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**of the**
**House Committee on Oversight and Government Affairs**

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Thank you for the opportunity to be here today. I am Cindy Smith, Administrator of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS is a multi-faceted Agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating organisms derived through biotechnology, administering the Animal Welfare Act, and carrying out wildlife damage management activities.

I began my career with APHIS in 1979, and prior to becoming Administrator was Deputy Administrator of APHIS' Biotechnology Regulatory Services (BRS), shaping the agency's biotechnology regulatory structure, establishing more rigorous requirements for field tests of crops derived through biotechnology, and initiating efforts to review and strengthen the agency's overarching biotechnology regulations. Michael Gregoire, current Deputy Administrator of BRS, is here with me today. We are pleased to provide the Committee with an overview of APHIS' role in regulating agricultural biotechnology.

Biotechnology is a vibrant and promising field that has generated substantial academic and commercial interest, and as Federal regulators it is critical that we keep pace with this new technology. Since USDA first began regulating biotechnology in 1986, we have overseen more than 21,000 permits and notifications for field tests or movements of organisms derived through biotechnology. Here at APHIS, we are committed to meeting not only the challenges that we can see ahead on the horizon but also those that science has yet to discover. It is our responsibility to thoroughly evaluate organisms derived through biotechnology to determine whether they pose a plant pest risk and to ensure they are just as safe for agriculture and the environment as traditionally bred crop varieties, which have been the cornerstone of American agriculture. If they do pose a plant pest risk, it is our responsibility to ensure that such organisms are appropriately regulated and confined.

The regulation of plants derived through biotechnology is where APHIS has the most regulatory focus. The Agency has long recognized that plant-derived biotechnology research was increasing and becoming much more complex. In order to ensure that the Agency remained at the forefront in developing appropriate regulatory policies to address the latest advances in the technology, APHIS created BRS in June of 2002. The program, which started with 25 employees, has grown to a staff of more than 60.

APHIS' regulation of biotechnology has changed a great deal since I first joined BRS, and even more so since 10 or 20 years ago. The creation of BRS was an important step in APHIS' overall

enhancement of the way we regulate biotechnology. While APHIS had adequate controls in place 20 years ago to regulate biotechnology, we recognized that the world we operated in was changing as the field of biotechnology grew. So too did we acknowledge that as we gained increasing experience in regulating biotechnology, we must develop a robust regulatory system using that new knowledge and the latest science available.

With the creation of BRS, we also recognized the need to broaden our outreach to stakeholders beyond the industry that we regulate. As a result, BRS has made a concerted effort to reach out to stakeholders interested in biotechnology including states, tribes, non-governmental organizations, organic growers, food and grain industry, commodity groups, biotechnology providers, and others to make sure that they fully understand the important regulatory changes that have taken place.

APHIS has also strengthened its two-way communication with a varied group of stakeholders through the USDA Advisory Committee on Biotechnology & 21st Century Agriculture. This committee was established in 2003 to examine the long-term impacts of biotechnology on the U.S. food and agriculture system and USDA, and provide guidance to USDA on pressing issues related to the application of biotechnology in agriculture. The committee has 20 members, including academic scientists; representatives from consumer and environmental groups; representatives from biotechnology, food, and shipping industries; farmers, extension specialists, and ex officio members representing other Federal and State agencies. The Committee recently addressed coexistence among diverse agricultural systems in a dynamic, evolving, and complex marketplace through a report released on March 5, 2008, and has addressed other topics including the impacts of mandatory labeling and traceability requirements for biotechnology-derived crops, opportunities and challenges in agricultural biotechnology in the decade ahead, and planning for the future.

In the last 6 years, we have made a number of significant regulatory changes as well as numerous revisions to permit requirements and our decision making process in order to review and further strengthen USDA's existing biotechnology regulatory system. This includes the development of more rigorous measures for crops producing pharmaceutical and industrial compounds, initiation of a process to revise APHIS' current biotechnology regulations, and the launch of a new quality management system for biotechnology developers. I am confident that all of these changes have made a considerable, positive impact on our regulatory system for biotechnology, and that because of this, we are less likely to face the challenges we have in the past.

Regulation of biotechnology is a responsibility that we share with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Under what is known as the Coordinated Framework, we work in concert to ensure that products derived through biotechnology have been reviewed for safety not only for agriculture and the environment, but also for the food supply. APHIS is responsible for protecting agriculture and the environment. FDA has primary oversight of the safety of food and animal feed. EPA regulates pesticides, including crops with plant-incorporated protectants (pesticides intended to be produced and used in a living plant) to ensure public safety from their use, including pesticide residue on food and animal feed. This coordinated effort is critical for reassuring industry, consumers, and other

groups—both here in the United States and, increasingly, abroad—that biotechnology-derived crops, animal vaccines, and other products are rigorously reviewed for safety.

**Biotechnology in the United States**

Before I provide you with a more detailed explanation of APHIS' role in regulating organisms derived through biotechnology, I would like to discuss this issue more broadly as it relates to U.S. agriculture and related industries. First, it is imperative that I mention that APHIS regulates agriculture biotechnology products; however we do not promote their use. That being said, it is important that we remain cognizant of trends and information in this country as well as around the world, so that we can respond and adjust our regulatory system appropriately.

Biotechnology is being increasingly adopted around the world for a variety of reasons such as environmental benefits from decreased pesticide use, increased crop yields, and enhanced nutritional value. According to a report released last month by the International Service for the Acquisition of Agri-biotech Applications, in 2007, the United States retained its #1 ranking for adoption of crops derived through biotechnology, with 50% of the world's crop area. We were followed by Argentina, Brazil, Canada, India, and China. And in 2007, USDA National Agricultural Statistics Service NASS reported that 89% of soybean, 92% of cotton, and 86% of corn planted in the United States were biotechnology varieties.

I point these statistics out because it is important to recognize that biotechnology is being adopted in the United States. The U.S. system for regulating biotechnology is based on safety; however the U.S. agricultural industry takes into account many other considerations related to biotechnology such as market effects, international acceptance of the technology, and costs to grow a specific crop. APHIS plays a critical role in biotechnology development in the United States, and that is to determine, based on science, whether a crop derived through biotechnology poses a plant pest risk which may threaten agriculture and the environment, and to take appropriate steps to protect other crops until the plant pest potential can be determined. We achieve this through a specific regulatory structure that guides the safe introduction of organisms derived through biotechnology. Our role as regulators is to maintain a transparent system in which the safety of plant health and the environment is the priority, and once safety is established, to allow the production of all crops deemed to be safe by APHIS, in consultation with our partners in the Coordinated Framework.

As I mentioned, we recognize that there are other factors, beyond safety, for the agricultural industry to consider. That said, it is up to the entire U.S. agricultural industry to determine how to grow individual crops—whether they be traditional, organic, or biotechnology-derived—in a way that will preserve their identity and meet the demands of their markets. For example, the 89% of soybeans grown in the United States have biotechnology-derived traits and have been deemed by APHIS to pose no greater plant pest risk than the 11% of traditional soybeans being grown. Because plant pest risk has been determined not to be a factor in these plants, it is now the responsibility of traditional growers as well as growers of crops derived through biotechnology to take the steps they need to address market issues beyond that risk.

As we monitor the trends in biotechnology in our country and around the world, our regulatory system continues to focus on the safety of the products derived from biotechnology, as the science behind it evolves. We believe it is in the best interest of U.S. agriculture to focus our efforts on these priorities while allowing the industry to determine how varied products can be grown and coexist successfully.

## Regulatory Overview

For our part in the coordinated Federal effort, APHIS, under the Plant Protection Act, regulates the interstate movement, importation, and field release of plants, insects, and microorganisms derived from biotechnology through permitting and notification procedures. APHIS works to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of plants derived through biotechnology.

### The Permitting and Notification Process

APHIS' field testing requirements for regulated plants are designed to prevent the unintentional environmental introduction, whether by pollen movement, seed or grain commingling, or other means, of a protein or trait produced in these plants that would present a potential plant pest risk to agricultural crops or the environment. Simply put, we don't allow field trials and other introductions of plants derived through biotechnology without adequate safeguards in place to prevent the spread of plant pests.

Companies, universities, and other researchers wishing to introduce a new plant derived through biotechnology must obtain APHIS' authorization before proceeding. This is a step-by-step process in which the applicant must meet multiple requirements. Depending on the nature of the plant, the developer files either a notification or a permit application with APHIS. With either process, the developer must adhere to APHIS regulations and requirements to ensure, through appropriate measures, confinement of the regulated material.

Most plants derived through biotechnology qualify for, and are field tested under, the notification process. The notification process expedites approvals for field testing for certain types of low-risk plants that APHIS has considerable experience in regulating. Examples of plants that may qualify for field testing under the notification process include those altered for pest resistance, herbicide tolerance, male sterility, and delayed fruit ripening. To qualify for the notification process, a plant or trait must meet six safety-related eligibility criteria that center on the plant's potential to pose a risk to plant health or the environment. An applicant must submit required information on the movement, importation, or field release, which APHIS scientists review to determine whether to authorize the applicant's request. To ensure confinement, the developer must perform the field test in a way that meets performance standards that are specified in APHIS' regulations. If a plant does not meet the criteria for notification, the applicant must follow the permitting process.

Permits are more restrictive than notifications and are used for any type of biotechnology-derived plant that may pose an elevated risk to plant health or the environment, or for which APHIS has less regulatory experience and familiarity, such as plants engineered to produce pharmaceutical or industrial compounds. In addition to detailed information on the biological

properties of the biotechnology-derived plant, the permit applicant also must provide thorough descriptions of how field tests will be performed, including specific measures for ensuring confinement and reducing any potential risk that may be associated with the plant. Applicants must also detail how the crops at the site will be destroyed once the field test is complete to prevent persistence in the environment. The planting conditions detailed in the application must meet or exceed the stringent requirements set forth by APHIS. These requirements are specific to each plant variety, and we continually evaluate them to ensure that the latest scientific evidence is taken into account. Using this information, APHIS scientists create a set of permit conditions that applicants must meet when conducting approved field trials or transporting plants derived through biotechnology. Both the permitting and notification process are subject to the requirements of the National Environmental Policy Act (NEPA).

APHIS is committed to ensuring that state interests are fully considered and accommodated in the Agency's permit and notification review processes. Before approving a notification or permit field test in any state, we provide state officials with detailed information about the proposed field test for review and concurrence. If a particular state has science-based concerns, BRS works with that state to address the outstanding concerns, altering test requirements or adding additional safety- or risk-based permit conditions that the state feels is necessary. States are also notified before APHIS issues a permit for the importation or interstate movement of regulated organisms derived through biotechnology.

Pharmaceuticals and Industrials

Science is moving rapidly for crops producing pharmaceuticals and industrials. We recognize that the regulation of these crops must be approached differently than the regulation of other crops derived from biotechnology, and have taken a proactive approach to safely regulating these types of field tests. APHIS' recent efforts to strengthen regulations have provided additional assurances that field trials are safe for agriculture and the environment.

Developers have produced pharmaceutical and industrial compounds using rice, corn, barley, tobacco, and safflower. These crops are grown to produce research chemicals, vaccines, human antibodies, and human blood proteins. Although there has been much attention on these products, relatively few pharmaceutical and industrial field tests have actually taken place. About 60 permits to field test crops that produce pharmaceutical and industrial compounds have been issued since 2003. In comparison, we've approved thousands of field tests for crops derived through biotechnology during that time. APHIS issues permits for crops that produce pharmaceutical and industrial compounds and determines appropriate permit conditions on a case-by-case basis. The Agency conducts NEPA analyses, some of which include public comment periods, to evaluate the environmental effects of such regulatory proposals. I will discuss NEPA compliance in more detail shortly.

We expect research into crops that produce pharmaceutical and industrial compounds to continue growing and that's why we've made changes in our regulatory process to make certain that these crops are evaluated rigorously. In 2003, APHIS imposed new measures for all crops that produce pharmaceuticals and industrials. We increased APHIS' role in the oversight of these products, as well as requirements for the regulated community. We imposed more stringent confinement measures requiring increased isolation distances and fallow zones, the use of

dedicated farm equipment, and restrictions on post-harvest land use on planting food or feed crops on land used to produce pharmaceutical and industrial crops, among other measures.

To ensure that permit conditions for crops producing pharmaceutical or industrial compounds are met, APHIS inspectors conduct at least 5 inspections during the growing season for these crops. These inspections coincide with key times during the growing season: pre-planting, after planting, just prior to harvest, at harvest, and post harvest. After the field test is complete, Agency inspectors follow up with 2 additional inspections to ensure that the plot was completely destroyed and no plants remain.

Compliance

Given the growing scope and complexity of biotechnology, now more than ever, APHIS recognizes the need for scientifically sound, effective safeguards and greater transparency of the regulatory process to ensure that all those involved in the field testing of biotechnology-derived crops understand and adhere to the regulations set forth by the Agency. This need is echoed by the biotechnology industry, stakeholders, and consumers. To that end, in 2003, APHIS established a dedicated Compliance and Enforcement unit in BRS to further ensure adherence to permit conditions.

To ensure compliance with the permit or notification conditions, APHIS inspectors perform targeted inspections and audits of field tests using the relative risk of each type of trial to determine the frequency and number of inspections performed. For example, for sites where developers are cultivating plants to produce pharmaceutical and industrial proteins, APHIS generally inspects seven times throughout field testing, including before, during, and after the field trial. APHIS also maintains oversight of the movement of regulated plants to and from field trial locations. For notifications, which pose less risk and APHIS has more familiarity, criteria are established so that a percentage of these field trials are inspected. This permitting and notification system is designed to restrict introductions of biotechnology-derived plants and plant materials as long as they are regulated by the agency. Under APHIS regulations, companies, universities and other researchers are required to report immediately, orally and in writing, any potential problems, so that the issue can be addressed as quickly as possible.

We at APHIS take compliance and enforcement very seriously. The Agency has authority under the PPA to take or order remedial measures which include the authority to hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of regulated materials if it is determined that such measures are necessary to prevent the dissemination of a plant pest within or throughout the United States. In addition, the PPA allows for civil penalties up to $500,000 for violations of the Agency's biotechnology regulations.

Compliance with APHIS' stringent permit conditions is high, and that is due in large part to the Agency's efforts to work with researchers to ensure that they understand our requirements and can implement them in the field. There have been relatively few compliance incidents, with only 297 in the past five years. Of those, about half were considered minor, such as printing the incorrect name on a permit. We take all violations of our authorities under the PPA seriously and will pursue a variety of enforcement and legal actions, when appropriate.

APHIS' permitting system is designed to prevent any unauthorized spread of materials derived through biotechnology. In August of 2002, the White House's Office of Science and Technology Policy issued a policy statement that acknowledges the potential for low level mixing of genes and gene products from unintended plant sources, and describes the actions the coordinated framework agencies would take in addressing this issue. This mixing can be caused by natural processes such as the movement of seeds or pollen, or human-mediated processes associated with field testing, plant breeding, or seed production.

APHIS recognizes the interest, both domestically and internationally, by stakeholders in understanding how the Agency responds to situations involving an unauthorized low level presence of regulated organisms derived through biotechnology. As many other countries are determining how to approach low level presence situations, APHIS has taken a leadership role in articulating its approach in responding to low level presence. In situations involving the unauthorized release of regulated biotechnology-derived materials, APHIS responds with remedial action that is appropriate to the level of risk and warranted by the facts in each case. We always initiate an inquiry to determine the circumstances surrounding the release, evaluate the risk, and determine, if appropriate, remedial and enforcement actions. If an incident would result in the introduction of material that could pose a risk to agriculture or the environment, the Agency will use its authority under the PPA to mitigate that risk and require remediation measures.

In those cases in which the occurrence of a plant material derived through biotechnology poses no risk to plant health and the environment, APHIS may determine that remedial action is not necessary. This could include occurrences involving a plant that qualifies for APHIS' notification process, which is used for those plants that present minimal risk, as well as if the biotechnology-derived plant is similar to another that has already been deregulated, or shown to not pose a plant pest risk. However, even if APHIS determines that no remedial action is required, this does not preclude the Agency from taking legal action against a company or individual for violation of APHIS regulations.

Deregulation

After a plant derived through biotechnology has been field-tested extensively and the developer can show that it does not pose a plant pest risk, the developer may file a petition for deregulation, which would enable the petitioner to commercialize the product without further APHIS oversight. The developer must submit extensive information about the plant's biology and field test results. In considering the petition, a multidisciplinary team of APHIS scientists carefully reviews the data submitted by the developer, and also weighs other pertinent scientific studies and information.

After conducting an environmental assessment (EA) or an environmental impact statement (EIS) and seeking public comment, APHIS may approve a petition for deregulation if it reaches the conclusion that the biotechnology-derived plant does not pose a plant pest risk. Even if APHIS deregulates a particular biotechnology product, the company must still comply with applicable FDA or EPA requirements. Since we began regulating organisms derived through biotechnology in 1986, we have deregulated more than 70 products.

Alternatively, an extension process can be used in cases where a biotechnology-derived plant is similar to a previously deregulated plant. The extension process, which was established in 1997 and has been used numerous times since, is based on the premise that a plant derived through biotechnology that is similar to a previously deregulated plant with respect to plant genotype and the expressed protein(s) is also similar in terms of any potential risk. Based on a thorough review of information in the extension request, which includes data showing similarity, APHIS may conclude that the new plant, like the previously deregulated plant, does not pose a plant pest risk and therefore will no longer be regulated.

National Environmental Policy Act

While APHIS' determination about the safety of a product derived through biotechnology ultimately is determined on the basis of its plant pest risk to agriculture and the environment, we also must weigh potential impacts on the quality of the human environment as required by NEPA. The Act guides Federal agencies on the integration of environmental and public considerations into decisionmaking processes. NEPA regulations ensure that environmental impacts of proposed actions and reasonable alternatives to those actions are considered but it does not require that the agency plan of action necessarily be the most environmentally benign. That is, under NEPA, environmental impacts inform, not dictate, the decisionmaking process.

Before approving notifications or granting permits for introductions of biotechnology-derived organisms that are considered new or novel (the crop species, the trait, or both), APHIS drafts an EA or EIS, when appropriate, and gives the public the opportunity to comment. We also prepare an EA or an EIS, as appropriate, when determining if a plant or microorganism derived through biotechnology can be deregulated.

The EA preparation process includes consultation and coordination with other Federal, Tribal, State, or local agencies when appropriate; publication and comment on the draft EA; and publication of the final EA. The EA discusses the need for the proposed action, possible alternatives including the "no action" alternative, the potential impacts of the proposed action and alternatives, and information regarding any consultation or agency coordination. If the proposed action does not have a significant impact on the environment, APHIS will issue a Finding of No Significant Impact (FONSI). We have substantially enhanced our development of EAs over the years as we have gained more knowledge and experience with the process. For example, EAs developed by APHIS now contain much more detailed scientific analysis than they did in the past and include more scientific references, analysis of the effects on organic production, and a toxicity table for effects of GE crops on non-target insects.

If we determine that any aspect of the quality of the human environment may be significantly affected by a proposed action, then we will prepare an EIS, which involves a more in-depth inquiry into the proposal and any reasonable alternatives to it. The EIS evaluates the environmental impacts of broad agency actions, such as rulemaking. APHIS may also use the NEPA process to better inform the decisionmaking behind projects of a more narrow scope, such as the deregulation of a specific crop. The evaluation includes a discussion of direct, indirect, and cumulative impacts resulting from the adoption of one of several reasonable alternatives, including the no-action alternative. Additionally, APHIS may also discuss actions that would mitigate any impact of the biotechnology product. An EIS is developed by a multidisciplinary

team and can take several months to several years to complete. The environmental impact statement preparation process includes consultation and coordination with other Federal, Tribal, State, or local agencies when appropriate; publication and comment on the draft EIS; publication of the final EIS; and in some cases, public meetings.

Because APHIS is committed to the NEPA process, the Agency has requested an increase in fiscal year 2009 of $4 million and 21 staff years to further strengthen its regulatory biotechnology oversight through enhanced environmental review and assessments, as well as monitoring and surveillance.

Alfalfa EIS

In order to comply with a March 12, 2007, preliminary injunction order by the United States District Court for the Northern District of California, APHIS brought back under regulation Roundup Ready (RR) alfalfa, until the agency issues a new determination consistent with court requirements. APHIS had previously prepared an EA to determine whether deregulating the alfalfa could have a significant impact on the environment and issued a finding of no significant impact.

The court did not overturn federal conclusions that the alfalfa did not pose a plant pest risk and that it was safe for food and feed purposes, but rather concluded that APHIS had not adequately documented potential environmental impacts. A future decision regarding the deregulation of RR alfalfa will be issued after the completion of an appropriately documented EIS.

To inform the public of our intent to prepare an EIS and invite their participation in the scoping process, a Notice of Intent (NOI) was published in the *Federal Register* on January 7, 2008. The NOI identifies and seeks public comment on potential issues and alternatives to be studied in the EIS. APHIS has identified 18 issues that will be studied in the EIS, including impacts on food and feed, U.S. trade, and threatened and endangered species. The public comment period closed on February 6, 2008, and APHIS is reviewing the responses and is evaluating how these responses may affect the scope of the analysis. Following this analysis, a draft EIS will be prepared and published for public comment.

## Regulating for the Future

Programmatic Review and Revision of the Biotechnology Regulations

Efforts to further strengthen our regulations and improve compliance and enforcement have enhanced our ability to protect agriculture and the environment while allowing for the safe field testing, interstate movement, and importation of crops derived through biotechnology. However, as I've mentioned throughout my testimony, we recognize that the science of biotechnology is going to continue to evolve and we must be prepared to keep pace with those changes. That is why APHIS announced plans to review and strengthen our current biotechnology regulations in January 2004, and released a draft EIS related to this proposal in July 2007.

Let me say a few words about our plans for reviewing and strengthening our regulations. Again, we want to make sure we prepare for the future, as the science and technology behind these products continue to evolve. But, just as importantly, we also want to review the entire history

of our regulation of these products and apply the knowledge and experience we've gained to develop a comprehensive revision of the regulations. As I've said, over the last 20 years, we've done an excellent job of making adjustments to our regulations and approach to regulating these products. But these have been incremental changes over time; we are now focused on consolidating and modernizing those previous adjustments, as well as making other broader changes.

The draft EIS is one step in the regulatory revision process and helps inform the development of new regulations. APHIS will use the information and analysis in the draft EIS, public comments that are received, and the latest scientific information to develop new regulations through the rulemaking process. As a part of the rulemaking process, a final EIS will also be prepared to address the public comments received in response to the draft EIS.

The draft EIS evaluates a number of environmental issues associated with potential revisions to existing regulations. Under the PPA, APHIS has broad authority to safeguard American agriculture and protect the environment. The draft EIS considers utilizing authorities in the PPA to expand APHIS' regulatory scope beyond biotechnology-derived organisms that may pose a plant pest risk to include those that may pose a noxious weed risk and those that could be used as biological control agents. In addition, these broader authorities would allow APHIS to evaluate a wider range of impacts to support the Agency's regulatory decisions.

Through the draft EIS, APHIS is also evaluating a tiered permitting system based on potential environmental risk. Under such a system, APHIS would require greater confinement measures and more inspections for field testing biotechnology-derived organisms posing a greater risk or for those with which the Agency has less familiarity. Additionally, we are evaluating a process for continued oversight of crops that do not meet the criteria for deregulation. This permitting system would provide greater transparency to the regulated community and the public on how each organism would be regulated by APHIS.

Revising the current regulatory system will better allow APHIS to meet current and future needs in evaluating and addressing the risks associated with the introduction of organisms derived through biotechnology. It is essential that APHIS have the ability to conduct rigorous assessments and provide sufficient oversight for new and higher risk categories of products. However, when APHIS has enough experience and familiarity with the safety of certain classes of biotechnology-derived organisms, the program also needs the flexibility to allow for streamlined reviews and less oversight. The proposed changes will allow APHIS to focus its oversight and resources on higher risk organisms, while allowing for additional flexibility for those products that have demonstrated safety.

Biotechnology Quality Management System

Last September, APHIS announced a new, voluntary program to enhance the ability of universities, small businesses, and large companies to meet our current regulatory requirements. APHIS is developing the Biotechnology Quality Management System (BQMS) to help the biotechnology industry become better stewards by focusing on the implementation of best management practices so that problems can be prevented. We plan to implement the BQMS system on a limited basis for evaluation purposes this growing season.

In developing the BQMS, APHIS' goal is to assist the regulated community in approaching research in a manner that ensures the greatest level of security and compliance with our regulations. In this way, we're continuing our efforts to reach out to the regulated community and educate them on systematic approaches that can be taken to ensure compliance with our regulations.

The BQMS consists of two program levels that incorporate industry best management practices and principles established by national and international standard setting bodies. The Level-A program will be designed for participants that do not have formal management systems in place, such as small businesses and universities, and will focus on their ability to develop documented procedures, to identify risk control points, and to take preventive action. On the other hand, the Level-B program is intended for participants that have formal management systems in place and grow biotechnology-derived plants at multiple sites, often through the use of cooperators. To meet the additional complexity of this type of operation, Level-B will incorporate ISO 9001 business standards.

The BQMS will include an audit component to verify that participants have procedures in place and that they are performed correctly to meet the regulatory requirements for any given field trial or movement. APHIS will oversee the BQMS program in partnership with USDA's Agricultural Marketing Service (AMS), which will manage the audit component of the program and accredit third party auditors.

Participating organizations will be required to ensure that all personnel are properly trained on the standard operating procedures for working with organisms derived through biotechnology. They must consider the potential impact of early decisions on later steps in the introduction (e.g., plant choice, equipment choice, field test site). They will be required to identify vulnerabilities in their processes and potential risk control points for any introduction, as well as control measures to minimize the risk or occurrence of unauthorized releases.

The BQMS complements a program called, "Excellence Through Stewardship," which is already underway in the biotechnology industry. While industry's program is focused on quality management to ensure product integrity of biotechnology-derived plant products throughout the product life cycle, APHIS' program will emphasize the quality of the process for safely introducing these organisms in compliance with federal regulations.

The BQMS and its associated audits will complement, not replace, APHIS' regulatory compliance and inspection process by focusing on planning and good management practices that can improve a participant's ability to meet regulatory requirements. The current inspection program will continue to cover specific permits and notifications to ensure compliance with regulations.

Lessons Learned

Since 1985, BRS has carried out an effective regulatory program for plants and plant products derived through biotechnology. During this 20 year period, BRS has developed and refined risk-based regulatory requirements, performance standards and permit conditions. These

requirements are based on the best available science.

Over that period, APHIS has effectively overseen approximately 12,000 field trials under the notification procedures and 1,500 field tests under the permitting procedures. These field tests were conducted at over 65,000 sites under notification and 14,000 sites under the permitting procedures. I'm proud to say that there have only been a handful of situations involving serious noncompliance with our regulations.

But as I've mentioned previously, our goal at APHIS is to keep pace with the changing science of biotechnology and enhance our regulatory system as we gain new insight on ways to protect agriculture and the environment from plant pests and diseases. To that end, in October 2007, APHIS released a "Lessons Learned" document outlining additional changes we are considering to strengthen our regulatory system. The document was developed as a result of the lessons learned from the Agency's investigation into the presence of trace amounts of regulated biotechnology-derived rice in two commercial long-grain rice varieties, as well as other biotechnology investigations. We will continue to thoroughly investigate any such incident and are committed to holding parties responsible if they are found to have violated our biotechnology regulations under the PPA, and are also looking at other ways we can prevent such an occurrence in the future and improve the effectiveness of investigations into compliance incidents. Changes we are considering include, among others, increasing isolation distances, requiring developers to create comprehensive contingency plans, and enhancing recordkeeping.

A number of the potential changes are already underway, and a number are being considered in our programmatic EIS. APHIS has taken steps to improve the capabilities of the ePermits, our online permitting system, to more quickly retrieve information that could be pertinent to an investigation. Applicants can now submit permits and notifications online, and we are currently working with stakeholders to design the inspection and enforcement components of ePermits. In addition, we require contingency plans for field trials of plants that produce pharmaceutical compounds, and are considering implementing these requirements across the board.

APHIS is also partnering with several organizations with specialized experience that will complement our current regulatory work. In the fall of 2007, APHIS and the Association of Official Seed Certifying Agencies put in place an agreement to gather and peer review scientific information regarding outcrossing and isolation distances for six key crops, beginning with rice. The results of this analysis will aid APHIS in ensuring that the latest science is incorporated into biotechnology-derived crop isolation distances. APHIS also entered into an agreement with USDA AMS to provide assistance in the event of future potential violations of our biotechnology regulations. This agreement puts in place a specific blueprint detailing how sampling and testing would be conducted by AMS, as they did with the rice investigation. We are also exploring similar agreements with other agencies to utilize their unique expertise.

Finally, I'd like to close by saying that as we continue to make changes to improve the regulatory system for products of biotechnology, we believe it is essential to always keep in mind that this is a constantly evolving system. As always, APHIS is committed to using the latest science to assess how the system is working and to take the steps necessary to ensure that organisms derived through biotechnology are introduced in a way that is safe for U.S. agriculture and the

environment. We're very excited about the regulatory changes that have already occurred as well as those that are on the horizon. In partnership with our sister Agencies FDA and EPA, we're confident that we're ready for the future of agricultural biotechnology.

Thank you again for the opportunity to be here. I'm happy to answer any questions that you may have.