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Introduction

Good afternoon Chairman Kucinich, Ranking Member Jordan, and Members of the Committee. I am pleased to appear before you today to discuss the Environmental Protection Agency's (EPA) regulation of transgenic *Bacillus thuringiensis* (B.t.) crops. I welcome the opportunity to participate on this panel and explain the steps that EPA has taken to forestall the development of insect resistance to these important crops. Further, I look forward to discussing EPA's involvement with the U.S. Department of Agriculture in their assessments of the environmental impacts of herbicide tolerant crops and herbicide resistant weeds. EPA provided technical expertise to USDA to assist in the development of herbicide stewardship plans. More recently, as USDA has engaged in analysis of these crops under the National Environmental Policy Act (NEPA), EPA is expanding its support to USDA in its environmental analyses.

The Coordinated Framework and NEPA

EPA and USDA share responsibility, along with FDA, for regulating agricultural biotechnology. The Coordinated Framework for the Regulation of Biotechnology, released in 1986, describes each agency's role and sets forth a comprehensive scheme for federal regulation of biotechnology. The basic framework was that the products of biotechnology were to be regulated under existing statutory authorities and in a manner similar to products produced by means other than biotechnology. Thus, EPA regulates products produced through biotechnology that are intended to have a pesticidal effect under its authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the sections of the Federal Food, Drug, and Cosmetic Act (FFDCA) applicable to residues of pesticides in food and feed.

Under the Plant Protection Act, USDA's Animal and Plant Health Inspection Service (APHIS) regulates the introduction of organisms altered or produced through genetic engineering that are plant pests, may be plant pests, or may be related to plant pests. APHIS has procedures whereby a person may petition APHIS for a determination that an otherwise regulated article does not pose a plant risk and should not be regulated. USDA recently completed a NEPA analysis of glyphosate-tolerant alfalfa and EPA provided comments on the sections of that Environmental Impact Statement that discuss development of resistance. EPA is also providing support to USDA on an EIS for glyphosate-tolerant sugarbeet that is under development. EPA stands ready to provide whatever additional assistance may be needed in the future.

EPA's Regulation of B.t. Plant Incorporated Protectants

EPA first registered a transgenic B.t. crop product in 1995. Over the past fifteen years, B.t. crops have substantially reduced the need for growers to apply older, more risky conventional chemical pesticides to corn and cotton crops. As B.t. crops now comprise over 60% of planted corn acreage, and over 90% of planted cotton acreage, the decreasing usage of more risky pesticides has significantly reduced health risks to farm workers. Also as a condition of B.t. corn and cotton registrations, EPA required that registrants conduct field surveys to assess biodiversity in B.t. crop fields compared to non-B.t. crop fields.

Those data, along with independent assessments published in the scientific literature, have conclusively demonstrated that there is significantly greater insect biodiversity in B.t. crop fields compared to fields treated with conventional pesticides. Because sprayable B.t. formulations are naturally derived organic pesticides, they are very important to organic farmers and organic agricultural production in general. Given the importance of this technology to organic agriculture, EPA has, from the very beginning of its regulation of transgenic B.t. crops, addressed the potential issue of resistance by requiring that B.t. crop registrants market these products with specific mandatory insect resistance management (IRM) requirements. These requirements have evolved as the science has evolved, and we have altered and tailored the IRM requirements to match the latest and most relevant scientific data and information.

EPA's development of a regulatory scheme for plant incorporated protectants (PIPs) began in the 1980s. EPA held public meetings with the Agency's Biotechnology Safety Advisory Committee (BSAC), the FIFRA Scientific Advisory Panel (SAP), the Office of Pesticide Programs Pesticide Program Dialogue Committee (PPDC), and numerous public meetings and workshops with interested stakeholders. Through this long process of stakeholder consultation and external scientific peer review, EPA developed a rigorous and robust regulatory approach to PIPs that was based on the most up to date science. From the very beginning, it was clear that developing methodologies and approaches to forestall the development of insect resistance should be a major focus of the Agency in its regulation of B.t. crops. EPA has regularly met with the SAP on IRM issues, and, as the IRM requirements have evolved on the basis of new data and information, the SAP has provided key input into these regulatory developments.

To address the potential of insect resistance to B.t. proteins, EPA has imposed IRM requirements on registered B.t. PIPs. EPA would consider the development of insects resistant to B.t. toxins as a result of unmitigated exposure to PIPs to constitute an adverse effect on the environment. EPA's strategy to address insect resistance to B.t. is two fold: (1) mitigate any significant potential for pest resistance development in the field by instituting IRM plans; and (2) continually investigate and understand better the mechanisms behind pest resistance. Initially, IRM plans incorporating “refuges” (portions of the crop that did not produce and were not treated with B.t.) were determined on a case by case basis using data submitted with each application. As a consequence,

IRM requirements varied from product to product. In 2000, based upon input from the SAP, and working with the National Corn Growers Association and other groups, EPA imposed across the board IRM requirements of a 20 percent refuge for B.t. corn and a 5 percent refuge for B.t. cotton.

The baseline 20 percent refuge for corn and 5 percent refuge for cotton held for a number of years until more complex products were developed and supporting scientific data indicated that it was appropriate to alter these requirements. For B.t. cotton, registrants developed "pyramided" products that contained more than one B.t. protein efficacious against a specific pest ("stacked" products contain B.t. toxins efficacious against more than one pest). By targeting the pest with independently acting toxins, the likelihood of resistance developing to either toxin was substantially decreased, and it became possible for EPA to decrease the percentage of refuge crop required for a pyramided crop.

Also, registrants developed data demonstrating that in many cotton producing areas, non-cotton plants that are food sources for cotton pests often surround, or are close by cotton fields. In effect, in these areas, the cotton fields are surrounded by "natural" refuges.

These large alternative sources of habitat for cotton pests, combined with pyramided B.t. cotton products, precluded the need for growers to plant refuges for those products. Thus, for pyramided B.t cotton products planted from Maryland to Kansas,

there are no refuge requirements. Those same products planted outside of these areas maintain the requirement for planted refuges. Similarly for B.t. corn, new products are being developed that support refuge requirements different from the baseline 20 percent corn refuge. Registrants have developed pyramided corn products that require refuges of 5 percent or 10 percent non-B.t. corn seed. Also, registrants are developing products that incorporate refuge seed in the same seed bag as the B.t. corn seed, such that when planted, an in field refuge is automatically put in place. To date, there have been no confirmed instances of B.t. resistant pests appearing in the field in the Continental United States. We will maintain our diligent approach to forestalling potential resistance to B.t. crops.

In addition to requiring that registrants require purchasers of their products to plant crop refuges, EPA mandates that registrants monitor for resistant insects emerging during the growing season as an important early warning sign of resistance developing in the field and a check as to whether IRM strategies are working. Grower participation, e.g., reports of unexpected damage, is a critical component of such monitoring. Resistance monitoring is also important because it provides validation of biological parameters used in models. In 2000, the SAP concluded that resistance monitoring programs should be peer reviewed and used to assess the success of IRM plans. EPA's Office of Research and Development, National Risk Management Research Laboratory and Office of Pesticide Programs held a small expert group workshop in July, 2001, that provided guidance on insect resistance monitoring plan design and detection techniques for B.t. corn.

EPA and USDA Cooperation on Herbicide Resistance Concerns

USDA regulates genetically engineered herbicide-tolerant crops, while EPA regulates the herbicides used on these crops. Recognizing the need for EPA and USDA/APHIS to coordinate their reviews, the agencies developed a Memorandum of Understanding (MOU) in 2001 outlining a process for improved communication and information-sharing to facilitate better coordination of regulatory activities between the two agencies. Under the MOU, USDA was to request that each petition for "deregulated" status include a voluntary stewardship plan for the management of herbicide resistance, and then consult with EPA as to the viability of the stewardship plan during its environmental assessment.

To implement relevant portions of the MOU, USDA and EPA developed a draft document to assist applicants in the preparation of voluntary resistance management stewardship plans to be submitted with petitions for nonregulated status of herbicide-tolerant (HT) crops, and with applications to EPA to register herbicides intended to be used on HT crops. Initial efforts by EPA and USDA to implement the provisions of the MOU were met, however, with resistance from both users, pesticide registrants, and the technology providers. At that time, the development of resistance in weeds as a result of the use of HT crops was not widely documented in the scientific literature, nor was it viewed as a significant problem by these stakeholders, who considered the economic costs of developing and implementing a stewardship program unnecessary.

In 2007, responding to increases in reported cases of resistance, EPA and USDA held discussions on the extent to which herbicide resistant weeds were occurring in herbicide tolerant crops. As a result of these discussions, EPA and USDA initiated a project with the Weed Science Society of America (WSSA) to develop a comprehensive manuscript to better understand the scope of herbicide resistance in genetically engineered and nongenetically engineered cropping systems. This report is due later this year.

As glyphosate resistant weeds have become more widespread in HT crops, technology providers and users have become less resistant to efforts to address herbicide resistant weeds. The support for resistance management from technology providers and users has spurred the development of strategies to prevent or manage herbicide resistant weeds in HT crops. More recently, EPA has provided comments on the section of USDA's EIS that discuss the development of resistance as a result of the deregulation of glyphosate-tolerant alfalfa.

EPA and USDA are working with researchers and professional societies, including the Weed Science Society of America (WSSA), to expand resistance management education and promote research aimed at increasing understanding of the best practices and strategies for preventing and managing HT weeds in HT crops. EPA is also working with pesticide registrants, encouraging them to include mechanism of action information on herbicide labels. This information is critical to the implementation of resistance management plans, which typically involve rotation to herbicides with a

different mechanism of action as a proven strategy for preventing or delaying development of resistance.

There has been much attention given to the best way to delay or prevent the development of pesticide resistance to pests in general, beyond resistance in weeds in glyphosate-tolerant crops. Professional scientific societies, e.g., the Weed Science Society of America, the Entomological Society and the American Phytopathology Society, as well as Resistance Action Committees (composed of technical staff from pesticide producers) have been involved in identifying ways to accomplish this goal. EPA has been in discussion with each of these groups to obtain their input on how to incorporate guidance on resistance management on pesticide labels.

Additionally, EPA has been collaborating with its NAFTA partners (The Pest Management Regulatory Authority (PMRA) of Canada and Cicoplafest of Mexico) to develop harmonized approaches to resistance management language on pesticide labels EPA has and continues to encourage pesticide registrants to include mechanism of action information on pesticide labels to better inform growers and other pesticide users of one proven strategy for preventing or delaying development of resistance.

In summary, the early efforts by EPA and USDA to implement the resistance management provisions of the 2001 MOU were hindered by the lack of interest and support from the technology providers and user community. Recently, however, with the support of these sectors, EPA and USDA have reinvigorated their efforts in this area,

working collaboratively to promote resistance management in HT crops and preserve this valuable technology.

We look forward to continuing our work with this Committee, our fellow agencies, our stakeholders, and the public to ensure an environmentally and economically healthier country for all Americans.