRAC makes ongoing contributions to the knowledge base that supports this effort and asked members to share their ideas and recommendations in this area. In the discussion that followed, members noted the future value of local and heirloom varieties, in addition to the wild and semidomesticated relatives of commercial crops, along with the need to

increase public awareness of where food comes from and the importance of genetic resources in adapting to change.

Wednesday, September 24, 2014

Genetic Resources Issues Impacting Tribal Nations

Leslie Wheelock (director, USDA Office of Tribal Relations) reported on a recent “food sovereignty” conference that was characterized by a general “anti-Monsanto” mood but raised two important issues:

1. The intersection between intellectual property and cultural heritage, where greater effort is needed to protect heirloom species and prevent the exploitation of pharmaceutical patents (e.g., the anticancer drug Taxotere, which was developed from needles of native yew trees); and
2. The importance of protecting traditional crops from GE contamination and protecting their wild and semidomesticated relatives, many of which are important sources of wild foods and medicines.

The discussion that followed revealed a growing awareness of the importance of native species to native peoples, both as a part of their cultural identity and as a part of their diet that can protect their health and well-being. Increasingly, income from other sources draws young workers away from the cultivation or collection of traditional crops on tribal land. In addition, tribal reservations are often like islands – not apart from the larger environment, but unable to change location even as many of their landscape changes and plant and animal crops migrate northward or downslope. Native Americans are uniquely dependent on Federal lands, but the United States doesn’t have a cultural heritage law. Patent laws do not protect traditional crops, and the tribes are reluctant to share the ceremonial information that would support their claims to specific landscapes, species and uses.

Within USDA, the U.S. Forest Service might do more to protect sacred sites and special sources, and several tribes are currently working with USFS on a guidance document. Past treaties committed the government to cultural preservation, but there has never been an effort to spell out just what those treaties promised, or what “cultural preservation” would mean in its fullest sense. And in any event, all 385 of those treaties have been violated. Native Americans can offer a unique knowledge of how ecosystems operate, but they don’t want to see that knowledge exploited without at least the potential for mutual benefit.

Native American groups have already taken the first steps toward building regional genebanks of important species (salmon in the Pacific Northwest, ash trees in the North Central states, native cranberries elsewhere). They can use help, but that help should be at the request of the tribes, based on their priorities. The most basic steps would be training in how to collect and characterize genetic materials; where to store it and how to share information about it will have to be taken up later, on a government-to-government basis.

Update of the National Genetic Resources Program

Peter Bretting (National Program Leader, ARS, USDA) reported that genetic materials from NGRS have contributed to new plant varieties with improved yield or disease resistance, varieties worth billions of dollars per year to U.S. agriculture. NGRS currently receives about 560,000 accessions per year and distributes more than 200,000 samples to researchers and breeders, in addition to handling over 2 million website hits. In the face of rising demand for samples, and despite a flow of ex-PVP lines that will soon grow from a trickle to a tsunami, its budget remains flat or declining in real dollars. NGRS has a separate line item for microbes and animals.

In the discussion that followed, participants noted that NPGS uses information technology to replace personnel, but this tactic has its limits. Its collection contains a lot of tropical-adapted species whose curation and development can be problematical; many accessions are not identified as to species or subspecies, and characterization can be scanty or nonexistent. Breeders always want to work with “elite materials,” but expired corn lines that are 20 years old might still be considered “elite” and are often among the most heavily requested. NPGS expects 30 to 50 expired PVP species per year for the foreseeable future, but in many cases it will be traits from wild ancestors that are needed to adapt to heat, drought and emerging plant diseases.

The meeting adjourned for a tour of the North Central Regional Plant Introduction Station and later reconvened.

NGRAC Response to AC21 Recommendations

The following points continue the summary to accompany the NGRAC Matrix, described above.

- At present the standard for organic purity is process-based: if the seed comes from an organic line, and it is grown in organic soil under organic conditions, then the product is organic and “pure.” Alternatively, if the Organic Trade Association convinces the National Organic Program (NOP) that a product is “pure,” then that certification becomes the standard. Actual genetic testing technologies are of course available, or could be easily developed by NPGS or others. Overall, the goal would be to reduce the cost and complexity of nondestructive testing for the presence of GE traits. One possibility would be visible markers for newly deregulated GE traits. Another possibility would be to restrict GE traits to the female seed line, so it can’t “escape.”
- The NOP Standards Board is considering new guidelines for certification of purity for GE seed lines.

There being no public comment, the meeting adjourned for the evening at 5:30 p.m. and reconvened the following morning.

Thursday, September 23, 2014

Work Session

Members continued their discussion of seed purity *in collections*, acknowledging that it is not their role to *solve* the problem, only to point the way to a solution.

- The solution to seed purity must address both regulated and unregulated traits. USDA already does a good job of regulating and monitoring protected traits; the problem arises when those traits lose their protection under PVPA.
- Effective regulation of post-PVPA traits will require both *genetic technology* for detecting them and *statistical techniques* for monitoring them. It is to the advantage of all parties to be able to detect these traits, and (arguably) a natural extension of the developer's stewardship role. Corn seed developers already use molecular markers to test for the presence of traits of interest, but these markers are less useful for detecting the traits as contamination. Canola is notorious for out-crossing, a big problem in seed-producing regions. Back-pollination to wild species has not been a problem thus far but might be in the future.
- USDA must work with industry to plug these gaps at each stage of the seed development process (see matrix, attached). Plant genomes are extremely complex, and it can be next to impossible to develop accurate tests without the keys to what and where modifications have been made. In response to AC21, NPGS has developed draft procedures and practices for GE seed breeding, with guidelines for best management practices at critical control points, point of release, guidelines for mitigation, communications strategies, etc.
- NGRAC recognizes that industry has already developed most of the necessary tests, for their own purposes; after all, industry has a vested interest in the presence or absence of specific traits. It is the consensus of the Council that testing methodology needs to be shared more widely to ensure that seed varieties do contain the desired traits and do not contain unintended traits. To do so will be in everyone's interest; failure to do so could lead to industry-wide catastrophe.
- "Who pays?" is always a critical issue. In this case, the cost of developing simple, inexpensive tests for GE traits should be the responsibility of the developer of the traits, simply as a cost of doing business. Reputations are at stake, and so is the global grain trade; perhaps shaming for past errors would be an effective strategy for encouraging future cooperation.
- NPGS aspires to zero tolerance for adventitious presence of unwanted traits, but at present it cannot test for it. Similarly, APHIS requires the best available testing technologies for deregulated (post-PVPA) traits, but industry still has the best, most sensitive tests. The coming tsunami of post-PVPA traits, with their attendant promoters and regulators, represents a serious threat to the status quo.
- The EU already requires breeders to submit information not only on GE sequences but also for primers associated with the transgene. For USDA this is voluntary.
- The goal should be to develop *and make available* sensitive, cost-effective, validated tests without placing an undue burden on industry or the public. One option would be an assessment based on annual sales; another would be to impose a regulatory fee to pay for public testing.

- It will also be necessary to develop statistical models for determining the proper sampling protocols and thresholds for the adventitious presence of unwanted traits.
- The farmer, for his part, would like to see mandatory testing and genotyping before a new line is released. This heightens the importance of production standards, truth in labeling, and a purity threshold that is carefully thought out and rigorously enforced.

Council Business

Boyer will brief the NAREE Advisory Board on NGRAC's deliberations during the next Board meeting, October 21-23. NGRAC will finalize its report at its next meeting in spring 2015, about a month before the next Board meeting. This meeting might be in DC, but there are opportunities to visit additional seed storage and introduction facilities in Hilo, Miami, Corvallis, Pullman, and Atlanta.

There being no public comment, the meeting adjourned at 12:00 noon. Some of the participants took a tour of the DuPont Pioneer Hi-Bred research facility in nearby Johnston, IA.

Action Items and Recommendations

- NGRAC will adopt the use of “genetically engineered” (GE) and “non-GE,” as opposed to the use of “GMO” and “non-GMO.”
- A subcommittee will develop a more careful definition of the term “characterization” and more focused recommendations for characterization work at NPGS and ARS.
- Misra, Snow and Esch will serve as a subcommittee to polish NGRAC recommendations on AC21.
- A subcommittee (Bretting, Esch, Misra, Williams) will prepare a preamble and conclusion to accompany the NGRAC Matrix.
- NGRAC recommends that USDA convene a series of workshops with public and private breeders to address the issue of seed purity and the availability of sensitive, cost-effective tests for the presence of unwanted genetic traits.
- NGRAC reiterates its support for U.S. ratification of the International Treaty for Plant Genome Research for Food and Agriculture, which came into force in June 2004 and has been ratified by 40 other nations.
- ERS and NASS should look for opportunities to collect and analyze data pertinent to organic and non-GE demand and production in additional crops.