

National Agricultural Research, Extension, Education and Economics Advisory Board

Office of the Executive Director
Whitten Building, Room 332A
REE Advisory Board Office
U.S. Department of Agriculture
Washington, DC

Mailing Address:
STOP 0321
1400 Independence Ave SW
Washington, DC 20250-0321
Telephone: 202-720-8408
Fax: 202-720-6199

REPORT AND RECOMMENDATIONS OF THE NATIONAL GENETIC RESOURCES ADVISORY COUNCIL (NGRAC)

April 24, 2015

Executive Summary

The National Genetic Resources Advisory Council (NGRAC) recognizes and appreciates the United States Department of Agriculture (USDA) commitment to genetic resources through the reactivation of NGRAC. The NGRAC is equally committed to the current and future stewardship and enhancement of the nation's genetic resources.

This report addresses a direct charge from the Secretary to respond to a specific recommendation of the Advisory Committee on Biotechnology in the 21st Century (AC21), in its report entitled *Enhancing Coexistence: A Report of the AC21 to the Secretary of Agriculture* (Recommendation V)¹ and provides the NGRAC's advice and recommendations to USDA on: (1) the on-going evaluation of the pool of commercially available non-genetically engineered (GE) and organic seed varieties, (2) identification of market needs for producers serving GE-sensitive markets and (3) advice for developing a plan for USDA to work with industry and other stakeholders to ensure that a diverse commercial seed supply exists to meet the needs of all farmers. A detailed rationale and explanation of how the NGRAC developed these recommendations is presented in the subsequent sections of the report. Presented immediately below is a summary of the recommendations from the NGRAC in response to the AC21 recommendations.

Area 1. Ongoing evaluation of the pool of commercially available non-GE and organic seed varieties.

Recommendation 1

USDA should encourage and facilitate seed producers to provide information on the available pool of appropriate organic and non-GE seed.

¹ http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pdf

Recommendation 2

USDA should work with plant breeders and other seed providers to increase the availability of organic and non-GE germplasm.

Recommendation 3

USDA should commission a study of the release and availability of inbred lines and varieties developed at public universities in order to determine the extent to which they deliver optimal crop genetics for different agricultural systems. This should include an assessment of the unintended impacts of the Bayh-Dole Act on public sector capacity to serve all agriculture.

Area 2. Identify market needs for producers serving GE-sensitive markets.

Recommendation 4

USDA should conduct an ongoing assessment of the non-GE and organic seed market value to understand and relay to stakeholders value and investment opportunities in the seed sector. Market demands should be identified by crop for organic and non-GE for each of the crops affected by commercial GE trait adoption by region, acreage, maturity and adaptation.

Area 3. Ensure that a diverse and high quality commercial seed supply exists that meets the needs of all farmers.

Recommendation 5

USDA should convene regular balanced roundtables on extending GE trait stewardship to encompass prevention and mitigation of adventitious presence in non-GE breeding programs and genebanks.

Recommendation 6

To facilitate coexistence and maintain stewardship, USDA should work with and encourage industry to develop and provide low cost assays of GE traits.

Recommendation 7

The NGRAC encourages USDA to promote diversity in agriculture by devoting additional resources to organic and non-GE agriculture in the areas of genotyping, phenotyping, evaluation, breeding and/or pre-breeding.

USDA should facilitate more public, private, and/or tribal partnerships in developing, characterizing, and evaluating genetic resources from the NPGS and non-U.S. sources adapted to U.S. growing conditions. Further assessment is needed for developing, characterizing, and evaluating tribal genetic resources.

Recommendation 8

USDA should identify gaps in genetic diversity and/or passport information, including samples or accessions with known use restriction issues, and remedy those omissions by additional collection or documentation.

Recommendation 9

USDA should communicate to State seed foundations and ASTA the importance and need for inbred lines and foundation seeds that are not treated with chemicals prohibited by USDA National Organic Program.

Table of Contents

Current State of U.S. Agricultural Plant Genetic Resources	5
Overview and Role of NGRAC	6
Access to Seed and Germplasm for GE-Sensitive Markets.....	9
Recommendations in Response to AC21 Requests:	10
Area 1. Ongoing evaluation of the pool of commercially available non-GE and organic seed varieties	10
Recommendation 1	10
Recommendation 2	11
Recommendation 3	11
Area 2. Identify market needs for producers serving GE-sensitive markets.	12
Recommendation 4	12
Area 3. Ensure that a diverse and high quality commercial seed supply exists that meets the needs of all farmers.	12
Recommendation 5	12
Recommendation 6	14
Recommendation 7	15
Recommendation 8	15
Recommendation 9	16
Conclusion	17
Appendix 1.....	19

Current State of U.S. Agricultural Plant Genetic Resources

The U. S.'s genetic resources relevant to food and agriculture comprise genetic materials of plants, animals, microbes, and invertebrates. In accordance with USDA Secretary Thomas Vilsack's immediate charge to the NGRAC, this discussion of the current state of U.S. agricultural genetic resources will focus mainly on genebank (*ex situ*) collections that conserve and encourage the use of plant genetic resources that are in the public domain.

Public and private sector engagement in the utilization and conservation of genetic resources for all life forms is essential in addressing national and international consumer demands and sustainable agricultural productivity. Broadly speaking, U.S. genetic resources are highly diverse, enabling public-private efforts to address the pressing food production concerns on a global scale. Under-pinning these efforts are the USDA Agricultural Research Service's (ARS) agricultural genetic resources in its genebanks.

Because the state of the U. S.'s plant genetic resources for food and agriculture (PGRFA) has already been summarized comprehensively by the Food and Agriculture Organization of the United Nations (FAO) in 2007², the present discussion will focus on those aspects of particular interest or concern to the NGRAC.

Most of the U. S.'s PGRFA are conserved and distributed by the U.S. National Plant Germplasm System³ (NPGS) genebanks, a partnership between USDA, the State Agricultural Experiment Stations and Land-Grant Universities, and the private-sector. The NPGS currently conserves, characterizes, evaluates, enhances and distributes more than 570,000 samples (accessions) representing more than 14,900 species. It also makes available voluminous descriptive data for NPGS accessions via the Germplasm Resources Information Network⁴ (GRIN). During the last five or so years, the NPGS distributed to domestic and international requestors an average of more than 250,000 samples per year, and GRIN annually hosted an average of more than 1.6 million web site visits. Thus, because of its size, quality, and volume of samples distributed, the NPGS is considered one of the premier national PGRFA management systems in the world. It safeguards and delivers large volumes of genetic diversity key for maintaining and accelerating plant breeding efforts that underpin U.S. food security. For example, adapting U.S. crops to rapid changes in climates and more frequent climatic extremes relies on plant breeding that incorporates new sources of genetic diversity from NPGS collections.

Despite those strengths, the NGRAC has identified and discussed, during the last three years, important challenges facing the NPGS and PGRFA in general. There is a growing mismatch

² United States of America Country Report on the State of Plant Genetic Resources for Food and Agriculture http://www.fao.org/fileadmin/templates/agphome/documents/PGR/SoW2/country_reports/americas/US.pdf

³ Website U.S. National Plant Germplasm Network (GRIN) <http://www.ars-grin.gov/npgs/index.html>

⁴ <http://www.ars-grin.gov/>

between the shrinking budgetary resources available to the NPGS, and the substantially increasing demand for NPGS germplasm and information. For the many different crop production systems to coexist successfully, sources of true-to-type, diverse seeds must be available. The NPGS manages seeds suited for research, breeding and production of organic, non-GE and GE crops. Handling all these different seed types successfully represents both budgetary and managerial challenges for the NPGS, and for U.S. crop agriculture as a whole.

The NPGS collections contain gaps in their genetic coverage, especially for the wild relatives of crops, which must be filled via exchange/acquisition, or safeguarded *in situ* reserves. But, international exchange of PGRFA has become increasingly restricted. The NGRAC strongly supports the U.S. ratifying and becoming a Party to the FAO International Treaty on Plant Genetic Resources for Food and Agriculture which would provide U.S. requestors with facilitated access to international sources of PGRFA, via standard terms and conditions, and the chance to effect positive changes in the treaty.

To address the charge to respond to the AC21 Report Recommendation V, NGRAC evaluated the state of genetic resources in relation to access, markets, and new variety development for GE-sensitive markets at different stages of germplasm access. Ultimately, it is important to foster vertically integrated relationships to have the right seeds for producers to be able to grow the crops that buyers need, be it for direct sale, conditioning, or retail.

Overview and Role of NGRAC

The NGRAC was originally established by the Food, Agriculture, Conservation and Trade Act of 1990 to advise the Secretary of Agriculture and the Director of the National Genetic Resources Program (NGRP) on the activities, policies, and operation of the NGRP. The NGRAC was established and continued to exist via the 1990 Farm Bill, but it underwent a period of inactivity from 2002 until it was reestablished under the direction of USDA Secretary Thomas Vilsack in 2011. At that time the NGRAC was reactivated as a subcommittee of the National Agricultural Research, Extension, Education and Economics (NAREEE) Advisory Board.

The scope of activities of the NGRAC includes providing advice on acquisition, preservation, access, distribution and exchange of genetic resources of life forms important to American agriculture, including plants, forest species, animals, aquatic species, insects, and microbes.

The responsibilities of the NGRAC are to formulate recommendations on actions and policies for the collection, maintenance, and utilization of genetic resources; to make recommendations for coordination of genetic resources plans of several domestic and international organizations; and to advise the Secretary of Agriculture and the NGRP Director of new and innovative approaches to genetic resources conservation.

In 2012, the Secretary also directly charged the NGRAC with responding to a specific recommendation of the AC21, in its report entitled *Enhancing Coexistence: A Report of the AC21 to the Secretary of Agriculture* (Recommendation V) :

USDA should task the NGRAC to develop a plan in conjunction with the seed industry for ongoing evaluation of the pool of commercially available non-GE and organic seed varieties and identification of market needs for producers serving GE-sensitive markets. USDA should work with seed suppliers to ensure that a diverse and high quality commercial seed supply exists that meets the needs of all farmers, including those supplying products to GE-sensitive customers. These activities should be conducted in such a way as not to interfere with functioning markets and the activities should be independent of regulatory approvals for GE products.

Upon its reactivation and organization under the NAREEE Advisory Board, the Council met twice formally in 2013 and submitted an interim report to the Secretary in September 2014 which provided interim recommendations in response to the AC21⁵. However, due to two lapses in the Farm Bill, the NGRAC determined that it needed additional time to meet with stakeholders and the seed industry to fully respond to the charge of the AC21. While the recommendations of the NGRAC have expanded with further interaction and input from industry and stakeholders, the recommendations provided in the interim report are still relevant and important for USDA consideration.

In 2014, the NGRAC formally met once and worked closely with stakeholders, including genetic resource conservators and providers, to provide a basis to further develop and refine our recommendations to USDA. Some of these contributors include: Dr. Peter Bretting, National Program Leader, USDA-ARS; Dr. Ann Marie Thro, National Program Leader, USDA-National Institute for Food and Agriculture (NIFA); Dr. Candice Gardner, Research Leader, U.S. North Central Regional Plant Introduction Station, USDA-ARS; Dr. Mark Millard, Geneticist/Maize Curator, Plant Introduction Research Unit, USDA-ARS; Dr. Harvey Blackburn, Research Geneticist, Plant and Animal Genetic Resources Preservation Research Unit, USDA-ARS; Charles Brown, Owner CB Seed and Chair of the ASTA Organic Seed Committee; Dr. Bernice Slutsky, Senior Vice President, Domestic and International Policy, ASTA; Michael Sligh, Program Director, Rural Advancement Foundation International (RAFI USA); Dr. Wallace Huffman, Economics Professor, Iowa State University; and Dr. Catherine Greene, Economist, USDA-Economics Research Service (ERS). The members of the NGRAC themselves bring

⁵ *Report of the National Genetic Resources Advisory Council to the Secretary of Agriculture*, <http://www.ree.usda.gov/nareeeab/reports/NGRAC-Report%20Sept2013.pdf>

experience on seed production, germplasm availability, including specific experience in breeding and seed production in organic agriculture.

Recently, the NGRAC has been provided the opportunity to review the (draft) USDA-ARS document, “ARS Procedures and Best Management Practices for Genetically-Engineered Traits in Germplasm and Breeding Lines.” This document includes information regarding issues of developing diverse and high quality seed supplies to meet the needs of all farmers, including those supplying products to GE-sensitive markets. The NGRAC appreciates the opportunity to review this document and endorses these efforts of USDA-ARS.

Our recommendations note that ensuring commercial seed availability is linked to seed purity requirements and expectations in GE-sensitive markets such as, USDA Organic and Non-GMO Project Verified. Producers, seed companies and public and private plant breeders need access to high quality seed that includes a high level of genetic trueness to type. NGRAC is not making recommendations on thresholds. Realistic, practical thresholds for the minor presence of GE traits in non-GE and organic crops can be established, however it is our view that thresholds cannot be de-coupled from the economic costs. It is clear that both private and public sector breeders and seed producers have financial burdens from such testing. NGRAC urges the AC-21 to continue to seek solutions that address who incurs the burdens and costs for such testing and market losses when they occur from no fault of the farmers and marketers.

The NGRAC charge to address AC21 Report Recommendation V deals with the ability to develop improved seed varieties to serve organic and non-GE agricultural markets. These markets need access to well adapted and good quality seed, in the appropriate form (i.e., without unapproved seed treatment), that is reasonably free from adventitious presence of GE traits. Genetic purity of any commercial agricultural product propagated by seed begins with purity of the seed planted, so concerns of access and availability extend beyond existing commercial seed to the ability to develop appropriate new and improved seed varieties. It is difficult to assure that no off-type plants or pollen are present in seed production fields and breeding nurseries, and that seed conditioning equipment is completely free of unintended contamination. The Association of Official Seed Certification Agencies⁶ (AOSCA) notes state seed laws and seed certifying agencies set purity thresholds that depend on the biology of the crop (cross- or self-pollinated), type of variety (hybrid or open-pollinated), and market-driven standards for final products. However, these thresholds vary considerably, and are traditionally based on visual assessment of seed or plants for morphological off-types rather than unseen characteristics including GE traits.

⁶ Association of Official Seed Certification Agencies, <http://www.aosca.org/>

Access to Seed and Germplasm for GE-Sensitive Markets

NGRAC was tasked to provide guidance to USDA on how the Department 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 appropriate germplasm for breeding organic, non-GE and GE crops.

The process that led to the recommendations was as follows:

First, we focused on 8 major crops that currently have GE varieties available in the U.S. These crops are: Corn, Soybean, Cotton, Canola, Alfalfa, Sugar Beet, Squash, and Papaya (though GE Papaya production is geographically restricted and may be visibly differentiated from non-GE papaya). Issues identified herein could also be relevant to crops that may have commercial GE traits in the future, such as non-browning apples and potatoes.

Second, we undertook a comprehensive approach to the availability of genetic resources that identified the principal players, problems, and solutions. Types of germplasm and opportunities for access vary greatly according to specific stages from pre-breeding (germplasm conservation and evaluation) through on-farm production. We therefore examined each of these stages. The recommendations were developed as an initial means to help describe germplasm components, recognize issues, and address problems and gaps that were identified at each stage and collectively.

The various stages considered were:

- Uncharacterized germplasm for breeding
- Characterized germplasm for breeding
- New inbred lines and varieties in the appropriate form including Foundation seed, which is the first generation multiplication of breeder's seed and a critical step in developing the seed for use by the farmer
- Seed for farmers
- Harvested products for processors and consumers

For each of these stages we considered the issues and components to formulate recommendations for the USDA. We considered the issues for two types of GE-sensitive markets: 1) non-GE agriculture and products and 2) organic agriculture and products, recognizing that these sectors differ. For example, organic farming can place greater demands on plant breeders, seed producers, and farmers because agronomic challenges such as weeds, insect pests, and pathogens can require increased use of cultural practices and genetic inputs rather than solutions that rely on synthetic chemical inputs and/or genetically engineered traits. Nonetheless, many issues and recommendations are common and relevant to both non-GE and organic agriculture. Issues and recommendations considered at each stage are presented in Appendix 1.

Third, we categorized the preliminary recommendations according to the three areas that NGRAC was specifically charged to address by the AC21. These three response categories are:

- **Ongoing evaluation of the pool of commercially available non-GE and organic seed varieties.**
- **Identify market needs for producers serving GE-sensitive markets.**
- **Ensure that a diverse and high quality commercial seed supply exists that meets the needs of all farmers.**

Recommendations in Response to AC21 Requests:

These recommendations apply to 8 crops that currently have commercial GE traits: Corn, Soybean, Cotton, Canola, Alfalfa, Sugar Beet, Papaya, and Squash. These are current priorities because GE versions exist for these crops. These recommendations should also be relevant to additional crops that commercialize varieties with GE traits in the future. Though the recommendations pertain to issues identified in germplasm access and availability related to coexistence between GE and non-GE agricultural production, it is recognized that issues have varying degrees of complexity among the crops depending of their biology, variety type, regional adaptation, and level of GE adoption.

Area 1. Ongoing evaluation of the pool of commercially available non-GE and organic seed varieties

Recommendation 1

USDA should encourage and facilitate seed producers to provide information on the available pool of appropriate organic and non-GE seed.

Approach – The NGRAC recommends that USDA:

- i. support the Organic Seed Finder database (managed by AOSCA) and similar efforts; and
- ii. support regional evaluation networks and performance trials that include commercially available organic and non-GE varieties.

Rationale: USDA-administered testing networks might exist, and national or regional non-GE standards can be included; or a separate test for organic and non-GE varieties can be included to be conducted in the appropriate management system, such as on certified organic land, organically managed, or managed independent of GE trait efficacy for lepidopteran insect or herbicide resistance.

Expected Outcome: The availability of more opportunities for annual and on-going variety testing might encourage increased development of suitable varieties and will

increase access to these varieties by providing relevant agronomic performance information on organic and non-GE varieties available for commercial use compared to those already commercialized for appropriate agricultural system and according to regional adaptation.

Recommendation 2

USDA should work with plant breeders and other seed providers to increase the availability of organic and non-GE germplasm.

Rationale: ASTA has begun working with its members to identify maize breeders and seed producers who would willing to provide or consider providing maize inbred lines and/or hybrid varieties that would be suitable for non-GE and organic seed production and use on farms. USDA should work with ASTA to make widely available this information and request that similar information be obtained to include other crops that already have commercially available GE varieties.

Expected Outcome: There are numerous plant breeders and seed producers, many of whom already do or who may be willing to provide seed suitable for non-GE or organic seed production and agriculture. A comprehensive survey would help identify breeders and seed producers who might be able and willing to meet market opportunities that arise as a result of consumer demand for organic and non-GE products.

Recommendation 3

USDA should commission a study of the release and availability of inbred lines and varieties developed at public universities in order to determine the extent to which they deliver optimal crop genetics for different agricultural systems. This should include an assessment of the unintended impacts of the Bayh-Dole Act on public sector capacity to serve all agriculture.

Rationale: The Bayh-Dole Act⁷, adopted in 1980, allows universities to claim intellectual property rights to federally funded research. There is a concern that implementation of the Bayh-Dole Act might have focused on the development of varieties suitable for the largest economic markets and thus have had an unintended negative impact on the ability of public breeding programs to deliver commercially available organic and non-GE varieties for GE-sensitive markets.

Currently, some university breeding programs expect a return on research investment in their breeding programs, and licensing or royalty income is limited in germplasm without a GE trait. These issues can impact program support of breeding programs that might be

⁷ Full Text of the Bayh-Dole Act <http://www.gpo.gov/fdsys/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35-partII-chap18.pdf>

able to provide appropriate seed for emerging non-GE markets. NGRAC recognizes the efforts by USDA to stimulate public breeding through grant programs such as: NIFA Specialty Crops Research Initiative (SCRI), the NIFA Organic Agriculture Research and Extension Initiative (OREI), and the NIFA AFRI Plant Health and Production and Plant Products Program Area (Program Area Priority Code A1141, Plant Breeding for Agricultural Production). It should be noted that Program Area Priority Code A1141 was able to fund only 7% of proposals submitted in the last cycle.

Expected Outcome: The Bayh-Dole Act has been in place for nearly 30 years and an evaluation of the effect of its implementation on supporting the needs for a diverse U.S. agriculture is warranted. Such an evaluation would be an important component of ensuring sufficient diversity in varieties to meet the demands of a diversity of farming approaches and consumer demands for a diversity of food and food production.

Area 2. Identify market needs for producers serving GE-sensitive markets.

Recommendation 4

USDA should conduct an ongoing assessment of the non-GE and organic seed market value to understand and relay to stakeholders value and investment opportunities in the seed sector. Market demands should be identified by crop for organic and non-GE for each of the crops affected by commercial GE trait adoption by region, acreage, maturity and adaptation.

Rationale: It is important to have market demand data available so that breeders, seed producers, and farmers can plan ahead and initiate breeding programs, increase seed, and determine consumer or processor demand for grain production and thus planting needs. *The Market for Organic & Ecological Seed in Canada: Trends and Opportunities 2014*⁸ is a good example of the information needed.

Area 3. Ensure that a diverse and high quality commercial seed supply exists that meets the needs of all farmers.

Recommendation 5

USDA should convene regular balanced roundtables on extending GE trait stewardship to encompass prevention and mitigation of adventitious presence in non-GE breeding programs and genebanks.

Rationale: Development of a high quality seed supply for different farming systems depends on the abilities of variety developers and seed producers to effectively deliver

⁸ https://payment.csfm.com/donations/usc/bauta/images/seedmarketstudy_EN_Oct27.pdf

seed appropriate for the intended purpose, including seed that is reasonably free from unintended adventitious presence of GE traits in organic and non-GE varieties.

Biotechnology companies have stewardship policies for product research, deregulation, development, commercialization, and phase-out of GE traits, which are ultimately owned by the companies. When novel DNA in a plant agricultural biotechnology product is approved and made commercially available, it can be detected at very low levels, analogous to DNA fingerprinting. Stewardship efforts should address the prevention and mitigation problems encountered by GE-sensitive breeders, farmers, and producers. Seed purity has traditionally been the responsibility of the seed producer, but this recommendation recognizes that adventitious presence of GE traits presents a challenge for organic and non-GE variety development and production. There may be regulatory issues and with current testing methods, levels of GE presence can be detected at levels well below any thresholds that have hitherto been employed in the seed industry. In this aspect, testing for GE presence is not alone. The potential use of DNA methods for testing of varietal identity and purity also enable threshold levels to be so extreme as to be impractical to achieve and maintain.

Current regulations the U.S. do not specify any particular acceptable threshold for adventitious presence of GE traits in non-GE varieties intended for organic or non-GE identity-preserved (IP) production. For these markets, it is impractical to achieve zero tolerance, just as with other parameters bearing upon seed quality (e.g. germination) or varietal identity. Current commercial GE traits do not change seed appearance or plant morphology, so standard contamination mitigation practices do not apply. GE traits are not usually detectable by visually assessment, but can be detected by relatively expensive molecular tests at extremely low levels. Practical thresholds for off-types other than GE are established to develop guidelines by crop type, contamination type, and seed multiplication generation. Crops that currently have commercial GE traits and those that might have commercial GE traits in the future vary by biology, variety type, and regional adaptation, so setting thresholds specific for GE traits may represent different burdens for different crops.

Currently, GE-sensitive seed markets are small, but growing, compared to GE markets in agronomic crops with commercial GE traits, especially corn, soybean, cotton, canola, alfalfa, and sugar beet. Public sector breeding programs that could be geared to supplying underserved markets face quality control cost issues and the perception that germplasm without GE traits has limited commercial value in crops dominated by GE varieties. It is easier to develop GE varieties pure for GE trait of interest, especially coupled with herbicide resistant traits (the off-types can be eliminated by spraying herbicide) than to develop non-GE varieties in crops that encompass up to 12 commercial GE events and commercial varieties containing up to four independently segregating GE traits.

These roundtables should include balanced and broad-based stakeholders from organic, public cultivar developers, and private, GMO and non-GMO seed and crop production stakeholder groups.

Expected Outcome: Available testing methodologies are rapidly developing. It is in the interests of all participants in plant breeding, seed production, and agriculture to have applicable and cost effective means to measure and thus to help ensure varietal identity and purity, including to avoid adventitious presence of GE. Attendance at regular roundtable discussions would help all parties understand their common interests and encourage them to work together to find practical and cost effective mitigation strategies including testing for GE presence.

Recommendation 6

To facilitate coexistence and maintain stewardship, USDA should work with and encourage industry to develop and provide low cost assays of GE traits.

Rationale: The costs of GE trait assays (available from manufacturers with license from biotechnology companies that own the trait) are time and volume-sensitive. Therefore, relative costs are much higher for small, regional breeding, public-sector, and foundation seed programs which are more likely to serve organic and non-GE agricultural markets.

One study relative to corn seed production practices estimates the cost to achieve higher level of purity (to a 0.3 GE contamination threshold), would increase production cost 35%⁹. Convenient available detection assays that can be ordered from laboratories that manufacture them under license from GE technology owners are time and volume sensitive, so the cost is higher for small companies or breeding entities than for large GE seed companies. This additional cost is a burden on public breeding and foundation seed programs and seed companies developing varieties for organic and non-GE seed markets that do not have a revenue stream from technology fees to support additional quality control measures. The cost could also be a deterrent for GE seed companies to offer non-GE varieties because meeting implied purity standards could be too difficult or cost-prohibitive.

Expected Outcome: Greater availability of economically feasible testing capabilities either in house or via third parties would facilitate monitoring of adventitious presence of GE traits. This is particularly beneficial for small regional breeding and foundation seed programs.

⁹ Kalaitzandonakes, N. and A. Magnier 2004. Biotech labeling standards and compliance costs in seed production. Choices 19(2): 1-9

Recommendation 7

The NGRAC encourages USDA to promote diversity in agriculture by devoting additional resources to organic and non-GE agriculture in the areas of genotyping, phenotyping, evaluation, breeding and/or pre-breeding.

USDA should facilitate more public, private, and/or tribal partnerships in developing, characterizing, and evaluating genetic resources from the NPGS and non-U.S. sources adapted to U.S. growing conditions. Further assessment is needed for developing, characterizing, and evaluating tribal genetic resources.

Rationale: NGRAC recognizes the efforts by USDA to stimulate public breeding through its competitive grant programs. Efforts are underway to characterize germplasm in the genebanks, though there are still a lot of accessions in the collection for which little is known. A challenge for plant breeders is not only to understand the genetic basis of complex trait variation, but then also apply that knowledge effectively to crop improvement. Tribal genetic resources have a lot to offer to the diversity of U.S. agriculture. Discovering important genes from all available sources and successfully utilizing them in plant breeding requires acquiring, preserving, characterizing, and documenting all of our genetic resources.

Expected Outcome: Additional genotyping, phenotyping, evaluation, breeding and/or pre-breeding will increase the flow of genetic diversity into U.S. agriculture and thus increase the potential to meet a greater diversity of national and regional needs including different farming systems and tribal farmers.

Recommendation 8

USDA should identify gaps in genetic diversity and/or passport information, including samples or accessions with known use restriction issues, and remedy those omissions by additional collection or documentation.

Rationale: The USDA NPGS has a large diversity of accessions for numerous crop species, including representation of varieties grown or once grown in the US and from other countries and regions. Collections usually include “passport information” which describes the location where the accessions were collected (optimally with global positioning system (GPS) coordinates), date collected, name of collector, and some information on the ecology and climate. Such passport information is essential for the potential use and adaptation of the germplasm by breeders. Such information greatly helps facilitate the use of the collections. It is advisable to be aware of any gaps in the USDA collection in respect to either seed accession or passport information compared to the global distribution of varieties. These are likely gaps in the availability of genetic diversity that might otherwise be of future potential use in breeding of new varieties that

are genetically better adapted to similar environments, pests, or diseases occurring in the U.S.

There is an urgent need to increase the capacity of public plant breeding for all forms of agriculture. Public sector breeding can complement private sector, particularly filling in gaps for regions and crops that either not served or under-served by the private sector. USDA should increase and encourage current resource priorities to ensure greater focused land grant university capacity and USDA competitive grants to address the unmet needs for public cultivar development including education of the future generations of plant breeders and seed scientists. Hatch, McIntire-Stennis, Evans-Allen, and tribal capacity funds are sources of critical funding that provide stability for breeding programs in ways that competitive grants cannot address. We recommend a 10% increase in Hatch formula funds to support cultivar development and education of plant breeders and seed scientists. Experiment stations receiving this increase should use this to develop crop cultivars grown by farmers/producers in that state/region. The priorities in competitive funding should be aligned with these proposed increases.

The NGRAC also encourages the Foundation for Food and Agriculture (FFAR) to prioritize an investment in cultivar development and the education of plant breeders and seed scientists.

Expected Outcome: The desired outcome is to maximize the availability and utility of genetic resource diversity to plant breeders, especially for those serving US agriculture so they can more rapidly respond to the changing demands for varieties to fit market needs. Different varieties or populations can be individually well adapted to a diversity of changing agroecologies, farming practices, meeting threats from evolving pests and diseases, and changing consumer demands.

Recommendation 9

USDA should communicate to State seed foundations and ASTA the importance and need for inbred lines and foundation seeds that are not treated with chemicals prohibited by USDA National Organic Program.

Rationale: It is important that breeders and seed producers know which seed chemical treatments are prohibited by the USDA National Organic Program in order for plant breeders and seed producers to generate and produce seed that is adapted and applicable to organic agriculture.

Expected Outcome: Plant breeders and seed producers will be more likely to have seed available in a suitable form for use in organic agriculture and thus help further ensure a supply of seed in a form suitable for organic production.

Conclusion

This report is the result of a comprehensive examination of components and issues that impact the current state of plant genetic resources and evaluation of their availability. The recommendations will hopefully provide elements to a path forward for USDA in identifying useful and effective ways to interact and work with industry to ensure seed availability for all markets.

The NGRAC thanks the USDA and the Secretary for the opportunity to comment and provide recommendations in response to the AC21 recommendations. The NGRAC looks forward to engaging with USDA on other pertinent issues and to providing additional advice and recommendations on the collection, maintenance, and utilization of genetic resources.

**Report Developed by the National Genetic Resources Advisory Council, a Subcommittee of
the NAREEE Advisory Board**

Dr. Manjit Misra (Chair), Professor/Director of the Seed Science Center and Director of the Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP), Iowa State University

Dr. Jane K. Dever, Professor, Texas A&M AgriLife Research

Dr. Stephen Smith, Research Fellow of Pioneer Hi-Bred International, a DuPont Company

Matthew Dillon, Sr. Manager Agricultural Programs and Director of Seed Matters, Clif Bar & Company

Dr. Karen Moldenhauer, Professor & Rice Industry Chair for Variety Development, University of Arkansas, Division of Agriculture, Rice Research and Extension Center

Dr. Allison A. Snow, Professor, Department of Evolution, Ecology, and Organismal Biology at Ohio State University

Terry Williams, Fisheries and Natural Resources Commissioner, Tulalip Tribes

Dr. Mulumebet Worku, Professor/Biotechnologist, Department of Animal Sciences, North Carolina Agricultural and Technical State University

Additional support and input was provided by several Ex-Officio members and additional members of the public:

Dr. Peter Bretting, National Program Leader, USDA Agricultural Research Service

Preston Hardison, Watershed Resource Analyst, Office of Treaty Rights, Tulalip Tribes

Dr. Gary Pederson, Supervisory Geneticist, Plant Genetic Resources Conservation Unit, for the USDA-ARS

Dr. Ann Marie Thro, National Program Leader, USDA National Institute for Food and Agriculture.

Appendix 1

<i>Non GE and Organic</i>		
Germplasm Access Points	Issues (I)/Components (C)	Recommendations
Access to uncharacterized germplasm for breeding	<p>C: Primarily NPGS, and also other sources.</p> <p>I: Material Transfer Agreements associated with other public-sector collections may restrict access and use.</p> <p>I: Gaps in NPGS accessions for 8 priority crops</p> <p>I: Curtailed collection efforts restrict accessibility of potentially important wild relatives</p> <p>I: Lack of recognition of tribal governance over genetic resources and address tribal issues in germplasm collections.</p>	<p>Increase NPGS effectiveness in providing access to germplasm including information on priority crops</p> <p>Identify where there may be use restriction issues</p> <p>Survey the curators of the NPGS to identify an inventory of uncharacterized germplasm missing from the NPGS for the eight crops.</p> <p>Where appropriate, USDA should facilitate collection of and access to uncharacterized germplasm currently outside of its management and control.</p> <p>Facilitate (collection of and) access to uncharacterized germplasm for priority crops</p>
Access to characterized germplasm for breeders	<p>Current sources (C):</p> <ul style="list-style-type: none"> • Seed Companies with parent seed programs • Public Breeding Programs • International Breeders (ie, CGIAR) • Farmer Breeders • NGOs 	<p>Encourage USDA to increase investment in NPGS characterization through genotyping and phenotyping.</p> <p>USDA should ask ASTA to survey members to identify sources of non-GE germplasm.</p> <p>Where appropriate, USDA should facilitate collection of and access to characterized germplasm currently outside</p>

Non GE and Organic		
Germplasm Access Points	Issues (I)/Components (C)	Recommendations
	<ul style="list-style-type: none"> • NPGS <p>(I) Practical exploitation of the rich allelic diversity in germplasm collections is limited without characterization.</p> <p>(I) In some open-pollinated crops, germplasm is inaccessible in non-GE form.</p> <p>(I) Material Transfer Agreements associated with other public-sector collections and public breeding programs may restrict access and use.</p>	<p>of its management and control.</p> <p>Encourage USDA-ARS to promote diversity in agriculture by filling gaps, for example, to devote work to organic agriculture in the areas of breeding and pre-breeding in priority crops.</p> <p>Encourage USDA to continue to develop and strengthen partnerships with plant breeders, for example the Genetic Enhancement of Maize project.</p> <p>Recognize tribal governance over tribal genetic resources and address tribal issues in germplasm collections. Address tribal issues related to access to and development of characterized germplasm resources in collections.</p>
Access to new lines, varieties and hybrids in appropriate form	<p>Current sources (I):</p> <ul style="list-style-type: none"> • Seed Companies • Public Breeding Programs • International Breeders (ie, CGIAR) • Farmer Breeders • NGOs <p>(I) In some crops, newly developed adapted lines are accessible only in the converted (GE)</p>	<p>USDA should encourage ASTA to continue working with members to expand access to inbred lines and varieties in the appropriate form.</p> <p>Pursuant to their interagency agreement and cognizant of other priorities, the NPGS should work with the PVPO to ensure access to products for which IP has expired.</p> <p>USDA should review impacts of the Bayh-Dole Act on release and availability of inbred lines and varieties</p>

<i>Non GE and Organic</i>		
Germplasm Access Points	Issues (I)/Components (C)	Recommendations
	<p>form.</p> <p>(I) Non-GE and organic seed producers require inbreds in appropriate form, including:</p> <p>a) untreated seeds for organic seed production. Leased seed from genetic providers is often not available untreated.</p> <p>b) seed free of the presence of GE traits. At present many non-GE and organic seed production firms cannot test or otherwise determine if the lines they are leasing from genetic providers contain GE traits.</p> <p>(I) Cultivar development efforts at public universities are not adequate and release policies are inconsistent and often not conducive to addressing smaller market segments in priority crops.</p> <p>(I) Recent releases from public university breeding programs in priority crops favor mapping populations and characterized germplasm over adapted non-GE cultivars; cultivars have limited commercial value without</p>	<p>developed at public universities to support crop genetic diversity and different agricultural systems.</p> <p>Encourage USDA-ARS to support diversity in agriculture by filling gaps, for example, by appropriate prioritization of breeding varieties for non-GE and organic agriculture.</p> <p>Initiate a 10% increase in Hatch formula funds to support cultivar development. Experiment stations must demonstrate that funds are being used to create crop cultivars grown by farmers/producers in that state/region. This should be coupled with increase in research appropriations targeted at increasing NIFA grant funds to better match public requests.</p>

Non GE and Organic		
Germplasm Access Points	Issues (I)/Components (C)	Recommendations
	GE traits.	
Access for farmers to seed in appropriate form	<p>Current sources (C):</p> <ul style="list-style-type: none"> • Seed companies • Other farmers • Self-produced • NGOs • Public programs with access to seed multiplication (foundation seed) • Contract Company <p>(I) Resources for purity testing in non-GE and organic cultivar development and production are limited.</p> <p>(I) Public cultivars licensed to seed companies in priority crops are converted to GE from before sales to farmers</p>	<p>Encourage USDA National Organic Program to continue support management of the Organic Seed Finder (AOSCA managed) database.</p> <p>USDA should explore feasibility for low cost, non-destructive assays for the presence of GE traits.</p> <p>USDA should work with industry for future releases to encourage transgenic trait to be in the female parent in hybrid crosses.</p> <p>Encourage USDA-APHIS to re-establish and/or re-examine the long-proposed biotech rules as outlined in the PPA.</p> <p>APHIS could encourage applicants to provide a conflict analysis (CA) prior to or concurrent with submitting a petition for determination of non-regulated status of genetically engineered (GE) plants. The CA could be used by USDA in developing the socio-economic impact portion of a NEPA analysis, helping both to facilitate timely NEPA analysis, and to address a broad range of potential conflicts including drift of GE traits into non-GE breeding and commercial seed stock.</p>