

APHIS Administrator Dr. Gregory Parham
Remarks for the Biotechnology Industry Organization (BIO)
Food and Agriculture Section Governing Board
June 27, 2011

- Thank you for the opportunity to speak with you today.
- I've been the Administrator of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) for 2 months now. Although I'm new to this role, I'm not new to the Agency or to USDA.
- Since I first came to USDA in 1982, I've served in a number of roles—including stints with the Food Safety and Inspection Service (FSIS) and Cooperative State Research, Education, and Extension Service, now called the National Institute of Food and Agriculture.
- My father, a veterinarian like me, spent his entire civilian career in APHIS and its predecessor agencies. A lot has changed since my father began helping to eradicate and control diseases 60 years ago. One of the most dramatic changes has been the genetic era ushered in by the discoveries of Watson and Crick.
- Who better understands this than those of you in the field of biotechnology, which holds promise for addressing any number of domestic and global challenges, from food security to climate change?
- As it turns out, I'm beginning my tenure as APHIS Administrator at a very important time in biotechnology and biotechnology regulation.
- I also understand that June 26 was the 25th anniversary of the Coordinated Framework.
- That said, continuity is important to me, and I am pleased that my predecessor, Cindy Smith, is here with me today.

Cindy Smith's New Role

- Cindy has taken on a new—and newly-created—role in APHIS, serving as the Agency's Chief Advisor for Government, Academia, and Industry Partnership.
- In this capacity, Cindy is well-positioned to help the Agency better engage in and build on partnerships, expanding the pool of expertise, ideas, and resources we draw from when identifying the most effective ways to regulate.
- This goes along with President Obama's call for Government Reform for Competitiveness and Innovation. By actively listening to our stakeholders, and being open to new or creative approaches, APHIS can be more efficient and effective in carrying out our regulation, facilitating the innovation and competitiveness of American business while effectively safeguarding the health of U.S. agriculture.

Budget

- The President's budget request for fiscal year (FY) 2012 reflects this Administration's commitment to bringing safe genetically engineered (GE) crops to market. Specifically, the President's Budget requests more than \$25 million dollars for Biotechnology Regulatory Services (BRS). This represents about a \$12 million increase over our FY 2011 appropriation, the largest single increase in APHIS.
- Although the U.S. House of Representatives has approved a smaller increase—in the amount of \$3.83 million—it is an increase, nonetheless. And this is certainly significant at a time when we, like a lot of Federal agencies, are having to take a close look at all of our programs and make some hard choices in terms of scaling back or eliminating programs.
- The budget is still a work-in-progress and has yet to make its way through the U.S. Senate.

Agricultural Biotechnology Evolves

- Increased financial resources are much needed, of course, given the expanding and changing landscape of agricultural biotechnology, and the fact that we want to ensure that the United States continues to lead the world in sustainable crop production and biotech crop exports.
- There has also been a gradual shift in the traits that GE products are being engineered to produce. While APHIS continues to receive petitions for determination of nonregulated status for herbicide-tolerant (HT) and insect-resistant (BT) crops, HT and BT crops are no longer the only varieties being considered.
- From drought tolerant corn and cold tolerant eucalyptus to soybeans engineered to have enhanced nutritional properties, the biotechnology field is evolving rapidly. We must do the same to keep pace while maintaining a science-based system.

Petition Improvement Process

- APHIS must be flexible and create a regulatory framework that ensures the safety of agriculture while allowing the benefits of novel varieties to be realized. In short, new science and new techniques necessitate a strong, well-defined regulatory structure and improved processes.
- To support continued innovation, APHIS is undertaking efforts to improve the petition process for nonregulated status of GE organisms.
- In recent years, the time it takes to process each petition has grown and this has resulted in a backlog. Currently, we have 22 petitions pending, compared to only 5 petitions pending 10 years ago. The longer timeframes are a result of the increased complexity of petitions; litigation brought against APHIS; and, an increased number of public comments to which the Agency must respond.
- To improve the efficiency of the petition process, we've hired additional staff, we've awarded a number of contracts to expedite processing, and

we're conducting a detailed process analysis to identify efficiency opportunities.

- APHIS has created a team tasked with identifying and implementing solutions to significantly improve the speed and predictability of the process. The team is using "Lean Six Sigma" techniques, a set of highly effective business process tools that have significantly improved many other business, manufacturing, and service systems. They are analyzing data about the current petition process, which will be used to inform decisions about how to best improve it.
- Our efforts are bearing fruit. We're on track to meet or exceed our target of publishing in the Federal Register four final determinations this year, and to publish six petitions with draft environmental assessments for public comments.

National Environmental Policy Act (NEPA) Team and Pilot Project

- We're also reorganizing our biotechnology staff to streamline responsibilities. For example, we've established a National Environmental Protection Act (NEPA) team devoted exclusively to preparing environmental documents.
- This will free up plant pest risk assessors to focus only on pest risk. Meanwhile, the NEPA team can concentrate on preparing high-quality environmental documents to better inform our regulatory determinations and strengthen them against legal challenges. APHIS recently hired an additional member of the NEPA team, bringing the total on the team to five.
- In addition, we've begun implementing a NEPA pilot project to evaluate the effectiveness of applicant-prepared or -funded environmental documents. This project will allow third-party contractors to conduct environmental analyses for petitions under the direction of APHIS and through applicant funds. It will also test the feasibility of applicants preparing environmental reports for their submitted petitions.
- In early April, APHIS announced that it is seeking participation in the 2-year voluntary pilot project.

- During the pilot project, we'll continue to make APHIS' pest risk analysis and all environmental documents available for public review and comment in the same way that they are in the current process. We'll also make available to the public guidance developed through this pilot and updates on the number and status of petitions in the pilot.
- The White House Council on Environmental Quality (CEQ) has invited Federal agencies to nominate pilot projects that demonstrate a more efficient approach to NEPA implementation and accomplish the goals of improved transparency and informed decision making. Our NEPA Pilot Project applied to be part of this program. [Background: The application period closed on June 15, 2011.]

340 Rule

- In October 2008, APHIS proposed the most comprehensive review and revision of our biotechnology regulations since they were first developed in 1987. I am, of course, referring to the "340 Rule."
- Revising these regulations will allow us to ensure effective oversight for years to come.
- When the third comment period on the proposed rule closed in June 2009, APHIS had received more than 66,000 comments. To gather additional feedback, we also held five public meetings on the proposed rule. Since that time, we've been carefully reviewing the comments.
- Responding to the concerns of our stakeholders and moving forward with these revisions continues to be a high priority. APHIS is currently engaged with USDA policy officials to determine the next steps.

GE and Non-GE Crops

- For all of the dramatic expansion that has happened and continues to happen in the biotechnology field, organic and other non-GE agriculture sectors have also experienced exponential growth over the last 25 years.

- Although this brings increasing challenges, to be sure, it does not represent an inevitable collision course that means growers will have to give up “choice” in the types of crops they can grow and where they can grow them.
- During the public comment period on the final environmental impact statement, or EIS, for Roundup Ready alfalfa, we brought together representatives from various sectors of agriculture and asked them to share their challenges and concerns. That discussion helped indicate areas of consensus, areas of disagreement where further dialogue will be important, and areas where USDA could play a helpful role.

AC21

- To further build on these efforts, Secretary Vilsack announced that USDA would be reestablishing the Advisory Committee on Biotechnology and 21st Century Agriculture, or AC21.
- The committee was originally established in 2003. Under its charter, the AC21 helps USDA maintain an intensive and broad-based dialogue to explore and understand the wide array of issues related to agricultural biotechnology.
- The AC21 will continue to provide USDA with guidance on practical measures and effective tools that can be developed to continue the success of the GE, organic, and other non-GE sectors of agriculture.
- In March, USDA published a notice in the Federal Register requesting nominations for AC21 members. The Department accepted written nominations through mid-April and last week announced the members of the Committee.
- Cindy Smith will serve as Technical Advisor to this committee.
- USDA has also developed a draft charter for the National Genetic Resources Advisory Committee and will soon be publishing a Federal Register notice requesting nominations for committee members.

Closing

- In closing, I want to return to my veterinary background for just a moment to make a larger point.
- You may have seen recent news coverage of the fact that, for the first time ever, an animal disease has been stamped out worldwide. The eradication of rinderpest, a devastating and centuries-old cattle disease, is a remarkable milestone that shows how researchers and farmers working together can prevent disease and increase food availability for all.
- Similarly, agricultural biotechnology holds the promise of new tools farmers can use to ensure that our food supply keeps pace with the needs of our growing planet.
- I've told you today about our efforts to actively listen to stakeholders, and the steps we're taking to expand efficiencies in the petition process while maintaining a science-based system.
- But I can't emphasize enough the role that industry-to-industry efforts are going to play in charting a course as we move forward.
- Industries need to talk with each other and build trust among sectors if we're going to make sure that everyone—from growers to processors to consumers—will have the “choice” that we all value so highly.
- We all want to keep American agriculture dynamic, our products abundant, and our choices numerous.
- Thank you again for the opportunity to speak with you today.