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INTRODUCTION

Good morning, Mr. Chairman and members of the Subcommittee. 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. We are working 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, the Agency is committed to ensuring that our regulatory decisions are based on rigorous scientific information, the highest scientific standards, with a high degree

of transparency to ensure our decisions are available to the public for understanding and oversight. By following these principles, our program ensures the protection of public health and the environment, while promoting consumer confidence in our regulatory decisions. Biotechnology is a rapidly evolving field, and requires that the federal government's regulatory program similarly advance to ensure the continued protection human health and the environment. The Agency believes that regulated biotechnology products are safe, provided they are used according to the approved labeling. Given our intellectual and scientific investment in regulating biotechnology, the Agency stands ready to meet the future challenges.

COORDINATED FEDERAL FRAMEWORK

In the early 1980s, companies began to apply the techniques of bioengineering to agriculture for eventual commercial use. Also at this time, the federal government began to evaluate its options for regulating products created using biotechnology. In 1986, the federal government released a document entitled: "Coordinated Framework for Regulation of Biotechnology" which laid out the broad approach to regulating biotechnology products. In summary, the products of biotechnology would be regulated under existing statutes and in a manner similar to the regulatory approach used for products not produced through this technology.

The Framework established an approach to regulating the products of this new technology based on the characteristics of the products and the specific use of

the product, not the process used to create it. Rather than seek new legislative authority, the federal government concluded that it could appropriately regulate these products using existing laws, but also recognized that, in some cases, new regulations would be needed. Thus, products that are intended to be used as pesticides are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). Also, under the Toxic Substances Control Act (TSCA), EPA reviews bioengineered microbes and the substances they produce when the genes come from a different type of microbe. The Framework has been reaffirmed by several Administrations, including the current one, and current efforts are aimed to make the coordination between EPA, FDA, and USDA even stronger, while ensuring a comprehensive and seamless regulatory system.

STATUTORY FRAMEWORK

Under the Framework, EPA regulates products under FIFRA and Section 408 of the FFDCA; this includes bioengineered (and naturally occurring) microorganisms with pesticidal action as well as products produced by plants that act within the living plant as pesticides to protect the plant. Any remaining residues of these pesticides are regulated under FIFRA and the FFDCA. The products produced by plants which are intended to act as pesticides, along with the genetic material necessary to produce these substances, are called "plant-incorporated protectants" or "PIPs."

EPA proposed two different sets of rules for these two different types of

products. In 1992, the Agency proposed rules tailoring the experimental use regulations for microbial pesticides. EPA finalized rules dealing with field testing of microbial pesticides in 1994. Similarly, EPA proposed an approach to PIPs in 1994, and major portion of these regulations were finalized in 2001. These rules formalized regulatory procedures for plants bioengineered to exhibit pesticidal traits. PIPs created through conventional breeding were exempted from regulation. A National Academy of Sciences study in 2000 urged, after examining the existing knowledge, EPA to reconsider some of the PIP exemptions originally proposed in 1994. In 2001, EPA asked for additional public comment on these specific exemptions and the NAS analysis. EPA is currently considering comments received, the NAS analysis, and the record on the scientific merit and potential risks associated with granting these exemptions.

THE BIOTECHNOLOGY PROCESS

To fully understand our regulatory approach to PIPs, some basic information on biotechnology may be helpful. EPA's jurisdiction under FIFRA is limited to pesticides. For example, the sale of a plant that has been bioengineered to resist insect damage would be subject to FIFRA, whereas a plant engineered to resist drought would not. Such products come under our authority because the substance produced by the plant is intended to function as a pesticide by affecting a pest. In this latter instance, a substance produced by the drought resistant plant may result in, for example, deeper roots to enable the plant to access more water reserves. This bioengineered plant would be subject to USDA authorities, and any food or feed obtained or produced from such a plant would be subject to FDA authorities.

Up until the last quarter of the twentieth century, growers have relied on plant breeders to provide them with hardier and more disease-resistant crop varieties. This is done primarily through plant breeding and transferring pollen from one variety of crop to the flower of another variety, or mating a crop plant with a wild or related plant to produce offspring with the desired trait. It is the way that we got bigger roses and more robust tomatoes.

In the early 1980s, scientists began to move single genes selectively through biotechnology techniques. The transfer of desired traits could now be accomplished more broadly and more rapidly. Science is at the point now where genes can be moved between unrelated species. In the case of PIPs, scientists alter plants to produce pesticidal substances from any source, for example, from another plant, a bacterium or virus, etc. The most well known example is 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 the process of biotechnology, scientists can remove the genes that produce the toxic protein from the bacterium and place them 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.

EPA'S REGISTRATION REQUIREMENTS AND PROCESS FOR PIPS

EPA has been working with companies and individuals since the early-80s in developing a regulatory approach for pesticide related biotechnology products. In developing our approach, EPA has held numerous public meetings with

extramural panels of scientific experts; e.g., the Agency's Biotechnology Science Advisory Committee, 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. Through this process, the Agency has developed robust regulatory and scientific standards for biotechnology products going through the registration process.

Specifically, 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, 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. Once the Agency receives a complete package for a new PIP active ingredient, it typically takes about 18 months for the Agency to review the data and reach a registration decision.

For the PIPs products EPA has registered to date, we review data in five categories: product characterization, toxicology, non-target organism effects, and 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 laboratory animals 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 and used for the testing.

It should be noted that to date, all of the PIPs reviewed by EPA are protein based. For protein based 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 determination of the potential of the protein to be toxic or an allergen. EPA and FDA are working together on this issue. Currently, for an allergenicity assessment, EPA requires 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 predators of the pesky Colorado potato beetles. 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. Currently, monitoring of potentially affected organisms in fields planted with PIPs is also required. EPA also can evaluate the degradation rates of the proteins in soil and plant residues.

If any concerns or questions arise from the testing, a second or higher tier of testing is required to allow EPA to more thoroughly evaluate the potential risks.

EPA routinely consults with our Scientific Advisory Panel, the USDA, the FDA and others as we carefully evaluate the scientific and regulatory issues.

Currently, EPA has registered 11 separate PIP products. Ten 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 issued for Bt tomatoes and Bt soybeans. The Agency has also established tolerance exemptions for pesticidal proteins from viruses that have been moved 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 existing Bt registrations, to make sure that all uses were up to current regulatory and scientific standards. All stakeholders were encouraged to participate and the Scientific Advisory Panel was convened to peer review EPA's scientific findings. As a result, those Bt products that were reregistered were supported by the latest scientific data requirements and are being used under updated and more stringent regulatory conditions.

Recently EPA has approved two new products that should help farmers reduce reliance on chemical pesticides. The first product is a new version of Bt cotton with an additional pesticidal protein that is expected to improve resistance management. It should control more insect pests than the previously-registered Bt cotton product. The second is the first Bt corn product to control the most

important corn pest -- the corn root worm. We estimate that this product can reduce chemical insecticide use by 7.5 million acre treatments in the first three years of its registration.

OTHER CHALLENGES

EPA believes that these are promising times for advancing better, lower risk solutions to pest control needs. We believe that these products have great potential. However, the Agency is proceeding cautiously to ensure protection to all citizens and to our environment. At this juncture, I would like to turn the discussion to some of the other issues that have been raised and what EPA is doing to address them.

The Monarch Butterfly

Back in 1999, the Monarch butterfly made headlines when researchers at Cornell University determined that immature Monarchs might be susceptible to pollen from some Bt corn plants. As a result of this information, EPA required registrants of Bt corn to undertake exhaustive and comprehensive studies to determine the toxicity and exposure of immature Monarch butterflies to Bt corn products. The results of these studies, which were published in the Proceedings of the National Academy of Sciences, have shown that none of the existing registrations have any effects on Monarch butterfly populations.

StarLink Corn

When StarLink corn was registered in 1998, the data concerning the digestibility of the protein was insufficient to make a complete assessment on the potential for the protein to be a potential food allergen. EPA registered StarLink with restrictions designed to keep it out of the human food supply (such as allowing sales only to animal feed and industrial processors, and requiring buffer zones between non-StarLink corn). Despite these restrictions, the protein from StarLink corn was discovered in human food (taco shells). As a result EPA, FDA, and USDA worked closely together to both divert all corn containing the protein to non- human food uses and to ensure that corn seed for growers would be StarLink-free. Additionally, an assessment on the potential reports of allergenicity in people was conducted in cooperation with the Centers for Disease Control and Prevention (CDC). No incidents of allergenicity have been confirmed from the CDC investigations. The registration for StarLink corn has been cancelled. EPA meets regularly with FDA and USDA to monitor the success of the containment program for StarLink, and determine if any changes are necessary in the testing program for corn being used in dry milling. In order to assure that the StarLink situation does not occur again, EPA has instituted a policy of not approving registrations that are restricted to animal and industrial uses in crops people use for food.

Insect Resistance Management

The Agency has placed specific requirements on pesticide manufacturers to prolong the life of Bt pesticides, and delay the development of insect resistance. EPA's strategy to address insect resistance is threefold: (1) closely monitor and if resistance is detected, take immediate steps to mitigate any future potential for

resistance development in the field, (2) implement restrictions to prevent resistance, and (3) continue research on the best techniques to prevent resistence.

EPA'S OTHER BIOTECHNOLOGY REGULATORY PROGRAMS

EPA also administers regulatory oversight over the commercial introduction of new microorganisms and the significant new uses of existing microorganisms under the authority of The Toxic Substances Control Act, also known as TSCA. 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's jurisdiction generally covers 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. This process determines if a new microorganism, when used under certain conditions, would not pose any unreasonable risk to public health or the environment.

Types of microorganisms that fall under TSCA are ones that are used in the production of industrial or specialty enzymes, e.g., detergent formulation, processing aid in the pulp and paper industry. These microorganisms are generally produced under closed systems. Microorganisms that are intended to be released to the environment include ones used in bioremediation, biosensors or agriculture applications, such as nitrogen-fixing bacteria for increased yield in alfalfa or soybean production. Because TSCA specifically excludes pesticides and food, this program has few notifications with agriculture applications.

INTERNATIONAL ACTIVITIES

Biotechnology also holds great global promise, and the federal government is actively engaged in a wide array of international activities. Specifically, 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.

EPA is also working on several international fronts in an effort to share data

and foster collaborative relationships in various regulatory and scientific issues regarding biotechnology. EPA, in conjunction with USDA and FDA, was instrumental is establishing two workgroups with the Organization for Economic Cooperation and Development. These groups provide information useful to EPA as it performs risk assessments on products of modern biotechnology. EPA, along with other federal agencies, has been developing a workable implementation of the Cartegena Protocol on Biosafety with the involved parties. We have also been involved in standard setting activities under the International Plant Protection Convention. In addition, EPA has been active in many bilateral exchanges of information and expertise. For example, we receive numerous international visitors a year who come to learn about our regulatory process. Some of these visitors are building their own regulatory structures and find our information valuable. Others come just to understand our risk assessment process so they can be more assured about eating foods derived from biotechnology and produced in the United States. We have also worked with U.S. Agency for International Development to provide information on how our regulatory process participates in ensuring the safety of domestically grown grain both for the public and recipients of USAID's food aid programs. All of these activities have been valuable to ensure the U.S. remains a recognized leader in regulating biotechnology products.

CONCLUSION

Thank you for allowing EPA to share its experience with biotechnology. The Agency's biotechnology program is based on five important principles: sound science, transparency in decision making, consistency and fairness, collaboration

with regulatory partners, and building public trust. EPA believes that the regulatory system is based on the most rigorous scientific information available, is credible, is defensible, and will serve to protect the environment and public health, and can evolve to meet the important challenges that lie ahead. It is important that all parties work together to ensure the proper oversight and management of biotechnology so its considerable potential can be fully realized.

Thank you for the invitation to appear before your Subcommittee. I will be happy to answer any questions you may have.