Good afternoon, Mr. Chairman and members of the Committee. I am pleased to appear before you today to discuss the Environmental Protection Agency's (EPA) role in the assessment and regulation of products produced through biotechnology. I welcome the opportunity to participate on this panel and explain what the Agency is doing to regulate biotechnology products and our plans for the future. We work closely with our partner agencies, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) to ensure that crop plants created using biotechnology, and food from such plants, are safe to both people and the environment.

Biotechnology holds great promise. For example, it can reduce our reliance on some older, potentially more risky pesticides, while also reducing potential risks to farm workers and the environment. Given these and other potential benefits, we are committed to ensuring that this technology is used appropriately. The Agency's regulatory decisions are based on rigorous scientific information, high scientific standards, and transparency to promote public understanding and oversight. By following these principles, our program strives to ensure the protection of public health and the environment. Biotechnology is a rapidly evolving field. The federal government's regulatory program must similarly advance to ensure the continued protection human health and the environment. Given our intellectual and scientific investment in regulating biotechnology, the Agency stands ready to meet the future challenges.

Coordinated Framework

In the 1980s, it became clear that companies would soon begin to apply the techniques of genetic engineering to agriculture and that biotechnology products for use in agriculture would soon become available for widespread commercial use. Also at that time, the Federal government began to evaluate its options for regulating commercial products created using biotechnology. In 1986, the federal government, under the auspices of the Office of Science and Technology Policy, released the "Coordinated Framework for Regulation of Biotechnology", which laid out the broad outlines of its approach to regulating biotechnology products. In general, the Framework established an approach to regulating the products of this new technology based on use, not the process used to create them. Rather than seek new legislative authority, these products are regulated using existing laws.

Under the Coordinated Framework, the oversight responsibility for agricultural biotechnology products is shared by three Federal agencies: the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA). Efforts in this Administration, as in previous Administrations, have been aimed at making the coordination between EPA, FDA, and USDA on biotechnology issues even stronger, while ensuring a comprehensive and seamless regulatory system.

Under the Coordinated Framework, products of biotechnology are regulated under existing statutes and in a manner similar to the regulatory approach used for products developed through other techniques. Thus, products of biotechnology intended to be used as pesticides are regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the sections of the Federal Food, Drug and Cosmetic Act (FFDCA) that address pesticide

residues in food and feed. Under the Toxic Substances Control Act (TSCA), EPA reviews novel microorganisms that are products of biotechnology.

Coordinated Framework and Pesticides

Within the Coordinated Framework, EPA regulates all biotechnology products that meet the definition of a pesticide under FIFRA; this includes genetically engineered microorganisms with pesticidal action as well as pesticidal products produced by plants that act within the living plant to protect the plant from pests. The second category is referred to as plant-incorporated protectants, or PIPs.

To fully understand EPA's current regulatory approach to PIPs, some basic information may be helpful. EPA's jurisdiction under FIFRA is limited to pesticides. For example, the sale of a PIP engineered into a plant to assist the plant to resist insect damage would be subject to FIFRA, whereas a plant engineered to resist drought would not. The former comes under EPA authority because the substance produced by the plant is intended to function as a pesticide by "preventing, destroying, repelling, or mitigating" a pest. A plant bioengineered to resist drought, through for example deeper root growth to access water, would be subject to USDA authorities, and any food or feed produced would be subject to FDA authorities.

Up until the end of the 20th Century, plant breeders have supplied farmers with hardier and more disease-resistant crop varieties through conventional breeding. This is done primarily by mating a crop plant with a wild or related plant and selecting offspring with the desired trait, or by inducing mutations in a plant and mating that plant with others while selecting desirable traits. It is in this way that we got bigger roses and more robust tomatoes.

In the early 1980s, scientists began to move genetic information selectively between organisms through biotechnology techniques. The transfer of desired traits could now be accomplished more broadly and more rapidly, including between unrelated species. In the case of PIPs, scientists move genetic material encoding the information to produce pesticidal substances from any source into plants. Information can be moved into a plant, for example, from another plant, a bacterium or virus, an insect or an animal. One of the best known biotechnology product is based upon genetic information from the bacterium Bacillus thuringiensis, or simply "Bt". This bacterium, when sprayed on plants, is toxic to certain types of pest insects that feed on the plant. Through biotechnology, scientists can take the genetic material encoding the information to make the pesticidal protein from the bacterium and place it in, for example, a corn plant. The corn plant can now synthesize its own Bt protein and ward off pests on its own. No external spraying for the target pest is necessary.

Pesticide Registration

In developing our approach for an appropriate risk assessment for these products, EPA has held numerous public meetings with extramural panels of scientific experts; e.g., the FIFRA Scientific Advisory Panel, the Office of Pesticide Programs' Pesticide Program Dialogue Committee, and with interested stakeholders at a number of public hearings and workshops throughout the country. Additionally, EPA makes all of the submitted data concerning human

health and environmental effects available for inspection and review through a public docket. Every new PIP is announced in the Federal Register with an invitation for public comment. Scientific Advisory Panel meetings are open meetings, and comments from interested parties are accepted either in person or in writing. Through this open participatory process the Agency has developed a risk assessment approach for products going through the registration process.

A potential registrant typically comes in for a meeting with our scientific staff, at which time we decide upon the appropriate data requirements to support the Experimental Use Permit (EUP), the tolerance or tolerance exemption, or for the full commercial approval and registration. The studies done under the EUP are used to obtain the data necessary to support the application for the full registration. Under the Pesticide Registration Improvement Act (PRIA), the decision times for such applications are mandated between 18 and 24 months. All PIP decisions have been completed within PRIA timeframes so far.

For the PIPs products EPA has registered to date, we review data in five categories: product characterization, toxicology, non-target organism effects, exposure and environmental fate, and resistance management. Product characterization includes reviewing the source of the gene and how the gene is expressed in a living organism, the nature of the pesticidal substance produced, modifications to the introduced trait as compared to that trait in nature, and the biology of the recipient plant.

For toxicology, an acute oral toxicity test of the pesticidal substances on mice is required. At times, it has not been possible to make enough of the substance for testing purposes in the plant itself so EPA has allowed the exact same protein to be produced by bacteria as long as there are sufficient data to show that the protein produced by the bacteria are identical to that produced by the plant. It should be noted that to date, all of the PIPs reviewed by EPA are proteins. For protein PIPs, EPA requires a digestibility test where the amount of time it takes for the protein to break down in gastric and intestinal fluids is determined. This information is relevant to a simulated determination of the potential of the protein to be an allergen. Determination of whether an introduced protein is likely to be an allergen is one of the major challenges for the Federal agencies. EPA and FDA are working on this issue together. For allergenicity assessment, EPA requires in addition to the digestibility test, tests for heat stability, and a comparison of the structure of the protein to the structures of known food allergens.

For ecological effects, EPA examines the exposure and toxicity of the PIPs to non-target organisms, such as wildlife and beneficial insects. These tests are unique to the crop and pests involved. For example, during the review of the Bt-potato, a test of potential effects of the introduced protein to lady beetles was conducted and showed that there were no adverse effects to these beneficial insect predators because they are related to the target pest, the Colorado potato beetle. For Bt-corn, tests were conducted on the potential effects on fish because field corn may be manufactured into commercial fish food. No effects were observed in the tests. Monitoring of potentially affected organisms in fields planted with PIPs is also required. EPA also has evaluated the degradation rates of the proteins in soil and plant residues.

If adverse effects or potential adverse effects are observed in the testing, a second or higher tier of testing is required to allow EPA to evaluate the risks. EPA routinely consults with USDA and FDA on data reviews of these PIPs. EPA, USDA, and FDA have frequent contact to

insure cooperation and open communication between the agencies.

Currently, EPA has twelve active registered PIP products (see the attached list). Eleven of these products are for a Bt protein. The crops have included potatoes, cotton, field corn, sweet corn, and popcorn. There have also been Experimental Use Permits for Bt tomatoes and Bt soybeans. The Agency has also established tolerance exemptions for pesticide proteins from viruses that have been moved via recombinant DNA technology to plants like watermelon, cucumber, potato, and papaya. In 1998, EPA registered a PIP based on the potato leaf roll virus (PLRV) and a Bt protein. The Bt protein and the PLRV protein were combined to provide virus and insect protection.

In 2001, EPA completed a reassessment of all of the then existing Bt PIP registrations, to make sure that all uses were up to current regulatory and scientific standards. All stakeholders were encouraged to participate and the FIFRA Science Advisory Panel was convened to peer review EPA's findings. As a result, those Bt PIPs that continued to be registered are supported by the latest scientific data requirements and are being used under updated regulatory conditions.

Biotechnology Products under the Toxic Substances Control Act

The Biotechnology Program in EPA's Office of Pollution Prevention and Toxics administers regulatory oversight over the commercial introduction of new microorganisms and the significant new uses of existing microorganisms under its Toxics Substances Control Act (TSCA) authority.

This law gives EPA the authority to take action on "chemical substances" which may present an unreasonable risk of injury to health or the environment. TSCA authorities generally cover all new and existing chemical substances, except for certain products, including: pesticides, tobacco products, certain nuclear material, food, food additives, drugs, and cosmetics.

Under this framework, EPA has established procedures for the regulation of microorganisms that are products of biotechnology as "new chemical substances."
The rule is designed to ensure that EPA can adequately identify and regulate potential risk associated with microbial products of biotechnology without unnecessarily hampering this important technology.

Under Section 5 of TSCA, if a person wishes to commercialize a new microorganism, or plans to introduce such microorganisms into the environment for commercial research purposes, EPA requires a notification at least 90 days prior to commercialization and the submission of certain information. EPA reviews the information to determine whether the intended activity may present an unreasonable risk to health or the environment. Decisions on what action to take for each submission are based upon reviews by a multi-disciplinary team of scientists.

International Activities

EPA is working on several international fronts in an effort to share data and foster collaborative relationships in the field of biotechnology. EPA, in conjunction with USDA and FDA, was instrumental is establishing two working groups within the Environment Policy Committee of

the Organization for Economic Cooperation and Development. The two groups are the working Group on Harmonization of Regulatory Oversight in Biotechnology and the Task Force for the Safety of Novel Foods and Feeds. These groups provide information useful to EPA as it performs risk assessments on genetically modified organisms, including plant and microorganisms under three of its jurisdictional statutes, FIFRA, FFDCA, and TSCA.

The U.S. has also been active in negotiating a workable implementation of the Cartegena Protocol on Biosafety and the EPA has played a role in those activities. We have also been involved in standard setting activities under the International Plant Protection Convention, as well as many bilateral exchanges of information and expertise.

EPA participated as part of the U.S. delegation to the Codex Task Force to develop guidelines and principles for assessing foods derived from biotechnology. This international effort by regulators and scientists sets forth a set of principles and guidelines any country can use to assess these products. These guidelines reflect the U.S. approach to assessing biotechnology products. EPA will be part of the U.S. delegation to the anticipated second round efforts in Codex addressing other biotechnology food and feed issues.

Conclusion

We appreciate the opportunity to present an overview of EPA's activities to regulate products produced through biotechnology. Five important principles guide EPA's biotechnology program: sound science, transparency in decision making, consistency and fairness, collaboration with regulatory partners, and building public trust. EPA is committed to a regulatory program based on the most rigorous scientific information available so that our decisions are credible, defensible, and protective of the environment and public health as we address the challenges associated with biotechnology.

Thank you for the invitation to appear before your committee this morning. I will be glad to answer any questions you may have.