



PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY

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To: House Energy and Commerce Subcommittee on Environment and Climate Change
RE: Implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

From: Tim Whitehouse, PEER Executive Director

Date: October 26, 2021

Overview:

Following landmark 2016 amendments to Toxic Substances Control Act ("The Frank R. Lautenberg Chemical Safety in the 21st Century Act"), EPA undertook evaluation of risks from both existing and new chemical substances. These risk assessments are the safety net to protect workers, consumers, the general population, and susceptible subpopulations (i.e., children, pregnant people, etc.) from harmful exposures to these chemicals.

Yet, according to EPA's data, out of the 3,364 chemicals reviewed from June 22, 2016, through October 1, 2021, zero chemicals were prohibited from commercializing under TSCA. Only 12 chemicals were not allowed to commercialize pending development of information, but none of these chemicals has been prohibited from commercializing outright.

EPA scientists represented by PEER have documented how this stunningly one-sided track record is a function of the inordinate influence the chemical industry has within EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). They detailed how the chemical industry has – and still exercises – a disturbing level of direct, personal access to program managers to ensure resulting in risk assessments that improperly minimize or completely excise risk findings.

As the conditions they describe within OCSPP still persist, PEER would request that your oversight include a focus on three points:

1. No Reassessments of Flawed Risk Reviews

Our clients charge that management in OCSPP routinely deletes hazard identifications and alters risk conclusions in risk assessments on specific chemicals without their knowledge or approval. Due to these improper alterations, risk cannot be appropriately communicated using Safety Data Sheets and other methods, thus endangering workers as these methods are used by employers and workers when making decisions

regarding mitigation of risks in the workplace. Removal of hazard assessments precludes workers from being able to make informed decisions about their personal safety.

This is no small concern. Occupational diseases caused by industrial chemicals result in an estimated annual 50,000 to 70,000 deaths and 350,000 cases of illness in the United States.

Yet, OCSPP has no plans to reassess any of the assessments identified as inaccurate and/or incomplete. Indeed, it appears that even when manufacturers become aware of new information about risks posed by chemicals already on the market, EPA does not use these data to reassess those chemicals or warn the public. The agency should be pressed to disclose its plan to remedy this critical failure, including the timeline for completing these reassessments.

II. No Discipline of Responsible Managers

Our clients identified OCSPP managers who issued these improper orders yet, these same managers remain in place. One manager repeatedly named in these complaints was recently named to lead efforts “to triage scientific integrity issues” and develop a “rapid response” to “mediate” concerns raised by staff scientists.

This manager is also married to a consultant for the chemical industry. The exact nature of the spouse’s work has not been disclosed as a PEER Freedom of Information Act request has revealed there is no recusal by the EPA manager on file.

According to scientists’ disclosures, several managers consistently take a pro-industry stance on a wide range of chemicals and advocate for the removal of whole areas of chemical risk entirely from assessments. They also frequently pressured scientists to hurry approval of favorable (“not likely to pose a risk”) assessments.

These managers are central figures in accommodating industry complaints that trigger putting a chemical assessment in a category called “hair on fire” (“HOF” for short) cases that are then prioritized by the agency managers for review. In one recent email, a manager urged scientists: “Please move this not likely expeditiously, as the submitter is anxious.” The submitter is the chemical manufacturer, and “not likely” is shorthand for “not likely to present risk.”

In this new “triage” position, this manager is able to stifle additional scientific complaints before they become formal.

In another case, another manager asked consultants to provide a “science override button,” whereby they could ignore the risk assessors’ conclusions. We would urge the Subcommittee to explore whether the “culture” of an organization can be changed if the main architects of that culture remain in place.

III. Flawed Review Process

In a report this February, the National Academies of Sciences, Engineering, and Medicine give EPA's OCSPP a failing grade for the manner in which it evaluates the health risks of chemical exposures. Entitled "The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations," the report calls into question the quality of vital EPA scientific work and argues for an overhaul of the management of agency chemical assessments, concluding that the process OCSPP employs to develop risk assessments suffers from "inadequate documentation, itself an indication of failing at being comprehensive, workable, objective, and transparent."

Criticisms included –

- EPA lacks "a clear, documented approach to evidence synthesis and to integration," which means "the risk evaluation process becomes unworkable because staff have to decide on approaches for these critical steps for each new evaluation rather than relying on a protocol or guidance."
- EPA's approach is "lacking objectivity at each step, from not using a defined approach to documenting how the problem formulation and protocol are developed."
- The "transparency of the entire risk evaluation process is compromised across all of its elements."

The report's principal recommendations are that EPA "comprehensively reevaluate its approach to systematic review methods," develop a documented, consistent protocol, and dramatically improve its transparency. Yet, the agency has not formally responded to this report or addressed the issues therein.

Moreover, the recent moves to create a Science Policy Council and a New Chemical Advisory Committee within OCSPP do not directly address the concerns raised and may, depending upon how they are implemented, make matters worse.

Aggravating the above is that employees in the New Chemicals Division are given performance reviews based on how many chemicals get out on the marketplace within 90 days. This increases the assembly-line nature of the current process, emphasizing and rewarding speed over accuracy. Moreover, these timeframes are unreasonable when the risk assessors are not allowed by management to stop the 90-day clock and request additional data from submitters.

We would urge the Subcommittee to seek substantive answers that specify how the EPA chemical assessment process will become more accurate, transparent, and protective of human health and the environment.