safety, marine or other environmental resources, and access to ports.

2. Does the recommended Portland Eastern Approach Fairway provide a safe and efficient route for vessels transiting to and from the Eastern Approach TSS? Why or why not? If not, what would you recommend instead?

3. Would the recommended Portland Eastern Approach Fairway have any positive or negative environmental impacts?

4. Would the recommended Portland Eastern Approach Fairway have any positive or negative tribal impacts?

C. Gulf of Maine Fairway

The Coast Guard is proposing a Gulf of Maine Fairway to meet the needs of vessel traffic primarily proceeding between Boston, Massachusetts, and the Bay of Fundy. The Coast Guard may consider design alternatives to the recommended Gulf of Maine Fairway to ensure safe transit for vessels, while providing ocean space for wind energy leasing.

1. Are there any positive or negative economic impacts from the recommended Gulf of Maine Fairway?

2. Is the recommended Gulf of Maine Fairway necessary to provide safe and efficient routes for vessels transiting to and from domestic and international ports? Why or why not? If not, what would you recommend instead?

3. What are the positive or negative vessel transit impacts to altering the recommended fairway's design, location, and characteristics, such as narrower width and change in cardinal direction? Please explain your answer, including specific comments on how any changes to this recommended fairway would affect maritime traffic patterns, navigational safety, marine or other environmental resources, and access to ports.

4. What other offshore uses may be positively or negatively impacted by alteration to this recommended fairway design, location, and characteristics, such as narrower width and change in cardinal direction? Please include specific locations, potential impact, and associated costs or benefits. Please also describe the safety significance of alterations to this recommended fairway on other offshore use activity.

5. If this fairway is established as recommended, what persons, entities, or organizations would be positively or negatively impacted? In other words, which groups of people, businesses, or industries (maritime and non-maritime) would be positively or negatively impacted by this recommended fairway?

6. Would the recommended Gulf of Maine Fairway have any positive or negative environmental impacts?

7. Would the recommended Gulf of Maine Fairway have any positive or negative tribal impacts?

Linda L. Fagan,

Admiral, U.S. Coast Guard, Commandant.

[FR Doc. 2024–26830 Filed 11–18–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2024–0403; FRL–11628–01–OCSPP]

RIN 2070–AL16

N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine (6PPD) and its Transformation Product, 6PPD-quinone; Regulatory Investigation Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: In granting a petition filed under the Toxic Substances Control Act (TSCA) by Earthjustice on behalf of the Yurok Tribe, the Port Gamble S'Klallam Tribe, and the Puyallup Tribe of Indians, the Environmental Protection Agency (EPA or Agency) committed to pursuing an action to solicit and collect information from the public on the potential risks associated with N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine (6PPD) (CASRN 793–24–8, DTXSID 9025114) and its transformation product, 6PPD-quinone (CASRN 2754428–18–5, DTXSID 301034849). With this document, EPA is soliciting that information, along with information about potential alternatives and regulatory options to help inform the Agency's consideration of potential future regulatory actions under TSCA.

DATES: Comments must be received on or before January 21, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2024–0403, through *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information: Wyn Zenni, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 565–6294; email address: *zenni.wyn@epa.gov.*

For general information on TSCA: The TSCA Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import), process (including recycling), distribute in commerce, dispose of, or use 6PPD and/or 6PPD-quinone. The following list of North American Industry Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- 325130 Synthetic Dye and Pigment Manufacturing;
- 325199 All Other Basic Organic Chemical Manufacturing ;
- 325212 Synthetic Rubber Manufacturing;
- 325998 All Other Miscellaneous Chemical Product and Preparation Manufacturing;
- 326211 Tire Manufacturing (Except Retreading);
- 326291 Rubber Product Manufacturing for Mechanical Use;
- 336999 All Other Transportation Equipment Manufacturing; and
- 424690 Other Chemical and Allied Products Merchant Wholesalers.

If you have any questions regarding the applicability of this action to you, please consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

This action is being taken under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*

TSCA section 21 allows any person to petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under

TSCA sections 4, 6, or 8 or an order under TSCA sections 4, 5(e) or (f). If EPA grants the petition, the Agency must promptly commence an appropriate proceeding.

Under TSCA section 6(a), if EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance presents an unreasonable risk to human health or the environment, it must ''apply one or more of the [TSCA section 6(a)] requirements . . . to the extent necessary so that the chemical substance . . . no longer presents such risk,'' which may range from prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of the chemical substance (or a particular use), to commercial use requirements or disposal restrictions, to labeling and recordkeeping.

C. What action is the Agency taking?

EPA is seeking public comment on all of the information included in and referenced by this ANPRM. EPA also seeks any additional information relevant to 6PPD, 6PPD-quinone, and potential 6PPD substitutes that could help inform potential future rulemakings. Topics in this ANPRM include but are not limited to: Information on the chemicals' environmental effects on aquatic and terrestrial ecosystems, potential human health effects, environmental fate and transport, exposure pathways, persistence and bioaccumulation, additional uses of 6PPD, and releases from consumer products (*e.g.,* sneakers, playgrounds, rubber-modified asphalt, reused tire or other rubber products, etc). EPA is also seeking comment and information related to alternatives to 6PPD, as well as potential chemical transformation products associated with potential alternatives.

When submitting information, the Agency is interested in receiving quantitative information, data and/or case examples, including peer-reviewed studies, statistical analyses, and industry, scientific, or technical reports describing datasets or syntheses of environmental or human health impacts of 6PPD, 6PPD-quinone, or potential alternatives for 6PPD.

D. What are the incremental costs and benefits of this action?

This action does not propose or impose any requirements, and instead seeks comments and suggestions that will help inform the Agency's consideration of potential future actions for 6PPD and/or 6PPD-quinone. As such, there are no incremental costs or benefits associated with this ANPRM. Should the Agency pursue a rulemaking in the future, EPA will conduct the appropriate assessments of the potential costs and benefits associated with the proposed action.

E. What should I consider as I prepare my comments for EPA?

1. Submitting CBI

Do not submit CBI to EPA through *https://www.regulations.gov* or email. If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703.

2. Tips for Preparing Your Comments

When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.html.*

II. Background

A. What was requested in the TSCA section 21 petition for 6PPD?

On August 1, 2023, Earthjustice, on behalf of the Yurok Tribe, the Port Gamble S'Klallam Tribe, and the Puyallup Tribe of Indians, filed a TSCA section 21 petition requesting that EPA establish regulations prohibiting the manufacturing, processing, use, and distribution of 6PPD (CASRN 793–24–8, DTXSID 9025114) in and for tires under EPA's TSCA section 6(a) authority, 15 U.S.C. 2605(a). The petitioners requested that such regulation take effect as soon as practicable to eliminate the unreasonable risk 6PPD in tires presents to the environment (Ref. 1).

In the petition, concerns were raised that the chemical 6PPD, which has been used in tires since the 1960s to prevent tire degradation (Ref. 2), poses unreasonable risk to the environment due to the acute toxicity of its transformation product, 6PPD-quinone (CASRN 2754428–18–5, DTXSID 301034849), to coho salmon *(Oncorhynchus kisutch)* and other fish species. The petition described that the presence of 6PPD-quinone in stormwater runoff and urban watersheds are at levels that can kill coho salmon *(O. kisutch)*, steelhead trout *(Oncorhynchus mykiss)*, and other aquatic organisms. The petition also referenced the presence of 6PPD-quinone in sediments and soils, road and household dust, and the urine of pregnant women, with emerging science pointing to potential risks to human health and to a larger extent, toxicity in mammals (Ref. 1).

On November 2, 2023, EPA granted the petition, stating that the petition, along with information reasonably available to EPA, set forth facts establishing that it was appropriate to initiate a TSCA section 6(a) proceeding to address risks to the environment from 6PPD and its transformation product, 6PPD-quinone (Ref. 3 [3]). Specifically, EPA committed to: (a) Issuing an ANPRM for 6PPD and 6PPD-quinone under TSCA section 6(a) by fall 2024; and (b) Finalizing a TSCA section 8(d) rulemaking by the end of 2024 that would require persons who manufacture (including import) 6PPD to submit lists or copies of unpublished health and safety studies to EPA. With this action, the Agency has promptly commenced an appropriate proceeding. The expected information resulting from this action will inform the Agency's consideration of future potential action though, as noted in the petition response, EPA cannot commit to a specific timeframe or outcome (Ref. 3).

B. What is 6PPD?

1. Physical and Chemical Use Properties

6PPD is the organic compound N-(1,3-dimethylbutyl)-N′-phenyl-p-phenylenediamine (CASRN 793–24–8, DTXSID 9025114), which is added to tires and other rubber products to prevent degradation. As a solid, 6PPD is dark brown with violet flakes and is generally sold as pellets, pastilles, or in liquid form (Refs. 4 and 5). 6PPD can diffuse easily to the surface of a rubber product and quickly react with ozone (O_3) to protect the rubber polymers from oxidation (Ref. 5). This chain of events occurs quickly enough to effectively protect the rubber but slowly enough to last for the lifetime of the product, which has made 6PPD a useful antidegradant for use in rubber products (Ref. 6).

2. 6PPD's Use in Tires

6PPD has been used globally since the 1960s as an antidegradant and antiozonant to prevent automobile tire degradation caused by exposure to ozone, oxygen, and temperature fluctuations (Refs. 2 and 7). By continuously migrating to the surface of the tire to fill microcracks and react with oxygen and ambient ozone in the environment, 6PPD protects the tire's rubber polymers from becoming brittle and cracked over time (Ref. 4). In doing so, 6PPD increases tire longevity, safety, and performance due to its ability to protect tires from premature degradation (Ref. 4).

Products that use recycled tire crumbs or pieces such as rubber-modified asphalt, playgrounds (rubber mulch), artificial turf, and sneakers may also contain 6PPD (Refs. 8 and 9).

3. 6PPD's Use in Other Products

6PPD is also used as an additive in other rubber goods (*e.g.,* conveyor and transmission belts, hoses, and gaskets), other automotive parts (*e.g.,* engine mounts, grommets, bushings, and seals), polymers, lubricants, dyes, and other house-hold or recycled rubber products (Refs. 4, 10, and 11). Little information on the release of 6PPD and/or 6PPD-quinone from these non-tire products currently exists.

4. Environmental Fate and Transport of 6PPD

Although more information is needed on the environmental fate and transport of 6PPD, one source of 6PPD in the environment occurs through the release of tire wear particles (TWP) from tires containing 6PPD (Refs. 12, 13, 14, and 15). Though limited data suggest 6PPD has a short half-life (hours to several days) in aqueous solutions (Ref. 16), TWP are continuously being emitted into the environment, especially as cars brake, accelerate, or turn (Refs. 17, 18, and 19). It is believed that TWP reach soils and aquatic media close to roadways, with a small fraction emitted into the atmosphere or sorbed to sediments (Refs. 4 and 19). During rainfall events, TWP can be mobilized from roads and road dust into nearby waterbodies (Ref. 20). For example, one study in Denmark investigating the annual TWP generated in a local road network and released into the aquatic environment found that 8–40 percent of the TWP from the roads reached surface waters after storm events depending on the stormwater treatment system (Ref. 21).

Once TWP containing 6PPD enter the environment, it is hypothesized that the environmental transformation of 6PPD primarily occurs through hydrolysis (water breaking down chemical bonds) or by reaction with oxygen and ozone and photodegradation from exposure to sunlight and air (Ref. 4). The more frequent detection of 6PPD in extractions from TWP but not road runoff suggests that these reactions occur on the surface of the tire or road and/or that 6PPD rapidly transforms once released from the tire (Ref. 4). However, fully understanding these processes since 6PPD is such a reactive compound remains an information gap.

Abiotic degradation of 6PPD occurs in water and the atmosphere. In water, 6PPD is highly reactive and can be affected by the water's pH, temperature, available sunlight, and other constituents in water such as metals (Ref. 4). Reported half-lives in water have ranged between 3.4 hours to less than a day, with warmer waters containing more heavy metals leading to a shorter half-life of 6PPD (Refs. 4 and 16). In the atmosphere, 6PPD can degrade quickly via indirect photodegradation, with a half-life in air between 1–2 hours, further limiting the gas phase dispersal of the unreacted chemical (Ref. 22). Direct entry into the environment in the gas phase is likely limited given the low vapor pressure of 6PPD (Ref. 22).

As for 6PPD's degradation in sediments, very little is known. Initial indications suggest that 6PPD is likely to adsorb to organic matter such as soil, sediments, and suspended particulate matter once released into the environment. This suggests that it may persist in aquatic and terrestrial sediments unless it undergoes photodegradation and hydrolysis through resuspension (Ref. 4). There are no available data on how 6PPD adheres to and binds to soil under different environmental conditions, but leaching of 6PPD through soil to groundwater is anticipated to be unlikely (Ref. 4). EPA's Estimation Program Interface (EPI) Suite estimates 6PPD's half-life to be 75 days in soil with photodegradation likely being the main process in which it is lost in surface soils (Refs. 4 and 23).

5. 6PPD's Transformation Products

Both in tires and in TWP, 6PPD reacts at the rubber's surface with ambient ozone (O_3) and possibly secondary O_3-related oxidants (*e.g.,* OH-). 6PPD has less reactivity with molecular oxygen (O_2) and other ambient air constituents (Refs. 18 and 22). 6PPD's high reactivity with ozone triggers chemical reactions, resulting in the formation of transformation products (TPs) as the chemical undergoes structural changes and/or the formation of degradants as the chemical breaks down into smaller molecules (Refs. 18 and 24). The resulting transformation products can be more or less mobile and more or less toxic in the environment than their parent compound, with 6PPD-quinone generally being more toxic to fish, more stable, and more mobile than 6PPD according to available data (Refs. 18, 25, and 24). Studies have identified 25–38 ozonation transformation products for 6PPD that form depending on the environmental conditions, but more research on the hazard traits and behaviors of these transformation products is needed as data are still insufficient (Refs. 18 and 26). One recent study identified four of 6PPD's most abundant transformation products, including 6PPD-quinone, as the most environmentally relevant because they were observed in roadway runoff, indicating that they may be ubiquitous contaminants in roadway-impacted environments and need further investigation (Ref. 26).

C. What is 6PPD-quinone?

1. Physical and Chemical Properties

One of 6PPD's transformation products is 6PPD-quinone, or 2-anilino-5-(4-methylpentan-2-ylamino) cyclohexa-2,5-diene-1,4-dione (CASRN 2754428–18–5, DTXSID 301034849). Due to 6PPD's highly reactive nature, it is thought that 6PPD is continually reacting with ozone at the surface of tires to form 6PPD-quinone (Refs. 6 and 27). As 6PPD-quinone forms on the surface of the tire, it adds to the protective film that 6PPD naturally creates, providing further protection from cracking of the tire rubber (Refs. 6, 27, and 28). However, this also means that 6PPD-quinone and 6PPD are likely present in most TWP that are common in the environment (Refs. 12, 29, and 30).

2. Environmental Fate and Transport

There are currently little data available to describe the environmental fate and transport of 6PPD-quinone, but data from several monitoring studies suggest that it persists longer in the environment than 6PPD (Ref. 31). One study found that 6PPD-quinone had a half-life of 33 hours in dechlorinated tap water compared to 5 hours for 6PPD (Ref. 16). The longer persistence of 6PPD-quinone in water indicates more potential exposure time to induce toxic effects in aquatic life (Ref. 16). Another study found that leachate from TWP remained toxic after exposure to extreme heat (80 °C) for 72 hours, suggesting that 6PPD-quinone is stable under extreme heat conditions (Ref. 32). It is also likely that the polar carbonyl groups (added oxygen atoms from oxidation) may make 6PPD-quinone more mobile in the environment than 6PPD (Ref. 33).

D. What are the ecological effects caused by 6PPD and 6PPD-quinone?

1. Aquatic Ecosystem Effects

The number of studies on 6PPD and/or 6PPD-quinone's impacts on aquatic ecosystems has increased since 6PPD-quinone from TWPs was identified in 2020 as the likely causative agent for urban runoff mortality syndrome (URMS) (Ref. 32). URMS has been occurring in the Pacific Northwest at least since it was first reported between 1999–2001, and refers to the death of adult fish (particularly coho salmon) that return to urban waterways to spawn (Refs. 32 and 34). However, much is still unknown about the chemicals' effects on aquatic life generally. As of December 2023, there were 16 available studies on the hazard effects of 6PPD on aquatic species and 26 available studies on the hazard effects of 6PPD-quinone that were identified by and included in the EPA's ECOTOX Knowledgebase (Ref. 35). Those studies along with additional online publications (as of July 2024) have primarily evaluated 6PPD-quinone's acute mortality impacts on aquatic species (*i.e.,* lethal concentration (LC) values) due to its higher reported toxicity, with the majority focusing on fish species, compared to aquatic invertebrates and plant species.

For the hazard effects of 6PPD on aquatic species, there are acute toxicity data for nine freshwater species as of December 2023. The following acute toxicity data includes both the author-reported mortality values (LC_{50}) and the EPA-adjusted values (if needed) to account for observed chemical loss in studies that only measured exposure concentrations at the beginning of the study or not at all (Ref. 36). Of the nine studied species, Medaka (*Oryzias latipes*) (author-reported LC_{50} of 28 μg/L after 96 hours of exposure), rare minnows (*Gobiocypris rarus*) (author-reported LC_{50} of 162 μg/L after 96 hours of exposure; EPA-adjusted LC_{50} of 94.94 μg/L), coho salmon (*Oncorhynchus kisutch*) (author-reported juvenile LC_{50} of 251 μg/L after 24 hours of exposure; EPA-adjusted LC_{50} of 143.7 μg/L), and amphipods (*Hyalella azteca*) (author-reported juvenile LC_{50} of 250 μg/L after 96 hours of exposure; EPA-adjusted LC_{50} of 159.7 μg/L) were the most sensitive aquatic species to acute 6PPD exposure (Refs. 16, 37, 38, 39, and 40). As for 6PPD's chronic effects on aquatic species, data are available for only two aquatic species: Medaka (*Oryzias*) (author-reported lowest observed effect concentration (LOEC) of 11 μg/L after an early-life stage test of unknown duration) and fathead minnows (*Pimephales*) (author-reported LC_{50} of 150 μg/L after 28 days of exposure) (Refs. 37 and 41). Although additional research on the chronic effects of 6PPD will be important, acute toxicity is expected to be a more important driver for aquatic risk compared to chronic toxicity given the quick degradation of 6PPD. In addition, studies on 6PPD's effects on estuarine and marine species, as well as algae and vascular plants, are extremely limited.

For the hazard effects of 6PPD-quinone on aquatic species, coho salmon (*O. kisutch*) are the most sensitive species to acute 6PPD-quinone exposure identified to date, with an author-reported lethal concentration (LC_{50}; the concentration that is lethal to 50 percent of tested organisms) value of 0.041 μg/L for juveniles in less than 24 hours (EPA-adjusted LC_{50} of 0.036 μg/L) (Refs. 42 and 43) and up to 0.095 μg/L for adults after 24 hours (EPA-adjusted LC_{50} of 0.092 μg/L) (Refs. 43 and 44), indicating potential age-related differences in sensitivity. Other identified fish species that are acutely sensitive to 6PPD-quinone include: lake trout (*Salvelinus namaycush*) (LC_{50} of 0.5 μg/L after 24 hours of exposure; EPA-adjusted LC_{50} of 0.5186 μg/L) (Ref. 45), white-spotted char (*Salvelinus leucomaenis pluvius*) (<1 year juvenile LC_{50} of 0.80 μg/L after 24 hours; EPA-adjusted LC_{50} of 0.5709 μg/L) (Refs. 43 and 46), brook trout (*Salvelinus fontinalis*) (~1 year juvenile LC_{50} of 0.59 μg/L after 24 hours) (Ref. 47), rainbow trout (*Oncorhynchus mykiss*) (~2 month juvenile LC_{50} of 0.64 μg/L; EPA-adjusted LC_{50} of 0.2961 μg/L) (~2 year juvenile LC_{50} of 1.00 μg/L after 96 hours) (Refs. 38, 43, and 47), and chinook salmon (*Oncorhynchus tshawytscha*) (582-day old LC_{50} of 82.1 μg/L after 24 hours; EPA-adjusted LC_{50} of 65.68 μg/L) (Refs. 43 and 48).

These LC_{50} values for both chemicals were also used to support EPA's published screening values for acute 6PPD and 6PPD-quinone exposure for freshwater fish species (published June 2024) which are 8.9 and 0.011 μg/L, respectively (Refs. 36 and 43). EPA's acute screening values (published under Clean Water Act Section 304(a)(2)) are the maximum concentrations of 6PPD and 6PPD-quinone (not in mixtures) with associated frequency and duration specifications that are expected to support protection of aquatic life from acute effects in freshwaters based on currently available scientific data (Refs. 36 and 43*).* For comparison, one study that measured the concentration of 6PPD-quinone in roadway runoff, stormwater-affected creeks, and watersheds throughout the U.S. west coast found a widespread occurrence of 6PPD-quinone at concentrations ranging from 0.3–19 μg/L following storm events, which exceeds EPA's published acute screening value for 6PPD-quinone (Refs. 32 and 43). Overall, although there is available information on the acute LC_{50} values and impacts on multiple fish species, more studies identifying the concentrations of 6PPD and 6PPD-quinone measured in U.S. waterbodies, the sublethal and chronic effects of 6PPD and 6PPD-quinone exposure, and additional toxicity data on other aquatic species are important.

Studies have also identified that certain fish species appear to be significantly more sensitive to 6PPD-quinone exposure than other species. For example, studies show that coho, steelhead, and chinook salmon are sensitive to 6PPD-quinone exposure; however, sockeye and chum salmon lacked a similar response and were not significantly affected by 6PPD-quinone (Refs. 12 and 49). The modes of action driving the large variation in the toxicity of 6PPD-quinone across species remains unknown, but one study suggests that a tissue-specific disruption of mitochondrial respiration is involved. Increased ventilation and gasping of sensitive species (coho salmon, brook trout, rainbow trout) was observed after exposure, suggesting that 6PPD-quinone exposure (5–80 μg/L) impacts cellular respiration and the oxygen consumption rate (Ref. 50). Another study found that the large increases in hematocrit commonly associated with coho salmon mortality after being exposed to roadway runoff could be due to a disruption in the blood-brain barrier since plasma leakage from the cerebrovasculature was observed (Ref. 51). This early research indicates that neurologic, metabolic, and mitochondrial disruption may be involved (Refs. 50, 51, and 52), but more research and tests are needed to confirm the specific modes of action for 6PPD-quinone and why it is acutely toxic to certain species. The mode of action driving 6PPD's toxicity may be different from 6PPD-quinone's, as 6PPD is toxic to many tested aquatic organisms but never reaches the high toxicity exerted by 6PPD-quinone to selected species.

Further, although EPA's published acute screening values for 6PPD and 6PPD-quinone in freshwater provided critical concentrations for protecting aquatic life from the two chemicals, the reports suggest that additional research will be important to fully characterize the toxicity of 6PPD-quinone and other key transformation products and degradants of 6PPD to aquatic life (Refs. 36 and 43). For example, the reports indicated that additional research that includes analytical confirmation of 6PPD-quinone is needed, as some of the available studies lacked analytical measurements of 6PPD-quinone at the end of the tests, which is important given the uncertainty of 6PPD-quinone's fate in lab water. In addition, the screening value reports noted that most of the available aquatic species' tests on acute toxicity were run for only 24 hours (standard test duration for acute toxicity tests are 96 hours) and occasionally in overcrowded fish tanks (Refs. 36 and 43).

For these reasons, additional acute and chronic toxicity studies that include full analytical measurements at appropriate intervals across the study duration that are conducted using standard toxicity test guidelines would be useful. Additionally, the completion of tests on a broader range of aquatic taxa would provide a broader understanding of how these chemicals are impacting fish and other aquatic species (Refs. 36 and 43).

2. Terrestrial Ecosystem Effects

There are very limited data publicly available on how 6PPD and/or 6PPD-quinone may impact terrestrial ecosystems. As of December 2023, there was one available terrestrial study on the hazard effects of 6PPD on chicken embryos (*Gallus gallus*) and five available studies on the hazard effects of 6PPD-quinone on nematodes (*Caenorhabditis elegans*) and springtails (*Folsomia candida*) that passed EPA's ECOTOX screening. (Ref. 35).

In the one terrestrial study focused on the hazard effects of 6PPD, 3-day old chicken embryos were exposed to 80 different rubber tire chemicals in either acetone or water (Ref. 53). Exposure to 6PPD resulted in deaths and malformations (EC50 of 1.5 umol 11 days post-exposure), but the authors reported an incomplete, irregular or flat dose-response curve for early death and malformations (Ref. 53). Given the incomplete dose-response characterization, more information on avian species and other terrestrial organisms will be important to further characterize the potential hazard effects of 6PPD.

Of the five other studies on the hazard effects of 6PPD-quinone on terrestrial organisms, four studies investigated the chronic effects of 6PPD-quinone exposure on nematodes (an invertebrate). One study on nematodes found that prolonged exposure to 6PPD-quinone at 1–10 μg/L shortened lifespan by up to 27.4 percent due to insulin signaling pathway dysfunction, decreased the amount of fertilized eggs due to DNA and signaling pathway damage, and decreased pharyngeal pumping and locomotion behavior (Ref. 54). Another study by the same authors found that after exposing nematodes to environmentally relevant concentrations of 6PPD-quinone (0.1–100 μg/L) for 4.5 days (from the larval to adult stage), several forms of abnormal locomotion behavior and neurodegeneration was observed, with exposure to 100 μg/L causing 5 percent lethality (Ref. 55). A similar study on nematodes found that 6PPD-quinone exposure negatively affected their digestive systems and lipid metabolism, with evidence of lipid accumulation and fatty acid deposition (Ref. 56) and that plastic nanoparticles in the environment enhanced the neurotoxicity and accumulation of 6PPD-quinone in nematodes (Ref. 57). In springtails, a soil organism, one study found that 6PPD-quinone exposure impaired the survival of the organisms, with a LC_{50} of 16.31 μg/kg after 28 days of exposure (Ref. 58). The studies meeting inclusion requirements for the EPA's ECOTOX knowledgebase primarily focus on the impacts of 6PPD-quinone on invertebrates such as nematodes and springtails; however, published data in rodents that are commonly used to inform human health hazards and are summarized in Unit II.E.2 may also be informative of the ecological effects on mammalian species (Ref. 35). Overall, the limited studies available indicate that prolonged exposure to environmentally relevant concentrations of 6PPD-quinone induces a multisystem toxic response, including neurotoxicity, reproductive risks, intestinal damage, and dysfunctions in lipid metabolism with bioaccumulation concerns in at least terrestrial invertebrates (Refs. 54, 55, and 57). However, more studies on the effects of 6PPD and/or 6PPD-quinone on terrestrial organisms and ecosystems would provide a more comprehensive understanding of the impacts of these chemicals across the environment.

E. What are the potential exposures to and human health effects of 6PPD and 6PPD-quinone?

There are limited data on the exposure pathways of 6PPD and 6PPD-quinone, however several recent studies in Asia have predicted potential exposure through dust inhalation and ingestion. For example, one study in Hangzhou, China measured 6PPD and 6PPD-quinone levels in indoor dust and estimated the daily intake of 6PPD and 6PPD-quinone for children based on expected ingestion and inhalation rates for indoor dust (Ref. 59). The study found 6PPD and 6PPD-quinone to be the predominant phenylene diamine (PPD) and PPD-q in indoor dust and that children, especially infants, were potentially ingesting 6PPD and 6PPD-quinone through indoor dust based on the measured concentrations and daily intake estimations (Ref. 59). A similar study measured 6PPD-quinone levels in outdoor dust near roads, homes, and kindergartens in Guiyu, an e-waste-exposed area, and in Haojiang, a reference area, from 2019–2021 (Ref. 60). The study found that 6PPD-quinone levels were significantly higher in home and kindergarten classroom dust within the e-waste-exposed area compared to the reference area, indicating that dust may be an exposure pathway for humans and that e-waste may be another potential source of 6PPD-quinone in the environment (Ref. 60). Using the measured concentrations of 6PPD-quinone in dust, the study also estimated that higher daily intakes of 6PPD-quinone from kindergarten classroom dust could be associated with lower body mass indexes and higher incidences of influenza and diarrhea in kindergarten children, although these data are potentially confounded by other environmental stressors and chemicals that may be found within e-waste-exposed areas (Ref. 60). Another study in Hong Kong that measured the environmental occurrence of 6PPD and 6PPD-quinone in road dust to estimate potential pathways of human exposure found that exposure levels for contaminated road dust were higher for 6PPD-quinone than for 6PPD (Ref. 61).

Although these studies were primarily done in Asia and under unique exposure scenarios (*i.e.,* near an e-waste recycling facility), these studies indicate environmental occurrence of 6PPD and 6PPD-quinone in indoor and outdoor dust, suggesting that human exposure to 6PPD and 6PPD-quinone is plausible and may be occurring through dust ingestion, inhalation, and dermal absorption, with potential effects on body mass index (Refs. 7, 59, 60, and 61).

A limited number of biomonitoring studies in Asia identified 6PPD-quinone in human samples, some of which also monitored for 6PPD. However, it is important to note that many of these studies had a small sample size. In one study, after 6PPD-quinone levels were recorded in the cerebrospinal fluid (CSF) of 13 patients with Parkinson's disease (PD) and 11 control participants, researchers found that 6PPD-quinone levels were twice as high in PD patients compared to controls and confirmed through immunostaining assays that 6PPD-quinone at environmentally relevant concentrations exacerbated the formation of Lewy neurites and impaired mitochondrial activity (Ref. 62). Four other studies detecting PPDs and PPD-qs in human urine and blood found that the median concentrations of 6PPD and 6PPD-quinone were significantly higher than other PPD and PPD-qs measured in the study, especially in pregnant women and people with liver disease which may indicate lipid oxidative damage (Refs. 7, 63, 64, and 65). Additional biomonitoring studies with larger sample sizes and in different locations are needed since factors influencing exposures can vary by region and be influenced by other environmental stressors.

Although there are limited data available on the potential human health effects of 6PPD and/or 6PPD-quinone, the health effects of 6PPD are better characterized than 6PPD-quinone in the scientific literature (Refs. 4, 25, and 66). 6PPD is a known skin-sensitizer that can lead to contact dermatitis in sensitized individuals and is listed as a category 1B reproductive toxicant by the European Chemicals Agency (Ref. 67).

Preliminary toxicity studies in rodents may also inform human health effects. For example, one study found that 6PPD and 6PPD-quinone bioaccumulate in the liver, with higher doses of both chemicals potentially causing an inflammatory response, altered hepatic metabolism, and hepatotoxicity in mice (Ref. 62) while another study identified that repeated exposure over 4 weeks to 6PPD-quinone (4 mg/kg) caused multiple organ injury in male BALB mice (Ref. 68). These early mammalian toxicity studies indicate that repeated exposure to 6PPD and 6PPD-quinone may affect organ function, metabolism, bioaccumulation, and inflammation in humans, but more studies are needed on 6PPD and 6PPD-quinone's impacts on human health.

As for bioaccumulation potential, one study found that when lettuce plants were exposed to TWP-derived 6PPD and 6PPD-quinone (among other TWP compounds) in hydroponic solutions over 14 days in a lab, the chemicals were taken up and metabolized by the lettuce with concentrations of 6PPD and 6PPD-quinone found in the plant's roots, leaves, and nutrient solution (Ref. 69). Other limited studies that reported bioaccumulative potential of 6PPD-quinone in aquatic species predicted that although there is potential for uptake, the data suggests that 6PPD-quinone does not significantly accumulate in fish tissues and instead metabolizes rapidly *in vivo* (Refs. 38 and 70). Further, the predicted bioconcentration factors (BCF) for 6PPD and 6PPD-quinone are currently below 1,000, suggesting a low to moderate bioaccumulative potential based on EPA policy, which identifies chemicals with BCFs above 1,000 as bioaccumulative (Refs. 4, 38, 70, and 71). That said, additional data and field studies are needed on the potential for bioaccumulation in plant and animal species as well as on the potential for 6PPD to metabolize to 6PPD-quinone within humans.

Overall, more research on the effects, characteristics, relevant exposure pathways, and dose-response data are needed to identify the potential human health impacts from exposure to 6PPD and 6PPD-quinone. This is of particular importance for pregnant women and children, communities and workers near roadways, people with existing medical conditions, populations that participate in subsistence activities (*i.e.,* fishing, hunting), and communities with environmental justice concerns.

F. What are the potential impacts on Tribal Nations?

In their petition, the Yurok Tribe, the Port Gamble S'Klallam Tribe, and the Puyallup Tribe of Indians present many potential impacts of 6PPD's transformation product, 6PPD-quinone, on their resources. They explain that their health, wellbeing, and culture are intimately connected to the health of their waters and ecosystems. The petition states that many Tribes share an important connection with their waterbodies, rendering them culturally significant and protected resources. The petitioners, along with additional Tribes that EPA engaged with related to this action, all emphasized that thriving shellfish and abundant salmonids are essential for their subsistence, cultural, and economic lifeways and has been one of their most important resources since time immemorial (Refs.1, 72, and 73).

The petition further explains that ''exposure to 6PPD-q[uinone] can kill a coho salmon within hours, and the chemical is responsible for 'urban runoff mortality syndrome,' which kills up to 100% of coho returning to spawn in urban streams'' (Refs. 1 and 32). Petitioners state that the decline of coho salmon has negatively impacted their access to commercial fishing income, food security, health, and wellbeing and has affected their ability to pass on traditional ceremonial and ecological knowledge to future generations. Decreased fish populations and diminished water quality have also meant a loss of cultural identity and have led to increased reliance on expensive, less-healthy food sources, especially in rural, low-income communities (Refs. 1, 72, and 73).

Petitioners also assert that Tribal Treaty Rights, such as the Treaty of Point No Point, ''guarantees the Tribe[s] access to salmon . . . and that any action that reduces the number of salmon available for harvest by Tribal members is a violation of its rights under this treaty.''

The Tribes also conclude that, ''salmon and steelhead populations, central to the ecosystems, Tribal cultures, and economies of the West Coast, have already declined dramatically, due in part to exposure to 6PPD-q[uinone], and they cannot recover without its removal from the environment . . . We therefore call on EPA to exercise its authority under TSCA to protect the environment from the unreasonable risk presented by the use of 6PPD in tires'' (Ref. 1).

G. What are the potential sources and geographic extent of 6PPD and/or 6PPD-quinone contamination in the environment?

Studies have shown that one source of 6PPD and 6PPD-quinone contamination in the environment is from TWP that are constantly entering the environment as tires roll across the road's surface (Ref. 30). These chemicals can also enter the environment from tire rubber if tires are disposed of in or near waterways. Tires and tire pieces are sometimes used as parts of dams, embankments, and erosion-control infrastructure, but little is known about whether 6PPD and 6PPD-quinone leach from these structures into the environment (Ref. 74). E-waste recycling and rubber-modified asphalt have been identified as other potential sources (Refs. 60 and 75). For example, a recent study found that rubber-modified asphalt containing 6PPD was acting as a sorbent for tire-derived 6PPD-quinone that released 6PPD-quinone into the environment after simulated rainfall events, with 0.0015–0.0049 μg/L of 6PPD-quinone recorded in the rainfall runoff (Refs. 76 and 77).

Additionally, although 6PPD has been identified in other non-tire rubber products (described in Unit II.B.3.) (Refs. 78, 79, and 80), more research is needed to determine the full suite of products that may contain 6PPD and the extent to which these products may be contributing to environmental contamination and exposure.

Monitoring studies have measured both 6PPD and 6PPD-quinone in air (Refs. 61 and 81), water (Ref. 61), outdoor and indoor dust (Refs. 82 and 59), sediments, and soil (Ref. 61), indicating that 6PPD and 6PPD-quinone contamination is widespread across multiple media (Ref. 83). Overall, 6PPD and 6PPD-quinone have been measured in environmental media around the world and a limited number of studies have shown both chemicals in human biomonitoring samples (Refs. 62, 63, 64, and 65).

H. What actions can be taken under TSCA section 6?

TSCA section 6 requires EPA to take action to address unreasonable risks of injury to human health or the environment from a chemical substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk. If EPA determines that a chemical substance presents unreasonable risk to health or the environment, it must promulgate requirements under TSCA section 6(a) that can include one or more of the following actions, alone or in combination, to the extent necessary such that the chemical no longer presents the unreasonable risk:

- Prohibit or otherwise restrict the manufacturing (including import), processing, or distribution in commerce of the substance, or limit the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce (TSCA section 6(a)(1)).
- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance for a particular use or above a specific concentration for a particular use (TSCA section 6(a)(2)).
- Limit the amount of the substance which may be manufactured, processed, or distributed in commerce for a particular use or above a specific concentration for a particular use (TSCA section 6(a)(2)).
- Require clear and adequate minimum warning and instructions with respect to the substance, distribution in commerce, or disposal, or any combination of those activities, to be marked on or accompanying the substance (TSCA section 6(a)(3)).
- Require manufacturers and processors of the substance to make and retain certain records or conduct certain monitoring or testing (TSCA section 6(a)(4)).
- Prohibit or otherwise regulate any manner or method of commercial use of the substance (TSCA section 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal of the substance, or any article containing such substance, by its manufacturer or processor or by any person who uses or disposes of it for commercial purposes (TSCA section 6(a)(6)), and
- Direct manufacturers or processors of the substance to give notice of the unreasonable risk determination to distributors, certain other persons, and the public, and to replace or repurchase the substance (TSCA section 6(a)(7)).

Per TSCA section 6(c)(2)(B), in selecting among prohibitions and other restrictions, EPA must factor in, to the extent practicable, the effects of the substance on human health and the environment, any benefits of uses of the substance, and the reasonably ascertainable economic consequences of the rule.

In addition, TSCA section 6(g) allows EPA to grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that: the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available; compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

I. What are the alternatives to 6PPD for use in tires?

At this time, an effective alternative to 6PPD's use in tires has not been identified, but multiple researchers, states, and tire manufacturers are studying potential replacements. For example, in October 2023, California's Department of Toxic Substances Control (DTSC) listed tires containing 6PPD as a Priority Product under the Safer Consumer Products Regulations (SCPR, Cal. Code Regs. Tit. 22, § 69511.7). Manufacturers of tires which contain 6PPD and are entered into the stream of commerce in California have submitted Preliminary Alternatives Analysis Reports to California DTSC, including a submission from the United States Tire Manufacturers Association's (USTMA) consortium of over 30 tire manufacturers (Refs. 2 and 84). Many of the identified potential alternatives in phase I of USTMA's alternatives analysis were other PPDs or non-PPD alternatives, including: 7PPD (CASRN 3081–01–4; DTXSID 5027516), IPPD (CASRN 101–72–4; DTXSID 1025485), 77PD (CASRN 3081–14–9; DTXSID 2024618), CCPD (CASRN 4175–38–6; DTXSID 8063335), and NA (an unnamed, specialized graphene nano-platelet). According to the report, early data suggests that these potential alternatives would have reduced impacts on salmonids and overall hazard relative to 6PPD based on screening level performance data and acceptable physical and chemical properties indicative of exposure potential (Ref. 2). California has granted a Notice of Compliance for the Preliminary (Stage 1) Alternatives Analysis report, and manufacturers will proceed with a Stage 2 Alternatives Analysis to confirm their list of possible alternatives, assess the potential impacts of these options, and initiate a more detailed review of the chemicals' potential hazards and exposure-related properties (Ref. 85).

Similarly, Washington State's Department of Ecology recently published a 6PPD Alternatives Assessment Hazard Criteria and an Alternatives Assessment (AA) Guide for them and other businesses to use when conducting an AA for 6PPD in tires (Ref. 86). The State of Washington also included 6PPD as a proposed priority chemical under their Safer Products of Washington law which will result in a list of products containing 6PPD in 2025 (Ref. 87).

Efforts are also underway to analyze other potential alternatives. For example, researchers are investigating gallates (antioxidant food preservative), lignins (plant-based polymer), Durazone-37 (another existing rubber antiozonant), Graphene, and N,N′-dicyclohexyl-1,4-phenylene diamine (CCPD) as potential replacements for 6PPD in tires (Ref. 88). USTMA and the U.S. Geological Survey are testing the toxicity of potential 6PPD alternatives and refining methods for evaluating potential alternatives, including the ones identified in USTMA's alternatives analysis report in California (Ref. 89). The U.S. Department of Agriculture's Western Regional Research Center and Flexsys are collaborating to explore a bio-based alternative to 6PPD (Ref. 90). EPA is funding multiple research efforts to test and identify potential alternatives, including EPA-funded Small Business Innovation Research (SBIR) grants (Ref. 91). Efforts are also underway to identify other potential solutions to reducing the risks posed by 6PPD and 6PPD-quinone, including reformulating tires using natural rubbers without 6PPD or modifying 6PPD molecules to avoid transformation into 6PPD-quinone (Ref. 88).

III. Specific Requests for Comment, Data, and Information

EPA is seeking public comment on all information included or referenced in this ANPRM and is also seeking any other information relevant to 6PPD and/or 6PPD-quinone. The Agency is particularly interested in receiving quantitative information, data and/or case examples (*e.g.,* peer-reviewed studies and industry scientific and technical reports describing datasets and/or syntheses of environmental and human health impacts that include statistical analyses) addressing the following topics and questions. To avoid duplicative submissions, studies that have already been cited in this ANPRM or that have been submitted through another regulatory reporting requirement are not being requested via this ANPRM.

A. What information is the Agency requesting on environmental effects of 6PPD and/or 6PPD-quinone on aquatic ecosystems?

EPA is interested in all information regarding 6PPD and/or 6PPD-quinone's effects on aquatic ecosystems (such as aquatic toxicity data). Adherence to standard guidelines or laboratory practices (*e.g.,* EPA's 850 Ecological Effects Test Guidelines, American Society for Testing and Materials (ASTM) methods, or Organization for Economic Co-operation and Development (OECD) methods) is preferred but not required. Note that high-quality analytical measurements throughout toxicity tests are important because of the instability of 6PPD and 6PPD-quinone under conditions relevant to aquatic environments.

1. To ensure that EPA has robust, reasonably available data and information that is consistent with the best available science, EPA requests monitoring data reporting 6PPD and/or 6PPD-quinone concentrations and detection frequency in groundwater, surface waters, wastewater, saltwater, or estuaries across the United States. Specifically, EPA is requesting information and data on the volumes, locations, sources, dates/timeframes, and types of 6PPD and/or 6PPD-quinone contamination in impacted surface waters and sediments (*e.g.,* through TWP or direct contact with the tire), including the concentration, field methods/SOPs for collection of the data, and analytical methods used to detect the chemicals (including quantification limits and other quality assurance details) when available.

2. EPA is interested in information and data concerning the acute exposure hazard effects of 6PPD and/or 6PPD-quinone on a broader range of aquatic species than are discussed in Unit II.D.1 of this ANPRM, as well as chronic effects on all aquatic taxa. Even for species and effects that have been investigated previously, repeated high-quality tests with analytical measurements following testing guidelines are desired. Such hazard information includes, but it is not limited to, mortality (lethal concentrations), growth, developmental, behavioral, reproductive, hormonal, immunological, neurological, cardiovascular, respiratory, and renal effects from the cellular level to the organismal and population levels that might inform lethal and sub-lethal physiological, histological, and accumulative effects as well as any other hazard information that may be relevant to 6PPD and/or 6PPD-quinone. EPA seeks hazard effects information for any aquatic species, including but not limited to:

- Fish species (*e.g.,* Salmonidae, Cyprinidae, Centrarchidae, Serranidae, Percidae, Ictaluridae, Acipenseridae, etc.);
- Aquatic studies done using new approach methodologies such as fish cell line assays or in vitro methods;
- Species of Tribal or cultural significance such as lamprey and mussels;
- Aquatic plants (including vascular and non-vascular (algae) species);
- Aquatic invertebrates (including benthic species);
- Aquatic and aquatic-dependent vertebrates other than fish (*e.g.,* mammals, amphibians, reptiles, birds);
- Bacteria/microbiome; and
- Any other potentially sensitive species.

3. EPA is requesting information and data concerning known concentrations of 6PPD and/or 6PPD-quinone found in aquatic animal and plant tissue that may indicate the bioaccumulation of 6PPD and/or 6PPD-quinone in these species, particularly in species which are culturally significant to Tribes or subsistence fisher populations. This information may have important implications for potential exposure through the consumption of affected plant and animal species.

B. What information is the Agency requesting on environmental effects of 6PPD and/or 6PPD-quinone on terrestrial ecosystems?

EPA is interested in all information regarding 6PPD and/or 6PPD-quinone's effects on terrestrial ecosystems (such as terrestrial toxicity data). Data collected by any means is requested. Adherence to standard guidelines or laboratory practices (*e.g.,* EPA's 850 Ecological Effects Test Guidelines, American Society for Testing and Materials (ASTM) methods, or Organization for Economic Co-operation and Development (OECD) methods) is preferred but not required.

1. To ensure that EPA has robust, reasonably available data and information that is consistent with the best available science, EPA requests monitoring information and data reporting for 6PPD and/or 6PPD-quinone concentrations and detection frequency in air, soil, and other terrestrial media. Specifically, EPA is requesting information and data on the volumes, locations, sources, dates/timeframes/pollutographs, and types of 6PPD and/or 6PPD-quinone contamination (*e.g.,* through TWP or direct contact with the tire) in terrestrial environments, including the concentration and field methods and analytical methods used to detect the chemicals (including quantification limits) when available.

2. EPA is also interested in information and data concerning the hazard effects of 6PPD and/or 6PPD-quinone on a broader range of terrestrial species than are discussed in Unit II.D.2 of this ANPRM. Such hazard information includes, but it is not limited to, data on mortality (lethal concentrations), growth, development, genetics, behavior, and reproduction as well as data on the cellular, hormonal, immunological, neurological, accumulative, histological, and physiological effects of 6PPD and/or 6PPD-quinone and any other hazard information. EPA seeks hazard effects information for any terrestrial species, including:

- Terrestrial vertebrates (*e.g.,* mammals, birds, reptiles, amphibians);
- Soil fauna (*e.g.,* worms, microbes, nematodes) with an emphasis on roadside soil fauna;
- Land invertebrates (*e.g.,* insects, worms, slugs, snails, spiders);
- Terrestrial plants (including nonvascular plants such as moss and lichen) with an emphasis on roadside plants;
- Fungi;
- Bacteria/microbiome; and
- Potentially sensitive species.

3. EPA is requesting information and data concerning known concentrations of 6PPD and/or 6PPD-quinone found in terrestrial animal and plant tissue that may indicate the bioaccumulation of 6PPD and/or 6PPD-quinone in these species, particularly in species which are culturally significant to Tribes or subsistence fisher populations. This information may have important implications for potential exposure through the consumption of affected species.

4. EPA is requesting information and data on any used methods of detection of 6PPD and/or 6PPD-quinone in biota, sediments, and soils.

C. What are the potential human health and Tribal effects of 6PPD and/or 6PPD-quinone?

1. As discussed in Unit II.E. of this ANPRM, there are limited data on the

human health effects of 6PPD and/or 6PPD-quinone, including toxicity studies (*in vivo* and *in vitro*) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity and toxicokinetics (absorption, distribution, metabolism, or elimination), including modelling studies in humans. To ensure that EPA has robust, reasonably available data and information that are consistent with the best available science, EPA requests information and data on the human health effects of 6PPD and/or 6PPD-quinone on the general population, and on specific subpopulations including the following:

• Pregnant women and children;

• Workers, including roadway workers, auto repair workers, racetrack maintenance crews, tire manufacturers or recyclers, and others who may be more frequently exposed to tires, TWP, vehicle dust, and road dust that may contain 6PPD and/or 6PPD-quinone; and

• Other potentially exposed or susceptible subpopulations (PESS), which may include:

—Communities that engage in subsistence fishing and/or gathering activities (*e.g.,* Tribal communities and other populations engaging in fishing in urban or semi-urban waterways);

—Near-roadway communities that may be more frequently exposed to tires, TWP, vehicle dust, and road dust that may contain 6PPD and/or 6PPD-quinone;

—Communities living near goods-movement facilities, such as seaports, inland ports, land ports of entry, intermodal facilities and warehouse distribution centers;

—Populations with existing disabilities or medical conditions whose inhalation or ingestion of 6PPD and/or 6PPD-quinone may exacerbate existing medical concerns; and

—Populations that are otherwise vulnerable or experiencing multiple environmental stressors; and

• Studies showing the composition and purity of test substances should be reported, if available.

2. As discussed in Unit II.E. of this ANPRM, there is also limited data on relevant human exposure pathways (the ways a person can be exposed to 6PPD and/or 6PPD-quinone), including inhalation, ingestion, or direct contact with the chemicals in media such as air, water, soil, and dust. To ensure that EPA has robust, reasonably available data and information that is consistent with the best available science, EPA requests information and data on human exposure pathways of 6PPD and/or 6PPD-quinone on the general population, and especially for the following:

• Pregnant women and children;

• Disproportionately affected workers, including roadway workers, auto repair workers, and others who may be more frequently exposed to tires, TWP, vehicle dust, and road dust that may contain 6PPD and/or 6PPD-quinone; and

• Other potentially exposed or susceptible subpopulations (PESS), which may include:

—Communities that engage in subsistence fishing and/or gathering activities (*e.g.,* Tribal communities and other populations engaging in fishing in urban or semi-urban waterways);

—Near-roadway communities that may be more frequently exposed to tires, TWP, vehicle dust, and road dust that may contain 6PPD and/or 6PPD-quinone;

—Populations with existing disabilities or medical conditions whose inhalation or ingestion of 6PPD and/or 6PPD-quinone may exacerbate existing medical concerns; and

—Populations that are otherwise vulnerable or experiencing multiple environmental stressors.

3. EPA is requesting information on the cultural, political, economic, and environmental justice impacts of 6PPD and 6PPD-quinone contamination on Tribes.

4. EPA is requesting information and data on the detection of 6PPD and/or 6PPD-quinone contamination in drinking water. Specifically, EPA is requesting information on the volumes, locations, sources, and types of 6PPD and/or 6PPD-quinone contamination in drinking water, including the concentration and analytical method used to detect the chemicals (including quantification and detection limits) when available.

D. What is 6PPD's use in tires, releases of 6PPD and/or 6PPD-quinone into the environment, and remediation technologies?

1. To help inform EPA's understanding of how 6PPD from tires and/or TWP enters the environment, EPA is requesting information on the use of 6PPD in tires, including quantity and concentration. For example, this information includes but is not limited to the following:

• How many and what types of businesses are engaged in importing, manufacturing, processing, distributing in commerce, using, and disposing of 6PPD?

• What percent by weight of 6PPD meets the minimum criteria for the chemical's function within tires? Since the concentration of 6PPD in tires is not necessarily equivalent to the concentration that is released by tires, due to varying tire structures and designs, the amount and production of 6PPD's transformation products such as 6PPD-quinone and other degradants may be among the considerations for this response.

• What concentration of 6PPD is currently used during the tire manufacturing process? How does this vary across tire manufacturing companies and processes, as well as across different types of tire use (*e.g.,* cars vs. large trucks, electric vehicles vs. gas powered)?

• What is the rate of release of 6PPD and 6PPD-quinone from tires on electric vehicles vs. gas-powered vehicles?

• What is the concentration of 6PPD in the finished tire and where in the tire is 6PPD present (*i.e.,* in the sidewalls, tread, inner liner, etc)? Include the different concentrations for different types of tires, if applicable.

• How does the concentration of 6PPD in the tire change over time during normal wear and tear—after one year of use, versus after 5 years, etc over the normal lifespan of a tire? Does the 6PPD concentration decrease steadily, or are there seasonal or other variations?

• Whether, and if so how, 6PPD content in tires has changed over the last several decades. Specifically, has 6PPD content changed on a per-pound basis? Or has it changed on a per-tire basis given that tire size and formulation can vary for light versus heavy duty vehicles?

• Has the trend toward increased specialization in light duty vehicle tires altered 6PPD use/content in tires? In particular, has the use of high-performance summer tires, winter tires, and tires with off-road capability increased over time?

• What are the water discharges from tire manufacturing facilities, including wastewater from processing and stormwater originating from these sites? Are monitoring data from near such sites available?

• What are the water discharges from other aquatic and terrestrial sites that use or reuse tires, including but not limited to artificial reefs, playgrounds that use crumb rubber or artificial turf, and/or tire dumps? Are monitoring data from near such sites available?

2. EPA is requesting data and information concerning the contribution of tire disposal, tire recycling, and tire reuse on environmental releases of, and

wildlife exposures to 6PPD and 6PPD-quinone.

3. For EPA to better understand the fate and transport of 6PPD and 6PPD-quinone, EPA is requesting data and information on 6PPD as it moves from tires into the environment, reacts with ozone, and evolves into multiple transformation products, such as 6PPD-quinone. EPA is requesting information and data regarding the fate and transport of 6PPD and/or 6PPD-quinone in and for use in tires, as well as the fate and transport of TWP containing 6PPD and/or 6PPD-quinone. For example, EPA is requesting information on, but not limited to, the following:

• What factors influence the transformation of 6PPD to 6PPD-quinone and other transformation products (*e.g.,* how does the concentration of ozone in ambient air impact the reaction rate of 6PPD to 6PPD-quinone and other products)?

• What are the degradation and transformation products of 6PPD, how do they move through the environment (*e.g.,* via TWP, road dust, etc), and how are they absorbed in aqueous media, air, and soil/sediments? For aqueous fate and transport, conditions of interest under variable water quality conditions could include but are not limited to a broad range of pH (5–9), dissolved oxygen (2–10 mg/L), conductivity (0–50,000 µS/cm), and temperature (0–30C).

• How do 6PPD and 6PPD-quinone react with water quality sampling equipment (*i.e.,* water grab and passive samplers) such as resins, filtration media with plastic or silica-based tubs, caulking, or tubing (polytetrafluoroethylene—lined and others), deployment times, or flow rate meters?

4. To gain a better understanding of 6PPD's uses, EPA is requesting information and data regarding other products that contain 6PPD and the potential for 6PPD and/or 6PPD-quinone contamination from these other sources, some of which are mentioned in Unit II.G. (sneakers, plumbing seals, elastics, etc).

5. EPA is requesting information and data on successful water, air, soil, or sediment remediation and mitigation technologies that help reduce 6PPD and/or 6PPD-quinone exposure, such as green infrastructure, bioinfiltration basins, or technologies that capture TWP before they enter the environment, including methods that reduce 6PPD and/or 6PPD-quinone bound to airborne particulate matter. EPA is interested in information on remediation technologies once 6PPD and/or 6PPD-quinone has entered the environment and the scalability and feasibility of implementing those remediation approaches for reducing 6PPD and/or 6PPD-quinone in the environment.

6. EPA is requesting information and data regarding the cost and efficacy of technologies for remediating water sources that have been contaminated with 6PPD and/or 6PPD-quinone. EPA is particularly interested in examples or case studies of remediation efforts that have addressed 6PPD and/or 6PPD-quinone contamination, and cost and efficacy comparisons with other remediation efforts.

E. What are the alternatives to 6PPD's use in tires?

1. There are multiple efforts underway investigating potential alternatives to 6PPD in tires, many of which are summarized in Unit IV of this ANPRM. EPA is requesting information and data on potential alternatives and their associated transformation or degradation products, including those not identified in this ANPRM, that may replace 6PPD as an antiozonant in tires. In addition to identifying potential alternatives, EPA is requesting information and data on the following:

• What concentration of the potential alternative would be used during the tire manufacturing process and what concentration would be present in the finished tire? How would this vary across different types of tire use (*e.g.,* car tires vs. large truck tires)?

• What are the degradation and transformation products of the potential alternative, how do they move through the environment (*e.g.,* via TWP, road dust, etc.), and how are they absorbed in aqueous media, air, and soil/sediments once they're in the environment?

• What are the risks posed by potential alternatives to 6PPD on human health and the environment, including but not limited to hazard and toxicity effects of the parent and/or its transformation and degradation products on humans, aquatic and terrestrial species and ecosystems, and on air quality, greenhouse gas emissions, and potential disposal;

• What are relevant considerations to include when evaluating an alternative that might replace 6PPD in tires (*e.g.,* the standards used to assess the efficacy of potential alternatives); • What is the durability of the alternative (how long would it last as an antidegradant in the tire) and what is its ability to protect tires from degradation compared to 6PPD;

• Are there any potential non-chemical alternatives to 6PPD, such as, but not limited to, bio-based alternatives, self-healing polymers, or making physical changes to the tire or 6PPD molecule that could result in less release into the environment of 6PPD or TWP; and

• Any other exposure information, properties, or considerations of the potential alternatives.

2. More generally, EPA is requesting information and data on the potential challenges and timelines of transitioning to using an alternative to 6PPD as a tire antiozonant, such as:

• What is a timeframe for finding an alternative that presents no/less hazards than 6PPD?

• Once an alternative is identified, how long would it take for the alternative to be screened for feasibility in terms of its use in tires (*e.g.* ability to incorporate into manufacturing processes at large scale, ability to protect the tires from degradation)?

• What safety testing and approval processes need to occur on the alternative to ensure it passes federal highway safety regulations? What are the relevant timeframes for completing those processes?

• Once there is a feasible alternative that has passed initial safety screenings and is scalable, how might an extended phaseout be implemented to replace tires currently in use that contain 6PPD with the new tires?

• How much time would be necessary for tire and rubber manufacturers to phase out and/or replace 6PPD as an antiozonant from their production cycle once a safe and feasible alternative was ready to be implemented?

• What is a reasonable timeframe to phase out existing stocks of 6PPD that have already been produced for use in tires? Can existing stocks of 6PPD that have not been added to tires yet be safely disposed of (include associated methodologies)?

• What is a reasonable timeframe to phase out existing stocks of 6PPD-containing tires?

• How can 6PPD-containing tires be disposed of or repurposed (include associated methodologies) and what are the potential impacts of such actions?

• What is a reasonable timeframe to phase out the need for further introduction into commerce of 6PPD-containing tires?

• What transition periods (*e.g.,* 3, 5, 10 years) would be necessary and what would the likely associated impact be on the price or supply of tires and rubber products?

• If a ban on the use of 6PPD in tires were in place, how long would it take to replace all tires currently in use given the expected lifespan of current tires (7–10 years)? EPA is requesting information and data regarding impacts on human health or the environment that might result from the phase out or restricted use of 6PPD as a tire additive and antiozonant (*e.g.,* reduced tire safety, disposal issues due to more frequent changing of tires).

3. EPA is requesting information and data on the economic considerations and tradeoffs of removing 6PPD from tires and switching to an alternative formulation, process, or chemical.

4. EPA is requesting information and data based on actual releases to the environment of potential alternatives and their associated transformation products and degradants; including degree of contamination, and the cost and efficacy of the technologies available to remediate such contamination. Specifically, EPA is requesting, to the extent possible, information on the volumes, concentrations, locations, sources, and types of contamination from potential alternatives in water, soil, and air.

F. What actions could the Agency take under TSCA?

As explained in this ANPRM, EPA is gathering information on a potential rulemaking. EPA requests comment on:

1. If the Agency moves forward with a proposed rule after the ANPRM is published, what potential actions could EPA take under TSCA section 6(a)? Potential options include:

• Regulate the manufacturing, processing, or distribution in commerce of the chemical, including a complete ban of any such activity or limiting the amounts of the chemical manufactured, distributed, and/or included in tires;

• Regulate the manufacturing, processing, or distribution in commerce of the chemical for particular uses, including banning any such activity for a particular use; limiting the concentration of the chemical that may be used; or limiting the amounts of the chemical for particular uses;

• Require warning statements and/or instructions for use with respect to the chemical's use in tires and non-tire materials (*e.g.,* rubber modified asphalt, sneakers, elastics, etc.), distribution in commerce, and/or disposal of the chemical or products containing the chemical;

• Require manufacturers/processors to make and retain such records of the manufacturing process and/or monitor or conduct tests to ensure compliance with a TSCA section 6 rule;

• Prohibiting or regulating any manner or method of commercial use of the chemical;

• Prohibit or regulate the disposal of the chemical; and

• Require manufacturers/processors to provide warnings to distributors or users and to replace or repurchase the chemical.

2. TSCA provides EPA authority to select a combination of TSCA section 6(a) actions and limit the geographic application of a rule under TSCA section 6(a). EPA is requesting comment on whether, and if so, where EPA should consider limits to the geographical scope of any potential action under TSCA section 6(a)?

3. TSCA section 9 provides that the EPA Administrator shall consult and coordinate with the heads of other appropriate federal executive departments or agencies to achieve maximum enforcement of TSCA, while imposing the least burden of duplicative requirements. The Administrator is also directed to coordinate actions taken under TSCA with actions taken under other federal laws administered by the EPA, such as the Resource Conservation and Recovery Act, the Clean Air Act and the Clean Water Act. Are there other statutory authorities administered by EPA that could be used to eliminate or reduce to a sufficient extent any risk identified?

4. As discussed in Unit II.H., TSCA section 6(g) allows EPA to grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that: the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available; compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. What should EPA consider regarding a potential TSCA section 6(g) exemption for 6PPD use in tires? If so, what conditions may be necessary to protect health and the environment while achieving the purposes of an exemption?

IV. References

The following is a list of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

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V. Statutory and Executive Order Reviews

Additional information about these statutes and executive orders can be found at *https://www.epa.gov/regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to a requirement for Executive Order 12866 review.

B. Other Regulatory Assessment Requirements

Because this action does not impose or propose any requirements, the various other review requirements in statutes and Executive Orders that apply when an agency imposes or proposes requirements do not apply to this ANPRM. Should EPA subsequently determine to pursue a rulemaking, EPA will address the requirements in the statutes and executive orders as applicable to that rulemaking.

List of Subjects in 40 CFR Part 751

Chemicals, Environmental protection, Exports, Hazardous substances, Imports, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

[FR Doc. 2024–26894 Filed 11–18–24; 8:45 am]

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