



U.S. ENVIRONMENTAL PROTECTION AGENCY

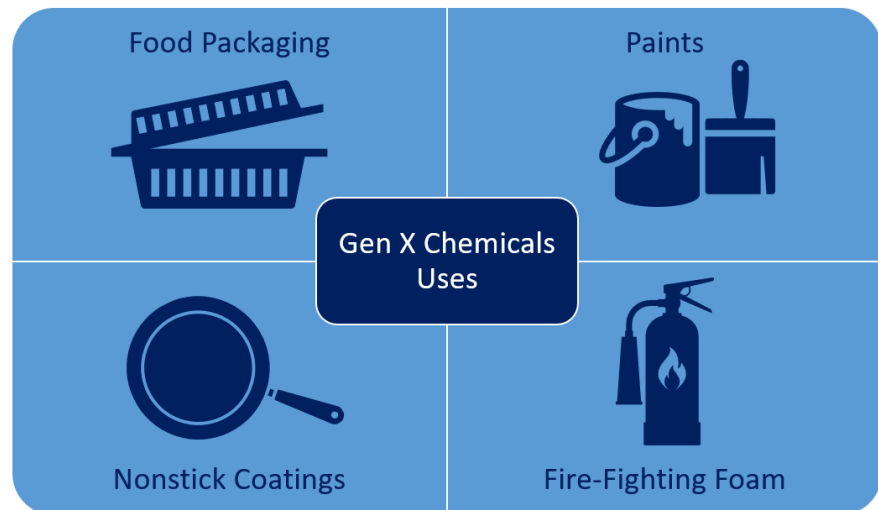
OFFICE OF INSPECTOR GENERAL

Ensuring the safety of chemicals

EPA Toxic Substances Control Act Consent Orders Need Better Coordination

Report No. 20-E-0177

May 28, 2020



Report Contributors:

Sarah Davidson
Jeffrey Harris
Natasha Henry
Chad Kincheloe
Barry Parker

Abbreviations

| | |
|------|--|
| EPA | U.S. Environmental Protection Agency |
| OCSP | Office of Chemical Safety and Pollution Prevention |
| OECA | Office of Enforcement and Compliance Assurance |
| OIG | Office of Inspector General |
| TSCA | Toxic Substances Control Act |

Cover Image: Examples of GenX chemicals uses. (EPA OIG graphic)

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At a Glance

Why We Did This Project

The U.S. Environmental Protection Agency's Office of Inspector General conducted this evaluation to determine what actions the EPA took to verify compliance with the requirements of the 2009 Toxic Substances Control Act Premanufacture Notice Consent Order with DuPont (responsibilities transferred to The Chemours Company in 2015) to prevent the release of GenX chemicals in the Cape Fear River in North Carolina.

GenX chemicals are a type of per- and polyfluoroalkyl substances, known as PFAS, found in surface water, groundwater, drinking water, rain water, and air emissions. There is toxicological evidence that some PFAS chemicals have adverse developmental and immunological effects in animals and humans.

This report addresses the following:

- Ensuring the safety of chemicals.

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[List of OIG reports.](#)

EPA Toxic Substances Control Act Consent Orders Need Better Coordination

What We Found

We found insufficient communication and coordination between the two EPA offices responsible for developing and enforcing the consent order requirements designed to reduce risks in the manufacture of GenX chemicals.

Regions need to be aware of the TSCA Section 5(e) Consent Orders in their region, and the Office of Enforcement and Compliance Assurance should approve, in advance, the terms and conditions of each consent order.

In 2008, the EPA received premanufacture notices from DuPont to manufacture two new GenX chemicals. In 2009, the Office of Chemical Safety and Pollution Prevention issued the company a TSCA Premanufacture Notice Consent Order with terms and conditions related to the manufacturing of the chemicals. The Consent Order required the company to determine how to recover and capture 99 percent of GenX's manufacturing discharges and air emissions. However, the Consent Order was not reviewed or approved by the Office of Enforcement and Compliance Assurance, which is responsible for conducting inspections to verify compliance. Until June 2017, the EPA's actions to verify compliance with the 2009 Consent Order and new chemicals testing requirements consisted of tracking and reviewing information provided by the manufacturer.

Following the local media coverage of the presence of GenX chemicals in the Cape Fear River in 2017, Region 4 and EPA contractors conducted the EPA's first on-site compliance monitoring inspection at the Fayetteville Works facility, which manufactures GenX. We found that the Region 4 inspectors were unaware of the 2009 Consent Order and its requirements until the inspection was requested by EPA headquarters.

Recommendations and Planned Agency Corrective Actions

We recommend that the EPA establish and implement processes:

1. For the Office of Enforcement and Compliance Assurance to review and approve the terms and conditions of TSCA Section 5(e) Consent Orders that it is responsible for verifying during compliance monitoring and enforcement activities.
2. To provide final TSCA Section 5(e) Consent Orders to regions and verify that the regions have the final consent orders.

The EPA did not provide an acceptable corrective action for Recommendation 1, and we consider this recommendation unresolved. For Recommendation 2, the Agency provided an alternative course of action that we find acceptable. We consider Recommendation 2 resolved with corrective action pending.



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

THE INSPECTOR GENERAL

May 28, 2020

MEMORANDUM

SUBJECT: EPA Toxic Substances Control Act Consent Orders Need Better Coordination
Report No. 20-E-0177

FROM: Sean W. O'Donnell

A handwritten signature in blue ink, reading "Sean W O'Donnell", is placed over the printed name.

TO: Alexandra Dapolito Dunn, 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 is OA&E-FY19-0348. 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 evaluation resolution procedures.

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

We made two recommendations in this report. In accordance with EPA Manual 2750, your Office provided an acceptable corrective action and estimated milestone date for Recommendation 2. This recommendation is resolved, and no final response is necessary

Action Required

For Recommendation 1, your Office did not provide an acceptable corrective action and estimated milestone date. Therefore, Recommendation 1 is unresolved. In accordance with EPA Manual 2750, the resolution process begins immediately with the issuance of this report. We are requesting a meeting within 30 days between the assistant administrator for Chemical Safety and Pollution Prevention and the OIG's assistant inspector general for Audit and Evaluation. If resolution is still not reached, the Office of Chemical Safety and Pollution Prevention is required to complete and submit a dispute resolution request to the chief financial officer.

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 evaluation to determine what actions the EPA took to verify compliance with the requirements of the 2009 Toxic Substances Control Act Premanufacture Notice Consent Order with DuPont to prevent the release of GenX chemicals in the Cape Fear River basin, located in North Carolina. In 2015, DuPont's manufacturing rights and interest for the chemicals subject to the Consent Order were transferred to The Chemours Company.

We limited our review to the EPA's actions related to the 2009 TSCA Consent Order with DuPont, now Chemours. Other authorities that are not covered in this review also address impacts of the Cape Fear River GenX contamination. For example, in 2019, the North Carolina Department of Environmental Quality signed a consent order with Chemours and other parties regarding chemical contamination, including GenX releases in the Cape Fear region. This North Carolina order requires Chemours to address all sources of per- and polyfluoroalkyl substances, known as PFAS, at the Fayetteville Works facility, a chemical plant located adjacent to the Cape Fear River. North Carolina's order is designed to prevent further impacts to air, soil, groundwater, and surface waters and is intended to provide relief to people around the facility and communities downstream.

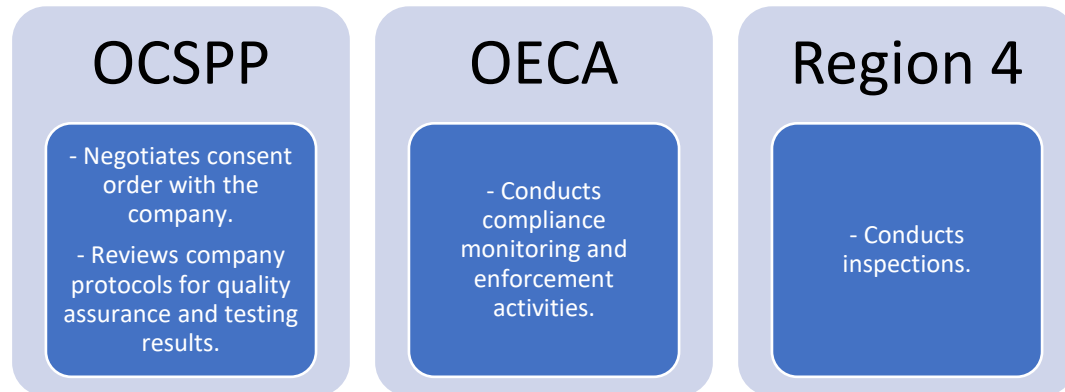
Background

EPA New Chemical Program Regulation of GenX

Under TSCA, the EPA is responsible for assessing and managing risks to human health and the environment before a new chemical substance is introduced into commerce. Section 5 of TSCA requires a premanufacture notice to be provided to the EPA before a new chemical substance for a nonexempt commercial purpose is manufactured in or imported to the United States.

The Office of Chemical Safety and Pollution Prevention reviews premanufacture notices to identify any risks that the new substance could pose to human health and the environment and develops TSCA Section 5(e) Consent Orders to address risks, if necessary. As shown in Figure 1, the Office of Enforcement and Compliance Assurance at EPA headquarters and the Enforcement and Compliance Assurance Divisions in the EPA regions conduct inspections to verify compliance with the consent orders.

Figure 1: EPA Section 5(e) Consent Order roles and responsibilities for the Fayetteville Works facility



Source: OIG analysis.

In 2008, the EPA received premanufacture notices from DuPont for two chemical substances that are used to manufacture GenX chemicals. GenX chemicals, which are a type of PFAS, are used in many applications because of their unique physical properties such as resistance to high and low temperatures, resistance to degradation, and nonstick properties. PFAS chemicals have been used in the United States since the 1940s and are found in many consumer products such as paints, food packaging, and stain repellants.

GenX chemicals have been found in surface water, groundwater, drinking water, rain water, and air emissions. There is toxicological evidence that some PFAS have adverse developmental and immunological effects in animals and humans.

The EPA's review of DuPont's GenX premanufacture notices found the following:

- The information available to the Agency was insufficient to permit a reasoned evaluation of the health and environmental effects of the chemicals.
- The uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the chemicals may present an unreasonable risk to health or the environment.
- The chemical substances will be produced in substantial quantities and will likely enter the environment in substantial quantities, and there may be significant or substantial human exposure to the substance.

These findings constituted the basis for the TSCA Section 5(e) Consent Order with DuPont.

In 2009, the EPA and DuPont signed a TSCA Section 5(e) Consent Order, which stipulated terms and conditions for DuPont to manufacture premanufacture notice substances in the United States, including in Dupont's Fayetteville Works facility. The 2009 Consent Order provided requirements to recover and capture (destroy) or recycle premanufacture notice substances from all effluent process streams and air emissions at an overall efficiency of 99 percent, allowing for up to 1 percent of the discharges and emissions generated from the manufacturing, processing, distributing in commerce, using, and disposing of the substances to be released into the air and water. According to OCSPP staff, it was up to the company to determine how to achieve compliance with this requirement. The Consent Order also controlled worker exposure by requiring the use of personal protective equipment, such as respiratory and skin protection, and testing for human health or environmental effects from exposure to the premanufacture notice substance. Testing protocols and results were to be sent to the EPA.

Under certain circumstances, EPA can use a TSCA Section 5(e) Consent Order to place restrictions on the manufacturing of a new chemical pending development of test data. The order allows the manufacturing of the new chemical be subject to restrictions on processing methods, production volume, or use that reduce or limit risks to human health or the environment.

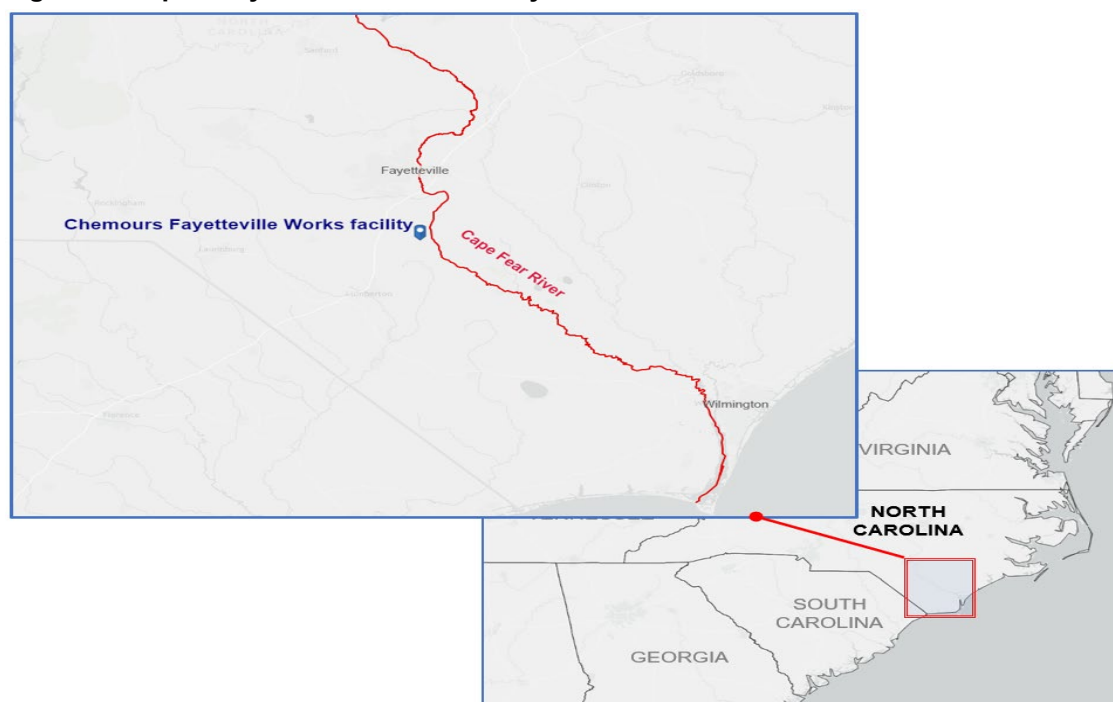
GenX Released into the Cape Fear River

In June 2017, local media in North Carolina reported the presence of GenX chemicals in the Cape Fear River. In July 2017, the governor of North Carolina sent a letter to the EPA concerning chemical releases into the Cape Fear River. The letter identified the GenX discharge as problematic since the chemicals are unregulated and do not have an established maximum contaminant level. The letter stated that the EPA bears sole responsibility for regulating the introduction of new chemicals and asked the Agency to review the 2009 Consent Order.

Chemours' Fayetteville Works Facility

The North Carolina Department of Environmental Quality is the lead stewardship agency for the protection of the state's environmental resources. According to its website, the Chemours Fayetteville Works facility has historically discharged water in the Cape Fear River and has operated various sources of air emissions and air pollution control technology pursuant to an air quality permit.

Figure 2: Map of Fayetteville Works facility



Source: The EPA OIG.

Scope and Methodology

We conducted this evaluation from October 2019 through January 2020 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 plan and perform the evaluation to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings, conclusions, and recommendations based on our evaluation objective. We believe that the evidence obtained provides a reasonable basis for our findings, conclusions, and recommendations based on our evaluation objective.

To understand the Agency's oversight of the 2009 Consent Order, some of the documents we reviewed include:

- OECA and OCSPP National Program Guidances.
- OECA Compliance Monitoring Strategy.
- The 2009 TSCA Section 5(e) Consent Order, with confidential business information redacted.
- Inspection reports, with confidential business information redacted.
- February 2019 Notice of Violation to Chemours.

We interviewed staff from the OCSPP, OECA, and Region 4. We also reviewed information and documentation from the North Carolina Department of Environmental Quality website.

Results

Until June 2017, the EPA's actions to verify compliance with the 2009 Consent Order and new chemicals testing requirements consisted of tracking and reviewing information provided by Chemours. Following the local media coverage of the presence of GenX chemicals in the Cape Fear River, Region 4 and EPA contractors conducted the Agency's first on-site TSCA compliance monitoring inspection at the Fayetteville Works facility in June 2017. Region 4 was unaware of the 2009 Consent Order and its requirements until the inspection was requested by EPA headquarters. We found that insufficient communication and coordination between OECA, the OCSPP, and Region 4 hampered the Agency's ability to monitor and determine compliance with the 2009 Consent Order requirements.

EPA Actions to Confirm Consent Order Compliance

EPA Tracked Consent Order Testing Requirements

For this 2009 Consent Order, the OCSPP tracked and reviewed information provided by Chemours regarding compliance with the testing requirements. According to an OCSPP manager, a program manager is assigned to each TSCA Section 5(e) Consent Order and is largely responsible for communicating with the premanufacture notice submitter and verifying compliance with any testing requirements included in the order. According to OCSPP personnel, there were no known issues with Chemours performing the Consent Order's testing requirements. The OCSPP provided the OIG with a spreadsheet documenting Chemours' compliance with the testing requirements. An EPA review of these data was the extent of enforcement and compliance oversight of the Consent Order until 2017.

EPA First Inspected for TSCA Compliance in June 2017

EPA headquarters requested that Region 4 conduct an on-site TSCA compliance monitoring inspection at the Fayetteville Works facility after local media reported the presence of GenX chemicals in the Cape Fear River. Region 4 and EPA contractors conducted the Agency's first on-site TSCA compliance monitoring inspection at the Fayetteville Works facility on June 28 and 29, 2017. Region 4 personnel informed us that they do not know all the headquarters-negotiated consent orders within their Region. In fact, they did not know about the 2009 Consent Order with Chemours until the inspection was requested. Upon request, OECA supplied the 2009 Consent Order to Region 4 in June 2017.

We asked OCSPP staff for an Agency policy or procedure for disseminating final consent orders to applicable regions. The OCSPP provided a September 2019 transmittal document that describes a process in which EPA contractors

develop a memorandum to send to the applicable region, notifying it of a consent order. The OCSPP could not identify an EPA policy that contained defined roles and responsibilities, such as how the contractor receives the information to develop the memorandum and how the EPA knows the regions and OECA received the consent orders. The OCSPP needs written policies and procedures to verify that applicable regions receive final consent orders so that the regions are aware and knowledgeable of TSCA activities to assist in prioritizing inspections.

Results of TSCA Inspection

On April 24, 2018, Region 4 issued a report on the results of the Fayetteville Works TSCA compliance inspection, which included a review of the 2009 Consent Order. On February 13, 2019, OECA's Office of Civil Enforcement sent a TSCA Notice of Violation to Chemours, which was applicable to two facilities using the GenX manufacturing process: the Fayetteville Works facility and the Washington Works facility in West Virginia. The Notice of Violation did not include any violations of the 2009 Consent Order at the Fayetteville Works facility.

According to the Notice of Violation, "The EPA continues to investigate and review information concerning the compliance status of these and other Chemours facilities relating to TSCA. ... The EPA may find additional TSCA violations as the investigations continues."

Requirements of 2009 Consent Order

As shown in Figure 3, the 2009 Consent Order required the GenX chemical manufacturing process operations to "recover and capture (destroy) or recycle the [premanufacture notice] substances at an overall efficiency of 99% from all the effluent process streams and the air emissions (point source and fugitive)."

Figure 3: Consent Order requirement



Source: The EPA OIG.

According to OCSPP personnel, the 99 percent removal efficiency requirement was a stringent but "achievable" level and recognized that a 100 percent removal efficiency requirement was not achievable when negotiating the terms of the 2009 Consent Order with the manufacturer. They also stated that consent orders commonly either require no emissions or discharges of certain substances or set a numerical limit for emissions or discharges of certain substances rather than a percentage requirement. OCSPP staff added that it was up to the company to determine how to achieve compliance with this requirement. OECA, which is responsible for on-site

compliance inspections for this requirement, was not consulted when the requirement was established.

We believe that OECA should review and approve, in advance, the TSCA Section 5(e) Consent Order compliance monitoring and enforcement requirements for which it is responsible.

Conclusions

While the EPA has taken steps to verify compliance with the 2009 TSCA Consent Order, improved communication between OECA, the OCSSP, and Region 4 would help the Agency to better determine compliance with its requirements. Region 4 did not receive a copy of the Consent Order when it was signed in 2009 and had to request it prior to conducting an inspection in 2017. The OCSSP should implement procedures to improve coordination between the offices and assist the EPA in determining compliance with this Consent Order.

Recommendations

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

1. Implement a process so that the Office of Enforcement and Compliance Assurance reviews and approves the Toxic Substances Control Act Section 5(e) Consent Orders terms and conditions that it will be responsible for verifying during compliance monitoring and enforcement activities.
2. Implement a process to provide final Toxic Substances Control Act Section 5(e) Consent Orders to regions with facilities subject to the terms and conditions of the Consent Orders in an appropriate time frame, and verify that EPA regions acknowledge receipt of the final Toxic Substances Control Act Section 5(e) Consent Orders.

Agency Response and OIG Assessment

The Agency provided a response to our draft report on April 17, 2020 (Appendix A). The EPA's proposed corrective action for Recommendation 1—to memorialize a protocol for OECA engagement during the development of TSCA Section 5(e) Consent Orders—did not meet the intent of this recommendation because the response did not explicitly state that OECA would agree or concur with the conditions of the consent orders that it would be responsible for ensuring compliance and enforcing. On April 28, 2020, the Agency provided a revised response (Appendix B), which included a statement that the proposed protocol will provide a consultation role for OECA on the conditions of future Section 5(e) Consent Orders. The OIG concluded that the proposed corrective action does not

meet the intent of this recommendation because the response does not explicitly state that OECA would approve the compliance monitoring and enforcement requirements of the consent order.

The EPA's proposed corrective action for Recommendation 2 provides an alternative course of action that meets the intent of this recommendation. The OIG recommended that regions be directly notified of new consent decrees within their jurisdictions. The Agency has identified a corrective action that will provide a searchable database of TSCA Section 5(e) Consent Orders that will enable regions to focus on compliance monitoring and enforcement activities they perform per OECA's National Program Guidance for fiscal years 2020–2021. The search tool is expected to be completed by December 31, 2020. The OIG considers Recommendation 2 resolved with the corrective action pending.

The Agency provided specific suggestions for our consideration, and we made revisions to the report as appropriate.

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 | 7 | Implement a process so that the Office of Enforcement and Compliance Assurance reviews and approves the Toxic Substances Control Act Section 5(e) Consent Orders terms and conditions that it will be responsible for verifying during compliance monitoring and enforcement activities. | U | Assistant Administrator for Chemical Safety and Pollution Prevention | | |
| 2 | 7 | Implement a process to provide final Toxic Substances Control Act Section 5(e) Consent Orders to regions with facilities subject to the terms and conditions of the Consent Orders in an appropriate time frame, and verify that EPA regions acknowledge receipt of the final Toxic Substances Control Act Section 5(e) Consent Orders. | R | Assistant Administrator for Chemical Safety and Pollution Prevention | 12/31/20 | |

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

Agency Comments on Draft Report



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 17, 2020

MEMORANDUM

SUBJECT: Response to Draft Report for Project Number OA&E-FY19-0348

FROM: Alexandra Dapolito Dunn
Assistant Administrator

ALEXANDRA
DAPOLITO DUNN
Digitally signed by ALEXANDRA
DAPOLITO DUNN
Date: 2020.04.17 21:34:07 -04'00'

TO: Sean W. O'Donnell
Inspector General

This memorandum responds to the OIG's Draft Report entitled "EPA Toxic Substances Control Act Consent Orders Need Better Coordination," dated April 8, 2020.

I. General Comments:

The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's effort in evaluating EPA's actions to verify compliance with the requirements of the Agency's 2009 Toxic Substances Control Act Premanufacture Notice Consent Order with DuPont/Chemours. That consent order required certain actions by the company to prevent the release of GenX chemicals, which are a type of PFAS, into the Cape Fear River in North Carolina.

The Office of Enforcement and Compliance Assurance (OECA) and OCSPP have reviewed the Draft Report and generally agree to the recommendations. Consequently, this response includes a discussion of our actions to implement those recommendations, which in our view are sufficient to declare the recommendations to be completed and resolved at the issuance of the Final Report.

We also discuss below our specific concerns with the Report's characterization of the Agency's regulatory actions with respect to PFAS. Separately, we are conveying to your office the Agency's Technical Comments, which we respectfully request remain internal to EPA.

II. The Report Mischaracterizes Existing and Ongoing PFAS Regulatory Actions:

The Draft Report states that there are “no federal regulatory guidelines for PFAS.” This statement is significantly erroneous; there are numerous regulatory actions that have been taken involving PFAS under TSCA, as well as other Agency actions related to PFAS.

First, the review of new chemical submissions puts in place restrictions as necessary to ensure no unreasonable risk, using Section 5 Consent Orders and Significant New Use Rules (SNURs), which constitute regulatory actions. Second, OPPT has promulgated SNURs for hundreds of PFAS that are existing chemicals under TSCA. For a list of existing chemical SNURs promulgated under TSCA, see the webpage: Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA.¹

Furthermore, PFAS actions are a top EPA priority, and EPA has made significant progress in implementing its PFAS Action Plan.² The PFAS Action Plan demonstrates the agency’s critical national leadership by providing both short-term solutions and long-term strategies to address this important issue. The Action Plan provides a multi-media, multi-program, national research, and risk communication plan to address this emerging environmental challenge.

OPPT has several actions tracked in the Action Plan including the addition of PFAS to the Toxics Release Inventory (TRI) and the finalization of the Long Chain PFAS Significant New Use Rule. The FY 2020 National Defense Authorization Act (NDAA) added certain PFAS chemicals to the TRI effective on January 1, 2020 and set up a process for reviewing and potentially adding others. In 2015, EPA proposed a TSCA SNUR to require manufacturers, importers and processors of PFOA and PFOA-related chemicals to submit a notice to EPA before starting or resuming new uses of these chemicals in any products. On March 3, 2020, EPA issued a supplemental proposal for this rule. This rule would give EPA the opportunity to evaluate these uses and, where necessary, take action to prohibit or limit the activity before it occurs. The NDAA requires EPA to finalize the PFAS SNUR by June 22, 2020.

An inventory of other EPA regulatory and management actions completed or underway by other EPA Offices are outlined in the Agency’s PFAS Action Plan.

OIG RESPONSE: The OIG statement was intended to address the lack of PFAS maximum contaminant levels in drinking water and listing PFAS as hazardous substances, enabling the EPA to use the Comprehensive Environmental Response, Compensation, and Liability Act for cleanup orders and cost recovery, as identified in the EPA’s February 2019 PFAS Action Plan. We realize that this is under the heading of the EPA’s New Chemical Program Regulation, which might confuse the reader. As such, we deleted the sentence from the final report.

¹ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas>

² <https://www.epa.gov/pfas/epas-pfas-action-plan>

III. Response to the Recommendations:

Recommendation 1: “Implement a process so that the Office of Enforcement and Compliance Assurance reviews and approves the Toxic Substances Control Act 5(e) Consent Orders terms and conditions that the Office will be responsible for verifying during compliance monitoring and enforcement activities.”

Recommendation 2: “Implement a process to provide final Toxic Substances Control Act 5(e) Consent Orders to regions with facilities subject to the terms and conditions of the consent order in an appropriate time frame and verify that EPA regions acknowledge receipt of the final Toxic Substances Control Act 5(e) Consent Orders.”

Corrective Actions Underway and Completed: OECA and OCSPP have already enhanced coordination and developed new tools to assist with compliance monitoring activities by OECA and the Regions. These efforts include:

- Enhanced tracking of TSCA section 5(e) orders and elevation of PFAS chemicals as an enforcement focus area for TSCA section 5 compliance monitoring activities: OECA has already implemented an internal protocol for tracking TSCA section 5(e) orders received from OCSPP, which includes reviewing and capturing specific information from each order in an internal database broadly covering substances regulated under TSCA section 5. OECA has populated the database with Regional and facility-specific information and shared it with the Regions via OPPT’s Confidential Business Information (CBI) LAN, accessible through the Virtual Desktop Infrastructure (VDI). OECA and the Regions can consider this information as part of a consolidated Core TSCA targeting and compliance monitoring approach (see Compliance Monitoring Strategy for TSCA).³ OECA issues regular enforcement program guidance that focuses on specified national compliance monitoring activities and priorities. OECA identified PFAS chemicals as a priority area for TSCA section 5 compliance monitoring activities in OECA’s National Program Guidance for fiscal years 2020-2021.⁴
- Developing new chemical database search functionality: Since implementing the Virtual Desktop Infrastructure in 2016, OCSPP, OECA and Regional users can remotely access the Chemical Information System (CIS) and search for TSCA section 5(e) orders by company or chemical. To improve geographic and facility-based queries of substances regulated under TSCA section 5, OECA and OPPT are developing a dynamic search tool that will enable OECA and Regional users to have full access to documents that are part of the TSCA section 5 chemical review and regulatory process. This search tool will extract information from a variety of chemical databases housed on the OPPT LAN, including chemical risk and facility location information. The search tool is expected to be completed by the end of calendar year 2020.
- Developing a new model TSCA section 5(e) order and protocol for OECA input in the development of orders: OECA and OCSPP have collaborated on an updated model TSCA

³ <https://www.epa.gov/sites/production/files/2014-01/documents/tsca-cms.pdf>

⁴ <https://www.epa.gov/sites/production/files/2019-06/documents/fy-20-21-oea-np-guidance.pdf>

section 5(e) Order. The offices worked together in 2019 to strengthen and clarify the model document that will serve as the baseline in negotiations between EPA and companies with regard to the new chemical substance submissions. Discussions are underway between offices to memorialize a protocol for OECA engagement during the development of TSCA section 5(e) orders. The protocol is expected to be completed by the end of calendar year 2020.

OIG RESPONSE: The EPA’s proposed corrective action for Recommendation 1—to memorialize a protocol for OECA engagement during the development of TSCA Section 5(e) Consent Orders—did not meet the intent of this recommendation because the response did not explicitly state that OECA would agree or concur with the conditions of the consent orders that it will be responsible for ensuring compliance and enforcing.

The EPA’s proposed corrective action for Recommendation 2 provides an alternative course of action that meets the intent of this recommendation. The OIG recommended that regions be directly notified of new consent decrees within their jurisdictions. The Agency has identified a corrective action that will provide a searchable database of TSCA Section 5(e) Consent Orders that will enable regions to focus on compliance monitoring and enforcement activities they should perform per OECA’s National Program Guidance for fiscal years 2020–2021. The search tool is expected to be completed by December 31, 2020. The OIG considers Recommendation 2 resolved with corrective action pending.

cc: All OCSPP DAA/AAAs
Program Office OD, DODs
Jeffrey Harris, OIG
Sarah Davidson, OIG
Natasha Henry, OIG
Chad Kincheloe, OIG
Barry Parker, OIG
Janet L. Weiner, OCSPP Audit Liaison
John Latham, OPPT Program Office Audit Liaison
Susanna Blair, OPPT
Susan Bodine, OECA AA
Larry Starfield, OECA PDAA
Rosemarie Kelley, OECA/OCE
James Miles, OECA/OCE
Gwendolyn Spriggs, OECA Audit Liaison

Supplemental Comments on Draft Report



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 28, 2020

MEMORANDUM

SUBJECT: Clarification on Proposed Corrective Actions in Response to Draft Report for Project Number OA&E-FY19-0348

FROM: Alexandra Dapolito Dunn
Assistant Administrator

ALEXANDRA
DAPOLITO DUNN

Digitally signed by ALEXANDRA
DAPOLITO DUNN
Date: 2020.04.28 19:23:35 -04'00'

TO: Sean W. O'Donnell
Inspector General

This memorandum provides additional requested clarification about the Agency's proposed Corrective Actions to respond to the OIG's Draft Report entitled "EPA Toxic Substances Control Act Consent Orders Need Better Coordination," dated April 8, 2020.

Amended Response to the Recommendations:

Recommendation 1: "Implement a process so that the Office of Enforcement and Compliance Assurance reviews and approves the Toxic Substances Control Act 5(e) Consent Orders terms and conditions that the Office will be responsible for verifying during compliance monitoring and enforcement activities."

- Development of a new Model TSCA Section 5(e) Order and Protocol for OECA input in the development of orders: OECA and OCSPP have collaborated on an updated Model TSCA Section 5(e) Order. In 2019, the offices worked together to strengthen and clarify the Model Order, which will serve as the baseline for negotiations between EPA and companies with regard to new chemical substance submissions. In 2020, OCSPP and OECA are working to memorialize a Protocol for OECA engagement during the

development of TSCA section 5(e) orders. The Protocol will provide a consultation role for OECA on the conditions of future TSCA section 5(e) orders. (OCSPP and OECA expect they will agree on those conditions.) OCSPP will complete the Protocol by December 31, 2020.

Recommendation 2: “Implement a process to provide final Toxic Substances Control Act 5(e) Consent Orders to regions with facilities subject to the terms and conditions of the consent order in an appropriate time frame and verify that EPA regions acknowledge receipt of the final Toxic Substances Control Act 5(e) Consent Orders.”

- OECA has already implemented an internal protocol for tracking TSCA section 5(e) orders received from OCSPP, which includes reviewing and capturing specific information from each order in an internal database broadly covering substances regulated under TSCA section 5. OECA has populated the database with Regional and facility-specific information and shared it with the Regions via OCSPP/OPPT’s Confidential Business Information (CBI) LAN, accessible through the Virtual Desktop Infrastructure (VDI). Since implementing the Virtual Desktop Infrastructure in 2016, OCSPP, OECA and Regional users can remotely access the Chemical Information System (CIS) and search for TSCA section 5(e) orders by company or chemical. To improve geographic and facility-based queries of substances regulated under TSCA section 5, OECA and OCSPP/OPPT are developing a dynamic search tool that will enable OECA and Regional users to have full access to documents that are part of the TSCA section 5 chemical review and regulatory process. This search tool will extract information from a variety of chemical databases housed on the OPPT LAN, including chemical risk and facility location information.

To enable Regions to focus compliance monitoring and enforcement activities required by OECA’s National Program Guidance for FY2020-2021, the Agency will develop a searchable database of TSCA 5(e) orders. OCSPP/OPPT will complete the search tool by December 31, 2020.

OIG RESPONSE: The corrective action in this amended response falls short of meeting the intent of Recommendation 1. The amended response states, “The Protocol will provide a consultation role for OECA on the conditions of future TSCA section 5(e) orders. (OCSPP and OECA expect they will agree on those conditions.)” This language does not provide sufficient assurance that compliance monitoring and enforcement requirements in future TSCA 5(e) orders will be agreed to by the OCSPP and OECA. Therefore, the OIG considers this recommendation unresolved.

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