TESTIMONY OF
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BEFORE THE
SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

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Good morning, Chairman Roberts, Ranking Member Stabenow, and other members of the committee. My name is William Jordan; I serve as the Deputy Director for Programs in the Office of Pesticide Programs at the U.S. Environmental Protection Agency. Thank you for the opportunity to testify about the agency's role in the federal government's Coordinated Framework for Regulation of Biotechnology, and the principles under which the EPA operates in its regulation of products of biotechnology.

The EPA is one of three regulatory agencies administering statutes used to regulate products of modern biotechnology, along with the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). As described in the Coordinated Framework, the EPA regulates the sale and distribution of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to ensure that pesticides are used in a way that is safe for humans and the environment. The EPA also regulates the safety of any residual amounts of a pesticide that occur in or on food by establishing maximum residue limits (called "tolerances") or tolerance exemptions under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). The statutory definition of "pesticide" is broad, including any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest, including, for example, insects, rodents and weeds. Modern biotechnology has been used to develop products that fall

under this definition, including substances with pesticidal properties genetically engineered into plants. The agency calls this type of pesticide a "plant-incorporated protectant" or "PIP."

The pesticide laws provide strong regulatory authorities and establish protective standards. Under FIFRA, every pesticide product, with some minor exceptions not applicable to PIPs, must be registered before being sold or distributed in the United States. To obtain a registration, an applicant must demonstrate to the agency's satisfaction that, among other things, the pesticide product will not cause "unreasonable adverse effects" on humans or the environment. If use of a pesticide is likely to result in residues in food, the EPA may establish a tolerance or an exemption for the residues only if the EPA finds there is "reasonable certainty that no harm will result" from exposure to residues of the pesticide in all foods, as well as all from other, non-occupational sources of exposure.

As the EPA regulates the products of modern biotechnology that fall within our jurisdiction, the agency is guided by several principles. Our decisions are based on the best available science; we operate with consistency and fairness in a transparent manner; and we collaborate fully with our regulatory partners in the Coordinated Framework.

Making regulatory decisions based on the best available science is the foundation of the EPA's decision making. The agency recognizes that it must be fully informed by the best available information and expert advice. To this end, the EPA generally requires applicants for registrations and tolerances to provide extensive data on their products. The EPA has a robust, well developed program for evaluating the information and data submitted to the agency to prove that a product meets the statutory standards for approval. For a PIP, an applicant typically must submit the following data: product composition, studies of potential allergenicity and toxicity to humans, studies of environmental fate and effects, and data and information used to develop

programs to manage the potential for resistance to a pesticide to emerge in the target pest population, called "resistance management" programs.

The agency seeks to ensure that the EPA staff have the training and experience to ensure a technically sound analysis and that the agency obtains the advice of leading technical experts as it makes major regulatory decisions and determinations. The EPA's staff includes experts trained in a variety of scientific disciplines who keep up with new knowledge in the various scientific disciplines important to understanding and evaluating the potential effects of biotechnology products. The EPA undertakes "horizon scanning" activities to ensure we are aware of and well prepared to evaluate new products efficiently and effectively. These include interaction with academic scientists through EPA-invitation presentations, webinars, grant review activities, and scientific meetings and conferences. Further, biotechnology companies in the process of developing new products routinely meet with the agency to describe products that may come to the EPA for registration. These meetings frequently include descriptions of any new technology, as well as the potential product. Information gleaned from these various sources informs the development of our assessment strategies for novel products as well as informing the assessment of individual products resulting from advances in scientific knowledge.

The EPA also seeks the advice of national experts in various scientific disciplines to inform agency scientists of the newest information emerging from laboratory research activities. One mechanism through which the EPA seeks such advice is the FIFRA Scientific Advisory Panel (SAP), a federally chartered advisory committee of external, independent experts, specialists in their fields, which the agency convenes regularly as its program for regulation of products of modern biotechnology evolves. Since the EPA first began evaluating the safety of PIPs, the EPA has held nearly two dozen SAP meetings focusing on such topics as data

requirements, how to assess potential allergenicity, how to assess risks to non-target insects, and how to predict and manage pest resistance.

The EPA believes we have a responsibility to convey to the public that our decisions are consistent, scientifically solid, and fully protective of human health and the environment. To this end, the EPA uses several mechanisms to increase transparency and solicit public input.

- For difficult scientific issues, we seek review by the SAP. Each meeting of the SAP is open to the public, and part of the meeting is reserved for the public to comment on the issues.
- The agency seeks public comment when it proposes to approve registration of a pesticide containing a new PIP, as well as when we are developing significant new policies affecting the products of modern biotechnology. The EPA provides public access to the documents concerning the proposed registration or policy by making them available in a docket open to the public. In addition, the agency addresses substantive comments and makes those written responses public along with its final action.
- The EPA's website provides general information to the public on its activities, including information on products of modern biotechnology. The website also provides guidance to developers for products subject to FIFRA and FFDCA section 408.

One of several principles laid out by the 1986 Coordinated Framework for Regulation of Biotechnology is that "agencies should operate their programs in an integrated and coordinated fashion and together should cover the full range of plants, animals, and microorganisms derived by the new genetic engineering techniques." The three regulatory agencies of the Coordinated Framework have attempted, through their regulatory actions, to cover the full range of products

derived by the new genetic engineering techniques, and the three agencies will continue to follow this principle.

The three regulatory agencies have operated their programs in an integrated and coordinated fashion over the last three decades. An example of this coordinated activity can be seen in the regulation of plants engineered to be tolerant of an herbicide. The USDA regulates the plant that has been modified to tolerate the herbicide. The EPA regulates the herbicide when used on such plants. The EPA has a well-developed approach to chemical risk assessment decisions, and it applies this approach to its evaluation of herbicides. The EPA and the USDA coordinate closely in their regulation of the herbicide and tolerant plant combination. For example, the EPA will not register the herbicide for use on the plant until the USDA completes its regulatory process for the engineered plant. When both agencies have reached a determination, the EPA and the USDA coordinate the announcement of their decisions.

The EPA also works closely with the FDA. The authority to establish tolerances or exemptions from the requirement of a tolerance for pesticide residues rests with the EPA under section 408 of the FFDCA. Other sections of FFDCA, administered by the FDA, are used in enforcement of the tolerances issued by the EPA. The EPA and the FDA work closely on all tolerance and tolerance exemption issues and do so for products of modern biotechnology, including for pesticidal substances engineered into a plant (PIPs).

In addition, under the Coordinated Framework, the EPA works with the FDA and the USDA, using our regulatory authorities appropriately to ensure the safety of products of modern biotechnology and, in general, sharing information. In some instances, the three agencies hold joint pre-submission meetings with technology developers in order to ensure that the companies are aware of the requirements of all three agencies. This type of activity smooths the regulatory

path for, in particular, small entities or individual researchers who may be less familiar with regulation by the federal government of products of modern biotechnology.

The EPA has issued eighty-six PIPs registrations. Most of these are for products that have introduced genetic material from the Bacillus thuringensis (Bt) microbe. Bt microbes produce a protein that is toxic to particular species of insects, and there is a broad scientific consensus that it has practically no effect on humans or other species. (Bt microbes, in fact, are approved as organic pesticides.) Growers have widely adopted PIP products in their farming operations. Today, more than 80 percent of the corn and cotton acreage in the United States, totaling nearly 100 million acres, is being planted with EPA approved varieties of PIPs. The EPA's experience with PIPs over the last 20 years is that such pesticides have been safe and generally have provided effective alternatives to conventional pesticides.

A number of groups – ranging from academicians to the federal government to the National Academy of Sciences – have studied how the introduction of PIPs has affected the use of synthetic chemical pesticides. These experts have concluded that by planting PIPs, growers have reduced by more than a third – many millions of pounds – their reliance on broad spectrum, synthetic insecticides. The result is reduced exposure to such pesticides for workers and non-target wildlife, less ground and surface water contamination by such pesticides, and less residue of such pesticides in food.

In addition, PIPs have been able to address pest problems that conventional chemical pesticides have not. For example, plum pox is a virus causing a devastating disease in stone fruits. While not endemic in the U.S., over the past few years plum pox has been detected in several locations in northeastern U.S. and Canada. The EPA has approved a PIP that, when introduced through a graft onto root stock, makes a tree able to successfully resist the disease.

This PIP provides a less expensive and more effective alternative to the traditional methods of controlling plum pox, which otherwise would require bulldozing and disposal of infected vegetation, quarantine surveys, and use of synthetic chemical pesticides to control the insects that spread the disease.

The use of PIPs in agriculture has already produced real benefits, and new PIPs hold promise for additional human health and environmental benefits. We cannot say, however, that future products of biotechnology would always be risk free, since by definition pesticides are intended to adversely affect some organism, even if only in a limited range. Therefore, before a new PIP is introduced into the environment, it is important that EPA have sufficient data and opportunity to evaluate the potential for risks to non-target organisms, and what, if any, species may be adversely affected.

In addition, controlling pest resistance to PIPs has long been, and will likely continue to be, a challenge. Experience has shown that target pests can, over time, develop mechanisms making them less susceptible to the effects of a pesticide. Widespread, repeated use of a PIP, or any other type of pesticide accelerates the pace at which pests develop resistance, and that has been an issue especially for Bt-based PIPs. Once resistance arises broadly in an insect population, that pesticide is no longer useful in controlling the population.

Because PIPs have proven to be effective and safer alternatives to conventional pesticides, EPA determined that use of PIPs, Bt PIPs in particular, should be managed in a way that should preserve the technology long into the future. In the case of Bt PIPs, following the guidance of nationally recognized experts, the agency has placed conditions on PIP registrations that reduce the possibility target insects could develop resistance to the PIP. The conditions require each farmer planting a Bt-based PIP to maintain a “refuge” of non-PIP plants that allows

populations of the target insect to develop without exposure to the Bt PIP. Each registrant must distribute grower guides that explain the resistance management requirements for the product and must conduct and report annually on the level of compliance. In addition, registrants must conduct annual resistance monitoring to assess changes in pest susceptibility and investigate cases of unexpected pest damage to PIP-containing crops. Altogether, these measures should slow the development of resistance.

In conclusion, the EPA recognizes the potential benefits that products created through modern biotechnology can bring to U.S. agriculture and the environment. At the same time we also believe that it is essential to have a strong, science based effective, and efficient regulatory system – one capable of responding to new technological developments in the field of modern biotechnology. We believe we have such a system at the EPA – a system that embodies the principles of sound science, transparency, and collaboration. Working with our colleagues at USDA and FDA, we look forward to continuing to fulfill our responsibility for ensuring the safety of the products of modern biotechnology.

I am happy to answer any questions.