Environmental Protection Network

Resetting the Course of EPA

Reducing Toxic Risks

This paper is part of the Resetting the Course of EPA project by the Environmental Protection Network (EPN), a bipartisan network of more than 500 former EPA career employees and political appointees across the country who served under multiple Democratic and Republican administrations.

Resetting the Course of EPA outlines specific and actionable steps that EPA leadership can take to reset the course of the agency to address the most significant and pervasive threats to public health and our environment. As there is no single roadmap, EPN looks forward to collaborating with others to advance the dialogue around the future of EPA and set ideas into motion that will better protect the health and wellbeing of everyone.

Additional Resetting the Course of EPA documents are available here:
https://www.environmentalprotectionnetwork.org/reset

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Summary

EPA leadership should focus on changing the agency's current toxic substances approach, which runs contrary to the best available science. The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Chemical Safety Act) amended the Toxic Substances Control Act (TSCA) and established deadlines for EPA to evaluate chemical risk. Since then, EPA's initial ten chemical risk evaluations have been intensely criticized by EPA's independent Science Advisory Committee on Chemicals (SACC) and others for disregarding conditions of use and pathways of exposure.

In 2019, the Ninth Circuit Court of Appeals overturned in part EPA's July 2017 "framework rule," which attempted to establish how the agency should evaluate chemical risk. The court ruled that EPA must stop ignoring the historic or "legacy" use and disposal of dangerous chemical products, like asbestos, when evaluating risk. The court also stated that the framework rule did not allow EPA to "pick and choose" which uses and pathways of exposure to consider in determining unreasonable risks (Safer Chemicals, Healthy Families v. US EPA, 943 F. 3d 397).

EPA should pay close attention to worker exposure to toxic chemicals and exposures from legacy uses and disposal of toxic chemicals, which disproportionately affect vulnerable subpopulations, including communities of color.

Recommendations

1. **Conduct chemical risk evaluations that fully protect public health**. Rework the risk evaluations of the first ten chemicals to consider all missing conditions of use and pathways of exposure. Assure these conditions of use and pathways are also addressed in the next round of risk evaluations. [Read More]
2. **Replace the flawed TSCA systematic review process to better incorporate quality, peer-reviewed research**. Immediately start using a peer-reviewed, scientifically defensible process to evaluate the risks of chemicals under TSCA. Develop a new agency-wide systematic review process endorsed by the National Academies of Science (NAS). [Read More]
3. **Require industry to provide missing data for chemical risk evaluations**. Systematically identify missing data on chemicals of interest and require industry to provide these data for both existing and new chemical risk evaluations. Use the enhanced authority under the Lautenberg Chemical Safety Act to require industry to conduct the testing needed to fill serious data gaps for determining chemical risks. [Read More]
4. **Act on immediate risks to exposed people while a draft risk evaluation is being finalized**, including issuing public health advisories, recommending ways to reduce exposure, and using EPA's TSCA authority to declare unsafe chemicals to be imminent hazards. When a risk evaluation finds that a chemical or substance poses immediate harm to people or the environment, EPA should propose a rule to address the risks when it finalizes the risk evaluation and make it immediately effective under TSCA. [Read More]
5. **Provide additional budget resources and staff to support EPA's expanded workload and protect the public from toxic substances**. [Read More]

Recommendation #1: Conduct chemical risk evaluations that fully protect public health.

EPA must conduct chemical risk evaluations that fully protect public health as required under TSCA and the Lautenberg Chemical Safety Act. Specifically, EPA must consider legacy uses, current disposal of legacy wastes, all conditions of use/pathways regardless of regulation by other EPA statutes, and worker exposures without personal protective equipment (PPE).

Immediate Actions

- Announce a new approach to risk evaluations that meets the requirements of TSCA, follows the SACC expert peer review recommendations, and complies with the current risk evaluation framework rule.
- As part of this approach, commit to addressing all pathways of exposure and conditions of use, including ongoing use and disposal of legacy products; determining risks to workers without assuming the use of PPE to prevent exposure; combining risks across routes and pathways of exposure consistent with legislative intent to protect highly exposed subpopulations; assuring protection of susceptible subpopulations at higher risk than the general population as required by TSCA; addressing all health and environmental endpoints identified using the best available science; and assessing risk to humans and environmental species using the most sensitive endpoint.

Early Actions, Including the First 100 Days

- Rework the first ten chemical risk evaluations as necessary to assure complete and protective risk determinations in accordance with TSCA and this new approach.
- Apply the new approach immediately to the next 23 risk evaluations EPA is currently conducting.
- Expand the current narrow asbestos risk evaluation to include all fiber types and health endpoints and ongoing use and disposal of legacy asbestos products.

First Year and Sustained Actions

- Finalize previously proposed bans of certain uses of methylene chloride, N-Methyl-2-Pyrrolidone (NMP), and trichloroethylene (TCE).
- Initiate risk management actions on additional uses of these and other chemicals determined to present unreasonable risks in the initial ten risk evaluations, including bans when necessary to eliminate these risks.
- Develop a consultation process with the Occupational Safety and Health Administration (OSHA) on ways to protect workers when unreasonable risks are posed by chemicals.
- Propose and promulgate revisions to the 2017 risk evaluation framework rule to eliminate any discretion to disregard conditions of use and pathways of exposure in determining unreasonable risk of injury to human health or the environment.

Recommendation #2: Replace the flawed TSCA systematic review process to better incorporate quality, peer-reviewed research.

EPA has developed and used a deeply flawed systematic review process that may select biased studies to evaluate the risks of chemicals under TSCA. EPA must immediately start using a peer-reviewed, scientifically defensible process under TSCA and ultimately develop a new agency-wide systematic review process endorsed by the NAS.

Immediate Actions

- Stop using the flawed TSCA systematic review process, which can result in the exclusion of high-quality studies, particularly epidemiology studies. The process is based on an arbitrary quantitative scoring system influenced more by the quality of the reporting than the quality of the research. In conducting the ongoing 23 evaluations, use the National Toxicology Program's Office of Health Assessment and Translation (OHAT) Method or Navigation Guide while beginning to develop a new NAS-reviewed agency-wide systematic review process for use in all EPA scientific assessments.

First Year and Sustained Actions

- Based on NAS reviews of both the Integrated Risk Information System (IRIS) and TSCA systematic review processes, develop an agency-wide systematic review process for use in scientific assessments.
- Submit that new process to the Science Advisory Board (SAB) for review, followed by public notice and comment.

Recommendation #3: Require industry to provide missing data for chemical risk evaluations.

Despite serious gaps in available data for determining risks to human health and the environment for some chemicals, EPA has completed risk evaluations without using the enhanced authority under the 2016 Lautenberg Chemical Safety Act to require industry to conduct the testing needed to fill those gaps.

EPA leadership should develop a process to systematically identify missing data on chemicals of interest and use TSCA authorities to require industry to provide these data for both existing and new chemical risk evaluations. Specifically, EPA should begin using testing orders, rules, consent agreements, and authorities under TSCA Sections 4 and 8 to require industry to report all available use and exposure information.

Early Actions, Including the First 100 Days

- Develop a systematic process for screening chemicals of interest to identify the minimum toxicological and exposure data needed to evaluate health and environmental risks for the general population and vulnerable subpopulations.

- Use appropriate uncertainty factors for database deficiencies in ongoing priority chemical risk evaluations if EPA cannot request and obtain the missing data needed to meet the minimum data needed.
- Revise the process for existing chemical risk evaluations and prioritization so that sufficient time is available to issue orders and rules requiring development and submission of critical missing data under TSCA Sections 4 and 8.

First Year and Sustained Actions

- Start using rules, orders, and consent agreements to require industry to provide critical missing data under TSCA Sections 4 and 8.

Recommendation #4: Act on immediate risks to exposed people while a draft risk evaluation is being finalized.

EPA spends years completing risk evaluations and analyzing risk management options before protecting exposed populations. EPA should act on immediate, significant risks while a draft risk evaluation is being finalized. These actions could include issuing public health advisories, recommending ways to reduce exposure, and using EPA's authority under TSCA to declare unsafe chemicals to be imminent hazards.

When a risk evaluation finds that a chemical or substance poses immediate harm to people or the environment, EPA should propose a rule to address the risks when it finalizes the risk evaluation and make it immediately effective under TSCA.

Early Actions, Including the First 100 Days

- Develop a two-phased process to speed risk management actions to address immediate and unreasonable risks:
  - When a draft risk evaluation determines certain uses pose immediate and serious risks of harm, use public health advisories, recommendations to industry to reduce exposure, and, if necessary, an imminent hazard action under TSCA Section 7 to prevent unsafe exposures.
  - At the same time as a final risk evaluation determines certain uses pose severe acute or chronic health risks, issue a proposed risk management rule eliminating these risks, and make that rule immediately effective under TSCA.

First Year and Sustained Actions

- Begin implementation of the new process under TSCA authority to provide timely protection against serious and immediate risks identified in EPA risk evaluations—including voluntary action, Section 7 imminent hazard proceedings, and immediate effective Section 6 rules as appropriate.

Recommendation #5: Provide additional budget resources and staff to support EPA's expanded workload and protect the public from toxic substances.

EPA must request a substantial increase in staff and contract dollars in the president's budget and expand the SACC membership in order to meet TSCA requirements.

Early Actions, Including the First 100 Days

- Request more positions (full-time equivalents (FTE)) and contract dollars to support EPA's expanded workload, including for the premanufacture notice (PMN) program, the EPA Chemical Information and Testing Branch, and chemical risk evaluations and risk management rulemakings. Starting in 2020, TSCA requires EPA to double the number of risk evaluations to 20 every 3.5 years, and to issue risk management rules under Section 6(a) within two years after completing a risk evaluation determining that a substance presents an unreasonable risk of injury. Continued implementation of Section 5 authorities for new chemical review and an increased use of testing and reporting authorities in Sections 4 and 8 will also place additional demands on the agency.
- Expand the SACC to ensure its capability to review all risk evaluations under law. The SACC should follow the approach of the SAB's Chemical Assessment Advisory Committee, which supplements its membership with needed experts for specific chemical reviews and divides the chemical reviews among multiple subcommittees.

First Year and Sustained Actions

- Increase requests for increased funding for FTE and contract dollars to support the TSCA program and the expanded SACC.
- As soon as the statute allows, propose and finalize a new rule increasing the fees paid by companies to support the TSCA program.

Participants in the EPN Workgroup
Reducing Toxic Risks

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