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Thank you for the opportunity to be here today to discuss the U.S. Department of Agriculture's (USDA) biotechnology regulatory program, as well as the issue of herbicide resistant weeds. I am Ann Wright, Deputy Under Secretary of Marketing and Regulatory Programs. In this capacity, I oversee a broad array of issues within three USDA agencies, including the Animal and Plant Health Inspection Service (APHIS), which, among other things, regulates organisms derived through biotechnology. Additionally, several other USDA agencies are looking at herbicide resistant weed issues and I look forward to updating you on those efforts. Sidney Abel, Assistant Deputy Administrator of APHIS' Biotechnology Regulatory Services program, is joining me today.

First I would like to emphasize that at USDA, we support all forms of agriculture—conventional (including the use of genetically engineered (GE) products) and organic—to meet the nation's and the world's need for food security, energy production, and the economic sustainability of farms. As the world's population increases, the demand for food is growing and the land available to farm is shrinking. Innovation in agricultural production systems is vital to maintain the competitiveness of the U.S. agricultural sector and to help supply the world's food needs. This is why USDA is pursuing policies that promote the coexistence of conventional, organic, and GE crops. USDA believes that our future food security necessitates that all types of agriculture be able to coexist and thrive.

At the same time, it is critical that we ensure our regulatory oversight is consistent, effective, and science-based, that we are keeping pace with the latest scientific developments, and that we do so transparently. As you know, the Plant Protection Act authorizes USDA, through APHIS, to regulate the importation, interstate movement, and safe field testing of GE organisms that may pose a pest risk to plants. In regulating the products of biotechnology, APHIS works closely with the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency (EPA). Together, we ensure that the development, testing, and use of the products of biotechnology occur in a manner that is safe for plant and animal health, human health, and the environment.

In March 2008, APHIS Administrator Cindy Smith updated this Subcommittee on a number of actions the Agency had taken to build a strong program for regulating the products of biotechnology. This included the development of more detailed environmental analyses, increased oversight of pharmaceutical and industrial crops, and the creation of a dedicated staff for compliance and enforcement. Today I would like to update you on more recent initiatives

that we are undertaking with our biotechnology regulatory program, as well as discuss activities we are undertaking to address herbicide resistant weeds.

USDA's Biotechnology Regulatory Program – A Constant Evolution

USDA's biotechnology regulatory program has been in place since 1986, and as I mentioned, we continue to evolve as the field of biotechnology grows and changes. Over time, we have developed a framework for regulating the products of biotechnology that is rigorous and science-based, and which serves as a model globally that encourages the safe and unimpeded trade in these products. Since the program began, APHIS has effectively overseen the safe adoption of products of biotechnology, with 26,000 field trials grown under our notification procedures and 3,000 field tests grown under the permitting process, encompassing field trials at 86,000 different locations. In addition, we have deregulated over 75 products in that time. While our current biotechnology regulations have been effective in ensuring the safe introduction of GE organisms, we're constantly learning from our experiences, reforming, and refining our first-rate program to protect American agriculture and the environment.

The broadest of these efforts is a comprehensive update to our current biotechnology regulations—to better position APHIS to address new challenges, as well as meet current needs in evaluating and addressing the plant pest or noxious weed risks associated with regulated GE organisms. We accepted public comments on the proposed regulatory changes for over 6 months and held 5 public meetings, resulting in over 66,000 public comments by the time the comment period closed last June. Many important policy issues were raised, and USDA's policymakers are currently examining those issues to determine how to proceed. Ultimately, we want to advance a rule that will continue to support innovation in biotechnology in a responsible way that provides farmers and consumers with safe and beneficial options.

In addition to our larger effort to improve our biotechnology regulations, we have made other changes to keep pace with innovation in this growing field. We have welcomed the critical looks taken by the Government Accountability Office and USDA's Inspector General, and have made improvements to our regulatory program consistent with their recommendations. We have addressed the majority of recommendations—many which were in line with ongoing Agency initiatives at the time—through efforts such as requiring additional information on field trials and enhancing tracking of inspections and field test reports.

Additionally, the 2008 Farm Bill included recommendations that APHIS had made and begun implementing in late 2007 to improve the management and oversight of regulated biotechnology products. A number of those recommendations are addressed in our proposed revisions to our biotechnology regulations. Others are ongoing, such as our partnership with the Association of Official Seed Certifying Agencies to examine isolation distances for field trials.

The Farm Bill also directed APHIS to take steps to ensure the quality and completeness of records and to develop standards for quality management and effective research. These and other issues are being addressed through our expanding Biotechnology Quality Management System (BQMS) Program—a voluntary compliance assistance program—to help biotechnology researchers and companies develop plans and manage their operations to comply with USDA's

biotechnology regulatory requirements. The program provides participating organizations with improved management capabilities for regulated activities, and requires internal as well as independent third-party audits to make sure that the quality management system is being followed at all levels of the organization. In 2009, five organizations representing large and small companies and university researchers participated in the BQMS pilot program and helped APHIS refine the program. We are now preparing to implement the refined BQMS program and are soliciting additional organizations to join. We are encouraging broad participation from large and small companies and academic research communities. We are also finalizing the BQMS audit standards and program requirements and have begun training our second cohort of participating organizations.

APHIS' biotechnology program has also evolved as more varied environmental issues have arisen that should be considered under the National Environmental Policy Act (NEPA), as well as in response to several NEPA-related lawsuits on APHIS regulatory decisions. However, it is important to point out that we've made thousands of regulatory decisions without legal challenge, and none of our plant pest determinations have been overturned in court. We have taken these decisions and built into our program process improvements to ensure that we fully document information pertaining to environmental issues so that we meet all environmental requirements.

We have also taken and continue to take other steps to improve the environmental review process within our biotechnology regulatory program. For example, Secretary Vilsack approved a reorganization of APHIS' biotechnology staff that includes the establishment of a new NEPA team that is devoted to preparing high-quality environmental documents to better inform our regulatory decisions.

As we move forward with making future reviews of the potential environmental issues associated with the regulatory requests before the Agency, APHIS will continue to use the best available scientific information, data, and expert advice to prepare the appropriate level of NEPA analysis. We consider each regulatory action on a case-by-case basis, in accordance with Council on Environmental Quality (CEQ) NEPA implementing regulations and the USDA and APHIS NEPA regulations and procedures. And we will continue to consult with EPA on our analyses related to requests to remove products from regulation, which currently include GE alfalfa and sugar beets. In these ongoing consultations, EPA provides valuable feedback to the Agency on its analysis and proposed alternatives. And we are receiving a positive response to our efforts—EPA, in a letter on our draft environmental impact statement (EIS) for alfalfa, indicated no objection to APHIS' determination to grant non-regulated status and rated the draft EIS as "Lack of Objections," which indicates EPA had no concerns regarding APHIS' determination.

Herbicide Resistance – Issues, Challenges, and USDA's Role

At USDA, we recognize that herbicide resistant weeds pose an important challenge. You've asked me to speak to the Subcommittee today about how USDA approaches this issue in relation to the regulation of GE crops. I'd like to lay out this relationship, and then discuss how we're looking at herbicide resistance more broadly within USDA.

First, the development of herbicide resistance among weeds is a natural and evolutionary process. Many weed species evolved resistance to a wide variety of herbicides long before the advent of GE crops, resulting from the common use of herbicides in agriculture for decades. This is not a new concern for agriculture and is not exclusively associated with GE crops. Any time an herbicide or any other weed control tactic is used continually—whether with GE or non-GE crops—it is going to put pressure on weeds to develop resistance. USDA understands that growers are being challenged by these issues, and that they're looking for guidance and assistance. And we want to help, which is why we have a number of initiatives underway that I'll mention shortly.

Second, we are committed to meeting our obligations under NEPA and are committed to performing the appropriate NEPA environmental reviews and seeking the views of the public on these issues. However, while the consideration of herbicide resistance in weeds under the NEPA process informs our decision making, USDA decisions on the regulation of GE crops are ultimately based on plant pest risk, consistent with our authority under the Plant Protection Act (PPA). Relatedly, I would like to clarify, in response to two questions the Subcommittee has asked me to discuss, that, because our regulatory decisions are ultimately based on plant pest risk under the PPA, 1) Herbicide resistance in weeds is not being addressed in APHIS' proposed revisions to its biotechnology regulations and, 2) APHIS has not considered alternatives to full deregulation of a GE product in order to address herbicide resistant weeds, because there must be a plant pest risk to deny a full deregulation, and herbicide resistance does not constitute a plant pest risk.

Third, as policy considerations are made, we must be cognizant not to lose the many benefits of GE crops, such as overall reduced pesticide use, increased use by farmers of less damaging pesticides, and decreased soil erosion due to increased use of no-till farming. According to the National Research Council's 2010 report, *The Impact of Genetically Engineered Crops on Farm Sustainability in the United* States:

For GE farmers, the general increase in yield, reduction in some input costs, improvement in pest control, increase in personal safety, and time management benefits have generally outweighed the additional costs of seed. The use of [herbicide resistant] crops...has generally improved weed control...improved farmers' incomes by saving time thus facilitating more off-farm work or providing more management time on the farm.

Additionally, advances in biotechnology have provided farmers with safe, environmentally friendly tools for feeding our country and the world. If we limit the use of herbicide tolerant crops, farmers will likely have to return to older, often costly, and less environmentally-friendly weed control methods. At the same time, we are mindful of the economic impact on farmers caused by herbicide resistant weeds. This is why, as I'll discuss next, we are investing in research on solutions to this growing issue.

Multiple USDA agencies are engaged in addressing herbicide resistant weeds through research, education, and partnerships with other Departments and outside groups. USDA's National Institute of Food and Agriculture (NIFA) supports research, education, and extension programs

in the Land-Grant University System and other partner organizations. In 2009, NIFA relaunched its competitive grants program as the Agriculture and Food Research Initiative (AFRI), and offered \$4.6 million in the Biology of Weedy Invasive Species in Agroecosystems program area. In 2010, NIFA restructured AFRI to be more responsive to important national issues. Of the five societal challenge areas scientists receiving grants will work under, weed science is included in both Climate Change and Global Food Security, and can also be addressed under the Sustainable Bioenergy Production focus area.

Providing the connection between the results of scientific studies and their actual application on farms is key to addressing herbicide resistance among crops derived through conventional methods and biotechnology. This is why NIFA supports Extension outreach programs to actively disseminate research findings to agricultural producers who could benefit from new knowledge about the management of herbicide resistance. For example, Extension weed scientists along with Extension integrated pest management and pesticide safety education specialists regularly discuss the issue of herbicide resistance management during training sessions and field day activities with growers. NIFA is also supporting the development of a web-based training system, called IPM³, which offers training in a wide variety of topics related to integrated pest management (IPM). IPM³ offers a weed module that includes herbicide resistance issues and management strategies. Anyone who completes this training will have a good understanding of weed biology and science-based management strategies that will reduce the potential for the development of herbicide resistance.

USDA's principal in-house research agency, the Agricultural Research Service (ARS) is funding nearly \$4.4 million in herbicide resistant weed research in FY 2010, which is part of ARS' \$36 million research effort this year on all weed science issues. I will briefly mention just two of the research projects underway. First, scientists at ARS' Crop Production Systems Research Unit in Stoneville, MS, are conducting studies on the development and management of herbicide-resistant weeds. The studies will examine the mode-of-action of herbicides and mechanisms of resistance, the reproduction and spread of weeds, and the development of integrated weed management techniques, in order to develop strategies for sustainable management of existing herbicide-resistant weed populations and to prevent future incursions. Second, scientists at the Natural Products Utilization Research Unit in University, MS, are conducting studies to discover natural product-based chemistries in order to provide new tools to control weeds resistant to current herbicides.

Additionally, APHIS has partnered with the Weed Science Society of America (WSSA) to identify methods being used to manage the spread and development of herbicide resistance in weeds, assess their effectiveness and degree of adoption, understand the reason for adoption or non-acceptance, and identify what can be done to increase the use of integrated resistance management programs. WSSA also recently completed a project for APHIS, in coordination with EPA, to understand the extent of herbicide resistance in managed ecosystems.

While these are just a few examples of USDA's efforts to address herbicide resistant weeds, we are committed to continuing to work with our partners to identify potential solutions and alternative techniques and technologies to address this important issue. This is going to require a coordinated effort by everyone involved—the government, researchers, the agricultural

community, technology and crop protection companies, and public interest groups, to name a few.

Moving Forward with Addressing Biotechnology in USDA

Biotechnology is a critical tool in addressing important global issues, including food security, biomass production, sustainability, and climate change. USDA continues to be committed to a strong, science-based regulatory system that ensures that the products of biotechnology are safe for agriculture and the environment, food, and feed. At the same time, we continue to see the direct results that the benefits that biotechnology can offer.

With that in mind, we are working to maintain rigorous polices and regulations that ensure product safety. We are also working to ensure that our policies and regulations keep pace with new technologies as they develop. And we want to develop and implement policies that promote the coexistence of genetically engineered, conventional, and organic crops, to help meet the agricultural challenges and consumer needs of the 21st century. Products produced through biotechnology will continue to be an important part of U.S. agriculture, and USDA has a complex and critical role in protecting consumers, the environment, and the farm economy while also contributing to global food needs.

Herbicide resistant weed development is not wholly a biotechnology issue, and we at USDA are looking at it in a much broader context to determine how everyone involved with this issue can evolve to address this challenge. Our agricultural producers are a resilient group, and we are confident that together, we can find sound solutions that make sense.

Thank you for the opportunity to testify today. I'd be happy to answer any questions.