



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Chemical Safety

EPA Needs Better Data, Plans and Tools to Manage Insect Resistance to Genetically Engineered Corn

Report No. 16-P-0194

June 1, 2016



Report Contributors:

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Abbreviations

ABSTC	Agricultural Biotechnology Stewardship Technical Committee
BRAD	Biopesticide Registration Action Document
Bt	Bacillus thuringiensis
CAP	Compliance Assurance Program
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
IRM	Insect Resistance Management
OIG	Office of Inspector General
OPP	Office of Pesticide Programs
PIP	Plant-Incorporated Protectant
USDA	U.S. Department of Agriculture

Cover photo: Images of cornfields and a corn rootworm. (EPA OIG photos)

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At a Glance

Why We Did This Review

We conducted this review to determine the U.S. Environmental Protection Agency's (EPA's) ability to manage and delay increased insect resistance to genetically engineered *Bacillus thuringiensis* (Bt) corn. Specifically, we reviewed whether the EPA collects and reviews industry Compliance Assurance Program reports, and what actions are taken by the EPA when registrants report increased insect resistance.

In 2015, the corn crop in the United States was valued at nearly \$50 billion, and 80 percent of the acreage consisted of Bt plantings. Bt crops use less conventional pesticides, which has both environmental and human health benefits. Consequently, the EPA considers the protection of insect susceptibility to Bt to be in the "public good." The EPA oversees its Insect Resistance Management (IRM) program through terms and conditions placed on industry registrants.

This report addresses the following EPA goal or cross-agency strategy:

- *Ensuring the safety of chemicals and preventing pollution.*

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EPA Needs Better Data, Plans and Tools to Manage Insect Resistance to Genetically Engineered Corn

What We Found

The EPA's ability to manage and delay increased insect resistance to Bt corn is hindered by existing IRM program challenges. Changes are needed to the IRM program to increase the agency's ability to proactively detect resistance, confirm and address potential resistance, and share program information with stakeholders.

Bt crops have reduced insecticide applications by 123 million pounds. The EPA can preserve this significant public benefit through enhanced monitoring and preparation to address insect resistance in Bt corn.

The EPA's IRM program collects and reviews annual Compliance Assurance Program reports. Our review of the reports found that the program's compliance is increasing. However, we found that, beyond compliance, more is needed to detect, report and prepare for insect resistance. For example:

- The EPA has not provided industry with a standard methodology to confirm resistance, resulting in the use of inconsistent and differing methods to determine what constitutes resistance.
- Growers of Bt corn, as well as those conducting scientific research on Bt corn, lack a direct means to report resistance information to the EPA. Currently, growers and researchers must report resistance information through an industry highly invested in the economic success of Bt corn.
- The EPA needs to ensure the development of remedial action plans for registrants and growers to address resistance before it occurs. Current practice is to develop remedial action plans after resistance is detected, which can be too late to successfully prevent or mitigate resistance.

The EPA does not currently release compliance reports or resistance monitoring data developed by registrants to the public. Through website postings, the agency has the ability to publicly share information on its IRM program for the benefit of researchers, stakeholders and the public.

Recommendations and Planned Agency Corrective Actions

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention: (1) standardize a testing method for confirming resistance, (2) develop a method to allow researchers and growers to directly report resistance concerns, (3) prepare remedial action plans before resistance occurs, (4) increase the requirement for resistance monitoring data, (5) make Compliance Assurance Program reports and resistance monitoring data publically available, and (6) improve the EPA's website. The EPA generally agreed with our recommendations and provided acceptable corrective actions. All report recommendations are resolved. Many actions were completed in February 2016, and the agency plans to complete all actions by July 2017.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

June 1, 2016

MEMORANDUM

SUBJECT: EPA Needs Better Data, Plans and Tools to Manage Insect Resistance to Genetically Engineered Corn
Report No. 16-P-0194

FROM: Arthur A. Elkins Jr.

A handwritten signature in black ink, appearing to read "Arthur A. Elkins Jr.", is written over the printed name.

TO: Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this report was OPE-FY15-0055. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The office responsible for issues evaluated in this report is the Biopesticides and Pollution Prevention Division of the Office of Pesticide Programs, within the EPA's Office of Chemical Safety and Pollution Prevention.

Action Required

In accordance with EPA Manual 2750, your office provided acceptable corrective actions and milestone dates in response to OIG recommendations. Therefore, all recommendations are resolved and no final response to this report is required.

We will post this report to our website at www.epa.gov/oig.

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Chapter 1

Introduction

Purpose

The U.S. Environmental Protection Agency's (EPA's) Office of Inspector General (OIG) conducted this review to determine the EPA's ability to manage and delay increased insect resistance to genetically engineered *Bacillus thuringiensis* (Bt) corn. Specifically, we sought to determine (1) the extent to which the EPA's Office of Pesticide Programs (OPP) collects and reviews industry Compliance Assurance Program (CAP) reports submitted by genetically engineered corn seed registrants; and (2) the actions taken by OPP when registrants report increased insect resistance to genetically engineered Bt corn.

Background

A pesticide is any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest. Before a pesticide can be registered and used in the United States, the EPA must evaluate the proposed pesticide to assure that its use will not pose unreasonable risks of harm to human health and the environment when used according to directions. A plant-incorporated protectant (PIP) is a pesticidal substance that plants produce after genetic material has been added to crop seeds.

Agricultural crops, such as corn, have been genetically engineered to produce PIPs, and once ingested by pests—such as the corn rootworm—causes death. Through natural selection, pest insects not adversely affected by PIPs have the potential to pass these traits for resistance onto their offspring. Insect resistance affects the long-term viability of PIPs, and growers may experience damage to agricultural crops. The EPA works to mitigate insect resistance to PIPs, to preserve this technology as a public good.

Federal Responsibilities for Genetically Engineered Crops

The EPA, the U.S. Department of Agriculture (USDA), and the U.S. Food and Drug Administration (FDA) have shared responsibility to ensure that there is coordinated regulatory oversight for genetically engineered crops. The FDA works to ensure that genetically engineered crops with pesticidal traits are safe for use in food and feed. USDA is charged with assessing the safety of the genetically engineered plant for agriculture and the environment. The EPA ensures that genetically engineered crops are safe to use as a pesticide. Figure 1 depicts each agency's area of responsibility.

Figure 1: Federal responsibilities for genetically engineered crops

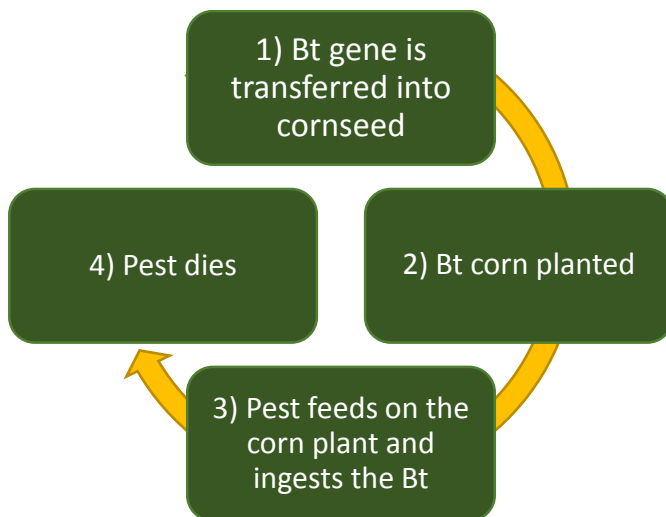
USDA	EPA	FDA
• Plant	• Plant pesticide	• Food and feed

Source: EPA OIG.

Plant-Incorporated Protectant: Bacillus thuringiensis

One of the most widely used PIPs is a protein produced by a naturally occurring soil bacterium called *Bacillus thuringiensis* (Bt). The Bt protein produces a toxin that is fatal to pest insects once ingested, and has been used since the 1960s as a conventional pesticide and in organic farming. In the early 1990s, scientists began to incorporate into plants the genetic material necessary to produce the Bt toxin. The Bt plants developed, which include corn, are now able to make their own Bt protein to kill pests (Figure 2).

Figure 2: How Bt corn works



Source: EPA OIG.

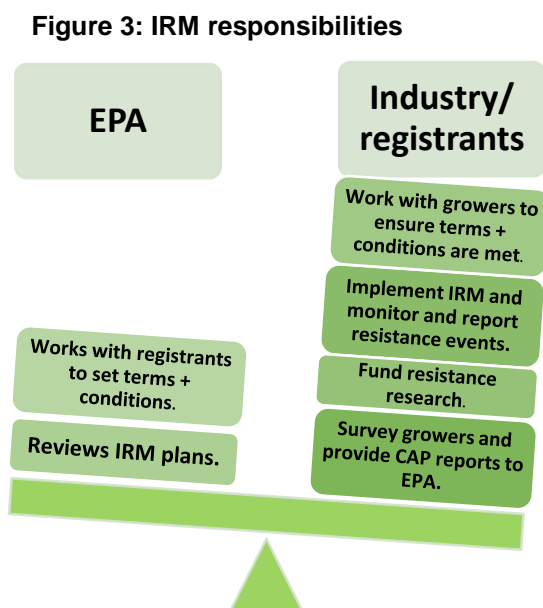
The EPA considers the development and use of Bt as a public good because of the environmental and human health benefits resulting from the reduced use of broad-spectrum insecticides. For instance, USDA documented an association between the use of Bt and decreased insecticide use. In 2010, for example, only 9 percent of all U.S. corn farmers applied insect pesticides to crops. The year before genetically engineered corn was introduced in 1995, 0.21 pounds of insecticide was planted per corn acre. This figure dropped to 0.06 pounds of insecticide in 2005, and 0.02 pounds in 2010. In addition, the use of Bt PIPs has resulted in reduced greenhouse gas emissions, lower pesticide cost and increased yields for growers.

Insect Resistance Management

The registration process for a PIP is generally the same as it is for other pesticides, plus some additional information requirements. One additional requirement is that the registrant must submit data that the EPA compiles into a Biopesticide Registration Action Document (BRAD). The BRAD addresses registrant reporting requirements for resistance monitoring, in addition to providing detailed information about product use, and changes and updates to the development of the product. The BRAD also addresses insect resistance management (IRM), and contains the terms and conditions that establish the contractual relationship between the EPA and the registrant.¹

The EPA uses IRM to reduce the potential for insect pests to become resistant to a PIP. Effective IRM can delay resistance development. The EPA's IRM strategy has two parts, designed to: (1) mitigate any significant potential for pest resistance development in the field by instituting IRM plans; and (2) better understand the mechanisms behind pest resistance.² Although IRM specifically targets growers and their genetically engineered crops, the EPA does not have direct authority over IRM implementation by individual growers. The EPA relies on registrants to work with growers to implement IRM plans. Registrants must have a contract

with individual growers to determine grower roles and responsibilities, such as refuge requirements and compliance (Figure 3).



Source: EPA OIG.

A key component in IRM plans is the requirement for a refuge. A refuge is a portion of a field that does not contain Bt plants. Intended to delay the development of resistance, non-Bt plants increase the probability that susceptible insects will mate with potential resistant insects, thereby reducing their potential to be resistant. The size and design of a refuge differs for each Bt corn product and biology of intended target pests. The most common type of refuge currently used in the Corn Belt is the seed mixture or the “refuge in a bag” type, in which a mixture of Bt and non-Bt seed is contained in one bag to ensure compliance.

¹ A registrant is an industry partner who has registered a pesticide product with the EPA. Industry (also, industry partners) refers to the grouping of agricultural biotechnology companies.

² The EPA's IRM program contains seven elements: (1) knowledge of pest biology and ecology, (2) dose (level of toxin expressed in the Bt crop), (3) refuge design and deployment (non-Bt plants producing Bt-susceptible insects), (4) effective field monitoring for insect resistance and a remedial action plan if resistance occurs, (5) integrated pest management, (6) communication and education strategies on use of the product, and (7) development of alternative modes of action. IRM plans also include grower education and measurement of the level of compliance.

Industry Roles and IRM Reporting Requirements

Industry/registrants have significant responsibility managing Bt corn and delaying insect resistance. The EPA mandates that registrants actively monitor and submit data on insect resistance. Registrants then work with growers and researchers to collect data and report activities to the EPA through the CAP³ and resistance monitoring data.

After registrants develop a PIP seed product, they work with the EPA, growers and researchers to comply with legal requirements. This includes working with the EPA to register the PIP (which includes the submission of information for the BRAD), submitting data on IRM plans, and submitting CAP reports. With the grower, registrants are responsible for ensuring that IRM plans are implemented (including appropriate planting of refuges and grower education). Registrants also work with the grower to gather information for CAP reports (including surveys), and have responsibility to create and implement remedial action plans as needed. Some registrants also provide funding to researchers for studies and data collection.

Industry registrants formed the Agricultural Biotechnology Stewardship Technical Committee (ABSTC) to compile compliance data for the CAP. The CAP report is submitted annually to the EPA as a single report for all registrants. The EPA analyzes this report, monitors the report for trends, and can make recommendations to ABSTC based on the information provided in the CAP report.

Individual registrants provide resistance monitoring data annually to the EPA as a condition of PIP registration. The registrants' data summarize their efforts to monitor insect resistance and report unexpected insect damage in fields.

Remedial Action Plans

Remedial action plans are designed to reduce the effects of resistance in a local pest population before it becomes widespread. Registrants propose remedial action plans and are required to submit plan details only after resistance is confirmed. To confirm resistance, diet-based assay testing must be conducted on the target pest (e.g., corn rootworm) to confirm survival is attributable to the genetic tolerance to the Bt toxin.

The remedial action plan should clearly indicate actions the registrants will take in cases of “suspected” resistance (i.e., unexpected field damage), and “confirmed” resistance (i.e., demonstrable survival in field-reproduced conditions). The plan

³ There are a number of mandated components to the CAP and include: (1) Grower Agreements—a contractual arrangement between the registrant and grower to obligate adherence to IRM requirements; (2) Annual IRM survey—a survey (conducted by an independent third party) intended to provide a statistically representative sample of grower compliance from corn-growing regions; (3) On-farm assessments—registrants developed an on-site assessment program in which trained personnel make visits to Bt-corn growing farms; (4) Phased Compliance Approach—a consistent set of procedures to be employed to address grower noncompliance; and (5) Tips and complaints—registrants must establish a means for reporting and investigating incidents of refuge noncompliance.

should also include adaptations for regional variation and the inclusion of appropriate stakeholders. A critical component of a remedial action plan is to ensure that sales of all Bt corn that express a similar protein are stopped in the affected region.

Corn Rootworm

Bt corn has a significant financial impact on the economy, which has been estimated to be a nearly \$231 million benefit to farmers.⁴ However, there is growing concern that widespread planting of genetically engineered crops will hasten the development of insect resistance to Bt toxin. According to a 2002 estimate, U.S. corn crops experienced over \$1 billion dollars in annual yield losses and control cost as a result of insect pest damage.⁵

In 2009, Iowa researchers discovered and documented instances of resistance to Bt corn developing in corn rootworm, a major pest to U.S. cornfields.⁶ After conducting laboratory bioassays, Iowa researchers concluded that corn rootworm had developed resistance to the Bt toxin and suggested that improvements in resistance management were needed. This study was the first demonstrable case of insect resistance in corn rootworm to Bt corn.⁷



Adult corn rootworm feeding on a corn plant. (USDA photo)

Based on these concerns, in 2013 the EPA decided that its IRM plan did not adequately address corn rootworm, and changes were needed. The EPA convened a Scientific Advisory Panel meeting in December 2013 to address scientific uncertainties associated with corn rootworm resistance monitoring. Afterwards, the EPA developed a set of proposals designed to enhance current resistance management and monitoring programs for corn rootworm. These proposals include the following:

- Integrated Pest Management as a component of corn rootworm resistance management.
- Responses to unexpected damage in fields containing Bt corn.

⁴ Marra MC, Piggott NE, Goodwin BK. 2012. The impact of corn rootworm protected biotechnology traits in the United States. *AgBioForum* 15 (2) 217-230.

⁵ *Ibid.*

⁶ “Field-Evolved Resistance to Bt Maize by Western Corn Rootworm.” Maize is the technical term for corn, and is preferred in scientific literature.

⁷ There is also a case of documented resistance to Bt corn in Puerto Rico, with the fall armyworm. Because the armyworm is not considered to be a primary pest to Bt corn in the continental United States, the armyworm is often not included in the literature.

- Elimination of the requirement for annual random sampling of corn rootworm from the Corn Belt.
- Use of on-plant assays for resistance determinations.
- Enhancements to current remedial action plans.

Responsible Office

The office responsible for issues evaluated in this report is OPP's Biopesticides and Pollution Prevention Division, within the EPA's Office of Chemical Safety and Pollution Prevention.

Scope and Methodology

We conducted our work from August 2015 through March 2016. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

During our interviews, we obtained information about the EPA's Bt corn IRM activities, such as the CAP report reviews, data verification, performance measurement, and the budget. We determined the universe of plant-incorporated protectants from 1995 through 2015. We also reviewed the EPA's 2014 draft proposal to address Bt corn rootworm resistance. In addition, we:

- Reviewed and analyzed relevant EPA regulations, policies and procedures.
- Conducted a review of Bt corn IRM reports and articles.
- Met with the USDA and the FDA to discuss their roles and responsibilities regarding biotechnology and biopesticides under the White House Coordinated Framework for Biotechnology.
- Met with stakeholders and field experts in biopesticides and biotechnology (e.g., the National Corn Growers Association, the ABSTC, North Carolina State University, and Pennsylvania State University).

Chapter 2

Despite Compliance Improvements, Challenges to EPA's Management of Insect Resistance Remain

Although data on compliance is improving, the EPA's ability to manage and delay increased insect resistance to Bt corn is hindered by challenges associated with detecting, reporting and preparing for resistance. The EPA needs to provide a standardized method for registrants to use to ensure that all parties are determining resistance in the same manner (and with the same method), to allow for comparisons to be drawn across reports. As a means to ensure the agency obtains current compliance and resistance information, the EPA needs to develop a system to allow growers and researchers to directly report resistance and field observations. In addition, registrants should be required to develop specific, implementable remedial action plans prior to resistance development. Finally, changes are needed to the EPA's current IRM program to increase the agency's ability to proactively detect resistance, confirm and address potential resistance, and share relevant information about resistance issues with stakeholders.

Compliance Has Improved

The EPA collects and reviews compliance information from industry on an annual basis. The ABSTC submits CAP reports to the EPA, and the agency reviews the reports to monitor compliance trends. CAP report data is self-reported, summary information, and the EPA said it does not conduct any data verification on the reports. We reviewed CAP reports, and found an average compliance rate of 75 percent for 2011 through 2014. The EPA and industry state that compliance is increasing due to the use of "refuge in a bag" products. Compliance data is one of the indicators used to determine the efficacy of the EPA's IRM program.

EPA Needs to Take Actions to Delay Insect Resistance

The EPA should take additional actions to manage and delay increased insect resistance to Bt corn. Changes needed include providing a standardized testing methodology to registrants, developing a mechanism for information sharing between researchers and growers, and requiring industry to develop resistance management plans prior to resistance confirmation.

Determining resistance is hindered due to the lack of a standardized testing methodology. Researchers we spoke with also stated there is no standardized testing methodology for registrants to use to identify and confirm resistance. The EPA needs to provide a standardized method to registrants to use to ensure that all parties are determining resistance in the same manner.

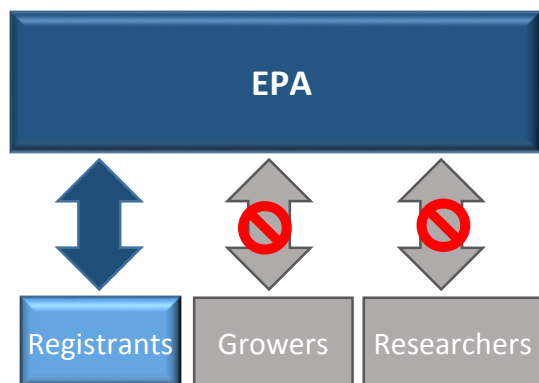
Both the EPA and academics stated that the current diet-based testing assay is unreliable because it cannot sustain insect populations to determine resistance.⁸ The Iowa resistance study pioneered an on-plant testing assay instead of a diet-based test to reproduce sufficient populations in a laboratory setting. This on-plant testing assay is also supported by the EPA, and was required as part of some of the resistance monitoring activities done by industry. According to the agency, registrants currently conduct the on-plant testing assay in at least two different ways;⁹ therefore, registrants' reports to the EPA may not be comparable.



Biological aides and technicians prepare cages used to catch corn rootworm beetles for study. (USDA photo)

Under the existing IRM structure, registrants are the only ones who provide resistance information to the EPA (Figure 4).¹⁰ The agency's reliance on industry

Figure 4: EPA's relationships with IRM stakeholders



Source: EPA OIG.

to provide information on resistance can result in data gaps. For example, the Iowa case of insect resistance found in 2009 was not reported by registrants. Moreover, we were informed by the agency and the academic expert that registrants denied the researcher's findings. Researchers and growers do not have a direct method to report resistance concerns to the EPA. We interviewed one person who made a call to a registrant to report unusual field observations, but the registrant was uninterested. The EPA could enhance its reporting structure by including a feedback loop that allows stakeholders to provide information on unexpected field damage and other concerns directly to the EPA. The agency could also provide access to a hotline.

Finally, the EPA does not require the development of remedial action plans to prepare for insect resistance events. When the Iowa resistance case was confirmed, the related registrant was not required to implement a remedial action plan. In part, this was because the registrant did not agree with the EPA that resistance had occurred. Therefore, the registrant pushed back on the need for a remedial action plan. By the time the registrant conceded that resistance had

⁸ The current strategy focuses on a feeding test, which has such a high mortality rate the test is inconclusive for most pest populations, including corn rootworm.

⁹ The EPA said that two on-plant assays have been developed (with methodology in the public literature) to confirm resistance: the single on-plant assay (Gassmann); and the Sublethal Seedling assay (Pioneer).

¹⁰ The EPA has limited or no direct relationship with growers and researchers.

occurred, a remedial action plan was no longer an effective action because the registrant's agreement came after the growing season had passed.

Registrants should develop specific, implementable remedial action plans prior to resistance development. This would enable registrants to now plan the steps that need to be taken when faced with unexpected field damage or confirmed resistance.

Information Needs to Be Collected and Shared

The EPA needs to obtain more resistance monitoring data. Although the EPA collects compliance data, this data does not provide information on the state of resistance. Data collection for resistance monitoring is currently limited. The EPA needs to collect more resistance monitoring data so the agency can better understand the frequency and patterns of resistance.

The Iowa resistance studies concluded that insufficient planting of refuges may have contributed to resistance. The studies also highlighted the need for improvements in resistance management. Because the two work together—compliance and resistance—the EPA has indicated that it would be more effective to focus on proactive detection and responses to unexpected damage. Researchers with whom we spoke agree with the EPA, and provided consensus that field damage is the first real indicator of potential resistance.

The EPA needs to focus on unexpected field damage that occurs before resistance is confirmed, because confirming resistance is a very extensive process. The agency currently collects resistance monitoring information from individual registrants. While these data include information on unexpected field damage, the information provided is trait-specific and does not give statistically significant information that could help the EPA track and analyze resistance.

Transparency is an EPA core value. The EPA OIG has previously reported on the value to stakeholders and the public of increased transparency regarding the EPA's management of chemicals¹¹ and pesticides.¹² Currently, neither compliance nor resistance monitoring data developed by registrants are released to the public. Academic researchers with whom we spoke stated that such data would be useful to their work, and we found there are no restrictions on data release.

When asked, EPA program staff stated that the agency's website should be improved. For example, EPA's website could provide better information to stakeholders, such as access to registrant compliance reports and resistance

¹¹ EPA OIG, *EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities*, Report No. [10-P-0066](#), February 17, 2010.

¹² EPA OIG, *Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act*, Report No. [2006-P-00003](#), October 19, 2005; and EPA OIG, *EPA Needs Policies and Procedures to Manage Public Pesticide Petitions in a Transparent and Efficient Manner*, Report No. [16-P-0019](#), October 27, 2015.

monitoring data. Furthermore, the EPA does not provide clear and concise information regarding its IRM program. Websites for other similar EPA programs (e.g., the Integrated Pest Management in Schools program) provide detailed information on the mission, role of stakeholders, and goals of the program. However, the agency's IRM program does not explain what role various stakeholders play, or provide information on insect resistance in a clear manner. As a global leader in biotechnology, stakeholders look to the EPA to provide information on genetically engineered crops. The EPA has both information and the means to enhance transparency regarding its regulatory oversight of genetically engineered crops such as Bt corn.

Conclusion

Bt corn represents the vast majority of corn grown in the United States. In addition, Bt corn has a significant financial impact on the economy, which has been estimated to be a nearly \$231 million benefit to farmers. A key element that supports the durability and benefit of Bt corn is the proactive management of insect resistance. Although compliance with refuge requirements has improved, there is still a need for increased resistance detection and monitoring. The EPA's management of the Bt corn IRM program also faces challenges regarding the collection and dissemination of reliable resistance information. To mitigate these challenges, the EPA needs better data and tools to increase the agency's ability to manage and delay insect resistance.

Recommendations

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention:

1. Standardize and require the use of one specific, on-plant testing assay for Bt corn resistance determinations of corn rootworm.
2. Establish a method for growers and researchers to independently report findings of unexpected damage or resistance, noncompliance and other concerns.
3. Enhance current remedial action plans to require that plans be developed prior to a resistance finding.
4. Require industry to conduct increased resistance monitoring and testing for unexpected damage by corn rootworm.
5. Make CAP reports and resistance monitoring data publically available on the EPA's website.

6. Improve the EPA's website by adding more general information about biotechnology and genetically engineered crops, specifically Bt corn and insect resistance.

Agency Comments and OIG Evaluation

The agency agreed with our recommendations, and provided corrective actions and estimated completion dates that meet the intent of the recommendations. Many actions were completed in February 2016, and the agency plans to complete all actions by July 2017. All recommendations are resolved. No further response to this report is required. The agency's detailed response and our embedded comments on the responses are in Appendix A.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in \$000s)	
Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Claimed Amount	Agreed-To Amount
1	10	Standardize and require the use of one specific, on-plant testing assay for Bt corn resistance determinations of corn rootworm.	C	Assistant Administrator for Chemical Safety and Pollution Prevention	2/18/16		
2	10	Establish a method for growers and researchers to independently report findings of unexpected damage or resistance, noncompliance and other concerns.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	3/31/17		
3	10	Enhance current remedial action plans to require that plans be developed prior to a resistance finding.	C	Assistant Administrator for Chemical Safety and Pollution Prevention	2/18/16		
4	10	Require industry to conduct increased resistance monitoring and testing for unexpected damage by corn rootworm.	C	Assistant Administrator for Chemical Safety and Pollution Prevention	2/18/16		
5	10	Make CAP reports and resistance monitoring data publically available on the EPA's website.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	7/31/17		
6	11	Improve the EPA's website by adding more general information about biotechnology and genetically engineered crops, specifically Bt corn and insect resistance.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	7/31/17		

¹ O = Recommendation is open with agreed-to corrective actions pending.
 C = Recommendation is closed with all agreed-to actions completed.
 U = Recommendation is unresolved with resolution efforts in progress.

Agency Response to Draft Report and OIG Comments



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Comments on the OIG's Draft Report: "EPA Needs Better Data and Tools to Manage Insect Resistance to Genetically Engineered Corn," Project No. OPE-FY15-0055

FROM: James J. Jones
Assistant Administrator

TO: Arthur A. Elkins, Jr.
Inspector General

This memorandum is in response to the Office of Inspector General's (OIG) Draft Report entitled "EPA Needs Better Data and Tools to Manage Insect Resistance to Genetically Engineered Corn," (March 28, 2016). The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's effort in evaluating:

1. The extent to which the Office of Pesticide Programs (OPP) collects and reviews industry Compliance Assurance Program (CAP) reports submitted by genetically engineered corn seed registrants; and
2. The actions taken by the OPP when registrants report increased insect resistance to genetically engineered Bt corn.

The Draft Report contains six recommendations for the Office of Pesticide Programs. The OCSPP generally agrees with the recommendations, though we differ on several details in the report and recommendations. When germane, our response includes corrective actions and a time frame for their completion. Many of the issues raised in the Draft Report were also addressed by a Scientific Advisory Panel (SAP) held in 2013. The SAP report from this meeting

included guidance for improving resistance management for corn rootworm. In implementing the SAP's recommendations, OCSPP believes many of OIG's concerns have also been addressed.

The OSCPP notes that the Draft Report did not specify the pest complex (lepidopteran or corn rootworm; see the background section below) to which the recommendations refer. Given the context of the report, the OCSPP assumes that corn rootworm was the major focus of the investigation and recommendations. However, our responses below address both pest complexes.

I. Background

Plant-incorporated protectants (PIPs) are pesticidal substances (typically proteins) that have been genetically engineered to be produced by plants to protect against insect or disease pests. The most common PIPs have been derived from the bacterium *Bacillus thuringiensis* (*Bt*), in which scientists take the gene for a specific Bt pesticidal protein and introduce the gene into the plant's genetic material. Then the plant manufactures the pesticidal protein that controls the pest when it feeds on the plant.

Two types of Bt corn PIPs have been developed to date. One class of Bt PIPs targets Lepidopteran corn pests such as European corn borer, southwestern corn borer, and corn earworm. The second group targets a Coleopteran pest, corn rootworm. A number of Bt corn products have been developed to express both types of these Bt PIPs to target multiple pest complexes.

As pesticides, Bt corn PIPs are regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Both the PIP substance and its genetic material are regulated by the EPA; the plant itself is not regulated. Under FIFRA regulation, the EPA requires that Bt PIPs include an insect resistance management (IRM) strategy to mitigate the potential for resistance to develop among the target pests. IRM strategies for Bt corn include the use of refuge (non-Bt plants that serve as a source of susceptible insects), resistance monitoring, grower education, refuge compliance programs, and reporting to the Agency.

With respect to corn rootworm, the EPA convened a Scientific Advisory Panel (SAP) meeting in December, 2013 to address concerns in light of documented cases of resistance to Bt corn. The panel report provided guidance to strengthen IRM for rootworm, including the use of Integrated Pest Management tactics, standardized responses to unexpected pest damage in Bt corn fields, improved resistance detection assays, and mitigation measures for confirmed resistance. The OCSPP has implemented many of the SAP's recommendations, which the OCSPP believes also address a number of the concerns raised in the OIG's report.

II. OCSPP's Response to the Recommendations

Recommendation 1: Standardize and require the use of one specific, on-plant testing assay for Bt corn resistance determinations.

OCSPP Response:

The Draft Report did not specify which pest complex, lepidopteran or coleopteran (or both), to which this recommendation pertains. But given the reference to “on-plant” assays, which have been developed for resistance determinations with corn rootworm, the OCSPP assumes for this response that the Draft Report refers to the latter.

The OCSPP agrees with the OIG’s recommendation that a standardized testing approach is needed for corn rootworm. Furthermore, the bioassay should function as a “diagnostic” test (i.e., capable of clearly distinguishing resistant populations from susceptible ones). However, the OCSPP differs from the OIG’s perspective that a single, specific on-plant assay is a necessity for all four registered Bt toxins. Alternate approaches (including an improved diet bioassay) may achieve the OCSPP’s goals of having a reliable resistance detection tool for corn rootworm.

As noted in the Draft Report, testing with diet bioassays to date has revealed inconsistent and variable results, making resistance determinations difficult. Alternate approaches, using live corn plants, have been developed by researchers at Iowa State University and DuPont Pioneer (formerly Pioneer Hi-Bred). These on-plant assays more closely resemble field conditions (i.e., the insect’s natural environment) and have been used to make resistance determinations with populations collected from damaged Bt fields (see Gassmann et al. 2011, 2014).

Despite the OCSPP’s preference to utilize on-plant assays, it may be difficult to arrive at a single assay approach for all four of the registered corn rootworm Bt traits. To illustrate, the on-plant assay developed by DuPont Pioneer (the “Sublethal Seedling Assay”) is specific to the Cry34/35 toxin and has not been adapted to the other three toxins. The “Gassmann” approach has been used for Cry3Bb1, mCry3A, and Cry34/35 in testing at Iowa State University, though registrants have reported difficulties in replicating the test at their facilities. In addition, the 2013 SAP noted that Bt expression in live plants could decline over time and improvements may be needed for on-plant approaches.

A number of academic researchers, industry (ABSTC), and the 2013 SAP have recommended that the EPA maintain diet bioassays for corn rootworm. The arguments experts cite for maintaining diet assays include the precise nature of the assays, the breadth of data that can be collected (lethal and sublethal responses), and that they can be more easily standardized between laboratories.

In discussions with ABSTC on a new IRM framework for corn rootworm that incorporates measures to address the recommendations of the SAP, the OCSPP ultimately agreed to permit three possible assay approaches, but standardized the way the tests are interpreted for resistance determinations. The assays include the two on-plant assays (Iowa State and Pioneer) as well as an improved diet bioassay. For all three of these tests, they must meet the OCSPP’s requirement to be a “diagnostic” assay capable of clearly distinguishing between resistant and susceptible populations. In addition, the EPA requires two statistically relevant comparisons for each assay approach: 1) a field population compared to a susceptible laboratory colony when both are exposed to Bt (on-plant or in diet), and 2) a field population exposed to both Bt vs. non-Bt (plant or diet). Registrants are also required to include resistant laboratory colonies as a

separate (positive) control. As well as standardizing the interpretation of the assays, the use of multiple metrics will reduce the likelihood of false positives or negatives. Regardless of the assay approach, the new framework requires that registrants obtain approval from EPA for their method prior to initiating testing.

The OCSPP believes that consistent criteria to evaluate bioassays, the use of a resistant colony control group, and the need to seek the EPA approval on the testing method will achieve the goals behind the OIG's recommendation to standardize testing for corn rootworm resistance determinations. These measures have already been implemented as part of the Agency's new framework for corn rootworm IRM.

Therefore, the OCSPP believes this recommendation has been sufficiently addressed and is not providing a time frame for completion.

OIG Response to Recommendation 1: We have clarified this recommendation to refer specifically to corn rootworm. Requirements in the EPA's Framework to Delay Corn Rootworm Resistance (issued February 28, 2016) constitute acceptable corrective actions for this recommendation. Since the framework includes the option of using a single, specific on-plant assay, this recommendation is resolved.

OIG Recommendation 2: Establish a method for growers and researchers to independently report findings of unexpected damage or resistance, noncompliance and other concerns.

OCSPP Response:

The OCSPP agrees that growers and independent researchers have important roles in IRM, and supports efforts to better engage with them as part of the Agency's regulatory oversight of Bt corn. The OCSPP also believes an improved web site (see Recommendation #6 below) will facilitate better interactions with stakeholders, including growers and researchers. However, the OCSPP differs somewhat from the OIG on the potential benefits of growers reporting unexpected damage or non-compliance claims directly to the EPA.

Reports of unexpected damage (UXD) are key potential indicators of resistance developing in the field. As part of the recently-completed framework to improve corn rootworm IRM, the EPA standardized and strengthened the way cases of UXD are investigated by registrants. All claims of UXD must be investigated; those that exceed damage triggers (based on a quantification of root damage) must undergo a resistance determination process that includes insect sampling, testing with a standardized approach (see Recommendation #1), and mitigation measures to manage the field population (in case the population is found to be resistant). Each registrant must submit an annual report to the EPA detailing these UXD investigations, including information on the number of cases, locations, sampling/assay results, and ultimate disposition of each case. The Agency intends to compile these reports into a publically-releasable form that will provide information on potential resistance to growers, crop consultants, extension personnel, and other stakeholders. The reports will be made available on an improved web site for IRM (see Recommendation #6 below) and/or in the current public IRM docket (EPA-HQ-OPP-2011-0922). The OCSPP expects to start this process by early 2017 with

the UXD reports that will cover the 2016 growing season, which are due to be submitted to EPA by November 30, 2016.

With respect to growers reporting UXD cases directly to EPA, OCSPP believes that such reports will likely be of limited value to the Agency. A UXD case may or may not be due to resistance and an investigation (as described above) is needed to make a proper evaluation. The EPA lacks the means and resources to investigate grower reports, which necessarily would include insect sampling and testing. Nor would the Agency be able to make effective and credible resistance determinations from the likely piecemeal and anecdotal UXD reports that would be received without the detailed follow up investigations described above. The OCSPP believes a better approach is to have the Bt registrants vet cases of UXD and make annual reports to the EPA (as they are required to do under the new IRM framework). From a resource and logistical perspective, registrants are in a much better position to conduct these investigations. Registrants have a contractual relationship with their customers, provide grower education material (including contacts and instructions for UXD), and employ personnel capable of scouting and assessing rootworm damage. It should also be noted that failure to investigate a UXD claim by a registrant would be a violation of the terms and conditions of registration which could result in penalties up to cancellation of the registration.

Regarding independent researchers, the OPP's Biopesticides and Pollution Prevention Division (BPPD) routinely interacts with entomologists specializing in corn insects and IRM. During the corn growing season, BPPD conducts monthly teleconferences with the NC-205 (lepidopteran) and NCCC46 (corn rootworm) research groups to discuss pest conditions and resistance issues in corn-growing states. The BPPD staff also regularly attend scientific meetings (e.g., Entomological Society of America) where research and finding related to IRM are frequently discussed.

Similar to UXD, the OCSPP believes direct reports to the EPA on non-compliance from growers or researchers would be an inefficient method to address compliance. Under FIFRA, the EPA lacks authority to directly assess compliance with refuge requirements. Since EPA does not regulate the corn plant, the Agency does not conduct on-site inspections for compliance. Therefore, the EPA would have limited ability to follow-up on individual reports of non-compliance. Registrants are already required to assess refuge compliance, including third party surveys and on-farm visits, and report the results to the EPA annually. The EPA evaluates the annual reports and, in cases of low compliance, has made improvements to the program (e.g., the 2010 Bt corn registration extensions included new terms for compliance). As noted in the Draft Report, the popularity of "Refuge-in-the-Bag" products has greatly reduced non-compliant acres with Bt corn. Nonetheless, OCSPP is amenable to independent assessments of compliance by academic researchers or other interested parties and will assist in providing data or other information to do so (see Recommendation #5 below).

The OCSPP believes the improvements to UXD investigations required by the new IRM framework for corn rootworm, current practices regarding UXD and compliance reporting, and ongoing interactions with corn entomologists largely address the OIG's recommendation. In addition, the OCSPP will make improvements regarding the dissemination of data

(Recommendation #5) and an improved web site (Recommendation #6) that address further aspects of OIG’s concerns.

The OCSPP expects to begin disseminating UXD reports by March 2017, which will include information submitted for the 2016 growing season.

OIG Response to Recommendation 2: The OIG believes that the EPA should provide direct access for entities outside of registrants to report resistance. The intent of this recommendation is not to assess compliance, but rather to create a system of checks and balances. Since the EPA’s planned improvements to the corn rootworm framework will result in less reliance on industry to report resistance and allow growers and researchers to be able to inform the process more, we accept the corrective action provided. This recommendation is resolved.

Recommendation 3: Enhance current remedial action plans to require that plans be developed prior to a resistance finding.

OCSPP Response:

The OCSPP agrees that remedial action plans need to be in place before resistance is detected. As part of the new IRM framework for corn rootworm, the Agency revised and enhanced the previous remedial action approach to include more prescriptive measures intended to better mitigate resistance events. Once resistance is confirmed (using the bioassay approach described in Recommendation #1 above), the remedial action measures include:

- Establishment of a “Mitigation Action Area” (MAA, defined by the dispersal potential of corn rootworm);
- Notification to stakeholders (growers, extension agents, crop consultants, and other registrants) selling the compromised Bt trait within the MAA;
- Prohibition against selling single trait products with the compromised trait within the MAA;
- Requirement that any pyramids containing the compromised trait must be planted with a larger refuge (20% instead of 5%) within the MAA;
- Requirement that the company work with the affected grower to implement Best Management Practices (BMPs) to control the resistant population (includes crop rotation, use of non-compromised pyramids or different CRW traits, non-Bt corn, insecticide controls);
- Requirement to conduct additional resistance monitoring within the MAA.

These measures must be continued until the resistant population is demonstrated to have been mitigated, either by sampling and bioassay results (from additional monitoring) or until the field has been rotated to a non-host crop such as soybean.

Existing remedial action plans for lepidopteran pests follow a similar approach to the corn rootworm strategy. Registrants with confirmed resistance cases must notify the EPA and stakeholders, cease selling products with the compromised trait in the affected area, utilize

alternate control measures, and increase resistance monitoring until resistance has been mitigated.

With the implementation of the EPA's improved framework for corn rootworm IRM, the OCSPP believes we have addressed OIG's recommendation to enhance current remedial action strategies. Accordingly, no further action or a time table is proposed for this recommendation.

OIG Response to Recommendation 3: Requirements in the EPA's Framework to Delay Corn Rootworm Resistance (issued February 28, 2016) constitute acceptable corrective actions for this recommendation. This recommendation is resolved.

Recommendation 4: Require industry to conduct increased resistance monitoring and testing for unexpected damage.

OCSPP Response:

The OCSPP agrees that an improved resistance monitoring program is needed for corn rootworm. However, the OCSPP believes that the resistance monitoring program for lepidopteran pests, which were not the focus of the OIG's report, is adequate as currently designed.

As noted above, based on the 2013 Scientific Advisory Panel meeting, the EPA has developed a new framework for corn rootworm IRM. As part of this framework, the Agency has restructured and improved resistance monitoring for corn rootworm. The previous approach relied upon annual sampling of corn rootworm populations that were collected from random locations in the Corn Belt. Since these populations were not tracked over time, it was not possible to determine if their susceptibility to the Bt traits had changed. Also, corn rootworm are less sensitive to Bt than other pests, and it is difficult to tease out subtle shifts in susceptibility before the insects are capable of causing field damage. The OCSPP believes that a better approach is to focus on cases of unexpected damage (UXD) to Bt corn, which is likely the most reliable indicator of early resistance development. The EPA's new IRM framework standardizes and increases the rigor in how these UXD cases are investigated. All cases must be investigated and, if damage triggers are exceeded, corn rootworm beetles must be sampled for testing to make a resistance determination. In addition, registrants must immediately work with the affected grower to implement measures (Best Management Practices or BMPs) designed to control the putative resistant population. The measures are to be in place proactively – i.e., before the bioassay results are available.

In cases of confirmed resistance, registrants must conduct additional monitoring in the mitigation action area until the resistance has been demonstrated to have been successfully mitigated.

The monitoring approach for lepidopteran pests of Bt corn differs somewhat from that used for corn rootworm. This is largely because the main lepidopteran pests are more sensitive to Bt toxins, and it may be possible to observe shifts in susceptibility before field failures occur. Lepidopteran monitoring involves annual sampling of pest populations which are compared to

historic baseline levels. Statistically significant shifts in susceptibility are further investigated for potential resistance. Similar to corn rootworm, all reports of UXD must be investigated.

The OCSPP believes the improvements made to the corn rootworm monitoring program address Recommendation 4, and that current monitoring strategies for lepidopteran insects are adequate as currently designed. Therefore, no additional actions or a time table is proposed for this recommendation.

OIG Response to Recommendation 4: We have clarified this recommendation to refer specifically to corn rootworm. Requirements in the EPA's Framework to Delay Corn Rootworm Resistance (issued February 28, 2016) constitute acceptable corrective actions for this recommendation. This recommendation is resolved.

Recommendation 5: Make CAP reports and resistance monitoring data publically available on the EPA's website.

OCSPP Response:

The OCSPP agrees that compliance and resistance monitoring data should be publically available. The OCSPP is aware that a number of researchers are interested in these data, and supports further independent studies relating to IRM. At present, researchers have been able to access compliance and monitoring data through FOIA. The OCSPP understands, however, that the FOIA process can be cumbersome, and a more direct dissemination of data would be favorable to interested members of the public.

The OCSPP believes this objective can be obtained by including the submitted studies as content on a redesigned web site (see Recommendation #6 below), or as part of the existing general purpose IRM docket (EPA-HQ-OPP-2011-0922). The EPA currently uses the IRM docket to disseminate Agency reviews of data, but generally does not include the studies themselves. The OCSPP will work with the Bt corn registrants (via ABSTC) to ensure that the submitted studies are in a format that can be released to the public.

Since this recommendation will likely overlap with the web site redesign (Recommendation #6), the OCSPP is proposing a one year time frame to address this recommendation. This time frame would correspond to July 2017.

OIG Response to Recommendation 5: The OIG accepts the corrective action, with the understanding that the release of study data refers to both compliance and resistance monitoring data. This recommendation is resolved.

Recommendation 6: Improve the EPA’s website by adding more general information about biotechnology and genetically engineered crops, specifically Bt corn and insect resistance.

OCSPP Response:

The OCSPP agrees that an improved website is needed for biotechnology and IRM. Improving the website will also help address other recommendations (#2 and #5) of the Draft Report, and will further the Agency’s goals of transparency and effective IRM.

The OCSPP (OPP/BPPD) has conducted initial discussions on a website improvement, but time will be needed for design, content development, and approval. Accordingly, the OCSPP is proposing a one year time frame to address this recommendation, which would correspond to July 2017.

OIG Response to Recommendation 6: The OIG accepts the corrective action. This recommendation is resolved.

III. Conclusion and Contact Information:

Overall, OCSPP is pleased that the Draft Report aligns with many of the recommendations of the 2013 SAP, supports steps the EPA has taken in its new IRM framework to implement those recommendations, and recognizes the EPA’s continuing efforts to improve the policies, oversight and management of resistance management and delay increased insect resistance to genetically engineered *Bacillus thuringiensis* (Bt) corn.

If you have any technical questions regarding these responses, please contact Alan Reynolds and Kimberly Nesci of OPP/BPPD. If you have other questions, please contact Janet Weiner, OCSPP’s Audit Liaison, at weiner.janet@epa.gov.

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