

Summary of main USDA activities initiated in response to the November, 2012 AC21 report

Compensation measures plus relevant new market-related information

New Economic Research Service (ERS) study underway on the economic implications of coexistence

ERS is planning to publish a report within the next several months that broadly examines the economic issues related to coexistence of organic, genetically engineered (GE), and non-GE crop production, including adoption trends for these crops and their identity-preserving differentiated product markets and labels. American consumers continue to fuel a fast-growing market for organic food, and a market for non-GE conventional products has emerged as well. The U.S. also has continued strong domestic and international demand for commodity crop production, much of which involves GE crops. In order to maintain the integrity of GE-differentiated markets, organic and conventional non-GE farmers are using a variety of practices to avoid the presence of GE material in their crops. The ERS report examines commonly used coexistence practices used during crop production, and discusses the economic losses from the presence of GE material in organic crops.

Improvement of crop insurance options for farmers not growing commodity crops.

Since 2012, USDA has eliminated the insurance premium surcharge for organic farmers, added price elections for 52 crops, and created the contract price addendum, which is available for 73 crop types. The contract price addendum allows producers to use their contract price to establish crop insurance guarantees rather than USDA-established prices. In its first year of operation, nearly 10 percent of the organic policies utilized the price addendum. Overall, these changes contributed to a 25 percent increase in organic acreage covered by crop insurance. From 2012 to 2015, there has been a 24 percent increase in the number of organic policies. There are continuing efforts to increase the number of organic crops with price elections. In addition, as provided for in the latest Farm Bill, USDA can now offer farmers insurance under Whole Farm Revenue Protection, a crop insurance policy that allows producers to ensure every commodity on the farm. This tool offers the potential to provide a safety net for people who have never before had the option of crop insurance. Beginning with the 2016 crop year, the Whole Farm Revenue Protection insurance policy will be available to producers in all States.

New USDA Market News Report with Non-GE/GMO Commodity Focus

On September 2, 2015, the Agricultural Marketing Service (AMS) Livestock, Poultry, and Seed Program (LPS) started publishing a weekly Market News report focusing on non-GE/GMO grain commodities. This national weekly report is issued on Wednesdays and highlights the corn and soybean trade; other commodities will be added as the Market News contact base is increased. The report is available at: http://www.ams.usda.gov/mnreports/gl_gr112.txt.

Consultation with Office of General Counsel (OGC) on current authority to implement compensation-related coexistence measures. OGC has indicated that USDA currently lacks the legislative authority to implement a crop insurance program that would address economic losses to farmers resulting from unintended presence of GE material. OGC has also indicated that USDA currently lacks the legislative authority to implement a program to incentivize the development of joint coexistence plans by neighboring farmers. Also see Research, below, on survey of GE-related losses incurred by organic farmers.

Stewardship and Outreach

Seeking public input through the Federal Register on how to foster communication and collaboration to strengthen coexistence. On November 4, 2013, USDA published a notice requesting public input for a 60-day comment period, and subsequently extended the comment period for an additional 60 days. There were 4,171 comments received. In brief, relatively few commenters offered comments that were directly responsive to the items in USDA's request for information. Many or most of those who provided comments who did not specifically address the issues on which USDA requested information had serious concerns or issues they wished to raise, but much of their comments were outside the scope of the intended discussion. The majority of commenters generally opposed the growing, production, and marketing of GE products, and some favored banning GE crops. Many commenters raised concerns not included in the Request for Information, including GE labeling, potential human and animal health effects from ingesting GE-derived products, effects of pesticide use, contamination risks for heirloom and conventional seed stocks, international trade, and consumer rights, among others. Most comments that referenced the AC21 report opposed the premise that coexistence would provide adequate protection for organic farmers and consumers. A number of comments described the burden of addressing unintended GE presence as falling disproportionately on organic and conventional growers, and argued for additional regulatory controls on the commercial production of GE crops. In contrast, other comments argued that coexistence is nothing new for agriculture and is generally working. Many expressed the view that the responsibility for preventing contamination of IP and organic production should lie with GE growers and the GE industry. Most commenters who opposed coexistence did not discuss any of the AC21 report's recommendations in detail.

Among the relatively small number of comments that were directly responsive to USDA's specific requests in the Request for Information, many highlighted the need for additional information—whether about best practices in crop production or contracting, about economic damages, about seed purity, about locations of neighboring plantings, or other topics, or a general need for increased education around any of these issues or the science underlying them. Some highlighted the need for confidentiality for some information that might be provided to the government. Some commenters discussed the issue of farmer-to-farmer communication. Some noted the value of such communications and indicated that such communications may take place but do not guarantee particular behavior changes. Other farmers, in discussing their neighbors, did not express an interest in entering into dialogue with them. Some called for local, cropspecific solutions led by farmers and educators.

Holding a stakeholders workshop on coexistence. In order to continue the discussion on how to foster communication and collaboration to strengthen coexistence, USDA decided to hold an invitation-only stakeholder workshop on coexistence, which took place on the campus of North Carolina State University in Raleigh, NC, on March 12-13, 2015. At the workshop, USDA focused on activities either completed or under development in response to the AC21 recommendations and solicited comments from participants and members of the public in following weeks. USDA listened carefully to the views offered at the workshop.

In its official requests for comment, approximately 475 comments were received, from organic farmers, conventional farmers, and farmers that grow genetically engineered (GE) crops, as well as national, regional, and State trade organizations representing each of these; seed companies; organic product retailers; consumer rights, environmental protection, and other nonprofit advocacy organizations; consumers of organic foods; scientific research organizations, and members of the public. The majority of commenters categorically opposed the growing, production, and marketing of GE products, and many questioned whether agricultural coexistence is even possible. A broad range of concerns was expressed. Many commenters objected to the invitation-only restriction for the workshop and thought it to be a "lost opportunity" for a balanced dialogue about GE crops and coexistence and a smaller number of commenters offered the view that the workshop had been a useful forum for promoting coexistence.

While most commenters stated their concerns generally and without reference to the workshop, some did specifically address the workshop discussions, presentations, existing and proposed USDA initiatives, and conclusions drawn during the workshop. With regard to the slate of USDA initiatives, the following items (described throughout this document) received the most support:

 Work to bolster the purity of USDA germplasm repositories and develop best management practices for GE seeds

- Support for the Organic Seed Finder (with a recommendation from some that USDA develop a comparable non-GE seed finder as well)
- Use of Natural Resource Conservation Service (NRCS) programs where applicable to facilitate achievement of coexistence goals
- All of the ongoing research efforts through the Agricultural Research Service (ARS), ERS, the National Institute for Food and Agriculture (NIFA), and the National Agricultural Statistics Service (NASS), including work on restricting gene flow or characterizing its impacts, studying the potential economic impacts of coexistence, and surveying organic producers for losses (with a recommendation from some that non-GE producers also be surveyed)
- The use of the AMS Process Verified Program for identity-preserved products (though some in the organic industry worried that it could create a weaker label than "organic" or discourage producers or brands from transitioning to organic).

An APHIS proposal for voluntary submission of conflict analyses and coexistence plans by developers also received some support from organic producers although a number of those commenters thought such efforts should be made mandatory and/or completed by USDA in the absence of a voluntary plan. In addition, a number of commenters offered the view that APHIS should revise its Part 340 regulations to institute mandatory restrictions on pollen flow from commercial GE crops. There was relatively little support for USDA proposals on an overall outreach and education strategy and on farmer toolkits and for the new USDA website on coexistence.

Provision of informational materials describing voluntary and outcome-based strategies for facilitating production of all types of identity preserved products

Information was developed which was provided at the Raleigh workshop about the use of pinning maps, grower zones, screenable markers, pollen-excluding traits, and procedures in place in the organic industry to prevent commingling and unintended presence.

Toolkits providing resources that encourage communication, planning, and crop-specific practices to reduce unintended gene flow or post-harvest mixing, as well as information on contract issues and incentives, plus other relevant informational materials

USDA is now hosting a Web site devoted to informational resources about coexistence. The site consolidates and presents coexistence-related information and resources from across all USDA agencies, as well as partners in the States, industry, and scientific communities. Content on the site is intended to help support continued discussion and engagement regarding agricultural coexistence. There are a series of factsheets that define agricultural coexistence, explain its

importance, and highlight key aspects supporting coexistence in different sectors of U.S. agriculture. USDA welcomes additional refinements and updates to these materials. USDA may explore developing additional toolkit products for the Web site that will support ongoing dialogue about coexistence and encourage adoption of best practices. USDA looks forward to expanding the information and resources for the Web site, as well as ideas about additional toolkit products that are needed to help advance coexistence.

Separately, in the spring of 2015, the National Organic Standards Board (NOSB) published two discussion documents for public comment: "Discussion Document on Excluded Methods Terminology" and "Prevention Strategy Guidance for Excluded Methods." With the first document, the NOSB sought to update the definition of excluded methods in order to clarify and modernize the terminology in light of new technologies. With the second, the NOSB sought to solicit input and feedback from the organic community on precautions that organic producers and handlers should take to prevent and minimize unintended GE presence/GMO contamination in organic production and processing. USDA's Agricultural Marketing Service (AMS) expects the NOSB to make recommendations based on these documents in May 2016, after which AMS can consider further guidance or rulemaking actions.

Use of AMS Process Verified Programs to verify non-genetically engineered crops/processes

The USDA Process Verified Program provides companies that supply agricultural products or services the opportunity to assure customers of their ability to provide consistent quality products or services. It is a fee for service program and is limited to programs or portions of programs where specified process verified points are supported by a documented quality management system. The specified process verified points are identified by the supplier. Companies with approved USDA Process Verified Programs are able to make claims associated with their process verified points and their verified process points are documented and available for public view on the AMS website. The USDA Process Verified Program does not relieve the company of meeting regulatory requirements issued by other Federal Departments or USDA Agencies. In February 2015, AMS approved the first USDA Process Verified Program (USDA PVP) for Non-GE/GMO products. The program is currently approved only for the bulk food grade corn and soybeans processed at one SunOpta facility in Minnesota. The process specifies that products verified as Non-GMO are made from ingredients that were not produced using genetic engineering (GE) and meet SunOpta's standard of 99.1% Non-GMO/Non-GE minimum (or testing specification 0.9% GMO/GE Maximum). AMS expects the first retail launch of a Non-GMO/Non-GE USDA PVP marketing claim on a retail label in 2016. Several other applications for similar Non-GE/GMO PVP claims are in process.

Potential use of conservation programs in some instances to facilitate farmers' measures to promote coexistence

Conservation programs administered by Natural Resources Conservation Service (NRCS), and the practices used to implement conservation, must focus on natural resource concerns. Although genetic isolation is not a natural resource concern, there may be occasional opportunities where producers can mutually achieve conservation and coexistence goals. However, because NRCS does not have the expertise for addressing genetic isolation issues, it would need to rely heavily on USDA and university scientists for the needed technical information. With this information, NRCS could consider the potential usefulness of its conservation practices in some circumstances to address coexistence concerns, and application of the practices could be attempted first on a localized, pilot-scale basis.

Research

Gathering information from farmers about actual economic losses incurred as a result of unintended GE presence

The 2014 Organic Survey was conducted as a collaborative effort between USDA's National Agricultural Statistics Service (NASS) and its Risk Management Agency (RMA). The survey population was those producers certified as meeting the USDA standards for organic production, those exempt from certification, and those transitioning to certified organic production. In the survey, among many other questions, respondents were asked to answer several questions related to economic losses received from unintended presence of GE material in an organic crop produced for sale. Results from the survey were published on September 17, 2015. The survey established that such losses exist and that those losses came to roughly \$6.1 million over the years 2011-2014. This compares to \$5.5 billion in overall sales for organic farmers as a group in the one year 2014. The number of farmers reporting losses, 0.65% of farmers surveyed, was very small relative to the overall response rate to the survey instrument. Further analysis suggests that these losses are not evenly distributed geographically. While less than one percent of all certified organic farmers in California, Indiana, Maine, Minnesota and Michigan experienced losses due to the unintended presence of GE material, in a few states, such as Illinois, Nebraska, and Oklahoma, between 6 and 7 percent of certified organic farmers experienced losses. However, commodity-specific estimates cannot be reported due to data limitations.

Funding or conducting research relevant to crop stewardship and gene flow risk mitigation. Under USDA's Biotechnology Risk Assessment Research Grants (BRAG) program, starting with the FY 2013 Request for Applications (RFA), relevant topics in these areas (e.g., assessment of the efficacy of existing techniques for mitigating unintended presence on a crop by crop basis and/or in seed production/multiplication systems on a crop by crop basis; and development of novel strategies to mitigate unintended presence of GE traits in non-GE production systems) have been included as priority funding areas.

Relevant funded research projects include, among others: three projects studying technologies to inhibit gene flow either by developing male sterility, pollen confinement, or plastid transgene containment; one project investigating the impact of GE traits on insect migration; one project investigating the control of seed dormancy for reducing fitness of GE plants in the environment; and one project studying an inexpensive, in-the-field detection method for monitoring GE organisms in the environment. These research projects are ongoing. In addition, a National Academy of Sciences public workshop on the environmental effects of GE and non-GE crops in Washington, D.C. was funded in 2015.

Conducting research on landscape-scale gene flow in alfalfa.

USDA scientists have an ongoing research project to examine the movement of the Roundup-Ready herbicide resistance trait in alfalfa in the field. The three main project objectives are: (1) to assess the role of feral alfalfa in transgene transmission; (2) to determine the impact of pollinator behaviors on pollen-mediated gene flow; and (3) to analyze the flow of transgenes from Roundup-Ready alfalfa (RRA) seed production fields to conventional alfalfa seed fields in different environments.

Feral alfalfa management. USDA scientists confirmed that genetically engineered alfalfa has dispersed into the environment. The data suggest that eradicating feral alfalfa along road sides and minimizing seed spillage would be effective strategies for minimizing transgene dispersal. Manuscript in review.

Pollinator-mediated gene flow. USDA scientists analyzed the rate of inadvertent carry-over of GE alfalfa pollen in honey bee hives. The adventitious presence (AP) of GE pollen was extremely low. Thus, hive movement resulting from standard beekeeping practices is unlikely to result in cross-pollination between transgenic and GE-sensitive alfalfa seed varieties. By contrast, USDA results show that alfalfa leaf cutter bees (ALCB) frequently forage at ranges that exceed previous estimates. However, the rate of GE trait detection in harvested seed is dramatically lower than that detected in pollen, indicating that pollinator-mediated cross-pollination between transgenic and conventional alfalfa seed varieties occurs at extremely low rates, despite regular ALCB foraging visits across field edges. Manuscript accepted (*Apidologie*, 2016).

Field-to-field transgene transmission. To better understand how landscape affects gene flow from transgenic to conventional alfalfa seed production fields USDA scientists are analyzing seeds collected from different zones in 24 commercial fields. Results regarding gene flow and AP in alfalfa seed and hay have been shared extensively through outreach efforts at industry meetings, conferences, and through personal communication with growers, industry representatives and academia. 10 publications/presentations given in 2015. Manuscript in preparation.

Conducting research on the control of corn pollen germination. USDA researchers and land-grant university researchers are collaborating in long-term research that focuses on developing strategies for deploying genes to control pollen germination on receptive corn plants on which the pollen lands. These "gametophytic incompatibility genes" can limit undesired outcrossing among corn market classes. The private sector is also working on this trait, and new corn hybrids that will not accept GE pollen are becoming available for some specialty types in organic systems. Future research may include development of similar systems for other types of specialty corn, as well as genetic studies to look for similar systems that might be found in other crops.

Work with seed industry on specialized seed availability and farmer-seed industry interactions

USDA has had discussions with the American Seed Trade Association (ASTA) regarding the availability of seed to meet grower demand for the GE, identity-preserved non-GE, and organic markets and about resources for seed purchasers about best production practices for coexistence. As noted at the USDA Stakeholders Workshop on Coexistence held in March, 2015, it is challenging to accurately forecast total annual organic commercial grain production and demand, and seed production for relatively small markets requires advance planning—seed for specialized markets is not produced absent specific, known demand. For such organic and non-GE markets (and particularly for crops for which most overall demand is for GE crop varieties rather than for organic or non-GE seed), ASTA has indicated that it is imperative that growers talk with seed producers well in advance of signing production contracts, and at least a year ahead of planting, preferably longer. ASTA also indicated that it has efforts underway to develop a process to facilitate the licensing of elite germplasm for further breeding for non-GE markets. With regard to provision of information to farmers about coexistence practices, ASTA has stressed the role of State and local channels in providing the most accurate best practice information related to specific crops and geographies.

Seed Quality

Support for the development of an "Organic Seed Finder" database. The Agricultural Marketing Service (AMS) National Organic Program (NOP) awarded a one-year contract to the Organic Seed Alliance (OSA) and its partner, the Association of Official Seed Certifying Agencies (AOSCA), in February 2014. The objective of this contract is to better understand the organic seed market, communicate about the organic seed market and resources – including the Seed Finder database - to certifying agents and organic operations, and identify needs for increased sources of specific types of organic seed. The project was intended to provide USDA with: reports about organic seed needs; educational outreach materials about the organic seed market, seed finder database, and other resources; and specific targeted reports about the types

and locations of certain types of organic seeds available to organic producers. AMS did not provide additional support to the Organic Seed Finder database in 2015.

Development of an approach for examining trueness-to-type of holdings in the USDA/ARS National Plant Germplasm System (NPGS). A plan has been developed to prioritize NPGS accessions (samples) for closer examination of their trueness-to-type. There are roughly 574,000 NPGS accessions of about 15,000 plant species in the NPGS. But only about 20 of these species include genetically-engineered varieties that have been granted non-regulated status by USDA's Animal and Plant Health Inspection Service (APHIS). Roughly 5-6% of the total 574,000 accessions in the NPGS belong to these 20 species and were either acquired since GE varieties began commercial cultivation in the U. S. or were regenerated in the field since then. These 30,000 or so accessions (90%+ from the three crops soybean, corn, and cotton) are the focus for current re-examination of stewardship procedures and practices (see subsequent paragraph). Staff have initiated a small-scale project, in collaboration with seed industry partners, focused on identifying cost-effective means for testing and monitoring genebank samples and breeding stock for the unintended presence of transgenes in one major crop. This project provided important practical information for developing the updated best management practices described in the subsequent paragraph.

Development of updated procedures and best management practices for GE traits in plant germplasm and breeding stocks

The Agricultural Research Service (ARS) has revised and updated Agency-wide procedures and practices for handling GE traits and unintended presence of the latter in USDA/ARS crop breeding stocks and genebank collections. The procedures and practices focus on the five major crops with widely cultivated varieties that incorporate deregulated GE traits: cotton, maize, soybean, alfalfa, and sugarbeet. These procedures and practices encompass five major elements:

- 1. Well-documented, reviewed, and accessible best management practices (BMPs) for maintaining seed purity in both breeding and genebank programs.
- **2.** Testing for purity at critical control points.
- **3.** Mandatory purity testing of new varieties or enhanced germplasm prior to formal release.
- **4.** Guidelines for mitigating the effects of unintended presence of GE traits in breeding stocks and germplasm accessions.
- 5. Communication strategies for disseminating information about Agency procedures and practices and for handling future occurrences of unintended presence of GE traits.

The updated procedures and practices have been reviewed internally and by numerous external stakeholders, including the National Genetic Resources Advisory Council. They have also been provided as a courtesy to members of the AC21.

On-going evaluation of the pool of commercially available non-GE and organic seed varieties and identification of market needs for producers serving GE-sensitive markets. On-going 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 reestablished the National Genetic Resources Advisory Council (NGRAC) as a subcommittee of its National Agricultural Research, Extension, Education and Economics Advisory Board in 2012. Among the work projects for the NGRAC is to develop a plan for how USDA should work with industry and other stakeholders to accomplish this goal. The Committee met several times in 2013 and 2014 and submitted an interim report to the Secretary of Agriculture in August 2014. The NGRAC met again at the end of March 2015 and completed its final report in response to the AC21. The report will be delivered to the Secretary by the second week of December 2015.