PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY
962 Wayne Ave • Suite 610 • Silver Spring, MD 20910

June 28, 2021

Representative Ro Khanna, Chair
Oversight Environment Subcommittee
House Committee on Oversight and Reform
306 Cannon House Office Building
Washington, DC 20515

Dear Representative Khanna,

Public Employees for Environmental Responsibility (PEER) is representing four scientists working within the U.S. Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention (OCSPP). They have disclosed disturbing evidence of fraud and corruption in OCSPP, involving deliberate tampering with chemical risk assessments conducted under the Toxics Substances Control Act (TSCA), including PFAS (a.k.a. "forever chemicals"), and the deletion of potential health effects without the knowledge or consent of the human health assessors.

All four clients have experienced numerous instances where their risk assessments were changed by their managers or by colleagues in response to direction by management. These changes include –

- Deleting language identifying potential adverse effects, including developmental toxicity, neurotoxicity, mutagenicity, and/or carcinogenicity;

- Major revisions that alter the report conclusions to indicate that there are no toxicity concerns despite data to the contrary; and

- Risk assessments being reassigned to inexperienced employees in order to secure their agreement to remove issues whose inclusion would be protective of human health.

In cases documented in the attached disclosure where this type of interference has occurred, the revisions to the assessment concealed risks to workers. Thus, the resulting Safety Data Sheets lack information workers need to protect themselves, such as proper handling procedures, personal protection needed, accidental release measures, and first aid and firefighting measures. In addition, the changes resulted in the removal of hazards from the "Toxicological Information" section, which precludes workers from being able to make informed decisions about their

personal safety. This is a particular concern for susceptible subpopulations, including pregnant people.

On behalf of our clients, EPA scientists [redacted] PEER is requesting that your office ensure that EPA's Inspector General –

1. Conduct a performance audit to identify risk assessments that have been altered without knowledge or consent of the risk assessor specialists and recommend the optimal fashion for correcting these assessments (for example by reinserting inappropriately excised risk information);

2. Review apparent violations of EPA's Records Management Policy, which requires the retention of substantive comments on draft documents which record important Agency decision-making processes. Many of the altered risk assessment documents have been overwritten and intermediate comments have been erased; and

3. Evaluate the quality control process that allowed these improper changes to be made and remain uncorrected. All of our clients have already attempted to address these issues through internal EPA channels such as their managers and agency Scientific Integrity officials, but to little avail. In addition, our clients have been harassed and retaliated against by managers.

Significantly, our clients attest that the problems in OCSPP are not due solely to the Trump Administration and its appointees. The issues faced by our clients occurred prior to Trump taking office, throughout the Trump years, and continue under the current administration.

The thrust of these disclosures is that malfeasance in OCSPP has trickled down below political appointees to SES managers and career employees. PEER and our clients do not believe that the culture of OCSPP can change unless there are repercussions for this misconduct. Further, it is our belief that the potential adverse health and environmental consequences flowing from altered risk assessments demand immediate attention on a prioritized basis.

Our clients have a moral duty to come forward and to act in accordance with the April 12, 2021 memo that EPA Administrator Michael Regan wrote to EPA employees, which stated unequivocally that "public trust requires transparency." Administrator Regan also stated that, "Nothing contained in this memorandum interferes with your right to petition or to furnish information to Congress or a Member of Congress, as provided under applicable law, or to engage in protected whistleblowing activities." As such, we respectfully submit this congressional disclosure on behalf of our clients.

Thank you for your attention to this matter. Please do not hesitate to contact me at 202-265-7337 to discuss this matter further.

Sincerely,

Timothy Whitehouse
Executive Director

cc: U.S. Environmental Protection Agency Office of Inspector General

Attachments:

- Client Bios
- Legal and Policy Setting
- Allegations

Allegations Not Attached to
this copy 7-2-21

Client Bios

[redacted]

[redacted]

[redacted]

Legal and Policy Setting

Office Organization. EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) comprises three offices, the Office of Pollution Prevention and Toxics (OPPT), the Office of Pesticide Programs (OPP), and the Office of Mission Support (OMS), which provides administrative support. OPPT contains five divisions, including the New Chemicals Division and the Existing Chemicals Risk Assessment Division, which administer the Toxic Substances Control Act (TSCA) and its implementing regulations.

Operations of the New and Existing Chemicals Offices. Section 8(b) of TSCA requires EPA to publish a list, called "the TSCA Inventory," of each chemical substance that is manufactured, processed, or imported in the United States. If a chemical is on the TSCA Inventory, it is considered an "existing chemical" in U.S. commerce. If a chemical is not on the TSCA Inventory, it is considered a "new chemical."

New Chemical Review. Section 5 of TSCA requires a manufacturer or importer of a new chemical to provide EPA with a premanufacture notice (PMN) at least 90 days before such manufacture or importation. After EPA has completed its review of the PMN, the applicant must provide a Notice of Commencement of Manufacture or Import (NOC) to EPA within 30 calendar days of the date the substance is first manufactured or imported. Once an NOC is received by EPA, the chemical is on the TSCA Inventory and becomes an "existing chemical." EPA receives approximately 400 NOCs each year.

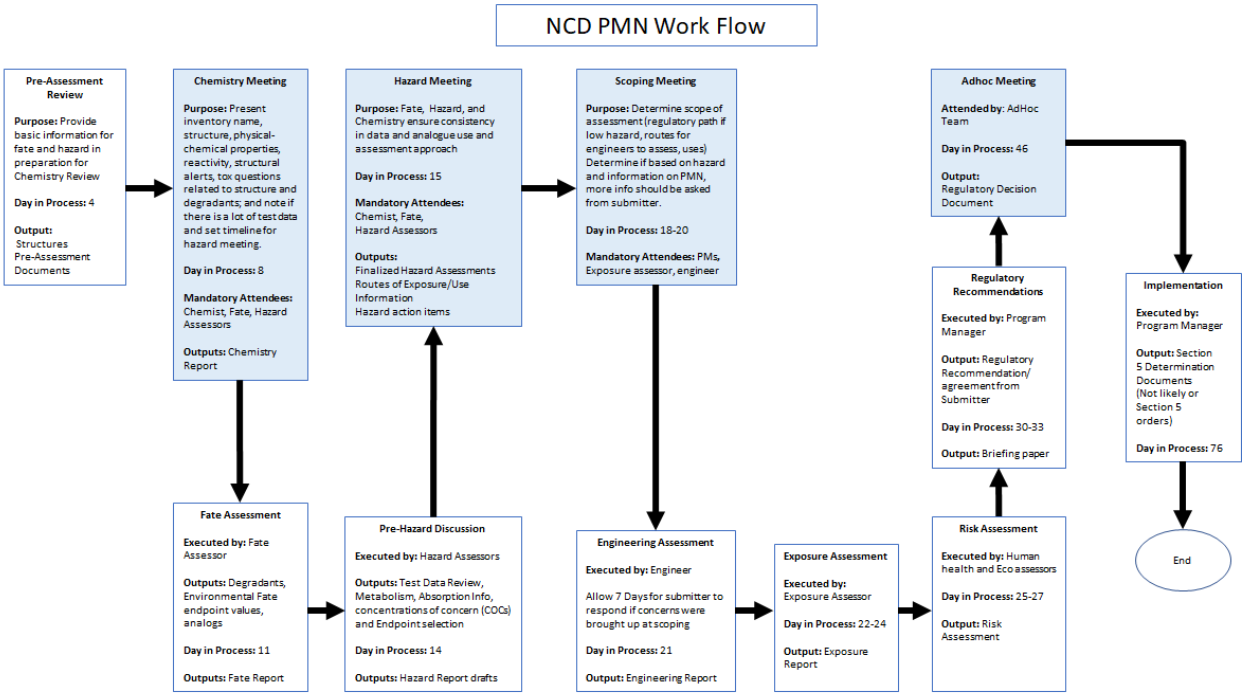
The New Chemicals Program reviews these PMNs, and identifies conditions to be placed on a new chemical, up to and including a ban on production, before it is entered into commerce. According to EPA, the PMN review has:

> …evolved into an efficient mechanism for identifying those new chemicals which are of greatest concern early on in the 90-day review process. A detailed analysis is focused on these cases with the ultimate goal of identifying and controlling unreasonable risks. EPA uses an integrated approach that ***draws on knowledge and experience across disciplinary and organizational lines*** to identify and evaluate concerns regarding health and environmental effects, exposure and release and economic impacts (emphasis added).

PMNs are submitted to the Agency through the Chemical Data Exchange (CDX) interface by chemical manufacturers and/or importers. From there, they undergo an initial review by the chemists in the Industrial Chemistry Branch (ICB) of the New Chemicals Division (NCD) to determine a) if the submission meets the minimum notice requirements under TSCA and the regulations, b) if the submission is in fact on a new chemical substance, or if it is for a substance that is already on the inventory, and c) predict physical-chemical properties when experimental data is not provided. After the chemists' review in ICB, the case is transferred to the Risk Assessment Branches (RAB1 and RAB2) in NCD. Five disciplines evaluate each case in RAB: 1) environmental fate and transport (i.e., "fate"); 2) environmental and ecological toxicology (i.e., "ecotox"); 3) exposure science; 4) engineering; and 5) human health toxicology. An initial

human health hazard report (a hazard is an adverse biological effect) is generated within a week of the Chemistry meeting while the final human health risk assessment incorporates the results of every assessment other than the ecotox assessment, which is completed in parallel. Because human health risk assessment requires data from the chemistry, fate, engineering, and exposure reports, it is one of the last reviews performed. This is important because TSCA specifies a 90-day review period and the human health review often is performed under intense time constraints, which leads to management pressure on the assessors to "speed up" their process.

Also involved are program managers, typically Environmental Protection Specialists who are located in the Risk Management Branches (RMB) of NCD. A flow chart describing the new chemical review process, together with the approximate days in the process, is below:



Note: "Day in process" is from the LEAN schedule distributed April 2019

Much of OPPT's human health assessment for new chemicals is based on abstracts of studies rather than the full study data. Abstracts frequently report only the study author's conclusions. In cases where studies are sponsored by industry, there is an additional risk of bias in the "top-level" conclusions presented in the abstract that could only be resolved by referring to the individual animal data documented in the full study report. This issue is compounded by: 1) TSCA language that requires submitters to provide only information in their possession (as opposed to developing new information); 2) the statutory turnaround time for PMN review; 3) the insistence from managers on minimizing the amount of time spent per case; and 4) the lack of information technology support or library resources to organize available information in an easy-to-search format.

According to OPPT's timeline, the chemistry report is scheduled to be presented to NCD within eight days of the PMN being submitted to the Agency, which triggers the beginning of the fate, ecotox, and human health reviews. One week after the Chemistry meeting, the fate, ecotox, and

human health assessors along with the program managers (from RMB) attend the Hazard meeting to discuss their initial reviews. The engineers then begin their review, which includes, but is not limited to, the occupational exposure values and environmental releases. Following the completion of the engineering report, the exposure assessors begin their review, using the environmental releases from the engineering report to estimate exposure values for the general population and consumers. The human health assessors can then complete their assessment using the exposure values from the engineering and exposure reports. A week after the Hazard meeting, the case goes to Scoping and two weeks after Scoping, the case is supposed to be complete and is listed on the Risk Assessment Complete (RAC) agenda. Both Scoping and RAC include the human health and ecotox assessors, and the program managers. Once the assessment is finalized, the program managers hold an "Options" meeting where they make the final unreasonable risk determination on the case, and then the entire package goes to the NCD Director (currently Ms. Madison Le) for review and signature. Risk management can include a Consent Order or a Significant New Use Rule (SNUR) under Section 5 of TSCA that can impose restrictions on manufacturing, processing, use, or disposal of the new chemical substances.

Existing Chemicals Review. The Existing Chemicals Program evaluates, as required by TSCA, the safety of existing chemicals via a three-stage process. The three stages of EPA's process for ensuring the safety of existing chemicals are: 1) prioritization; (2) risk evaluation; and (3) risk management, as described more fully below:

> 1) ***Prioritization*** is a risk-based screening process that designates chemicals as either High-Priority Substances for risk evaluation, or Low-Priority Substances, where risk evaluation is not currently warranted. Prioritization is the responsibility of the Data Gathering and Analysis Division (DGAD).
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> 2) If a chemical is designated as a High-Priority Substance, the chemical moves to the ***risk evaluation*** phase. EPA uses the risk evaluation as a basis to determine whether the chemical presents an unreasonable risk to health or the environment under the chemical's conditions of use. Risk evaluation is the responsibility of the Existing Chemicals Risk Assessment Division (ECRAD).
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> 3) If EPA determines that a chemical presents an unreasonable risk to health or the environment, the chemical moves to ***risk management*** action under TSCA. EPA is required to implement, via regulation, regulatory restrictions on the manufacture, processing, distribution, use or disposal of the chemical to eliminate this unreasonable risk. Risk management is the responsibility of the Existing Chemicals Risk Management Division (ECRMD).

The process for existing chemicals closely aligns with the 1983 National Academies report on risk assessment (a.k.a. "the Red Book"),[1] while for new chemicals, there are significant departures. In the Existing Chemicals Program, there is an organizational separation of risk assessment and risk management steps into different divisions, while in the New Chemicals

[1] National Research Council (US) Committee on the Institutional Means for Assessment of Risks to Public Health. Risk Assessment in the Federal Government: Managing the Process. Washington (DC): National Academies Press (US); 1983. PMID: 25032414.

Program, both are contained within the same division and report to the same Division Director, Ms. Madison Le, who also signs the finalized assessments. In addition, before Ms. Le signs, all assessments undergo comment and revision from Dr. Tala Henry, who sits above Ms. Le in the organizational structure, which is another point at which risk management concerns frequently intrude on risk assessment science. Page 3 of the Red Book states:

> Regulatory actions are based on two distinct elements, risk assessment, the subject of this study, and risk management. Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. Risk assessments contain some or all of the following four steps:
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> - Hazard identification: The determination of whether a particular chemical is or is not causally linked to particular health effects.
> - Dose-response assessment: The determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question.
> - Exposure assessment: The determination of the extent of human exposure before or after application of regulatory controls.
> - Risk characterization: The description of the nature and often the magnitude of human risk, including attendant uncertainty.
>
> In each step, a number of decision points (components) occur where risk to human health can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among possible inferential bridges, and we have used the term risk assessment policy to differentiate those judgments and choices from the broader social and economic policy issues that are inherent in risk management decisions. At least some of the controversy surrounding regulatory actions has resulted from a blurring of the distinction between risk assessment policy and risk management policy.[2]

It is clear from this excerpt that, even in 1983, it was understood that the stakes were high when it comes to the process by which risk assessments are conducted. Without appropriate internal controls, organizational checks and balances, and transparent guidelines and procedures, we cannot protect the public nor maintain their faith that the government is acting in their interest.

Outcomes of chemical review. According to EPA's data, out of the 3,753 new chemical substances reviewed from June 22, 2016 through June 1, 2021, *zero* chemicals were prohibited from commercializing under TSCA. Only 11 chemicals were not allowed to commercialize pending development of information. In the US, chemicals are assumed to be innocent unless proven guilty; most other jurisdictions have minimum data sets for testing of new chemical substances based on production volume, while the US has none.

[2] Id. At 3.

TSCA, if implemented in accordance with legislative intent, gives EPA the authority to restrict or prohibit chemicals. However, the culture of OCSPP is to reward the expeditious approval of chemical substances, and to penalize employees who ask for more data or attempt to restrict chemical approvals based on risk.