Thank you for the opportunity to be here today. I am pleased to provide the Committee with an overview of the Department of Agriculture's (USDA) role in regulating agricultural biotechnology.

This is a science that is rapidly evolving, and as Federal regulators it's critical that we keep pace with this new technology. Here at USDA, we're committed to meeting not only the challenges that we can see ahead on the horizon but also those that science has yet to discover. Since USDA first began regulating biotechnology in 1986, we have deregulated more than 60 genetically engineered (GE) agricultural products. In that time, we have also overseen more than 10,000 biotech field tests. It's the responsibility of USDA to thoroughly evaluate GE organisms to verify that they are just as safe for agriculture and the environment as traditionally bred crop varieties, which have been the cornerstone of American agriculture.

This is a responsibility that we share with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), who are also here today. Under what is known as the Coordinated Framework, we work in concert to ensure that biotech crops are safe not only for agriculture and the environment, but also the food supply. 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 regulated for safety.

Regulatory Overview

For its part in this coordinated effort, USDA's Animal and Plant Health Inspection Service (APHIS), under the Plant Protection Act, regulates the interstate movement, importation and field release of GE plants, insects and microorganisms through permitting and notification procedures. In other areas, APHIS regulates biotechnology- derived veterinary biologics under the Virus-Serum toxin Act. The Agency is also evaluating its role in the regulation of GE animals, pathogens and pests under the authority of the Animal Health Protection Act, which was passed as part of the 2002 Farm Bill.

The regulation of GE plants, however, 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 Biotechnology Regulatory Services (BRS) in June of 2002. The program, which started with 25 employees, has grown to a staff of more than 50. In the last 3 years, the program has made a number of changes to review and further strengthen USDA's existing biotechnology regulations. During this
time, BRS has also made a concerted effort to reach out to stakeholders interested in biotechnology, including industry, non-governmental organizations, States and others to make sure that they fully understand the important regulatory changes that have taken place.

In general, 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

risk or potential risk to agricultural crops or the environment.

Companies, universities and other researchers that wish to field test such crops must submit permit applications, with information about the plant variety being tested, the purpose of the test, how it will be conducted, as well as the specific confinement conditions taken to prevent the escape of pollen, plants, or plant parts from the field test site. Applicants must also detail how 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.

APHIS also has a streamlined permitting process, called notification, in place. Most of the field tests carried out in the United States are authorized 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. Under the notification procedure, the regulated article to be field tested must be a plant, and the genetic modifications to that plant must meet established criteria. During the permitting and notification process, APHIS also takes into account the requirements of NEPA.

I want to emphasize that APHIS is committed to ensuring that State interests are fully considered and accommodated in the Agency's biotechnology field test permit and notification review processes. Before any field test can be undertaken in a given State, APHIS officials provide detailed information pertaining to the proposed field test to their counterparts in that State for review and concurrence. If a particular State has science-based concerns about the confinement measures described in the documentation, APHIS works with that State to address the outstanding concerns and add any additional conditions the State deems necessary to ensure that the field test can be conducted safely. The Agency has never approved a field test permit over the objections of State counterparts.

Pharmaceuticals and Industrials

Science is moving rapidly for crops producing pharmaceuticals and industrial, and APHIS has taken a proactive approach to safely regulating these types of field tests. APHIS' recent efforts to strengthen regulations have provided additional assurances to States that field trials are safe for agriculture and the environment. In 2003, APHIS imposed new measures for all crops genetically engineered to produce pharmaceuticals and industrials.

Developers are producing 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 90 permits to field test pharmaceutical and industrial crops have been issued since 1991 in about 15 States. In comparison, we've approved thousands of field tests for GE crops as a whole. This is an area of research, however, where we expect to see more growth and that's

why we've made changes in our regulatory process to make clear that pharmaceutical and industrial crops are evaluated rigorously.

APHIS issues permits for pharmaceuticals and industrials on a case-by-case basis. The Agency also conducts environmental assessments, which include public comment periods, whenever required under the National Environmental Policy Act and based on established safety criteria. APHIS further imposes stringent confinement measures requiring increased isolation distances and fallow zones, dedicated farm equipment, and restrictions on planting food or feed crops on land used to produce pharmaceutical and industrial crops. For example, the isolation distance for open-pollinated corn is 1 mile. This means that such a field test cannot be planted within 1 mile of other corn crops.

To ensure that these permit conditions are being met, APHIS inspectors conduct at least 5 inspections during the growing season for all pharmaceutical and industrial 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 two additional inspections to ensure that the plot was completely destroyed and no left over plants remain. These volunteer plants, if detected, must be immediately destroyed.

Compliance

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. 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 GE crops understand and adhere to the regulations set forth by BRS. This need is echoed by the biotech industry, stakeholders, and consumers. To that end, in 2003, APHIS' Biotechnology Regulatory Services established a new Compliance and Enforcement unit to further ensure adherence to permit conditions. In addition to ensuring that permit conditions and recordkeeping requirements are met by researchers, APHIS has also instituted new training programs for inspectors who inspect and audit field trials of GE crops. This ensures inspectors know what to look for in the field and that they handle each inspection with consistency and uniformity. The unit also encourages self-reporting by researchers should they identify a potential infraction. Under APHIS regulations, companies, universities and other researchers are immediately required to report, verbally and in writing, any potential problems, so that the issue can be resolved as quickly as possible in order to confine the transgenic organisms.

Deregulation

After successfully completing the field-testing and data collection stage of a new plant variety's development, a permit holder can petition APHIS to deregulate the biotechnology crop. In support of this petition, the permit holder must submit further information on the results of the field-testing, in addition to information documenting that the plant poses no risk to agricultural crops or the environment. In considering the petition, APHIS carefully reviews the data submitted by the permit holder, and also weighs other pertinent scientific studies and

information. When APHIS deregulates a biotechnology-derived plant, it does so because the plant poses no pest risk to other crops or plants. After submission of a complete petition, deregulation process requires that APHIS publish a Federal Register notice thereby making the documents available to the public and providing the public with an opportunity to comment. Once APHIS deregulates a particular biotechnology product, the company must still comply with applicable FDA or EPA requirements prior to marketing. In addition, APHIS can bring a product back under regulation at any time if the Agency becomes aware of evidence indicating that the product may pose some sort of plant pest risk.

Environmental Impact Statement

Efforts to further strengthen our regulations and improve compliance and enforcement have improved our ability to protect agriculture and the environment while allowing for the safe field testing of GE crops. 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 in January of 2004, APHIS announced plans to review and strengthen APHIS' current biotechnology regulations. As a result of that announcement, APHIS is currently conducting a programmatic Environmental Impact Statement to evaluate our biotechnology regulations. The decision to undertake this EIS is the result of inter-agency discussions, which included our sister agencies, EPA and FDA.

The EIS, which is currently being drafted, evaluates environmental issues associated with potential revisions to existing regulations. Under the Plant Protection Act of 2000, APHIS has broad authority to safeguard American agriculture and protect the environment. The EIS will look at expanding APHIS' regulatory scope beyond GE organisms that may pose a plant pest risk to include GE plants that may pose a noxious weed risk and GE organisms that could be used as biological control agents.

As part of the EIS, APHIS is also evaluating the benefit of developing new criteria, based on risk, familiarity, and intended use for reviewing applications to conduct GE crop field tests. Under the proposed approach, APHIS would move away from our current system of permits and notifications in favor a multi-tiered permitting system. This new system would utilize the knowledge we've gained about biotechnology in the last 19 years to help streamline the permit process for familiar field tests, so we can focus our resources and attention on new requests with which we have less experience. Over time, this
science-based approach would reduce the regulatory burden and allow APHIS to concentrate oversight on new GE products based on science and potential risk.

The EIS will also consider the environmental effects of exempting, from regulation, the low-level and intermittent occurrence of certain GE organisms that have not completed all applicable review, provided they meet safety criteria and there has been adherence to regulatory requirements. This issue is known by many as adventitious presence.

While I've briefly highlighted some of the main issues, the EIS is much more broad in scope. In fact, the current programmatic review of BRS' existing biotechnology regulations is USDA's largest effort of its kind since the Coordinated Framework for biotechnology regulations was first established in 1986. We've established an ambitious timeline for completing the

comprehensive draft EIS and hope to publish the document in the Federal Register this fall. Throughout this initiative we will continue to coordinate with our interagency partners and communicate with the public to hear their views and ensure that they understand what it is that we're considering. As a result of the initial scoping process we've already received more than 2,000 public comments. APHIS also held several days of meetings to hear from interested stakeholders, including industry, non-governmental organizations and others. As a follow up to that process, BRS will again be reaching out to the public this summer by holding open forums once a month to hear from anyone interested in our regulatory review. These comments will all be considered as we continue to move forward in this process.

Finally, I'd like to close by saying that our emphasis on communications is part of an on-going effort to be more transparent regarding the regulatory process. The easier it is for people to understand our regulations, the more confidence we believe they will have in APHIS' ability to protect 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.