



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Chemical Safety

EPA Can Strengthen Its Oversight of Herbicide Resistance With Better Management Controls

Report No. 17-P-0278

June 21, 2017



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Abbreviations

2,4-D	2,4-Dichlorophenoxyacetic acid
CFR	Code of Federal Regulations
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
MOA	Mechanism of Action
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPP	Office of Pesticide Programs
PRN	Pesticide Registration Notice
USDA	U.S. Department of Agriculture
WSSA	Weed Science Society of America

Cover photo: Images of herbicide-resistant weeds. (EPA OIG photos)

Disclaimer: Any product names used in this report are for illustrative purposes only and do not constitute an endorsement of any products.

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At a Glance

Why We Did This Review

We conducted this review to assess the U.S. Environmental Protection Agency's (EPA's) management and oversight of resistance issues related to herbicide-resistant genetically engineered crops. We looked at EPA processes and practices, steps the EPA has taken to validate risk, and how the agency collects herbicide resistance data.

Approximately 90 percent of the U.S. soybean, corn and cotton crops are genetically modified to withstand herbicide applications on surrounding weeds. However, when weeds adapt and acquire the ability to withstand the effects of herbicides, this results in herbicide resistance. According to the EPA, the Federal Insecticide, Fungicide, and Rodenticide Act designates herbicide resistance as a risk. The EPA considers herbicide resistance to be one of the farmer's biggest challenges in crop production. Substantiated resistance must be reported to the EPA.

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

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

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EPA Can Strengthen Its Oversight of Herbicide Resistance With Better Management Controls

What We Found

The EPA's Office of Inspector General (OIG) found that the agency has taken few steps to address herbicide resistance. The EPA believes that a delay in herbicide resistance is in the "public good." Delaying resistance minimizes the amount and type of herbicides applied to combat weeds, reduces human and environmental exposure, and increases grower productivity. However, the EPA has several management and oversight challenges related to the agency effectively addressing herbicide resistance.

Billions of dollars in U.S. crop value are at risk due to the threat of herbicide-resistant weeds. With private and public partners, the EPA can establish better controls to manage and minimize the threat.

We found that the EPA uses the pesticide registration process to collect information on human health and environmental risks from pesticides used on herbicide-resistant weeds, but no information is collected regarding synergism. Synergy occurs when the effect of a mixture of chemicals is greater than the sum of the individual effects.

In addition, labels for products such as glyphosate currently do not require information about the chemical pathway that describes how a herbicide causes harm to a plant (i.e., the "mechanism of action"). Not requiring this information on labels can result in the improper use of pesticides to combat herbicide-resistant weeds. The EPA's pesticide registration and reporting processes also do not generate necessary herbicide resistance information for tracking, monitoring and identifying where resistance occurs.

There is a lack of communication and collaboration between the EPA and its public and private stakeholders regarding herbicide resistance management. This limits the reach of actions proposed and taken by the EPA, the development of meaningful alternatives, and the agency's ability to proactively respond to herbicide resistance in the field. The EPA also does not have measures to track its progress addressing and slowing the spread of herbicide resistance. With improved management and oversight controls, the EPA can be better prepared to assess and develop actions to address and prevent future herbicide resistance issues.

Recommendations and Planned Agency Corrective Actions

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention (1) consider requiring herbicide labels include mechanisms of action, (2) assess the need for more information on synergism, (3) improve data collection and reporting on herbicide resistance, (4) develop performance metrics, and (5) develop a plan for establishing consistent communication with stakeholders. The EPA agreed with our recommendations. All recommendations have been resolved with corrective actions pending.



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

THE INSPECTOR GENERAL

June 21, 2017

MEMORANDUM

SUBJECT: EPA Can Strengthen Its Oversight of Herbicide Resistance With Better Management Controls
Report No. 17-P-0278

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: Wendy Cleland-Hamnett, Acting 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 evaluation was OPE-FY16-0023. 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.

Action Required

In accordance with EPA Manual 2750, your office provided planned corrective actions in response to our recommendations. All recommendations are considered resolved. You are not required to provide a written response to this final report because you provided agreed-to corrective actions and planned completion dates for the report recommendations. The OIG may make periodic inquiries on your progress in implementing these corrective actions. Please update the EPA's Management Audit Tracking System as you complete planned corrective actions. Should you choose to provide a final response, we will post your response on the OIG's public website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

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 (EPA), Office of Inspector General (OIG), assessed the EPA's management and oversight of resistance issues impacting herbicide-resistant genetically engineered crops. Specifically, our objectives were to determine the following:

- What processes and practices, including alternatives, has the EPA provided to delay herbicide resistance?
- What steps has the EPA taken to determine and validate the accurate risk to human health and the environment for approved pesticides to be used to combat herbicide-resistant weeds?
- Does the EPA independently collect and assess data on, and mitigate actual occurrences of, herbicide resistance in the field, and prevent improper use of registered pesticides?

Background

Herbicides (a type of pesticide) are chemicals used to manipulate or control undesirable vegetation such as weeds. Because weeds can adapt and acquire the ability to withstand the effects of herbicides, this natural phenomenon is referred to as herbicide resistance.¹ Resistant weeds can survive herbicide applications that were previously known to control the weed population. Herbicide-resistant crops are genetically engineered to tolerate one or more specific broad-spectrum herbicides that kill the surrounding weeds but leave the cultivated crop intact. The EPA does not regulate these crops; rather, the U.S. Department of Agriculture (USDA) regulates the crops, and the EPA regulates the herbicides used on the crops. The U.S. Food and Drug Administration reviews the crops for food safety.

The EPA regulates all herbicides for use on crops under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and the Federal Food, Drug, and Cosmetics Act, as amended by the Food Quality Protection Act. When a new pesticide is registered, the EPA determines and evaluates risks to human health and the environment. The registered pesticide should not generally cause “unreasonable adverse effects on the environment.”

¹ The term “herbicide tolerant” can also be used to describe the natural phenomenon known as “herbicide resistance.” There continues to be discussion over which term (herbicide resistant or herbicide tolerant) is most appropriate. For this report, we will use the term the EPA prefers, which is herbicide resistant.

Herbicides can be sprayed directly onto herbicide-resistant crops and surrounding weeds, and the herbicides will not harm the herbicide-resistant crops and just kill the weeds. In crops that are not herbicide resistant, this direct herbicide application could harm the crop. USDA reported that more than 90 percent of soybeans grown in the United States, and 89 percent of domestic cotton and corn, were genetically modified to withstand herbicide applications in 2015 and 2016. Over 80 percent of all genetically engineered crops grown worldwide are engineered for herbicide resistance. These crops include alfalfa, canola, corn, cotton, soybeans, sugar beets and rice.

According to the EPA, weed control is one of the grower's biggest challenges in crop production. Poorly controlled weeds in agriculture drastically reduce crop yield and quality. Uncontrolled weeds often result in an increase in the use of herbicides by farmers. Herbicide resistance is a costly and escalating issue. It is particularly serious for growers who have relied on a herbicide employing a single mechanism of action² (MOA). An MOA is the specific physiological pathway that a herbicide uses to cause harm to a weed.

Data indicates that in the United States and Canada, half of several key crops could be lost because of uncontrolled weeds, costing growers about \$43 billion annually. To control weeds, farmers often use broad-spectrum herbicides that kill nearly all kinds of plants. For this reason, industry created genetically engineered crops that are resistant to certain herbicides. As of November 2016, the EPA had registered five herbicidal active ingredients to be used on genetically engineered crops.

While many weeds may have been controlled in the past by a particular herbicide, once weeds become resistant, the herbicide is no longer effective. Figure 1 illustrates that unique resistant weed cases have steadily increased over the last 40 years.

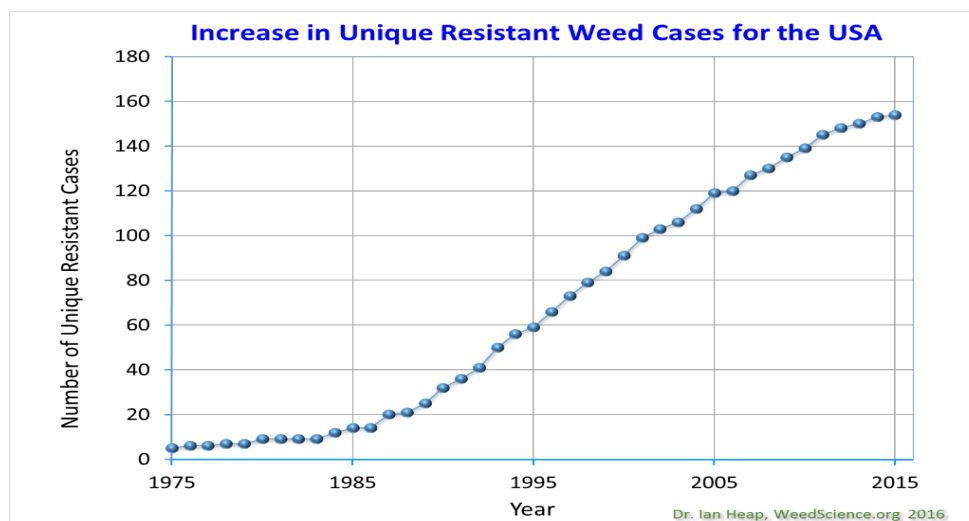


Left side of image: Uncontrolled weeds compete for nutrients and reduce crop yield.

Right side of image: Weeds are controlled. (EPA OIG photo)

² MOA is also referred to as Mode of Action. Mechanism of Action and Mode of Action both refer to the way a herbicide acts on a plant, and the terms are often used interchangeably. However, Mechanism of Action refers to a sequence of events that cause harm or death at the molecular level, and Mode of Action refers to only the critical steps. For the purposes of this report, we will use Mechanism of Action.

Figure 1: Increase in unique resistant weeds in the United States (1975–2015)



Source: Heap, I. The International Survey of Herbicide Resistant Weeds. February 7, 2016.

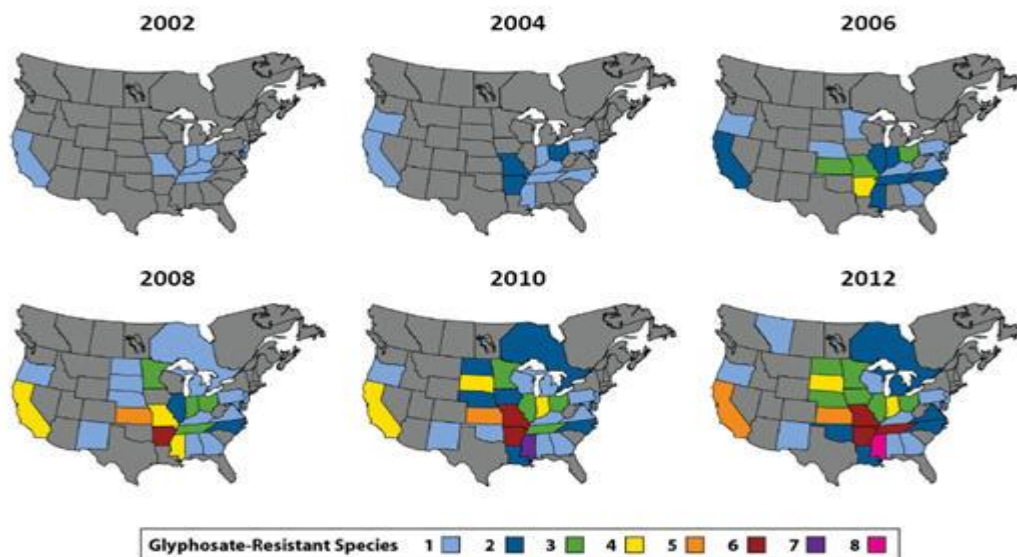
The most commonly grown herbicide tolerant crops were engineered to be resistant to the herbicide glyphosate. Glyphosate is applied primarily to genetically engineered, herbicide-resistant varieties of soybeans, corn, canola and cotton. Because of its broad spectrum and relatively low toxicity to animals, it has a variety of uses in agriculture. At least 283.5 million pounds of glyphosate were used in U.S. agriculture in 2012,³ up from 110 million in 2002.

Herbicide resistance was first reported in 1968. The widespread adoption of genetically engineered crops led to reductions in the diversity of weed-control tactics used and a reliance on single-herbicide farming. This in turn created selection pressure⁴ for several weeds to develop resistance to herbicides like glyphosate (Figure 2).

³ The most recent year for available data is 2012.

⁴ Selection pressure is the set of factors that affect the survivability and reproduction of a population. Application of a herbicide may result in differential survivability and reproduction of individual weeds with particular genotypes leading to changes in the frequency of these genotypes in the population of the weed species.

Figure 2: Confirmed glyphosate-resistant weed populations in North America (2002–2012)



Source: [Pioneer website](#).⁵

Other examples of resistant weeds include Palmer amaranth in cotton, Waterhemp in corn, and Horseweed in soybeans. Both Palmer amaranth and Waterhemp have shown resistance to glyphosate and other herbicides with the same properties.

Weeds can be prolific seed producers, which multiplies the impact of a single plant. A single Palmer amaranth can produce a million seeds. Cotton farmers battling Palmer amaranth have found it can have a devastating impact on crop yields and is costly to control. According to agricultural experts, its stems are tough enough to damage farm equipment.



Palmer amaranth weed with exposed root system. (EPA OIG photo)

The EPA believes that a delay in herbicide resistance is in the “public good.” Delays in herbicide resistance means fewer chemicals are introduced into the environment and onto crops, and grower productivity is increased. However, with increased resistance, these environmental and economic benefits are reduced.

According to stakeholders such as growers and researchers, the proliferation of herbicide-resistant weeds has prompted many growers to apply more glyphosate

⁵ Website was last accessed February 3, 2017.

and other herbicides to combat weeds.⁶ This increased use of glyphosate can produce higher concentrations of the chemical running off into nearby ecosystems. At elevated concentrations, glyphosate is capable of causing environmental harm. For instance, one peer-reviewed study⁷ concluded that worldwide, glyphosate contaminates drinking water sources, especially in agricultural regions.

EPA's Herbicide Resistance Activities

The EPA acknowledges that resistant weeds can reduce the efficacy of EPA-registered herbicides.⁸ The EPA's Office of Pesticide Programs (OPP) has explained that its goal is to extend the useful life of chemicals used for pest control by (1) slowing the development of pest resistance to fungicides, herbicides and insecticides, and (2) extending the useful lifespan of herbicides and related technology.

OPP has identified a number of ongoing activities to support the above herbicide resistance goal. The EPA utilizes Pesticide Registration Notices (PRNs) to provide information to registrants and growers, and for education and outreach. OPP issues PRNs to inform pesticide registrants and other interested parties about important policies, procedures and regulatory decisions. In 2016, the agency released and asked for comment on two PRNs that focus on herbicide resistance management strategies:

- (1) *The Draft Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling* focuses on pesticide product labels.
- (2) *The Draft Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship* focuses on suggested best management practices, such as taking a more holistic and proactive approach to herbicide resistance management.

⁶ Myers, J. P., Antoniou, M. N., Blumberg, B., Carroll, L., Colborn, T., Everett, L. G., Benbrook, C. M. (2016). Concerns over use of glyphosate-based herbicides and risks associated with exposures: A consensus statement. *Environmental Health Environ Health*, 15(1). doi:10.1186/s12940-016-0117-0.

⁷ Ibid.

⁸ To be granted a registration under FIFRA, the applicant must show that using the pesticide according to specifications will not generally cause "unreasonable adverse effects on the environment." FIFRA § 2(bb) defines the term "unreasonable adverse effects on the environment" to mean the following:

- (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under Section 408 of the Federal Food, Drug and Cosmetic Act.

FIFRA also provides the EPA with broad authority to establish or modify data needs for individual pesticide registration actions to achieve statutory and program objectives.

The EPA also uses education and outreach to achieve its herbicide resistance goal. Agency employees attend professional conferences to learn from and interact with current researchers in the field. In addition, the EPA does literature searches during the development of risk assessments for the pesticide registration process, which helps to inform decisions with relevant and reliable data from the field.

Currently, there is little or no communication between the EPA and growers. The EPA cited the importance of feedback and data from grower groups and crop consultants, and indicated the agency is trying to increase communication with these two groups. The EPA does communicate regularly with the Weed Science Society of America (WSSA), an organization that fosters an awareness of weeds and their impact on the environment. To gain needed information about herbicide resistance, the EPA works informally with the WSSA. In fact, the EPA has maintained a liaison with the WSSA for many years, and that person provides access to available weed science data.

Herbicide Resistance Data Collection

The EPA has three data collection systems that are used to collect data related to herbicide resistance:

- (1) **The FIFRA Section 6(a)(2) database.** Requires pesticide registrants to report any unreasonable adverse effects of their products to the EPA (including incidents of resistance) via the Section 6(a)(2) database. The requirements are listed in 40 CFR Section 159.188(c).⁹
- (2) **The Incident Data System.** An internal OPP system used to collect data on pesticide incidents since 1992. The system is not specific to resistance and includes data on other issues such as bee kills. The Incident Data System is based on voluntary, self-reported incident data that can be submitted by anyone, including registrants. In addition to utilizing information from Section 6(a)(2), OPP receives calls, emails or letters from the public, including university researchers, growers or environmental organizations, which provide the agency with information about resistance incidents that have been witnessed.
- (3) **The Emergency Exemption Section 18 database.** When resistance becomes unmanageable, federal agencies and states have the option to

⁹ The following requirements from 40 CFR Section 159.188 Part C relate to the development of pesticide resistance:

[I]nformation must be submitted concerning substantiation of any incident of a pest having developed resistance to any pesticide (both public health and non-public health) that occurred under conditions of use, application rates and methods specified on the label if either of the following conditions is met: (1) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions. (2) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.

request an emergency exemption from the EPA to use registered herbicides not approved for the requested use.¹⁰ The requestor submits information that describes the pest emergency to the EPA, and requests permission to use a specific pesticide even though it is not currently registered for that use. Information about emergency exemption requests are recorded in the Emergency Exemption Section 18 database. For the 10-year period October 2006 through September 2016, the database shows the EPA received 46 emergency exception requests related to weed resistance; 33 were approved.

Responsible Office

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

Noteworthy Achievements

The EPA implemented a best practice for herbicide resistance management. The EPA developed terms of registration that require MOAs to be listed on the labels for certain pesticide products. By requiring an MOA to be on the label, stakeholders are able to make informed decisions about the products they use and subsequent decisions about herbicide resistance management at the local level.

Scope and Methodology

We conducted our work from April 2016 through April 2017. 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 herbicide resistance activities, such as program goals, a timeline of actions taken on resistance management, data verification, performance measurement, and program staffing. In addition, we performed the following:

- Reviewed and analyzed relevant EPA regulations, policies and procedures.
- Conducted a review of herbicide resistance management reports and articles.

¹⁰ FIFRA § 18; 40 CFR Part 166.

- Met with staff representatives from relevant OPP divisions such, as the Biological and Economic Analysis Division and the Registration Division.
- Met with USDA to discuss its roles and responsibilities with regard to biotechnology and resistance management.
- Met with stakeholders and field experts in herbicide resistance management, including, but not limited to, the WSSA; CropLife America; the North Carolina State Extension Service; agricultural retailers; and academics from North Carolina, Pennsylvania, Arkansas, Michigan, Kentucky and Oregon.

Prior Evaluation and Audit Coverage

The OIG has not conducted prior work on herbicide resistance issues. However, we did evaluate insect resistance to biopesticides in EPA OIG Report No. [16-P-0194](#), *EPA Needs Better Data, Plans and Tools to Manage Insect Resistance to Genetically Engineered Corn*, issued June 1, 2016. In that report, the OIG found changes are needed in the EPA's Insect Resistance Management program to increase the agency's ability to proactively detect resistance, confirm and address potential resistance, and share program information with stakeholders. Most recommendations were implemented upon report issuance. The final three corrective actions are expected to be completed by July 2017.

Chapter 2

EPA Can Strengthen Its Management and Oversight of Herbicide Resistance

The EPA does not have sufficient management and oversight controls to address potential risks and consequences of herbicide resistance. The EPA has not fully utilized the registration and labeling processes to help mitigate herbicide resistance. Although data collection is essential to tracking and monitoring herbicide resistance, the EPA has not collected any herbicide resistance data through its adverse incident reporting database.

There is also a lack of communication and collaboration between public and private stakeholders regarding resistance management, which limits the reach of actions proposed and taken by the EPA, the development of alternatives, and the agency's ability to proactively respond to resistance in the field.

In addition, the EPA does not have measures to track progress in addressing and slowing the spread of resistance. Improved management and oversight controls will support the EPA's ability to assess the effectiveness of actions taken to address current, or prevent future, herbicide resistance.

Opportunities Exist to Better Utilize Labeling to Manage Herbicide Resistance Risks

The EPA uses its registration process to assess and evaluate the risk to human health and the environment from pesticides used to combat herbicide-resistant weeds. For certain products used on resistant crops, the EPA has made it a requirement for the MOA to be placed on the label as a best practice for managing herbicide resistance. However, despite increasing evidence that herbicide resistance (specifically glyphosate resistance) is spreading, the EPA has yet to require the MOA to be placed on labels for glyphosate or similar products.

The EPA currently encourages MOA labeling on products like glyphosate through a voluntary process. While some larger companies have put MOAs on their product labels, many smaller companies have not chosen to do so. Including the MOA on the label has been highlighted as a best practice by the EPA, academia and retailers. According to an Australian weed expert, providing the necessary information like the MOA on the label helps to delay herbicide resistance, because the MOA provides growers with essential information to assist in decision-making with regard to resistance solutions.

The EPA's recently proposed updates for PRNs include a suggestion—not a requirement—for placing the MOA on pesticide (including herbicide) labels. The addition of the MOA on the label is important, because right now a grower cannot

identify the MOA associated with a pesticide product. Having MOA information on the label makes a difference in what products may be combined with the pesticide and what amount may be used to combat weed resistance. The addition of the MOA on the label for products like glyphosate will allow users to have information to assist in their decision-making about herbicide resistance management. In addition, having the MOA on the label provides a management control for consistently informing users about the improper use of chemicals.

Additional Data on Synergy Can Help Reduce Uncertainties

During the pesticide registration process, the EPA collects information on the human health and environmental risks of a pesticide. This information is used to make decisions regarding the short- and long-term effects of a pesticide. However, no information is currently requested about possible synergy in combination products. Synergy occurs when the effect of a mixture of chemicals is greater than the sum of the individual effects. Synergism data is important because the data allow the EPA a greater ability to assess human health and environmental risks combined with real-world pesticide use. The example below highlights the potential for uncertainty when the EPA does not request data on synergy during the registration process.

The Enlist Duo Case

Enlist Duo is the first combination product (a mixture of glyphosate and 2,4-Dichlorophenoxyacetic acid (2,4-D)) that the EPA has approved registration for use on genetically engineered herbicide-resistant crops. Although no synergism was claimed in the original registration application to the EPA, during litigation in 2015, it was discovered that the pesticide registrant claimed synergism in a patent application to the U.S. Patent and Trademark Office. Because the EPA became aware of the synergism information after the agency had made its registration decision, the EPA determined that it could no longer represent to the court that its conclusions were correct regarding the registration.

The EPA requested that the U.S. Court of Appeals for the Ninth Circuit (Case No. 14-73353 et al.) remand and vacate the registration while the EPA re-examined it. The court denied the motion, which allowed the registration to remain in effect while the agency re-examined the registration. The EPA requested and received additional synergy data from the registrant. The EPA reviewed the additional data on synergy and confirmed its initial finding of no synergy in the Enlist Duo formulation.

A 2016 research paper published by the Center for Biological Diversity reviewed the EPA's pesticide mixture approval process.¹¹ The research paper reported that there was evidence of synergy in the patent application of nearly 70 percent of multi-ingredient pesticide products (including herbicides, insecticides, and fungicides/nematicides) approved by the EPA in the last 6 years, and from four major agricultural companies. The report found 140 products with at least two active ingredients were registered between June 2010 and June 2016. Some of the most frequently used herbicides in the United States (e.g., glyphosate; atrazine; 2,4-D; Dicamba; and neonicotinoids) were present in the majority of these patent applications.

EPA Can Improve Herbicide Resistance Data Collection and Use

In order to delay herbicide resistance, information is needed on where resistance is occurring and what crops are affected. However, we found that the EPA does not have a systematic, comprehensive data collection process to determine the extent of resistance to its registered herbicides. Without this data, the agency cannot develop measures to track progress on slowing the spread of resistance.

We found that the EPA has not received any information related to herbicide resistance in the last 10 years through FIFRA Section 6(a)(2). The EPA stated that Section 6(a)(2) is the mechanism used to collect herbicide resistance data. Registrants are required to report information on adverse incidents, including resistance incidents. Resistance reporting is further detailed in 40 CFR §159.188 (c). It states, in part, that information concerning substantiation of any incident of a pest having developed resistance to any pesticide (which includes herbicides) that occurred under conditions of use, application rates and methods specified on the label must be reported if certain conditions are met.¹²

According to limited information found on the EPA's [Incident Reporting by Pesticide Manufacturers/Registrants](#) web page,¹³ there is no specific required format for reporting an incident. The lack of a specific format creates the risk of the EPA receiving inconsistent herbicide resistance data that varies in quality and utility. In addition, the actual incident report is a paper submission that must be mailed to EPA headquarters. There is no option to send the incident report electronically.

The EPA said it has an ongoing effort to improve incident reporting. There is an effort from the EPA's pesticide incident work group to provide OPP with advice

¹¹ Donley, Nathan. "Toxic Concoctions: How the EPA Ignores the Danger of Pesticide Cocktails," Center for Biological Diversity. July 2016.

¹² If either of the following conditions were met: (1) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions; or (2) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.

¹³ Web page was last accessed December 6, 2016.

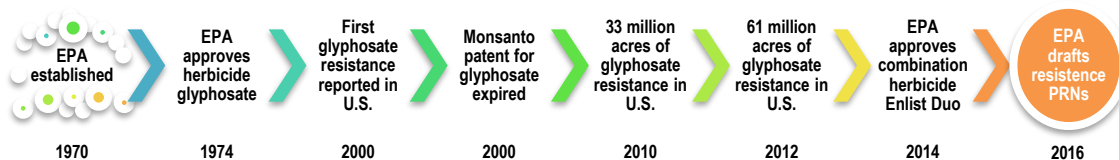
about critical data elements needed as part of a new or enhanced incident data system. Without data on herbicide resistance, the EPA cannot provide information on when and where herbicide resistance occurs. The EPA needs to strengthen herbicide resistance data submission under Section 6(a)(2) by modernizing the submission process and promoting its use to stakeholders and farmers.

EPA Action on Resistance Is Hindered by Inconsistent Communication and Stakeholder Collaboration

The agency does not have a procedure or routine method for communicating and collaborating with stakeholders on herbicide resistance information. The lack of communication between the EPA and those directly engaged in agriculture has contributed to agency's delayed action in addressing resistance. The EPA needs to address communication and collaboration limitations to better manage herbicide resistance.

Herbicide resistance was first found in 1968. The first resistant weed to arise among herbicide-resistant crop systems came in 2000, only 4 years after the introduction of herbicide-resistant corn and soybeans. The EPA's herbicide resistance activities started in 2014 with the registration of Enlist Duo,¹⁴ a combination product of glyphosate and 2,4-D (Figure 3).

Figure 3. Timeline of glyphosate resistance and EPA actions



Source: EPA OIG-generated figure based on EPA data.

The lack of communication between the agency and stakeholders in the resistance community contributed to the EPA's delay in taking action to address the issue of resistant weeds. As we reported in the previously mentioned EPA OIG report, *EPA Needs Better Data, Plans and Tools to Manage Insect Resistance to Genetically Engineered Corn*, the OIG found that the agency had a delayed response to resistance issues.¹⁵ The EPA's prior response to resistance issues makes the agency's response to addressing glyphosate resistance important.

The EPA's delayed reaction undermines its goal to extend the useful life of chemicals used for pest control by (1) slowing the development of pest resistance

¹⁴ Enlist Duo was designed to address resistant weeds. Its manufacturer, the Dow Chemical Company, notes that growers need new ways to meet the problem of herbicide-resistant and hard-to-control weeds. The Enlist™ weed-control system builds on the Roundup Ready® system, with tolerance for a new formulation of 2,4-D.

¹⁵ EPA OIG Report No. [16-P-0194](#) issued June 1, 2016.

to fungicides, herbicides and insecticides, and (2) extending the life of advancements in technology such as genetically engineered crops.

Communication among stakeholders is an important aspect of herbicide resistance management. However, there is no mechanism by which growers and researchers directly provide information on herbicide-resistant weeds to the EPA. Consistent dialogue between the EPA and stakeholders would strengthen the agency's awareness and information on herbicide resistance. The EPA frequently uses comment periods to gather information about herbicide resistance for practices and policies, but the agency does not have a routine method or procedure for consistent communication with relevant parties in herbicide resistance.

Unlike Bt corn resistance management, where stakeholders meet and discuss issues via a consortium group,¹⁶ herbicide resistance does not have a similar group or even an annual meeting to discuss herbicide resistance. Industry groups, agricultural experts, environmental advocacy groups, and extension agents all expressed concern regarding the EPA's lack of communication. Those involved in herbicide resistance management on the ground all expressed a need to communicate their challenges and experiences with resistant weeds to the EPA.

To facilitate increased collaboration regarding herbicide resistance information, we found that state extension agencies can be a useful resource. The EPA currently relies on its informal relationship with the WSSA for herbicide resistance information. However, state extension agents funded, in part, by USDA are an underutilized source for local herbicide resistance information.¹⁷ Through extension agencies, land-grant colleges and universities reach out to offer their resources to address public needs, including herbicide resistance management.

Extension agents educate growers on business operations and agricultural science and technologies. Extension agents also conduct surveys that include mapping out plots in an atlas and sampling fields for resistant weeds. Extension agents know where herbicide resistance is located, and they have mapped it in some states. This type of expertise and on-the-ground knowledge of herbicide resistance held by extension agents can be beneficial to the EPA as the agency works to establish a system for collecting and disseminating herbicide resistance information.

EPA Does Not Track Success of Its Herbicide Resistance Actions

We found that the EPA lacks performance metrics for evaluating the success of the herbicide resistance program. The program currently does not use a measure or set of measures to determine success. Measuring progress and reporting the results are

¹⁶ Ibid.

¹⁷ Many extension agents are also members of WSSA.

essential to the EPA's public accountability.¹⁸ Office of Management and Budget (OMB) Circular No. A-123 defines management's responsibility for internal control in federal agencies. The circular states that management has a fundamental responsibility to develop and maintain effective internal control.

OMB Circular A-123 provides internal control guidance that includes, by reference, performance measurement, which is the monitoring and reporting of program accomplishments. Performance measures may address the type of program activities conducted, the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). When asked, EPA management could not define what performance measures would look like for herbicide resistance management.

Conclusion

The EPA has tools and resources that can be better utilized to strengthen the agency's oversight and management of herbicide resistance. The EPA needs to facilitate data collection and sharing, develop performance measures for herbicide resistance, determine how to enhance and leverage its weed science expertise, and develop a routine communication method to gather and share herbicide resistance information in a timely manner. Improved management controls are also essential for the agency to establish and execute effective oversight of herbicide resistance.

Recommendations

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

1. Consider requiring mechanisms of action be included on relevant herbicide labels.
2. Determine whether synergistic effects data should be required for the pesticide registration process, and document the results of that determination.
3. Improve data collection and reporting by developing an efficient system for the agency to collect and share herbicide resistance data using a standardized reporting format.

¹⁸ The proper stewardship of federal resources is an essential responsibility of agency managers and staff. Federal employees must ensure that federal programs operate, and federal resources are used efficiently and effectively to achieve desired objectives. Management is responsible for developing and maintaining effective internal control. Effective internal control provides assurance that significant weaknesses in the design or operation of internal control, that could adversely affect the agency's ability to meet its objectives, would be prevented or detected in a timely manner.

4. Determine what performance metrics are suitable to document the progress of the EPA's actions related to slowing herbicide resistance.
5. Establish a procedure to increase communication with government agencies, industry, academia, growers and other stakeholders regarding herbicide resistance. The procedure should include specific details concerning increased communication and collaboration with extension agents.

Agency Comments and OIG Evaluation

In the EPA's official comments, the agency agreed with two of the five recommendations. After further discussions with the agency, agreement was reached on the remaining three recommendations.

The agency has provided corrective actions and estimated completion dates that meet the intent of our recommendations. 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

Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Potential Monetary Benefits (in \$000s)
1	14	Consider requiring mechanisms of action be included on relevant herbicide labels.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	6/30/19	
2	14	Determine whether synergistic effects data should be required for the pesticide registration process, and document the results of that determination.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	6/30/19	
3	14	Improve data collection and reporting by developing an efficient system for the agency to collect and share herbicide resistance data using a standardized reporting format.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	3/31/18	
4	15	Determine what performance metrics are suitable to document the progress of the EPA's actions related to slowing herbicide resistance.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/18	
5	15	Establish a procedure to increase communication with government agencies, industry, academia, growers and other stakeholders regarding herbicide resistance. The procedure should include specific details concerning increased communication and collaboration with extension agents.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	3/31/18	

¹ C = Corrective action completed.

R = Recommendation resolved with corrective action pending.

U = Recommendation unresolved with resolution efforts in progress.

Agency Response to Draft Report and OIG Evaluation



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

[March 23, 2017]

MEMORANDUM

SUBJECT: OCSPP Comments on OIG Draft Report “EPA Can Strengthen Its Oversight of Herbicide Resistance With Better Management Controls.”

FROM: Wendy Cleland-Hamnett, Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention

TO: Arthur A. Elkins, Inspector General

This memorandum is in response to the Office of Inspector General's (OIG) February 15, 2017, Draft Report; entitled “EPA Can Strengthen Its Oversight of Herbicide Resistance With Better Management Controls,” Project No. OPE-FY16-0023.

OIG’s stated objective for this evaluation was to answer the following questions:

1. What processes and practices, including alternatives, has the EPA provided to delay herbicide resistance?
2. What steps has the EPA taken to determine and validate the accurate risk to human health and the environment for approved pesticides to be used to combat herbicide-resistant weeds?
3. Does the EPA independently collect and assess data on, and mitigate actual occurrences of, herbicide resistance in the field, and prevent improper use of registered pesticides?

OCSPP Responses to OIG's Recommendations:

The Draft Report contains five recommendations for the Office of Pesticide Programs (OPP). The OCSPP generally agrees with several of the OIG's the recommendations and as required by EPA Order 2750, this response addresses all of the OIG recommendations. The OIG recommended that the Assistant Administrator for Chemical Safety and Pollution Prevention take the following actions:

OIG Recommendation 1: Require that mode of action be included on relevant herbicide labels.

OCSPP Response: To impose a new requirement that all registrants of herbicide products include mode of action (MOA) information on their labels would require formal Notice and Comment rulemaking. While the Agency considers whether such a rulemaking is necessary, OCSPP has been undertaking several important actions to increase MOA information on labels, specifically:

- During the registration review process for conventional active ingredients, OPP has been strongly recommending that registrants place the mode of action on herbicide labels.
- During the registration process for new conventional products, OPP has been strongly recommending that registrants place the mode of action on herbicide label for new registrations and routine label updates.

In most cases, registrants have agreed to add the mode of action when requested by OPP.

The OCSPP is committed to accomplishing this objective and believes that the actions discussed above have been successful. Since most registrants have agreed to add the MOA when requested, the program intends to continue to use this approach, which achieves the goals of the OIG recommendation.

Therefore, the OCSPP believes this recommendation has been sufficiently addressed and is accordingly not providing a timeframe for completion of additional corrective actions.

OIG Response to Recommendation 1: We acknowledge that the Office of Chemical Safety and Pollution Prevention (OCSPP) has taken actions to increase MOA information on labels. After further discussions with OCSPP, agreement was reached on Recommendation 1, and we amended this recommendation. By June 2019, OCSPP will consider whether initiating a rulemaking to place MOA information on labels might be appropriate or needed to advance this effort. This proposed corrective action and date meets the intent of our recommendation. Recommendation 1 is resolved with corrective action pending.

OIG Recommendation 2. Determine whether synergistic effects data should be required for the pesticide registration process, and document the results of that determination.

OCSPP Response: Synergy is a distinct and separate issue from herbicide resistance management and synergy is not restricted to herbicides but in fact, may occur between any type

of pesticide and non-pesticide substances. Development of scientific policy regarding synergy is best consigned to an integrated approach, which in part will include herbicides. As the science regarding synergy evolves, weed scientists and researchers (including EPA scientists) will continue to contribute to the growth of the synergy dialog within the scientific community. The OCSPP is already collecting data and considering synergy in an effort separate from resistance management work. EPA routinely requires the submittal of acute oral mammalian and plant toxicity data for multiple active ingredient formulated products, to determine if registered co-formulated products exhibit greater than additive toxicity as compared to the single active ingredients. EPA also qualitatively considers available data on synergistic effects of mixtures from the open literature. In addition, EPA is currently developing a strategy to search and determine the relevance of U.S. Patent data that include claims of toxicity in excess of expected additive response for the pesticide active ingredient proposed for registration, when applied with other pesticide chemicals.

Consideration of the potential for interactions of herbicides to influence resistance management should also include mixtures of active ingredients that together result in less than additive effects (i.e., antagonistic effects). EPA understands that researchers associated with the Weed Science Society of America are actively involved in a comprehensive evaluation of the publicly available literature concerning herbicide interactions both synergistic and antagonistic. The goals of this effort are to:

- develop sound evaluation techniques both mathematically and experimentally;
- create a standardized methodology for defining and evaluating interaction relationships; and
- produce an evaluation of the mixture effects of active ingredients within and across mechanistic classes.

Two presentations made at the WSSA's 57th annual meeting presented the initial findings of this effort: "Review of herbicide Interactions: Predictable Trends or Interaction Soup?" (B.G. Young, Purdue University) and "Experimental Design and Data analysis for Herbicide Interaction Research" (A.R. Kniss, University of Wyoming.). EPA anticipates that growers, applicators and extension specialists will make appropriate resistance decisions with the WSSA effort forming a basis for looking at interactions.

Therefore, the OCSPP believes this recommendation has been sufficiently addressed via the above described separate mechanism and is accordingly not providing a timeframe for completion of additional corrective actions.

OIG Response to Recommendation 2: After further discussions, OCSPP amended its response. OCSPP stated that synergy is not related to herbicide resistance management, but it is a factor that should be considered in evaluating risk. OCSPP’s methods for evaluating pesticide risk are thorough and scientifically robust. Synergy considerations present a source of uncertainty that might be germane to risk assessments and regulatory decisions in certain instances. Patent data, in particular, has been noted to be a potential source of information where claims of toxicity in excess of an expected additive response are being made. OCSPP has developed an interim, draft patent data search strategy and will examine that patent data for relevancy to risk assessment in its regulatory programs. Depending on this analysis, OCSPP will consider how best to use this type of information in future evaluations and decisions by June 2019. This proposed corrective action and date meets the intent of our recommendation. Recommendation 2 is resolved with corrective action pending.

OIG Recommendation 3. Improve data collection and reporting by developing an efficient system for the Agency to collect and share herbicide resistance data using a standardized reporting format.

OCSPP Response: While FIFRA requires registrants to report information about adverse effects as they become aware of those effects, EPA’s legal authority to compel pesticide users or other persons to report such information is very limited. Nevertheless, the OPP has been considering potential options to improve the data collection and reporting of herbicide resistance cases, including the development of a standard reporting “form” and a mechanism to send the herbicide resistance data to an electronic reporting system.

The OCSPP agrees with OIG’s recommendation that data collection and reporting can be improved by developing an efficient system for the Agency to collect and share herbicide resistance data using a standardized reporting format. Since the OPP has recently begun to require reporting of suspected resistance as a term of registration for several herbicides, the program will develop a working plan to consider options to improve the collection and reporting of herbicide resistance cases and will include a draft standard reporting form. It is important to note that if this information is collected, the data would be highly variable and uncertain due to the many factors that influence growers’ choices that drive the development of weed resistance. Therefore, these data may not be useful as a metric for measuring success.

The OCSPP would complete the first working draft of the plan to improve data collection and reporting related to herbicide resistance data by March 2018.

OIG Response to Recommendation 3: The EPA’s planned corrective actions are acceptable. Recommendation 3 is resolved with corrective action pending.

OIG Recommendation 4. Develop performance metrics to document the progression of slowing the spread of herbicide resistance.

OCSPP Response: Developing performance metrics to document trends in the spread of herbicide resistance is beyond the scope of EPA’s regulatory authority and resource availability.

However, OCSPP will continue to leverage good herbicide resistance management practices using the regulatory tools it currently uses – through advisory language on pesticide labels and participation in general outreach and communication efforts that involve other organizations. The development of meaningful metrics to quantify the success of any herbicide resistance effort is particularly difficult for the following reasons:

- There is a great diversity of weeds, herbicides, crops and crop production systems; developing meaningful metrics to document slowing the progression of herbicide resistance is inherently difficult.

There are approximately 3,000 weeds affecting U.S. agriculture that can lead to economic loss. These weeds occur in more than 600 commercially produced crops and managed areas (e.g., pastures/rangeland) that are grown on more than 920 million acres. More than 200 different herbicides are used for weed control in U.S. agriculture.

Specific cropping systems determine whether and how herbicides are used for weed control. Moreover, the same herbicide may be used at different times of the crop production cycle and may be used to target different weed species at each application. Many resistant weeds have only been identified in a few specific crops, production systems, and geographic locations, even though resistance to a particular herbicide in a given weed species often evolves in multiple locations. Because of the thousands of weeds and hundreds of crops and herbicides, and the vast geographic diversity in U.S. agriculture, resistance would have to be tracked by weed, crop, herbicide and region to provide a meaningful measure of the success of a resistance management program. An effort of this magnitude is far beyond the capability of EPA and would detract from the agency's other important work in pesticides.

- EPA/OPP is only one of many stakeholders involved in efforts to reduce the onset of herbicide resistance. EPA's direct influence is limited to pesticide labeling and to the terms of registration for herbicides.

Many stakeholders other than EPA have more direct influence on the behavior of growers and on weed control practices that influence the development of herbicide resistance. For example, sales and technical representatives of pesticide registrants have direct interactions with pesticide dealers and those who use pesticides. State extension specialists and land-grant university scientists, in addition to registrant representatives, often work directly with growers and make recommendations for control of weeds and other pests. Other organizations with direct interest in herbicide resistance management include USDA, the Weed Science Society of America, the Herbicide Resistance Action Committee, organized grower groups that represent various commodities (corn, soybean, wheat, cotton, etc.), as well as nonprofit organizations.

Perhaps most importantly, economic considerations frequently drive growers' choices of crops and crop production practices. For example, rotating crops from season to season is a good management practice that is a cornerstone of many resistance management programs. However, rotating crops may reduce a grower's economic returns in the near term, so growers may produce the same crop year after year and may rely more heavily on herbicides as a primary means of weed control. In cases where crops are not rotated, the same weeds are usually problematic from

year to year, and herbicides used against those weeds may be overused, thereby increasing selection pressure on those weeds to evolve resistance.

EPA has taken steps to improve its labels to maximize growers' use of best management practices that may delay the onset of resistance. For example, nearly all herbicide labels going through the registration and registration review process will contain the mechanism of action (MOA) for each herbicide. Herbicide labels also routinely advise growers to use practices that have been scientifically demonstrated to result in a delay of resistance. These include scouting field before and after herbicide application and reporting suspected resistance to registrants.

In some cases, EPA has leveraged the terms of registration of herbicides to require registrants to be proactive in seeking out and remediating cases of herbicide resistance. Growers are requested to report early signs of resistance to registrants who are charged with investigating these reports. These registrants are also required to work actively with growers to resolve the resistance problem and, in some cases, to report the resistance in a manner that warns other growers that resistance has been detected. Additional measures at the field level would be difficult for growers to adopt and for the EPA to enforce.

- Success is measured at the landscape scale but is due to the aggregation of individual grower actions.

Successfully reducing herbicide resistance requires that many growers in a given area use management practices designed to delay resistance. It may be possible, for example, to identify individual growers that use good practices, however, measuring success in terms of reduced incidences of resistance in a region would have to be the result of several years of growers' collective behavior. It is not practical for EPA to monitor herbicide resistance at the landscape scale.

- Developing performance metrics to document trends in the spread of herbicide resistance is beyond the scope of EPA's regulatory authority and resource availability.

The complexity of developing metrics and collecting information to document success in reducing the occurrence of herbicide resistance would require a multi-year effort and a major investment of resources. Moreover, EPA's only authority to mandate the collection of information on the scale needed for a system of metrics is FIFRA section 3(c)(2)(B) Information Collection Requests, which are applicable only to registrants. A registrant's ability to compel users to participate is limited and unlikely to continue once a grower has ceased using that registrant's herbicide. Even if such information could be collected, the data would be highly variable and uncertain due to the many factors that influence growers' choices, which drive the development of weed resistance. Ironically, weed resistance to herbicide can happen in as few as three generations. The complexities of developing and implementing a system of metrics could easily be overcome by a few cases of individual growers choosing not to follow recommended practices intended to delay resistance.

For these reasons, the OCSPP will not take further action on this recommendation and is not providing a timeframe for completion of additional corrective actions. The OCSPP believes that

developing performance measures to determine EPA's success of slowing the spread of herbicide resistance would entail factors beyond the scope of the Agency's regulatory authority under FIFRA.

OIG Response to Recommendation 4: Per OMB Circular 123, government programs must have internal controls in place to measure performance. We recognize that additional clarity was needed in the wording of our recommendation; therefore, we amended the recommendation. The amended recommendation specifically states that we are asking for metrics related to the EPA's direct actions in slowing herbicide resistance. After further discussions with OCSPP, agreement was reached on Recommendation 4. By September 2018, OCSPP will determine what performance metrics, if any, are suitable to document the EPA's actions related to slowing the spread of herbicide resistance. We accept the corrective action and its completion date. Recommendation 4 is resolved with corrective action pending.

OIG Recommendation 5. Establish a procedure to increase communication with government agencies, industry, academia, growers and other stakeholders regarding herbicide resistance. The procedure should include specific details concerning increased communication and collaboration with extension agents.

OCSPP Response: EPA's activities to date have been consistent with our role in promoting the adoption of practices that delay resistance. Over the last few years, the OPP has made a concerted effort to meet with and make presentations to a number of groups regarding the problem of pesticide resistance:

Grower Organizations

Corn, Cotton, Soybean, Sorghum, and Wheat

Professional Organizations

American Phytopathological Society and their OPP liaison Dr. Wayne Wilcox
Certified Crop Advisors
Entomological Society of America and their OPP liaison Dr. Allan Felsot
Fungicide Resistance Action Committee (FRAC)
Herbicide Resistance Action Committee (HRAC)
Herbicide Resistance Summit II
Insecticide Resistance Action Committee (IRAC)
National Association of Independent Crop Consultants
Weed Science Society of America and their OPP liaison Dr. Mike Barrett

Regulators and Government Agencies

Association of American Pesticide Control Officials (AAPCO)
Canada Pest Management Regulatory Agency (PMRA)
Office of Pest Management Policy at USDA
Pesticide Program Dialogue Committee (PPDC) US-EPA
State Issues Research and Evaluation Group (SFIREG)

At these meetings, the Agency has discussed the increasing problem of herbicide resistance and the potential role of the Agency in herbicide resistance management. The Agency has

communicated with the key influencers of user practices that can slow the spread of herbicide-resistant weeds. In the future, the Agency will evaluate this list of stakeholders and influencers to determine gaps and opportunities for increased communication. In future meetings the Agency will discuss resistance topics that would be useful to them.

The OCSPP agrees with OIG's recommendation that a plan with specific details to increase communication and collaboration with government agencies, industry, academia, growers and other stakeholders would increase promotion of herbicide resistance practices. OCSPP will complete the first working draft of this communications plan by March 2018.

OIG Response to Recommendation 5: We accept OCSPP's planned corrective action. Recommendation 5 is resolved with corrective action pending.

Distribution

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Agency Follow-Up Official (the CFO)
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