ASSISTANT ADMINISTRATOR FOR CHEMICAL SAFETY AND POLLUTION PREVENTION
WASHINGTON, D.C. 20460

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Re: Petition ID No. 001845: Toxic Substances Control Act Section 21 Petition Regarding N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (CASRN 793-24-8, aka 6PPD) in Tires - Final EPA Response to Petition

Dear Ms. Forsyth and Ms. O'Brien:

The U.S. Environmental Protection Agency received your petition dated August 1, 2023, submitted on behalf of the Yurok Tribe, the Port Gamble S'Klallam Tribe, and the Puyallup Tribe of Indians, requesting that the EPA "establish regulations prohibiting the manufacturing, processing, use, and distribution of N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine, CASRN 793-24-8, for and in tires under the EPA's TSCA Section 6(a) authority, 15 U.S.C. 2605(a), with such regulation to take effect as soon as practicable, in order to eliminate the unreasonable risk 6PPD in tires presents to the environment."

The EPA acknowledges that the Yurok, Port Gamble S'Klallam, and Puyallup Tribes are federally recognized Tribes with whom the EPA maintains a government-to-government relationship. The EPA recognizes that the Port Gamble S'Klallam Tribe is a signatory to the Treaty of Point No Point, while the Puyallup Tribe is a signatory of the Medicine Creek Treaty, and that under these treaties, the Port Gamble S'Klallam and Puyallup Tribes reserved the right to fish, hunt and gather. The EPA further acknowledges the importance of healthy and abundant salmon populations to these Tribes and to Tribal treaty rights.

This letter is to advise you that the EPA grants the petition. Specifically, the EPA plans to in the coming months: (a) commence a proceeding through issuance of an advance notice of proposed rulemaking for 6PPD under TSCA Section 6; and (b) initiate additional data gathering activities under TSCA to address data needed to understand and characterize risk associated with 6PPD-quinone and potential risks associated with 6PPD.

Statutory Requirements

TSCA Section 21(b)(1), 15 U.S.C. 2620(b)(1), requires that the petition "set forth the facts which it is claimed establish that it is necessary" to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). TSCA Section 21's "necessary" language implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, the EPA has reviewed this TSCA Section 21 petition by considering whether petitioners have established it is "necessary" to initiate 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.

TSCA prescribes the circumstances under which a TSCA Section 6(a) rulemaking may occur absent a TSCA Section 6(b)(4) risk evaluation. Thus, if a petitioner requests the initiation of a rulemaking under TSCA Section 6, the petitioner must establish that it is "necessary" for the agency to undertake a TSCA Section 6 rulemaking, and the relevant standard is found in TSCA Section 6(a), which specifies the Administrator must formally "determine" there is unreasonable risk before it may issue a rule under TSCA section 6. The purpose of the risk evaluation is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation identified as relevant by the Administrator. As part of this process, the EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA Section 6 to use the best available science, and ensure decisions are based on the weight-of-scientific-evidence. As part of this process, the EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA to use the best available science, and ensure decisions are based on the weight-of-scientific-evidence. 15 U.S.C. 2605(b)(4)(F); 15 U.S.C. 2625(h) and (i). A TSCA Section 21 citizen petitioner need only present facts demonstrating that a chemical substance poses an unreasonable risk due to one or more conditions of use, not all conditions of use. See *Food & Water Watch, Inc. v. EPA*, 291 F. Supp. 3d 1033, 1052 (N.D. Cal. 2017).

Under TSCA Section 6(a), if the EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the EPA conducts a rulemaking to apply one or more of TSCA Section 6(a) requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. In proposing and promulgating rules under TSCA Section 6(a), the EPA considers, among other things, the provisions of TSCA Sections 6(c)(2), 6(d), 6(g), and 9. In addition, to the extent that the EPA makes a decision based on science, TSCA Section

26(h) requires the EPA, in carrying out TSCA Sections 4, 5, and 6, to use "scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science," while also taking into account other considerations, including the relevance of information and any uncertainties. TSCA Section 26(i) requires that decisions under TSCA Sections 4, 5, and 6 be "based on the weight of scientific evidence." TSCA Section 26(k) requires that the EPA consider information that is reasonably available in carrying out TSCA Sections 4, 5, and 6.

Agency's Existing Commitment to Take Action on 6PPD

Notwithstanding the petition, the agency is firmly committed to fully protecting human health and the environment from adverse effects of exposure to 6PPD-quinone, a degradant of 6PPD. The EPA formed a cross-agency workgroup to facilitate inter-program office coordination for 6PPD-quinone in November 2022. This senior level workgroup is currently coordinating initiatives for addressing information gaps and commencing actions to address concerns regarding the use of 6PPD and adverse effects of the degradant 6PPD-quinone, including coordinating with external entities such as other federal agencies, Tribes, states, industry, and academia. Externally, the National Science and Technology Council's Joint Subcommittee on Environment, Innovation and Public Health offers the potential for cross-governmental coordinated research on human health effects. Further, EPA staff are actively involved with the Interstate Technology and Regulatory Council 6PPD-quinone workgroup, which has the goal of sharing information and coordinating among states and Tribal Nations. To learn more about how the EPA is addressing 6PPD and 6PPD-quinone, please see: *https://www.epa.gov/chemical-research/6ppd-quinone*.

The EPA's research activities to address these issues include planned studies in the Office of Research and Development's 2023-2026 research cycle, continued leveraging of the EPA Regional partnerships, and potential research collaborations with external entities. In the current ORD Strategic Research Action Plan (2023-26), there are multiple efforts which focus solely or in part on further investigation of 6PPD-quinone, including work on fate and transport, ecotoxicity, and green infrastructure solutions for stormwater contamination. Research activities include: Emission rates from motor vehicle brake and tire wear; ecological effects of tire wear particles and 6PPD-quinone on marine benthic communities; high-throughput hazard screening for 6PPD-quinone; development of metrics, models, and monitoring techniques to determine optimal green infrastructure placement and size for urban stormwater control; identification, assembly, and curation of toxicity data for ecologically relevant species for risk assessment (known as "ECOTOX"); and remediation of tire-related pollutants in stormwater.

ORD will continue leveraging EPA Regional partnerships to better understand the hazard of and potential exposure to 6PPD-quinone. Current ORD-Regional research collaborations include the following: Understanding airborne emissions and health impacts of 6PPD from tires conducted by EPA Region 3 and ORD; evaluating the bioactivity of the ubiquitous tire preservative 6PPD-quinone conducted by EPA Region 10 and ORD; fate, transport, and treatment of tire-derived pollutants in stormwater conducted by EPA Region 4 and ORD; and development of a rapid, low-cost bioassay to guide stormwater management and evaluate the potential toxicity of 6PPD alternatives conducted by EPA Region 10 and ORD.

In addition, EPA Region 10 has supported stormwater research via a federal interagency agreement with the U.S. Fish and Wildlife Service. EPA Region 10 also has funded state and academic research teams. Research publications resulting from EPA Region 10 funding contributions include: the seminal articles titled *A ubiquitous tire rubber-derived chemical induces acute morality in coho salmon* (Tian, et. al. 2021) that concluded mass pre-spawn mortality of coho salmon is linked to 6PPD-quinone found in stormwater runoff, and *Urban roadway runoff is lethal to juvenile coho, steelhead, and chinook salmonids, but not congeneric sockeye* (French et. al. 2022) that investigated additional salmonids. The EPA Region 10, through the Puget Sound Geographic Program, continues to fund relevant work on 6PPD and 6PPD-quinone, for example, via interagency agreements with the National Oceanic and Atmospheric Administration and the U.S. Geological Survey, and via cooperative agreement with the Washington Department of Ecology's Stormwater Strategic Initiative. Additionally, EPA Region 10 is working with the EPA's Office of Water to develop an analytical method for the detection of 6PPD-quinone as no standard method currently exists.

Summary of the Petition

The petition requests that the EPA promulgate a rule under TSCA Sections 6(a)(2)(A)(i) and 6(a)(5) to prohibit the manufacture, processing, use, and distribution of 6PPD in and for tires (Petition, pp. 1 and 16). The petition notes that 6PPD is present in "most if not all tires" and has been used in such products for more than six decades as an antioxidant and antiozonant to prevent tire degradation (Petition, pp. 1 and 6). The petition mentions that 6PPD is "highly reactive" by design, and can transform to the degradant 6PPD-quinone at the surface of a tire or when released into the environment (Petition, pp. 1 and 6). The petition describes the lethal effects for coho salmon exposed to 6PPD-quinone, as well as the presence of 6PPD-quinone in stormwater runoff and urban watersheds at levels "that can kill salmon, steelhead trout, and other aquatic organisms" (Petition, pp. 2 and 6). The petition also references the presence of 6PPD-quinone in "sediments and soils, road and household dust, and the urine of pregnant women, with emerging science pointing to toxicity in mammals and therefore potential risk to human health" (Petition, pp. 2 and 14).

EPA's Evaluation of the Petition

The petition, taken together with information reasonably available to the EPA, sets forth facts establishing that it is necessary to initiate a TSCA Section 6(a) rule to address risk to the environment from 6PPD-quinone, a degradant of 6PPD. The petitioners submitted sufficient evidence to show that 6PPD-quinone, a degradant of 6PPD, presents lethal hazards to coho salmon in the Pacific Northwest. This evidence supports a finding that 6PPD-quinone is acutely toxic to coho salmon at very low concentrations and additionally harms other fish species, with coho salmon being the most sensitive species studied to date. The petition also submitted evidence, in the form of measured exposure monitoring data, that there are exceedances of the LC_{50}, which is the concentration at which exposure results in mortality of 50 percent of animals in laboratory tests for coho salmon in the Pacific Northwest. Specifically, available information on 6PPD-quinone cited by petitioners indicates that concentrations in stormwater were found to be lethal for coho salmon following exposures that lasted only a few hours.

While the petition has shown that there is hazard from 6PPD-quinone, a degradant of 6PPD, and exposure to it, the petition alone does not demonstrate the facts which would establish that it is

necessary to issue a TSCA Section 6(a) rule. TSCA Section 26(h)-(i) require the EPA to evaluate and impose requirements under section 6 using the best available science and based on the weight of the scientific evidence. Thus, a risk determination consistent with the scientific standards required by TSCA Section 26 must contain sufficient scientific evidence and analysis.

However, the EPA in its discretion may consider all reasonably available information when evaluating a petition, and has done so in this instance. The agency has and is developing (or can readily develop) additional scientific information on 6PPD and its transformation products, including 6PPD-quinone. For example, OW and ORD have worked collaboratively to conduct comprehensive literature searches and screening of ecotoxicity data for 6PPD and 6PPD-quinone. The literature searches are conducted as part of regular updates to the agency's ECOTOX Knowledgebase, a publicly available resource providing single chemical environmental toxicity data on aquatic and terrestrial species. OW is also currently developing draft screening values for 6PPD-quinone and 6PPD to protect sensitive salmon and other aquatic life, and is evaluating data quality as part of this effort.

To increase certainty associated with the exposure data, it would be beneficial to have data showing 6PPD in tires is the primary source for 6PPD-quinone in stormwater and surface water in the Pacific Northwest. To do so, the agency would need to collect and assess data on other products and processes where 6PPD is found, like footwear, synthetic turf infill, and playgrounds, including the relative volume or mass of 6PPD used in each product type, and additional research on fate and transport of tire wear particles. However, taken together, the data that are currently reasonably available to the EPA suggest a link between 6PPD use in tires and the presence of 6PPD-quinone in urban streams in the Pacific Northwest and warrants granting the petition.

Additionally, in proposing and promulgating rules under TSCA Section 6(a), the EPA considers the provisions of TSCA Sections 6(c)(2), 6(d), 6(g), and 9. When deciding whether to prohibit or ban a use, as requested by petitioners, TSCA Section 6(c)(2)(C) requires EPA to "consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect." The petition merely suggests that a TSCA Section 6(a) ban would "spur the technological innovation needed to develop alternatives to 6PPD." Nevertheless, the agency has met with the California Department of Toxic Substances Control to better understand the California Safer Consumer Products regulation which requires manufacturers of motor vehicle tires for sale in California to evaluate safer alternatives to 6PPD. Under this regulation, domestic and foreign manufacturers of motor vehicle tires that contain 6PPD and whose products are placed into the stream of commerce in California must submit a Priority Product Notification for those products by November 2023. Thereafter, manufacturers have the option to submit by March 2024 one of several notifications related to removal/replacement of or alternatives to 6PPD in products. The agency also met with the Washington Department of Ecology regarding similar efforts to assess 6PPD in products and the environment, including a cross-agency 6PPD Action Plan, a hazards assessment, an alternatives assessment, and the inclusion of 6PPD in the most recent five-year cycle to of the Safer Products for Washington program. EPA intends to coordinate its own efforts to develop information on alternatives to 6PPD with federal agencies, states, Tribes, industry, and academia, who are already engaged in this arena, including the aforementioned ITRC.

Expected Actions on 6PPD under TSCA

While the agency will promptly commence an appropriate proceeding under TSCA Section 6(a), the agency cannot commit to a specific rulemaking timeframe or outcome. The statute does not dictate the precise timing of any the agency actions and the EPA will decide on the details and scheduling during subsequent stages of the proceeding. The EPA also retains discretion to determine the content of any regulation that may be issued subsequent to a grant of the petition, which need not conform precisely to the petitioner's requested action(s). The agency intends to publish by Fall 2024 an ANPRM for 6PPD under TSCA Section 6(a) associated with risk management of 6PPD and 6PPD-quinone.

Currently, there are limited data to inform a human health risk assessment for 6PPD-quinone. The agency is committed to working with federal partners on coordinated research on human health effects. The EPA plans to utilize other TSCA authorities to collect data to understand and characterize risk associated with 6PPD-quinone and potential risks associated with 6PPD. Such actions will build on efforts underway among governments (e.g., federal, Tribal, and state), non-governmental organizations, academia, and industry, to ensure that any risk associated with 6PPD-quinone, and any potential risks associated with 6PPD are appropriately evaluated and managed. For example, the EPA intends to pursue a rulemaking under TSCA Section 8(d) to require persons who manufacture (including import) 6PPD to submit certain lists and copies of available unpublished health and safety studies conducted or initiated by, known to, or reasonably ascertainable by such manufacturers (including importers). The EPA aims to finalize the rule before 2025 with required reporting to occur 90 days after publication. Based on the information received through this reporting, the agency, as necessary, would consider requiring by rule(s), order(s), or consent agreement(s) the development of new information related to 6PPD pursuant to TSCA Section 4. Such information will serve to inform the EPA's subsequent decisions on how to proceed with any evaluation and any necessary mitigation of risks associated with 6PPD and its degradant 6PPD-quinone under TSCA.

The EPA appreciates Tribal leadership on the 6PPD-quinone issue, and is committed to considering the interests (including treaty reserved rights) of the Tribal governments described in the petition. The agency intends to offer consultation to federally recognized Tribal governments in accordance with the EPA Policy on Consultation and Coordination with Indian Tribes.

Thank you for you continued interest in reducing exposure to 6PPD and 6PPD-quinone. If you have any questions relating to your petition or the EPA's guidelines for TSCA section 21 petitions, feel free to contact Thomas Groeneveld of my staff at (202) 566-1188 or *groeneveld.thomas@epa.gov.*

Sincerely,

MICHAL FREEDHOFF

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Michal Freedhoff