August 2, 2023

Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Administrator Regan:

We are writing regarding a recent consent order\(^1\) that EPA issued under the Toxic Substances Control Act (TSCA) section 5 new chemicals program for chemicals derived from the pyrolysis of plastic wastes. We have a number of serious concerns with this decision. This letter focuses on a major subset of those concerns, those involving the consent order, EPA’s approach to new chemicals from plastic wastes and the protection of at-risk populations under TSCA section 5. We strongly urge EPA to use its authority to withdraw the consent order because it is not protective against the unreasonable risks posed by these new chemicals.\(^2\)

The consent order was issued to Chevron to produce plastic waste-based fuels at its refinery in Pascagoula, Mississippi, and other undisclosed locations. The consent order identifies significant risks, including a 1 in 4 cancer risk, from exposure to new chemicals derived from pyrolyzed plastic waste intended to be used as a fuel. Some of our groups met with EPA on April 12, 2023 to better understand the basis for the consent order. EPA asserted that it used extremely conservative assumptions to arrive at its cancer risk estimate of 1 in 4 in the consent order and that the risk was incorrectly described in the order. However, the underlying risk analysis\(^3\) made available as part of the docket for the related Significant New Use Rule proposed on June 20, 2023 identified other significant risks *not* presented in the consent order, including a cancer risk of greater than 1 in 10 for stack air releases and a cancer risk of 7 in 100 for fish ingestion. In addition, multiple non-cancer risks were also identified, yet limited information is provided on these risks; the magnitude of the risks and the specific toxic harms associated with the non-


\(^2\) We recognize that EPA has recently proposed a Significant New Use Rule (SNUR) pertaining to plastic waste-derived substances approved in the consent order [EPA. Significant New Use Rules on Certain Chemical Substances (23–2.5e). Proposed Rule 88 Fed. Reg. 39804. June 20, 2023. https://www.federalregister.gov/documents/2023/06/20/2023-13012/significant-new-use-rules-on-certain-chemical-substances-23-25e]. While our organizations plan to comment on the proposed SNUR, the proposal does not address our concerns with EPA’s previous PMN approvals that are discussed in this letter.

cancer risks are not included in the risk analysis. As elaborated below, EPA’s assertion that the assumptions in the risk assessment are overly conservative is not supported. Accordingly, we continue to have serious concerns about this order and others like it that we believe EPA must address.

Specifically, we are concerned that EPA has not:

- adequately assessed the risks from the production and use of these new chemicals;
- sufficiently considered and protected higher risk groups subject to these risks;
- used its TSCA authority to require testing necessary to understand the toxic effects of these new chemicals;
- addressed the unreasonable risks using its TSCA authorities, instead of pointing to undefined controls under the Clean Air Act (CAA) and Occupational Safety and Health (OSH) Act;
- explained how the CAA and the OSH Act effectively address the unreasonable risk; and
- been transparent about why EPA used an expedited process intended for biofuel premanufacture notices (PMNs) to characterize and regulate the risks of the new chemicals derived from plastic wastes used as fuels.

EPA’s assessment and regulation of these new chemicals are not health protective and would not provide everyone the same degree of protection from health and environmental risks and equal access to decision-making. This is not in line with the agency’s environmental justice policy and the Executive Order on Revitalizing Our Nation’s Commitment to Environmental Justice for all. The community in Pascagoula, Mississippi is half Brown and Black and one quarter of the population lives in poverty. Further, the new chemical with the 1 in 4 cancer risk is intended to be used as a jet fuel. Studies have shown that many communities near airports are more likely to be Black and Brown and low-income communities.5,6

**Flaws and Limitations in EPA’s Risk Assessments.** When questioned about the extremely alarming cancer risks estimated in the Chevron consent order, EPA disavowed them as based on an overly conservative analog for the new chemicals and conservative exposure modeling. EPA also stated that the risks identified in the consent order did not apply to fenceline residents exposed to facility stack emissions as the order indicated but instead applied to worst-case scenarios during fuel use at airports. However, EPA has not explained how conservative the modeling and analog are (e.g., by a factor of 100, 1000, 10,000?), or what analogs and exposure models the agency considers appropriate. Thus, there is no clarity on the risks the agency now believes communities and workers actually face from these new chemicals. Having taken the extraordinary step of disavowing the risk calculations on which its own order is based, EPA must

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4 Ibid. For example, see Table 40. Summary of General Population Non-Cancer Risks. Even risks to infants from drinking water are listed only as “risks identified.”
disclose the basis for its new position that the risks to human health are in fact far less than the risk estimates on which EPA’s consent order is based.

While EPA has characterized its risk assessments for these new chemicals as conservative, there are several aspects of EPA’s analyses that undermine this characterization:

- Some risks were not quantified because there was insufficient toxicity information;
- Releases from industrial/commercial activities were underestimated by release models because of limits placed on chemical parameters, such as vapor pressure, that were significantly less than those actually measured for some of components of the new chemicals;
- Risks to potentially exposed or susceptible subpopulations were not characterized;
- The cumulative risks to fenceline communities and workers were not taken into account, despite the known exposure of these communities to chemicals emitted from the refinery that cause similar harms;
- A less protective cancer benchmark was used rather than the cancer benchmark of 1 in 1,000,000 typical for TSCA actions to protect non-worker populations;
- The persistence and bioaccumulation of the new chemicals were characterized but not considered in the estimation of risks;
- Very little data was provided on the composition of the new chemicals and no experimentally derived hazard data was provided for the new chemicals; and
- Some of the most toxic components were assumed to be present only at low levels despite EPA’s acknowledgment that the levels of the components of the new chemicals would vary, sometimes significantly.

Unwarranted Comparison to Existing Chemicals. EPA further discounted the risks for these new chemicals, including before it conducted its risk analysis, by asserting that they are comparable to the risks posed by similar chemicals (fuels) already on the market and better for the environment. This is contrary to the core premise of TSCA section 5 and the new chemicals program, which focuses on the specific risks of new chemicals and requires that EPA determine whether a new chemical “presents” or “may present an unreasonable risk.” Congress did not authorize EPA to deem risks “reasonable” based on their similarity to a substance or mixture already on the market. If EPA were to use this approach for PFAS, it could approve every new PFAS on the ground that there are hundreds, if not thousands, already in use. In addition, the data on the chemicals EPA considers to be similar to the PMN substances is incomplete and does not provide a basis for informed determinations of the risks presented by the new chemicals. Further, EPA has not explained how these new chemical fuels derived from plastics are “better for the environment.”

Lack of Testing Requirements. Despite the limited information available on the new chemicals, associated impurities and byproducts, and the analogs EPA used for its risk

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assessment, the agency did not exercise its TSCA section 5(e) authority to require testing. Such testing is critical to reduce the uncertainty in the toxicity of the new chemicals, to obtain data on the toxic effects for which the agency could not estimate risks, including on persistence and bioaccumulation for the chemicals it identified as persistent bioaccumulative toxic (PBT) chemicals, and to identify impurities or the potential formation of byproducts such as dioxins. TSCA section 5(e), titled “regulation pending the development of information,” specifically foresees the development of information in these cases. Indeed, this is clearly a case where the development of information should be required. EPA’s failure to require testing for these chemicals raises significant concerns about the potential long-term effects of the PMN substances on human health, and the agency’s approach to ensuring the safety of new chemicals generally.

**Inadequate Protections.** Given EPA’s inability to demonstrate the absence of unreasonable risk and the potential hazards identified in the consent order, TSCA requires that the consent order afford protection to exposed populations. Yet the consent order only requires that the new chemicals not be produced other than as a fuel or fuel-related chemical and that workers wear gloves. It does not include any restrictions that would address the risks to those who live near the refinery nor does the consent order address the risks to exposed workers from inhalation. While the order states that the new chemicals will be used in compliance with CAA and Occupational Safety and Health Administration (OSHA) regulations, there is no explanation of the extent to which reliance on these non-TSCA regulations will mitigate the unreasonable risk from the new chemicals (including the cancer risks of 1 in 4, greater than 1 in 10, and 7 in 100). As EPA has acknowledged, CAA and OSHA regulations are based on standards different than those under TSCA, which requires that a determination be made “without consideration of costs or other nonrisk factors” and the consideration of “potentially exposed or susceptible subpopulations.” In addition to these different standards, many of OSHA’s occupational exposure limits “are outdated and inadequate for ensuring protection of worker health,” as OSHA has explained on its website. OSHA’s “outdated and inadequate standards” cannot be presumed to address the TSCA unreasonable risks. Reliance on these standards is thus inconsistent with TSCA and with EPA’s commitment to “ensure necessary protections for workers identified in its review of new chemicals through regulatory means.”

**Use of an Inappropriate Expedited Process.** Further, we are concerned these new chemicals were derived from the pyrolysis of plastics but were reviewed using the expedited process called for by EPA’s *Integrated Approach for Biofuel Premanufacture Notices.* Waste

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8 “The Company must refrain from manufacturing these New Chemical Substances other than for use as a fuel, fuel additive, fuel blending stock, or refinery feedstock (including, but not limited to: cracking, coking, hydrosprocessing, distillation, or deasphalting) subject to 40 C.F.R. Part 79 or 1090.”

9 OSHA. Permissible Exposure Limits – Annotated Tables. https://www.osha.gov/annotated-pels

10 EPA. Important Updates on EPA’s TSCA New Chemicals Program. https://www.epa.gov/chemicals-under-tsca/important-updates-epas-tsca-new-chemicals-program

plastics pyrolyzed for use as fuels are not biofuels, are not derived from bio-based materials and have none of the potential environmental benefits of biofuels. The streamlined review and approval of these plastics-derived new chemicals using the biofuel PMN program was not clearly disclosed to the public but was only discovered after substantial research. It is not apparent why EPA would want to expedite the review of chemicals derived from waste plastics for use as fuels given the toxicity of the chemicals produced, the impurities and the byproducts.

This lack of transparency is also reflected in the review and approval for these new chemicals derived from waste plastic. There are excessive redactions in the premanufacture notices and the consent order. In addition, EPA’s risk assessments and other supporting assessments were missing from the public files until the publication on June 20, 2023 of the proposed SNUR. Further, the risk assessment does not indicate the magnitude of the non-cancer risks. The risk assessment only states “risks identified.” Unfortunately, this lack of transparency – to all except the submitter of the new chemicals – is typical of many aspects of the new chemicals program.

It is crucial for the public to have access to comprehensive information about the risk assessments and decision-making processes concerning new chemicals, including those derived from plastics pyrolysis. It is not sufficient for EPA to say that the risks presented by these chemicals are not of concern because the agency used purportedly “conservative” assumptions, or because the new chemicals supposedly present risks comparable to similar chemicals on the market and are “better for the environment.” Transparency is vital for fostering public trust and ensuring accountability.

In light of these concerns, we strongly urge EPA to withdraw the TSCA section 5 consent order because the agency does not address the unreasonable risks these new chemicals pose, including to higher-risk groups such as fenceline communities, children and workers. EPA should also remove the review of any waste-plastic derived new chemicals from the Integrated Approach for Biofuel Premanufacture Notices and give this plastics-waste derived category of new chemicals rigorous scrutiny, including any additional plastic-waste derived substances that were reviewed under the streamlined program. New chemicals derived from the pyrolysis of plastics warrant rigorous scrutiny because of:

- The toxicity of the impurities resulting from the plasticizers and other additives used in the plastics;
- The toxicity, persistence and bioaccumulative potential of the byproducts such as dioxins that can be produced during the pyrolysis of the waste plastics and carried along in the pyrolysis oils that are further processed and used; and
- The cumulative and other impacts on the higher-risk populations that live near and work in the facilities that produce and use these new chemicals.

EPA should identify how its risk assessments will effectively characterize the types of risks specific to this category of new chemicals and the TSCA risk mitigation actions it believes will address the unreasonable risks. EPA should also use both its sections 4\textsuperscript{12} and 5 authorities to

\textsuperscript{12} TSCA section 4(a)(2)(A)(i) explicitly provides EPA with the authority to require testing to review a notice under section 5.
require testing on new chemicals derived from the pyrolysis of plastics, including testing on the cumulative effects\textsuperscript{13} from these chemicals.

New chemical reviews that comply with TSCA by considering the risks to all, including those most vulnerable, and effectively regulate the unreasonable risks that may be presented by a new chemical are critical to ensure the health of communities, workers and ecosystems.

Thank you for your consideration.

Respectfully,

Beyond Plastics
Environmental Defense Fund
Moms Clean Air Force
Natural Resources Defense Counsel
Sierra Club
Toxic-Free Future

cc:
Dr. Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention

Grant Cope, Senior Counselor to the Administrator

\textsuperscript{13} TSCA section 4(b)(2)(A).