U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Ensuring the safety of chemicals

EPA Mostly Adheres to Regulations When Assessing Risks of New Pesticides but Should Improve Internal Controls

Report No. 21-P-0070 **February 8, 2021**

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Abbreviations

C.F.R.	Code of Federal Regulations
EFED	Environmental Fate and Effects Division
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HED	Health Effects Division
OIG	Office of Inspector General
OPP	Office of Pesticide Programs
RD	Registration Division
U.S.C.	United States Code

Cover Photo: Pesticides for purchase. (EPA OIG photo)

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U.S. Environmental Protection Agency
Office of Inspector General

21-P-0070
February 8, 2021

At a Glance

Why We Did This Audit

The U.S. Environmental Protection Agency's Office of Inspector General conducted this audit to review the EPA's adherence to applicable regulations, policies, and procedures in assessing the risks of pesticides to human health and the environment during the pesticide registration process.

Pursuant to Federal Insecticide, Fungicide, and Rodenticide Act requirements, the EPA's Office of Pesticide Programs regulates all pesticides that are sold and distributed in the United States. For each pesticide registration application, the OPP has the discretion to *unconditionally register* the pesticide under FIFRA Section 3(c)(5) if the application is complete and all criteria are met or to *conditionally register* the pesticide under FIFRA Section 3(c)(7) if additional data are needed.

This audit addresses the following:

- *Ensuring the safety of chemicals.*

This audit addresses a top EPA management challenge:

- *Complying with key internal control requirements (data quality).*

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EPA Mostly Adheres to Regulations When Assessing Risks of New Pesticides but Should Improve Internal Controls

What We Found

By implementing stronger internal controls, the EPA can decrease the risk of issuing a pesticide registration that does not comply with regulatory requirements.

For the nine unconditional pesticide registrations we reviewed, we found that the OPP is mostly adhering to applicable regulations, policies, and procedures in assessing the risks of the pesticides to human health and the environment during the issuance process for unconditional pesticide registrations. Federal regulation 40 C.F.R. § 152.112, *Approval of registration under FIFRA sec. 3(c)(5)*, establishes eight criteria for the issuance of an unconditional pesticide registration. The OPP fully complied with four of these criteria, while two were not applicable to the pesticide registrations that we reviewed. The two remaining criteria address, in part, toxicology and ecological data requirements that the OPP must assess to determine whether the pesticide's intended use will have unreasonable adverse effects on human health and the environment. For these two criteria, the OIG:

- Independently verified that the OPP met all toxicology data requirements. The OPP develops a summary table addressing toxicology data requirements for pesticide registrations.
- Could not independently verify that the OPP met all ecological data requirements. The OPP does not develop a summary table addressing ecological data requirements for pesticide registrations.

In addition, the OPP lacks a standard operating procedure governing how to conduct initial pesticide registrations to ensure adherence to 40 C.F.R. § 152.112. The lack of an ecological data requirement summary table and a standard operating procedure for initial registrations increases the risk that the OPP will issue a pesticide registration that does not comply with the pesticide registration statutes and regulations.

Recommendations and Planned Agency Corrective Actions

We make two recommendations to the assistant administrator for Chemical Safety and Pollution Prevention: (1) develop and incorporate an ecological data requirement summary table or similar internal control into the OPP's ecological risk assessments and (2) develop and implement a standard operating procedure for the initial registration of a pesticide. The Agency provided acceptable corrective actions, and both recommendations are resolved with corrective actions pending.

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

THE INSPECTOR GENERAL

February 8, 2021

MEMORANDUM

SUBJECT: EPA Mostly Adheres to Regulations When Assessing Risks of New Pesticides but Should Improve Internal Controls
Report No. 21-P-0070

FROM: Sean W. O'Donnell

TO: Michal Ilana Freedhoff, Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject audit conducted by the Office of Inspector General of the U.S. Environmental Protection Agency. The project number for this audit was OA&E-FY20-0095. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The Office of Chemical Safety and Pollution Prevention is responsible for the issues discussed in this report.

In accordance with EPA Manual 2750, your office provided acceptable planned corrective actions and estimated milestone dates in response to OIG recommendations. All recommendations are resolved with corrective actions pending, and no final response to this report is required. If you submit a response, however, it will be posted on the OIG's 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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Purpose

The U.S. Environmental Protection Agency's Office of Inspector General conducted this audit to review the EPA's adherence to applicable regulations, policies, and procedures in assessing the risks of pesticides to human health and the environment during the pesticide registration process.

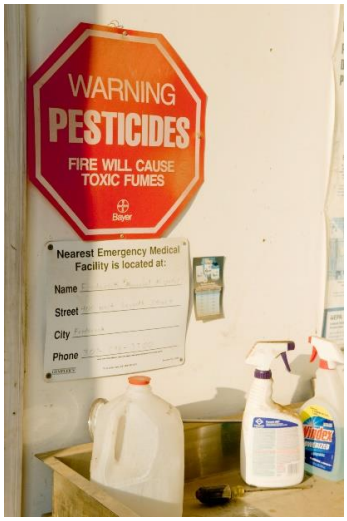
Top Management Challenge

This audit addresses the following top management challenge for the Agency, as identified in OIG Report No. 20-N-0231, *EPA's FYs 2020–2021 Management Challenges*, issued July 21, 2020:

- Complying with key internal control requirements (data quality).

Background

Pesticides are chemical substances used to prevent, destroy, repel, or mitigate undesirable organisms. Examples of pesticides are insecticides used against harmful insects, herbicides used to control weeds, fungicides used to control plant diseases, rodenticides used to kill rats and mice, and germicides used in disinfectant products. Pesticides increase agricultural yields by preventing crop damage and improve public health by reducing disease-carrying pests.



Pesticide warning sign. (EPA photo)

By design, pesticides are inherently toxic to certain organisms. When pesticides are used properly, the toxicity is limited to the undesirable organism being targeted. To prevent pesticides from affecting other organisms and to ensure the safety of the public, the food supply, and the environment, the EPA must carefully regulate the use of pesticides.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. § 136 et seq., the EPA must register all pesticides that are distributed or sold in the United States. According to the EPA, as of August 2020, there are just over 18,000 registered pesticides. FIFRA sets an overall risk/benefit standard for pesticide registration, requiring that pesticides perform their intended function when used according to labeling directions and without posing unreasonable adverse effects on human health or the environment.[1] FIFRA has been amended several times, notably by the:

- Food Quality Protection Act of 1996, which requires the EPA to, among other things, (1) set maximum pesticide residue levels in food to ensure a reasonable certainty of no harm from pesticide exposure and (2) consider the specific risks pesticides might have for infants and children.

[1] FIFRA defines *unreasonable adverse effects on the environment* as "(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" that is not consistent with the standard under Section 408 of the Federal Food, Drug, and Cosmetic Act.

- Pesticide Registration Improvement Act of 2003, which was reauthorized most recently by the Pesticide Registration Improvement Extension Act of 2018. The Pesticide Registration Improvement Act established a service fee system for registering pesticides, as well as provided requirements for the EPA to make determinations on pesticide registration applications within specified time frames.

EPA's Pesticide Registrations

For a pesticide to be sold or distributed in the United States, the pesticide must be registered or exempted by the EPA's Office of Pesticide Programs, or OPP. There are several categories of pesticides:

- *Conventional pesticides*, which contain active ingredients other than those found in biological pesticides and antimicrobial pesticides.

- *Antimicrobial pesticides*, which include active ingredients used to destroy or suppress the growth of harmful microorganisms—such as bacteria, viruses, or fungi—on inanimate objects and surfaces.

- *Biopesticides*, which include active ingredients derived from certain natural materials.

A company, or *registrant*, that wants to sell or distribute a pesticide product must submit an application for a pesticide registration to the EPA. A registrant must submit an application not only for new pesticide products but also for new uses of a previously registered pesticide product. According to the EPA's "Pesticide Registration Manual: Chapter 2 – Registering a Pesticide Product" webpage, the EPA uses the following terms to refer to registrations of new products and uses:

- *New Chemical* or *New Active Ingredient*. This term "refers to a pesticide registration application for a product that contains a pesticide active ingredient not contained in any other pesticide product currently registered with the Agency." For the purpose of this report, we refer to the registration of a new chemical or new active ingredient as an *initial registration*.

- *New Use*. This term refers to a "registration application amendment … to [add] a use for previously registered active ingredient(s), where the requested use is not currently included in the labeled directions for use of any product that contains that active ingredient(s)."

- *Identical/Substantially Similar*. This term refers to a pesticide registration application for a new pesticide product that is "identical in its uses or formulation," is "substantially similar" to a currently registered product, or

"differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment."

As part of the pesticide registration application, the registrant must specify the pesticide product's composition; the pesticide product's intended use; and the proposed pesticide product label, which details how the product can be correctly and legally used. The registrant must also submit other data, including toxicology and ecological scientific studies conducted by the registrant that allow the EPA to assess the potential human health and environmental effects of using the pesticide product. Specifically, as set forth in 40 C.F.R. Part 158, the registrant must provide the data necessary to address concerns pertaining to product chemistry, product performance, toxicology, ecological effects, human exposure (both application and post-application exposure), spray drift, environmental fate, and residue chemistry.

After receiving an application for a pesticide registration, the EPA has the discretion to *unconditionally register* the pesticide product under FIFRA Section 3(c)(5) or to *conditionally register* it under FIFRA Section 3(c)(7):

- *Unconditional registration*. If the EPA determines that the application is complete and that no additional data are necessary, the Agency may grant the registrant an unconditional registration. The EPA must meet four general criteria identified in FIFRA Section 3(c)(5), as well as the eight more specific criteria in 40 C.F.R. § 152.112(a) through (h), which are listed in the blue sidebar, before issuing an unconditional registration. Among the criteria that the EPA must meet is finding that the pesticide's use will not cause unreasonable adverse effects on human health or the environment.

Eight Specific Criteria for Unconditional Registrations

As outlined in 40 C.F.R. § 152.112, the EPA must:

(a) Determine that the application is complete.
(b) Review all relevant data.
(c) Determine that no additional data are necessary.
(d) Determine that the product's composition warrants the proposed efficacy claims.
(e) Determine that the product will perform its intended function without unreasonable adverse effects.
(f) Determine that the product is not misbranded, mislabeled, or mispackaged.
(g) Determine that all necessary Federal Food, Drug, and Cosmetic Act regulations are complied with for pesticides to be used on food or animal feed.
(h) Have been notified by the U.S. Food and Drug Administration, if a product is also a drug, that the product complies with the administration's requirements.

See Table A-1 in Appendix A for expanded descriptions of these criteria.

- *Conditional registration*. If the registrant has not submitted all the required data, then the EPA may decide to conditionally register the pesticide under FIFRA Section (3)(c)(7)(A) as long as the pesticide is identical or substantially similar to any currently registered pesticide and as long as the EPA determines that use of the pesticide would not significantly

increase the risk of unreasonable adverse effects on humans or the environment. The registration will be granted with conditions that require the registrant to provide the required data to the EPA within a specified time frame. If the registrant does not comply with the given conditions, the EPA may subsequently cancel the registration after it has been conditionally approved.

If the application for either the conditional or unconditional pesticide registration does not meet the necessary statutory and regulatory requirements at the time the application is submitted to the Agency, then the application is denied.

This audit reviewed the unconditional registrations of conventional pesticides.

Use of Risk Assessments in the Pesticide Registration Program

FIFRA requires the EPA to restrict the use of pesticides as necessary to prevent unreasonable adverse effects on humans or the environment. The EPA assesses the potential adverse effects from the pesticide's use by conducting risk assessments. The EPA conducts the following two types of risk assessments during the pesticide registration process:

- A *human health risk assessment* is a scientific analysis of the pesticide's toxicology data to determine what exposure levels might induce adverse health effects on humans from the pesticide's intended use. One critical outcome of this analysis is the EPA's establishment of maximum pesticide residue levels—also called "tolerances"—that are allowed in food and animal feed. Within the OPP, the Health Effects Division, or HED, conducts the human health risk assessments, which are then used by the OPP's Registration Division, or RD, to help make the pesticide registration decision.

- An *ecological risk assessment* is a scientific analysis that determines what environmental risks are posed by the pesticide's use and whether changes to its proposed use are necessary to protect the environment. This analysis determines what plants and animals are exposed, to what degree they are exposed, and whether or not that level of pesticide exposure is likely to cause harmful ecological effects. Within the OPP, the Environmental Fate and Effects Division, or EFED, conducts ecological risk assessments, which are then used by the RD to help make the pesticide registration decision.

EPA's Process for Registering Conventional Pesticides

The process of registering a conventional pesticide comprises scientific, legal, and administrative procedures through which the EPA examines, among other items, the:

- Ingredients of the pesticide.
- Site or crop on which the pesticide is to be used.
- Amount, frequency, and timing of the pesticide's use.
- Storage and disposal practices.

Within the OPP, the following divisions work collaboratively to process a conventional pesticide registration application:

- The RD is responsible for three overarching processes: completeness check, risk assessment review, and final risk management decision. The RD may also have other responsibilities depending on the specific pesticide registration, such as product chemistry and acute toxicity reviews. The completeness check reviews the application to determine whether it contains all the necessary documentation to complete the required risk assessments and to make a registration decision. Initial registrations are a core function of the RD.

- After the completeness check, the RD relies on the expertise of the EFED and the HED to ensure that all required data are included in the application and that there are no deficiencies within the data. The EFED is responsible for evaluating and validating the ecological data submitted, while the HED is responsible for reviewing and validating the toxicology data and characterizing and assessing the exposure and risks to humans. These scientific divisions review all the scientific data on the pesticide product and develop comprehensive human health and ecological risk assessments that examine the potential unreasonable adverse effects.

- The Biological and Economic Analysis Division provides biological, economic, and chemical analyses of pesticides to support the development of risk assessments, risk management decisions, enforcement activities, and regulatory actions.

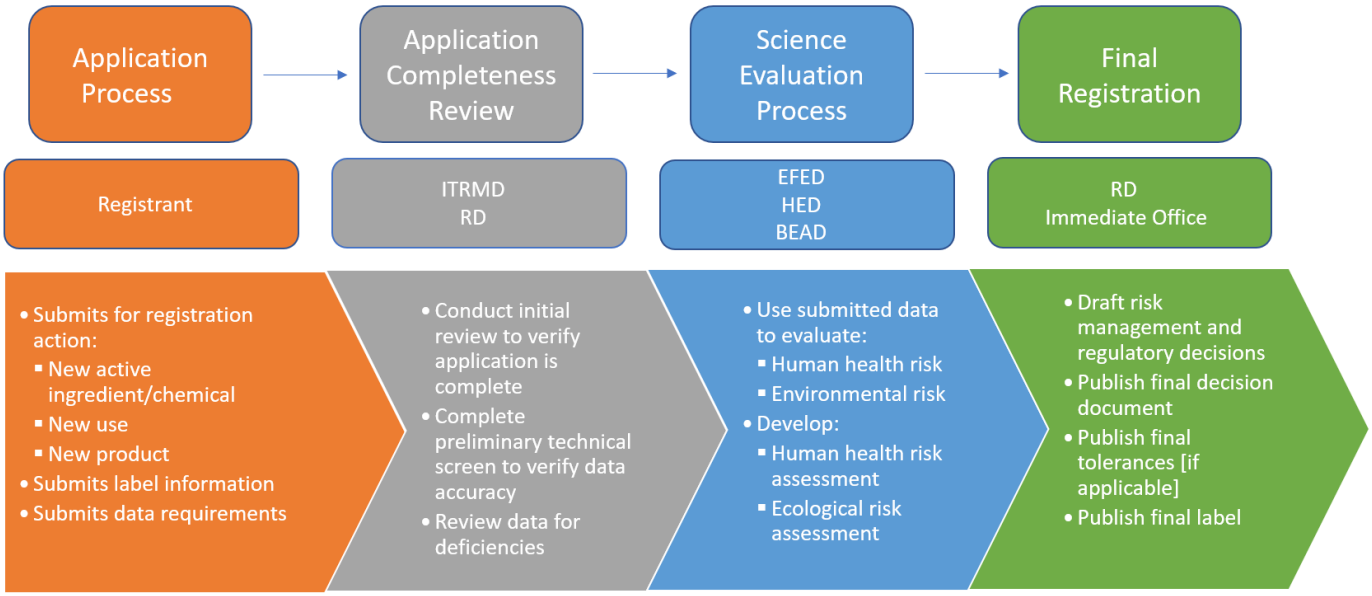
The RD then makes the final risk management and regulatory decisions, considering the results from the risk assessments, to determine whether the pesticide registration is approved or denied. The RD also evaluates and approves the language that appears on each pesticide label to ensure that the directions for use and the prescribed safety measures are appropriate for any risk. It is a violation of federal law to use a pesticide in a manner inconsistent with its labeling.

If the EPA determines that registering the pesticide product will not generally cause unreasonable adverse effects to humans or the environment and if the application meets all other requirements, the Agency approves the application for the pesticide registration. This registration allows the registrant to legally sell and distribute the pesticide product in the United States. Once an EPA registration has been granted, registrants will then need to comply with any registration

requirements imposed by the states in which they wish to sell or distribute their products.

Figure 1 illustrates the OPP's collaborative registration process.

Figure 1: OPP's conventional pesticide registration process



Source: OIG analysis of EPA information. (EPA OIG image)

Note: ITRMD is the Information Technology and Resources Management Division within the OPP. BEAD stands for the Biological and Economic Analysis Division, also within the OPP.

Responsible Office

The Office of Chemical Safety and Pollution Prevention's OPP is responsible for the pesticide registration process.

Scope and Methodology

We conducted our audit work for the findings in this report from February through December 2020. 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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

We reviewed relevant materials, including laws, policies, procedures, decision documents, and prior analyses, to establish criteria and conduct our analysis. We interviewed EPA managers and staff from the Office of Chemical Safety and Pollution Prevention and the OPP to understand the pesticide registration process.

Analysis Methodology

Unconditional pesticide registration regulations require the EPA to meet eight criteria, as set forth in 40 C.F.R. § 152.112(a) through (h), before issuing an unconditional registration. We reviewed nine pesticide registrations for adherence with the regulations in 40 C.F.R. § 152.112 (Table 1). Specifically, we continued our analysis of sulfoxaflor's registration,[2] and we selected the other eight registrations based on the following criteria:

- Issuance during the 2014–2019 time frame.
- Unconditional registration.
- Conventional pesticide.
- Initial registration of a new active ingredient.
- Intended use on food, which requires the manufacturer to submit more studies to satisfy the toxicology data requirements than for nonfood use.

See Appendix A for additional details regarding our analysis methodology.

Table 1: Pesticides selected for OIG audit

Pesticides	Used as	Registered (fiscal year)
Bixafen	Fungicide	2019
Afidopyropen	Insecticide	2018
Pydiflumetofen	Fungicide	2018
Benzobicyclon	Herbicide	2017
Tioxazafen	Nematicide	2017
Cyclaniliprole	Insecticide	2017
Tolpyralate	Herbicide	2017
Oxathiapiprolin	Fungicide	2015
Sulfoxaflor	Insecticide	2013

Source: OIG analysis. (EPA OIG table)

Results

The EPA mostly adhered to the eight criteria in 40 C.F.R. § 152.112 for the unconditional pesticide registrations for the nine pesticide registrations that we reviewed. The OPP fully complied with four of these criteria, while two were not applicable to the pesticides registrations that we reviewed. For the two remaining criteria, which in part address the toxicology and ecological data requirements, the OIG:

[2] We initially sought to determine the EPA's compliance with human health and ecological risk assessment requirements for conditional and unconditional pesticide registrations for imidacloprid, thiamethoxam, clothianidin, and sulfoxaflor. We found that the EPA Pesticide Registration Review program was reviewing the registrations of imidacloprid, thiamethoxam, and clothianidin to determine whether these pesticides continue to meet the FIFRA standard for registration. We therefore removed these three pesticides from our sample.

- Independently verified that the OPP met all toxicology data requirements. The OPP develops a summary table addressing toxicology data requirements for pesticide registrations.

- Could not independently verify that the OPP met all ecological data requirements. The OPP does not develop an ecological data requirements summary table or similar internal control procedure to ensure that all ecological data requirements for pesticide registrations have been met.

If the EPA cannot assure that it is in full compliance with the ecological data requirements, there is an increased risk that the Agency will issue a pesticide registration that does not comply with applicable regulations.

We also found that the OPP's RD does not have a standard operating procedure governing how to conduct the initial registration of a new pesticide to ensure adherence to 40 C.F.R. § 152.112. A standard operating procedure establishes the process by which work is conducted to comply with applicable laws and regulations. In addition, Office of Management and Budget Circular No. A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control,* requires federal managers to implement the U.S. Government Accountability Office's Green Book,[3] which provides the framework for establishing and maintaining internal controls. Management is responsible for designing and having staff implement these policies and procedures. Because the RD lacks adequate internal controls—such as standard policies and procedures or a standard operating procedure—for initial registrations, the EPA should develop and implement this internal control as prescribed by the Green Book.

EPA Adhered to Most Registration Risk Assessment Requirements but Could Improve Internal Controls over Data Requirements

As seen in Table 2, the Agency mostly adhered to 40 C.F.R. § 152.112 for the nine unconditional pesticide registrations that we reviewed. The OPP fully complied with criteria (a), (e), (f), and (g). Criteria (d) and (h) were not applicable for these nine pesticide registrations. For criteria (b) and (c), we could verify that the human health risk assessment fully complied with the toxicology data requirements of 40 C.F.R. § 158.500. We could not, however, verify for criteria (b) and (c) that the ecological risk assessment addressed the ecological data requirements of 40 C.F.R. § 158.630. We therefore could not verify that all regulatory ecological data requirements were reviewed and approved prior to issuing the registration.

[3] GAO-14-704G, *Standards for Internal Control in the Federal Government.*

Table 2: EPA's adherence to pesticide registration requirements

Regulatory criteria (40 C.F.R. § 152.112)			Could the OIG verify that criteria were satisfied for each pesticide registration?[a]								
			Bixafen	Afidopyropen	Pydiflumetofen	Benzobicyclon	Tioxazafen	Tolpyralate	Cyclaniliprole	Oxathiapiprolin	Sulfoxaflor
(a)	Application was complete and satisfied data requirements.		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
(b)	Relevant data were reviewed.[b]	EFED: Ecological risk assessment using data from 40 C.F.R. § 158.630.	No	No	No	No	No	No	No	No	No
		HED: Human health risk assessment using data from 40 C.F.R. § 158.500.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
(c)	No additional data were needed.	EFED: Ecological risk assessment using data from 40 C.F.R. § 158.630.	No	No	No	No	No	No	No	No	No
		HED: Human health risk assessment using data from 40 C.F.R. § 158.500.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
(d)	Product's efficacy claims are verified.[c]		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
(e)	Product will perform intended function and will not cause unreasonable adverse effects on environment.		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
(f)	Label complies with requirements.		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
(g)	Tolerances are established.[d]		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
(h)	Product complies with U.S. Food and Drug Administration requirements, if product is also a drug.[e]		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Source: OIG analysis of EPA pesticide registrations. (EPA OIG table)

[a] While we confirmed the existence of documentation for each regulatory criterion, we did not review the underlying scientific merit or accuracy of either the EPA's risk assessment findings or the documents submitted to the EPA by the registrants.

[b] Data requirements under 40 C.F.R. Part 158 are numerous and varied. The OIG's audit assessed compliance with the toxicology data requirements listed in 40 C.F.R. § 158.500 and the ecological data requirements listed in 40 C.F.R. § 158.630.

[c] Under 40 C.F.R. § 158.400(e)(1), EPA pesticide registration regulations provide a waiver that releases registrants from providing a pesticide's efficacy data unless the pesticide controls pest microorganisms threatening human health or unless the pesticide claims to control certain vertebrate animals that may transmit diseases to humans.

[d] If required, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under the Federal Food, Drug, and Cosmetic Act, Section 408.

[e] If the pesticide product is requesting use as a drug within the meaning of Federal Food, Drug, and Cosmetic Act, Section 201(q), the EPA must have been notified by the Food and Drug Administration that the product complies with Food and Drug Administration requirements.

Criteria (b) and (c) Toxicology Data Requirements

For all nine pesticide registrations, the HED included a "Toxicology Data Requirements" summary table with its human health risk assessments. This summary table outlined the toxicology studies required by regulation, if applicable to the pesticide being registered; identified which toxicology studies were applicable for each application; and indicated whether the registrant submitted all data requirements pertinent to those studies. If the data requirement was not satisfied, the HED documented why the data requirement

was waived for that pesticide registration. Figure 2 shows the HED summary table for bixafen.

Figure 2: EPA's summary toxicology data requirements table for bixafen

Table A.1 Bixafen Toxicology Data Requirements

Study		Technical	
		Required	Satisfied
870.1100	Acute Oral Toxicity	yes	yes
870.1200	Acute Dermal Toxicity	yes	yes
870.1300	Acute Inhalation Toxicity	yes	yes
870.2400	Acute Eye Irritation	yes	yes
870.2500	Acute Dermal Irritation	yes	yes
870.2600	Skin Sensitization	yes	yes
870.3100	Oral Subchronic (rodent)	yes	yes
870.3150	Oral Subchronic (nonrodent)	yes	yes
870.3200	21/28-Day Dermal	yes	yes
870.3250	90-Day Dermal	no	–
870.3465	90-Day Inhalation	yes	no+
870.3700a	Developmental Toxicity (rodent)	yes	yes
870.3700b	Developmental Toxicity (nonrodent)	yes	yes
870.3800	Reproduction	yes	yes
870.4100a	Chronic Toxicity (rodent)	yes	yes
870.4100b	Chronic Toxicity (nonrodent)	yes	yes
870.4200a	Oncogenicity (rat)	–	–
870.4200b	Oncogenicity (mouse)	yes	yes
870.4300	Chronic/Oncogenicity (rat)	yes	yes
870.5100	Mutagenicity—Gene Mutation - bacterial	yes	yes
870.5300	Mutagenicity—Gene Mutation - mammalian	yes	yes
870.5375	Mutagenicity—Structural Chromosomal Aberrations	yes	yes
870.5395	Mutagenicity—Other Genotoxic Effects	yes	yes
870.6100a	Acute Delayed Neurotox. (hen)	no	-
870.6100b	90-Day Neurotoxicity (hen)	no	-
870.6200a	Acute Neurotox. Screening Battery (rat)	yes	yes
870.6200b	90-Day Neuro. Screening Battery (rat)	yes	no+
870.6300	Develop. Neuro	no	--
870.7485	General Metabolism	yes	yes
870.7600	Dermal Penetration	yes	yes
870.7800	Immunotoxicity	yes	no+

+ the registrant has requested a waiver for the data requirement, and the HASPOC has determined the study is not required at this time (M. Wilson, TXR 0057713, 02/22/2018).

Source: EPA. (EPA image)

Using these summary tables, we were able to determine that the OPP satisfied the data requirements of 40 C.F.R. § 158.500 for the nine pesticide registrations that we reviewed. Specifically, we could verify that at least the minimally required toxicology data requirements were reviewed and determined to be acceptable. We could also conclude that no additional data were needed before the EPA issued each pesticide registration.

Criteria (b) and (c) Ecological Data Requirements

For the nine pesticide registrations that we reviewed, we could not verify, as we could for the toxicology data requirements, whether the registrants submitted the ecological studies required by 40 C.F.R. § 158.630, nor could we determine whether the EPA reviewed and determined that each ecological

data requirement was satisfied. We did not find that the EFED used a summary table or other internal control to clearly outline the required ecological studies and whether the registrants submitted those studies. The EFED director confirmed during an interview that the OPP does not generate a data requirement summary table for its ecological risk assessments.

Because we could not determine whether the EPA reviewed all the relevant ecological data requirements for these nine registrations, we also could not conclude that no additional ecological data were needed prior to registration.

Without an ecological data requirement summary table or other similar internal control for the EFED's ecological risk assessments, there is an increased risk that the EPA could issue a pesticide registration that does not comply with the ecological data requirements. The OPP could improve its internal control system to ensure that it complies with 40 C.F.R. § 152.112(b) and (c) for the initial registration of new active ingredients.

EPA Needs a Standard Operating Procedure Governing Initial Registration of New Active Ingredients

To conduct our audit, we requested the RD's standard operating procedure for the initial registration of new active ingredients. Although the RD has standard operating procedures for other registration activities, such as the registration of additional food and nonfood uses for currently registered pesticides, it does not have a standard operating procedure for the initial registration of new active ingredients. Instead, the RD uses a draft decision memorandum template to develop the pesticide registration decision for a pesticide's initial registration. This draft decision memorandum template, however, is not a standard operating procedure, is not finalized, and is not approved by management.

A standard operating procedure would facilitate compliance with registration requirements and consistent implementation of the pesticide registration process, thereby increasing the quality of the issued pesticide registrations by consistently implementing pesticide regulations. The OPP should develop and implement this internal control as prescribed by the Green Book.

Conclusion

The EPA's pesticide registration process aims to ensure that a pesticide will not cause unreasonable adverse effects on human health or the environment if the pesticide is used in accordance with its label. To improve the effectiveness and efficiency of its registration process and comply with applicable laws and regulations, the EPA needs to add internal controls. A stronger internal control system will decrease the EPA's risk of issuing a pesticide registration that does not comply with statutory and regulatory requirements.

Recommendations

We recommend that the assistant administrator for Chemical Safety and Pollution Prevention:

1. Develop and incorporate an ecological data requirement summary table or similar internal control into the Office of Pesticide Programs' ecological risk assessments as verification that all ecological data requirements have been met.

2. Develop and implement a standard operating procedure for the initial pesticide registration of new active ingredients.

Agency Response and OIG Assessment

The Agency provided acceptable corrective actions and estimated completion dates. Both recommendations are resolved with corrective actions pending. The Agency also provided technical comments on the draft report, which we considered when preparing our final report.

We included the Agency's full response to our draft report in Appendix B.

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	12	Develop and incorporate an ecological data requirement summary table or similar internal control into the Office of Pesticide Programs' ecological risk assessments as verification that all ecological data requirements have been met.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	1/31/22	
2	12	Develop and implement a standard operating procedure for the initial pesticide registration of new active ingredients.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	1/31/22	

1 C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

Appendix A

Detailed Analysis Methodology

To determine whether the EPA demonstrated adherence under 40 C.F.R. § 152.112, we reviewed the following OPP documents for each of the nine pesticides:

- Final registration decision memorandums.
- Ecological risk assessments.
- Human health risk assessments.
- Verification documents for the initial screen of the applications.
- Verification or evidence of label review.
- Established pesticide tolerances.

Eight pesticide registration criteria with which the EPA must comply are listed at 40 C.F.R. § 152.112. Table A-1 lists the criteria and which OPP documents we reviewed to determine the Agency's compliance.

Table A-1: Registration criteria and EPA compliance documents reviewed

Criteria in 40 C.F.R. § 152.112, *Approval of registration under FIFRA sec. 3(c)(5)*		**Primary EPA documents reviewed to determine compliance**
(a)	The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part.	• EFED technical screen verification and completeness check. • HED technical screen verification and completeness check.
(b)	The Agency has reviewed all relevant data in the possession of the Agency.	• Human health risk assessment. • Ecological risk assessment.
(c)	The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application.	• Human health risk assessment. • Ecological risk assessment • EPA Form 8570-6.
(d)	The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted for the product by part 158 or part 161 of this chapter, as applicable.	Not applicable. The EPA did not evaluate efficacy for the selected pesticides. We identified a blanket wavier in the regulations. See 40 C.F.R. § 158.400(e)(1).
(e)	The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment.	Final registration decision memorandums.
(f)	The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter.	Documents with evidence of label review.

Criteria in 40 C.F.R. § 152.112, *Approval of registration under FIFRA sec. 3(c)(5)*		Primary EPA documents reviewed to determine compliance
(g)	If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under [Federal Food, Drug, and Cosmetic Act] FFDCA sec. 408.	Final rule and establishment of tolerances in the Federal Register.
(h)	If the product, in addition to being a pesticide, is a drug within the meaning of [Federal Food, Drug, and Cosmetic Act] FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.	Not applicable. None of the selected pesticides is a drug within the meaning of the Federal Food, Drug, and Cosmetic Act.

Source: 40 C.F.R. § 152.112 and OIG summary of collected EPA documents. (EPA OIG table)

We reviewed and analyzed the OPP-provided documents to determine adherence to each of the eight criteria in 40 C.F.R. § 152.112 for the nine pesticide registrations that we reviewed. The analysis for our audit focused on the OPP's use of risk assessment findings and supporting documents to make a final pesticide registration decision. We did not assess the scientific merit of the risk assessments.

The following list details how we used the provided documents to verify that the criteria of 40 C.F.R. § 152.112 were satisfied:

- For criterion (a), which addresses application completeness, we reviewed the HED and EFED technical screens. The technical screens for each data package allow the OPP to determine whether the registrant has submitted a "reasonably complete package." Technical screens are not a comprehensive evaluation of the submitted data but allow the packages to begin the science review process. We determined compliance with the criterion if the EFED and HED technical screens were completed or if the EPA requested that the registrant provide additional data to be submitted for review.

- For criteria (b) and (c), which address data review and data needs, we assessed whether the OPP reviewed all relevant data and determined that no additional data were necessary prior to the EPA granting the pesticide registration. Although the pesticide registration regulations list various data requirement tables in 40 C.F.R. Part 158, the OIG's audit only assessed compliance with the following two: the toxicology data requirement table in 40 C.F.R. § 158.500 and the ecological data requirement table in 40 C.F.R. § 158.630. We reviewed compliance with only two of the ten data requirement tables to limit the scope of the audit to a manageable size and to concentrate our efforts on the primary data requirements used for risk assessment. The human health and ecological risk assessments also provide information to determine data requirement compliance. For example, many of the risk assessments address areas of uncertainties or explanation of data gaps within the submitted data. We determined compliance with the criteria if there was evidence to demonstrate that the OPP reviewed the relevant data and concluded that no further data were needed for at least the minimally required ecological and toxicology data requirements.

- For criterion (d), which addresses efficacy data, the EPA pesticide registration regulations under 40 C.F.R. § 158.400(e)(1) provide a blanket waiver that releases all manufacturers from providing proof of a pesticide's efficacy unless the pesticide controls microorganisms threatening human health or controls vertebrate animals that may transmit diseases to humans, such as rats, mice, bats, wolves, and skunks. We determined that this criterion was not applicable to our audit, as none of the selected pesticides were being registered to control microorganisms or vertebrate animals; therefore, the blanket waiver applied to all nine pesticides.

- For criterion (e), which addresses intended pesticide use and "unreasonable adverse risks to the environment," we reviewed the risk assessments and final decision documents. We identified whether the OPP provided rationale and documented the registration decision, so that the basis of its decision was transparent and available for the public and the scientific community to review how a pesticide's intended use does not pose "unreasonable adverse effects on the environment."

- For criterion (f), which addresses label compliance, we reviewed the OPP's various pesticide registration documentation to verify evidence of label review and approval prior to registration.

- For criterion (g), which addresses pesticide tolerances, we used the *Federal Register* as evidence to locate the published final tolerances. A *pesticide tolerance* is the maximum amount of pesticide allowed to remain in or on human food or animal feeds marketed in the United States. The EPA must develop and issue pesticide tolerances if the pesticide is to be used on food crops. All nine of the selected pesticides requested use on various food crops; therefore, a tolerance, tolerance exemption, or applicable food additive regulations must have been issued under Section 408 of the Federal Food, Drug, and Cosmetic Act.

- For criterion (h), which addresses pesticide use as a drug, we determined that none of the reviewed pesticide registrations requested use as a drug. This criterion was therefore not applicable to our audit.

Agency Response to Draft Report

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Draft Report entitled "EPA Mostly Adheres to Regulations When Assessing Risks of New Pesticides but Should Improve Internal Controls."

FROM: Alex Dapolito Dunn
Assistant Administrator

ALEXANDRA DAPOLITO DUNN
Digitally signed by ALEXANDRA DAPOLITO DUNN
Date: 2021.01.20 09:48:28 -05'00'

TO: Sean W. O'Donnell
Inspector General

This memorandum responds to the Office of Inspector General's December 10, 2020 Draft Report entitled "EPA Mostly Adheres to Regulations When Assessing Risks of New Pesticides but Should Improve Internal Controls," Project No. OA&E-FY20-0095.

I. General Comments:

The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's effort in evaluating the following:

- EPA's adherence to pesticide registration risk assessment regulations, policies and procedures.

OCSPP accepts the OIG's recommendations and will complete appropriate follow up, as described below.

Attached to this memo are OCSPP's Technical Comments, which we respectfully request remain internal to EPA. Technical comments are proposed language changes.

II. OCSPP's Response to the Recommendations:

The draft report contains two recommendations for OCSPP's Office of Pesticide Programs (OPP).
Recommendation 1: Develop and incorporate an ecological data requirement summary table or similar internal control into the Office of Pesticide Programs' ecological risk assessments as verification that all necessary ecological data requirements have been met.

• **Proposed Corrective Action 1**: OCSPP will develop an internal memo or include in an ecological risk assessment template a requirement to incorporate a data requirement summary table or similar internal control into the OPP's ecological risk assessments for new active ingredients as verification that all necessary ecological data requirements have been satisfied.
• **Target Completion Date**: January 31, 2022.

Recommendation 2: Develop and implement a standard operating procedure for the initial pesticide registration of new active ingredients.

• **Proposed Corrective Action 2**: OCSPP will develop and implement a standard operating procedure for the initial pesticide registration of new active ingredients. Specifically, OCSPP will complete a standard operating procedure for the review of conventional pesticide new active ingredients.
• **Target Completion Date**: January 31, 2022.

cc: All OCSPP DAAs
Ed Messina, Acting Director, OPP
Mike Goodis, Acting Deputy Director of Programs, OPP
Marietta Echeverria, Acting Director RD
Jan Matuszko, Acting Director, EFED
Chad Kincheloe, Acting Director OIG Office of Evaluation
Janet L. Weiner, Senior Audit Advisor, OCSPP
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Appendix C

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