



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 28, 2023

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

The Honorable Jeffrey Merkley
United States Senate
Washington, D.C. 20510

Dear Chairman Jeffrey Merkley:

Thank you for your letter, dated April 5, 2023, addressed to EPA Administrator Michael Regan regarding the EPA's program under the Toxic Substances Control Act (TSCA) to streamline reviews of new chemicals to make waste and bio-based transportation fuel substitutes, and expressing your concerns that fuels derived from plastic waste reviewed under the program may present significant toxic chemical exposure to communities living near a refinery. This response is intended to provide more information on EPA's TSCA New Chemicals Program, its approach to standardize review of certain fuel-related pre-manufacture notices (PMNs), and the risk assessment and risk management approaches for the particular chemical(s) referenced in the recent news report and your letter.

EPA takes these concerns very seriously. EPA is implementing new protections to address the risks posed by chemicals following Congress' 2016 update to TSCA and wants to clarify the record as to EPA's actions related to its review of waste and bio-based fuel substitutes. In short, the news report referenced in your letter contains several inaccuracies and lacks important context. We welcome this opportunity to clarify the Agency's approach to reviewing these chemicals, communicate more clearly about the risks associated with the submissions the Agency has already reviewed, and share ways the Agency plans to improve this approach in the future.

Background on TSCA New Chemical Reviews and its January 2022 Biofuels Announcement

Between the enactment of TSCA in 1976 and the amendments to TSCA in 2016, EPA had a requirement to review the potential risks associated with new chemicals, but companies were able to move them into commerce if EPA didn't finish its review within 90 days. Consequently, EPA completed formal reviews on only about 20% of new chemicals during those four decades. As you know, when TSCA was amended in 2016, one of the fundamental reforms was to require EPA to do formal reviews of potential risks for 100% of new chemicals within 90 days before the chemicals went into commerce, dramatically increasing the Agency's workload.

The previous Administration never asked for additional funding from Congress to meet the responsibilities of the new law. For the past two years, EPA has requested more funding for the TSCA

program, but has not received all that was requested. Given the program's limited resources and increased responsibility, OCSPP has started to find ways to categorize types of chemistries for which the Agency receives a high volume of new chemical submissions and standardize the review process for those.

In January 2022, EPA announced a new effort to standardize the review of certain new chemicals used as transportation fuels, based on a growing number of applications from companies who wanted to make transportation fuels by mixing together a small amount of bio-or waste-based fuel feedstocks into a much larger amount of petroleum-based feedstocks at a traditional refinery. These transportation fuels, produced by refining a blend of waste or bio-based feedstocks with petroleum-based feedstocks, when not already on the TSCA Inventory are considered "new chemicals" under TSCA and as such are subject to the new chemicals review process.

The intent of this initiative was to create a more streamlined process for reviewing mixtures of different combinations of feedstocks used to make new fuels. EPA's rationale for creating a more streamlined review process was based on a belief that the new fuels were substantially similar to existing fuels, such as gasoline or jet fuel. This is because the 'new' fuels would consist of hydrocarbon mixtures, essentially the same as traditionally refined gasoline or jet fuel.

In EPA's January 2022 announcement, EPA also stated that the effort would support the goals under EPA's Renewable Fuel Standard (RFS) program, which has Congressional mandates to replace or reduce quantities of petroleum-based transportation fuel, heat oil, or jet fuel with biofuels that are projected to have lower lifecycle greenhouse gas emissions. Only fuels made from feedstocks that meet the definition of renewable biomass and other requirements under the Clean Air Act can qualify as such under the RFS program. The projected volumes referenced in the EPA's announcement did not include any volumes associated with the waste-based fuels, as these would not qualify under the RFS program.

Summary Information about the Plastic-Based Feedstock Oils

Your letter raised questions regarding pyrolysis of plastic, and concerns that those feedstock oils may be contaminated with impurities. There are several previously-approved plastic-based feedstocks (or precursors) that are associated with PMNs that EPA reviewed under this standardized approach, meaning that some of the 'new' fuels that would be reviewed by EPA are expected to include a small amount of 'feedstock oil' made from the pyrolysis of plastic.

1. ***No fuels using plastic-based feedstock oils have been commercialized.*** While a number of press reports have raised concerns that fuels using plastic-based feedstock oils are currently being manufactured, that is not the case. EPA has yet to receive a 'Notice of Commencement' for any of the new fuels planned to be made using plastic-based feedstock oils.
2. ***The plastic-based feedstock oils were approved by EPA years ago, and the data on impurities received at that time showed no impurities of concern.*** All of the PMNs for the individual precursor plastic-based feedstock oils were reviewed and approved by EPA years ago - in both 2015 and 2019. At the time they were approved, the feedstock oil companies provided some data on impurities and these data showed there were no impurities of concern, and in one case the Agency required some additional testing to prove no dioxins were being formed as a result of the pyrolysis process.

3. ***EPA plans additional effort to ensure no impurities are present in plastic-based feedstock oils.***

EPA recognizes that the data and testing that was required in 2015 and 2019 for these plastic-based feedstock oils might not reflect as complete an understanding of the potential range of impurities that the Agency now knows to be potentially present in plastics. EPA is aware of concerns about the potential health and environmental risks posed by impurities that may be present in pyrolysis oils generated from plastic waste. Accordingly, EPA intends to require companies submitting new pyrolysis oil chemicals to the Agency for review under TSCA to conduct testing for impurities that could be present in the new chemical substance prior to approval, and ongoing testing to ensure that variation over time in the sources of the plastic waste stream used to generate the pyrolysis oil does not introduce new impurities.

EPA’s Risk Assessment for the Plastic-Based Fuels

Under TSCA, EPA’s review process for all new chemical substances looks at the lifecycle of a chemical, including manufacturing, processing, distribution, use, and disposal. Risk is a function of hazard and exposure. EPA applies a screening level analysis to assess if the new chemical substance poses risks to humans and environment. Typically, the Agency uses conservative assumptions for both hazard and exposure in its models and calculations, and looks at worker, general population, consumer and fenceline risks for the entire lifecycle of the substance, including risks to potentially exposed or susceptible subpopulations as the law requires. The following sections describe some of EPA’s considerations when assessing the specific new chemical referenced in your letter – a new jet fuel mixture made by co-processing feedstocks from both waste plastic-derived feedstock oil and petroleum-based oil at a traditional refinery.

1. ***EPA’s hazard estimates were based on an analogue and conservative assumptions.*** When EPA receives a new chemical submission, it does not always have precise or complete information about the potential health hazard. When the new chemical resembles a chemical the Agency has reviewed in the past and has a more complete understanding of, those older chemicals are sometimes used as analogues to estimate hazard, with conservative assumptions built in. EPA determined that the ‘new’ fuel that would result from co-processing a small amount of waste plastic-derived feedstock oil into a significantly larger amount of petroleum-based oil did not have an appropriate analogous petroleum stream to evaluate cancer hazard. Instead, EPA used a hydrocarbon mixture called a “Stoddard solvent.” EPA knows the cancer hazard associated with the Stoddard solvent, and because the Agency did not know exactly what percentage of the new fuel contained this Stoddard-like component, EPA’s risk assessment included the assumption that 100% of the new jet fuel was Stoddard solvent, an assumption we know to be very conservative.
2. ***The worst-case exposure scenario cited in the ProPublica report was not at the refinery, and estimated refinery risks are not high relative to traditional fuels.*** Your letter references a news report that described a 1 in 4 cancer burden falling on people who live within 3 miles of a facility that refines a mixture of plastic-based feedstock oil with petroleum oil. This report is inaccurate. In fact, for the referenced jet fuel PMN, the general population risks associated with refinery emissions that EPA calculated in its risk assessment were on the order of one in a hundred thousand, consistent with the Agency’s benchmark residual cancer risk levels for refineries, and

risks to workers in the refinery were found to be orders of magnitude lower than that – about one in ten million.

- 3. *The worst-case exposure scenario the Agency identified did not represent a realistic exposure scenario, and actual worst-case risks are expected to be vastly lower.*** The exposure scenario that led to the 1 in 4 cancer risk referenced in reports is not one that would realistically be expected to occur. In general, to develop its exposure scenarios, the New Chemicals Program took the entire projected future annual production volume of the new jet fuel - and for each type of exposure (e.g., worker in a refinery, worker in a gas station, person living near the refinery, etc.), the Agency used conservative assumptions and generic scenarios to calculate potential exposure to each category of potentially exposed person.

In the exposure scenario for the jet fuel PMN that led to the 1 in 4 cancer risk referenced in reports, the Agency divided the total projected future annual production volume of the new jet fuel by the total number of locations expected to receive the fuel (about 100 locations). The Agency then assumed each location could be an end-use location (e.g., airport), and also assumed that these locations were where all of the fuel would be burned. The scenario that was modeled in effect presumed that every plane at the airport was idling at the same time on a runway burning an entire tank's fuel without ever taking off, that the components of the fuel that contribute to cancer risk are not fully combusted and are present in the exhaust, and that residents living nearby would continuously breathe the exhaust each day over many years in their lifetime. This is not an exposure scenario that would ever actually occur. Upon receiving the exposure model output that was used to estimate risk to nearby communities associated with airport exposures as 1 in 4, EPA should have recognized an issue and documented that exposures from mobile transportation fuels - generally many orders of magnitude lower - were not well-addressed in its model. EPA should have then taken steps to either adjust its model, or better communicate and provide the context for the model's output in the risk assessments.

Risk Management Approach

Your letter also asked several questions related to the Agency's risk management approach. Given initial data indicating that the plastic-based feedstock oils did not contain impurities of concern and that the worker and community risks at the refinery from the 'new' fuels were estimated to be the same as 'traditional' fuels, EPA continues to believe that it was appropriate for the Agency to rely on the sufficiency of existing regulations governing traditional fuels to protect human health and the environment, but some additional explanation follows below.

- 1. *EPA's risk management approach for the fuel PMNs ensures appropriate protections for health and the environment.*** EPA's consent order required the company to comply with existing regulations under the Clean Air Act, OSHA, DOT, and Coast Guard as well as anything else that was applicable to the manufacture, transportation, storage, dispensing, use and disposal of the new fuels. Specifically, the consent orders required compliance with existing regulations, including, but not limited to:

- regulations affecting fuel standards - 40 CFR Part 1090 and 40 CFR Part 79;

- regulations affecting storage and transport of fuels - 40 CFR Part 63 and 49 CFR parts 100-180;
- regulations affecting workers handling fuels including hazard communication, monitoring for benzene and other hazardous materials, flammability, and marine fuels - 29 CFR parts 1910 and 1917;
- any other regulations that apply to the manufacture, transport/storage, dispensing, use and disposal of the new fuels; and
- some additional requirements including use of personal protective equipment (PPE) for workers and recordkeeping under TSCA.

2. *The reference to OSHA requirements in the consent order is not at odds with EPA's policy regarding consideration of worker exposures.* Your letter raised questions with respect to consistency of the Agency's actions on the fuel PMNs with EPA's March 2021 announcement regarding worker exposures. In that announcement, EPA stated it would ensure necessary protections for workers identified in its review of new chemicals through regulatory means. More specifically, where EPA identifies a potential unreasonable risk to workers that could be addressed with appropriate PPE and hazard communication, EPA will no longer assume that workers are adequately protected under OSHA's worker protection standards and updated Safety Data Sheets (SDS). Instead, EPA will identify the absence of worker safeguards as "reasonably foreseen" conditions of use, and mandate necessary protections through a TSCA section 5(e) order, as appropriate. For these new fuel PMNs, EPA did identify risks to workers and – through its consent order – mandated necessary protections, including compliance with OSHA requirements as well as additional requirements regarding use of PPE. This is consistent with the EPA's current policy for worker protection. While the 2015 and 2019 PMNs for the plastic-based feedstock oils were not reviewed under this policy, EPA did include conditions for worker protection in the consent orders for those PMNs as well. For the 2019 PMNs, EPA required compliance with monitoring requirements by OSHA for benzene and toluene, and for the 2015 PMNs, EPA required dermal PPE and hazard communication.

Other Specific Requests/Questions:

The following information is responsive to other specific requests or questions in your letter that are not otherwise addressed in this response:

1. *Request for a list of the new chemical waste-based fuels that were approved as part of this program.* Although these PMNs are available in ChemView, the PMN numbers cannot be shared within this context because the companies claimed both the biobased and waste-based sources of the fuels as confidential. Sharing the PMN numbers in response to this request would reveal confidential business information (CBI). The Agency is in the process of preparing versions of the risk assessments for the PMNs that have CBI redacted and will make those available once that work is complete. Please find attached the sanitized orders for the two biofuels cases not claimed as CBI: P-21-0141 (CASRN 2529890-37-5) and P-22-0147 (CASRN 2779559-23-6).

2. ***Request for the number of fuels approved under the bio-based fuel program made fully, or partially, from plastic waste, and from byproducts of petrochemical manufacture and refining processes?*** EPA has processed a total of 35 submissions under the new fuels approach, of which 17 are expected to be manufactured using some feedstocks made from plastic waste. None of the chemicals are byproducts of petrochemical manufacture or refining processes.
3. ***Request related to the company's prior enforcement history.*** Enforcement history is typically not a factor in risk assessments and risk determinations. EPA's New Chemicals Program does, however, work closely with colleagues in EPA's Office of Enforcement and Compliance Assurance to support any TSCA compliance and enforcement related matters. Since the new fuel blends are also subject to various existing regulatory requirements, EPA's offices responsible for implementation of those regulations would also be involved in the event of future non-compliance or violations of the requirements.

We thank you for this opportunity to clear up several misconceptions and to provide additional details that describe our actions going forward. If you would like to discuss this matter further, please contact Laura Gentile (Gentile.Laura@epa.gov or 202.805.3243) in the EPA Office of Congressional Affairs.

Sincerely,

Michal Freedhoff, Ph.D.
Assistant Administrator