

**Center for Environmental Health <> Defend Our Health <> Earthjustice <>
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Chemicals Healthy Families**

December 14, 2021

Honorable Michael Regan
Administrator
US Environmental Protection Agency Mail Code 1101A
1200 Pennsylvania Ave. NW
Washington, DC 20460

Dr. Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
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Re: Scientific Misconduct Issues in TSCA New Chemicals Program

Dear Administrator Regan and Assistant Administrator Freedhoff:

On June 28, four scientists in the New Chemicals Division of the Office of Pollution Prevention and Toxics (OPPT) provided EPA leadership with documentation of serious scientific integrity violations and other improper practices in the review of new chemicals under section 5 of the Toxic Substances Control Act (TSCA) that have continued for several years. To date, the Agency has not taken sufficient action to address these serious issues and ensure that the TSCA New Chemicals Program is adhering to the Agency's Scientific Integrity Policy and basing new chemical safety decisions on the best available science and protection of public health and the environment.

We have carefully reviewed the accounts of the whistleblower complaints published in the [Intercept](#). These descriptions of scientific misconduct are detailed and explicit. If true, they demonstrate that managers in OPPT have fostered an unhealthy culture in the New Chemicals Program, including improper industry influence, intimidation and coercion of experts raising legitimate scientific concerns, and manipulation and redaction of scientific assessments to downplay potential risks and rationalize decisions not to regulate chemicals that are or may be unsafe.

As you well know, Congress revamped the TSCA new chemicals program in 2016 to ensure more rigorous assessment of premanufacture notices (PMNs), strengthen protection of health and the environment, require more testing, and increase EPA's accountability for new chemical safety determinations. Misconduct like that described by the whistleblowers undermines these objectives and subverts the enhanced protections that Congress enacted.

We appreciate Assistant Administrator Freedhoff's stated commitment to ensuring and restoring scientific integrity to the New Chemicals Program. While a step in the right direction, however, the initial [actions announced](#) on October 14 are insufficient to address the concerns raised. We recommend that the following additional measures be taken while awaiting results of the Office of Inspector General's (OIG's) investigation of the whistleblowers' complaints:

- Condemn the improper practices alleged by the whistleblowers, direct EPA supervisors and managers to halt any such practices immediately, and establish clear and transparent public standards and expectations for ensuring scientific integrity in new chemicals reviews.
- Commit to removing EPA staff from supervisory roles in the TSCA program in circumstances, like those described by the whistleblowers, where the evidence shows that they engaged in serious misconduct that failed to conform to EPA scientific integrity principles or otherwise violated agency policies.
- Return staff to the New Chemicals Program who resisted pressure to alter assessments and were removed from the Program.
- Audit new chemical assessments that may have been compromised by scientific integrity violations to determine if they reflect the best available science and, if appropriate, take risk management action to address risks that were overlooked or improperly discounted.
- Disavow policies of the Trump Administration that prioritized rapid approval of new chemicals at the expense of careful scientific reviews, health protective determinations of risk and testing to resolve uncertainties, and provide clear direction on incorporating scientific integrity and best practices into the New Chemicals Program.

Our recommendations are presented more fully below.

Condemn Actions Alleged by Whistleblowers

Although EPA continues to investigate the allegations of the whistleblowers, the alleged misconduct, if true, has no place within the New Chemicals Program. Yet EPA leadership has not spoken out directly against this misconduct during the five months since the whistleblower complaints were filed. We urge that EPA staff be sent a clear message that the alleged actions will no longer be tolerated, that scientific misconduct in the PMN program will no longer be rewarded and that the overriding goal of PMN reviews will be public health and environmental protection, not rapid approval of new chemicals in order to placate industry submitters.

Commit to Removing EPA Staff Who Have Engaged in Serious Misconduct Violating EPA's Scientific Integrity, Recordkeeping and Transparency Policies from Supervisory Positions in the New Chemicals Program

The conduct outlined by the whistleblowers goes well beyond the normal give-and-take among scientists who may disagree about matters of scientific interpretation. Instead, as described by the whistleblowers, these actions violated several core tenets of EPA's [Scientific Integrity Policy](#).

The Policy prohibits EPA employees “from suppressing, altering, or otherwise impeding . . . scientific findings or conclusions” and “from intimidating or coercing scientists to alter scientific data, findings, or professional opinions.” Yet as described by the *Intercept*, the whistleblower complaints contain “detailed evidence of pressure within the agency to minimize or remove evidence of potential adverse effects of the chemicals, including neurological effects, birth defects, and cancer” and demonstrate that “[o]n several occasions, information about hazards was deleted from agency assessments without informing or seeking the consent of the scientists who authored them.”

Similarly, the Policy requires “differing scientific opinions [to] be reflected in the Agency’s deliberative documents for the policy makers’ consideration” and directs “scientists and managers . . . to . . . [r]epresent Agency scientific activities clearly, accurately, honestly, objectively, thoroughly, without political or other interference.” According to the whistleblower complaints, however, certain EPA supervisors “tampered with the assessments of dozens of chemicals to make them appear safer” and staff scientists’ “findings were altered or deleted from assessments without their knowledge” or the awareness of senior managers responsible for risk management decisions. Such actions prevent EPA from assessing new chemical risks thoroughly, objectively and without regard to political or industry interference, and from providing the public with critical information about potentially dangerous chemical exposures. They also represent violations of Executive Branch record-keeping requirements, which call for preserving drafts of scientific and policy documents so that the basis for Agency decisions and the input considered are documented.

It would be inaccurate to describe these actions as involving legal or policy determinations that fall within the discretion of EPA managers. Instead, as presented by the whistleblowers, they involved scientific judgments about the selection of appropriate analogues, determinations of sensitive endpoints, interpretation of studies, and evaluation of the adequacy of available data that resulted in new chemical approvals without any conditions for entry onto the market. These are core scientific functions that are squarely within the protections of the Scientific Integrity Policy.

If these clear-cut scientific integrity violations occurred, the supervisors and managers who committed them should no longer exercise influence over the assessment of the hazards and risks of chemicals and pesticides within the Office of Chemical Safety and Pollution Prevention (OCSPP). Instead, they should be transferred from their responsibilities in OCSPP. This is a standard practice when employees are unable to perform their duties in accordance with program goals, agency policies and leadership expectations. In addition, no EPA employee for whom there are credible allegations of integrity violations should have any role in overseeing implementation of the Agency’s Scientific Integrity Policy within OCSPP.

Transferring responsible employees out of the TSCA chain of command would send a powerful message that deviations from scientific integrity principles which compromise safety determinations on new chemicals have no place in the TSCA program and will be forcefully rooted out. We recognize that the OIG is still investigating the whistleblower complaints and await its findings. However, completion of the investigation is likely months away and OCSPP leadership has a responsibility to review the evidence at hand and take action now, if warranted,

to ensure the integrity of ongoing TSCA new chemical reviews.

Identify and Remedy Instances in Which Staff Were Penalized for Resisting Pressure

Similarly, staff who resisted pressure to alter assessments and were moved out of the New Chemicals Division should have the opportunity to return to their old positions. These employees report that they were improperly pressured to alter risk assessments, given negative performance reviews and ultimately transferred to other programs after protesting actions by supervisors that violated EPA's Scientific Integrity Policy. It is deeply disturbing, and indicative of the profound problems with the "culture" in OCSPP, that staff would suffer career setbacks for insisting on good science.

Conduct Independent Audits of New Chemical Approval Decisions that May Have Been Compromised by Scientific Integrity Misconduct

Where the whistleblower complaints or other information identifies PMN actions that may have been influenced by improper interference by industry or EPA supervisors with risk assessments and resulting safety determinations, EPA should reexamine these decisions – along with a subset of all PMNs from the past four years – to assess whether they were based on incorrect scientific findings that understated risks to health and the environment. This audit of scientific findings should be carried out by scientists outside of OCSPP. If the audit reveals that risks were erroneously evaluated because of scientific integrity misconduct, EPA should revisit risk management decisions where appropriate and consistent with TSCA and take action to ensure that risks which were not fully identified or were improperly minimized during PMN review are acknowledged and adequately addressed. The audit findings should be made available to the public.

Provide Clear Direction on Incorporating Scientific Integrity and Best Practices Into the Workings of the PMN Program

OCSPP's October 14, 2021 announcement created a new OCSPP Science Policy Council to provide advice on science policy and scientific integrity issues that arise within OPPT and OPP. It also created a New Chemicals Advisory Committee to review scientific and science policy issues related to new chemical reviews. It is not clear how these new bodies will be constituted but they should not include any OCSPP staff cited for scientific misconduct in the whistleblower complaints and should seek input from other EPA offices, as well as from non-OCSPP members of [the EPA Scientific Integrity Committee](#). Moreover, the October 14 announcement does not provide clear guidance and direction to the Council and Committee to ensure that they will effectively remedy the scientific integrity violations described in the whistleblower complaints and strengthen transparency and public health protection in the PMN program. To guide the work of these bodies and provide direction to the OCSPP workforce, we believe the following goals and principles should be adopted and clearly articulated:

1. **Prioritize health and the environment in new chemicals review.** The 2016 Lautenberg Chemical Safety Act (LCSA) strengthened the new chemicals program by requiring a safety determination before all new chemicals could enter commerce and directing EPA

to restrict substances that lack sufficient data or may present an unreasonable risk to health or the environment. Congress also removed a provision that “deemed” new chemicals approved after 90 days if EPA had not taken action. The Trump EPA undermined these protections by measuring program success by how quickly PMNs are approved and sharply increasing the number of new chemicals entering commerce without restrictions. It is critical to make clear, for EPA staff and the public, that these performance metrics are no longer in force and that, consistent with Congress’ reforms, a top priority of the program will be conducting thorough, scientifically rigorous assessments of new chemical risks and erring on the side of fully addressing concerns about health and the environment.

2. **Provide scientists with the time and support to apply the best available science.** Consistent with this change in focus, staff scientists should no longer be pressured to complete assessments on a timeline that precludes adequate literature reviews, identification of appropriate analogues, and modeling of potential risks. Under LCSA, new chemicals cannot enter commercial production until EPA has made an affirmative safety determination, and the Agency has several tools to extend the 90-day PMN review period to ensure that this determination is based on the best available science. Program managers should ensure that staff scientists have the time and support needed to carefully analyze potential risks, rather than stigmatizing them for adhering to their professional obligations and refusing to cut corners to expedite PMN approvals, as the whistleblower complaints allege.
3. **Ensure that data needs are adequately addressed.** LCSA reinforces the importance of testing of new chemicals by directing EPA to require the PMN submitter to conduct additional studies where available information is “insufficient” for a reasoned evaluation of the health and environmental effects of a new substance. The Trump EPA largely ignored this expanded authority and instead greatly scaled back orders requiring new chemical testing. The whistleblower complaints provide evidence that, consistent with this bias against testing, recommendations by staff scientists for toxicity studies on new chemicals of concern were discouraged by supervisors and ignored by managers. It should be made clear that testing is an important tool for assessing new chemicals and managing their risks and that staff scientists are encouraged to identify data needs during their assessments and managers should carefully consider these recommendations and act on them where warranted.
4. **Allow scientific disagreements to be fully aired and elevated to higher-level managers without reprisal.** If supervisors disagree with staff scientists on selection of an analogue, estimates of exposure, choice of endpoints, or other scientific questions, these disagreements must be resolved respectfully and collaboratively. Staff scientists should have an opportunity to elevate differences of opinion to higher-level managers without fear of reprisal or censure. Areas of scientific debate and controversy should be presented to these managers accurately and objectively in accordance with the Scientific Integrity Policy. The resolution of such questions should be based strictly on scientific best practice and consistency with EPA risk evaluation guidelines, not political considerations or industry lobbying. To ensure reliance on the best available science, independent EPA experts outside OCSPP should be used as arbiters and peer reviewers where there are

differing views on science issues within the New Chemicals Program itself.

5. **Stop sharing draft assessments exclusively with PMN submitters.** According to the whistleblowers, hazard, exposure, and risk assessments have been shared with members of industry, who have been allowed or even encouraged to dispute EPA scientists' findings and recommend changes in approach. These interactions with PMN submitters have not been disclosed publicly and members of the public have had no opportunity to comment on industry concerns and recommendations. These one-sided and clandestine communications provide an avenue for improper external interference in the scientific process that is at odds with the Scientific Integrity Policy. They also violate the Administrator's April 12, 2021 "fishbowl" [memo](#) emphasizing that "public trust requires transparency" and reiterating EPA's "dedication to open communication, fairness, and transparent engagement with the public." Unless EPA provides public access to its new chemical assessments, with sufficient time to review and comment on them, it should not make those assessments available to the chemical industry prior to the completion of the PMN review process.
6. **Prohibit pressuring EPA scientists to modify scientific findings and analyses.** Under no circumstances should risk assessment findings and analyses be altered or deleted by supervisors without informing the staff scientists who drafted them, and these scientists should not be strong-armed into acquiescing in revisions of their work against their will. If they are uncomfortable with these changes, their access to higher-level managers and scientific experts within the PMN program should not be limited, and independent EPA scientists should be asked to resolve the areas of disagreement. No higher-level supervisor should justify modifying risk assessments on the basis of industry pressure and no staff scientist should be threatened with legal action or other reprisals for refusing to modify assessments.
7. **Forbid shortcuts in PMN review procedures to satisfy industry pressure for expedited decisions,** The *Intercept* articles describe a special "hair on fire" procedure for bypassing the normal PMN review process where industry is demanding rapid action on a new chemical. This procedure has empowered designated supervisors to make expedited decisions to approve substances without full consultation with staff scientists and consensus by expert reviewers that the substance does not present risks that warrant regulatory action. There should be no exceptions to the normal review process and it should be made clear that industry pressure should play no role in the speed of new chemical reviews or their outcome. Assessments of chemicals that were in the past approved through the "hair on fire" procedure should be reexamined to ensure that they correctly describe the risks of the chemicals involved and manage those risks accordingly.
8. **Ensure compliance with recordkeeping requirements.** The whistleblower complaints detail violations of EPA record-keeping policies in the new chemicals program, including the failure to retain drafts of assessments, other technical analyses which document differences of opinion on science issues, and revisions made by supervisors that overrule or delete the findings and recommendations of staff scientists. The October 14 OCSPP announcement emphasizes that "[p]roper documentation of decisions, and any differing

scientific opinions of those decisions are a significant component of EPA's Scientific Integrity Policy." Such records are required to be preserved in accordance with the Federal Records Act and the applicable EPA documents retention [schedule](#) for the PMN program. It should be a high priority to fully implement required documentation procedures as soon as possible. To ensure there is full transparency for industry efforts to influence EPA decisions on new chemicals, a central database should be created and made public to document all contacts between EPA staff and outside parties, including those from industry, on specific PMNs. The database should make clear both the nature of the communications between staff and industry, and any changes in risk assessments or risk management decisions made based on them.

- 9. Increase transparency and public access.** The risk assessments and other technical analyses that form the basis for the disposition of PMNs are not accessible outside the Agency, and public explanations of EPA's safety determinations are limited and largely uninformative. Especially, in light of the serious questions raised by the whistleblowers about the integrity of the PMN review process and EPA's safety decisions on new chemicals and evidence of one-sided access to draft EPA assessments by PMN submitters, greater transparency is essential to create public trust in the program. To accomplish this, it should be routine practice to publicly post all risk assessments - including any draft or interim risk assessments - and related documents on EPA's website and to Chemview within one week of the completion of PMN review, subject only to eligible and legally-valid confidential business information (CBI) protections.

In sum, we strongly urge EPA leadership to speak out directly on the scientific integrity concerns raised by the whistleblowers and put in place concrete reforms and safeguards that will help to establish the credibility of the PMN program and protect staff scientists from censure, reprisals and coercion for doing their jobs.

We would be pleased to meet with you to discuss our recommendations. Please contact Bob Sussman, counsel for Safer Chemicals Healthy Families, with questions or to arrange a meeting at bobsussman1@comcast.net.

Sincerely yours

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