Testimony for the Record

Submitted to the

Senate Committee on Environment & Public Works

Subcommittee on Chemical Safety, Waste Management, Environmental Justice, and Regulatory Oversight

For the hearing to examine the potential environmental impacts of 6PPD

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July 31, 2024

Chairman Merkley, Ranking Member Mullin and Members of the Subcommittee, thank you for inviting me to participate in today's hearing on 6PPD.

My name is David Fischer, and I am Counsel with the law firm Keller & Heckman, LLP where I work with chemical industry clients on environmental, policy, and health and safety matters, with a concentration on the Toxic Substances Control Act (TSCA). Prior to joining Keller and Heckman, I had the great privilege of serving as the Deputy Assistant Administrator (DAA) for EPA's Office of Chemical Safety and Pollution Prevention. During my tenure as DAA, I was deeply involved in TSCA implementation. I have also held senior-level positions at the American Chemistry Council (ACC), including co-managing ACC's Chemical Products and Technology Division, where I led the implementation of the 2016 amendments to TSCA.

Today's hearing on 6PPD, its environmental impacts, and ongoing research into potential alternatives, prompts a discussion of EPA's new chemicals program and section 5 of TSCA, which governs the review of new chemicals and new chemical uses. Afterall, a 6PPD alternative will need to undergo substantive review by EPA's New Chemicals Division before it can be used in tires or other applications.

We all know this, but it is worth repeating - nothing is possible without chemistry. And the nearly infinite permutations of chemicals help drive innovation, including the development of chemicals in vehicle tires. But innovation in the U.S. necessarily relies on a wholly functioning and efficient New Chemicals Division.

TSCA section 5 requires any company planning to manufacture (including import) a new chemical substance for a commercial purpose to submit a premanufacture notice (PMN) to EPA for approval. EPA has 90-180 days thereafter to review the PMN and determine the new chemical substance's effects on human health and/or the environment. Prior to the 2016 TSCA amendments, if EPA did not act on the PMN submission prior to the expiration of 90 days, then the submitter could commence commercial manufacturing of that chemical. All that changed in 2016.

The TSCA amendments now require an affirmative determination by EPA. Section 5(a)(3) sets forth five possible determinations:

1. The chemical or significant new use presents an unreasonable risk of injury to health or the environment;

2. Available information is insufficient to allow the Agency to make a reasoned evaluation of the health and environmental effects associated with the chemical or significant new use;

3. In the absence of sufficient information, the chemical or significant new use may present an unreasonable risk of injury to health or the environment;

4. The chemical is or will be produced in substantial quantities and either enters or may enter the environment in substantial quantities or there is or may be significant or substantial exposure to the chemical; or

5. The chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment.

And unless EPA makes one of these determinations, however long that may take, the submitter is in limbo and cannot commercially manufacture the chemical.

But even beyond this new affirmative determination requirement, the manner in which EPA conducts new chemical reviews has made 90 days or even 180 days, a distant memory. Reviews now take many months, sometimes over a year or more. As a result, some manufacturers have opted to abandon the U.S. marketplace by not filing PMNs. Other manufacturers are increasingly relying on exemptions, such as the low-volume exemption, but processing these exemptions also exceeds EPA's review timelines.

EPA recognizes the current challenges facing the New Chemicals Division and has taken noteworthy programmatic steps to streamline the new chemical review process for at least some categories of new chemical notices, including biofuel PMNs and mixed metal oxide PMNs.

But absent significant changes to the regulations themselves to facilitate an efficient process to review all new chemical substances, companies will continue to face avoidable roadblocks and delays in bringing new, innovative, and sustainable chemistries to the marketplace.

In November 2022, I submitted a petition for rulemaking that included numerous regulatory changes aimed at addressing the ongoing, unduly time-consuming process by which EPA reviews PMNs. Some of the changes reflected in Appendix A include the following:

- Require EPA to conduct reviews of PMNs in a fit for purpose manner, in which the review is commensurate with the specific circumstances applicable to the new chemical substance, and to conduct reviews consistent with the risk characterization TCCR principles of transparency, clarity, consistency, and reasonableness as described in EPA's Risk Characterization Handbook, December, 2000;

- Require EPA to generally grant pre-submission meetings requested by the submitter. EPA shall address issues raised by the submitter no later than five business days after such meeting;
- Limit the amount of time EPA may extend the notice review period, require EPA to reimburse the submitter 50% of the notice fee if the review period extension does not fall under the good cause exemption, reset the review period if the submitter substantially amends the original PMN submission, and allow a submitter to extend the suspension period for more than 90 days only for good cause;
- Require EPA to rely on the data provided by the submitter unless EPA can demonstrate that such data does not represent the best available science;
- Place greater emphasis on the Central Data Exchange (CDX) to allow for more accessible and efficient communication between PMN submitters and EPA;
- Require EPA to review new chemical submissions in the order in which they are submitted to EPA, unless the submission qualifies for expedited review as described in Appendix A;
- Require EPA to provide a brief written statement identifying the basis for each determination, including the identification of foreseeable uses that were the basis for any determination under proposed §720.60(c)(i) or (iii);
- When evaluating unreasonable risk, require EPA to reach a determination based on certain probabilities, ensure that EPA does not render unreasonable risk determinations based on the worst-case scenarios involving unreasonable assumptions, and provide EPA with alternative options to section 5(e) Orders;
- Require EPA to notify a submitter of errors in the notice or that the submission is incomplete within 15 days of receipt;
- Describe what constitutes a major amendment to a PMN and present options for the submitter to take if EPA designates the amendment as "major;" and
- Provide the PMN submitter with the option to administratively appeal a risk determination, which shall be reviewed de novo by three EPA senior scientists within 60 days of receipt and determined by a simple majority vote.

Unfortunately, when EPA did propose changes to the regulations on May 26, 2023, they were geared more to ensure that the regulations comported with the 2016 TSCA amendments and failed to include any of the substantive changes that were included in our petition. EPA plans to finalize the regulations later this year, so EPA may yet incorporate at least some of these recommended changes.

Today's hearing also prompts comments on the TSCA section 21 petition process, which Earthjustice relied on in seeking a TSCA section 6 rule to prohibit the use of 6PPD in tires. In its response granting the petition, EPA reviewed the petition to determine "whether petitioners have established that it is 'necessary' to initiative a proceeding for a rule under TSCA section 6.

Notwithstanding that the burden is on the petitioners to present 'the facts which it is claimed establish that it is necessary' for the EPA to initiate the proceeding sought, the EPA in its discretion also considered relevant information that was reasonably available to the agency during the 90-day petition review period."[1]

It is unclear what this relevant information is because EPA does not furnish that information in its response. Moreover, EPA granted the petition and plans to initiate rulemaking this fall, even though EPA also plans to collect data to inform a human health risk assessment on 6PPD-q, and may issue section 4 test orders to require the development of new information.

The petition process as currently implemented by EPA stands in stark contrast to the section 6 prioritization, risk evaluation, and risk management paradigm for existing chemicals. Although EPA must seek public comment for any rule issued pursuant to section 21, EPA does not need to request either public comment or scientific peer review on a section 21 petition itself or on EPA's basis for granting the petition.

And with respect to 6PPD, EPA appears to have granted the petition with respect to a single condition of use, 6PPD's use in tires. For section 6 risk evaluations, however, EPA recently changed its regulations to mandate a whole chemical approach in which EPA reviews all conditions of use (COU) and exposures of a chemical and renders a single unreasonable risk determination for the whole chemical, rather than for any COU.

My fear is that section 21 is fast becoming an end run around section 6, especially at a time when EPA's refrain is a plea for more funds to implement sections 5 and 6. It may be that Congress will need to further amend TSCA to address this issue, and to provide greater flexibility to EPA within section 6 to more nimbly address concerns like those identified for 6PPD. I believe other changes to TSCA will be needed as well, but that is a topic for future hearings of this subcommittee.

[1] *See* EPA's response to the petition at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#6ppd%20in%20tires.