State Water Resources Control Board

February 04, 2022

Karl Palmer, Deputy Director
Safer Consumer Products Program
Department of Toxic Substances Control

Subject: Final Response to Request for External Scientific Peer Review of the Scientific Basis of the Proposed Adoption of Motor Vehicle Tires Containing N-(1,3-Dimethylbutyl)-N'-Phenyl-p-Phenylenediamine (6PPD) as a Priority Product

Dear Mr. Palmer,

This letter responds to the attached 21 October 2021, request for external scientific peer review for the subject noted above. The review process is described below. All steps were conducted in confidence. Reviewers' identities were not disclosed.

To begin the process for selecting reviewers, I contacted the University of California, Berkeley (University) and requested recommendations for candidates considered qualified to perform the assignment. This service is supported through an Interagency Agreement co-signed by CalEPA and the University. The University was provided with the request letter and attachments. The University interviews each promising candidate.

Each candidate who was both qualified and available for the review period was asked to complete a Conflict of Interest (COI) Disclosure form and submit to the CalEPA Peer Review Program for review, with their Curriculum Vitae. The cover letter for the COI form describes the context for COI concerns that must be taken into consideration when completing the form: "As noted, staff will use this information to evaluate whether a reasonable member of the public would have a serious concern about [the candidate's] ability to provide a neutral and objective review of the work product."

For each candidate judged to be free of conflict, I approved that person as reviewer, affirmed by an approval letter to initiate the review. These letters provided access instructions to a secure FTP site where all material to be reviewed was placed. Each reviewer was asked to address each conclusion for which he or she had previously agreed, and these were identified in the letter. Thirty days were provided for the review, unless a reviewer requested additional time.

Guidance was provided a) to ensure confidentiality through the review process; and b) for format presentation to meet “accessibility” requirements.

Reviewers’ names, affiliations, curriculum vitae, initiating letters and reviews are being sent to you now with this letter. This information can be accessed easily through the bookmarks listed on the left of the screen, or by scrolling down.

Approved reviewers:

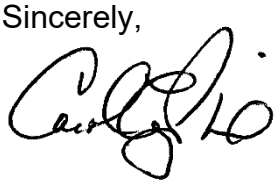
1. Markus Brinkmann, Ph.D.
   University of Saskatchewan
   School of the Environment & Sustainability and Toxicology Centre
   44 Campus Drive, Saskatoon, SK S7N 5B3, Canada

2. Pertti J. Hakkinen, Ph.D., F-SRA
   "NIH Special Volunteer" in Toxicology and Environmental Health Sciences
   National Center for Biotechnology Information
   National Institutes of Health
   Kailua, Hawaii 96734

3. Staci L. Simonich, Ph.D.
   Executive Associate Dean and Professor
   Department of Environmental and Molecular Toxicology and the
   Department of Chemistry
   Oregon State University, 430B Strand Agricultural Hall
   Corvallis, OR 97330-2140

If you have any questions, or require clarification from the reviewers, please contact me directly.

Sincerely,



Carol Perkins
Manager, CalEPA External Scientific Peer Review Program
Office of Research, Planning, and Performance
State Water Resources Control Board
1001 “I” Street, 13th Floor Sacramento, California 95814
Carol.Perkins@waterboards.ca.gov

Attachments:

(1) 21 October 2021 Request by Karl Palmer for Scientific Peer Review

(2) 10 December 2021 Errata to the Request by Karl Palmer for Scientific Peer Review

(3) Letters to Reviewers Initiating the Review
   i. Markus Brinkmann, Ph.D.
   ii. Pertti J. Hakkinen, Ph.D., F-SRA
   iii. Staci L. Simonich, Ph.D.

(4) Curriculum Vitae
   i. Markus Brinkmann, Ph.D.
   ii. Pertti J. Hakkinen, Ph.D., F-SRA
   iii. Staci L. Simonich, Ph.D.

(5) Reviews
   i. Markus Brinkmann, Ph.D.
   ii. Pertti J. Hakkinen, Ph.D., F-SRA
   iii. Staci L. Simonich, Ph.D.

cc: Nancy Ostrom, Chief
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Safer Consumer Products Program
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Gavin Newsom
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TO: Carol Perkins
Manager, CalEPA Scientific Peer Review Program
Office of Research, Planning, and Performance
California State Water Resources Control Board

FROM: Karl Palmer
Deputy Director, Safer Consumer Products Program
Department of Toxic Substances Control

CC: Nancy Ostrom
Chief, Regulations and Policy Unit, Safer Consumer Products Program
Department of Toxic Substances Control

DATE: October 21, 2021

SUBJECT: Request for External Scientific Peer Review of the Scientific Basis of the Proposed Adoption of Motor Vehicle Tires Containing N-(1,3-Dimethylbutyl)-N'-Phenyl-p-Phenylenediamine (6PPD) as a Priority Product

Title of Proposal for Review

This request is regarding a proposed regulation to adopt the following product-chemical combination as a Priority Product:

Motor Vehicle Tires Containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)

Safer Consumer Products staff requests that you initiate the process to identify external scientific peer reviewers for the proposal to adopt motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product, per the requirements of California Health and Safety Code section 57004.

We intend to release a Notice of Proposed Action for this proposed regulation in January of 2022, with adoption of the proposed regulation in the first quarter of 2023.

Purpose of Review

The California Safer Consumer Products (SCP) regulations, California Code of Regulations, Title 22, sections 69503 – 69503.7, require the Department of Toxic Substances Control (DTSC) to identify product-chemical combinations that pose risks to people or the environment and to adopt them as Priority Products in regulation. "Priority Products" are consumer products that a) contain chemicals included in DTSC's Candidate Chemicals List; b) may expose people or the environment to these chemical(s) through normal use; and c) have been adopted in regulation. Candidate Chemicals exhibit hazard traits or environmental or toxicological endpoints and are included on authoritative lists established by government agencies or scientific organizations (http://www.dtsc.ca.gov/SCP).

Prior to proposing a product-chemical combination for adoption as a Priority Product, DTSC must ensure that the product-chemical combination meets both of the following criteria: 1) there must be potential public and/or environmental exposure to the chemical(s) in the product; and 2) there must be potential for one or more exposures to contribute to or cause significant or widespread adverse impacts (22 CCR section 69503.2(a)).

In accordance with Health and Safety Code section 57004, DTSC requests external scientific peer review of the basis for proposing *motor vehicle tires containing 6PPD* as a Priority Product. As required by regulation, DTSC reviewed reliable scientific literature and concluded that this product-chemical combination meets the required regulatory criteria for listing as a Priority Product because there is potential for exposure of aquatic organisms to 6PPD and its reaction product, 6PPD-quinone, and the potential for these exposures to contribute to or cause adverse impacts, particularly to California's threatened and endangered populations of coho salmon as well as other aquatic organisms and the Native American tribes that rely on them.

When References will be Available at the FTP Site

The documents are ready for review at any time.

Requested Review Period

We request that scientific peer review be accomplished within 30 days.

In accordance with CA AB 434 (California Government Code section 11546.7), DTSC requests that documents submitted as part of this review are compliant with Web Content Accessibility Guidelines (WCAG) 2.0, Level AA.

Necessary Areas of Expertise for Reviewers

For this review, DTSC recommends that reviewers have expertise in one or both of the

following areas:

- Environmental chemistry, especially regarding stormwater-derived pollutants or tire-related contaminants; this expertise is needed for Conclusion 1, as defined in the attachment.

- Aquatic toxicity, especially regarding organic pollutant effects on salmonids and other endangered fishes; this expertise is needed for Conclusion 2, as defined in the attachment.

We estimate that at least three reviewers will be adequate to cover all the necessary areas of expertise. Two reviewers per area of expertise are needed.

Refer to Attachment 2 for more details.

Contact Information

Please direct inquiries regarding this request to Nancy Ostrom, of my staff, at nancy.ostrom@dtsc.ca.gov or 916-445-3077.

Attachments

Attached please find:

1. Attachment 1: Plain English Summary.
2. Attachment 2: Scientific Assumptions, Findings, and Conclusions to Review.
3. Attachment 3: Individuals who Participated in the Development of the Proposal.
4. Attachment 4: References Cited.

Attachment 1: Plain English Summary

Brief Statement of Conclusions

DTSC has determined that motor vehicle tires containing 6PPD meet the key prioritization criteria (California Code of Regulations, title 22, section 69503.2(a)) for listing a Priority Product:

> (1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
>
> (2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

6PPD has been used as an antidegradant for decades and is found in most if not all motor vehicle tires. 6PPD performs the critical function of protecting rubber from reactions with ozone and oxygen, which can lead to cracks. However, 6PPD is toxic toward algae and other aquatic organisms at multiple trophic levels and can impair wildlife survival. Moreover, the chemical compound 6PPD-quinone, a reaction product of 6PPD, is acutely toxic to coho salmon (*Oncorhynchus kisutch)*, including juveniles, and kills fish just a few hours after exposure. 6PPD-quinone has been identified as the causal agent in urban runoff mortality syndrome (URMS) observed in the Puget Sound area of Washington state, and it kills coho salmon as they migrate upstream, before they are able to spawn.

While it is unclear exactly where and how 6PPD-quinone is formed, detections of 6PPD-quinone in California waterways clearly indicate that it is sufficiently persistent in aquatic systems for aquatic organisms to potentially be exposed. 6PPD-quinone has been measured in California streams at concentrations above those shown to kill at least half of coho salmon in laboratory experiments. 6PPD-quinone may have contributed to the decline in the coho population over the past 60-70 years. Its continued presence in California's waterways threatens the state's remaining coho salmon populations (one of which is endangered and the other threatened) and may jeopardize the recovery of this species, which faces a number of additional challenges including climate change, habitat destruction and loss, and exposure to other contaminants found in urban runoff.

Given the very recent discovery of 6PPD-quinone, little is known about its effects on other aquatic organisms. However, it is potentially toxic to other economically important species that are closely related to coho such as chinook salmon, steelhead, and the California golden trout. Coho salmon represent a food source for many marine organisms such as seals and sharks and are a source of ocean-derived nutrients to inland ecosystems. In addition to impacts to aquatic organisms, loss of coho salmon in California has significantly impacted California's Native American tribes. The loss of core traditional food sources for tribal communities can be tied to loss of culture, increased physical and mental health issues, and increased poverty.

While there are currently no regulations restricting the use of recycled tires related to the presence of 6PPD or 6PPD-quinone, increased regulatory scrutiny and public concerns for 6PPD and other tire-derived contaminants may limit future end-of-life applications, potentially hindering recycling efforts and interfering with the California Department of Resources Recycling and Recovery's (CalRecycle) legislative mandate to divert tires from landfills. Additionally, the presence of 6PPD-quinone in California waterways at concentrations proven to be lethal to coho salmon indicates that current stormwater treatment efforts are often insufficient for the removal of 6PPD-quinone. If 6PPD or 6PPD-quinone were to be regulated in stormwater, many municipalities would have to adopt expensive special handling measures to meet discharge limits and ensure protection of local waterways.

Further studies may help inform DTSC's future decision-making. Despite known data gaps, DTSC has sufficient information regarding potential exposures and adverse impacts from motor vehicle tires containing 6PPD to designate this as a Priority Product.

Overview of the Safer Consumer Products Regulatory Program

The SCP regulations, implemented on October 1, 2013, specify the process for identifying consumer products that contain hazardous chemicals, evaluating safer alternatives to those chemicals, and eliminating or reducing potential exposures to and adverse impacts from these products. The regulations intentionally use a narrative standard for identifying and prioritizing product-chemical combinations, rather than a traditional risk-assessment-driven decision-making standard. This approach provides DTSC with a flexible process that allows the SCP program make decisions based on a reasonable amount of reliable information and the potential for exposure and adverse impacts. The SCP regulations also use the hazard traits, toxicological and environmental endpoints, and other relevant data contained in Chapter 54 of the California Code of Regulations, Title 22.

To adopt a Priority Product listing, DTSC must follow the procedure described in the SCP regulations and adopt the listings through a rulemaking procedure. CCR section 69503.2 *et seq* uses the following prioritization factors for listing Priority Products:

- There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and

- 22 CCR sections 69503.2 and 69503.3 specify that there must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

"Potential" is defined as reasonably foreseeable, based on reliable information (CCR section 69503.1(a)(51)). The potential for exposure is evaluated by considering one or more of the following factors: market presence of the product, the occurrence or potential occurrence of exposures to the Candidate Chemical in the product, the

household and workplace presence of the product, potential exposure to the Candidate Chemical in the product during the product's life cycle (CCR section 69503.3(b)).

22 CCR sections 69503.2 and 69503.3 specify that the potential to contribute to or cause adverse impacts is evaluated by considering reasonably available information about one or more of the following factors: hazard traits; toxicological endpoints; aggregate effects; cumulative effects; physicochemical properties; environmental fate; affected populations or organisms; potential for the Candidate Chemical(s) to degrade, form reaction products, or metabolize into another chemical that exhibits hazard traits or endpoints. DTSC shall give special consideration to the potential for adverse impacts to sensitive subpopulations, environmentally sensitive habitat, endangered and threatened species, and impaired environments. DTSC may also evaluate and consider adverse impacts associated with structurally or mechanistically similar chemicals with known toxicity profiles.

Once DTSC adopts a Priority Product listing, DTSC requires product manufacturers to submit a Priority Product notification per CCR section 69503.7 and conduct one of several types of Alternatives Analyses to determine if safer alternatives exist per CCR section 69505.1 *et seq*. Alternatively, product manufacturers may elect to:

- Remove or replace the chemical of concern in the product with a safer alternative; or

- Remove the product from the California marketplace.

If the product manufacturers do not comply, DTSC is authorized to require importers, assemblers, or retailers to stop selling the product in California.

Overview of the Proposal to Adopt Motor Vehicle Tires Containing 6PPD as a Priority Product

As required by regulation, DTSC considered several factors including the hazard traits, toxicological endpoints, and environmental fates associated with 6PPD and 6PPD-quinone, as well as potential adverse impacts to sensitive subpopulations and threatened and endangered species. After reviewing the scientific literature and obtaining stakeholder input during a public workshop, DTSC has determined that:

1. Coho salmon and other aquatic organisms may be exposed to 6PPD-quinone due to the use of 6PPD in motor vehicle tires.

2. The 6PPD contained in motor vehicle tires and its oxidation product 6PPD-quinone have the potential to contribute to or cause significant or widespread adverse impacts to the threatened and endangered populations of coho salmon in California, as well as to other aquatic organisms and the Native American tribes that rely on them.

Publicly available evidence suggests that 6PPD displays the following hazard traits:

- Phytotoxicity;
- Wildlife survival impairment;
- Reproductive toxicity;
- Dermatotoxicity;
- Ocular toxicity;
- Hepatotoxicity; and
- Hematotoxicity.

Additionally, publicly available evidence suggests that 6PPD-quinone displays the following hazard traits:

- Wildlife survival impairment;
- Loss of genetic diversity and biodiversity;
- Reactivity in biological systems; and
- Respiratory toxicity.

DTSC identified several priorities and considerations for implementation in its 2021-2023 Priority Product Work Plan, including "the potential for the product to release microplastics to the environment during the use or end-of-life stages of the products' life cycle. The SCP Program is concerned with microplastics because they have the potential to contribute significantly to adverse water quality impacts and aquatic pollution." Tire wear particles are some of the most common types of microplastics found in California waters. Addressing contaminants found in tire wear particles, like 6PPD and its reaction products, aligns with SCP's overarching goals.

Attachment 2: Scientific Conclusions to Review

Special Directions for Reviewers of Safer Consumer Products Conclusions

The statutory mandate for external scientific peer review (California Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether "the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices." Your task is to make this determination for the assumptions,

findings, or conclusions below that the CalEPA External Scientific Peer Review Program has determined you can address with confidence, based on expertise and experience. (If you decide to address other assumptions, findings, or conclusions, identify the expertise and experience you are relying on to do so.) We also invite you to address these questions:

- Are there any scientific subjects that are part of the scientific basis of the proposal that are not described below?
- Taken as a whole, is the proposal based upon sound scientific knowledge, methods, and practices?

Note that in evaluating DTSC's proposed action and conclusions, absolute scientific certainty is not required. Instead, the task is to determine if there is adequate scientific basis supporting potential exposures and impacts to support SCP's regulatory action, as described in the SCP law.

Reviewers should recognize that DTSC has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed regulation. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central regulatory elements being proposed.

For further direction, please see the attachment, "Guidance for Reviewers," on the FTP site and sent to you with the letter initiating your review.

Scientific Conclusions

Conclusion 1

Coho salmon and other aquatic organisms may be exposed to 6PPD-quinone due to the use of 6PPD in motor vehicle tires.

Conclusion 1 is supported by the following points, which are expanded upon in the Motor Vehicle Tires Containing 6PPD Product Chemical Profile:

- 6PPD is used in nearly all motor vehicle tires in California to protect the rubber from degradation by oxygen and ozone.
- 6PPD is a high-production volume chemical, and motor vehicle tires are one of its main uses.
- 6PPD is added to motor vehicle tires at concentrations of 1 to 2% and is designed to slowly migrate from the interior of the tire towards its surface over the lifetime of the tire, such that there is a constant supply of 6PPD and its oxidation products at the surface of the tire.

- By design, 6PPD is highly reactive and forms a number of reaction products when in contact with oxygen and ozone, including 6PPD-quinone.

- Tires release 6PPD and its reaction products into the environment through mechanical tire abrasion on the roads, which produces microplastics known as tire wear particles. It is estimated that in the United States 4.7 kilograms of tire wear particles are generated per person each year. Once in the environment, tire wear particles can release 6PPD and its reaction product 6PPD-quinone.

- In 2020 alone, over 171 million tires were driven on California's roads. The large number of tires used in California each year poses major challenges to their end-of-life disposition. After their useful life, tires can be landfilled, recycled, or reused. Many of the end-of-life uses of tires (such as for erosion control, flood control, stormwater treatment, or playground surfaces) provide a pathway for chemicals like 6PPD and its reaction products to migrate into the aquatic environment.

- Stormwater runoff, particularly from urban areas, can serve as a substantial source of tire-derived contaminants to local aquatic environments. The total loading of tire-derived contaminants to waterways has been found to be 3.5 times higher in rain events sampled early in the rain season as compared to later in the season, which can align with the presence of coho salmon migrating up streams for spawning.

- 6PPD-quinone has been detected in California waterways at concentrations above those shown to kill at least half of coho salmon in laboratory experiments.

- Coho salmon are already extinct in California waters near highly populated, high traffic density areas. The remaining coho populations in the less heavily populated areas of the state are either threatened or endangered.

- The highest concentration of 6PPD-quinone measured to date in the San Francisco Bay Area came from a location whose watershed is 90% open space. However, the sampling point was located near a heavily trafficked road, indicating the potential for exposure of aquatic organisms to 6PPD-quinone even in more remote regions of the state.

- The presence of 6PPD-quinone in California waterways at concentrations proven to be lethal to coho salmon indicates that current stormwater treatment efforts are often insufficient for the removal of 6PPD-quinone.

The sections of the product-chemical profile (noted above) that pertain to Conclusion 1 include:

- Section 1 – Rationale for Product-Chemical Selection, pages 4– 6;
- Section 4 – Potential for Exposures to the Candidate Chemical in the Priority Product, pages 20 – 36;
- Section 5 – Potential for Significant or Widespread Adverse Impacts, pages 37 – 54; and
- Section 9 – Conclusions, pages 65 – 66.

Conclusion 2

The 6PPD contained in motor vehicle tires and its oxidation product 6PPD-quinone have the potential to contribute to or cause significant or widespread adverse impacts to the threatened and endangered populations of coho salmon in California, as well as to other aquatic organisms and the Native American tribes that rely on them.

Conclusion 2 is supported by the evidence for widespread exposures identified in Conclusion 1, and by the following points which are expanded upon in the Motor Vehicle Tires Containing 6PPD Product Chemical Profile:

- Both 6PPD and 6PPD-quinone display hazard traits of concern according to the Safer Consumer Products regulations. 6PPD displays phytotoxicity and wildlife survival impairment, whereas 6PPD-quinone displays loss of genetic diversity and biodiversity, as well as wildlife survival impairment, including to coho salmon, a threatened and endangered species in California
- Researchers in Washington state recently demonstrated that 6PPD-quinone is the causal agent in urban runoff mortality syndrome observed in Puget Sound.
- Exposure to very small concentrations of 6PPD-quinone can kill coho salmon as they migrate upstream, before they are able to spawn.
- The presence of 6PPD-quinone in California runoff and waterways at concentrations above levels that kill at least half of coho salmon in lab studies suggests that exposure to 6PPD-quinone may have contributed to the decline in the coho population over the past 60-70 years.
- The decline of the coho population has adversely impacted important marine food webs in California. Coho salmon represent a food source for many marine organisms such as seals and sharks and are a source of ocean-derived nutrients to inland ecosystems.

- In addition to impacts to aquatic organisms, loss of coho salmon in California has significantly impacted California's Native American tribes. The loss of core traditional food sources for tribal communities can be tied to loss of culture, increased physical and mental health issues, and increased poverty. For instance, the human toll of the decline of salmon has been well-documented by the Karuk Tribe in the Klamath Basin: diabetes, heart disease, hypertension, and stroke, diseases that are strongly influenced by diet, have become more common in the Karuk since the decline of the salmon fishery, costing the Karuk an estimated $1.9 million per year in health costs. Native American advocates assert that access to traditional food sources, such as salmon, helps to promote self-reliance among Indigenous peoples and is fundamentally important to protecting Native communities' health, well-being, economic resilience, and cultural heritage.

- 6PPD-quinone is also potentially toxic to other economically important species that are closely related to coho such as chinook salmon, steelhead, and the California golden trout.

- The presence of 6PPD in tires and associated release of 6PPD-quinone to the aquatic environment represent a threat to imperiled populations of coho salmon, negatively impact tribal communities that rely on these fish for cultural and subsistence purposes, may interfere with California's ability to reuse and recycle tires, and may require expensive special handling of stormwater runoff to mitigate adverse impacts.

The sections of the product-chemical profile (noted above) that pertain to Conclusion 2 include:

- Section 1 – Rationale for Product-Chemical Selection, pages 4 – 6;

- Section 3 – Candidate Chemical Definition and Properties, pages 7 – 20;

- Section 5 – Potential for Significant or Widespread Adverse Impacts, pages 37 – 54;

- Section 8 – Additional Considerations, pages 59 – 64; and

- Section 9 – Conclusions, pages 65 - 66.

References included in these sections will be provided to the reviewers as part of this request.

Attachment 3: Individuals who have Participated in the Development of the Proposal

Reviewers: in general, do not contact these individuals. For further direction, please see the attachment, "Guidance for Reviewers," on the FTP site and sent to you with the letter initiating your review.

Section A. California Department of Toxic Substances Control Personnel

Name	Title	Program
André Algazi	Senior Environmental Scientist (Supervisory)	Safer Consumer Products Program
Simona A. Bălan	Senior Environmental Scientist (Specialist)	Safer Consumer Products Program
Robert Brushia	Research Scientist III	Safer Consumer Products Program
Topher Buck	Senior Environmental Scientist (Specialist)	Safer Consumer Products Program
Julianne Culbert	Attorney III	Office of Legal Counsel
Anne Cooper Doherty	Senior Environmental Scientist (Specialist)	Safer Consumer Products Program
Michael Garland	Associate Toxicologist	Human and Ecological Risk Assessment Office
Kelly Grant	Senior Environmental Scientist (Specialist)	Safer Consumer Products Program
David Grealish	Graphic Designer III	Office of Communications
Kyle Harris	Research Data Specialist II	Safer Consumer Products Program
Stephanie Lewis	Senior Environmental Scientist	Office of Environmental Equity
Andres Martinez	Senior Environmental Scientist (Supervisory)	Office of Environmental Equity
Patricia Moran	Senior Environmental Planner	Office of Environmental Equity
Nancy Ostrom	Senior Environmental Scientist (Supervisory)	Safer Consumer Products Program
Karl Palmer	Deputy Director	Safer Consumer Products Program
Minoo Safai-Amini	Research Data Specialist I	Safer Consumer Products Program
Brian Taylor	Information Officer I (Specialist)	Office of Communications
Meredith Williams	Director	Department of Toxic Substances Control

Section B. External Participants/Reviewers.

Name	Title	Affiliation
Kyle De Julio	Senior Fisheries Biologist	Yurok Tribe
William Heung	Senior Waste Management Engineer, Tires, Oil, and Pharmaceutical Unit	CalRecycle
Erica Kalve	Engineering Geologist, Recycled Water, Desalination, and CECs Unit	California State Water Resources Control Board
Amanda Magee	Senior Engineering Geologist, Strategy to Optimize Resource Management of Stormwater (STORMS) Unit Manager	California State Water Resources Control Board
Terri McCartney	EPA Director	Hopland Band of Pomo Indians
Chris Ott	Environmental Director	Dry Creek Rancheria Band of Pomo Indians
Kyle Pogue	Environmental Program Manager I (Supervisor), Materials Management Section	CalRecycle
Rebecca Stanton	Staff Toxicologist, Fish, Ecotoxicology, and Water Section	California Office of Environmental Health Hazard Assessment
Michael Shaver	Environmental Director	Middletown Rancheria Band of Pomo Indians
Charles Striplen	Tribal Advisor and Liaison	California Fish and Game Commission
Stephen Swales	Senior Environmental Scientist (Specialist)	California Department of Fish and Wildlife
Patty Wong	Chief, Special Investigations Section	California Office of Environmental Health Hazard Assessment

Attachment 4: References Cited

Introduction

All references will be provided at an FTP site or are accessible using the links below.

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Adopting Motor Vehicle Tires Containing N-(1,3-Dimethylbutyl)-N'-Phenyl-p-Phenylenediamine (6PPD) as a Priority Product

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CC: Nancy Ostrom
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DATE: December 10, 2021

SUBJECT: Errata to the Request for External Scientific Peer Review of the Scientific Basis of the Proposed Adoption of Motor Vehicle Tires Containing N-(1,3-Dimethylbutyl)-N'-Phenyl-p-Phenylenediamine (6PPD) as a Priority Product

Errata to the External Scientific Peer Review Request

Background

On October 21, 2021, the Department of Toxic Substances Control requested external scientific peer review of the proposed adoption of motor vehicle tires motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product. Since requesting external scientific peer review, a few changes have been made to the technical document that supports the rulemaking, which, in turn, affects some of the content in the original request letter.

Changes to the Previous Request

Changes to the letter are indicated below. New language is underlined, deleted language is in strikethrough. The changes indicated below do not impact the scientific conclusions that the reviewers are being asked to review.

Carol Perkins
December 10, 2021

1. In Attachment 2: Scientific Conclusions to Review, Conclusion 1, the fourth bullet on page nine should be amended to read:

    - Stormwater runoff, particularly from urban areas, can serve as a substantial source of tire-derived contaminants to local aquatic environments. ~~The total loading of tire-derived contaminants to waterways has been found to be 3.5 times higher in rain events sampled early in the rain season as compared to later in the season, which can align with the presence of coho salmon migrating up streams for spawning.~~

2. In Attachment 2: Scientific Conclusions to Review, Conclusion 1, the seventh bullet point on page nine should be amended to read:

    - The highest concentration of 6PPD-quinone measured to date in the San Francisco Bay Area came from a location whose watershed is 90% open space, indicating that proximity to roads and associated tire wear particles may be more important than the extent of development of surrounding land. ~~However, the sampling point was located near a heavily trafficked road, indicating~~ This indicates the potential for exposure of aquatic organisms to 6PPD-quinone ~~even in more remote regions of the state~~ outside dense urban regions of the state if traffic patterns result in release of TWP to streams.

3. In Attachment 2: Scientific Conclusions to Review, Conclusion 1, bullets two through four on the top of page 10 should be amended to read:

    - Section 4 – Potential for Exposures to the Candidate Chemical in the Priority Product, pages ~~20 – 36~~ 25 – 43;

    - Section 5 – Potential for Significant or Widespread Adverse Impacts, pages ~~37 – 54~~ 44 – 62; and

    - Section 9 – Conclusions, pages ~~65 – 66~~ 73 – 74.

4. In Attachment 2: Scientific Conclusions to Review, Conclusion 2, the last four bullets on the bottom of page 11 should be amended to read:

    - Section 3 – Candidate Chemical Definition and Properties, pages 7 – ~~20~~ 25;

    - Section 5 – Potential for Significant or Widespread Adverse Impacts, pages ~~37 – 54~~ 44 – 62;

    - Section 8 – Additional Considerations, pages ~~59 – 64~~ 67 – 72; and

- Section 9 – Conclusions, pages ~~65 – 66~~ 73 – 74.

Additionally, the list of references cited as provided in Attachment 4, beginning on page 14, has been expanded. The complete list of references cited is below. All references will be provided at an FTP site or are accessible using the links below.

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State Water Resources Control Board

13 December 2021

Markus Brinkmann, Ph.D.
University of Saskatchewan
School of the Environment & Sustainability and Toxicology Centre
44 Campus Drive, Saskatoon, SK S7N 5B3, Canada

Sent via email

SUBJECT: INITIATION OF REVIEW OF THE SCIENTIFIC BASIS OF THE PROPOSED ADOPTION OF MOTOR VEHICLE TIRES CONTAINING N-(1,3-DIMETHYLBUTYL)-N'-PHENYL-P-PHENYLENEDIAMINE (6PPD) AS A PRIORITY PRODUCT

Dear Professor Brinkmann,

Thank you for accepting the role as an external scientific peer reviewer of subject request. The purpose of this letter is to initiate the external peer review.

Components of the review:

1. Guidance for reviewers.
2. Request for External Scientific Peer Review, with the following attachments:
   a. Attachment 1: Plain English Summary.
   b. Attachment 2: Scientific Assumptions, Findings, and Conclusions to Review.
   c. Attachment 3: Individuals who Participated in the Development of the Proposal.
   d. Attachment 4: References Cited.
3. Errata to the External Scientific Peer Review Request
4. Proposed rule or related documents (Product-Chemical Profile).
5. Electronic copies of references cited.

All components of the review are posted at a secure FTP site:

- Site: https://ftp.waterboards.ca.gov
- Username: gbowes-ftp33
- Password: 7nDAUW

The findings, assumptions, and conclusions that need review are listed in Attachment 2 of the review request. I ask that you review those findings, assumptions, and conclusions as outlined in your 24 November 2021 communication that indicates you can address with confidence, based on your expertise and experience. These are conclusions 1 and 2 (with some noted exceptions). Please document exceptions to Conclusion 2 in your report to the requesting organization if you find it necessary for completeness.

I will help with any questions you have. To ensure a clear record of our communication, all communications should be in writing (email is preferred).

Please email your reviews to me ***no later*** than 14 January 2022. I will subsequently forward all reviews and the curricula vitae of all reviewers to the requesting organization. All information may be posted at their website.

The organization requesting the review may require clarification or additional information on a specific subject. If this occurs, I will ask you to supplement your review to address those comments.

Your participation in this review assignment is most appreciated.

Sincerely,

Carol Perkins
Manager, CalEPA External Scientific Peer Review Program
Office of Research, Planning, and Performance
State Water Resources Control Board
1001 “I” Street, 13th Floor Sacramento, California 95814
Carol.Perkins@waterboards.ca.gov

Encl: *Guidance for Reviewers*

Guidance for Reviewers

Updated October 2021

Communication with the Peer Review Program. To ensure a clear record of our communication, all of our communications should be in writing (email is preferred).

Confidentiality. You are required to help maintain the confidentiality of this review process.

- Confidentiality began at the point you were contacted by the University of California, Berkeley.
- You should not inform others about your role as reviewer.
- You will not know the names of other reviewers until all reviews are complete and the organization decides to release reviews.
- You not allowed to discuss the proposal with employees of the requesting organization or individuals who participated in development of the proposal, unless you let us know you have a clarifying or technical question and we put you in contact with employees of the requesting organization. The individuals who participated in development are listed in Attachment 3 of the review request.

Independence. If you learn what you are reviewing was developed by someone with whom you share a common supervisor or have or had a working relationship, you must let us know so that we can determine whether to seek another peer reviewer.
For example, if the CalEPA organization asking for the review contracted with someone in your department or organization to help develop the material you were asked to review, you have a potential conflict of interest.

Your review. The statutory mandate for external scientific peer review (California Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether "the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices."

In your review, we request that you make that determination for the CalEPA organization's assumptions, findings, or conclusions—including the scientific material those assumptions, findings, or conclusions are based upon—that the CalEPA External Scientific Peer Review Program has determined you can address with confidence, based on your expertise and experience. Your review should take into account both the scientific basis for the proposed rule and the intended application or implementation of that science in the context of the proposed rule.

Note: you are also invited to identify and address additional subjects that should be considered as part of the scientific basis of the proposed rule, and to consider whether you conclude the proposed rule, taken as a whole, is based on sound scientific knowledge, methods, and practices. If you decide to address other assumptions,

findings, or conclusions than you were asked to, please clearly identify the expertise and experience you are relying on to do so.

You may have been asked to review the implementation or application of science that has previously been peer reviewed. In some cases, there is a clear, previously-reviewed scientific basis for what you are reviewing but the scientific basis of a new implementation of the science still must be reviewed. For example, the scientific foundation for a drinking water standard may have been reviewed when the drinking water standard was adopted, but you might determine that the same scientific foundation does not support the use of the same standard to protect aquatic life in a river.

You may ask for clarification or for additional specific supporting documents. We will provide what we can to you and all reviewers. Send clarification questions to Dr. Yoram Rubin (rubin@ce.berkeley.edu).

Text to include in your review.

- Your name, professional affiliation, and the date.
- The name of the item you are reviewing.
- Begin your review with, "Based on my expertise and experience, I am reviewing the findings, assumptions, or conclusions I agreed I could review with confidence:" and list them by number, as they are referred to in Attachment 2 of the review request.

Formatting your review. To ensure all people can perceive, understand, navigate, and interact with the materials posted on CalEPA websites, files posted on these websites must meet accessibility criteria. Your peer review may be posted on a CalEPA website so you should submit your review in an accessible format. The recommended way to make your file accessible is to use Microsoft Word to write your review and to use only basic text and headings during document creation. Then, run the built-in Word Accessibility Checker and resolve any accessibility issues.

Making your review accessible is your responsibility. We want to avoid—as much as possible—CalEPA staff making any kind of modification to your final peer review after you submit it. If your document does not meet accessibility requirements, we may send it back to you to fix and resubmit.

General accessibility criteria include:

- Text. Text should be black, in Arial, size 12 points or larger.
- Non-text elements. If you use them, graphs, figures, images, charts, or tables must follow accessibility criteria regarding meaningful captions and alternative text.

- Layout. Avoid complex document layouts, such as having text in more than one column, use of text boxes, use of color, and applying different font styles (i.e., bolding, underlining, etc.). It's best to avoid letterhead, headers, and footers, aside from page numbers.
- Other requirements. There are also additional accessibility formatting requirements, including meaningful hyperlink text and appropriate use of styles for headings and lists.

The links below provide some information on accessible online content:

- Resources for Creating Accessible Content (created by the California Department of Rehabilitation).
- Video lessons for accessible Word documents (created by Microsoft).
- State, Federal, and Other Related Laws & Regulations on Digital Accessibility (created by the California Department of Rehabilitation).

You may be asked to supplement your review. The organization requesting the review may require clarification or additional information on a specific subject. If this occurs, I will contact you to revise your review to address those comments.

If you are asked to discuss your comments. After you have submitted your review, you may be approached by third parties, the press, or by colleagues. You are under no obligation to discuss your comments with them and we recommend that you do not. Outside parties are provided an opportunity to address a proposed regulatory action during the public comment period. Discussions outside the provided avenues for comment could seriously impede the established process for vetting the proposal under consideration. Please direct third parties to us.

State Water Resources Control Board

13 December 2021

Pertti J. Hakkinen, Ph.D. Sent via email
"NIH Special Volunteer" in Toxicology and Environmental Health Sciences
National Center for Biotechnology Information
National Institutes of Health
Kailua, Hawaii 96734

SUBJECT: INITIATION OF REVIEW OF THE SCIENTIFIC BASIS OF THE PROPOSED ADOPTION OF MOTOR VEHICLE TIRES CONTAINING N-(1,3-DIMETHYLBUTYL)-N'-PHENYL-P-PHENYLENEDIAMINE (6PPD) AS A PRIORITY PRODUCT

Dear Dr. Hakkinen,

Thank you for accepting the role as an external scientific peer reviewer of subject request. The purpose of this letter is to initiate the external peer review.

Components of the review:

1. Guidance for reviewers.
2. Request for External Scientific Peer Review, with the following attachments:
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The findings, assumptions, and conclusions that need review are listed in Attachment 2 of the review request. I ask that you review those findings, assumptions, and conclusions as outlined in your 23 November 2021 communication that you can address with confidence, based on your expertise and experience. These are conclusions 1 and 2.

I will help with any questions you have. To ensure a clear record of our communication, all communications should be in writing (email is preferred).

Please email your reviews to me ***no later*** than 14 January 2022. I will subsequently forward all reviews and the curricula vitae of all reviewers to the requesting organization. All information may be posted at their website.

The organization requesting the review may require clarification or additional information on a specific subject. If this occurs, I will ask you to supplement your review to address those comments.

Your participation in this review assignment is most appreciated.

Sincerely,

Carol Perkins
Manager, CalEPA External Scientific Peer Review Program
Office of Research, Planning, and Performance
State Water Resources Control Board
1001 “I” Street, 13th Floor Sacramento, California 95814
Carol.Perkins@waterboards.ca.gov

Encl: *Guidance for Reviewers*

Guidance for Reviewers

Updated October 2021

Communication with the Peer Review Program. To ensure a clear record of our communication, all of our communications should be in writing (email is preferred).

Confidentiality. You are required to help maintain the confidentiality of this review process.

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- You should not inform others about your role as reviewer.
- You will not know the names of other reviewers until all reviews are complete and the organization decides to release reviews.
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Independence. If you learn what you are reviewing was developed by someone with whom you share a common supervisor or have or had a working relationship, you must let us know so that we can determine whether to seek another peer reviewer.
For example, if the CalEPA organization asking for the review contracted with someone in your department or organization to help develop the material you were asked to review, you have a potential conflict of interest.

Your review. The statutory mandate for external scientific peer review (California Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether "the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices."

In your review, we request that you make that determination for the CalEPA organization's assumptions, findings, or conclusions—including the scientific material those assumptions, findings, or conclusions are based upon—that the CalEPA External Scientific Peer Review Program has determined you can address with confidence, based on your expertise and experience. Your review should take into account both the scientific basis for the proposed rule and the intended application or implementation of that science in the context of the proposed rule.

Note: you are also invited to identify and address additional subjects that should be considered as part of the scientific basis of the proposed rule, and to consider whether you conclude the proposed rule, taken as a whole, is based on sound scientific knowledge, methods, and practices. If you decide to address other assumptions,

findings, or conclusions than you were asked to, please clearly identify the expertise and experience you are relying on to do so.

You may have been asked to review the implementation or application of science that has previously been peer reviewed. In some cases, there is a clear, previously-reviewed scientific basis for what you are reviewing but the scientific basis of a new implementation of the science still must be reviewed. For example, the scientific foundation for a drinking water standard may have been reviewed when the drinking water standard was adopted, but you might determine that the same scientific foundation does not support the use of the same standard to protect aquatic life in a river.

You may ask for clarification or for additional specific supporting documents. We will provide what we can to you and all reviewers. Send clarification questions to Dr. Yoram Rubin (rubin@ce.berkeley.edu).

Text to include in your review.

- Your name, professional affiliation, and the date.
- The name of the item you are reviewing.
- Begin your review with, "Based on my expertise and experience, I am reviewing the findings, assumptions, or conclusions I agreed I could review with confidence:" and list them by number, as they are referred to in Attachment 2 of the review request.

Formatting your review. To ensure all people can perceive, understand, navigate, and interact with the materials posted on CalEPA websites, files posted on these websites must meet accessibility criteria. Your peer review may be posted on a CalEPA website so you should submit your review in an accessible format. The recommended way to make your file accessible is to use Microsoft Word to write your review and to use only basic text and headings during document creation. Then, run the built-in Word Accessibility Checker and resolve any accessibility issues.

Making your review accessible is your responsibility. We want to avoid—as much as possible—CalEPA staff making any kind of modification to your final peer review after you submit it. If your document does not meet accessibility requirements, we may send it back to you to fix and resubmit.

General accessibility criteria include:

- Text. Text should be black, in Arial, size 12 points or larger.
- Non-text elements. If you use them, graphs, figures, images, charts, or tables must follow accessibility criteria regarding meaningful captions and alternative text.

- Layout. Avoid complex document layouts, such as having text in more than one column, use of text boxes, use of color, and applying different font styles (i.e., bolding, underlining, etc.). It's best to avoid letterhead, headers, and footers, aside from page numbers.
- Other requirements. There are also additional accessibility formatting requirements, including meaningful hyperlink text and appropriate use of styles for headings and lists.

The links below provide some information on accessible online content:

- Resources for Creating Accessible Content (created by the California Department of Rehabilitation).
- Video lessons for accessible Word documents (created by Microsoft).
- State, Federal, and Other Related Laws & Regulations on Digital Accessibility (created by the California Department of Rehabilitation).

You may be asked to supplement your review. The organization requesting the review may require clarification or additional information on a specific subject. If this occurs, I will contact you to revise your review to address those comments.

If you are asked to discuss your comments. After you have submitted your review, you may be approached by third parties, the press, or by colleagues. You are under no obligation to discuss your comments with them and we recommend that you do not. Outside parties are provided an opportunity to address a proposed regulatory action during the public comment period. Discussions outside the provided avenues for comment could seriously impede the established process for vetting the proposal under consideration. Please direct third parties to us.

State Water Resources Control Board

13 December 2021

Staci L. Simonich, Ph.D. Sent via email
Executive Associate Dean and Professor
Department of Environmental and Molecular Toxicology and Department of Chemistry
Oregon State University, 430B Strand Agricultural Hall
Corvallis, OR 97330-2140

SUBJECT: INITIATION OF REVIEW OF THE SCIENTIFIC BASIS OF THE PROPOSED ADOPTION OF MOTOR VEHICLE TIRES CONTAINING N-(1,3-DIMETHYLBUTYL)-N'-PHENYL-P-PHENYLENEDIAMINE (6PPD) AS A PRIORITY PRODUCT

Dear Professor Simonich,

Thank you for accepting the role as an external scientific peer reviewer of subject request. The purpose of this letter is to initiate the external peer review.

Components of the review:

1. Guidance for reviewers.
2. Request for External Scientific Peer Review, with the following attachments:
    a. Attachment 1: Plain English Summary.
    b. Attachment 2: Scientific Assumptions, Findings, and Conclusions to Review.
    c. Attachment 3: Individuals who Participated in the Development of the Proposal.
    d. Attachment 4: References Cited.
3. Errata to the External Scientific Peer Review Request
4. Proposed rule or related documents (Product-Chemical Profile).
5. Electronic copies of references cited.

All components of the review are posted at a secure FTP site:

- Site: https://ftp.waterboards.ca.gov
- Username: gbowes-ftp33
- Password: 7nDAUW

The findings, assumptions, and conclusions that need review are listed in Attachment 2 of the review request. I ask that you review those findings, assumptions, and conclusions as outlined in your 24 November 2021 communication that you can address with confidence, based on your expertise and experience. These are conclusions 1 and 2.

I will help with any questions you have. To ensure a clear record of our communication, all communications should be in writing (email is preferred).

Please email your reviews to me ***no later*** than 14 January 2022. I will subsequently forward all reviews and the curricula vitae of all reviewers to the requesting organization. All information may be posted at their website.

The organization requesting the review may require clarification or additional information on a specific subject. If this occurs, I will ask you to supplement your review to address those comments.

Your participation in this review assignment is most appreciated.

Sincerely,

Carol Perkins
Manager, CalEPA External Scientific Peer Review Program
Office of Research, Planning, and Performance
State Water Resources Control Board
1001 “I” Street, 13th Floor Sacramento, California 95814
Carol.Perkins@waterboards.ca.gov

Encl: *Guidance for Reviewers*

Guidance for Reviewers

Updated October 2021

Communication with the Peer Review Program. To ensure a clear record of our communication, all of our communications should be in writing (email is preferred).

Confidentiality. You are required to help maintain the confidentiality of this review process.

- Confidentiality began at the point you were contacted by the University of California, Berkeley.
- You should not inform others about your role as reviewer.
- You will not know the names of other reviewers until all reviews are complete and the organization decides to release reviews.
- You not allowed to discuss the proposal with employees of the requesting organization or individuals who participated in development of the proposal, unless you let us know you have a clarifying or technical question and we put you in contact with employees of the requesting organization. The individuals who participated in development are listed in Attachment 3 of the review request.

Independence. If you learn what you are reviewing was developed by someone with whom you share a common supervisor or have or had a working relationship, you must let us know so that we can determine whether to seek another peer reviewer.
For example, if the CalEPA organization asking for the review contracted with someone in your department or organization to help develop the material you were asked to review, you have a potential conflict of interest.

Your review. The statutory mandate for external scientific peer review (California Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether "the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices."

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You may ask for clarification or for additional specific supporting documents. We will provide what we can to you and all reviewers. Send clarification questions to Dr. Yoram Rubin (rubin@ce.berkeley.edu).

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- The name of the item you are reviewing.
- Begin your review with, "Based on my expertise and experience, I am reviewing the findings, assumptions, or conclusions I agreed I could review with confidence:" and list them by number, as they are referred to in Attachment 2 of the review request.

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- Layout. Avoid complex document layouts, such as having text in more than one column, use of text boxes, use of color, and applying different font styles (i.e., bolding, underlining, etc.). It's best to avoid letterhead, headers, and footers, aside from page numbers.
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If you are asked to discuss your comments. After you have submitted your review, you may be approached by third parties, the press, or by colleagues. You are under no obligation to discuss your comments with them and we recommend that you do not. Outside parties are provided an opportunity to address a proposed regulatory action during the public comment period. Discussions outside the provided avenues for comment could seriously impede the established process for vetting the proposal under consideration. Please direct third parties to us.

Prof. Dr. Markus Brinkmann

Family name:	Brinkmann
First name:	Markus
Date of birth:	16 May 1986 in Krefeld, Germany
Nationality:	Germany
Family status:	Married, 4 children
Current position:	Assistant Professor, tenure-track
Affiliation:	University of Saskatchewan School of the Environment & Sustainability and Toxicology Centre 44 Campus Drive, Saskatoon, SK S7N 5B3, Canada Phone: +1306-966-1204 E-Mail: markus.brinkmann@usask.ca Web: https://sens.usask.ca/people/faculty/core-faculty/markus-brinkmann.php

Education:

2012-2015	Doctoral Degree (Dr. rer. nat.) in Biology, RWTH Aachen University, Germany; Supervisor: Prof. Dr. Henner Hollert
2009-2011	Master of Science (MSc) in Ecotoxicology, RWTH Aachen University, Germany; Supervisor: Prof. Dr. Henner Hollert
2006-2009	Bachelor of Science (BSc) in Biology, Major in Environmental Research, RWTH Aachen University, Germany; Supervisor: Prof. Dr. Henner Hollert

Professional career:

Academic primary appointments

2018 - present	School of the Environment & Sustainability, University of Saskatchewan, Canada: *Assistant Professor*
2016-2018	Toxicology Centre, University of Saskatchewan, Canada: *Postdoctoral Fellow*
1997–2002	Institute for Environmental Research, RWTH Aachen University, Germany: *Research Associate*

Other appointments

2020-current	Meewasin Valley-wide Monitoring Framework - Technical Advisory Committee, Saskatchewan, Canada
2018-current	Health and Environmental Sciences Institute (HESI) Bioaccumulation Committee, Fish Sub-Team, USA
2011-current	Environmental Sciences Europe, Springer: *Member of the Editorial Board*
Grant review	Canada Foundation for Innovation John R. Evans Leaders Fund program (CFI-JELF), Canada; Initiative and Networking Fund, Helmholtz Association, Germany; Ontario Agri-Food Innovation Alliance (OMAFRA-UofG Partnership), Canada
Paper review	Reviewer for >23 scientific journals, including Aquatic Toxicology, Chemosphere, Environmental Science and Technology, Environmental Toxicology and Chemistry, Environment International, Environmental Pollution, Water Research.

Scientific profile:

Subject areas: Aquatic Toxicology, Ecotoxicology, Mechanistic Toxicology, Toxicokinetics, Physiology, Mechanistic Modelling

Professional memberships: Society of Environmental Toxicology and Chemistry (SETAC), Canadian Ecotoxicity Workshop (CEW), American Chemicals Society (ACS), American Geophysical Union (AGU)

Honours and prizes:

2020	Canadian Broadcasting Corporation (CBC) Saskatchewan Future 40 Award, Canada
2019	Thuenen Award for Excellent Scientific Achievements, Awarded to Marko Freese and the Research Team of PNAS Article, Germany

2019	NSERC Early Career Research Supplement, Natural Sciences and Engineering Research Council of Canada (NSERC), Canada
2017	Friedrich-Wilhelm Award, RWTH Aachen University, Germany
2016-2018	Banting Postdoctoral Fellowship, Natural Sciences and Engineering Research Council of Canada (NSERC), Canada
2016	Borchers Medal, RWTH Aachen University, Germany
2016	SETAC German Language Branch Research Award, Germany
2013-2015	Graduate Fellowship of the German Academic Scholarship Foundation, Germany

10 most important publications:

1. Grimard, C., Mangold-Döring, A., Schmitz, M., Alharabi, H., Jones, P.D., Giesy, J.P., **Hecker, M.**, **Brinkmann, M.** (2020) *In vitro-in vivo* and cross-life stage extrapolation of uptake and biotransformation of benzo[*a*]pyrene in the fathead minnow (*Pimephales promelas*). *Aquatic Toxicology*, 105616.
2. **Brinkmann, M.**, Alharbi, H., Fuchylo, U., Wiseman, S., Morandi, G., Peng, H., **Giesy, J.P.**, Jones, P.D., **Hecker, M.** (2020) Mechanisms of pH-dependent uptake of ionizable organic chemicals by fish from oil sands process-affected water (OSPW). *Environmental Science and Technology*, 54: 9547-9555.
3. Ouellet, J., Gembé, C., Buchinger, S., Reifferscheid, G., **Hollert, H.**, **Brinkmann, M.** (2020) Validation of the micro-EROD assay with H4IIE cells for assessing sediment contamination with dioxin-like chemicals. *Environmental Pollution* 265: 114984.
4. Freese, M., Rizzo, L., Pohlmann, J.-D., Marohn, L., Witten, P.E., Gremse, F., Rütten, S., Güvener, N., Michael, S., Wysujack, K., Lammers, T., Kiessling, F., **Hollert, H.**, Hanel, R., **Brinkmann, M.** (2019) Bone resorption and body reorganization during maturation induce maternal transfer of toxic metals in anguillid eels*. Proceedings of the National Academy of Sciences of America (PNAS)* 116: 11339-11344.
5. Xiao, H. & **Brinkmann, M.**, Thalmann, B., Schiwy, A., Große, B.S., Achten, C., Eichbaum, K., Gembé, C., Seiler, T., **Hollert, H.** (2017) Towards Streamlined Identification of Dioxin-like Compounds in Environmental Samples through Integration of Suspension Bioassay. *Environmental Science & Technology* 51: 3382-3390.
6. **Brack, W.**, Dulio, V., Ågerstrand, M., Allan, I., **Altenburger, R.**, **Brinkmann, M.**, Bunke, D., Burgess, R.M., Cousins, I., Escher, B.I., Hernández, F.J., Hewitt, L.M., Hilscherová, K., Hollender, J., **Hollert, H.**, Kase, R.,Klauer, B., Lindim, C., López Herráeza, D., Miègen, C., Munthe, J., O'Toole, S., Posthuma, L., Rüdel, H., Schäfer, R.B., Sengl, M., Smedes, F., van deMeent, D., van den Brink, P.J., van Gils, J., van Wezel, A.P., Vethaak, A.D., Vermeirssen, E., von der Ohe, P.C., Vrana, B. (2017) Towards the review of the European Union Water Framework Directive: Recommendations for more efficient assessment and management of chemical contamination in European surface water resources. *Science of the Total Environment* 576: 720–737.
7. **Brinkmann, M.**, Schlechtriem, C., Reininghaus, M., Eichbaum, K., Buchinger, S., Reifferscheid, G., **Hollert, H.**, Preuss, T.G. (2016) Cross-Species Extrapolation of Uptake and Disposition of Neutral Organic Chemicals in Fish Using a Multispecies Physiologically-Based Toxicokinetic Model Framework. *Environmental Science and Technology* 50: 1914–1923.
8. Schiwy, A. & **Brinkmann, M.**, Thiem, I., Guder, G., Winkens, K., Eichbaum, K., Nüßer, L., Thalmann, B., Buchinger, S., Reifferscheid, G., Seiler, T.-B., Thoms, B., **Hollert, H.** (2015) Determination of the dioxin-like potential of single substances, complex mixtures and environmental samples in the Micro-EROD assay with H4IIE cells. *Nature Protocols* 10: 1728–1741.
9. **Brinkmann, M.**, Eichbaum, K., Reininghaus, M., Koglin, S., Kammann, U., Baumann, L., Segner, H., Zennegg, M., Buchinger, S., Reifferscheid, G., **Hollert, H.** (2015) Towards science-based sediment quality standards for dioxin-like compounds – effects of field-collected sediments in rainbow trout (*Oncorhynchus mykiss*). *Aquatic Toxicology* 166: 50-62.
10. **Brinkmann, M.**, Eichbaum, K., Buchinger, S., Reifferscheid, G., Bui, T., **Schaeffer, A.**, **Hollert, H.**, Preuss, T.G. (2014) Understanding receptor-mediated effects in rainbow trout: *in vitro-in vivo* extrapolation using physiologically based toxicokinetic models. *Environmental Science and Technology* 48: 3303-3309.

Metrics: ORCID: 0000-0002-4985-263X; h-index Google Scholar: 22 (1383 citations total).

Third-party funds raised (last five years): Total value: 2.54 Mio C$: 4 x NSERC, 3 x Other Federal, 1 x Provincial, 2 x Industry and 4 x Other.

Biography:
Dr. Markus Brinkmann received his PhD from Aachen University in Germany and is currently an Assistant Professor in Exposure and Risk Assessment Modelling in the School of Environment and Sustainability at USask. He is a member of the Toxicology Centre, the GIobal Institute for Water Security, and the Centre for Hydrology. Dr. Brinkmann's research focuses on the movement of chemical contaminants through the aquatic environment and the process by which these contaminants are taken up and cause harmful effects in aquatic organisms. He combines expertise from toxicology, environmental chemistry, and hydrology, and uses computational models that are informed by experimental and field data. Some of his recent projects have focused on assessing the environmental impacts of stormwater and municipal wastewater effluents in cities across Canada, measuring sediment contamination in the Saskatchewan River, quantifying risks associated with oil sands developments, and improving the prospective environmental risk assessments of chemicals.

November 8, 2021

Pertti (Bert) J. Hakkinen, Ph.D., F-SRA

Permanent Home: 445 Kailua Road, #5207, Kailua, Hawaii 96734
Mobile Phone: 808-208-0436
Email: pertti.hakkinen@nih.gov

Note: *I retired from the U.S. National Institutes of Health (NIH) on 3/31/20 after being the Senior Toxicologist and Toxicology & Environmental Health Science Advisor at the NIH National Library of Medicine (NLM) since 2008. On 4/1/20, I became an "NIH Special Volunteer" in toxicology and environmental health at the NIH NLM's National Center for Biotechnology Information (NCBI).*

Current Affiliations:
"NIH Special Volunteer" in Toxicology and Environmental Health, NCBI, NLM, NIH. Efforts are focused on identifying new types and sources of toxicology and environmental health information (databases and documents) for NCBI's PubChem and Bookshelf, and facilitating interactions between NCBI staff and the developers of the possible new sources of information.
and
Adjunct Associate Professor in Preventive Medicine and Biostatistics in the F. Edward Hebért School of Medicine at the Uniformed Services University of the Health Sciences (USU) in Bethesda, Maryland. This includes giving lectures and having occupational and environmental medicine physicians do rotations (virtual in 2020-2021) with me. I have been affiliated with USU since 2008.
and
Since 2014, I have been a co-leader of the Environmental Health Sciences graduate level course offered by the Foundation for Advanced Education in the Sciences at the NIH (FAES@NIH). (This course was not offered in 2020-2021.)

Overview of Experience:
Extensive global professional experience in toxicology, pharmacology, databases, apps, and in assessing, managing, and communicating human exposures and risks.

Some Past Affiliations:
• Principal, Product Safety and REACH at Gradient Corporation in Cambridge, Massachusetts from mid-2006 – end of 2007.
• On the auxiliary staff of the European Commission from mid-2003 - mid-2006, primarily as a consumer product exposure and safety expert.
• On the staff of Toxicology Excellence for Risk Assessment (TERA), a non-profit organization between 2001 and 2003, and in early 2008 as a visiting scientist before starting the job at NIH.
• Procter & Gamble Company global toxicology, human exposure, risk assessment, risk management, consumer comments, and trade association and regulatory agency support between 1982 and 2001 (North and South America, Europe, and Asia, with on-the-ground assignments in the U.S. and also mid-1999 – mid-2000 in Japan).

Examples of Peer Reviews:

• I have been an invited expert or reviewer for U.S. EPA-, State of California-, Health Canada-, and European Commission-sponsored efforts to develop or revise human exposure assessment guidance, resource documents, and software.
• I have served in 2020-2021 as a peer reviewer for three chapters submitted for the new edition for Patty's Industrial Hygiene, and for manuscripts submitted to several journals, e.g., Chemosphere, Food and Chemical Toxicology, Frontiers in Public Health (Disaster and Emergency Medicine section), and the Journal of Exposure Science and Environmental Epidemiology.
• I have an ongoing role after nomination by NIH NIEHS on the Japanese Center for the Validation of Alternative Methods (JaCVAM) Peer Review Panel (PRP) for the evaluation, validation, and possible global regulatory acceptance of new alternatives to animal testing methods.

Education:

- Oak Ridge National Laboratory, Biology Division. Postdoctoral Investigator in Respiratory Toxicology, and Exposure and Risk Assessment. 1979 -1982
- University of California, San Francisco, Department of Pharmacology. Ph.D. in Comparative Pharmacology and Toxicology. 1974-1979
- University of California, Santa Barbara, Department of Biology. B.A. in Biochemistry and Molecular Biology. 1970-1974

Professional Society Involvement:

I am a member of the Society of Toxicology (SOT), a member of the International Society of Exposure Science (ISES) and am currently on ISES' Awards, General Scientific Meetings, and Publications Committees. Also, I am a member and Fellow of the Society for Risk Analysis (SRA).

Awards (Selected):

- Received SRA's 1996 Outstanding Service Award "in recognition of devoted and distinguished service to the Society."
- One of the National Institutes of Health (NIH) annual "Director's Awards" (August 2011), with this award recognizing a role in efforts led by NIEHS related to the Deepwater Horizon Gulf Oil Spill.
- Received the 2011 "Risk Communication Excellence Award" from the Alliance for Chemical Safety for work he and his project team did on the NIH NLM CHEMM project.
- Received the Fellow of the Society award (F-SRA) "in recognition of outstanding contributions to the profession of Risk Analysis." 2014. Society for Risk Analysis (SRA).

Publications:

I have authored and co-authored numerous other publications, including ones on consumer product exposure and risk assessments, consumer risk perceptions, toxicological interactions, respiratory tract toxicology, and computer software and databases. Recent publications include:

• New Studies About Everyday Types of Chemical Exposures: What Readers Should Consider.
• What online toxicology resources are available at no cost from the (US) National Library of Medicine to assist practicing OEM physicians?
• Exploring Global Exposure Factors: Resources for Use in Consumer Exposure Assessments.
• Exploring Current Read-across Applications and Needs Among Selected U.S. Federal Agencies, and
• One of three editors of The Practice of Consumer Exposure Assessment book published in 2019.

Staci L. Simonich

Executive Associate Dean and Professor, Department of Environmental and Molecular Toxicology and Department of Chemistry, Oregon State University, 430B Strand Agricultural Hall, Corvallis, OR 97330-2140 TEL: (541) 737-5032, staci.simonich@oregonstate.edu

Education

2020	M.B.A, Oregon State University, Corvallis, OR
1995	Ph.D., Chemistry, Indiana University, Bloomington, IN
1990	B.S., Chemistry, UW-Green Bay, Green Bay, WI

Relevant Expertise

Environmental analytical chemist with a focus on occurrence, fate, transport, and transformation of organic compounds in natural and engineered environments

Research and Professional Experience

2011-present	Professor, Department of Environmental and Molecular Toxicology and Department of Chemistry, *Oregon State University*
2006-2011	Associate Professor, Department of Environmental and Molecular Toxicology and Department of Chemistry, *Oregon State University*
2001-2006	Assistant Professor, Department of Environmental and Molecular Toxicology and Department of Chemistry, *Oregon State University*
1995-2001	Senior Scientist, The Procter & Gamble Company, Cincinnati, OH

Recent Relevant Service, Honors, and Achievements

2015	Excellence in Graduate Mentoring Award - Oregon State University Graduate School
2013-2020	Associate Editor, *Environmental Science & Technology Letters*
2013	Super Reviewer Award, *Environmental Science & Technology*
2013	Impact Award for Outstanding Scholarship – Oregon State University
2006	Savery Outstanding Young Faculty Award, Oregon State University (1999)
2003	National Science Foundation CAREER Award
2001	SETAC/Roy F. Weston Environmental Chemistry Award

Selected Relevant Publications

1. A. Kramer, S. Dorn, A. Perez, C. Roper, I. Titaley, K. Cayton, R. Cook, P. Cheong, S.L. Massey Simonich*. **2021**. "Assessing the Oxidative Potential of PAHs in Ambient PM2.5 using the DTT Consumption Assay", *Environmental Pollution,* 285, 117411.
2. L. St. Mary*, L. Trine, C. Roper, J. Wiley, S. Massey Simonich, M. McCoustra, T. Henry. **2021**. "Time-related Alteration of Aqueous Phase Anthracene and Phenanthrene Photoproducts in the Presence of TiO2 Nanoparticles", *Environmental Science & Technology,* 55(6), 3727-3735.
3. Afeng Chen, S.L. Massey Simonich, Hui Kang, Zhouqing Xie, Xiaoguo Wu*. **2021**. "Polycyclic aromatic hydrocarbons (PAHs) in urban stream sediments of Suzhou Industrial Park, an emerging eco-industrial park in China: Occurrence, sources and potential risk", *Ecotoxicology and Environmental Safety,* 214, 112095.

4. Afeng Chen, S.L. Massey Simonich, Hui Kang, Zhouqing Xie, Xiaoguo Wu*. **2021**. "Volatilization of polycyclic aromatic hydrocarbons (PAHs) over the North Pacific and adjacent Arctic Ocean: the impact of offshore oil drilling", *Environmental Pollution,* 268, 115963.
5. I. Titaley, S.L. Massey Simonich, M. Larsson. 2020. "Recent Advances in the Study of the Remediation of Polycyclic Aromatic Compounds (PAC)-Contaminated Soils: Transformation products, toxicity, and bioavailability analyses", *Environmental Science & Technology Letters, 7, 873-882.*
6. C. Roper, A. Perez, D. Barrett, S.L. Massey Simonich. 2020. "Workflow for comparison of chemical and biological metrics of filter collected PM2.5", *Atmospheric Environment*, 226 (117379).
7. A. Kramer, L. Campbell, J. Donatuto, M. Heidt, M. Kile, S.L. Massey Simonich. 2020. "Impact of local and regional sources of PAHs on tribal reservation air quality in the U.S. Pacific Northwest" *Science of the Total Environment,* 710, 136412.
8. A. Kramer, K. Suski, D. Bell, A. Zelenyuk, S.L. Massey Simonich. 2019. "Formation of polycyclic aromatic hydrocarbon oxidation products in α-pinene secondary organic aerosol particles formed through ozonolysis" *Environmental Science & Technology,* 53(12), 6669-6677.
9. L. Santiago Delgado Trine, E. Davis, C. Roper, L. Truong, R. Tanguay, S.L. Massey Simonich. 2019. "Formation of PAH Derivatives and Increased Developmental Toxicity During Steam Enhanced Extraction Remediation of Creosote Contaminated Superfund Soil" *Environmental Science & Technology,* 53(8), 4460-4469 doi: 10.1021/acs.est.8b07231
10. I. Titaley, D. Walden, S. Dorn, O. Ogba, S.L. Massey Simonich, P. Cheong. 2019. "Evaluating Computational and Structural Approaches to Predict Transformation Products of Polycyclic Aromatic Hydrocarbons" *Environmental Science & Technology*; 53(3):1595-1607, doi: 10.1021/acs.est.8b05198
11. C. Roper, L. Santiago Delgado, D. Barrett, S.L. Massey Simonich, R. Tanguay. 2018. "PM2.5 Filter Extraction Methods: Implications for Chemical and Toxicological Analyses" *Environmental Science & Technology,* 53(1):434-442*,* doi: 10.1021/acs.est.8b04308.
12. J. Rewert, J. Morre, S.L. Massey Simonich, J. Field. 2018. "In-Vial Extraction Large Volume Gas Chromatography Mass Spectrometry for Analysis of Volatile PFASs in Papers and Textiles" *Environmental Science & Technology,* 52(18):10609-16*.*
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Relevant Current Research Grants and Contracts

- Identification of Remediation Technologies and Conditions that Minimize Formation of Hazardous PAH Breakdown Products at Superfund Sites, NIEHS Superfund Research Program, S. Simonich (PI-Project 5) 4/20-3/25
- Development, Evaluation, and Technology Transfer of BMPs for Optimizing Removal of PAHs, PCBs, PFASs, and Metals from Stormwater at DoD Sites, DoD-SERDP, S. Simonich (PI) 7/18 – 1/22

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January 12, 2022

Review of the scientific basis of the proposed adoption of motor vehicle tires containing *N*-(1,3-dimethylbutyl)-*N'*-phenyl-*p*-phenylenediamine (6PPD) as a priority product

Based on my expertise and experience, I am reviewing the findings, assumptions, or conclusions I agreed I could review with confidence:

- **Conclusion 1:** Coho salmon and other aquatic organisms may be exposed to 6PPD-quinone due to the use of 6PPD in motor vehicles.
- **Conclusion 2:** The 6PPD contained in motor vehicle tires and its oxidation product 6PPD-quinone have the potential to contribute to or cause significant or widespread impacts to the threatened and endangered populations of coho salmon in California, as well as to other aquatic organisms and the Native American tribes that rely on them.
- Based on my expertise and experience, I cannot assess part of conclusion 2 with confidence, specifically "and the Native American tribes that rely on them." Therefore, I will exclude the sixth bullet and part of the eighth bullet of conclusion 2 from my peer review.

This review will be structured as follows: first, I will provide some general observations on the proposal; then, I will provide specific comments regarding my detailed review of conclusions 1 and 2 (with the exception noted above) and the supporting bullet points, as well as the Product-Chemical Profile, and last I will provide minor editorial comments and suggestions that I noticed during my review of the documents.

I want to begin by commending the DTSC for creating a compelling, comprehensive, and balanced Product-Chemical Profile that forms a solid basis for the proposed adoption of motor vehicle tires containing 6PPD as a priority product. Based on my thorough review of the provided materials (as outlined in the December 13, 2021, initiation letter), I conclude that the scientific portion of the proposed rule is based on sound scientific knowledge, methods, and practices.

Even though I am certain that a large body of peer-reviewed scientific research will become available in the very near future that will help DTSC's future decision-making (including from my own research group), I concur with the notion that, despite known data gaps, there is sufficient information regarding potential exposures and adverse impacts from motor vehicle tires containing 6PPD to designate this a Priority Product.

Any suggestions and comments provided below are submitted to the DTSC with the intention of further streamlining the Conclusions and the Product-Chemical Profile.

General Observations

- I understand that the Product-Chemical Profile likely follows a standardized template to fulfill a variety of regulatory requirements beyond my knowledge; however, I found that a number of sections, specifically those on environmental and toxicological hazard traits, were hard to follow due to the strictly separate discussion of 6PPD and 6PPD-quinone. A lot of the information on 6PPD that is presented has to be viewed in light of the recent discovery that 6PPD in aqueous solutions is readily and rapidly transformed into a variety of products, including 6PPD-quinone. This information is provided in the Product-Chemical Profile only after information on both compounds has been presented separately, and as you will see in my specific comments below, I strongly suggest providing this essential context before presenting information on both compounds individually.
- From the previous comment arises, in my view, a need to make sure that the conclusions (both conclusions 1 and 2 below, as well as those starting on page 73 in the Product-Chemical Profile) are based on the environmental risks of 6PPD-quinone alone, the presence of which in the environment is due to the use of 6PPD in motor vehicle tires, rather than also listing environmental and toxicological hazards of 6PPD. 6PPD breaks down rapidly in aqueous solutions and is therefore difficult to test in standardized biotests. It must be expected that the effects observed in these tests for 6PPD are a mixture effect of both 6PPD and 6PPD-quinone (and potentially other transformation products) and that effect thresholds derived from these experiments are associated with considerable uncertainty. In my view, there is a solid case to be made based on the presence of 6PPD-quinone and its toxicological hazards to coho salmon alone.
- The revised median lethal concentration of 6PPD-quinone in coho salmon mentioned by Koledziej (2021) has now been published (as of January 11, 2022) in the peer-reviewed literature (https://doi.org/10.1021/acs.estlett.1c00910). Please make sure to work this information into the Product-Chemical Profile and the conclusions.

Specific Comments

Scientific Assumptions, Findings, and Conclusions to Review

Conclusion 1: Coho salmon and other aquatic organisms may be exposed to 6PPD-quinone due to the use of 6PPD in motor vehicle tires.

This conclusion is thoroughly supported by the peer-reviewed literature, reports, and presentations cited in the Product-Chemical Profile. I recognize that the number of available monitoring studies specifically measuring 6PPD-quinone in surface waters in California is currently still limited, but I expect more data to become available in the following months, which will further consolidate the observed concentrations reported to date. Looking at other studies measuring the compound across the globe, we must assume that the compound is ubiquitously found wherever vehicles are driven on roads and often at concentrations above those that are lethal to coho salmon under laboratory conditions.

- 6PPD is used in nearly all motor vehicle tires in California to protect the rubber from degradation by oxygen and ozone.

  The literature that was summarized in the Product-Chemical Profile and that I reviewed supports the conclusion that 6PPD is used as an antidegradant to protect the tire rubber from oxygen and ozone in virtually all motor vehicle tires today. By extension, this can be assumed to be also true for the motor vehicle tire market in California.

- 6PPD is a high-production volume chemical, and motor vehicle tires are one of its main uses.

  Reports by the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) Commission and the Organisation for Economic Co-operation and Development (OECD) cited in the Profile conclude that 6PPD is a high-production volume chemical and that motor vehicle tires are the primary product in which 6PPD is used. None of the 26 companies directly producing or importing 6PPD in the US are located in California. Thus, it must be assumed that motor vehicle tires are the main pathway or product through which 6PPD can enter California's waterways, rather than direct emissions through manufacturing or transport of 6PPD.

- 6PPD is added to motor vehicle tires at concentrations of 1 to 2% and is designed to slowly migrate from the interior of the tire towards its surface over the lifetime of the tire, such that there is a constant supply of 6PPD and its oxidation products at the surface of the tire.

Reports by the OSPAR Commission and the US Tire Manufacturers Association (USTMA) support that new motor vehicle tires can contain up to as much as 1-2% of 6PPD. The mechanism through which 6PPD functions to protect the tire rubber is well-established in the scientific literature (e.g., Huntink et al. 2004, Cibulkova et al. 2005). 6PPD has been selected as an antidegradant based on finetuning the (1) diffusion coefficients in rubber required to ensure a constant re-supply of the compound on the tire surface, as well as (2) its anti-degradant potential. It is acknowledged that the selection of a suitable alternative that does not show the same or other hazard traits (either the parent or its transformation products) as 6PPD-quinone might require careful optimization. This can be expected to present challenges during the process of finding alternatives, especially when balancing environmental considerations with safety requirements, and will likely be a slow process.

- By design, 6PPD is highly reactive and forms a number of reaction products when in contact with oxygen and ozone, including 6PPD-quinone.

  This conclusion is supported well by initial studies conducted by Lattimer et al. as early as 1983, as well as several subsequent studies. Even though these studies have identified a number of transformation products (one of which had the same mass as 6PPD-quinone but was identified as a 6PPD-dinitrone instead), none of these studies were able to identify 6PPD-quinone, potentially due to the limited capabilities of analytical methods at the time. Tian et al. 2021 provided compelling evidence for the generation of 6PPD-quinone, which has since been analytically verified by a number of research groups and contract labs and confirmed with a variety of fully-synthetic preparations of neat 6PPD-quinone.

- Tires release 6PPD and its reaction products into the environment through mechanical tire abrasion on the roads, which produces microplastics known as tire wear particles. It is estimated that in the United States 4.7 kilograms of tire wear particles are generated per person each year. Once in the environment, tire wear particles can release 6PPD and its reaction product 6PPD-quinone.

  This conclusion is well-established: tires that are being driven on road surfaces generate tire wear particles, which in turn can release potentially harmful chemicals. Tian et al. (2021) and Klöckner et al. (2020, 2021) describe the association of 6PPD and 6PPD-quinone with tire wear particles. The estimated amounts of tire wear particles released per capita and year are well in line with values for other parts of the world, including other US states and Europe, and can be expected to be a thorough basis for mass balance analyses and risk assessments.

- In 2020 alone, over 171 million tires were driven on California's roads. The large number of tires used in California each year poses major challenges to their end-of-life disposition. After their useful life, tires can be landfilled, recycled, or reused. Many of the end-of-life uses of tires (such as for erosion control, flood control, stormwater treatment, or playground surfaces) provide a pathway for chemicals like 6PPD and its reaction products to migrate into the aquatic environment.

  The question of what to do with end-of-life tires has been an important and controversial topic for quite some time. A fraction of the large amounts of end-of-life tires generated each year is now increasingly recycled and put to use in many different sectors, which have been outlined in the Product-Chemical Profile. Landscaping and erosion control, recycled rubber driveways, sports tracks, playground surfaces, and filter materials are only some named examples. In each of these, 6PPD and its transformation products, such as 6PPD-quinone, could be released from the recycled rubber and enter the water cycle. Dedicated scientific research establishing a more quantitative estimate is urgently required.

- Stormwater runoff, particularly from urban areas, can serve as a substantial source of tire-derived contaminants to local aquatic environments.

  An extensive body of peer-reviewed literature has been generated over the past decades and has been thoroughly and comprehensively summarized in the Product-Chemical Profile. Thus, I consider this conclusion well supported.

- 6PPD-quinone has been detected in California waterways at concentrations above those shown to kill at least half of coho salmon in laboratory experiments.

  This conclusion is supported by data presented in Tian et al. (2021, 2022). The qualifying statement that these median lethal concentrations are based on laboratory experiments is important, as it can be expected that environmental effects might be modulated in the presence of combined stressors, that is, are likely to be more pronounced under hypoxic conditions, at temperatures outside of the optimal temperature range for coho salmon, or in combination with other chemical pollutants. It is important to note that the concentrations presented in Tian et al. (2021) were determined with a standard that was prepared by the authors through ozonation of 6PPD. Since synthetic, commercially-available neat 6PPD-quinone is available, the research team has confirmed that it generated a greater instrument response compared to the standard prepared by the authors (Koledziej 2021). As recently published by Tian et al. (2022), measured concentrations were overestimated by about 8 to 10-fold. At the same time, however, the same pertains to reported median lethal concentrations (the revised LC50 is as low as 95 ng/L), confirming that the concentrations measured in California are still well-above concentrations killing half of the coho salmon in laboratory experiments.

- Coho salmon are already extinct in California waters near highly populated, high traffic density areas. The remaining coho populations in the less heavily populated areas of the state are either threatened or endangered.

  The section "Potential for Adverse Impacts to Coho Salmon" establishes well that Coho salmon population trajectories have been declining in California for over half a century, by about 90% since the 1960s. Several populations are now listed as threatened and endangered, and coho salmon have been extirpated in the San Francisco Bay area, which is one of the most densely populated regions in California.

- The highest concentration of 6PPD-quinone measured to date in the San Francisco Bay Area came from a location whose watershed is 90% open space, indicating that proximity to roads and associated tire wear particles may be more important than the extent of development of surrounding land. This indicates the potential for exposure of aquatic organisms to 6PPD-quinone outside dense urban regions of the state if traffic patterns result in release of TWP to streams.

  While the dataset presented by Tian et al. (2021, 2022) is fairly limited with regards to the number of sampling locations, other studies, including one from our own lab (Challis et al. 2021), suggest that 6PPD-quinone mass loadings are positively correlated with roads and residential areas in an urban watershed. It can be assumed that the same can be generalized to other watersheds, thereby confirming this conclusion.

- The presence of 6PPD-quinone in California waterways at concentrations proven to be lethal to coho salmon indicates that current stormwater treatment efforts are often insufficient for the removal of 6PPD-quinone.

  Stormwater treatment efforts, including those described for California in the Product-Chemical Profile, are often insufficient for removing stormwater pollutants, including 6PPD-quinone. The fact that 6PPD-quinone is detected in stormwater and receiving water bodies at levels that are great enough to kill at least half of coho salmon in laboratory experiments is sufficient to show that current treatment efforts are insufficient for the removal of 6PPD-quinone. Spromberg et al. (2016) have demonstrated that toxicological impacts of highway runoff could be mitigated by treatment using bio-infiltration. Equipping all stormwater outfalls in California that discharge into critical coho salmon habitat with this or similar treatment infrastructure would be prohibitively costly for affected municipalities.

Conclusion 2: The 6PPD contained in motor vehicle tires and its oxidation product 6PPD-quinone have the potential to contribute to or cause significant or widespread impacts to the threatened and endangered populations of coho salmon in California, as well as to other aquatic organisms and the Native American tribes that rely on them.

This conclusion is thoroughly supported by the peer-reviewed literature, reports, and presentations cited in the Product-Chemical Profile. I recognize that the number of available toxicity studies quantifying lethality and sub-lethal effects of 6PPD-quinone in a diversity of aquatic species of relevance to surface waters in California is currently still limited. However, as with the chemical monitoring data discussed above, I expect more data to become available in the following months (including from our own group), which will further consolidate the risks observed and reported to date.

- Both 6PPD and 6PPD-quinone display hazard traits of concern according to the Safer Consumer Products regulations. 6PPD displays phytotoxicity and wildlife survival impairment, whereas 6PPD-quinone displays loss of genetic diversity and biodiversity, as well as wildlife survival impairment, including to coho salmon, a threatened and endangered species in California.

  I concur with the assessment that 6PPD-quinone displays hazard traits of concern, including loss of genetic diversity and biodiversity, as well as wildlife survival impairment, specifically to coho salmon that are threatened and endangered in California. I want to reiterate my concerns with the assignment of the noted hazard traits to the 6PPD parent chemical. While I assume that the studies were done according to the best available knowledge at the time, the fact that 6PPD degrades readily and rapidly in aqueous solutions to form oxidative transformation products, including 6PPD-quinone, makes these results questionable for risk assessment purposes, as the observed effects can be assumed to almost always be the result of mixture effects. This, in combination with the rapid degradation of 6PPD in aquatic systems, results in the main environmental concerns being driven by 6PPD-quinone. So while 6PPD might display hazard traits, the resulting risk of 6PPD exposure (relationship of hazard and exposure) can be assumed to almost always be much smaller than that of 6PPD-quinone.

- Researchers in Washington state recently demonstrated that 6PPD-quinone is the causal agent in urban runoff mortality syndrome observed in Puget Sound.

  The study by Tian et al. (2021) has impressively provided the missing link between the occurrence of urban runoff mortality syndrome (URMS) in coho salmon in Puget Sound and the causative agent, 6PPD-quinone. Follow-up studies will be needed to independently validate and confirm these findings, especially in other regions, such as British Columbia in Canada and California, to determine how widespread population-level impacts of 6PPD-quinone are. Currently, however, no information

would suggest that the same effects of 6PPD-quinone should not occur in other populations of coho salmon. Anecdotal knowledge provided in the Product-Chemical Profile suggests that URMS might occur in California, albeit not with the same visibility and frequency as in Puget Sound. However, it appears that more dedicated research on URMS in California is only starting and will provide a more thorough evaluation in the future.

- Exposure to very small concentrations of 6PPD-quinone can kill coho salmon as they migrate upstream, before they are able to spawn.

  While it has not been directly studied as of yet if neat 6PPD-quinone causes acute lethality in coho spawners, URMS is known to affect juvenile coho salmon, as well as spawners (McIntyre et al. 2018; Chow et al. 2019). Recognizing that 6PPD-quinone is the causative agent responsible for causing URMS, there is sufficient evidence that 6PPD-quinone can kill migrating coho spawners, with potentially drastic effects on the population trajectory.

- The presence of 6PPD-quinone in California runoff and waterways at concentrations above levels that kill at least half of coho salmon in lab studies suggests that exposure to 6PPD-quinone may have contributed to the decline in the coho population over the past 60-70 years.

  While it is not possible to quantify the role that 6PPD-quinone might have played in these population declines retrospectively, the fact that the species has been extirpated in the most densely-populated area of California suggests that it might have at least been a contributing factor. At this point, it is critical to the conservation of the remaining coho populations to reduce the potential impacts of stormwater runoff in general and of 6PPD-quinone specifically.

- The decline of the coho population has adversely impacted important marine food webs in California. Coho salmon represent a food source for many marine organisms such as seals and sharks and are a source of ocean-derived nutrients to inland ecosystems.

  Coho salmon are an item in the diet of a variety of marine and inland species, and their loss or decline might secondarily impact these species negatively. Inversely, Pacific salmon, including coho, collectively represent an important vector for marine nutrients to inland ecosystems and thereby are an important driver of ecosystem health on the Pacific Rim. It is now well-established that some of the normally nutrient-poor ecosystems in this area would not be able to thrive in the same way as they do in the absence of Pacific salmon runs.

- In addition to impacts to aquatic organisms, loss of coho salmon in California has significantly impacted California's Native American tribes. The loss of core traditional food sources for tribal communities can be tied to loss of culture, increased physical and mental health issues, and increased poverty. For instance, the human toll of the decline of salmon has been well-documented by the Karuk Tribe in the Klamath Basin: diabetes, heart disease, hypertension, and stroke, diseases that are strongly influenced by diet, have become more common in the Karuk since the decline of the salmon fishery, costing the Karuk an estimated $1.9 million per year in health costs. Native American advocates assert that access to traditional food sources, such as salmon, helps to promote self-reliance among Indigenous peoples and is fundamentally important to protecting Native communities' health, well-being, economic resilience, and cultural heritage.

  As indicated above, I cannot assess this part of conclusion 2 with confidence and have therefore excluded it from my peer review.

- 6PPD-quinone is also potentially toxic to other economically important species that are closely related to coho such as chinook salmon, steelhead, and the California golden trout.

  Results on the effects of neat 6PPD-quinone on salmonids other than coho salmon have not been reported in the peer-reviewed scientific literature yet. Other species of fishes studied to date, specifically zebrafish and Japanese medaka, were significantly less susceptible compared to coho salmon. In the absence of an established mechanism of toxic action of 6PPD-quinone, the assumption that closely related salmonids will show similar susceptibilities is rather speculative. Our research team has determined the acute toxicity of neat 6PPD-quinone to rainbow trout, brook trout, arctic char, and white sturgeon and is in the process of generating more data in short order. These datasets are currently being prepared for publication and will be submitted shortly. Therefore, results cannot yet be shared in this review.

- The presence of 6PPD in tires and associated release of 6PPD-quinone to the aquatic environment represent a threat to imperiled populations of coho salmon, negatively impact tribal communities that rely on these fish for cultural and subsistence purposes, may interfere with California's ability to reuse and recycle tires, and may require expensive special handling of stormwater runoff to mitigate adverse impacts.

  This summarizing conclusion is well-supported through the more specific bullets above. Please refer to the exceptions noted above.

Product-Chemical Profile

Comments in this section are provided in an itemized format, providing the page and paragraph number for reference. Suggested changes are indicated below. New language or formatting is underlined, deleted language is in strikethrough.

- Page 6, Product Definition and Scope: I believe that it would be beneficial to reiterate in this section that the Product-Chemical Profile, as well as the proposed rule, are focused on <u>motor</u> vehicle tires. As written, even when considering the noted exclusions, I believe the current definition would include the tires of bikes, bike trailers, wheelbarrows, etc.

- Page 9, second paragraph: Kolodziej (2021) noted in their presentation that net molecular charge and water solubility of 6PPD might be pH-dependent. I believe this information, along with an appropriate reference, might be important to add here.

- Page 9, Environmental Fate: I realize that this section likely follows a pre-defined format. However, I believe that it would benefit the reader to mention in this section that (1) the predominant route of entry of 6PPD into the environment is through tire wear particles (TWPs), and (2) the rapid abiotic degradation of 6PPD in both water and air indicates that 6PPD essentially only occurs in the environment in the particulate phase, bound to TWPs, and that risk assessments should focus predominantly on a comprehensive understanding of transformation products of 6PPD, including 6PPD-quinone. Information on TWPs as the predominant route of entry is provided on page 30, which in my view, is too late.

- Page 10, first paragraph: It is mentioned that 6PPD has a Kow and Koc. It would be beneficial for the reader to know what constitutes a high K_{ow} and K_{oc} according to the classification system used by the DTSC.

- Page 10, third paragraph: I agree that 6PPD is a challenging analyte even under laboratory conditions. However, under environmental conditions, due to the various reasons outlined above, 6PPD can be expected to be present at very low concentrations, again emphasizing the importance of focussing on transformation products such as 6PPD-quinone.

- Page 11, Degradation in Sediment: Again, this section does not mention the association of 6PPD with TWPs. I believe this is important when considering the fate of 6PPD in sediments, as TWPs essentially represent a large reservoir that could slowly release 6PPD and associated degradation products to the aqueous phase.

- Page 13, third paragraph: Please revise the sentence “…not toxic to coho salmon, suggesting that 6PPD-quinone ~~sticks~~ <u>binds</u> to particles.” as indicated.

- Page 13, fourth paragraph: The observation that the 6PPD-quinone water solubility is much lesser than estimated by models was also observed in our own research (currently unpublished).
- Page 14, Figure 2: I suggest replacing the solid arrow that indicates the conversion of 6PPD to 6PPD-quinone in the presence of ozone to a dashed arrow, indicating that this reaction follows an unknown reaction path.
- Page 14, fourth paragraph: While I agree that both 6PPD and 6PPD-quinone possess distinct hazard traits despite their structural similarity, I would argue that this section should be expanded to make the case that – due to the rapid conversion of 6PPD in aqueous solutions to 6PPD-quinone and other transformation products – commonly used toxicity tests will conceptually never be able to test the toxicity of 6PPD alone. As already highlighted in the General Observations, this, in my view, creates the false impression that the toxicity of 6PPD can be confidently distinguished from that of 6PPD-quinone. Environmental exposures that are driving the risks that initially motivated this rule-making process, however, are apparently and almost exclusively driven by 6PPD-quinone. Thus, I recommend making that statement early on, and most importantly, before listing the hazard traits for 6PPD and 6PPD-quinone individually. This statement is made explicitly on page 17, second paragraph, but should be presented much earlier to provide critical context for the information presented on pages 14 to 17.
- Page 18, second paragraph: I believe that the statement pertaining to the greater sensitivity of coho salmon as determined through exposures with a commercial, synthetic 6PPD-quinone preparation (Kolodziej 2021) in this paragraph should be accompanied by a statement that the measured concentrations reported in Tian et al. (2021) will have been over-estimations as well. This information is presented later on in the text but is critical for context here.
- Page 20: In my view, some of the evidence discussed on this page is suggestive of a potential mode of action of 6PPD-quinone, but not sufficient to conclude the search for the toxicity pathway ultimately causing death. While I agree that the evidence provided in Blair et al. (2021) suggests that exposure to urban runoff leads to altered permeability of the blood-brain barrier, which in turn could partly explain the drastically altered hematocrit, this experiment was not conducted with neat 6PPD-quinone, and it was not investigated if the altered permeability alone could cause the observed etiology of urban runoff mortality syndrome. Currently unpublished experiments conducted in my own lab suggest that other toxicity pathways are likely involved that by themselves are sufficient to explain the observed symptoms and biomarkers across a diversity of species. Additionally, Bolton et al. (2000) and Blair et al. (2021) are cited to suggest that 6PPD-quinone

might cause oxidative stress. While I generally concur with the hypothesis that 6PPD-quinone might cause oxidative stress, this has not been tested yet for this particular compound and is solely based on the assumption that 6PPD-quinone will behave in a similar manner to other quinones. It should be noted, however, that not all quinones cause oxidative stress. Thus, I recommend toning down the statements on this page to make sure that the assumptions and shortcomings of currently available data are clearly identified. The question of how exactly 6PPD-quinone causes urban runoff mortality syndrome in coho salmon (and other species) is of minor importance for the demonstration of adverse impacts arising from motor vehicle tires containing 6PPD to designate this a Priority Product; however, it will need to be an important consideration in the process of identifying alternatives to 6PPD.

- Page 21, Toxicological Hazard Traits: I understand that this section might be a required element of a Product-Chemical Profile; however, since the original concern that triggered the initiation of this rule-making process by the DTSC was the fact that 6PPD-quinone is responsible for causing urban runoff mortality syndrome in coho salmon, I believe that the sections on potential human exposures and potentially resulting toxicological risks in humans are distracting from the main concern.
- Page 24, Structural or Mechanistic Similarity to Chemicals with Known Adverse Impacts: This section suggests that 6PPD-quinone due to its quinone functional group is likely a redox-active chemical. While it is true that some quinones show these characteristics, this is not the case for all quinones. The language in this section has been carefully chosen to ensure that the suggestive nature of this evidence is highlighted; however, I believe it would be pertinent to include one or two more sentences emphasizing the potential shortcomings of this read-across approach, and potentially even provide a percentage of the quinones that have been studied to date for which these characteristics have been demonstrated. This would significantly strengthen this section.
- Page 25, last paragraph: The statement regarding the percent distribution of 6PPD between tread and wall of the tire by Patterson (2021) is rather limited and might be confounded by the rapid degradation of 6PPD during the laboratory procedures reported in the same presentation. I believe that the presence of 6PPD-quinone on the surface of the tire is a much more important takeaway from this work.
- Page 29, first and second paragraph: Again, I believe the emphasis on potential human exposure here distracts from the main environmental concern, namely the fact that the 6PPD transformation product 6PPD-quinone is the causative agent responsible for causing urban runoff mortality syndrome in coho salmon.

- Page 30, second paragraph: It would be useful to include a definition of what the DTSC and the SCP Program consider microplastics. I believe this would be helpful, as some authors in the recent literature argue that tire wear and other elastomer particles should be discussed separately from more crystalline polymer particles, commonly referred to as microplastics. I personally do not favor one particular definition but suggest adding the operational definition that the DTSC and the SCP Program use.
- Page 30, third paragraph: Another important consideration might be the type of tire (winter, summer, all-season).
- Page 41, first paragraph and Table 5: This statement regarding the potentially different results that would have been obtained using a commercial standard is extremely important. I believe that it would be pertinent to revise this table based on the new knowledge presented by Tian et al. (2022). This will facilitate comparison with the other studies measuring 6PPD-quinone in roadway runoff.
- Page 42, second paragraph: Should the statement “If 6PPD or 6PPD-quinone were to be regulated in stormwater, California municipalities could be required to install and maintain treatment infrastructure at considerable expense.” be amended to emphasize that this might only need to be required for some outfalls where salmonid habitat could be impacted, or where sufficient dilution of the discharge from an event cannot be guaranteed?
- Age 42, last paragraph: It is important to consider different elution profiles of various compounds across a storm event to be able to apply this approach. In our own study (Challis et al., 2021), we found that various rubber-derived chemicals eluted at different sampling times into a given storm event.
- Page 43, first paragraph: I did not see a reference to the results reported by the San Francisco Estuary Institute, which I believe would be helpful for context.
- Page 49, second paragraph: While these results have not been published in the peer-reviewed literature, my own research team has determined the acute toxicity of 6PPD-quinone to rainbow trout, brook trout, arctic char, and white sturgeon, and is the process of generating more data in short order. These datasets are currently being prepared for publication and will be submitted shortly. Therefore, results cannot currently be shared in this review.
- Page 53, Cumulative Effects with Carbon Dioxide and Climate Change: Due to the cardiorespiratory etiology of urban runoff mortality syndrome caused by 6PPD exposure, I believe a general statement on potential interactions with environmental hypoxia would be warranted.

- Page 54, first paragraph: I find the sentence regarding the potential interaction between thermal stress and hepatic biotransformation very speculative, as nothing is currently known about absorption, distribution, metabolism, and elimination of 6PPD-quinone in fish. Initial datasets are currently generated in my own research team.
- Page 54, Populations that May be Adversely Impacted: As indicated in the exceptions in the general remarks, I have excluded most of this section from my review.
- Page 61, Effects on Solid Waste…: I believe many products from recycled tires, such as crumb rubber and tire rubber much, are coated in polyurethane and other polymers. It would be interesting to study the potential effects of these coatings on the safety of these products, as rubber tires containing 6PPD otherwise have the potential to become an expensive legacy.
- Page 64, Potential Alternative: I am neither a polymer chemist nor a tire engineer or materials scientist. Thus, this section is well outside of my expertise and experience, and I will thus exclude it from my review. However, as mentioned above, I believe that a thorough understanding of the mechanisms through which 6PPD-quinone exerts its toxicity is critical to the process of identifying suitable alternatives that fulfill the requirement for being effective antioxidants/antiozonants while being environmentally safer compared to 6PPD.
- Page 69, fourth paragraph: While Tian et al. (2021) have demonstrated the toxicity of the ozonation product of 6PPD, as well as that isolated from rubber tires, only, which was then identified as 6PPD-quinone, fully synthetic standards are now available, and more research will be published very shortly further consolidating these findings.

Minor Editorial Comments

Product-Chemical Profile

Comments in this section are provided in an itemized format, providing the page and paragraph number for reference. Suggested changes are indicated below. New language or formatting is underlined, deleted language is in strikethrough.

- Page 2: “Appendix A: Potential Relevant Factors” is found on page 98, not 97 as listed.
- Page 7, second paragraph: Chemical names here, and throughout the provided documents, often do not consistently follow internationally accepted nomenclature conventions. Specifically, the location prefixes N and N’ in “*N*-(1,3-dimethylbutyl)-*N’*-

phenyl-*p*-phenylenediamine," as well as the substitution prefix p in "*p*-nitro" and "*p*-nitrosodphenylamine" should be italicized.

- Page 8, second paragraph: Please add a space before the reference in the sentence "…, which can compromise the performance and safety of tires (Cox 1959;…"
- Page 10, fifth paragraph: The sentence "Reported half-lives range from 3.4 ~~to~~ hours to less than a day…" should be revised as suggested.
- Page 26, fifth paragraph: The sentence "NAICS defines tire dealers as "- establishments primarily engaged in…" should be revised as suggested.
- Page 31, second paragraph: In the sentence "In a subsequent study, Klöckner et al. (2021b) demonstrated…," the ö should not be underlined.
- Page 50, Figure 6: Please include the scientific name "*Salmo trutta*" for the brown trout alongside the others in this figure.
- Page 69, second reference: It appears that a special character was parsed incorrectly.

January 16, 2022

Ms. Carol Perkins
Manager, CalEPA External Scientific Peer Review Program
Office of Research, Planning & Performance
State Water Resources Control Board
carol.perkins@waterboards.ca.gov

Dear Ms. Perkins:

I want to thank the CalEPA External Scientific Peer Review Program for inviting me to be an external scientific peer reviewer of the technical document (November 2021 ESPR version) that supports the rulemaking for the proposed adoption of motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product. As you know, I am reviewing the findings, assumptions, or conclusions that I can review with confidence based on my expertise and experience. They include:

> Conclusion 1 (as supported by the information in the technical document noted above). Coho salmon and other aquatic organisms may be exposed to 6PPD-quinone due to the use of 6PPD in motor vehicle tires.
>
> Conclusion 2 (as supported by the information in the technical document noted above). The 6PPD contained in motor vehicle tires and its oxidation product 6PPD-quinone have the potential to contribute to or cause significant or widespread adverse impacts to the threatened and endangered populations of coho salmon in California, as well as to other aquatic organisms and the Native American tribes that rely on them.

I know that I am also invited to address the following questions:

> Are there any scientific subjects that are part of the scientific basis of the proposal that are not described below?
>
> Taken as a whole, is the proposal based upon sound scientific knowledge, methods, and practices?

My background and expertise relevant to reviewing this technical document:

I am a native Californian with undergraduate and graduate degrees from two University of California campuses (B.A. in Biochemistry and Molecular Biology from UCSB and Ph.D. in Comparative Pharmacology and Toxicology from UCSF). I retired from the U.S. National Institutes of Health (NIH) on March 31, 2020 after being the Senior Toxicologist and Toxicology & Environmental Health Science Advisor at the NIH National Library of Medicine (NLM) since 2008. On April 1, 2020, I started as an "NIH Special Volunteer" in

toxicology and environmental health sciences at the NIH NLM's National Center for Biotechnology Information (NCBI). Also, I have served for many years as an Adjunct Associate Professor in Preventive Medicine and Biostatistics in the F. Edward Hebért School of Medicine at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda, Maryland, focused on toxicology and online toxicology and exposure resources. Further, I was a co-leader for over five years of the Environmental Health Sciences graduate level course offered by the Foundation for Advanced Education in the Sciences at the NIH (FAES@NIH).

In addition, I am a longtime member of the Society of Toxicology (SOT) and the International Society of Exposure Science (ISES), and a longtime member and Fellow of the Society for Risk Analysis (SRA). I have authored and co-authored numerous publications, including ones on consumer product exposures and risk assessments, toxicological interactions, respiratory tract and other aspects of toxicology, consumer risk perceptions and risk communication, and computer software and databases. Examples of my recent and other publications include "New Studies About Everyday Types of Chemical Exposures: What Readers Should Consider," "Risk Management Measures for Chemicals in Consumer Products: Documentation, Assessment, and Communication Across the Supply Chain," "Elements That Contribute to Healthy Building Design," "Exploring Global Exposure Factors: Resources for Use in Consumer Exposure Assessments," and being one of three co-editors of the 2019 "The Practice of Consumer Exposure Assessment" book. Two examples of the professional awards I have received are the SRA's 1996 Outstanding Service Award "in recognition of devoted and distinguished service to the Society" and one of the NIH annual "Director's Awards" in 2011 recognizing my contributions related to the Deepwater Horizon Gulf Oil Spill response led by the NIH National Institute of Environmental Health Sciences (NIEHS).

Also noteworthy to the current expert review are my three years on the auxiliary staff of the Institute for Health and Consumer Protection's (IHCP's) Physical and Chemical Exposure Unit (PCEU) at the European Commission's Joint Research Centre (JRC) in Italy, and 19 years as a product safety toxicologist at the Procter & Gamble Company (P&G) in the U.S. and Japan. The P&G work included a few years as the main scientist supporting all toxicology- and exposure-related aspects for a technology development division covering a major group of diverse product categories (disposable diapers, feminine hygiene, towels, tissues, etc.). My role supporting this technology development used a proactive approach to risk assessment and risk management, and the goal was to have an early as possible selection of substances, polymers, and other components with the best human and environmental safety profiles. This approach covered reasonably foreseeable consumer, occupational, and environmental exposures, the available and predicted toxicology information, and the design and conduct of various studies, e.g., extractability or migration of substances from polymers/materials.

My review of this technical document:

I know that my responsibility is to determine whether "the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices" [the statutory mandate for external scientific peer review (California Health and Safety Code Section 57004)]. Also, I know that this evaluation of DTSC's proposed action and conclusions does not require absolute scientific certainty and that my task is to determine if there is adequate scientific basis supporting potential exposures and impacts to support the Safer Consumer Products (SCP) regulatory action, as described in the SCP law.

The comments below are my own and do not necessarily reflect official Federal government opinions of the organizations that I am affiliated with. Also, as you know, I requested to not receive any remuneration from the State of California for doing this review.

I have followed the "Guidance for Reviewers" on the FTP site and in the letter initiating my review. Also, I recognize that the Department of Toxic Substances Control (DTSC) has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed regulation and that the reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central regulatory elements being proposed.

The Scientific Conclusions I peer reviewed in the technical document that support the rulemaking for the proposed adoption of motor vehicle tires motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product (also called the Motor Vehicle Tires Containing 6PPD Product Chemical Profile) are:

Conclusion 1
Coho salmon and other aquatic organisms may be exposed to 6PPD-quinone due to the use of 6PPD in motor vehicle tires.

The sections of the product-chemical profile that pertain to Conclusion 1 include:

Section 1 – Rationale for Product-Chemical Selection, pages 4– 6;
Section 4 – Potential for Exposures to the Candidate Chemical in the Priority Product, pages 25 – 43;
Section 5 – Potential for Significant or Widespread Adverse Impacts, pages 44 – 62; and
Section 9 – Conclusions, pages 73 – 74.

After reviewing the information in the technical document that supports the rulemaking for the proposed adoption of motor vehicle tires motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product (also called the Motor Vehicle Tires Containing 6PPD Product Chemical Profile), along with reading

the publications and other documents that are cited in the document, I conclude that the authors have developed a well-thought-out and well-referenced document that supports Conclusion 1. This conclusion considered the statutory mandate for external scientific peer review (California Health and Safety Code Section 57004) that a reviewer's responsibility is to determine whether "the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices."

I concluded that Conclusion 1 is supported by the following points that are expanded upon in the technical document:

> 6PPD is used in nearly all motor vehicle tires in California to protect the rubber from degradation by oxygen and ozone.
> (My comment is that this is firmly supported by the text and its relevant citations.)
>
> 6PPD is a high-production volume chemical, and motor vehicle tires are one of its main uses.
> (My comment is that this is firmly supported by the text and its relevant citations.)
>
> 6PPD is added to motor vehicle tires at concentrations of 1 to 2% and is designed to slowly migrate from the interior of the tire towards its surface over the lifetime of the tire, such that there is a constant supply of 6PPD and its oxidation products at the surface of the tire.
> (My comment is that this is firmly supported by the text and its relevant citations.)
>
> By design, 6PPD is highly reactive and forms a number of reaction products when in contact with oxygen and ozone, including 6PPD-quinone.
> (My comment is that this is firmly supported by the text and its relevant citations.)
>
> Tires release 6PPD and its reaction products into the environment through mechanical tire abrasion on the roads, which produces microplastics known as tire wear particles. It is estimated that in the United States 4.7 kilograms of tire wear particles are generated per person each year. Once in the environment, tire wear particles can release 6PPD and its reaction product 6PPD-quinone.
> (My comment is that this is firmly supported by the text and its relevant citations; however, please note my comments below about using the term "microplastics" and possibly considering wording to help minimize confusion in documents and outreach efforts.)
>
> In 2020 alone, over 171 million tires were driven on California's roads. The large number of tires used in California each year poses major challenges to their end-of-life disposition. After their useful life, tires can be landfilled, recycled, or reused. Many of the end-of-life uses of tires (such as for erosion control, flood control, stormwater treatment, or playground surfaces) provide a pathway for chemicals like 6PPD and its reaction products to migrate into the aquatic environment.

(Although this is firmly supported by the text and its relevant citations, a suggestion I have is about the "Athletes who use synthetic turf fields may inhale or ingest small crumb rubber particles that may contain 6PPD or 6PPD-quinone. As of this writing, there are no studies on 6PPD-quinone in crumb rubber, but its parent compound, 6PPD, has been found to have high migration rates in artificial sweat, suggesting that it can migrate from rubber into sweat and become available for dermal or ingestion exposure (Schneider et al. 2020b)" and "For example, people, including children, playing on synthetic turf may be exposed to 6PPD or 6PPD-quinone by inhaling or ingesting small crumb rubber particles or via dermal contact, especially when skin surfaces are wet or sweaty" statements. I suggest adding a sentence about possible exposures via clothing and shoes worn while playing on synthetic turf. For example, please see the "Exposure doesn't stop with the actual time spent on the playing fields or playgrounds - the small turf pieces routinely cling to clothes and shoes, and are therefore tracked into cars, homes, schools and child-care facilities" in the "FAQs: Crumb Rubber & Artificial Turf" from the Children's Environmental Health Network (CEHN, https://cehn.org/crumb-rubber-artificial-turf/). Another example mentioning this ("…track-in by field users or releases from shoes, clothing or other personal products; presence in and release from other synthetic turf field materials…") is U.S. EPA's 2019 "Synthetic Turf Field Recycled Tire Crumb Rubber Research…" report (EPA/600/R-19/051.1, https://www.epa.gov/sites/default/files/2019-08/documents/synthetic_turf_field_recycled_tire_crumb_rubber_research_under_the_federal_research_action_plan_final_report_part_1_volume_1.pdf).

Stormwater runoff, particularly from urban areas, can serve as a substantial source of tire-derived contaminants to local aquatic environments.
(My comment is that this is firmly supported by the text and its relevant citations.)

6PPD-quinone has been detected in California waterways at concentrations above those shown to kill at least half of coho salmon in laboratory experiments.
(While I feel that this is firmly supported by the text and its relevant citations, I am sure that it is obvious to anyone interested in 6PPD and 6PPD-quinone that there is the need to keep up with the emerging research findings. For example, I noticed this very recent (January 2022) publication by Tian and coauthors as I was completing this review:

> (I realize that this is probably the same information as already noted in the technical document as: "The authors of the Tian et al. paper conducted follow-up analyses using a better characterized, commercially available 6PPD-quinone standard and have indicated a revised LC_{50} of approximately 0.1 µg/L (Kolodziej 2021), suggesting that 6PPD-quinone may be several times more toxic to coho than previously estimated" and "More recent data suggest that the LC_{50} is closer to 0.1 µg/L, but that recalibration also reduces the estimated concentrations presented in Table 5 proportionally (Kolodziej 2021)." Kolodziej E. (2021). DTSC Workshop on Motor Vehicle Tires Containing 6PPD Priority Product

Proposal: Evaluation of water quality impacts on coho salmon. Beginning at 59 minutes, 40 seconds in recording. 6PPD-quinone mobility discussion around 1 hour 12 minutes, revised LC50 discussion around 1 hour 17 minutes. Available at: https://www.youtube.com/watch?v=OZwXNWYCoy4.")

"PPD-Quinone: Revised Toxicity Assessment and Quantification with a Commercial Standard"
https://pubs.acs.org/doi/10.1021/acs.estlett.1c00910
An excerpt from the abstract: "Peak area responses of the commercial standard were ~15 times higher than those of in-house standards, and the updated LC50 value (95 ng/L) was ~8.3-fold lower than that previously reported. These data support prior relative comparisons of the occurrence and toxicity while confirming the substantial lethality of 6PPD-Q. While environmental concentrations are expected to be lower, 6PPD-Q also was more toxic than previously calculated and should be categorized as a "very highly toxic" pollutant for aquatic organisms. Isotope dilution-tandem mass spectrometry methods enabled accurate quantification (limits of quantification of <10 ng/L) within environmental samples."

Also, a further online search found this 1/12/22 tweet by Dr. Tian that summarizes these findings:
https://twitter.com/tttonytian/status/1481447843281838081?s=20
"Our update on 6PPD-Q after ~1 yr. We got some commercial std, and found the homemade stds were not pure.
- Good news: environmental conc. are lower than expected.
- Bad news: lower LC50 to coho (95 ng/L), means it's more toxic than expected.
- The conclusion remains valid.")

Coho salmon are already extinct in California waters near highly populated, high traffic density areas. The remaining coho populations in the less heavily populated areas of the state are either threatened or endangered.
(My comment is that this is firmly supported by the text and its relevant citations.)

The highest concentration of 6PPD-quinone measured to date in the San Francisco Bay Area came from a location whose watershed is 90% open space, indicating that proximity to roads and associated tire wear particles may be more important than the extent of development of surrounding land. This indicates the potential for exposure of aquatic organisms to 6PPD-quinone even in more remote regions of the state outside dense urban regions of the state if traffic patterns result in release of TWP to streams.
(My comment is that this is firmly supported by the text and its relevant citations.)

The presence of 6PPD-quinone in California waterways at concentrations proven to be lethal to coho salmon indicates that current stormwater treatment efforts are often insufficient for the removal of 6PPD-quinone.
(My comment is that this is firmly supported by the text and its relevant citations.)

Conclusion 2

The 6PPD contained in motor vehicle tires and its oxidation product 6PPD-quinone have the potential to contribute to or cause significant or widespread adverse impacts to the threatened and endangered populations of coho salmon in California, as well as to other aquatic organisms and the Native American tribes that rely on them.

The sections of the product-chemical profile (noted above) that pertain to Conclusion 2 include:

Section 1 – Rationale for Product-Chemical Selection, pages 4 – 6;
Section 3 – Candidate Chemical Definition and Properties, pages 7 – 25;
Section 5 – Potential for Significant or Widespread Adverse Impacts, pages 44 – 62;
Section 8 – Additional Considerations, pages 67 – 72; and
Section 9 – Conclusions, pages 73 - 74.

After reviewing the information in the technical document that supports the rulemaking for the proposed adoption of motor vehicle tires motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product (also called the Motor Vehicle Tires Containing 6PPD Product Chemical Profile), along with reading the publications and other documents that are cited in the document, I conclude that the authors have developed a well-thought-out and well-referenced document that supports Conclusion 2. This conclusion considered the statutory mandate for external scientific peer review (California Health and Safety Code Section 57004) that a reviewer's responsibility is to determine whether "the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices."

I concluded that Conclusion 2 is supported by the following points that are expanded upon in the technical document:

Both 6PPD and 6PPD-quinone display hazard traits of concern according to the Safer Consumer Products regulations. 6PPD displays phytotoxicity and wildlife survival impairment, whereas 6PPD-quinone displays loss of genetic diversity and biodiversity, as well as wildlife survival impairment, including to coho salmon, a threatened and endangered species in California. (My comment is that this is firmly supported by the text and its relevant citations.)

Researchers in Washington state recently demonstrated that 6PPD-quinone is the causal agent in urban runoff mortality syndrome observed in Puget Sound.
(My comment is that this is firmly supported by the text and its relevant citations.)

Exposure to very small concentrations of 6PPD-quinone can kill coho salmon as they migrate upstream, before they are able to spawn.
(My comment is that this is firmly supported by the text and its relevant citations.)

The presence of 6PPD-quinone in California runoff and waterways at concentrations above levels that kill at least half of coho salmon in lab studies suggests that exposure to 6PPD-quinone may have contributed to the decline in the coho population over the past 60-70 years.
(My comment is that this is firmly supported by the text and its relevant citations; however, please note the very new publication by Tian and coworkers mentioned above.)

The decline of the coho population has adversely impacted important marine food webs in California. Coho salmon represent a food source for many marine organisms such as seals and sharks and are a source of ocean-derived nutrients to inland ecosystems.
(My comment is that this is firmly supported by the text and its relevant citations.)

In addition to impacts to aquatic organisms, loss of coho salmon in California has significantly impacted California's Native American tribes. The loss of core traditional food sources for tribal communities can be tied to loss of culture, increased physical and mental health issues, and increased poverty. For instance, the human toll of the decline of salmon has been well-documented by the Karuk Tribe in the Klamath Basin: diabetes, heart disease, hypertension, and stroke, diseases that are strongly influenced by diet, have become more common in the Karuk since the decline of the salmon fishery, costing the Karuk an estimated $1.9 million per year in health costs. Native American advocates assert that access to traditional food sources, such as salmon, helps to promote self-reliance among Indigenous peoples and is fundamentally important to protecting Native communities' health, well-being, economic resilience, and cultural heritage.
(My comment is that these statements are firmly supported by the text and its relevant citations.)

6PPD-quinone is also potentially toxic to other economically important species that are closely related to coho such as chinook salmon, steelhead, and the California golden trout.
(My comment is that this is firmly supported by the text and its relevant citations, with "potentially toxic" being the key wording.)

The presence of 6PPD in tires and associated release of 6PPD-quinone to the aquatic environment represent a threat to imperiled populations of coho salmon, negatively impact tribal communities that rely on these fish for cultural and

subsistence purposes, may interfere with California's ability to reuse and recycle tires, and may require expensive special handling of stormwater runoff to mitigate adverse impacts.
(My comment is that this is firmly supported by the text and its relevant citations, with "may require" and "may interfere" being key wording.)

Other comments:
(1) Other publications, theses, and content from web sites that might be of interest to DTSC and others now or later.
2) PubChem. I suggest adding the PubChem Chemical Identifier (CID 13101) for 6PPD. 3) PubChem. There is now a PubChem record for 6PPD-quinone ((CID 154926030).
3) The NORMAN Network and its Suspect List Exchange (SLE) is not noted and might be of interest to DTSC.
4) Add more about car vs. truck tires?
5) I want to call attention to the microplastic-related wording related to tires since I feel that it can lead to confusion since tire wear particles are not microplastics as generally thought of by some/many of the public and others.

1) As noted above, I am sure that it is obvious to anyone interested in 6PPD and 6PPD-quinone that there is the need to keep up with the emerging research findings. I already noted the very recent publication by Tian and coauthors I identified while completing this review. The following publications are not cited in this technical document but were identified while doing this review (I searched both the PDF of the document and also the updated listing of references used for the document). Also, I identified some content from theses and web sites. They (publications, theses, and web sites) might be of interest to DTSC and others now or later include the following:

   https://pubmed.ncbi.nlm.nih.gov/32422457/
   Baensch-Baltruschat B, Kocher B, Stock F, Reifferscheid G. Tyre and road wear particles (TRWP) - A review of generation, properties, emissions, human health risk, ecotoxicity, and fate in the environment. Sci Total Environ. 2020 Sep 1;733:137823

   Abstract: In this paper, the current knowledge on tyre and road wear particles (TRWP) is compiled regarding all environmental and health aspects. TRWP generated on roads during driving processes contribute to airborne non-exhaust emissions and are discussed in connection with the microplastic pollution…

   Also, not in the report is:

   (I realize that other work by Dr. Panko and her colleagues has been noted in the technical document and also covered elsewhere, e.g., in the 2020 6PPD and 6PPD-quinone DTSC-led July 2021 workshop).

https://www.sciencedirect.com/science/article/pii/B9780128117705000078
Julie Panko, Marisa Kreider, Kenneth Unice,
Chapter 7 - Review of Tire Wear Emissions: A Review of Tire Emission Measurement Studies: Identification of Gaps and Future Needs.
Editor(s): Fulvio Amato,
Non-Exhaust Emissions,
Academic Press, 2018, Pages 147-160.

Abstract: Tire wear particles are produced from the interaction of tires with the roadway surface during driving and are included in the non-exhaust vehicle emission category. These particles are distinct from tread rubber in terms of physical properties and chemical composition that are related to the wear processes exerted on the tread during driving. This chapter describes the state of knowledge regarding the unique characteristics of tire wear particles, their emissions, and measurement in the ambient air. Finally, data gaps that could be filled to improve the knowledge of this non-exhaust vehicle emission source are provided.

Other publications, theses, and content from web sites that might be of interest to DTSC and others now or later include: (Please note that these are listed alphabetically using the first author's last name and are not in the order of importance/relevance from my perspective. Also, I am only noting these for awareness and am not recommending that they be added to this technical document):

https://chemrxiv.org/engage/chemrxiv/article-details/60c754ab842e658615db41c8
Agua A, Stanton R, Pirrung M. Preparation of 2-((4-Methylpentan-2-Yl)amino)-5-(Phenylamino)cyclohexa-2,5-Diene-1,4-Dione (6PPD-Quinone), an Environmental Hazard for Salmon. ChemRxiv. Cambridge: Cambridge Open Engage; 2021; This content is a preprint and has not been peer-reviewed.

https://www.sciencedirect.com/science/article/abs/pii/S1309104220303561
A. Beji, K. Deboudt, S. Khardi, B. Muresan, L. Lumière,
Determinants of rear-of-wheel and tire-road wear particle emissions by light-duty vehicles using on-road and test track experiments, Atmospheric Pollution Research, Volume 12, Issue 3, 2021,
Pages 278-291.
(A comment from me is that the graphical abstract might be of interest for presentations or other purposes.)

Abstract: The purpose of this study is to identify the parameters governing particle emissions at the rear of the front wheel of an instrumented light-duty vehicle…

https://infoscience.epfl.ch/record/290018
Dudefoi, William ; Ferrari, Benoît Jean Dominique ; Breider, Florian ; Masset, Thibault Béranger ; Vermeirssen, Etienne ; Bergmann, Alan ; Schirmer, Kristin
In vitro acute toxicity assessment of tire tread particles using rainbow trout cell lines of gill and intestine.
SETAC North America - 42nd Annual Meeting, Virtual conference, November 14-18, 2021
Abstract: Tire and road wear particles (TRWP) are generated by the abrasion of tires while driving, and recent questions were raised in regards to their potential contribution to microplastics released into the aquatic environment and their potential toxicological impacts. Our study aimed …

https://www.sciencedirect.com/science/article/abs/pii/S004896971935689X
Louise L. Halle, Annemette Palmqvist, Kristoffer Kampmann, Farhan R. Khan.
Ecotoxicology of micronized tire rubber: Past, present and future considerations,
Science of The Total Environment, Volume 706, 2020, 135694.
Abstract: Micronized tire rubber has recently come into focus as black particles that are found in microplastic (MP) samples worldwide… This paper aims to (i) highlight similarities and differences of micronized rubber particles with the existing suite of polymer contaminants termed as ‘microplastics’ or ‘plastic debris’, (ii) survey the existing literature on environmental presence, fate, and interaction of micronized rubber particles with biota, and lastly (iii) present future research needs that require consideration in order to move this research area forward. Existing knowledge gaps that require attention include; determining the environmental presence and fate of micronized rubber within different environmental compartments, understanding the interaction of rubber particles with biota, particularly as potential impacts have so far been attributed solely to the leachate, and evaluating whether standard ecotoxicological protocols need to be adapted for particulate contaminants in general and specifically to suit rubber particulates and leachate.

https://www.proquest.com/openview/f66bfbf1501609876fed06a5f31e77a5/1?pq-origsite=gscholar&cbl=18750&diss=y
(A note from me is that this is a thesis. Also, I realize that publications from Ms. Johannessen and her coauthors are noted in the technical document. Also, please see below for another publication from a coauthor and her that might be of interest.)

Monitoring and Fate of Selected Tire-Derived Organic Contaminants. Johannessen, Cassandra. Trent University (Canada), ProQuest Dissertations Publishing, 2021. 28491859.
"…These samples were also analyzed for the tire additive, **6PPD**, and its oxidation by-product, **6PPD**-quinone, as well as 1,3… **6PPD** by ozonation. Brent's work allowed for the analysis of **6PPD-**quinone, which is a very valuable and exciting component of this thesis. …"

https://www.sciencedirect.com/science/article/abs/pii/S0045653521013850
(A note from me is that this publication is not about 6PPD or 6PPD-quinone.)
Cassandra Johannessen, J. Mark Parnis,
Environmental modelling of hexamethoxymethylmelamine, its transformation products, and precursor compounds: An emerging family of contaminants from tire wear, Chemosphere, Volume 280, 2021,130914.
Abstract: Hexamethoxymethylmelamine (HMMM) is a polymer crosslinking agent used commercially to manufacture tires. HMMM is a ubiquitous contaminant in urban surface waters due to its presence in tire-wear particles and its tendency to be transported into receiving waters during rain events through road runoff…This study provides insights into the fate and behaviour of HMMM and its transformation compounds and contributes to the growing literature on the hazards of organic chemicals derived from tire wear.

https://www.elibrary.ru/item.asp?id=46387946

Санитарно-Гигиенические Преимущества Использования Антиозонанта Кавантокс 3ppd-F В Производстве Шин И Рти По Сравнению С 6ppd (Ippd).
Кавун С.М., Меджибовский А. С.

Sanitary And Hygiene Advantages Of Using The Antiozonant Kavantox 3ppd-F In The Manufacture Of Tires And Rti Compared To 6ppd (Ippd).

Kavun S.M. [1] , Medzhibovsky A. S. [1]
[1] Npp Kvalitet Llc , Moscow Region, Lyubertsy, Russia

Type: Article In The Conference Proceedings. Language: Russian Publication Year: 2021. Pages: 20-23

Source:

Rubber Industry. Raw. Materials. Technologies
Reports Of The Xxvi Scientific-Practical Conference. Moscow, 2021

The Conference:

Rubber Industry. Raw. Materials. Technologies
Moscow, May 24–28, 2021

Summary in English: Some aspects of the sanitary and toxicological characteristics differences of the widely used (6PPD, IPPD) and the new - Kavantox 3PPD-F antiozonants for tires and rubber goods are considered…

https://www.sciencedirect.com/science/article/abs/pii/S0048969713004622
Ji-hyun Kwak, Hongsuk Kim, Janghee Lee, Seokhwan Lee,
Characterization of non-exhaust coarse and fine particles from on-road driving and laboratory measurements, Science of The Total Environment, Volumes 458–460, 2013, Pages 273-282.
Abstract: We investigated the physical and chemical properties of non-exhaust coarse and fine particles generated by on-road driving and in a laboratory setting using a mobile sampling system…

https://www.sciencedirect.com/science/article/abs/pii/S0048969721039747
Zhuanxi Luo, Xinyi Zhou, Yu Su, Haiming Wang, Ruilian Yu, Shufeng Zhou, Elvis Genbo Xu, Baoshan Xing,
Environmental occurrence, fate, impact, and potential solution of tire microplastics: Similarities and differences with tire wear particles, Science of The Total Environment, Volume 795, 2021, 148902.
(A comment from me is that the graphical abstract might be of interest for presentations or other purposes.)
Abstract: Tire microplastics (TMPs) are identified as one of the most abundant types of microplastics, which originate from rubber with intended or unintended release. While increasing knowledge about TMPs concentrates on tire wear particles (TWPs), TMPs from other potential sources like recycled tire crumb (RTC) and tire repair-polished debris (TRD) are much less understood… By collecting and analyzing the up-to-date literature, this review enhances our better understanding of the environmental occurrence, fates, impacts, and potential solutions of TMPs, and further highlights critical knowledge gaps and future research directions that require cooperative efforts of scientists, policymakers, and public educators.

https://pubmed.ncbi.nlm.nih.gov/34410108/
McIntyre JK, Prat J, Cameron J, Wetzel J, Mudrock E, Peter KT, Tian Z, Mackenzie C, Lundin J, Stark JD, King K, Davis JW, Kolodziej EP, Scholz NL. Treading Water: Tire Wear Particle Leachate Recreates an Urban Runoff Mortality Syndrome in Coho but Not Chum Salmon. Environ Sci Technol. 2021 Sep 7;55(17):11767-11774.
(This 2021 publication from McIntyre is another one from Tian and coworkers but is not focused on 6PPD and 6PPD-Quinone. Another comment from me is that the graphical abstract might be of interest for presentations or other purposes.)

Abstract: Tire tread wear particles (TWP) are increasingly recognized as a global pollutant of surface waters, but their impact on biota in receiving waters is rarely addressed. In the developed U.S. Pacific Northwest, acute mortality of adult coho salmon (*Oncorhynchus kisutch*) follows rain events and is correlated with roadway density. Roadway runoff experimentally triggers behavioral symptoms and associated changes in blood indicative of cardiorespiratory distress prior to death. Closely related chum salmon (*O. keta*) lack an equivalent response. Acute mortality of juvenile coho was recently experimentally linked to a transformation product of a tire-derived chemical. We evaluated whether TWP leachate is sufficient to trigger the acute mortality syndrome in adult coho salmon. We characterized the acute response of adult coho and chum salmon to TWP leachate (survival, behavior, blood physiology) and compared it with that caused by roadway runoff. TWP leachate was acutely lethal to coho at concentrations similar to roadway runoff, with the same behaviors and blood parameters impacted. As with runoff, chum salmon appeared insensitive to TWP leachate at concentrations lethal to coho. Our results confirm that environmentally relevant TWP exposures cause acute mortalities of a keystone aquatic species.
Another excerpt:
“In concert, future research will invariably address the occurrence of 6PPD-quinone and other TWP-derived chemicals in aquatic environments and begin assessing additional species for adverse outcomes. Finally, scrap tire yards, crumb rubber in playgrounds and artificial turf fields, and other reuses of tires must be evaluated for their contribution of tire-derived chemicals to receiving waters.”

https://pubs.acs.org/doi/full/10.1021/acs.estlett.1c00794
Joseph Monaghan, Angelina Jaeger, Alon R. Agua, Ryan S. Stanton, Michael Pirrung, Chris G. Gill, and Erik T. Krogh, A Direct Mass Spectrometry Method for the Rapid Analysis of Ubiquitous Tire-Derived Toxin *N*-(1,3-Dimethylbutyl)-*N*′-phenyl-*p*-phenylenediamine Quinone (6-PPDQ)
Environ. Sci. Technol. Lett. 2021, 8, 12, 1051–1056

https://sciex.com/content/dam/SCIEX/pdf/tech-notes/environmental-industrial/industrial/Tire-rubber_Nontarget-and-suspect-screening_X500R_RUO-MKT-02-13659-A.pdf
K.A. Oetjen.
Nontarget and suspect screening analysis of samples containing compounds derived from tire rubber.
sciex.com
… **6PPD**), as a potential source of acute mortality in US Pacific Northwest Coho salmon (Oncorhynchus kisutch).**6PPD** is used as a tire rubber antioxidant and it, along with its transformation product **6PPD**… amide compounds were identified in addition to **6PPD**-quinone. Of these 17, …

https://www.sciencedirect.com/science/article/abs/pii/S1352231013000654
Julie M. Panko, Jennifer Chu, Marisa L. Kreider, Ken M. Unice, Measurement of airborne concentrations of tire and road wear particles in urban and rural areas of France, Japan, and the United States, Atmospheric Environment, Volume 72, 2013, Pages 192-199.
Abstract: In addition to industrial facilities, fuel combustion, forest fires and dust erosion, exhaust and non-exhaust vehicle emissions are an important source of ambient air respirable particulate matter (PM10). Non-exhaust vehicle emissions are formed from wear particles of vehicle components such as brakes, clutches, chassis and tires. Although the non-exhaust particles are relatively minor contributors to the overall ambient air particulate load, reliable exposure estimates are few. In this study, a global sampling program was conducted to quantify tire and road wear particles (TRWP) in the ambient air in order to understand potential human exposures and the overall contribution of these particles to the PM10…

https://www.diva-portal.org/smash/record.jsf?pid=diva2%3A1611409&dswid=-7074
Patrício, J., Andersson-Sköld, Y., & Gustafsson, M. (2021). End-of-life tyres applications : technologies and environmental impacts. Retrieved from Statens väg- och transportforskningsinstitut website: http://urn.kb.se/resolve?urn=urn:nbn:se:vti:diva-17353

https://www.sciencedirect.com/science/article/pii/S004896972104907X
Juanita Rausch, David Jaramillo-Vogel, Sébastien Perseguers, Nicolas Schnidrig, Bernard Grobéty, Phattadon Yajan,
Automated identification and quantification of tire wear particles (TWP) in airborne dust: SEM/EDX single particle analysis coupled to a machine learning classifier, Science of The Total Environment, Volume 803, 2022, 149832.

https://iwaponline.com/wst/article/83/12/2863/82044/Loading-transport-and-treatment-of-emerging
Sumaiya Saifur, Courtney M. Gardner; Loading, transport, and treatment of emerging chemical and biological contaminants of concern in stormwater. *Water Sci Technol* 15 June 2021; 83 (12): 2863–2885.

https://onlinelibrary.wiley.com/doi/full/10.1002/pls2.10042
Sukatta, U, Rugthaworn, P, Seangyen, W, Tantaterdtam, R, Smitthipong, W, Chollakup, R. Prospects for rambutan peel extract as natural antioxidant on the aging properties of vulcanized natural rubber. *SPE Polymers*. 2021; 2: 199– 209.

https://www.sciencedirect.com/science/article/pii/S0141391021003335
Jomin Thomas, Seyed Kasra Moosavian, Teresa Cutright, Coleen Pugh, Mark D. Soucek,
Investigation of abiotic degradation of tire cryogrinds, Polymer Degradation and Stability,
Volume 195, 2022, 109814.
Abstract: The abundance of microplastics found in the environment is a major cause of concern. Tire tread particles containing additives such as curing accelerators and antioxidants, can be a major source of elastomer pollution in the environment. Such tire particles combined with road pavement particles are referred to as tire and road wear particles, TRWP. The environmental availability from parent elastomers and the release of additives in the process of abiotic degradation were evaluated using freeze-thaw, wet-dry and accelerated UV-weathering experiments…

https://pubmed.ncbi.nlm.nih.gov/34742612/
Varshney S, Gora AH, Siriyappagouder P, Kiron V, Olsvik PA.
Toxicological effects of 6PPD and 6PPD quinone in zebrafish larvae. J Hazard Mater. 2022 Feb 15;424(Pt C):127623.
Abstract. N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) is the most widely used antioxidant in automobile tyres and many rubber products. We investigated the impact of 6PPD and 6PPD quinone on acute toxicity, morphology, swimming behaviour, heart rate, and oxygen consumption in zebrafish larvae… Overall, our study shows that exposure of zebrafish embryos to 6PPD and 6PPD quinone at environmentally relevant concentrations (1 μg/L) does not affect its behaviour. However, exposure to higher but still sublethal concentrations of 6PPD and 6PPD quinone (10 and 25 μg/L) can affect behavioural endpoints. These findings reveal the toxicity of 6PPD and 6PPD quinone to early life stages of fish.

https://www.sciencedirect.com/science/article/pii/S0045653521036225
Stephan Wagner, Philipp Klöckner, Thorsten Reemtsma,
Corrigendum to “Aging of tire and road wear particles in terrestrial and freshwater environments – A review on processes, testing, analysis and impact” [Chemosphere 288 (2022) 132467],
Chemosphere, 2021, 133150.
And

https://www.sciencedirect.com/science/article/pii/S0045653521029398
Stephan Wagner, Philipp Klöckner, Thorsten Reemtsma,
Aging of tire and road wear particles in terrestrial and freshwater environments – A review on processes, testing, analysis and impact,
Chemosphere, Volume 288, Part 2, 2022, 132467.
Abstract: The environmental fate of tire and road wear particles (TRWPs) receives increasing attention due to the per capita emission volumes of

0.2–5.5 kg/(cap year) and recent reports on the environmental hazard of TRWP constituents. It is expected that aging impacts TRWPs fate in the environment but detailed knowledge is quite limited, yet. Making use of information on tire aging, the available knowledge on environmental aging processes such as thermooxidation, photooxidation, ozonolysis, shear stress, biodegradation and leaching is reviewed here… Aging in the environment needs to consider the TRWPs as well as chemicals released. Next steps for filling the gaps in knowledge on aging of TRWPs in the environment are elaborated.

https://www.mdpi.com/2071-1050/13/15/8172
Wang K, Chu X, Lin J, Yang Q, Fan Z, Wang D, Oeser M. Investigation of the Formation Mechanism and Environmental Risk of Tire—Pavement Wearing Waste (TPWW). *Sustainability*. 2021; 13(15):8172.

https://pubmed.ncbi.nlm.nih.gov/28112931/
Zheng W, Wu Y, Yang W, Zhang Z, Zhang L, Wu S. A Combined Experimental and Molecular Simulation Study of Factors Influencing the Selection of Antioxidants in Butadiene Rubber. J Phys Chem B. 2017 Feb 16;121(6):1413-1425.

2) PubChem. I suggest adding the PubChem Chemical Identifier (CID 13101) for 6PPD to this technical document's "Other identifiers." (PubChem 2021). See Page 9/100 of the document. PubChem CIDs are noted in many publications (two examples unrelated to 6PPD and 6PPD-quinone are: https://pubmed.ncbi.nlm.nih.gov/32535108/ and https://pubmed.ncbi.nlm.nih.gov/26092760/) and can help people locate and access PubChem content. The PubChem record for 6PPD is: https://pubchem.ncbi.nlm.nih.gov/compound/13101

   Also, not noted in this document but of very likely interest to DTSC and others is that there is now a PubChem record for 6PPD-quinone (CID 154926030). See: https://pubchem.ncbi.nlm.nih.gov/compound/154926030 . This record was created 2020-12-17. One example of likely interest is that the PubChem "Pharmacology and Biochemistry" section for 6PPD-quinone includes the 6PPD to 6PPD-quinone transformation from the NORMAN Network SLE noted below (https://pubchem.ncbi.nlm.nih.gov/compound/154926030#section=Pharmacology-and-Biochemistry).

3) The NORMAN Network (https://www.norman-network.com/ and https://www.norman-network.com/nds/) and its Suspect List Exchange (SLE, https://www.norman-network.com/nds/SLE/) is not noted in this document and might be of interest to DTSC and others now or later. It is one of the "data

sources" (also called "information sources") in PubChem, including the 6PPD and 6PPD-quinone records. It is described as:

> "The NORMAN network enhances the exchange of information on emerging environmental substances, and encourages the validation and harmonisation of common measurement methods and monitoring tools so that the requirements of risk assessors and risk managers can be better met. It specifically seeks both to promote and to benefit from the synergies between research teams from different countries in the field of emerging substances" (from https://pubchem.ncbi.nlm.nih.gov/source/NORMAN%20Suspect%20List%20Exchange).
>
> Here are two recent NORMAN Network and PubChem co-authored publications that might be of interest (a disclaimer is that while I am not a co-author of either publication, I interact frequently with the leaders of both teams in my "NIH Special Volunteer" in toxicology and environmental health sciences role at the NIH NLM NCBI):
>
> https://pubmed.ncbi.nlm.nih.gov/33685519/
> Schymanski EL, Kondić T, Neumann S, Thiessen PA, Zhang J, Bolton EE. Empowering large chemical knowledge bases for exposomics: PubChemLite meets MetFrag. J Cheminform. 2021 Mar 8;13(1):19.
>
> And
>
> https://pubmed.ncbi.nlm.nih.gov/34560325/
> Krier J, Singh RR, Kondić T, Lai A, Diderich P, Zhang J, Thiessen PA, Bolton EE, Schymanski EL. Discovering pesticides and their TPs in Luxembourg waters using open cheminformatics approaches. Environ Int. 2022 Jan;158:106885.

4) Add more about the compositions and magnitude of possible exposures from car tires vs. tires from other types of vehicles that are within the scope of this technical document? See Pages 6 and 7 of this technical document, e.g., "This Profile encompasses all parts of new tires (tread, sidewalls, etc.) and tire tread material (circular or linear precured tread and raw rubber for use in mold cure retreading) intended for use on light-duty vehicles (including passenger cars, light trucks, vans, and sport utility vehicles); motorcycles; motor homes; medium- and heavy-duty trucks; buses; and trailers (including trailer coaches, park trailers, and

semitrailers).” For example, Baensch-Baltruschat et al (2020) could be looked at for truck-related text to consider, e.g., “For truck tyres, which mainly contain natural rubber,…”

5) Microplastics. I noted and thought about the following statements during my reading associated with the peer review of this document:

> “The main way in which tires release 6PPD and its reaction products into the environment, however, is likely through mechanical tire abrasion on the roads, which produces microplastics known as TWP (OSPAR Commission 2006; Tian et al. 2021).”

In the plain English summary provided to me for this review is:

> “DTSC identified several priorities and considerations for implementation in its 2021- 2023 Priority Product Work Plan, including “the potential for the product to release microplastics to the environment during the use or end-of-life stages of the products’ life cycle. The SCP Program is concerned with microplastics because they have the potential to contribute significantly to adverse water quality impacts and aquatic pollution.” Tire wear particles are some of the most common types of microplastics found in California waters. Addressing contaminants found in tire wear particles, like 6PPD and its reaction products, aligns with SCP’s overarching goals.”

I know that the first sentences quoted above can also be found in DTSC’s 2021 – 2023 Priority Product Work Plan (https://dtsc.ca.gov/scp/priority-product-work-plan/). I want to call attention to the microplastic-related wording related to tires since I feel that it can lead to confusion since tire wear particles are not microplastics as generally thought of by some/many of the public and others, e.g., see the UC Davis’ ToxMSDT “ToxTutor” online resource’s Environmental Toxicology section (https://www.toxmsdt.com/161-environmental-toxicology.html -- a disclaimer is that I led the ToxTutor effort for several years before it moved to UC Davis) and NOAA’s “What are microplastics?” (https://oceanservice.noaa.gov/facts/microplastics.html). However, I realize that tire wear particles are microplastics for the purposes of this document as noted in some of its references, e.g.,:

> Kole PJ et al. (2017). Wear and tear of tyres: A stealthy source of microplastics in the environment. International Journal of Environmental Research and Public Health. 14(10):1265. doi: 10.3390/ijerph14101265.

My suggestion for documents now or later, and for presentations and other outreach-type efforts, is to consider developing additional microplastic-related wording related to being in/from tires.

Also, there is possibly useful text to consider in the Danish technical report noted below. For example, “This report makes use of a broad definition of plastics,

covering all the solid materials formed from polymers of a mainly petrochemical origin, meaning that small fragments resulting from, for example, wear of tires and paints are considered microplastics. Depending on the polymer chain length, polymers such as polyethylene (PE) can occur as a liquid, as a wax-like substance or as a solid. Only solid polymers are classified here as microplastics, although the waxy polymer may also occur in particulate form and have similar effects"
and
"There is a variety of sources of formation of secondary microplastics. The most important sources are considered to be wear on tires and road markings, wear and tear of clothes and other textiles made of synthetic fibres, wear and polishing of paint, wear of large surfaces of plastics e.g. vinyl flooring and roofing, and wear of shoe soles and kitchen utensils."

> Ministry of the Environment and Food of Denmark. (2015). Microplastics: Occurrence, effects and sources of releases to the environment in Denmark. Available at: https://www2.mst.dk/Udgiv/publications/2015/10/978-87-93352-80-3.pdf

Also, here is wording from a National Geographic article:

> https://www.nationalgeographic.com/environment/article/tires-unseen-plastic-polluter
>
> Tires: The plastic polluter you never thought about
>
> "Today tires consist of about 19 percent natural rubber and 24 percent synthetic rubber, which is a plastic polymer. The rest is made up of metal and other compounds."

Further, the Baensch-Baltruschat et al (2020) "Tyre and road wear particles (TRWP) - A review of generation, properties, emissions, human health risk, ecotoxicity, and fate in the environment" publication (https://pubmed.ncbi.nlm.nih.gov/32422457/) noted above includes this text:

> "Most authors refer to tyre wear as microplastics (MP) due to its (semi)-synthetically produced polymer structure, solid state, insolubility and particle size included in the size range defined for MP (1–1000 μm, see Hartmann et al. (2019)). Properties and environmental behaviour of elastomer particles from tyres, which are formed directly at the emission source 'road traffic', probably differ substantially from plastic items referring to the latters' partly crystalline structure, chemical compositions, shapes and surface. In the environment, pure tyre wear particles are rarely found."
>
> Finally, the "Graphical Abstract" for this publication might also be of interest for communications/presentations about tire wear-related releases.

Please feel free to let me know if you or others have any questions about what I have written above. Again, I want to thank the CalEPA External Scientific Peer Review Program for inviting me to be an external scientific peer reviewer of the technical document (November 2021 ESPR version). Finally, as noted above, these comments are my own and do not necessarily reflect official Federal government opinions of the organizations that I am affiliated with.

Sincerely,

Pertti J. Hakkinen, Ph.D., F-SRA
"NIH Special Volunteer" in Toxicology and Environmental Health Sciences
National Center for Biotechnology Information (NCBI)
National Institutes of Health (NIH)
Permanent Home: Kailua, Hawaii 96734
pertti.hakkinen@nih.gov

Review of: Review of the Scientific Basis of the Proposed Adoption of Motor Vehicle Tires Containing N-(1,3 – Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product

Staci L. Simonich, Ph.D.
Professor, Environmental & Molecular Toxicology and Department of Chemistry
Oregon State University

January 2, 2022

Based on my expertise and experience, I am reviewing the findings, assumptions, or conclusions I agreed I could review with confidence:

1. Coho salmon and other aquatic organisms may be exposed to 6PPD-quinone due to the use of 6PPD in motor vehicle tires.

2. The 6PPD contained in motor vehicle tires and its oxidation product 6PPD-quinone have the potential to contribute to or cause significant or widespread adverse impacts to the threatened and endangered populations of coho salmon in California, as well as to other aquatic organisms and the Native American tribes that rely on them.

Based on my review of the DTSC documents and relevant peer-reviewed and cited literature, I have determined that the scientific portion of the proposal rule is based upon sound scientific knowledge, methods, and practices.

I have the following recommendations:

1. Conclusion 2 should be changed to:

"6PPD-quinone has the potential to contribute to or cause significant or widespread adverse impacts to the threatened and endangered populations of coho salmon in California, as well as to other aquatic organisms and the Native American tribes that rely on them due to the use of 6PPD in motor vehicle tires."

2. The Product-Chemical Profile should include a summary on the global and U.S. regulatory status of 6PPD and 6PPD-quinone at the beginning of the document. Some of this information is given on page 72 in "Alignment with Other Efforts" but there should be a more thorough review of the global regulatory status of these two compounds and this should appear toward the beginning of the document.

3. The Product-Chemical Profile should include a section and table detailing all uses of 6PPD (and 6PPD-quinone) in California and/or the U.S. and the approximate volumes used at the beginning of the document. Although use of 6PPD in tires is likely the

greatest volume use of 6PPD, there are many other consumer product uses that could also result in discharge to water and this is not clearly established in the document with associated volumes. Large down-the-drain disposal consumer product uses of 6PPD would result in only partial removal of 6PPD during wastewater treatment and could also result in formation of 6PPD-quinone during wastewater treatment and discharge of 6PPD-quinone to waterways. A figure showing the volume use of 6PPD overtime in the U.S. and/or California would be helpful.

4. The Product-Chemical Profile should include a modeling section that estimates the impact the proposed regulatory changes will have on water concentrations of 6PPD and 6PPD quinone over time. This exercise will also help determine if changes in recycling and reuse of 6PPD and 6PPD-quinone containing tires is also needed. If these regulations are enacted, how long before the water concentrations are low enough that there is no or minimal risk to coho salmon? How long will it take to phase out 6PPD use in tires in California?

5. The Product-Chemical Profile should include a discussion around banning 6PPD in all California tires versus only in the geographic range of the evolutionary significant units for coho salmon (Figure 4).

6. The Product-Chemical Profile should include a figure that shows 6PPD volume use in California over time overlaid with coho salmon population declines in California over time. This could be done by modifying Figure 5 or compiling additional data.

7. The Product-Chemical Profile should include a table (that is similar to Table 1) for 6PPD-quinone relevant physicochemical properties, even if they are estimated.

8. All environmental measurements of 6PPD and 6PPD-quinone listed in the Product-Chemical Profile should state the year in which the environmental samples were collected, including tables.

9. The Product-Chemical Profile should clearly state if 6PPD and 6PPD-quinone have been measured in the tissue of aquatic organisms in the environment or in laboratory toxicity or bioconcentration factor testing.

10. The Product-Chemical Profile should clearly state if there are currently any tires sold in the U.S. or Europe that do not contain 6PPD.

11. Although mentioned late in the section on “Environmental Hazard Traits”, the beginning of the “6PPD” discussion should include a statement that any toxicity test conducted using 6PPD also includes some unknown concentration of 6PPD-quinone and that the

concentration of 6PPD-quinone in the test likely increases as the duration of the test increases (minimized if a static renewal test). This should also be stated in the title caption for Table 2.