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January 26, 2021
EWG TSCA 8(e) Request for Enforcement

VIA E-mail

Jane Nishida
Acting Administrator
U.S. Environmental Protection Agency
Washington, D.C.

Re: Solvay's failure to submit key health studies under the requirements of TSCA 8(e), 15 U.S.C. § 2607(e), within a timely manner.

Dear Acting Administrator Nishida:

As the Environmental Protection Agency continues to move forward with its assessment of risks posed by per- and polyfluoroalkyl substances (PFAS), address contamination, and protect public health, we write to notify you of an apparent violation of reporting requirements by Solvay under Section 8(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2607(e). Section 8(e) requires:

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e).

Solvay¹ – a leading PFAS manufacturer – obtained information that “reasonably supports the conclusion” that certain PFAS chemicals it manufactures present “a substantial risk of injury to health or the environment” but failed to “immediately inform” the EPA of that information. This reporting violation may have hindered the EPA’s ongoing PFAS assessments and put the public at risk. We request that you investigate this potential violation of law by Solvay and additionally review all 8(e) filings for PFAS chemicals from all submitters with respect to the timeliness of their

¹ Solvay is used here to collectively refer to Solvay Specialty Polymers, USA, LLC and its predecessor companies, including Solvay Solexis, Inc. and Ausimont USA, Inc. as well as any subsidiaries or affiliates.



submission to the agency. The agency should also request that companies submit and make public any additional relevant PFAS studies that may be subject to 8(e) reporting to allow for a more accurate assessment of the health risks posed by this entire family of concerning persistent global pollutants. Given the nature and seriousness of Solvay's omissions, we recommend that the agency levy the maximum allowable penalty under the law, a \$37,500 fine per day, to account for civil violations pursuant to 15 U.S.C § 2615(a). We also ask that you investigate potential criminal violations for Solvay's "knowing and willful" failure to produce these studies within 30 days, which would also subject the company to a maximum daily fine of \$50,000, per 15 U.S.C. § 2615(b).

Solvay withheld information from the EPA about substantial risks from PFAS for years

In November 2020, in response to a Freedom of Information Act request, the EPA published² toxicity studies Solvay submitted for the PFAS referred to here as chloroperfluoropolyether carboxylate compounds,³ which were used to replace PFNA. The study results and interpretation of these results by a toxicologist working within the New Jersey Department of Environmental Protection indicate that the chloroperfluoropolyether carboxylate compounds are potentially as toxic as PFOA or PFNA and as bioaccumulative.

Solvay was aware for more than six years of the substantial risk to human health and the environment that its replacement PFAS compounds posed before it submitted that information to the EPA. The EPA cover letter for Study 1,⁴ a four-week oral toxicity study in rats, is dated by the EPA as March 4, 2011. A summary of Study 1 is referred to in the 8(e) submission made by Solvay ("Study 7"), which was received by the agency on Feb. 23, 2011.⁵ The dates in Study 1 indicate that all study-based inspections, including blood

² Freedom of Info. Act Request No. EPA-HQ-2020-005778,
<https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-2020-005778&type=request>

³ Specific chemical names: 1-Propene, 1,1,2,3,3,3-hexafluoro-, telomer with chlorotrifluoroethene, oxidized, reduced, Et ester, hydrolyzed, sodium salt (CASRN 220207-15-8) & 1-Propene, 1,1,2,3,3,3-hexafluoro-, telomer with chlorotrifluoroethene, oxidized, reduced, hydrolyzed, ammonium salts (CASRN 330809-92-2).

⁴ See Study 1: 4-Week Oral Toxicity Study in Rats Followed by a 2-Week Recovery Period (March 4, 2011) (hereinafter "Study 1"),
<https://foiaonline.gov/foiaonline/api/request/downloadFile/Study%201.pdf/d87762b0-057f-4209-b967-8e665c1465ae>

⁵ See Letter from Laird McBeth, President, Solvay Solexis, to Env't Prot. Agency 8(e) Coordinator (Feb. 18, 2011) (hereinafter "Study 7"),
https://foiaonline.gov/foiaonline/api/request/downloadFile/Study%207_8e-HQ-11-18263_Redacted.pdf/403c7334-e609-4b49-ae71-69181c2606a3



sampling and necropsies, were completed and reported to company management on or before June 9, 2005, and the final report was dated October 17, 2006.

The findings in Study 1 indicate that Solvay's replacement chemicals, chloroperfluoropolyether carboxylate compounds, posed "substantial risk of injury to humans or the environment." Yet according to the signed study dates and the date the EPA stamped it upon receipt of the 8(e) filing, Solvay apparently waited 2,080 days from the day company management was alerted to the results before providing the EPA with a summary of its findings.

In addition to the animal toxicity findings in Study 1, Solvay has been aware since at least 2011 that the chloroperfluoropolyether carboxylate compounds bioaccumulate in human blood serum. A document Solvay submitted to the EPA on December 23, 2019, indicates that biomonitoring of workers had been occurring since 2011. Solvay's testing of workers' blood for nearly a decade shows that a half-life in humans is likely 2.5 to 3 years and, additionally, that internal testing discovered associations between blood concentrations and "triglycerides albumin, albumin/globulin ratio, and FT3, and negative statistical associations for alpha-2-globulins, IgG, IgM, and estradiol."⁶

Solvay's extreme delay in filing the required TSCA 8(e) report interfered with the EPA's ability to address situations involving unreasonable risks and substantially endangered health and the environment, and likely constitutes a "major extent" violation of 8(e), per the EPA's most recent Enforcement Response Policy.⁷

⁶ Letter from Solvay Specialty Polymers, to Greg Schweer, Chief, New Chemicals Management Branch, Env't Prot. Agency, re: 15-Day Notice Under 40 C.F.R. § 723.50(i) (Dec. 23, 2019) (hereinafter "Study 9"), <https://foiaonline.gov/foiaonline/api/request/downloadFile/Study%209.pdf/15a2e80d-ee08-432f-8ecc-39b03d584ebf>.

⁷ Memorandum from Jesse Baskerville, Director, Toxics & Pesticides Enf't Div., Env't Prot. Agency, re: Issuance of Revised Enforcement Response Policy for TSCA §§ 8, 12, & 13 (March 31, 1999), https://www.epa.gov/sites/production/files/documents/erp8_12r.pdf (finding that major extent violations include "violations of TSCA §§ 8(c), 8(d), or 8(e) which directly interfere with the agency's ability to address situations involving potential imminent hazard, unreasonable risks, or substantial endangerment to health or the environment").



Timeline of Solvay Studies					
Name	Description	Start of study	Results reported to management	Final report	Date reported to the EPA
Study 1	4-week oral toxicity study in rats	3/24/2005	6/9/2005	10/17/2006	Notice (2/18/2011) and results 3/4/2011
Study 9	Human biomonitoring of exposed workers	2011	2011	NA	12/23/2019

Solvay's reporting violations hid substantial risks from the EPA

- 1) *The chloroperfluoropolyether carboxylate compounds persist in the environment and have now been detected in soil and drinking water samples in the state of New Jersey*

Like all PFAS chemicals, the chloroperfluoropolyether carboxylate compounds are persistent and do not readily break down in the environment. The chloroperfluoropolyether carboxylate compounds have already contaminated New Jersey. Studies by EPA researchers, published this year, have identified these chloroperfluoropolyether carboxylate compounds, previously unknown to the public, in soil⁸ and drinking water⁹ in close proximity to the Solvay facility in New Jersey. The EPA researchers noted that some of these chemicals were detectable across the entire state and “might be dispersed beyond New Jersey state boundaries.” If Solvay had timely notified the EPA that these compounds posed a “substantial risk,” the EPA may have been able to take action to restrict usage, prevent these environmental releases, and mitigate the contamination.

- 2) *The chemicals in question are as toxic as PFOA based on the 4-week rat testing data*

⁸ John W. Washington et al., *Nontargeted Mass-Spectral Detection of Chloroperfluoropolyether Carboxylates in New Jersey Soils*, 386 *Science* 1103 (2020), <https://science.sciencemag.org/content/368/6495/1103>.

⁹ James P. McCord et al., *Emerging Chlorinated Polyfluorinated Polyether Compounds Impacting the Waters of Southwestern New Jersey Identified by Use of Nontargeted Analysis*, 7 *Env't. Sci. & Techn. Letters* 903 (2020), <https://pubs.acs.org/doi/10.1021/acs.estlett.0c00640>.



Study 1, the 2005 4-week toxicity study, could not identify a dose that did not cause harm to male rats. A New Jersey Department of Environmental Protection toxicologist who subsequently reviewed the study results summarized the findings by comparing the chloroperfluoropolyether carboxylate compounds to the toxicity of PFOA: “For comparison, the levels at which toxicity occurred for this substance are similar (or possibly even lower) than for PFOA and PFNA.”¹⁰

As discussed below, by the time Solvay received the final lab report for chloroperfluoropolyether carboxylate compounds in 2006, it had agreed to phase out PFOA, PFNA, and other long-chain PFAS chemicals through the PFOA stewardship program. Solvay was therefore well aware that the EPA had significant toxicity concerns related to PFOA and PFNA and would want to know about similarly toxic chemicals. Thus, the toxicity findings in Study 1 should have prompted an immediate filing 8(e) from Solvay alerting the EPA.

3) *The chloroperfluoropolyether carboxylate compounds in question bioaccumulate and have a half-life similar to PFOA, PFOS, or PFHxS.*

In Study 1, the 2005 4-week rat toxicity study, blood levels of the chloroperfluoropolyether carboxylate compounds were measured for two weeks after exposure, and the levels did not decrease significantly. The Study 1 laboratory report specifically noted that “Due to the high plasma levels reordered at 216 hours post-dose, a correct calculation of the half-life ($T_{1/2}$) was not possible, only estimations were performed, comprised in the range of 201-544 hours for males and 39-763 hours for females.” These half-life results for the chloroperfluoropolyether carboxylate compounds are very similar to the elimination half-lives in rats reported for PFOA, PFOS, and PFHxS and summarized in table form in the Agency for Toxic Substances and Disease Registry Draft Toxicological Profile for Perfluoroalkyls.¹¹

Solvay knew or should have known the EPA would consider that the information in Study 1 and Study 9 constitute “substantial risk” under section 8(e)

1) *Solvay was an active participant in the 2010/2015 PFOA Stewardship Program*

¹⁰ Ryan Felton, *New PFAS Compound in N.J. Water May Be More Toxic Than Older One, Regulators Say*, Consumer Reports (Nov. 10, 2020), <https://www.consumerreports.org/water-quality/new-pfas-compound-in-nj-water-may-be-more-toxic-than-older-one-regulators-say/>.

¹¹ U.S. Dep’t of Health & Hum. Serv., Agency for Toxic Substances & Disease Registry, Toxicological Profile for Perfluoroalkyls: Draft for Public Comment (2018), <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>.



Solvay's violation of the TSCA 8(e) reporting requirements is particularly egregious because Solvay knew the substantial risks identified in Study 1 would be of interest to the EPA when it received those results.

Solvay was engaged with the EPA in the PFOA Stewardship Program to phase out the use and release of PFOA and PFNA due to toxicity and bioaccumulation concerns when it received the test results in Study 1 showing that the chloroperfluoropolyether carboxylate compounds used to replace PFNA were likely as toxic and bioaccumulative as PFNA or PFOA. The EPA stated in a 2006 invitation letter to Solvay, which the company subsequently accepted, that it was working with companies "to better understand the sources and pathways of exposure to perfluorooctanoic acid (PFOA) and *related chemicals*."¹² The EPA further stated that "the data from the research and testing programs will allow the Agency and others to make informed decisions about any potential risk management actions that are warranted."¹³

Specifically, the EPA detailed how the phaseout agreement included the goal of furthering the agency's knowledge of the toxicity of the *entire family of PFOA and related chemicals*. The EPA letter to Solvay stated:

"Many activities are underway concerning PFOA and related chemicals, including additional research by companies, government agencies, and universities. Participation in the stewardship program will be in addition to a company's existing commitments to the Agency which may include research efforts, enforceable consent agreements, and memoranda of understanding. These ongoing efforts will combine with the 2010/2015 PFOA Stewardship Program to further our understanding of this family of persistent, bioaccumulative, and toxic chemicals, and to achieve true long-term environmental and public health benefits."¹⁴

Solvay apparently participated in the 2010/2015 PFOA Stewardship Program while withholding pertinent safety and bioaccumulation data on their particular replacement chemical from the agency for six years, thus undermining the goals of the program.

2) *DuPont's failure to comply with EPA 8(e) filing requirements for PFAS led to a significant penalty the same year Solvay received test results for their chemical*

¹² Letter from Stephen L. Johnson, EPA Adm'r, to Virginia Hubert, Vice President for Health, Safety, & Env't, Solvay Solexis (Jan. 25, 2006), <https://beta.regulations.gov/document/EPA-HQ-OPPT-2006-0621-0002> (emphasis added).

¹³ *Id.*

¹⁴ *Id.*



This apparent failure by Solvay to submit a timely 8(e) report occurred during the same period in December 2005 when DuPont agreed to pay the largest civil administrative penalty the EPA had obtained to date, in the amount of \$10.25 million,¹⁵ for failure to submit 8(e) studies¹⁶ to the EPA on the toxicity of PFOA. The civil penalty was widely publicized and should have put Solvay on notice as to the importance of promptly alerting the EPA to substantial risks through 8(e) filings.

The failure to provide information to the EPA affected the agency’s ability to adequately assess the safety of other PFOA/PFOS/PFNA replacement chemicals during a time of very active development.

The EPA’s Enforcement Response Policy for TSCA section 8 considers violations that interfere with the EPA’s ability to address situations involving unreasonable risks to be major violations.¹⁷ The PFOA Stewardship Program was intended to end the use of PFOA, PFNA, and other long-chain PFAS compounds. At the same time, companies involved in PFAS production transitioned to the production of replacement PFAS compounds. The timely submission of the toxicity and bioaccumulation data from Solvay may have informed EPA reviews of replacement chemicals for “unreasonable risk” under section 5 of TSCA, 15 U.S.C. § 2604. This is significant because the EPA noted that after initiating the 2010/2015 PFOA Stewardship Program, the Agency had approved more than 300 Pre-Manufacture Notices and Significant New Use Notices for PFAS and had granted most of the 300 PFAS Low Volume Use Exemption Applications.¹⁸ Thus, Solvay’s extreme delay in reporting 8(e) substantial risks undermined the EPA’s ability to address unreasonable risks under section 5.

Solvay’s reporting delay is a serious violation of section 8(e) of the Toxic Substances Control Act and should be subject to maximum penalties

¹⁵ Press Release, Env’t Prot. Agency, EPA Settles PFOA Case Against DuPont for Largest Environmental Administrative Penalty in Agency History (Dec. 14, 2005), <https://www.epa.gov/enforcement/reference-news-release-epa-settles-foa-case-against-dupont-largest-environmental>; *see also* Consent Agreement and Final Order, In the Matter of: E.I. du Pont de Nemours and Company, Docket No. TSCA-HQ-2004-0016, <https://www.epa.gov/sites/production/files/documents/dupontpfoasettlement121405.pdf>.

¹⁶ *See* Complaint and Notice of Opportunity for Hearing, In the Matter of: E.I. du Pont de Nemours and Company, Docket No. TSCA-HQ-2004-0016, <https://www.epa.gov/sites/production/files/2016-05/documents/dupont-pfoa-complaint.pdf>; Complaint and Notice of Opportunity for Hearing, In the Matter of: E.I. du Pont de Nemours and Company, Docket No. TSCA-HQ-2005-5001, <https://www.epa.gov/sites/production/files/2016-05/documents/dupont2-pfoa-complaint.pdf>.

¹⁷ *See* Memorandum from Jesse Baskerville, *supra* note 7, at 14.

¹⁸ Env’t Prot. Agency, EPA’s Per- and Polyfluoroalkyl Substances (PFAS) Action Plan (2019), https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.



Section 8(e) of TSCA requires that information reasonably supporting the conclusion that a substance “presents a substantial risk of injury to health or the environment” be “immediately” reported to the EPA 15 U.S.C. § 2607(e).¹⁹ EPA policy guidance clarifies that “a person has ‘immediately informed’ the Administrator if information is received by EPA not later than the 30th calendar day after the date the subject person obtained such information.”²⁰

Section 15 of TSCA creates civil and criminal penalties for entities that commit a prohibited act under TSCA 15 U.S.C. § 2615. Prohibited acts under TSCA include failure to “submit reports, notices, or other information.” 15 U.S.C. § 2614(3).

EPA considers 8(e) reporting violations to be one of the most serious reporting violations of TSCA because the information “may have bearing on the Agency’s chemical hazard/risk assessment and chemical control efforts.”²¹ As such, there is no cap on the number of days a penalty can be assessed for 8(e) violations.²²

For the failure to submit to EPA animal test results (“Study 1”) showing the extreme toxicity and bioaccumulation potential of their replacement PFAS, the agency should fine Solvay the maximum civil and criminal violations for the 2,050-day delay. Reflecting the severity of this TSCA violation would result in a civil fine of \$76,875,000 and a criminal fine of \$102,500,000.

For the failure to submit results from ongoing worker biomonitoring studies (“Study 9”) that detected PFAS and linked exposure to health effects, the agency should fine Solvay the maximum civil and criminal violations for the 8-year delay. This TSCA violation would result in a civil fine of approximately \$109,500,000 and a criminal fine of \$146,000,000.

¹⁹ TSCA §8(e) states “Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall *immediately* inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.” 15 U.S.C. § 2607(e)(emphasis added).

²⁰ TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129, 33138 (June 03, 2003), <https://www.govinfo.gov/content/pkg/FR-2003-06-03/pdf/03-13888.pdf>.

²¹ See Memorandum from Jesse Baskerville, *supra* note 7, at 23.

²² *Id.* at 16.



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Conclusion

The issues raised within this letter are of utmost public health importance and we appreciate the agency's prompt attention. It is imperative that TSCA requirements are enforced to the fullest extent of the law when violations may significantly impact and endanger human health and the environment. Emerging scientific evidence indicates that many of the chemicals introduced to replace PFOA, PFOS or PFNA are similarly toxic yet their use continues. The lack of public toxicity data or disclosure of non-public data to EPA has likely hindered the regulation and marketplace transition away from PFAS. EPA should review all 8(e) filings for PFAS chemicals from all submitters with respect to the timeliness.

The extent of PFAS contamination across the country is staggering, with our research indicating that likely more than 200 million Americans have PFOA and PFOS in their drinking water. The extent of contamination and potential harm caused by newer PFAS such as the chloroperfluoropolyether carboxylates is unknown, but the agency should be able to comprehensively assess the health risks with assurance that it has all relevant toxicity data. The redacted copies of the toxicity studies Solvay ultimately provided to the EPA masked the specific chemical names further hindering public and academic assessment of the risks of these new PFAS. Additionally, the EPA should make public the health information of every PFAS compound without confidentially claims hiding the name of the chemical that caused harm.

Sincerely,

Ken Cook
President
Environmental Working Group

cc Larry Starfield, Acting Assistant Administrator, Office of Compliance and Enforcement

Tala Henry, Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention