U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Ensuring the safety of chemicals

EPA Deviated from Typical Procedures in Its 2018 Dicamba Pesticide Registration Decision

Report No. 21-E-0146 **May 24, 2021**

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Abbreviations

BEAD	Biological and Economic Analysis Division
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
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
OPP	Office of Pesticide Programs
OTT	Over the Top
PRP	Product Review Panel
SIO	Scientific Integrity Official
U.S.C.	United States Code

Cover Photo: In 2018, the EPA extended the conditional registrations for three dicamba pesticide products used on genetically modified dicamba-tolerant soybean plants. (EPA photo)

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U.S. Environmental Protection Agency
Office of Inspector General

21-E-0146
May 24, 2021

At a Glance

EPA Deviated from Typical Procedures in Its 2018 Dicamba Pesticide Registration Decision

Why We Did This Evaluation

We performed this evaluation to determine the effectiveness of the U.S. Environmental Protection Agency's policies and procedures in addressing stakeholder risks in the 2016 and 2018 dicamba pesticide registration decisions.

The Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA, charges the EPA with balancing the uncertainties and risks posed by a pesticide against the benefits associated with the use of the pesticide. The EPA's Office of Chemical Safety and Pollution Prevention, or OCSPP, can conditionally register new uses of a pesticide if the Agency finds that the pesticide meets the standard for registration, but there is a need to collect additional monitoring data or conduct new scientific studies.

This evaluation addresses the following:

- *Ensuring the safety of chemicals.*

This evaluation addresses a top EPA management challenge:

- *Communicating risks.*

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List of OIG reports.

What We Found

The EPA needs to document and follow established procedures to ensure scientifically sound decisions regarding pesticides.

The EPA's *Scientific Integrity Policy* affirms that the Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which the EPA relies. Per the policy, the EPA's scientists and managers are expected to represent the Agency's scientific activities clearly, accurately, honestly, objectively, thoroughly, without political or other interference, and in a timely manner, consistent with their official responsibilities. Additionally, federal and EPA requirements include documenting the formulation and execution of policies and decisions. For pesticide registration decisions, the OCSPP's Office of Pesticide Programs must review registrations and document its decisions.

We found that the EPA's 2018 decision to extend registrations for three dicamba pesticide products varied from typical operating procedures. Namely, the EPA did not conduct the required internal peer reviews of scientific documents created to support the dicamba decision. While division-level management review is part of the typical operating procedure, interviewees said that senior leaders in the OCSPP's immediate office were more involved in the dicamba decision than in other pesticide registration decisions. This led to senior-level changes to or omissions from scientific documents. For instance, these documents excluded some conclusions initially assessed by staff scientists to address stakeholder risks. We also found that staff felt constrained or muted in sharing their concerns on the dicamba registrations. The EPA's actions on the dicamba registrations left the decision legally vulnerable, resulting in the Ninth Circuit Court of Appeals vacating the 2018 registrations for violating FIFRA by substantially understating some risks and failing to acknowledge others entirely.

Recommendations and Planned Agency Corrective Actions

We recommend that the assistant administrator for Chemical Safety and Pollution Prevention (1) implement a procedure requiring senior managers or policy makers to document changes or alterations to scientific opinions, analyses, and conclusions in interim and final pesticide registration decisions and their basis for such changes or alterations; (2) require an assistant administrator-level verification statement that *Scientific Integrity Policy* requirements were reviewed and adhered to during pesticide registration decisions that involve the immediate office; and (3) annually conduct and document training for all staff and senior managers and policy makers to affirm the office's commitment to the *Scientific Integrity Policy* and principles and to promote a culture of scientific integrity. Two recommendations are resolved with corrective actions pending, and one recommendation is unresolved.

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

THE INSPECTOR GENERAL

May 24, 2021

MEMORANDUM

SUBJECT: EPA Deviated from Typical Procedures in Its 2018 Dicamba Pesticide Registration Decision
Report No. 21-E-0146

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 evaluation conducted by the Office of Inspector General of the U.S. Environmental Protection Agency. The project number for this evaluation was OA&E-FY20-0122. 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 for Recommendations 1 and 3. These recommendations are resolved with corrective actions pending.

Action Required

Recommendation 2 is unresolved. The resolution process, as described in the EPA's Audit Management Procedures, begins immediately with the issuance of this report. Furthermore, we request a written response to the final report within 60 days of this memorandum. Your response 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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Appendices

Purpose

The U.S. Environmental Protection Agency's Office of Inspector General conducted this evaluation to determine whether EPA policies and procedures were effective in addressing stakeholder issues in the EPA's dicamba pesticide registration decisions in 2016 and 2018.

Top Management Challenge

This evaluation 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:

- *Communicating risks*.

Background

EPA's Pesticide Registration Process

The EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA. Per FIFRA, the EPA regulates pesticides to prevent "unreasonable adverse effects on the environment." FIFRA defines "unreasonable adverse effects on the environment" to mean:

> (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.

The EPA's website adds that the Agency evaluates:

> [I]nformation from all kinds of sources – pesticide companies, other governments, academia, and the published scientific literature. EPA scientists and analysts carefully review these data to determine whether to register (license) a pesticide product or use and whether specific restrictions are necessary.

FIFRA authorizes the EPA to conditionally amend an existing pesticide registration to add an additional use when the Agency finds that it has satisfactory data pertaining to the proposed new use. For this, the Agency may grant the application for registration with conditions that require the registrant to provide additional information within a specified time frame. If the registrant does not comply with the conditions, the EPA may, among other options, cancel the registration.

If the EPA has determined that no unreasonable adverse effects to human health or the environment will result from the sale or distribution of a pesticide product, the Agency grants the applicant a license—or registration—to legally sell and distribute the product in the United States. Upon granting the registration, the

EPA also approves a pesticide label for the product. The pesticide label contains end-user requirements for proper use and application of the product and restrictions that must be followed to protect both human health and the environment. Companies obtaining the registration also need to comply with any individual registration requirements imposed by the states in which they wish to have their product applied.

Roles and Procedures Used for Pesticide Registration

The EPA's Office of Chemical Safety and Pollution Prevention, or OCSPP, oversees the pesticide registration process through its Office of Pesticide Programs. The Registration Division within the OPP drafts the registration decision, which is the EPA's determination of whether a pesticide registration should be approved or denied. This division considers the results from risk assessments conducted by the OPP's Environmental Fate and Effects Division, or EFED, and the OPP's Health Effects Division, as well as analysis conducted by the OPP's Biological and Economic Analysis Division, or BEAD. The Registration Divison also reviews the draft language submitted by the registrant that appears on each proposed pesticide label and determines whether the directions for use and any other restrictions are adequate to warrant approving the registration.

EFED uses a two-tiered approach to conduct peer reviews of ecological risk assessments generated in its division. According to the *Update to the Environmental Fate and Effects Review Panel SOP and Branch QA/QC Expectations*, dated November 2017:

- The Environmental Risk Branch that is responsible for completing the assessment conducts the first peer review.
- The EFED review panel conducts the second review.

The EFED review panel examines the division's draft risk assessments and provides substantive or major comments as determined by the panel chair. If needed, the panel will meet with the chemical team to discuss the review panel's comments. According to the EFED update memorandum, the review panel chair is responsible for "recording the panel's direction and chemical team responses as a final report of review panel meeting decisions." The branch chief must ensure that all substantive review panel comments have been considered and adequately addressed in the revised risk assessment. The review panel chair will document areas of disagreement or issues that require further divisional guidance as part of the record. The chair will forward those matters to the EFED associate director, deputy division director, and the chemical team's branch chief to determine the most appropriate course of action. Each assessment is unique, and the level of intensity and effort allotted to any one assessment depends on a number of factors. The level of review remains within the discretion of the appropriate branch chief.

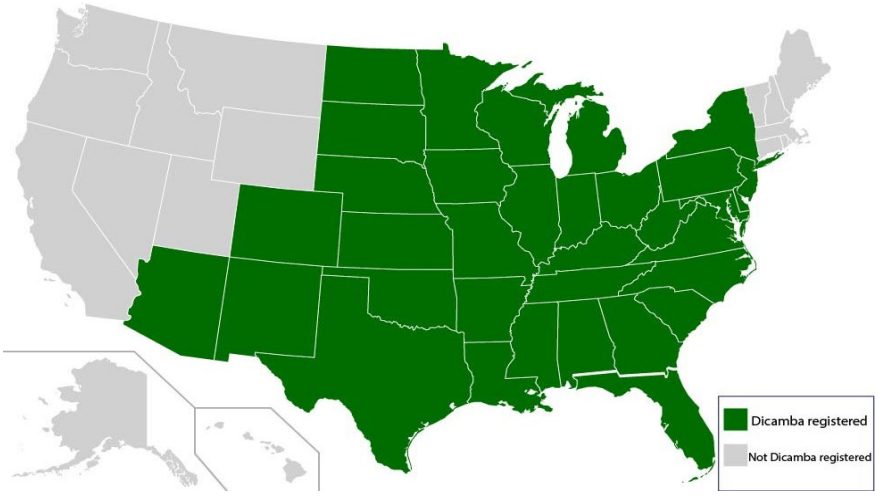
The BEAD Product Review Panel examines analysis conducted by its division prior to transmitting the analysis to the Registration Division. According to the *Organization and Operating Procedures for the Product Review Panel (PRP)*, dated February 2017, PRP review is required for any document produced by BEAD that is used to support a regulatory decision. The division uses a PRP to review work products before they are transmitted to customer divisions to ensure quality, consistency, and clarity. The list of documents reviewed includes benefits and impact analysis. PRP reviews focus on the following attributes of each document: issue, methodology, assumptions, uncertainties, and conclusions. These documents must be signed by the authors and the appropriate branch chief. The final document submitted to the appropriate branch chief and the BEAD director for signature must be accompanied by the PRP summary of the comments and the authors' responses. If a resolution of the issues cannot be reached by the document author(s) and the branch chiefs, the issues are raised to the BEAD director.

Dicamba Pesticide Registration Process and Legal Action

Dicamba is a herbicide that is widely used on agricultural crops, fallow land, pastures, turfgrass, and rangeland. Dicamba is used to control emerged broadleaf weeds and provides some residual control of germinating weeds. Dicamba was first registered in the United States in 1967. In late 2016 and early 2017, the Agency conditionally registered three "over the top," or OTT, dicamba products for use on post-emergent crops—after growth begins—complying with the terms and conditions under FIFRA. These dicamba products were to be used on genetically modified dicamba-tolerant cotton and soybean plants in 34 states (Figure 1). Any application of these products had to comply with any associated state requirements.

According to the EPA, OTT dicamba applications are post-emergent crop applications made to dicamba-tolerant soybeans and cotton. The use of dicamba applications should be consistent with their labeling requirements.

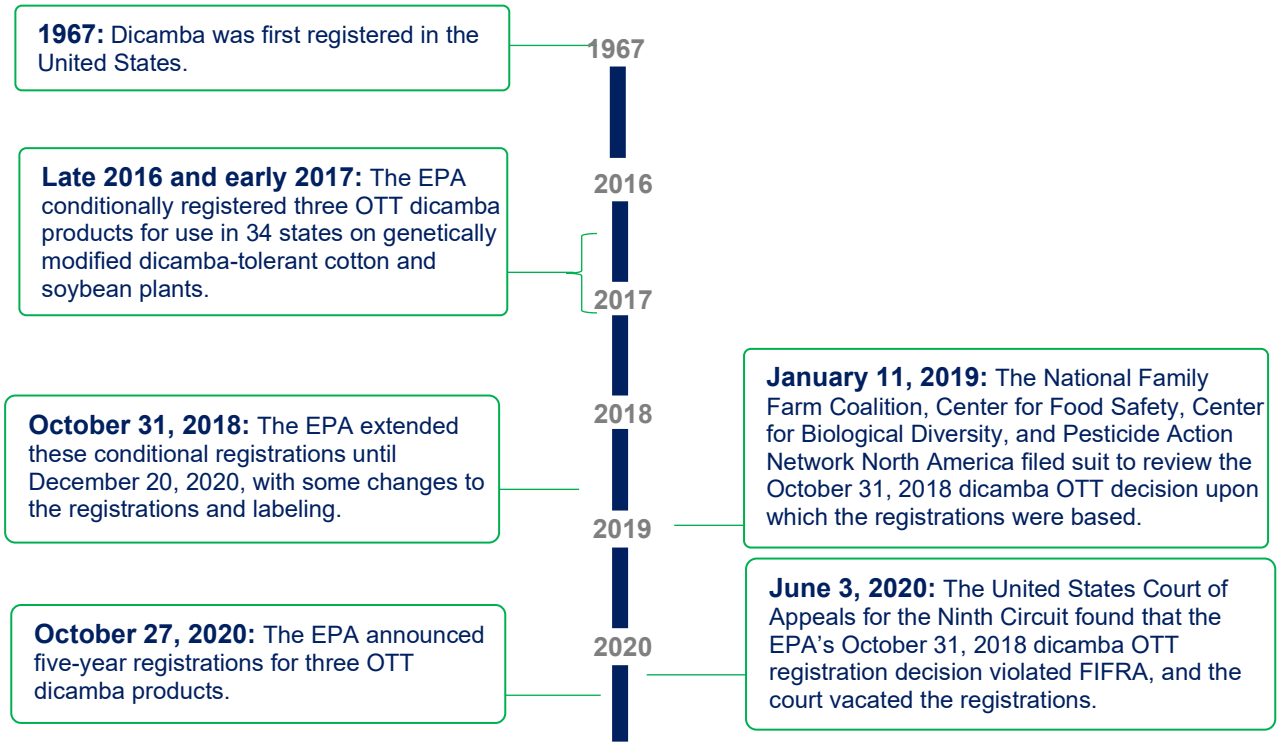
Figure 1: States in which dicamba products allowing OTT applications were registered



Source: OIG document reviews. (EPA OIG image)

The EPA's OTT conditional registrations were time-limited with automatic expiration dates unless the Agency granted an extension. On October 31, 2018, the EPA announced that it would extend these three conditional registrations until December 20, 2020, with some changes to the registrations and labeling. The conditional registrations required the registrants to meet certain terms and conditions, including collecting various monitoring data and conducting new scientific studies.

Figure 2: Timeline of dicamba registration actions



Source: OIG review of dicamba documents. (EPA OIG image)

Four advocacy groups—the National Family Farm Coalition, the Center for Food Safety, the Center for Biological Diversity, and the Pesticide Action Network North America—filed suit to review the EPA's October 31, 2018 dicamba OTT conditional registration decision. On June 3, 2020, the United States Court of Appeals for the Ninth Circuit found that the EPA's dicamba OTT conditional registration decision violated FIFRA, and the court vacated the three registrations.[1] On June 8, 2020, the EPA issued its *Final Cancellation Order for Three Dicamba Products*, prohibiting all use of the products covered under the 2018 dicamba pesticide conditional registration decision after July 31, 2020. On October 27, 2020, the EPA approved five-year registrations for two dicamba products, and extended the registration on an additional dicamba product for five years. Figure 2 includes these dicamba milestones.

[1] *National Family Farm Coalition v. U.S. EPA*, 960 F.3d 1120, 1145 (9th Cir. 2020).

The Ninth Circuit Court of Appeals stated that the "EPA substantially understated risks that it acknowledged and failed entirely to acknowledge other risks." One understated risk pertained to the amount of dicamba-tolerant seed acreage that had been planted in 2018 and, correspondingly, the amount of dicamba herbicide that had been sprayed on post-emergent crops. Additionally, the court noted that the EPA:

- [P]urported to be agnostic as to whether formal complaints of dicamba damage under-reported or over-reported the actual damage, when record evidence clearly showed that dicamba damage was substantially under-reported.

- [R]efused to estimate the amount of dicamba damage, characterizing such damage as "potential" and "alleged," when record evidence showed that dicamba had caused substantial and undisputed damage.

The court said that the EPA entirely failed to acknowledge:

- Record evidence showing the high likelihood that restrictions on OTT dicamba application imposed by the 2018 label would not be followed.

- The substantial risk that the registrations would have anticompetitive economic effects in the soybean and cotton industries.

- [T]he risk that OTT dicamba use would tear the social fabric of farming communities.

EPA's Scientific Integrity Policy and Office

The Agency issued its *Scientific Integrity Policy* in 2012. The policy notes that science is the backbone of the EPA's decision-making and that the Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which the EPA relies. According to the policy, all Agency employees, including scientists, managers, and political appointees, are required to follow the policy when engaging in, supervising, managing, or influencing scientific activities; communicating information in an official capacity about Agency scientific activities; and utilizing scientific information in making Agency policy or management decisions.

> "The Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies. Policies and decisions must be grounded in sound, high quality science."
>
> *-- Scientific Integrity Policy*

The EPA appointed a scientific integrity official in November 2013 to champion scientific integrity throughout the Agency. The SIO chairs a standing committee of deputy SIOs representing each EPA program office, including the Office of the Administrator, and region. These senior-level employees provide oversight for implementing the *Scientific Integrity Policy* at the EPA, act as liaisons for their respective programs and regions, and are available to address any questions or concerns on the policy.

To foster a culture of scientific integrity, the Agency's *Scientific Integrity Policy* identifies many ideals and actions. They include:

- Political or other officials should not suppress or alter scientific findings when operating a science and regulatory agency like the EPA.

- Reviews by Agency managers and other Agency leadership regarding the content of a scientific product are to be based only on scientific quality considerations. For example, they should review whether the methods used are clear and appropriate and the presentation of results and conclusions is impartial.

- Managers and other Agency leadership are prohibited from intimidating or coercing scientists to alter scientific data, findings, or professional opinions. In addition, policy makers shall not knowingly misrepresent, exaggerate, or downplay areas of scientific uncertainty associated with policy decisions.

The EPA OIG is responsible for investigating allegations of EPA-related misconduct. To support the OIG's mission, the EPA requires each employee to promptly report indications of wrongdoing or irregularities to the OIG, including indications of abuse of authority, mismanagement, and misconduct, including scientific misconduct. Specifically, the EPA's *Scientific Integrity Policy* recognizes that the OIG will normally adjudicate allegations of scientific misconduct and requires the SIO to coordinate with the OIG on issues of scientific misconduct. As part of this coordination, the SIO is required to report a misconduct allegation to the OIG within seven days of receiving the allegation, and the OIG is required to report an allegation of research misconduct within seven days to the SIO in order to discuss the allegation, as appropriate. Pursuant to the Inspector General Act of 1978, as amended, the OIG cannot disclose the identity of any EPA employee reporting allegations of misconduct unless that employee consents to disclosure or the inspector general determines that such disclosure is unavoidable during the course of an investigation. The SIO said that the Office of Science Advisor, Policy and Engagement, too, will not disclose the identity of any EPA employee reporting allegations to the extent the law allows.

Federal and EPA Requirements on Being Transparent and Documenting Decisions

Throughout the EPA's history, administrators have reaffirmed a commitment to transparency in the Agency's operations. Administrator memorandums concerning transparency have become known as "fishbowl memos" because they stress that the Agency should operate openly and transparently, as if it were in a fishbowl. Administrator Andrew Wheeler issued a memorandum on July 30, 2018, reaffirming that commitment, stating, "We are committed to earning and maintaining the public's trust through transparency and accountability in our actions." He also stated that the Agency's success depends on public trust and confidence. Current Administrator Michael Regan continued this commitment in a memorandum dated April 12, 2021, wherein he stated that "public trust requires transparency." Moreover, the *Scientific Integrity Policy* notes linkages between being transparent and promoting a culture of scientific integrity.

Federal employees are required to maintain federal records per the Federal Records Act. Specifically, 44 U.S.C. § 3101 requires the head of every federal agency to make and preserve records containing adequate and proper documentation of policies and decisions. Per 36 C.F.R. § 1222.22, agencies must "document the formulation and execution of basic policies and decisions and the taking of necessary actions." The EPA's *Interim Records Management Policy* cites this language and implements this regulatory provision.

Responsible Office

The OPP is responsible for the issues discussed in this report.

Scope and Methodology

We conducted this evaluation from April 2020 through March 2021 in accordance with the *Quality Standards for Inspection and Evaluation* published in January 2012 by the Council of the Inspectors General on Integrity and Efficiency. Those standards require that we perform the evaluation to obtain sufficient, competent, and relevant evidence to provide a reasonable basis for our findings, conclusions, and recommendations based on our objective. We believe that the evidence obtained provides a reasonable basis for our findings, conclusions, and recommendations.

We reviewed the 2016 and the 2018 dicamba registration decisions and documentation supporting those decisions, as well as concerns raised by stakeholders and the Ninth Circuit Court ruling. We reviewed internal guidance and procedures for pesticide registrations. We also interviewed career scientists and other staff within the OCSPP, the OPP, and the EPA's Office of General

Counsel. We also reviewed internal scientific integrity materials and corresponded with the SIO.

We focused our review on the 2018 dicamba registration decision, using information from the 2016 registration as background and context. As noted earlier, the EPA approved five-year registrations for two dicamba products and extended the registration on another dicamba product on October 27, 2020. We did not review this decision, as it was outside our scope.

Prior Report

On May 20, 2020, our office issued Report No. 20-P-0173, *Further Efforts Needed to Uphold Scientific Integrity Policy at EPA*. That report summarized the results of an agencywide survey of EPA employees and contractors on the implementation of and perspective on the Agency's *Scientific Integrity Policy*. Survey respondents were provided the opportunity to discuss their specific scientific integrity concerns with the OIG. Information gathered during this process was one of the reasons we conducted this review.

Results

The EPA's *Scientific Integrity Policy* notes that the Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which the EPA relies. Per the policy, the EPA's scientists and managers are expected to represent Agency scientific activities clearly, accurately, honestly, objectively, thoroughly, without political or other interference, and in a timely manner, consistent with their official responsibilities. Additionally, scientists and managers are expected to follow federal and EPA transparency requirements, including documenting the formulation and execution of policies and decisions. For pesticide registration decisions, the OPP must review registrations and document its decisions.

We found that the EPA's 2018 dicamba pesticide conditional registration decision varied from the OPP's written standard operating procedures, namely because the EPA did not conduct the required internal peer review of scientific documents created to support the dicamba decision. While OPP division-level management review is part of the typical operating procedure, staff scientists indicated that, in this instance, senior leaders in OCSPP's immediate office—specifically the former deputy assistant administrator, former deputy assistant administrator for Law and Policy, and former acting principal deputy assistant administrator (hereafter referred to as "senior management")—were more involved in the dicamba decision than in other pesticide registration decisions. This led to senior-level changes to or omissions from scientific documents, including omissions of some conclusions addressing stakeholder risks.

In separate interviews, scientists from the OPP's Registration Division, EFED, and BEAD all described feeling constrained or muted in sharing their scientific integrity concerns with senior management during the dicamba registration process. The EPA's actions on the dicamba registration left the decision legally vulnerable, resulting in the Ninth Circuit Court of Appeals vacating the three 2018 registrations for violating FIFRA by substantially understating some risks and failing to acknowledge others entirely.

Following established procedures, documenting management decisions, and raising awareness on the EPA's *Scientific Integrity Policy* should help assure the soundness of future pesticide decisions.

EPA's 2018 Dicamba Registration Decision Did Not Follow Procedures, and Reasons for Changes Were Not Documented

As noted earlier, OPP policies and procedures for scientific documents contain steps for divisional review and approval. We found that the 2018 dicamba registration decision did not utilize divisional internal review panels or a PRP. Scientists told us that following the internal review process would not have made a difference in this case due to significant involvement of senior management. We also found that some scientists did not sign off on final documents they drafted for the registration decision due to revisions made by OCSPP senior managers. We reviewed final documents for the 2016 and 2020 dicamba registration decisions and noted that the scientists had signed off on those documents.

Federal and EPA requirements include documenting the formulation and execution of basic policies and decisions. During PRP reviews, authors and branch chiefs will try to reach consensus on the major issues in each document that must be addressed by the document authors. A copy of the PRP notes for each document will accompany the document when it is submitted for branch chief review. If there are issues raised by PRP that have not been addressed in the final document, the author must include a justification or rationale.

In our interviews, OPP divisional scientists provided examples of where scientific analyses were changed to support senior officials' policy decisions.[2] For the examples listed below, scientists reported that changes from senior management did not make sense and seemed to convey a lack of understanding of the data or analyses. For example:

- According to one scientist, OCSPP senior management and policy makers decided to use plant height as the standard measure of dicamba effect on plants. This varied from the EPA scientists' recommended approach to use visual signs of plant injury—an approach used in academic and registrant direct-spray toxicity studies, in field studies evaluating off-field

[2] For some written materials we reviewed, we could not confirm the specific individuals who made changes, as the files simply said "author" as the source of suggested revisions.

movement, and in information reported in state investigations of dicamba damage. This direction by senior management changed the division's scientific conclusions.

- According to another scientist, OCSPP senior management provided direction to use registrants' data for reported dicamba damages instead of OPP divisional data sources. In its ruling to vacate the dicamba registrations, the Ninth Circuit Court found the dicamba damages to be substantially understated. Divisional scientists told us their original source data would have addressed the court's concerns.

- Multiple scientists in one division reported, and emails confirmed, that after OCSPP senior management review, scientists were provided with an outline from the assistant administrator's office for rewriting their benefits and impact analysis document. The outline removed several sections of the original document which the scientists said were relevant based on the analysis they completed.

While OPP division-level management review is part of the typical operating procedure, interviewees said that senior leaders were more involved in the dicamba decision than in other pesticide registration decisions. One scientist stated that "[they] never ha[d] this level of front office involvement" in the pesticide registration decision, and that "[they] almost never ha[d] underlying analysis changes, and this is the first exception [this scientist was] aware of." Multiple scientists said they felt directed to change the science to support a certain decision and that the reasons for senior managers' requested changes were not documented.

The OPP's acting deputy director of Programs noted that, due to its unique properties, "[d]icamba was in many ways a very unusual chemical to register." The acting deputy director of Programs added, "While generating the material there are usually standard processes, but in the dicamba case there was a lot of high-level involvement which is different." The OCSPP associate assistant administrator said that management sometimes makes different policy decisions based on scientific results and said, "[W]e cannot alter science, but we do not always make policy on it."

The EPA's *Scientific Integrity Policy* states that reviews by Agency managers and other leadership should be based only on scientific quality considerations. The policy also prohibits managers and leaders from altering scientific data, findings, or professional opinions or from knowingly misrepresenting or downplaying areas of scientific uncertainty.

The EPA acknowledged the importance of communicating scientific decisions in an October 8, 2020 document, *Approaches for Expressing and Resolving Differing*

Scientific Opinions. This document, issued by the Agency's scientific integrity program within the Office of Science Advisor, Policy and Engagement, states:

> In the interests of fostering the expression of differing scientific opinions, policy makers are encouraged to communicate final decisions and their basis back to the team and anyone who has formally expressed a differing scientific opinion on that particular matter.

Dicamba Discussed with SIO in 2018; Scientific Integrity Training Not Required for All Employees

During our review, the SIO was asked whether any scientific integrity concerns on the 2018 dicamba registration were received. The SIO said that, in 2018, dicamba was mentioned in a request for advice about a different issue. The SIO reported that, after the advice meeting, the individual who raised the concerns feared retaliation, retribution, or reprisal if the issue was taken any further, and the SIO said that the Office of Science Advisor, Policy and Engagement is prohibited from initiating an investigation unless a formal allegation has been reported. The SIO said that the concerns about the 2018 dicamba registration that were mentioned in a request for advice about a different issue were reported to the OIG in a quarterly coordination meeting.

According to the EPA's *2017 Annual Report on Scientific Integrity*, "[t]he Scientific Integrity Policy is most effective when agency employees are aware of its existence and its significance." In January 2017, scientific integrity training became mandatory for new EPA employees. This includes the EPA's senior leaders and political appointees, who have an option to receive the mandatory onboarding training through briefing packages or in person by the SIO, as the regular mandatory onboarding training is online.

Scientific integrity training is not one of the EPA's mandatory annual trainings. Although it was not required for employees who started working at the Agency prior to January 2017, the SIO stated the belief that it is likely that most staff in the OCSPP have received some form of scientific integrity training.

In their comments on our preliminary findings, OCSPP officials concurred with the importance of confirming their commitment to fully complying with the EPA's *Scientific Integrity Policy*. OCSPP leaders identified the following actions that the office could take to address our findings:

- Affirm the OCSPP's commitment to the *Scientific Integrity Policy* and to promote a culture of scientific integrity within the OCSPP.

- Train OCSPP managers and staff on the *Scientific Integrity Policy*.

- Foster widespread understanding and use of the EPA's October 8, 2020 document, *Approaches for Expressing and Resolving and Addressing Differing Scientific Opinions*.

- Welcome differing scientific opinions and repudiate retaliation, retribution, or reprisal with respect to such opinions.

We concur with these proposed actions and encourage the OCSPP to follow through with implementation. Additionally, a mandatory requirement for all, not just new, EPA staff participating in the pesticide registration processes to take scientific integrity training may also enhance compliance with the Agency's *Scientific Integrity Policy*.

Conclusions

The EPA needs to follow its processes and procedures for future pesticide registration decisions to ensure that the content of scientific products supporting decisions is based on scientific quality and that the scientific methods used are transparent and appropriate. Changing career scientists' analyses and conclusions and not documenting reasons for senior management changes resulted in risks not being fully addressed in the 2018 dicamba registration decision, as noted in the Ninth Circuit Court opinion. Following established procedures, documenting management decisions, and raising awareness of the EPA's *Scientific Integrity Policy* should help assure the soundness of future pesticide decisions.

Recommendations

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

1. Implement a procedure requiring senior managers or policy makers to document changes or alterations to scientific opinions, analyses, and conclusions in interim and final pesticide registration decisions and their basis for such changes or alterations.

2. Require an assistant administrator-level verification statement that *Scientific Integrity Policy* requirements were reviewed and adhered to for pesticide registration decisions that involve the immediate office.

3. Annually conduct and document training for all staff and senior managers and policy makers to affirm the office's commitment to the *Scientific Integrity Policy* and principles and to promote a culture of scientific integrity.

Agency Response and OIG Assessment

The Agency provided corrective actions and completion dates for all three recommendations. The Agency largely agreed with Recommendation 1 with some clarification, agreed in part and disagreed in part with Recommendation 2, and agreed with Recommendation 3. Recommendations 1 and 3 are resolved with corrective actions pending, and Recommendation 2 is unresolved. The Agency's full response is in Appendix A.

For Recommendation 1, the Agency agreed on the importance of appropriate documentation on "material changes to scientific conclusions or analyses achieved by excluding, including, downplaying or otherwise manipulating key data." The Agency proposed alternative corrective actions that it believes will accomplish the same goal as our recommendation. Specifically, the OCSPP will develop standard operating procedures or formal best practices on ensuring scientific integrity in pesticide regulatory decisions. The OCSPP said that the procedures or practices will ensure clear documentation and communication on material changes made by those outside of the authoring OPP division. We agree that these planned actions address the intent of our recommendation. Recommendation 1 is resolved with corrective actions pending.

For Recommendation 2, we initially recommended in our draft report that the OCSPP "[r]equire an assistant administrator-level verification statement that *Scientific Integrity Policy* requirements were reviewed and adhered to during each pesticide registration process" (emphasis added). As we note in our report, the assistant administrator-level involvement in the dicamba decision was highly unusual. During our exit conference to discuss the OCSPP's draft report comments, the office noted how few pesticide registrations rise to assistant administrator-level review—approximately 5 percent annually. The OCSPP said that requiring an assistant administrator-level verification statement for the remaining approximately 95 percent of pesticide registrations would have unintended consequences in terms of inefficiency. We agree and, as such, revised our recommendation to focus on those pesticide registration decisions that involve senior management, defined earlier in our report to include senior leaders in the OCSPP's immediate office.

In its response to our draft report, the Agency proposed that the OCSPP assistant administrator annually issue a memorandum to all OCSPP staff and management to affirm the office's commitment to the *Scientific Integrity Policy* and to establish clear expectations of behavior to uphold scientific integrity. This does not address the intent of our revised recommendation to require an assistant administrator-level verification statement on adhering to *Scientific Integrity Policy* requirements for those specific pesticide registration decisions that involve senior management. The Agency acknowledges that past senior managers chose to advance a policy outcome in a manner that may be inconsistent with the *Scientific Integrity Policy*. The message from the acting assistant administrator in

the Agency's response in Appendix A notes that, over the past few years, political interference has sometimes compromised scientific integrity. The Agency's statements support the need for safeguards to assure adherence to the EPA's *Scientific Integrity Policy* during the pesticide registration process, as intended by our recommendation. This recommendation is unresolved.

For Recommendation 3, the Agency acknowledged that training is imperative and described plans to provide annual scientific integrity training for all staff and senior managers and policy makers to affirm the OCSPP's commitment to the EPA's *Scientific Integrity Policy*. Additionally, the OCSPP plans to ensure that all new OCSPP staff and managers, including political appointees, take the "Scientific Integrity Mandatory Training for New Hires" within six months of their appointment. While the Agency's response did not specifically speak to text in our recommendation to "document training," the OCSPP indicated that it will "track" the corrective action on annual training for five years—and we noted the date of the first year as the corrective action date—as well as "compile an annual report" on organizational compliance with the scientific integrity training requirement. During our exit conference, the OCSPP verified that its annual report to the assistant administrator on organizational compliance with the training requirement will document the status of annual scientific integrity training for all staff and senior managers and policy makers. As such, Recommendation 3 is resolved with corrective actions pending.

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	Implement a procedure requiring senior managers or policy makers to document changes or alterations to scientific opinions, analyses, and conclusions in interim and final pesticide registration decisions and their basis for such changes or alterations.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	3/31/22	
2	12	Require an assistant administrator-level verification statement that *Scientific Integrity Policy* requirements were reviewed and adhered to for pesticide registration decisions that involve the immediate office.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
3	12	Annually conduct and document training for all staff and senior managers and policy makers to affirm the office's commitment to the *Scientific Integrity Policy* and principles and to promote a culture of scientific integrity.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	3/31/22	

[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

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Draft Report entitled "EPA Deviated from Typical Procedures in its 2018 Dicamba Pesticide Registration Decision."

FROM: Michal Freedhoff, Ph.D.
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention

MICHAL FREEDHOFF
Digitally signed by MICHAL FREEDHOFF
Date: 2021.04.19 15:27:25 -04'00'

TO: Sean O'Donnell
Inspector General

This memorandum responds to the Draft Report of the Office of Inspector General (OIG) entitled "EPA Deviated from Typical Procedures in its 2018 Dicamba Pesticide Registration Decision," Project No. OA&E-FY20-0122, dated March 29, 2021.

I. General Comments:

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

- The effectiveness of the U.S. Environmental Protection Agency's policies and procedures in addressing stakeholder risks in the 2016 and 2018 dicamba pesticide registration decisions.

The Draft Report appropriately observes that OCSPP, when making future pesticide registration decisions, must follow its existing processes and procedures. The long-standing framework for registration decisions cited in the Draft Report is indeed designed to – and as routinely implemented by our career scientists does indeed – ensure that our scientific products are sound and that scientific methods used are transparent and appropriate. This incident occurred despite the best efforts of OCSPP's career scientists and managers to recommend a different approach that was scientifically, procedurally and legally sound.

The Draft Report also states that senior managers – whether policy makers or scientists – must document their changes and record the reasons for them. OCSPP understands the Report as referring to material changes to scientific conclusions or analyses, or how those conclusions are presented. OCSPP also understands the Draft Report to refer to material changes to scientific conclusions or analyses achieved by excluding, including, downplaying or otherwise manipulating key data. A material change is one that affects the scientific content or how it may be understood. OCSPP agrees that documenting such changes is imperative. OCSPP understands the Draft Report *not* to refer to editorial or organizational changes intended to improve the clarity of the document or its ease of use. The Draft Report further notes that changes to scientific conclusions must be based exclusively on scientific (not policy) considerations. Again, OCSPP agrees. Indeed, OCSPP is emphasizing these points to all our managers.

As noted in the Draft Report, training is imperative. Contrary to a finding in the Draft Report, however, OCSPP staff and managers – and the senior leaders involved in the 2018 dicamba decision – *did* receive considerable scientific integrity training over the past four years. Moreover, such training has been required for all employees since 2018. In addition, there was a module specifically designed for supervisors and managers that was administered to all OCSPP leaders in 2018. In fact, EPA's Scientific Integrity Official, Dr. Francesca Grifo, reports more than 50 training events in OCSPP alone from 2017 to 2020. The dicamba incident described in this Draft Report did not occur due to a lack of awareness of or training on the agency's Scientific Integrity Policy. It occurred because OCSPP's past senior leadership consciously chose to advance a policy outcome in a manner inconsistent with the Scientific Integrity Policy.

II. OCSPP's Response to the Recommendations:

The Draft Report dated March 29, 2021, contains three (3) recommendations for OCSPP's Office of Pesticide Programs (OPP):

Recommendation 1: Implement a procedure requiring senior managers or policy makers to document changes or alterations to scientific opinions, analyses, and conclusions in interim and final pesticide registration decisions and their bases for such changes or alterations.

- **OCSPP Response:** OCSPP largely agrees with Proposed Recommendation 1, with some clarification. OCSPP agrees that appropriate documentation is imperative. See OCSPP's explanation below and Proposed Corrective Action 1.
    - First, Proposed Recommendation 1 appears to assume that non-scientist senior managers or policy makers will "change" or "alter" scientific opinions, analyses or conclusions. To so do could violate the Scientific Integrity Policy, even if they did document the change. OCSPP suggests the wording of this recommendation be clarified.
    - Second, OCSPP understands Proposed Recommendation 1 to refer to material changes to scientific conclusions or analyses achieved by excluding, including, downplaying or otherwise manipulating key data. A material change is one that affects the scientific content or how it may be understood. OCSPP agrees that documenting such changes is imperative. OCSPP proposes an alternate Corrective

Action that in our view will accomplish the same goal as Proposed Recommendation 1.

- **Proposed Corrective Action 1**: OCSPP's scientific integrity and quality assurance lead(s) will develop Standard Operating Procedures (SOPs) or formal Best Practices on ensuring scientific integrity in pesticide regulatory decisions. These SOPs will ensure that material changes to the risk assessment, risk characterization, and science documents from outside of the authoring OPP Division are clearly documented and communicated by those making the changes (e.g., by saving as a new EPA record each materially-amended document change, noting the author of each change and in language in redline/strikeout format). A "material change" to a scientific conclusion or analysis is one that affects the scientific content or how it may be understood and/or excludes, includes, downplays or otherwise manipulates key data. The SOPs will also make clear that scientific opinions, analyses, and conclusions may be changed only on scientific, not policy, grounds.
- **Target Completion Date**: CA 1: OCSPP will complete develop Standard Operating Procedures (SOPs) or formal Best Practices on ensuring scientific integrity in pesticide regulatory decisions by March 31, 2022.

Recommendation 2: Require an assistant administrator-level verification statement that Scientific Integrity Policy requirements were reviewed and adhered to during the pesticide registration process.

- **OCSPP Response:** OCSPP agrees in part and disagrees in part with Proposed Recommendation 2. The incidents described in this Draft Report reflected a purposeful decision made by the three senior leaders in OCSPP's immediate office at the time of the 2018 dicamba decision. The incidents did not reflect a failure of OCSPP's processes or typical practices. OCSPP has no reason to believe that a different "verification" requirement would have caused these individuals to make a different decision. Moreover, Proposed Recommendation 2 injects senior (political) leaders into the science review process where, currently, most of OCSPP's typical practices do not include such a role. (Most registration decisions are made at the Branch Chief level or lower.) OCSPP proposes an alternate Corrective Action that OCSPP believes accomplishes the overarching goal: obliging Assistant Administrator-level leaders to commit to adhere to the Scientific Integrity Policy.
- **Proposed Corrective Action 2a - d:** The OCSPP Assistant Administrator shall annually issue a memorandum to all OCSPP staff and management to affirm their own and the Office's commitment to the Scientific Integrity Policy and to establish clear expectations of behavior to uphold scientific integrity. OCSPP political leadership issued the first such memorandum on March 10, 2021. This Corrective Action will be tracked for 4 years, or until 2025.
- **Target Completion Dates**:
    - CA 2a: OCSPP shall issue its second annual memo to all OCSPP staff and management affirming the office's commitment to the Scientific Integrity Policy by March 31, 2022.
    - CA 2b: OCSPP shall issue its third annual memo for 2023 to all OCSPP staff and management affirming the office's commitment to the Scientific Integrity Policy by March 31, 2023.

- CA 2c: OCSPP shall issue its fourth annual memo for 2024 to all OCSPP staff and management affirming the office's commitment to the Scientific Integrity Policy by March 31, 2024.
- CA 2d: OCSPP shall issue its fifth annual memo for 2025 to all OCSPP staff and management affirming the office's commitment to the Scientific Integrity Policy by March 31, 2025.

Recommendation 3: Annually conduct and document training for all staff and senior managers or policy makers to affirm the office's commitment to the *Scientific Integrity Policy* and principles and to promote a culture of scientific integrity.

- **OCSPP Response:** OCSPP agrees with Proposed Recommendation 3 and proposes the following Corrective Actions to implement it.

- **Proposed Corrective Actions 3.1a through e:** The OCSPP Deputy Scientific Official, in consultation with the OCSPP Assistant Administrator and EPA's Scientific Integrity Official, shall provide annual Scientific Integrity training for all staff and senior managers or policy makers to affirm the office's commitment to the Scientific Integrity Policy and to promote sound behaviors essential to scientific integrity. On April 12, 2021, OCSPP conducted a OCSPP Scientific Integrity Town Hall featuring the Administrator, Dr. Grifo, and the OSCPP Principal Deputy Assistant Administrator to emphasize key elements of the Scientific Integrity Policy. In addition, over the next twelve months, OCSPP will conduct the following additional Town Hall-style scientific integrity training sessions for all OCSPP employees, including all political appointees, on the following topics:
  - Overview of EPA's Scientific Integrity Program
  - Understanding and honoring the difference between science and policy (risk assessments and risk management)
  - Tools to address differing scientific opinions
  - Whistleblower protections
  - Technical product clearance process and guidance
  - Use of internal and external peer review

  In subsequent years, the training series will address topics of particular significance at the time. This Corrective Action will be tracked for 5 years, or until 2026.
- **Target Completion Date**s:
  - CA 3.1a: OCSPP shall complete the first annual training series by March 31, 2022.
  - CA 3.1b: OCSPP shall complete the second annual training series by March 31, 2023.
  - CA 3.1c: OCSPP shall complete the third annual training series by March 31, 2024.
  - CA 3.1d: OCSPP shall complete the fourth annual training series by March 31, 2025.
  - CA 3.1e: OCSPP shall complete the fifth annual series by March 31, 2026.

- **Proposed Corrective Action 3.2a – e:** OCSPP shall ensure that all new OCSPP staff and managers, including all political appointees, take the Scientific Integrity Mandatory

Training for New Hires within six months of their appointment. This course is designed to increase awareness and understanding of the Agency's Scientific Integrity Policy and demonstrate how scientific integrity enhances the Agency's work. OCSPP will compile an annual report for the Assistant Administrator on organizational compliance with the training requirement by January 31 of each year. This Corrective Action will be tracked for 5 years, or until 2026.

- **Target Completion Dates:**
  - CA 3.2 a: OCSPP will compile its first annual report on organizational compliance with the training requirement by January 31, 2022.
  - CA 3.2 b: OCSPP will compile its second annual report on organizational compliance with the training requirement by January 31, 2023.
  - CA 3.2 c: OCSPP will compile its third annual report on organizational compliance with the training requirement by January 31, 2024.
  - CA 3.2 d: OCSPP will compile its fourth annual report on organizational compliance with the training requirement by January 31, 2025.
  - CA 3.2 e: OCSPP will compile its fifth annual report on organizational compliance with the training requirement by January 31, 2026.

III. Conclusion

OCSPP joins the Office of the Inspector General in affirming the importance of the Scientific Integrity Policy and its emphasis on communication, transparency, and respect for differing scientific opinions. OCSPP welcomes the OIG's efforts to strengthen scientific integrity in OCSPP.

Appendix to Agency Response

[The email below was sent by OCSPP Chief of Staff Tom Tyler on Behalf of Michal Freedhoff on March 10, 2021.]

Dear OCSPP Colleagues – By now, I've been a part of the OCSPP team for nearly seven weeks, and I continue to be deeply impressed by and grateful for your integrity, professionalism, and unmatched commitment to public service and the public good.

I have been particularly pleased to see OCSPP career professionals speak strongly in support of Scientific Integrity. As you know, science is the backbone of EPA. Scientific integrity, in turn, is a bedrock principle for President Biden, Vice President Harris, our incoming Administrator Michael Regan, and me. Scientific Integrity ensures that our science is sound and that we earn and maintain the public's confidence in our decision-making. I affirm my commitment to you to act with scientific integrity. I expect you to do likewise when working with me and with each other.

Our work as a science-based regulatory office requires us to embody scientific integrity in many contexts. For example, I expect:

- Robust exchange of scientific views, with differing scientific opinions expressed in writing early and shared with mangers throughout the process, including me.
- Truth-telling in briefings: what do I and other managers need to know?
- Courage to point out errors early in the process and a welcoming attitude by managers and peers to those communications.
- Respect for the role of science in risk assessments and the role of policy and law in risk management decisions. This requires the assurance that risk management considerations aren't the driving influences during the risk assessment phase, and it requires respect among scientists when difficult policy choices are ultimately made.
- Integrity of scientific products.
- Clear, real-time communication with scientists to explain senior scientists' changes to draft scientific products and an opportunity for scientists to express a different view.
- Understanding that, as a regulatory office, we also need to be mindful of statutory and other deadlines.

- An environment – led in the first instance by OCSPP managers – where everyone feels comfortable identifying errors, asking questions, and expressing differing scientific opinions, all without fear either of retaliation or being denigrated for speaking up.

- An environment free from political interference in the science.

Over the past few years, I am aware that political interference sometimes compromised the integrity of our science. Here are examples:

> *2018 Dicamba Registration Decision:* In 2018, OCSPP senior leadership directed career staff to: (1) rely on a limited data set of plant effects endpoints; (2) discount specific studies (some with more robust data) used in assessing potential risks and benefits; and (3) discount scientific information on negative impacts. This interference contributed to a court's vacating registrations based on these and other deficiencies, which in turn impacted growers' ability to use this product.
>
> *TCE:* White House staff directed OCSPP career staff to alter the draft TCE risk evaluation to change the point of departure used for making determinations of risk to a less sensitive endpoint. While the risk evaluation included a description of the more sensitive endpoint (fetal heart malformations), it was no longer used to determine whether there is unreasonable risk from TCE. Unreasonable risks were nevertheless identified for most uses of TCE, but the magnitude of the risk from exposures to TCE would have been greater had EPA relied upon the fetal cardiac defect endpoint that had been used in previous EPA peer-reviewed assessments.
>
> *PFBS Toxicity Assessment:* The PFBS Toxicity Assessment that was recently removed from EPA's website included conclusions purporting to reflect science when in fact they were the product of biased political interference directed in part by OSCPP's past political leadership. That interference undermined the agency's scientific integrity policy and eroded the trust that the American public has in EPA, the quality of our science, and our ability to protect their health and the environment.

This is a new day, about communication, trust, transparency and the importance of science in our regulatory decision-making process. All of us are responsible for ensuring the scientific integrity of our work. All of us are responsible for creating a work environment where everyone feels free to speak up without fear.

To this end, I encourage you to read the Scientific Integrity Policy. I encourage you to browse the Office of Scientific Integrity Intranet Page and refresh your knowledge by studying their resources and whiteboards. And please don't hesitate to contact OCSPP's Deputy Scientific Integrity Officer, Carol Ann Siciliano, at siciliano.carolann@epa.gov or (202) 564-5489, or EPA's Scientific Integrity Officer, Francesca Grifo at (202) 564-1687 (office) or (202) 657-8575 (mobile).

I also encourage you to attend the OCSPP Scientific Integrity Training series being launched by Carol Ann. You'll see more information about that shortly. The first session will feature a presentation and Q&A with Francesca Grifo. The second session will talk about ways to express and resolve Differing Scientific Opinions (DSO). Explore the DSO toolkit here. We also plan a training on Whistleblower protections. Get to know your rights here. More training subjects will follow.

Just as important, let's make Scientific Integrity part of our daily work and our daily conversations. You can count on me. And I know that I can count on you – managers and staff, scientists and non-scientists – to do the same.

All the best,
Michal

Michal Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency

Appendix B

Distribution

The Administrator
Deputy Administrator
Chief of Staff, Office of the Administrator
Deputy Chief of Staff, Office of the Administrator
Assistant Administrator for Chemical Safety and Pollution Prevention
Agency Follow-Up Official (the CFO)
Agency Follow-Up Coordinator
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Principal Deputy Assistant Administrator for Chemical Safety and Pollution Prevention
Deputy Assistant Administrators for Chemical Safety and Pollution Prevention
Director, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention
Director, Office of Continuous Improvement, Office of the Chief Financial Officer
Audit Follow-Up Coordinator, Office of the Administrator
Senior Audit Advisor, Office of Chemical Safety and Pollution Prevention
Audit Liaison, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention