

**UNDERSTANDING THE POTENTIAL
ENVIRONMENTAL IMPACTS OF THE
CHEMICAL 6PPD**

HEARING

BEFORE THE

SUBCOMMITTEE ON CHEMICAL SAFETY,
WASTE MANAGEMENT, ENVIRONMENTAL JUSTICE,
AND REGULATORY OVERSIGHT

OF THE

COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

JULY 31, 2024

Printed for the use of the Committee on Environment and Public Works



Available via the World Wide Web: <http://www.govinfo.gov>

U.S. GOVERNMENT PUBLISHING OFFICE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

THOMAS R. CARPER, Delaware, *Chairman*
SHELLEY MOORE CAPITO, West Virginia, *Ranking Member*

BENJAMIN L. CARDIN, Maryland	KEVIN CRAMER, North Dakota
BERNARD SANDERS, Vermont	CYNTHIA M. LUMMIS, Wyoming
SHELDON WHITEHOUSE, Rhode Island	MARKWAYNE MULLIN, Oklahoma
JEFF MERKLEY, Oregon	PETE RICKETTS, Nebraska
EDWARD J. MARKEY, Massachusetts	JOHN BOOZMAN, Arkansas
DEBBIE STABENOW, Michigan	ROGER WICKER, Mississippi
MARK KELLY, Arizona	DAN SULLIVAN, Alaska
ALEX PADILLA, California	LINDSEY O. GRAHAM, South Carolina
JOHN FETTERMAN, Pennsylvania	

COURTNEY TAYLOR, *Democratic Staff Director*
ADAM TOMLINSON, *Republican Staff Director*

SUBCOMMITTEE ON CHEMICAL SAFETY, WASTE MANAGEMENT, ENVIRONMENTAL
JUSTICE, AND REGULATORY OVERSIGHT

EDWARD J. MARKEY, Massachusetts, *Chairman*

BENJAMIN L. CARDIN, Maryland	PETE RICKETTS, Nebraska,
BERNARD SANDERS, Vermont	<i>Ranking Member</i>
SHELDON WHITEHOUSE, Rhode Island	KEVIN CRAMER, North Dakota
JEFF MERKLEY, Oregon	CYNTHIA M. LUMMIS, Wyoming
DEBBIE STABENOW, Michigan	MARKWAYNE MULLIN, Oklahoma
MARK KELLY, Arizona	ROGER WICKER, Mississippi
ALEX PADILLA, California	DAN SULLIVAN, Alaska
THOMAS R. CARPER, Delaware (<i>ex officio</i>)	LINDSEY O. GRAHAM, South Carolina
	SHELLEY MOORE CAPITO, West Virginia
	(<i>ex officio</i>)

C O N T E N T S

Page

JULY 31, 2024

OPENING STATEMENTS

Merkley, Hon. Jeff, U.S. Senator from the State of Oregon	1
Mullin, Hon. Markwayne, U.S. Senator from the State of Oklahoma	3

WITNESSES

Lassiter, Katrina, Program Manager, Hazardous Waste and Toxics Reduction Program, Washington State Department of Ecology	4
Prepared statement	6
Norberg, Tracey, Executive Vice President and General Counsel, U.S. Tire Manufacturers Association	24
Prepared statement	26
Responses to additional questions from Senator Capito	31
Fischer, David B., MPH, Counsel, Keller and Heckman LLP	34
Prepared statement	36

ADDITIONAL MATERIAL

Letter from The Yurok Tribe, the Port Gamble S'Klallam Tribe, and the Puyallup Tribe of Indians: Understanding the Potential Environmental Im- pacts of the Chemical 6PPD	87
Exhibit 1: Letter from Rob Southwick, Southwick Assocs., to Richard Pool, Golden Gate Salmon Association	92

UNDERSTANDING THE POTENTIAL ENVIRONMENTAL IMPACTS OF THE CHEMICAL 6PPD

WEDNESDAY, JULY 31, 2024

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON CHEMICAL SAFETY, WASTE MANAGEMENT,
ENVIRONMENTAL JUSTICE, AND REGULATORY OVERSIGHT,
Washington, DC.

The committee met, pursuant to notice, at 2:29 p.m. in room 406, Dirksen Senate Office Building, Hon. Jeff Merkley (chairman of the subcommittee) presiding.

Present: Senators Merkley, Mullin.

OPENING STATEMENT OF HON. JEFF MERKLEY, U.S. SENATOR FROM THE STATE OF OREGON

Senator MERKLEY. Good afternoon. The subcommittee hearing on Understanding the Potential Environmental Impacts of the Chemical 6PPD will come to order.

When we think about the Pacific Northwest, we think of salmon. Salmon are vital to my home State of Oregon's history, vital to our Tribes, vital to our ecosystems, vital to our economy. Unfortunately, since the middle of the 20th century, juvenile coho salmon have been dying at extraordinary rates. In the 1990's, they were listed under the Endangered Species Act.

In 2020, researchers linked some of the salmon deaths to the chemical known as 6PPD, and we will hear more about that from our witnesses. 6PPD is an additive to car tires that prevents the tires from wearing out as fast as they would otherwise. It has been used as an additive since the 1960's, around the same time we started noticing that coho salmon were suffering.

The process for how 6PPD gets from our tires in the waterways is straightforward: tires wear down, they create, essentially, tire dust. Those little particles contain the chemical 6PPD, and then it rains, and the rains sweeps it into the streams, and then that toxic chemical kills the salmon.

When it gets into the stream, by the way, it reacts with ozone, and it is that 6PPD-Q that becomes one of the most toxic chemicals to aquatic species ever evaluated by the Environmental Protection Agency.

So, that is a challenge. The EPA reports "concentrations of 6PPD-Q in stormwater in the Pacific Northwest were found to be lethal to coho salmon after only a few hours of exposure." 6PPD can be deadly to steelhead trout and deadly to other fish species, as well.

It is not just marine life. These chemicals are being found in sediments and soils, dirt and dust, and even inside all of us. In one study testing 150 people, 6PPD was found in nearly everyone. An intriguing situation is it was found in higher concentrations in pregnant women, though I do not yet know that we have an explanation for that.

6PPD is a disaster for the ecosystems, our economy, our tribes. That is why it is important as we wrestle with restoring salmon or recovering salmon, that we learn more about this issue.

In November 2023, 15 Northwest Tribal Nations shared how disappearing salmon populations have affected them. They are asking us to stop using 6PPD immediately. Sacred salmon, trout, and other fish species are unlikely to recover unless we do so.

In 2023, three tribes from across the Pacific Northwest petitioned the Environmental Protection Agency to establish regulations prohibiting the manufacturing, processing, use, and distribution of 6PPD in tires. Unfortunately, there is no known commercially viable replacements for 6PPD in tires. The U.S. Tire Manufacturers Association, with us here today, has been a strong voice to say that any replacements must provide equivalent tire safety while improving environmental impacts.

In Fiscal Year 2024, Congress invested \$1 million through the U.S. Department of Agriculture's Agricultural Research Service to develop an alternative to 6PPD. This research is being done in partnership with the company Flexsys, and we hope that it will accelerate the transition.

But stopping 6PPD's use is only one piece of the puzzle. We also need a strategy for dealing with it in our environment. It has been used, as I have mentioned, on tires for more than half a century. My home State of Oregon alone produces four million waste tires per year, two-thirds of which get shredded or illegally dumped. Even when tires are recycled and they are used in playground services, they are used for erosion or flood control, sometimes they are burned, all these things further allow 6PPD and other chemicals to continue to contaminate ecosystems.

The Department of Ecology for the State of Washington is with us here today. It and others are researching strategies to address these challenges, from stormwater mitigation to source control, street sweeping, the use of filters in water infrastructure, and so forth. These are difficult questions of science, of consumer safety, of tribal rights, of species extinction, so we are thankful to have today's panel of experts to help us understand these issues.

Katrina Lassiter is a program manager for the Hazardous Waste and Toxics Reduction Program at Washington State Department of Ecology. Her program identifies chemicals that pose the greatest risk to human health and the environment and finds ways to mitigate them.

Also joining us is Tracey Norberg, Executive Vice President and General Counsel for the U.S. Tire Manufacturers Association. She oversees the Association's environment, health, safety, and sustainability portfolio.

Finally, we are joined by David Fischer, Counsel for the law firm Keller and Heckman. He has served as Deputy Assistant Adminis-

trator for the EPA's Office of Chemical Safety and Pollution Prevention from 2019 to 2021.

Thank you all for taking the time to share your expertise with us today.

Now, let me turn this over to Ranking Member Mullin for any opening comments.

**OPENING STATEMENT OF HON. MARKWAYNE MULLIN,
U.S. SENATOR FROM THE STATE OF OKLAHOMA**

Senator MULLIN. Thank you, Chairman Merkley, and thank you to all our witnesses for attending today's hearing.

As we know, today we are here to discuss the alternatives to a chemical called 6PPD that has been used in automotive tires since the 1960's to help them last longer. In other words, every car on the road today, regardless if it is gas powered or electric powered, has tires containing 6PPD to protect them against oxygen exposure, which is what we call dry rot, which would otherwise cause them to quickly degrade.

This protection improves passenger safety by helping to prevent car accidents from tire blowouts and other tire-related issues. This is important, given that car accidents remain a leading cause of death in the U.S.

Very recently, scientists have discovered that when 6PPD and oxygen react, it forms a product called 6PPD-Q that can run off into streams, causing harm, specifically to fish like coho salmon. The problem is that there is no existing replacement to replace 6PPD currently available. The human health impacts of 6PPD are still unknown.

Once a science-backed replacement is found, EPA's unreasonable slow pace in approving new chemicals will further delay commercializing a replacement substance. Congress provided clear direction to the EPA to make determinations of new chemical approvals within 60 days under the Toxic Substance Control Act, and EPA consistently fails to meet their statutory deadline. Today, of the 413 new chemicals under EPA's review, only 48 have been under review for less than 90 days. That means 88 percent of those reviews do not meet the deadline.

Here is the real problem, though. Out of those 48, what percentage, at day 82, will be asked by the EPA to be paused, which is the way EPA currently is handling business? Chairman, I know you and I both have had different companies coming and telling us about this. When they pause it at day 82, it is sometimes paused for an indefinite amount of time.

This backlog is completely unacceptable from both the legal and domestic manufacturing perspectives. If we were to actually care about bringing a nontoxic replacement to 6PPD to the market, we also have to care about EPA's new chemical review failures.

If we were to get a sustainable chemical replacement to the market, how long would it take to improve? How long would it take for it to actually go into effect?

Today's hearing on 6PPD shows us why fixing our New Chemical program should not be a bipartisan fight. It should benefit everyone, and we should start by looking at the way the EPA reviews these chemicals.

Thank you, Chairman. I yield back.
Senator MERKLEY. Thank you very much.

We are now turning to your testimony. Katrina Lassiter, would you like to begin?

**STATEMENT OF KATRINA LASSITER, PROGRAM MANAGER,
HAZARDOUS WASTE AND TOXICS REDUCTION PROGRAM,
WASHINGTON STATE DEPARTMENT OF ECOLOGY**

Ms. LASSITER. Thank you, Chair Merkley, Ranking Member Mullin, and distinguished members of the subcommittee. My name is Katrina Lassiter, and as the Chair said, I manage the Hazardous Waste and Toxics Reduction Program at Washington State's Department of Ecology.

I am honored to be here today, and I thank you for holding this hearing. Some of this may sound redundant to Chair Merkley's opening statement.

For more than 20 years, scientists faced a mystery. Coho salmon in Washington streams and rivers were dying. The culprit was unknown, but it seemed linked to toxic chemicals running off roadways and into rivers and streams. To find the cause, researchers in Washington State spent 3 years searching through more than 2,000 chemicals that can leech from tires.

In 2020, they finally found it, a chemical called 6PPD-quinone, that kills coho salmon within hours of exposure. 6PPD-quinone comes from 6PPD. 6PPD is a chemical used in tires to prevent cracking and blowouts. It has been used for decades and is found in tires worldwide.

As traffic passes on roads, tire wear particles containing 6PPD travel through the air and stormwater runoff and enter rivers, creeks, and streams. When 6PPD reacts with ozone, it transforms into 6PPD-quinone, also known as 6PPD-Q.

6PPD-Q kills salmon at such low concentrations that it is one of the most toxic chemicals to aquatic life ever identified. I just want to repeat that for emphasis. It is one of the most toxic chemicals to aquatic life that has ever been identified. That is why we need to be doing two things. We need to find safer alternatives to 6PPD so we can get 6PPD out of tires, and we need stormwater control and treatment so we can reduce 6PPD chemicals in the environment.

The need for 6PPD alternatives and stormwater control is a national problem. Rainbow trout, steelhead brook trout, coho salmon, and lake trout, which are found throughout the Country, all die when they are exposed to 6PPD-Q at concentrations that we have measured in the environment. Depleted salmon and trout populations have negative economic impacts on recreational and commercial fisheries, tourism, employment, and food supplies, and there are growing concerns about potential impacts to human health, too.

We are still learning about 6PPD and 6PPD-Q, but tribes, States, and Federal agencies know enough to take action now. Federal agencies, including the EPA, but also NOAA, USDOT, and USGS are leading efforts to address 6PPD chemicals in the environment. Tribes are taking action to protect their treaty resources and have

petitioned the EPA to ban 6PPD manufacturing and use through the Toxic Substances Control Act.

In Washington State, we are tackling this problem head-on by researching and installing stormwater solutions to protect aquatic life now. We are developing methods to monitor 6PPD chemicals in the environment, and we are finding locations where these chemicals are causing harm. We are evaluating options for what to do with our used tires, and we are funding research to find a safety alternative for 6PPD.

In all of this, we are working with the tribes, Federal and State agencies, and industry. But solving this problem does require a national and coordinated effort.

Today, I ask for your support. Resource Federal agencies to make progress on this work. Invest in research to advance our understanding of 6PPD so we can find a safer alternative. Require nationwide transportation projects to include stormwater controls for roadway runoff to protect fish now. Help us work with manufacturers to increase transparency of chemicals used in products, and support legislation that reduces the use of 6PPD, because polluted waterways are not bound by State waters.

I want to thank those who have turned their attention to this problem. Thank you, and I look forward to answering your questions.

[The prepared statement of Ms. Lassiter follows:]

**Testimony of Katrina Lassiter
Program Manager, Hazardous Waste and Toxics Reduction,
Washington State Department of Ecology**

**U.S Senate Committee on Environment and Public Works
Subcommittee on Chemical Safety, Waste Management,
Environmental Justice, and Regulatory Oversight**

July 31, 2024

Good morning, Chair Merkley, Ranking Member Mullin, and Members of this esteemed Subcommittee.

My name is Katrina Lassiter and I am the program manager of the Hazardous Waste and Toxics Reduction Program at the Washington State Department of Ecology. Thank you for the opportunity to speak on the critical issue of N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine, better known as 6PPD.

6PPD-quinone: A Key Cause of Salmon Death

For decades, scientists in the Northwest hunted a mysterious killer. They knew something in urban streams was killing adult coho salmon as they migrated upstream to spawn. Washington's scientists first documented coho salmon dying at a hatchery in the late 1980s. Then, in the early 2000s, scientists at a National Oceanic and Atmospheric Administration lab in Seattle watched juvenile coho salmon die after adding runoff from a nearby highway in their tank. We knew then that there was a deadly chemical in the runoff, but we did not know what exactly. Finally, in 2020, there was a breakthrough.

Researchers at Washington State University and University of Washington pinpointed a chemical called 6PPD-quinone as the culprit. This discovery was a milestone moment for environmental science. It also marked the beginning of the race to solutions.

6PPD-quinone comes from a chemical added to tires called 6PPD. This chemical, 6PPD, is an antiozonant, which means it prevents the degradation of tire rubber by reacting with ozone in the air. This promotes tire longevity and safety. However, when 6PPD reacts with ozone, it transforms into the extraordinarily toxic 6PPD-quinone.

Because 6PPD is used as an antiozonant in all automobile tires today, 6PPD and 6PPD-quinone are everywhere. Think about the volume of rubber particles and tire dust that comes from tens of millions of tires on vehicles, washing off roads and into streams, rivers, lakes, and the sea.

This is not just a problem for one species of fish in Washington State – 6PPD-quinone harms fish species found throughout the United States. Rainbow trout, steelhead, brook trout, coho salmon, and lake trout all die when exposed to this chemical. And because salmon and trout are keystone species across the United States, the health of other fish and animals, and even entire ecosystems, depends on their existence. We see these impacts vividly in Washington with the decline of

Southern Resident Orcas, of which only around 75 remain. What we have learned about the impact of 6PPD elevates this issue to one of nationwide concern, and we are still learning more every day.

Economic Impacts of Depleted Fish Populations

People across the United States value fish as critical food sources, economic drivers, and connections to culture and tradition. Fisheries, large and small, rely on healthy fish populations to sustain their business operations. Depleted fish stock not only affects the bottom line, but also the families that rely on successful catch for their livelihood. And all of this has a rebound effect on our economy – fewer fish means fewer people fishing, which means higher unemployment and lower GDP.

Concerns around 6PPD and 6PPD-quinone do not end with fish, whales, or the economy. Our country has deep cultural ties to fishing and recreation. Children might grow up learning to fish for trout at the lake, then pass on those memories and traditions for generations. Fish are vital to Indigenous cultures and identities, food sovereignty, nutrition, traditional knowledge, and way of life.

Concerns About Human Health Impacts

We also have reasons to be concerned about impacts to human health, although we still need more research to fully understand the ways these chemicals affect us. We do know that the European Chemicals Agency has categorized 6PPD as a category 1B reproductive toxicant, which means it is presumed to be toxic to the human reproductive system.

Additionally, studies have found 6PPD and 6PPD-quinone at elevated concentrations in pregnant women compared to other adults and children. Studies indicate that both 6PPD and 6PPD-quinone cause damage to the liver of mice, and mother rats exposed to 6PPD experience lengthy, difficult births. Most recently, studies have concluded that 6PPD-quinone impairs sperm quality in male mice. We don't yet know the significance of these findings on our bodies, but researchers across the nation, and world, are currently searching for answers to these and the many other questions about 6PPD and 6PPD-quinone.

We also know that 6PPD-quinone's impact on fish populations directly reduces access to healthy foods for people who rely on fish for subsistence. This is particularly true for Tribes that consume salmon as a traditional food source and for the fishermen who fish to sustain their families. Not only this, but declining fish populations can erode mental health as culturally significant food sources become unavailable.

Nationwide Actions Needed to Find Solutions

Since the discovery of 6PPD-quinone's toxic effects in 2020, people across the nation have taken action. This is certainly not a problem that Washington or the West Coast can solve on our own. We are thankful for those who recognize this is a critical worldwide problem and have turned their attention, funding, and support towards finding solutions.

It is worth acknowledging these commitments and early accomplishments today. Progress anywhere benefits communities everywhere. It also shows how complex and critical this work is.

State, county, and local governments are evaluating stormwater projects to see whether certain stormwater best management practices reduce the amount of 6PPD-quinone that makes its way into rivers, creeks, and streams. This includes practices like building bioretention swales near busy roads and increasing street sweeping. Meanwhile, Tribes are taking action to protect treaty resources, including through a joint petition asking EPA to ban 6PPD under the Toxic Substances Control Act.

Federal agencies, including the U.S. Environmental Protection Agency, National Oceanic and Atmospheric Administration, and U.S. Geological Survey are prioritizing this work and leading efforts to address 6PPD and 6PPD-quinone in the environment. The EPA is funding stormwater effectiveness research in Washington State and coordinating across the nation to plan research within their Office of Research and Development. NOAA and USGS are leading the nation's research to identify how 6PPD-quinone enters fish and moves through their bodies. Tire manufacturers have also heard the concerns. They're here at the table with us, actively engaged in the search for a safer alternative to 6PPD.

Washington State's Interagency Approach

So, how is Washington addressing such an urgent, wide-spread problem? A problem this complex requires a holistic approach. We are not pursuing solutions to 6PPD through one avenue alone. To tackle this issue, we are working across state agencies to:

1. Evaluate chemical alternatives to determine if a safer and feasible alternative is available to restrict the use of 6PPD in tires.
2. Develop a statewide action plan to address short- and long-term actions that will mitigate the impacts of 6PPD and 6PPD-quinone on people and the environment.
3. Resolve some of the currently unanswered questions about 6PPD and 6PPD-quinone.
4. Minimize the amount of 6PPD-quinone that makes its way into waterways through stormwater treatment.

Finding a Permanent Solution to 6PPD-quinone

Pollution prevention (removing 6PPD from tires) is the cheapest and most effective way to reduce 6PPD harms to people and the environment. We understand that 6PPD ensures that the tires on our cars, trucks, and other vehicles are long-lasting, deliver the safety and performance we depend on, and available at an affordable price for consumers and businesses. We also understand that potential alternatives will need to meet similar criteria to achieve wide acceptance – as well as being demonstrably less toxic to people, fish, and the environment.

To find a safer replacement for 6PPD, Ecology is evaluating whether chemicals that could serve the same function in tires meet strict toxicity requirements. We've developed 6PPD hazard criteria that set a standard benchmark for identifying whether a chemical is safer than 6PPD. Our

hazard criteria incorporate input from the public, industry, academic researchers, and other interested parties.

We are also taking action through Ecology's Safer Products for Washington program. This program provides a state framework for regulating chemicals in consumer products. In the 2024 Legislative session, state legislators passed a bill that adds 6PPD as a priority chemical. When a safer alternative is found feasible and available, Ecology is authorized to restrict the sale of tires containing 6PPD.

Identifying actions to implement solutions to 6PPD-quinone

Our statewide 6PPD Action Plan will help us determine next steps and solutions to addressing 6PPD and 6PPD-quinone. Rather than waiting for more information, we must identify the actions we can take right now to protect people, the economy, and the environment. To this end, we convened a nationwide advisory committee of 52 people, including Federal, local, and Tribal government partners, industry experts, and community-based organizations, to help us define barriers and identify near-term actions around 6PPD.

A member of this advisory committee, representing the U.S. Tire Manufacturer's Association, is here speaking with us today. Additionally, 12 representatives from Tribal governments and commissions offered their expertise and perspectives on the advisory committee as co-managers of Washington State's natural resources. There are still many questions that must be answered before we can develop long-term recommendations, including what waterways most need to be protected, how we will fund the infrastructure needed to protect these waterways, and how these chemicals impact other fish – and humans.

Identifying Where and How 6PPD-quinone Causes Harm

One of the challenges with discovering a new toxic threat is the need to develop the standards and procedures that allow us to find trustworthy answers through verifiable and repeatable research. The Washington Department of Ecology was first in the nation to develop an accredited lab method to collect and test freshwater samples for 6PPD-quinone.

Ecology is currently sampling salmon-bearing streams to detect toxic levels of 6PPD-quinone to determine **where** the risks to salmon are highest, **when** those risks are highest, and **how long** toxic concentrations of 6PPD-quinone persist. Additionally, the Washington Department of Fish and Wildlife is sampling fish and mussels from Puget Sound habitats. Sampling data will help us understand the amount of exposure and toxicity fish species face from one watershed to the next.

Meanwhile, Washington's Department of Health is tracking and compiling research on human exposure and health effects of 6PPD, 6PPD-quinone, and other transformation products. These efforts are critical to learning more about how 6PPD and 6PPD-quinone affect people.

Preventing Fish Death Caused by 6PPD-quinone in Waterways

While we learn more about 6PPD and 6PPD-quinone, we must prevent toxic concentrations of 6PPD-quinone from making their way into our most vulnerable waterways. To accomplish this,

Ecology is evaluating which stormwater best management practices – like stormwater ponds, bioswales, and other green stormwater infrastructure – are most effective at protecting aquatic life. We're also requiring permittees to prioritize and implement best management practices to reduce, control, or treat 6PPD compounds in stormwater.

Additionally, we need to add effective stormwater treatment to address 6PPD compounds on more of our urban and suburban roadways. Washington's Department of Transportation's (WSDOT's) Move Ahead Washington transportation package includes funding for installation of stormwater treatment on existing roads to mitigate the impacts of toxic chemicals.

WSDOT has also received funding through the Federal Highway Administration's Transportation Pooled Fund to address toxics, including 6PPD-quinone, in highway runoff. Along with eight other states, including Oregon and California, WSDOT will evaluate highways to determine the best places to implement stormwater best management practices.

All of this helps protect our waterways not only from 6PPD and 6PPD-quinone, but other toxic chemicals, too. And better management of stormwater runoff can reduce flooding and improve the health of our streams and rivers. As a result, the actions we're taking promote salmon recovery, benefit ecosystem health, and reduce pollution across the state.

Our state and the federal government have already committed millions of dollars to funding research, pilot projects, and stormwater treatment that will help us improve stormwater management and prevent 6PPD-quinone from reaching local waters. But the geographic scope of this problem is vast and there are many locations in need of stormwater treatment. The Federal Leadership Puget Sound Stormwater and Transportation Charter Group has identified 16 demonstration projects to remove toxics from stormwater before they reach salmonid-bearing waterways; however, there is not yet funding to implement this work.

The benefit of this work reaches far beyond Washington and the Pacific Northwest – what we are learning will help all of us better manage our stormwater and the thousands of toxic chemicals released into our environment and finding their way to surface waters across the nation.

That said, stormwater management is only part of the answer when it comes to minimizing impacts from 6PPD-quinone. Ultimately, we know that reducing sources of 6PPD is the best way to protect people, fish, and the environment from 6PPD-quinone.

Immediate Federal Action Needed

Washington State is making progress on 6PPD every day. But solving this problem requires a nationwide, intergovernmental, coordinated effort. We are grateful to be here today to help elevate this conversation. We need the support of this committee, and Congress at large, to meet the challenge facing all of our communities and the people we all serve.

We urge you to resource Federal agencies in order to make progress on this work. Discuss this issue with your constituents. Help us build and maintain partnerships with the agencies,

organizations, and individuals who urgently want to solve this problem. Require transportation projects to include stormwater controls for roadway runoff. Invest in research so we can continue advancing our understanding of these chemicals, and support legislation that reduces the use of 6PPD.

Just like all of our waterways are interconnected, so too are all of the issues I've spoken about today. When we invest our time, energy, and resources into advancing environmental goals, we also advance our own health and prosperity.

As such, the solution to the 6PPD problem will never be "either/or." Finding a solution to 6PPD is not a choice between people or fish, between business or the environment. We can and must work together to find a solution that fosters the long-term well-being of all.

Thank you again for the opportunity to speak on this issue, and I'm happy to answer any questions you may have.

The Connection Between Tires, Fish, and Us

What's that chemical in your tires?

6PPD is a chemical used in tires to prevent cracking and blowouts. It has been used for decades and is found in tires worldwide. When 6PPD reacts with ozone, it transforms into 6PPD-quinone (often referred to as 6PPD-q).



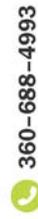
As traffic passes on roads, tire wear particles containing 6PPD and 6PPD-quinone are released into the environment.



6PPD and 6PPD-quinone then travel through air and stormwater runoff and enter rivers, creeks, and streams.

What are we doing to address 6PPD?

- 1. Understand the problem**
We are developing scientific methods to measure 6PPD-quinone in the environment and identifying affected areas.
- 2. Reduce sources of 6PPD**
We are searching for a safer alternative to use in tires and developing an action plan to guide our work.
- 3. Reduce stormwater pollution**
We are identifying and updating guidance on the best ways to capture and manage 6PPD-quinone before it reaches streams.



360-688-4993



6PPD@ecy.wa.gov

What's so bad about 6PPD-quinone?



How does 6PPD-quinone impact fish, ecosystems, and humans?

6PPD-quinone is highly toxic to coho salmon and kills these fish before they can lay eggs. It is also toxic to juvenile coho. This threatens the survival of a species that's critical to the resiliency of ecosystems.

People value salmon as an important food source and connection to culture and tradition. Salmon are vital to Indigenous cultures and identities, food sovereignty, traditional knowledge, and way of life.

6PPD-quinone is harmful to other aquatic organisms, including rainbow trout and brook trout. Scientists are also conducting research to learn how 6PPD and 6PPD-quinone may impact human health.



Without proper stormwater infrastructure, salmon migrating during rainfall are exposed to 6PPD-quinone.



Publication 23-04-058
Revised October 2023

To request an ADA accommodation, contact Ecology by phone at 360-407-6700, by email at hwtprubs@ecy.wa.gov, or visit ecology.wa.gov/accessibility.

For Relay Service or TTY call 711 or 877-833-6341.



Learn more
about 6PPD:

Focus on: Finding Solutions to 6PPD



Figure 1. The Washington Department of Fish and Wildlife and the Puyallup Tribe of Indians monitor toxic contaminants, including 6PPD-quinone, in seaward migrating juvenile Chinook salmon from the Puyallup/White River watershed. Photo: Andrew Berger, Puyallup Tribe of Indians.

6PPD in Washington State

6PPD is an antioxidant and antiozonant used in motor vehicle tires to prevent tire cracking and promote tire longevity. In 2020, Washington State University and University of Washington researchers discovered that 6PPD ozonation leads to the harmful breakdown product 6PPD-quinone (6PPD-q). This chemical has been identified as the second most toxic aquatic chemical ever measured and causes rapid mortality to species of cultural and environmental significance like the coho salmon.

Washington State's work focuses on three objectives:

1. Reducing sources of 6PPD in the environment, including identifying a safer alternative;
2. Minimizing and mitigating the impact of 6PPD in the environment; and
3. Furthering research to better understand 6PPD's effect on human health and key aquatic species.

Statewide Projects

6PPD Action Plan

Washington State is leading development of a statewide [6PPD Action Plan](#).¹ We are responding to emerging science by producing the plan in phases. Currently, we are developing recommendations that respond to priority and near-term research needs and data gaps. In future phases, we will develop long-term recommendations that reduce the impact of 6PPD and 6PPD-q on people and the environment.

State, Tribal, and Federal Puget Sound Stormwater and Transportation Charter Group

Washington State is partnering with the U.S. Environmental Protection Agency and Tribes in Washington to remove toxics from stormwater before they reach salmonid-bearing surface waters. We've identified 16 demonstration projects based on coho stream crossings along a gradient of traffic conditions.

Interstate Technology & Regulatory Council's Tire Anti-Degradant (6PPD) Team

Ecology and Health collaborate with Federal, State, and Tribal governments, municipalities, and community members to develop 6PPD and 6PPD-q guidance documents and tools, including [this fact sheet](#).² These resources are intended to broaden and deepen technical knowledge and expedite quality regulatory decision-making at the state and local level.

Department of Ecology

Alternatives Assessment

Ecology's alternatives assessment will identify, compare, and select safer alternatives to 6PPD in tires. In November 2021, Ecology published the [6PPD Hazard Assessment](#).³ The assessment reviewed existing anti-degradants that could potentially replace 6PPD in tires. The [6PPD Hazard Criteria](#),⁴ developed October 2023, describe specific data requirements and standards to assess chemical safety of alternatives to 6PPD. Ecology will use these hazard criteria when comparing the safety of possible replacement chemicals during the alternatives assessment.

Safer Products for Washington

Ecology has listed [6PPD as a priority chemical](#)⁵ and motorized tires as a priority consumer product under the Safer Products for Washington program. The Safer Products for Washington program provides a state framework for regulating chemicals in consumer products. If a safer alternative is feasible and available, Ecology could restrict the sale of tires containing 6PPD through this program.

Water Quality



Figure 2. We want to better understand the concentrations of chemicals in stormwater when it rains, including 6PPD-q. Field staff for King County Environmental Lab collect a stormwater runoff sample from the highway above. Photo credit: KCEL.

Ecology has proposed adding requirements to address 6PPD in multiple general permits. The updated [municipal stormwater permits](#)⁶ will be finalized by end of June 2024 and the [industrial stormwater general permit](#)⁷ will be finalized by December 2024. [Section 1.5](#)⁸ and the [Emerging Guidance Section](#)⁹ of the stormwater management manuals already contain guidance for effective 6PPD-q best management practices (BMPs). In February 2024, Ecology proposed a freshwater acute criterion for 6PPD-q in our draft [aquatic life toxics criteria rulemaking](#).¹⁰ In June 2022, Ecology, university researchers, and industry experts issued a [stormwater BMP effectiveness report](#)¹¹ providing best professional judgement on existing BMP options and their likelihood to manage 6PPD and 6PPD-q. Ecology continues to fund [BMP effectiveness projects](#).¹²

Sampling and Monitoring

Statewide partners supported Ecology's development of the [6PPD in Road Runoff](#)¹³ report. This report discusses the complexity of finding 6PPD-q in the environment and identifying the most vulnerable areas. Ecology's Manchester Environmental Laboratory was the first in the nation to produce an accredited [6PPD-q standard operating procedure](#)¹⁴ for analyzing 6PPD-q in water samples.

Mapping

Ecology developed [a tire contaminant story map](#)¹⁵ that details traffic, salmon distribution, and watershed characteristics. The story map identifies locations of coho salmon, brook trout, rainbow trout, and steelhead that are at risk of 6PPD-q exposure.

Department of Fish and Wildlife

The Department of Fish and Wildlife is partnering with chemists at the National Oceanic and Atmospheric Administration's Northwest Fisheries Science Center laboratory. They are developing analytical methods to test for 6PPD, 6PPD-q, and other tire-related compounds in juvenile Chinook salmon and bay mussels whole-body tissue and English sole bile and plasma. 6PPD-q was detected in a subset of all tissue samples. The potential impacts for each species at the measured concentrations are currently unknown. Learn more about how the Department of Fish and Wildlife's [Toxics Biological Observation System \(TBIOS\) monitors toxic contaminants in fish](#)¹⁶ and other organisms living in Puget Sound.



Figure 3. A mussel cage anchored at Duwamish Head in Elliott Bay during a 2020 TBIOS study. Photo credit: Puget Soundkeeper.

Department of Health

Department of Health toxicology staff are tracking and compiling research on human exposure and health effects of 6PPD, 6PPD-quinone, and other transformation products. They are preparing an assessment of available human health data and information gaps on 6PPD and its transformation products for the 6PPD Action Plan.

Department of Transportation



Figure 4. Stormwater retrofits help reduce 6PPD-q pollution. This pilot project tests the effectiveness of bioretention planter boxes to treat 6PPD-q. Photo credit: WSDOT.

The Move Ahead Washington transportation funding package includes \$500 million over 16 years for stormwater retrofits to enhance stormwater treatment from existing roads and infrastructure, with an emphasis on green infrastructure retrofits. This includes \$6 million to establish a new stormwater treatment facility and treat 6PPD-q at the Interstate 5 Ship Canal Bridge in Seattle. The Washington State Department of Transportation (WSDOT) is developing a prioritization plan to invest funds in cost-effective projects that accomplish the following goals:

- Provide benefits to salmon recovery and ecosystem health.
- Reduce pollution, including 6PPD-q.
- Address health disparities.

Learn more about stormwater retrofits on [WSDOT's Move Ahead Washington folio](#).¹⁷

Related Information

- [6PPD webpage: Tire anti-degradant \(6PPD\) and 6PPD-quinone](#)¹⁸
- [The Connection Between Tires, Fish, and Us](#)¹⁹
- [Focus on: Best Management Practices for 6PPD-q](#)²⁰
- [Focus on: Reducing Sources of 6PPD](#)²¹
- [Focus on: Monitoring 6PPD-q in the environment](#)²²
- [6PPD resources](#)²³
- [Join our 6PPD email list to stay up to date on Ecology's 6PPD work](#)²⁴

 <p>Tanya Williams Tanya.Williams@ecy.wa.gov 360-688-4993</p>	 <p>To request an ADA accommodation, contact Ecology by phone (360-407-6700) or email at hwtrpubs@ecy.wa.gov, or visit https://ecology.wa.gov/accessibility. For Relay Service or TTY call 711 or 877-833-6341.</p>
--	--

¹ www.ezview.wa.gov/site/alias__1962/37915/6ppd_action_plan.aspx

² 6ppd.itrcweb.org/wp-content/uploads/2023/09/6PPD-Focus-Sheet-Web-Layout-9.pdf

³ www.ezview.wa.gov/Portals/_1962/Documents/6ppd/6PPD%20Alternatives%20Technical%20Memo.pdf

⁴ apps.ecology.wa.gov/publications/SummaryPages/2304036.html

⁵ apps.ecology.wa.gov/publications/SummaryPages/2304038.html

⁶ ecology.wa.gov/muniswreissue

⁷ <https://apps.ecology.wa.gov/publications/SummaryPages/2410024.html>

⁸ ecology.wa.gov/SWMMWW/pollutantsimpacts

⁹ ecology.wa.gov/SWMMWW/emergingguide

¹⁰ ecology.wa.gov/Regulations-Permits/Laws-rules-rulemaking/Rulemaking/WAC-173-201A-Aquatic-Life-Toxics-Criteria

¹¹ <https://ecology.wa.gov/2022BMP6ppdreport>

¹² <https://ecology.wa.gov/sam-effectstudy>

¹³ apps.ecology.wa.gov/publications/documents/2203020.pdf

¹⁴ www.ezview.wa.gov/site/alias__1962/37858/addressing_6ppd.aspx

¹⁵ <https://gis.ecology.wa.gov/portal/apps/storymaps/stories/53b11807ac124735b281872a514809b5?>

¹⁶ wdfw.wa.gov/tbios

¹⁷ ftp.wsdot.wa.gov/public/StormwaterRetrofitMoveAheadWashington

¹⁸ ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals/Addressing-priority-toxic-chemicals/6PPD

¹⁹ apps.ecology.wa.gov/publications/SummaryPages/2304058.html

²⁰ apps.ecology.wa.gov/publications/documents/2310001.pdf

²¹ apps.ecology.wa.gov/publications/documents/2304017.pdf

²² apps.ecology.wa.gov/publications/documents/2303017.pdf

²³ ecology.wa.gov/6ppd-resources

²⁴ public.govdelivery.com/accounts/WAECY/subscriber/new?topic_id=WAECY_291

Focus on: Reducing Sources of 6PPD



Figure 1. A car driving on a road near a storm drain. Tires are a primary source of 6PPD-quinone in the environment.

The 6PPD Tire Problem

In 2020, scientists at the University of Washington-Tacoma, Washington State University, and other collaborators identified the chemical that causes pre-spawn mortality in coho salmon: 6PPD-quinone (pronounced “qui-KNOWN”), also known as 6PPD-q.¹ This chemical is a transformation product of 6PPD, a compound used in tires.

Tire manufacturers use 6PPD to reduce tire cracking and prevent tire blowouts, which keeps passengers safe. 6PPD also increases tire longevity, making them more economical and reducing the number of tires that end up in landfills.

As 6PPD performs these functions, it reacts with ozone in the air and turns to 6PPD-q. Tire dust holding 6PPD-q then washes into rivers and streams when it rains, killing coho salmon before they can spawn. Coho salmon are currently known to be the most sensitive to 6PPD-q, but this chemical is also harmful to other fish, like rainbow trout and brook trout, and possibly other aquatic species.

The discovery of 6PPD-q presents a complex problem: the best way to protect aquatic species is to reduce sources of 6PPD, but tire manufacturers can’t abruptly stop using this chemical because it plays a critical role in tire longevity and performance.

To find a solution, we’re working closely with research institutions; tire manufacturers; federal, state, local, and tribal governments; and other interested parties. Our long-term goal is to identify safer alternatives to 6PPD so we can reduce sources of 6PPD-q. To accomplish this, we must learn more about 6PPD, its toxicity to aquatic species and humans, and the chemicals that can potentially replace it.



Figure 2: A tire with and without 6PPD. Photo by the U.S. Tire Manufacturers Association.

6PPD Alternatives Research

Ecology is looking for alternatives and funding research with the Center for Urban Waters (UW-Tacoma), Washington State University, Emissions Analytics, Enthalpy Analytical, and ToxServices to:

- Prepare a hazards assessment for 6PPD and nine other antioxidants/antiozonants (completed in 2021).
- Compare the toxicity of 6PPD on coho salmon to other tire chemicals that could replace 6PPD.

¹ Tian, Z. et al. 2020. A ubiquitous tire rubber-derived chemical induces acute mortality in coho salmon. *Science* 371 (6525): 185-189. doi.org/10.1126/science.abd6951.

Hazardous Waste & Toxics Reduction Program



- Learn how environmental conditions (like water pH) impact the toxicity of 6PPD-q.
- Measure the presence of 6PPD, 6PPD-q, and other chemicals present in tires (including assorted brands of passenger car, light truck, and commercial truck tires).
- Test the toxicity of 6PPD on rainbow trout and potentially other aquatic species in the future.

Our goal in funding this research is to answer questions such as:

- Are there chemicals that meet the same tire performance requirements as 6PPD?
- Are the potential replacement chemicals safe for fish, other aquatic species, and humans?
- What criteria will we use to determine whether a chemical is safer than 6PPD?
- Can manufacturers make changes to tire design that remove the need for 6PPD or eliminate the pollution of 6PPD (and its transformation products) from tires?

To accelerate the pace of innovation for 6PPD alternatives, we're bringing interested parties together to share resources and ideas. In partnership with UMass Lowell, we held a forum in December 2022 for organizations to discuss collaborative needs and opportunities to find safer, effective alternatives to 6PPD. Participants shared insights and research around 6PPD and identified some critical next steps to solving this complex problem.

Looking Ahead: 6PPD Alternatives Assessment

In 2022, the Legislature allocated funding for Ecology to prepare a 6PPD alternatives assessment (AA). An AA identifies, compares, and selects safer alternatives to unsafe chemicals like 6PPD.

The research we're conducting is a critical step in preparing for the 6PPD AA. Before conducting the AA, Ecology will establish specific data requirements and standards (known as hazard criteria) to assess chemical safety.

When we evaluate potential alternatives in the AA, we can compare a chemical's toxicity, performance, availability, and cost to that of 6PPD. We will use this information to identify alternatives for 6PPD that: 1) meet tire performance requirements; and 2) are safer to humans, coho salmon, and other aquatic life.

Related Information

- [Ecology's 6PPD webpage](#)²
- [Technical Memo: Assessment of Potential Hazards of 6PPD and Alternatives](#)³
- [Collaborative Innovation Forum: Functional Substitutes to 6PPD in Tires \(Meeting Report\)](#)⁴

 <p>Tanya Williams tanya.williams@ecy.wa.gov 360-688-4993</p>	 <p>To request an ADA accommodation, contact Ecology by phone (360-407-6700) or email at hwtrpubs@ecy.wa.gov, or visit https://ecology.wa.gov/accessibility. For Relay Service or TTY, call 711 or 877-833-6341.</p>
--	---

² ecology.wa.gov/6PPD

³ www.ezview.wa.gov/Portals/_1962/Documents/6ppd/6PPD%20Alternatives%20Technical%20Memo.pdf

⁴ www.sustainablechemistrycatalyst.org/s/6PPD-in-Tires-Innovation-Forum-Meeting-Report.pdf



Understanding 6PPD

6PPD is a chemical that prevents tires from breaking down and helps them last longer. When this chemical is exposed to air, it reacts with ozone to create 6PPD-quinone or 6PPD-q. Recent research has shown that 6PPD-q is lethal to salmon, especially coho. This is a problem, as 6PPD-q can move from paved surfaces into waterbodies and harm aquatic life.

Specific to local salmon runs, research shows that 6PPD-q is responsible for the death of coho salmon migrating back to spawning grounds.

Research is ongoing for all of the potential impacts of 6PPD and 6PPD-q, including studying the effectiveness of different stormwater treatments in preventing 6PPD-q from reaching the water.

To learn more about all of Ecology's work on 6PPD, visit ecology.wa.gov/6PPD.

Washington's Municipal Stormwater Program

Stormwater runoff is a leading pollution threat to clean water in urban areas of Washington. As rain and snowmelt runs off buildings, paved roads, and parking lots, it increases in speed and volume, and can pick up pollution such as oil, fertilizers, pesticides, tire wear, trash, and pet waste. These pollutants and higher flows are carried into local water bodies, where they can harm water quality and habitat.

To manage this stormwater, Ecology has municipal stormwater permits for the state's most populated cities and counties. The permits are aimed at reducing stormwater pollution at its source, treating it, and controlling volume and flow, so cleaner water goes into creeks, rivers, lakes, groundwater, and Puget Sound.

The regulatory approach in these permits is a programmatic and a holistic approach to

stormwater management, which is different from the typical water quality permit. Municipal stormwater permittees are required to develop and implement Stormwater Management programs. These are comprehensive toolboxes of stormwater best management practices (BMPs) known to be effective at preventing, controlling and treating runoff from urbanized landscapes. We update the municipal stormwater permits every five years. The most recent permit updates were issued on July 1, 2024 and are effective from Aug. 1, 2024 to July 31, 2029.

To address 6PPD and 6PPD-q pollution, Ecology made updates to the municipal permits and the stormwater manuals that support permit implementation.

Updating permits for 6PPD and 6PPD-q

The best way to prevent pollution from reaching stormwater and local waterways is to control it at the source. For example, street sweeping, a commonly used source control best management practice (BMP), removes tire particles, heavy metals, sediment and other pollutants from the roadway before they move downstream by stormwater. Stormwater treatment BMPs remove many kinds of pollutants, including 6PPD-q, from stormwater before it is discharged to surface waters.

There are existing BMPs in the permits and manuals that are effective at addressing tire wear particles. Initial research shows these are effective BMPs for 6PPD and 6PPD-q. These BMPs were designed to address many different pollutants, from metals to fertilizers to tire wear particles, even before we knew about 6PPD.

The following permit changes will help further reduce pollution, including 6PPD, from reaching local waters in the near term and long term:

- Requiring more new development and redevelopment projects to incorporate Runoff Treatment and Flow Control BMPs.
- Increasing the amount of stormwater retrofits required for existing development, to address areas without adequate stormwater treatment.
- Adding a street sweeping requirement to collect pollutants before they are washed into downstream waters.
- Including a new emphasis on transportation-related projects in Stormwater Management Action Plans, as those are likely to generate tire particles and 6PPD-q. These plans also include planning for high priority receiving waters and identifying priority stormwater management activities.

One of the biggest issues when it comes to addressing 6PPD and 6PPD-q are areas without effective stormwater treatment. This will continue to improve as local governments install more stormwater treatment through retrofits of existing development and more stormwater management BMPs as a result of permit requirements.

What stormwater BMPs help with 6PPD and 6PPD-q?

There are a few types of common stormwater BMPs that initial research shows help with 6PPD and 6PPD-q. Research is ongoing to better understand just how effective these BMPs are and what other BMPs might be helpful. We issued our first report on the potential effectiveness of stormwater management BMPs for 6PPD-q in 2022. More information is in our report [focus sheet](#). The report looked at:

Stormwater source control BMPs: prevent stormwater contamination with methods such as street sweeping to remove 6PPD-q and tire wear

particles from roadways before they are washed into downstream waters.

Flow control BMPs: slow runoff down and reduce runoff volumes by holding stormwater back with structures such as ponds, infiltration basins, and bioretention.

Runoff treatment BMPs: remove 6PPD-q from stormwater runoff through physical filtration or chemical sorption media like biofiltration swales, bioretention, and certain manufactured treatment devices.

Ecology is funding BMP effectiveness research for 6PPD and 6PPD-q. Focus areas include: stormwater characterization, crumb rubber, street sweeping, decant facilities, soil and media mixes, swales, and embankments.

How communities are monitoring for 6PPD-q

A regional monitoring collective, the [Stormwater Action Monitoring \(SAM\)](#) program, remains the most effective monitoring option for municipal stormwater permittees.

SAM conducts long-term regional status and trends monitoring studies in western Washington. These studies aim to understand how collective stormwater management efforts are positively impacting streams and marine waters. Additionally, SAM and municipal stormwater permittees are researching the effectiveness of stormwater BMPs. SAM is studying 6PPD-q in some of its long-running and newer projects.

A SAM project starting in 2024 will analyze stormwater outfall samples from 16 basins across the Puget Sound. This analysis will focus on several Contaminants of Emerging Concern, including 6PPD-q. The study results will inform us of 6PPD-q concentrations in stormwater coming from industrial, commercial, and residential areas.

Related Information

- [Municipal Stormwater General Permits](#)
- [Stormwater Manuals](#)



Abbey Stockwell
abbey.stockwell@ecy.wa.gov
360-280-2934



To request an ADA accommodation, contact Ecology by phone at 360-407-6600 or email at Jessica.Shook@ecy.wa.gov, or visit <https://ecology.wa.gov/accessibility>. For Relay Service or TTY call 711 or 877-833-6341.

Focus on: Monitoring 6PPD-q in the environment



A scientist collects water samples from a salmon-bearing stream to measure levels of 6PPD-quinone. Impervious surfaces can deliver tire contaminants to our waterways.

6PPD-quinone in the environment

In 2020, after decades of investigative work by a cross-disciplinary research consortium, scientists from University of Washington Tacoma, Washington State University Puyallup, and their collaborators, identified 6PPD-quinone (also known as 6PPD-q) as the chemical that causes pre-spawn mortality in coho salmon. The chemical comes from 6PPD (6 p-phenylenediamine), found in tires and recycled tire products, when tire dust is exposed to air. When rain falls on tires and roads, it washes tire dust including 6PPD-q into rivers, streams, and estuaries.

To support long-term solutions, researchers are developing assessment studies to help us understand when, where, and how 6PPD-q ends up in the environment. These studies will support toxics-reduction planning and mitigation actions.

Initial assessment and recommended strategies

In October 2022, we [published a legislative report](#)¹ with key findings, research needs, and proposed strategies to reduce 6PPD-q in road runoff.

Important takeaways from the 2022 report to the Legislature:

- The amount and type of stormwater-management strategies to reduce tire contaminant exposure to vulnerable species varies from one watershed to another.
- We need consistent funding to support regional contaminant research to fill the many data gaps and for our partners to continue characterizing the chemicals and impacts associated with tires.
- At this early stage, we recommend using adaptive management strategies.
- Innovative sampling technologies and GIS mapping are decisive tools to measure and assess 6PPD-q.

¹ <https://apps.ecology.wa.gov/publications/SummaryPages/2203020.html>

Current and future 6PPD-q monitoring and testing

We are expanding our field monitoring and laboratory capacity to identify areas where the most vulnerable habitats are exposed to road runoff and 6PPD-q. For example:

- We have developed a laboratory method for measuring 6PPD-q in water. This will help us to quantify how much 6PPD-q is in aquatic environments and to evaluate stormwater-management actions.
- We are developing analytical methods for measuring 6PPD-q in stream sediments and fish tissue collected from aquatic environments.
- We are designing field studies to determine the most effective methods for evaluating the scope and scale of 6PPD-q pollution in rivers, streams, and estuaries.
- Mapping tools help us determine how traffic contributes to coho salmon and rainbow trout mortality, including pre-spawn adults and juveniles.
- We are coordinating with local stormwater and salmon monitoring leads to identify areas where tire pollution is most likely to impact aquatic life.



A chemist at Manchester Environmental Lab explains the process for testing 6PPD-q in water samples to Washington's Governor Jay Inslee.

Collaborating with partners

We continue to work closely with our partners on research and monitoring projects to reduce aquatic life exposure to 6PPD-q. Our partners include the Washington State departments of Transportation, Health, and Fish and Wildlife; University of Washington Tacoma's Center for Urban Waters; Washington Stormwater Center at Washington State University's Puyallup Research and Extension Center; National Estuary Program and Puget Sound Recovery at the U.S. Environmental Protection Agency; Puget Sound Ecosystem Monitoring Program; Northwest Indian Fisheries Commission; and local communities.

Related Information

- [6PPD in Road Runoff: Assessment and Mitigation Strategies](https://apps.ecology.wa.gov/publications/SummaryPages/2203020.html)²
- [Our 6PPD webpage](https://ecology.wa.gov/6PPD)³

 <p>Rhea Smith rhea.smith@ecy.wa.gov 360-763-2584</p>	 <p>To request an ADA accommodation, contact us by phone at 360-407-6831 or email at ecyadacoordinator@ecy.wa.gov, or visit https://ecology.wa.gov/accessibility. For Relay Service or TTY call 711 or 877-833-6341.</p>
--	--

² <https://apps.ecology.wa.gov/publications/SummaryPages/2203020.html>

³ <https://ecology.wa.gov/6PPD>

Senator MERKLEY. Thank you very much.

Now, we will turn to the perspective from the industry of making tires and the expertise they bring to bear, Tracey Norberg.

STATEMENT OF TRACEY NORBERG, EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL, U.S. TIRE MANUFACTURERS ASSOCIATION

Ms. NORBERG. Good afternoon, Chairman Merkley, Ranking Member Mullin, and distinguished members of the subcommittee. My name is Tracey Norberg, and I am testifying today on behalf of the U.S. Tire Manufacturers Association.

You have my written comments, so I will just touch on a few key points now. USTMA is the national trade association for tire manufacturers that produce tires in the United States. Tire manufacturing directly supports more than 291,000 U.S. jobs, and our 12 member companies and 4 affiliates account for roughly 82 percent of the 327 million tires shipped in the U.S. last year.

6PPD serves an essential safety function in tires, as we have heard from both the Chairman and the Ranking Member and my colleague from Washington Ecology. Protecting the components of the tire from attack by ozone, oxygen, and other factors are key to 6PPD's function. Without 6PPD, a tire's integrity would be seriously and severely quickly compromised, jeopardizing motorists' safety.

6PPD is currently used in all tires sold in the United States, including all of our member tires available for on-road use. We are not aware of any new motor vehicle tires available today that do not contain 6PPD.

6PPD-quinone is not used in tire manufacturing. This material is a recently discovered transformation product of 6PPD that may form when 6PPD reacts with ozone or oxygen under certain conditions. Today, there are no commercially available alternatives to 6PPD that both provide comparable safety and performance in motor vehicle tires and minimize the potential for environmental effects.

Nonetheless, our industry has embraced this challenge to find a suitable alternative. In December 2020, the same month that 6PPD-quinone was first identified, USTMA requested that the California Department of Toxic Substances Control prioritize the review of 6PPD in tires under its Safer Consumer Products regulations. To our knowledge, ours is the only industry that has ever invited this regulation upon itself.

USTMA assembled a consortium of 32 tire manufacturers from across the world to identify and evaluate potential alternatives to 6PPD in tires. In accordance with California regulations, each consortium member submitted the USTMA preliminary, or stage one, alternatives analysis this past spring and submitted an updated report last week in response to DTSC comments.

As part of the stage one report, we screened more than 60 potential alternatives for their suitability to replace 6PPD in tires, and 7 of those merited further evaluation in stage two of the process that will commence shortly.

By the end of this alternatives analysis process, we are optimistic that we will have identified one or more possible alternatives that

hold promise to replace 6PPD or materially reduce the level of 6PPD in motor vehicle tires, subject, of course, to future performance testing to ensure tire safety and performance.

The search for an alternative is complex, and research in this space is continually evolving. We continue to work actively, transparently, and collaboratively with a broad array of stakeholders and academia and at the State, Federal, tribal, and international levels on this important work.

Our collaboration with Washington Ecology extends back to 2019, actually predating the identification of 6PPD-quinone, and includes providing information on tire materials that may be found in stormwater runoff, providing technical expertise on identifying and researching tire and road-wear particles, and providing samples of cryogenically milled tire tread to support research.

I hope it is clear that the industry is moving forward with great alacrity. While efforts to find and implement a suitable alternative to 6PPD will take time, there are things that can be done now to reduce 6PPD and 6PPD-quinone in the environment. Those measures, some of them have already been mentioned, but they do include street sweeping in urban areas, choosing pavement surfaces such as rubber modified asphalt and permeable pavement that reduced tire abrasion and mitigate stormwater impacts, installing bioretention technologies to treat stormwater, and maintaining proper tire inflation pressure to reduce tire abrasion. Research in Oregon and Washington have demonstrated the effectiveness of some of these technologies in improving stormwater quality.

We welcome the opportunity to collaborate with Congress as well as regulators, affected partners, and interested stakeholders to develop policies that take advantage of technologies to help mitigate stormwater impacts associated with roadways for a more immediate positive effect on the aquatic environment.

We appreciate your time and the opportunity to be here today, and we welcome the opportunity to be part of this discussion moving forward. I am happy to answer your questions.

Thank you.

[The prepared statement of Ms. Norberg follows:]

U.S. Tire Manufacturers Association
Senate Environment and Public Works
Subcommittee on Chemical Safety, Waste Management,
Environmental Justice, and Regulatory Oversight

July 31, 2024

I. Introduction

Good afternoon, Chairman Merkley, Ranking Member Mullin and distinguished members of the Senate Environment and Public Works Subcommittee on Chemical Safety, Waste Management, Environmental Justice, and Regulatory Oversight. My name is Tracey Norberg, and I am testifying today on behalf of the U.S. Tire Manufacturers Association (USTMA).

II. USTMA overview

USTMA is the national trade association for tire manufacturers that produce tires in the United States. Our 12 member companies operate 57 tire-related manufacturing facilities across 17 states, making mobility possible. The U.S. tire manufacturing industry is responsible for more than 291,000 U.S. jobs in manufacturing, distribution, and retailing. The industry supports more than 510,000 additional U.S. jobs in supplier and induced activities, totaling more than 801,000 jobs nationwide. Tire manufacturing produces a direct economic impact of over \$68 billion and generates over \$21 billion in direct industry wages and nearly \$19 billion annually in state and local tax revenue. In addition, the U.S. military depends on the tire manufacturing industry to supply tires to protect our military preparedness, national defense and homeland security. USTMA advances a sustainable tire manufacturing industry through thought leadership and a commitment to science-based public policy advocacy.

III. Overview and Context

A. What is 6PPD?

6PPD serves an essential safety function in tires as an antioxidant and antiozonant, protecting the components of the tire from attack by ozone, oxygen, and other factors. Without 6PPD, a tire's integrity would be severely and quickly compromised, jeopardizing driver and passenger safety. Any alternative identified to replace 6PPD must continue to ensure compliance with Federal Motor Vehicle Safety Standards (FMVSS) and other consumer, vehicle, and tire manufacturer requirements.

6PPD is currently used in all USTMA member passenger, light truck, truck and bus radial, and motorcycle tires. USTMA is not aware of any new motor vehicle tires available today that do not contain 6PPD.

6PPD-quinone, or 6PPDQ, is a recently discovered transformation product of 6PPD that may form when 6PPD reacts with oxygen or ozone under certain conditions. 6PPDQ is not used in U.S. tire manufacturing. Today there is no commercially available alternative to 6PPD that both provides comparable safety and performance in motor vehicle tires and minimizes potential environmental effects.

B. Efforts underway to identify an alternative

In December 2020, the same month that 6PPDQ was identified, USTMA requested the California Department of Toxic Substances Control (DTSC) to prioritize a review of 6PPD in tires under the California Safer Consumer Products Regulations (SCPR). To our knowledge, ours is the only industry that has ever asked to be part of the California program.

Once DTSC listed 6PPD in tires as a priority product, USTMA assembled a consortium of 32 tire manufacturers from across the world to prepare a Preliminary (Stage 1) Alternatives Analysis (AA) to identify and evaluate potential alternatives to 6PPD in tires. Individual Consortium members submitted the report to DTSC to meet the March 29, 2024 compliance date. On July 22, USTMA submitted an updated report in response to DTSC comments.

The Consortium is actively working to identify possible alternatives (appropriate reactivity with oxygen and ozone, proper migration rates through the rubber matrix etc.) that warrant further review of their potential impact to sensitive aquatic species. In support of this work, USTMA has initiated a joint research project with the U.S. Geological Survey to assess and refine methods of evaluating potential alternatives to 6PPD for use in tires.

In total, over 60 initial candidate alternatives were identified for screening and scoring for their suitability as possible alternatives to 6PPD in tires. In the Stage 1 AA Report, the Consortium considered different types of alternatives to 6PPD as an antidegradant in tires, including: (1) other phenylene diamines ("PPDs") that are the most logical and possibly most straightforward alternatives to 6PPD, and (2) non-PPD possible alternatives that likely pose greater challenges in incorporating into tire chemistry.

40 of the over 60 initial candidates were subjected to an extensive review, which identified seven possible alternatives that warrant further evaluation in the Stage 2 AA. Of those seven possible alternatives, 4 are other PPD compounds, while 3 are non-PPD materials.

Below is a list of the possible alternatives identified:

Chemical Name	Acronym	CAS
N-(1,4-Dimethylpentyl)-N'-phenyl-p-phenylenediamine	7PPD	3081-01-4
N-Isopropyl-N'-phenyl-p-phenylenediamine	IPPD	101-72-4
N,N'-Bis(1,4-dimethylpentyl)-p-phenylenediamine	77PD	3081-14-9
N,N'-Dicyclohexyl-p-phenylenediamine	CCPD	4175-38-6
Specialized graphene ¹	NA	1034343-98-0
Octyl gallate ²	NA	1034-01-1
Nano calcium carbonate surface modified by gallic acid	NA	No CAS

¹The materials referred to as graphene in the USTMA 6PPD Consortium Preliminary AA Report are graphene-based materials (sometimes referred to as a graphene nano-platelet) with a surface area not greater than 180 m²/g, and a carbon content greater than 99% and an oxygen content less than 1%. The lateral particle size of these materials is between 100 nm and 5 μm.

²Octyl gallate was investigated instead of propyl, butyl or pentyl gallates. Propyl gallate has been tested as an antiozonant for non-rubber applications. Propyl gallate, however, is expected to be less suitable for rubber than other gallate esters with longer carbon chains. Propyl gallate melts at 150°C, which is the temperature at which rubber is mixed. Natural rubber compounds are sometimes mixed at a lower temperature. Unless propyl gallate completely melts and is dispersed in the compound, it will not have an opportunity to function as an antiozonant. Octyl gallate is a much better choice because it melts at approximately 100° C and is sure to melt during mixing. Butyl gallate melts at 144°C so it may be acceptable, but octyl gallate has been used as a food additive, is more readily available and has more hazard information.

At the end of the Stage 2 AA, we are optimistic that we will have identified one or more possible alternatives that hold promise to replace or materially reduce 6PPD in motor vehicle tires, subject to future performance testing to ensure comparable tire safety and performance. Additional toxicity testing may need to be performed to satisfy regulatory requirements and to fill important data gaps. Simultaneously, USTMA is coordinating with the Washington State Department of Ecology as it progresses through its own, separate alternatives analysis process. USTMA is working closely with Ecology to ensure that any possible alternatives identified through our work with DTSC also meet Washington's criteria as their evaluation moves forward.

Outside our work with state regulators, USTMA has established a 6PPD Platform to facilitate the development as quickly and efficiently as possible of one or more candidate alternatives to 6PPD that ensures the safety of motorists and considers potential environmental and societal effects of the possible alternatives. Consistent with U.S. competition laws, the USTMA 6PPD Platform recognizes the benefits of collaborating in the pre-competitive space to save time, money, and resources, thus promoting competition while enabling USTMA, in partnership with chemical manufacturers, to facilitate the development of one or more viable alternative(s) to 6PPD quickly, effectively, and economically.

C. Supporting research and filling data gaps

USTMA's collaboration with Washington State Department of Ecology extends back to 2019, predating the identification of 6PPDQ and includes providing information on tire materials that may be found in stormwater discharge, providing technical expertise on identifying and researching tire and road wear particles (TRWP), and providing samples of cryogenically milled tire tread (CMTT) to support research on TRWP.

USTMA also plans to work with the U.S. Environmental Protection Agency (EPA) officials as they continue their evaluations of 6PPD under the Toxic Substances Control Act (TSCA), and as appropriate in the other areas of focus for the Agency, including research and stormwater management.

USTMA has been working closely with the Interstate Technology and Regulatory Council ("ITRC") which includes many of the same officials we are working with at the state and federal levels, tribes, NGOs, and other stakeholders as part of the ITRC's project on tire anti-degradants.

In addition, part of the Alternatives Analysis, USTMA signed a Cooperative Research and Development Agreement ("CRADA") with the U.S. Geological Survey ("USGS") to test potential alternatives against coho salmon cell lines.

Similarly, a chemical manufacturer of 6PPD, Flexsys, has a CRADA with the U.S. Department of Agriculture's Agricultural Research Service to develop a biobased potential alternative to 6PPD.

USTMA is also working with our global partners to assess relevant data gaps.

IV. Comprehensive Approach: Research and Mitigation

USTMA is committed to working collaboratively with regulators, affected partners, and interested stakeholders to expeditiously identify an alternative that is protective of motorist safety and the environment.

While efforts to find and implement a potential alternative to 6PPD (while still complying with safety standards) will take time, there are things that can be done now to reduce 6PPD and 6PPDQ in the environment. Those measures include street sweeping in urban areas, choosing pavement surfaces (such as rubber modified asphalt and permeable pavement) that reduce tire abrasion and mitigate stormwater impacts, installing bioretention technologies to treat stormwater, and maintaining proper tire inflation to reduce tire abrasion.

Research done in Washington State has demonstrated the effectiveness of bioretention technologies such as rain gardens and bioswales, which can be installed to improve the quality

of stormwater. Additionally, research conducted in Oregon has shown the effectiveness of permeable pavements in improving stormwater quality.

USTMA is currently engaging with potential partners to advance the practical knowledge around promising stormwater solutions, and we are eager to share more about that work as those projects are formalized.

USTMA would welcome the opportunity to collaborate with Congress – as well as regulators, affected partners and interested stakeholders – to develop policies that take advantage of bioretention technologies, permeable pavements and other technologies to help mitigate stormwater impacts associated with roadways

V. Conclusion

The tire industry is working actively, transparently, and collaboratively with regulators, partners and interested stakeholders to identify an alternative to GPPD that is protective of motorist safety and the environment.

We appreciate your time, and we welcome the opportunity to continue to be part of this discussion moving forward.

I am happy to answer any questions you might have.

Senate Committee on Environment and Public Works
Subcommittee on Chemical Safety, Waste Management, Environmental Justice, and
Regulatory Oversight
Hearing Entitled “Understanding the Potential Environmental Impacts of the Chemical
6PPD”
July 31, 2024
Questions for the Record for Tracey Norberg

Ex-Officio Ranking Member Capito:

1. What was used before 6PPD to prevent oxidation of a tire?

6PPD is used in tires as an antidegradant, protecting the components of the tire from attack by ozone, oxygen, thermal degradation, mechanical fatigue, etc. Without 6PPD, tires would quickly develop cracks and fractures as the rubber compounds were degraded. The antidegradant function of 6PPD in tires is therefore essential to their safe use, and elimination of 6PPD without an available and suitable replacement is not an option.

The adoption of the use of 6PPD in tires was a gradual process. The effects of ozone on tires were not fully recognized until the 1950s. Wax was used to provide protection to tires stored in warehouses, but it was not effective once a tire was put into service. The first large scale commercial antiozonant was ethoxyquin, which provided some protection against ozone, but presented other technical challenges.

Research on the PPD family of materials began in the 1950s. The first PPDs developed were active antiozonants, but they were not as effective as 6PPD and did not provide protection of rubber compounds for more than one and a half years. Tire manufacturers began using 6PPD in tire manufacturing in the mid 1960’s and early 1970’s. By 1975, 6PPD comprised 60% of the antiozonant used in tires.

a. How long did those tires last versus tires today?

Just as the adoption of 6PPD in tires was a gradual process, improving tire life has likewise been a gradual process. In general terms, before the adoption of 6PPD in tires, a tire would last about a third as long as modern tires. Introduction of 6PPD in tires was a large factor, but not the only one contributing to improved tire life. Innovations in all aspects of tire design, engineering and construction have played roles in increasing tire life.

2. What would happen if 6PPD was banned for use in tires today?

USTMA member companies would never produce a tire that did not meet federal performance requirements or customer needs. However, theoretically, a tire without an effective antioxidant/antiozonant would be prone to catastrophic failure during use and would last only a fraction of their current lifespans. Additionally, a tire containing an antioxidant/antiozonant that is not sufficiently tested could have other environmental and/or performance impacts that are not well understood.

The U.S. generates 275 million scrap tires every year and only about 71% of those are consumed in beneficial end-use markets; if our annual generation was doubled or tripled (or worse), it would lead to a significant waste management crisis.

In 1990, there were more than a billion end-of-life tires in stockpiles across the country. Today, that number is closer to 50 million – a 95% reduction – and our industry is currently working with stakeholders at the state and federal levels to continue this progress, toward our end goal of 100% of tires being recycled in circular and sustainable markets.

Tire stockpiles present myriad risks including fires, and mosquito breeding grounds.

a. How would your members react?

We appreciate the recognition by state and federal regulators of the importance 6PPD to tire safety and performance and the great care that must be taken in identifying and validating an alternative to 6PPD. USTMA members would never sell tires that do not meet federal motor vehicle safety standards or customer needs.

A premature ban would not accelerate the development of a viable alternative to 6PPD in tires. USTMA is leading a 6PPD Alternatives Analysis Consortium to evaluate potential alternatives to 6PPD in tires pursuant to California Department of Toxic Substances Control's (DTSC's) Safer Consumer Products regulations (SCRR). In addition, USTMA has established a 6PPD Platform to facilitate the development as quickly and efficiently as possible of one or more candidate alternatives to 6PPD that ensures the safety of motorists and considers potential environmental and societal effects of the possible alternatives.

3. What role, if any, does the federal government have to assist in this issue?

Invest in direct industry-led basic research and interagency coordination. *In 2023, USDA Agricultural Research Service entered into a cooperative agreement with the only U.S. manufacturer of 6PPD to begin a collaborative process toward identifying an alternative. Congress must make additional resources available to support this important basic research and allow for greater interagency coordination towards identifying an alternative.*

Support and fund USGS Environmental Health Program Ecosystems Mission Area research. *The Survey's comprehensive research on 6PPD and 6PPDQ, including its innovative approach assessing alternatives through cell line research, is critical to the development of a suitable alternative to 6PPD in tires.*

Encourage EPA to establish toxicity requirements for a 6PPD replacement. *Coho salmon is not and was not included in any EPA toxicology testing requirements for 6PPD, nor was there a testing structure for the quinone. EPA can help the process by establishing toxicology requirements for a replacement chemical including potential environmental derivatives.*

Help EPA Prioritize and Improve the TSCA New Chemical Review Process. *Most new chemicals under review at EPA are languishing. Congress can help EPA prioritize chemicals for which federal action is needed and provide adequate funding to ensure a timely and thorough review process.*

Invest in stormwater mitigation projects. Stormwater mitigation projects should be implemented now to address issues related to stormwater runoff. Federal funding would enhance the breadth and effectiveness of these projects. These projects offer significant opportunities for substantial co-benefits, including mitigation of motor oil, paints, antifreeze, washer fluid, asphalt, concrete, galvanizing agents, and other contaminants in stormwater.

Senator MERKLEY. Thank you very much.

Both of you have submitted longer versions of testimony, and if there is no objection, we will submit the longer version for the record. You are kind of amazing us up here, you are completing exactly under the 5-minutes allocated. Really well presented.

Mr. Fischer, let's turn to you.

STATEMENT OF DAVID B. FISCHER, MPH, COUNSEL, KELLER AND HECKMAN LLP

Mr. FISCHER. Thank you. Good afternoon, Chairman Merkley, Ranking Member Mullin, and members of the subcommittee. Thank you for the opportunity to participate in today's hearing on 6PPD.

My name is David Fischer, and I am counsel at the law firm of Keller and Heckman where I help clients navigate the Toxic Substances Control Act (TSCA). Prior to joining Keller and Heckman, I had the great privilege of serving as the Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention at EPA.

Today's hearing on 6PPD, its environmental impacts, and ongoing research into potential alternatives prompts a discussion of EPA's New Chemicals Program and Section 5 of TSCA, which governs the review of new chemicals and new chemical uses. After all, a 6PPD alternative will need to undergo substantive review by EPA's New Chemicals Division before it can be used in tires or other applications.

We all know this, but it is worth repeating, that nothing is possible without chemistry. But innovation in the U.S. relies on a wholly functioning and efficient New Chemicals Division. Under the 2016 revisions to TSCA, Congress gave clear direction to the EPA on the timeline in which to complete new chemical reviews. EPA has 90 to 180 days to render a determination regarding the new chemical substance's effect on human health and/or the environment. But until EPA makes such a determination, however long that may take, the submitter is in limbo and cannot commercially manufacture the chemical.

Unfortunately, chemical reviews now take many months, if not years. If the ultimate goal is for industry to find a replacement for 6PPD, then we should all be concerned with a potential replacement getting held up in regulatory limbo at EPA. This is why EPA needs to amend its New Chemical regulations.

Unfortunately, in proposing regulatory changes last year, EPA missed an opportunity for real change. EPA's final regulations to be issued later this year may yet reflect the concrete suggestions made by me and others during the public comment period.

Today's hearing also prompts a closer look at the TSCA Section 21 petition process, which Earth Justice relied on in seeking a Section 6 rule to prohibit the use of 6PPD in tires.

EPA acknowledged that petitioners have the burden to show why a rule for 6PPD is necessary, but then EPA considered other available information that it did not present in granting the petition. Moreover, EPA granted the petition and plans to initiate rule-making this fall, even though EPA plans to collect data to inform

a human health risk assessment on 6PPD-Q and may issue Section 4 test orders to require the development of new information.

The petition process as currently implemented by EPA stands in stark contrast to the Section 6 prioritization, risk evaluation, and risk management paradigm for existing chemicals. Although EPA must seek public comment for any rule issued pursuant to Section 21, EPA does not need to request either public comment or scientific peer review on a Section 21 petition itself or on EPA's basis for granting the petition.

With respect to 6PPD, EPA appears to have granted the petition with respect to a single condition of use: 6PPD's use in tires. For Section 6 risk evaluations, however, EPA recently changed its regulations to mandate a whole chemical approach in which EPA reviews all conditions of use for a chemical and renders a single unreasonable risk determination for the whole chemical, rather than for any condition of use.

My fear is that Section 21 is fast becoming an end-run around Section 6, especially at a time when EPA's refrain is a plea for more funds to implement Section 5 and Section 6. By granting Section 21 petitions, EPA diverts resources away from its statutory obligations under Sections 5 and 6.

EPA does not collect fees from Section 21 petitioners, but it does collect these fees from new chemical submissions and Section 6 risk evaluations. It may be that Congress will need to further amend TSCA to address these and other ongoing challenges with TSCA implementation, but those are likely topics for future hearings.

I thank you for the opportunity and look forward to your questions.

[The prepared statement of Mr. Fischer follows:]

Testimony for the Record

Submitted to the

Senate Committee on Environment & Public Works

**Subcommittee on Chemical Safety, Waste Management, Environmental Justice, and
Regulatory Oversight**

For the hearing to examine the potential environmental impacts of 6PPD

**David B. Fischer, M.P.H., J.D.
Counsel, Keller & Heckman, LLP**

July 31, 2024

Chairman Merkley, Ranking Member Mullin and Members of the Subcommittee, thank you for inviting me to participate in today's hearing on 6PPD.

My name is David Fischer, and I am Counsel with the law firm Keller & Heckman, LLP where I work with chemical industry clients on environmental, policy, and health and safety matters, with a concentration on the Toxic Substances Control Act (TSCA). Prior to joining Keller and Heckman, I had the great privilege of serving as the Deputy Assistant Administrator (DAA) for EPA's Office of Chemical Safety and Pollution Prevention. During my tenure as DAA, I was deeply involved in TSCA implementation. I have also held senior-level positions at the American Chemistry Council (ACC), including co-managing ACC's Chemical Products and Technology Division, where I led the implementation of the 2016 amendments to TSCA.

Today's hearing on 6PPD, its environmental impacts, and ongoing research into potential alternatives, prompts a discussion of EPA's new chemicals program and section 5 of TSCA, which governs the review of new chemicals and new chemical uses. After all, a 6PPD alternative will need to undergo substantive review by EPA's New Chemicals Division before it can be used in tires or other applications.

We all know this, but it is worth repeating - nothing is possible without chemistry. And the nearly infinite permutations of chemicals help drive innovation, including the development of chemicals in vehicle tires. But innovation in the U.S. necessarily relies on a wholly functioning and efficient New Chemicals Division.

TSCA section 5 requires any company planning to manufacture (including import) a new chemical substance for a commercial purpose to submit a premanufacture notice (PMN) to EPA for approval. EPA has 90-180 days thereafter to review the PMN and determine the new chemical substance's effects on human health and/or the environment. Prior to the 2016 TSCA amendments, if EPA did not act on the PMN submission prior to the expiration of 90 days, then the submitter could commence commercial manufacturing of that chemical. All that changed in 2016.

The TSCA amendments now require an affirmative determination by EPA. Section 5(a)(3) sets forth five possible determinations:

1. The chemical or significant new use presents an unreasonable risk of injury to health or the environment;
2. Available information is insufficient to allow the Agency to make a reasoned evaluation of the health and environmental effects associated with the chemical or significant new use;
3. In the absence of sufficient information, the chemical or significant new use may present an unreasonable risk of injury to health or the environment;
4. The chemical is or will be produced in substantial quantities and either enters or may enter the environment in substantial quantities or there is or may be significant or substantial exposure to the chemical; or
5. The chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment.

And unless EPA makes one of these determinations, however long that may take, the submitter is in limbo and cannot commercially manufacture the chemical.

But even beyond this new affirmative determination requirement, the manner in which EPA conducts new chemical reviews has made 90 days or even 180 days, a distant memory. Reviews now take many months, sometimes over a year or more. As a result, some manufacturers have opted to abandon the U.S. marketplace by not filing PMNs. Other manufacturers are increasingly relying on exemptions, such as the low-volume exemption, but processing these exemptions also exceeds EPA's review timelines.

EPA recognizes the current challenges facing the New Chemicals Division and has taken noteworthy programmatic steps to streamline the new chemical review process for at least some categories of new chemical notices, including biofuel PMNs and mixed metal oxide PMNs.

But absent significant changes to the regulations themselves to facilitate an efficient process to review all new chemical substances, companies will continue to face avoidable roadblocks and delays in bringing new, innovative, and sustainable chemistries to the marketplace.

In November 2022, I submitted a petition for rulemaking that included numerous regulatory changes aimed at addressing the ongoing, unduly time-consuming process by which EPA reviews PMNs. Some of the changes reflected in Appendix A include the following:

- Require EPA to conduct reviews of PMNs in a fit for purpose manner, in which the review is commensurate with the specific circumstances applicable to the new chemical substance, and to conduct reviews consistent with the risk characterization TCCR principles of transparency, clarity, consistency, and reasonableness as described in EPA's Risk Characterization Handbook, December, 2000;

- Require EPA to generally grant pre-submission meetings requested by the submitter. EPA shall address issues raised by the submitter no later than five business days after such meeting;
- Limit the amount of time EPA may extend the notice review period, require EPA to reimburse the submitter 50% of the notice fee if the review period extension does not fall under the good cause exemption, reset the review period if the submitter substantially amends the original PMN submission, and allow a submitter to extend the suspension period for more than 90 days only for good cause;
- Require EPA to rely on the data provided by the submitter unless EPA can demonstrate that such data does not represent the best available science;
- Place greater emphasis on the Central Data Exchange (CDX) to allow for more accessible and efficient communication between PMN submitters and EPA;
- Require EPA to review new chemical submissions in the order in which they are submitted to EPA, unless the submission qualifies for expedited review as described in Appendix A;
- Require EPA to provide a brief written statement identifying the basis for each determination, including the identification of foreseeable uses that were the basis for any determination under proposed §720.60(c)(i) or (iii);
- When evaluating unreasonable risk, require EPA to reach a determination based on certain probabilities, ensure that EPA does not render unreasonable risk determinations based on the worst-case scenarios involving unreasonable assumptions, and provide EPA with alternative options to section 5(e) Orders;
- Require EPA to notify a submitter of errors in the notice or that the submission is incomplete within 15 days of receipt;
- Describe what constitutes a major amendment to a PMN and present options for the submitter to take if EPA designates the amendment as "major;" and
- Provide the PMN submitter with the option to administratively appeal a risk determination, which shall be reviewed de novo by three EPA senior scientists within 60 days of receipt and determined by a simple majority vote.

Unfortunately, when EPA did propose changes to the regulations on May 26, 2023, they were geared more to ensure that the regulations comported with the 2016 TSCA amendments and failed to include any of the substantive changes that were included in our petition. EPA plans to finalize the regulations later this year, so EPA may yet incorporate at least some of these recommended changes.

Today's hearing also prompts comments on the TSCA section 21 petition process, which Earthjustice relied on in seeking a TSCA section 6 rule to prohibit the use of 6PPD in tires. In its response granting the petition, EPA reviewed the petition to determine "whether petitioners have established that it is 'necessary' to initiate a proceeding for a rule under TSCA section 6.

Notwithstanding that the burden is on the petitioners to present ‘the facts which it is claimed establish that it is necessary’ for the EPA to initiate the proceeding sought, the EPA in its discretion also considered relevant information that was reasonably available to the agency during the 90-day petition review period.”¹

It is unclear what this relevant information is because EPA does not furnish that information in its response. Moreover, EPA granted the petition and plans to initiate rulemaking this fall, even though EPA also plans to collect data to inform a human health risk assessment on 6PPD-q, and may issue section 4 test orders to require the development of new information.

The petition process as currently implemented by EPA stands in stark contrast to the section 6 prioritization, risk evaluation, and risk management paradigm for existing chemicals. Although EPA must seek public comment for any rule issued pursuant to section 21, EPA does not need to request either public comment or scientific peer review on a section 21 petition itself or on EPA’s basis for granting the petition.

And with respect to 6PPD, EPA appears to have granted the petition with respect to a single condition of use, 6PPD’s use in tires. For section 6 risk evaluations, however, EPA recently changed its regulations to mandate a whole chemical approach in which EPA reviews all conditions of use (COU) and exposures of a chemical and renders a single unreasonable risk determination for the whole chemical, rather than for any COU.

My fear is that section 21 is fast becoming an end run around section 6, especially at a time when EPA’s refrain is a plea for more funds to implement sections 5 and 6. It may be that Congress will need to further amend TSCA to address this issue, and to provide greater flexibility to EPA within section 6 to more nimbly address concerns like those identified for 6PPD. I believe other changes to TSCA will be needed as well, but that is a topic for future hearings of this subcommittee.

¹ See EPA’s response to the petition at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#6ppd%20in%20tires>.

APPENDIX A**PART 720—PREMANUFACTURE NOTIFICATION****Contents****Subpart A—General Provisions**

- §720.1 Scope.
§720.3 Definitions.

Subpart B—Applicability

- §720.22 Persons who must report.
§720.25 Determining whether a chemical substance is on the Inventory.
§720.30 Chemicals not subject to notification requirements.
§720.36 Exemption for research and development.
§720.38 Exemptions for test marketing.

Subpart C—Notice Form

- §720.40 General.
§720.45 Information that must be included in the notice form.
§720.50 Submission of test data and other data concerning the health and environmental effects of a substance.
§720.57 Imports.

Subpart D—Disposition of Notices

- §720.60 General.
§720.61 Actions on Determinations.
§720.62 Notice that notification is not required.
§720.65 Acknowledgement of receipt of a notice; errors in the notice; incomplete submissions; and false and misleading statements.
§720.70 Notice in the Federal Register.
§720.75 Notice review period.
§720.76 Major amendments to Notices.
§720.77 Pre and post submission meetings.
§720.78 Recordkeeping.
§720.79 Administrative Appeal.

Subpart E—Confidentiality and Public Access to Information

- §720.80 General provisions.
§720.85 Chemical identity.
§720.87 Categories or proposed categories of uses of a new chemical substance.
§720.90 Data from health and safety studies.
§720.95 Public file.

Subpart F—Commencement of Manufacture or Import

- §720.102 Notice of commencement of manufacture or import.

Subpart G—Compliance and Inspections

§720.120 Compliance.

§720.122 Inspections.

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

SOURCE: 48 FR 21742, May 13, 1983, unless otherwise noted.

Subpart A—General Provisions**§720.1 Scope.**

This part establishes procedures for the reporting of new chemical substances by manufacturers and importers under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604. This part applies to microorganisms only to the extent provided by part 725 of this chapter. The rule defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices. The rule also establishes EPA policy regarding claims of confidentiality for, and public disclosure of, various categories of information submitted in connection with section 5 notices. In carrying out this part, EPA decisions based on science shall adhere to the scientific standards and weight of scientific evidence approach of TSCA sections 26(h) and (i), respectively.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 62 FR 17932, Apr. 11, 1997]

§720.3 Definitions.

(a)(1) For the purposes of this part, the terms *cosmetic*, *device*, *drug*, *food*, and *food additive* have the meanings contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, and the regulations issued under it. In addition, the term "food" includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 *et seq.*; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 *et seq.*; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 *et seq.*

(2) The term *pesticide* has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.* and the regulations issued under it.

(3) The terms *byproduct material*, *source material*, and *special nuclear material* have the meanings contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 *et seq.* and the regulations issued under it.

(b) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(c) *Article* means a manufactured item:

(1) Which is formed to a specific shape or design during manufacture;

(2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and

(3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as

Commented [A1]: This new language reflects the science standards of amended TSCA section 26.

described in §720.30(h)(5), except that fluids and particles are not considered articles regardless of shape or design.

(d) *Byproduct* means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

(e) *Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical, except that "chemical substance" does not include:

- (1) Any mixture.
- (2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide.
- (3) Tobacco or any tobacco product.
- (4) Any source material, special nuclear material, or byproduct material.
- (5) Any pistol, firearm, revolver, shells, or cartridges.
- (6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

(f) *Commerce* means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

(g) *Customs territory of the United States* means the 50 States, Puerto Rico, and the District of Columbia.

(h) *Director* means the Director of the EPA Office of Pollution Prevention and Toxics.

(i) *Distribute in commerce* means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after introduction into commerce.

(j) *EPA* means the U.S. Environmental Protection Agency.

(k) *Health and safety study or study* means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological, or other studies of a chemical substance or mixture, and any test performed under the Act. Chemical identity is always part of a health and safety study.

(l) Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included.

(2) Examples include:

(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatotoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; acute, subchronic, and chronic effects; and structure/activity analyses.

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: Acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies of: Biological, photochemical, and chemical degradation; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

(v) Any assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance.

(l) *Importer* means any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. "Importer" includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate:

(1) The consignee.

(2) The importer of record.

(3) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20, or

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR part 144. (See "principal importer.")

(m) *Impurity* means a chemical substance which is unintentionally present with another chemical substance.

(n) *Intermediate* means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

(o) *Inventory* means the list of chemical substances manufactured or processed in the United States that EPA compiled and keeps current under section 8(b) of the Act.

(p) *Known to or reasonably ascertainable by* means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

(q) *Manufacture* means to produce or manufacture in the United States or import into the customs territory of the United States.

(r) *Manufacture or import for commercial purposes* means:

(1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer or importer, and includes, among other things, "manufacture" of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development or as an intermediate.

(2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes. [\(See §720.30\(x\) and \(h\)\).](#)

(s) *Manufacture solely for export* means to manufacture or import for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

(1) Distribution in commerce is limited to purposes of export or processing solely for export as defined in §721.3 of this chapter.

(2) The manufacturer or importer, and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in §721.3 of this chapter), may not use the substance except in small quantities solely for research and development in accordance with §720.36.

(t) *Manufacturer* means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance. A person who contracts with a manufacturer to manufacture or produce a chemical substance is also a manufacturer if (1) the manufacturer manufactures or produces the substance exclusively for that person, and (2) that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

(u) *Mixture* means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except "mixture" does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical

Commented [A2]: This reference links to the section that addresses the circumstances in which chemicals (including byproducts and impurities) are not subject of TSCA notification requirements.

substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

(v) *New chemical substance* means any chemical substance which is not included on the Inventory.

(w) *Nonisolated intermediate* means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

(x) *Person* means any natural person, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency or instrumentality of the Federal Government.

(y) *Possession or control* means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner). Information is included within this definition if it is:

(1) In files maintained by submitter's employees who are:

(i) Associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

(ii) Reasonably likely to have such data.

(2) Maintained in the files of other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question in the course of their employment as such agents.

(z) *Principal importer* means the first importer who, knowing that a new chemical substance will be imported rather than manufactured domestically, specifies the identity of the chemical substance and the total amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

(aa) *Process* means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

(bb) *Processor* means any person who processes a chemical substance or mixture.

(cc) *Small quantities solely for research and development* (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

(dd) *State* means any State of the United States and the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

(ee) *Technically qualified individual* means a person or persons (1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

(ff) *Test data* means data from a formal or informal test or experiment, including information concerning the objectives, experimental methods and materials, protocols, results, data analyses, recorded observations, monitoring data, measurements, and conclusions from a test or experiment.

(gg) *Test marketing* means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

(hh) *United States*, when used in the geographic sense, means all of the States.

(ii) *Central Data Exchange or CDX* means EPA's centralized electronic document receiving system, or its successors.

(jj) *e-PMN software* means electronic-PMN software created by EPA for use in preparing and submitting Premanufacture Notices (PMNs) and other TSCA section 5 notices and support documents electronically to the Agency.

(kk) *Support documents* means material and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to, correspondence, amendments (if notices for these amendments were submitted prior to January 19, 2016), and test data. The term "support documents" does not include orders under TSCA section 5(e) (either consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)).

(ll) *Conditions of Use* means the circumstances, as determined by EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(mm) *Reasonably Foreseen Conditions of Use* means the circumstances, not intended by the submitter, under which a reasonably knowledgeable person likely to manufacture, process, use or dispose

Commented [A3]: This new definition provides boundaries as to what conditions of use are reasonably foreseen.

of the new chemical substance, and exercising good judgment, would be expected to manufacture, process, distribute in commerce or dispose of the new chemical substance. This term does not include any misuse. Uses that are uneconomic, technically impracticable, or present obvious risks are not reasonably foreseeable uses. The factual basis for any determination of a Reasonably Foreseen Conditions of Use shall be reflected in EPA's determination.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15101, Apr. 22, 1986; 75 FR 784, Jan. 6, 2010; 80 FR 42745, July 20, 2015]

Subpart B—Applicability

§720.22 Persons who must report.

(a)(1) Any person who intends to manufacture a new chemical substance in the United States for commercial purposes must submit a notice at least 90 days before manufacture or import unless the substance is excluded under §720.30.

(2) If a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process, that person must submit the notice. If it is unclear who must report, EPA should be contacted to determine who must submit the notice.

(3) Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a notice.

(b)(1) Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under §720.30 or unless the substance is imported as part of an article.

(2) When several persons are involved in an import transaction, the notice must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the notice for that transaction.

§720.25 Determining whether a chemical substance is on the Inventory.

(a) A new chemical substance is any chemical substance that is not currently listed on the Inventory.

(b)(1) A chemical substance is listed in the public portion of the Inventory by a specific chemical name (either a Chemical Abstracts (CA) Index Name or a CA Preferred Name) and a Chemical Abstracts Service (CAS) Registry Number if its identity is not confidential. If its identity is confidential, it is listed in the public portion of the Inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity. The confidential substance is listed by its specific chemical name only in the confidential portion of the Inventory, which is not available to the public. A person who intends to manufacture (including import) a chemical substance not listed by specific chemical name in the public portion of the Inventory may ask EPA whether the substance is included in the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture (including import) the chemical substance for commercial purposes.

Commented [A4]: These new definitions reflect amended TSCA.

Commented [A5]: This addition reflects amended TSCA section 5(a)(1)(B)(i).

(2) To establish a *bona fide* intent to manufacture (including import) a chemical substance, the person who proposes to manufacture the substance must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such *bona fide* intents to manufacture (including import) must be generated and completed using e-PMN software. See §720.40(a)(2)(ii) for information on how to access the e-PMN software. A *bona fide* intent to manufacture (including import) must contain:

(i) Except as provided in paragraphs (b)(3)(i) and (ii) of this section, the specific chemical identity of the substance that the person intends to manufacture (including import), using the currently correct CA Index name for the substance and the other correct chemical identity information in accordance with §720.45(a) (1), (2), and (3).

(ii) A signed statement that the person intends to manufacture (including import) that chemical substance for commercial purposes.

(iii)(A) A brief description of the research and development activities conducted to date related to the substance, including the year in which the person first started to conduct research or development activity on the substance, and the general types of research and development activities conducted thus far (e.g., synthesis, substance isolation/purification, formulating, product development, process development, end-use application, toxicity testing, etc.). The person must also indicate whether any pilot plant or production-scale plant evaluations have been conducted involving the manufacture or processing of the substance.

(B) If an importer is unable to provide the information requested in paragraph (b)(2)(iii)(A) of this section from the foreign manufacturer or supplier, the following information shall be submitted:

(1) A brief statement indicating how long the substance has been in commercial use outside of the United States.

(2) The name of a country in which it has been commercially used.

(3) Whether the importer believes that the substance has already been used commercially, in any country, for the same purpose or application that the importer is intending.

(iv) A specific description of the major intended application or use of the substance.

(v) An infrared spectrum of the substance, or alternative spectra or other data which identify the substance if infrared analysis is not suitable for the substance or does not yield a reasonable amount of structural information. When using alternative spectra or instrumental analysis, the person must submit a spectrum or instrumental readout for the substance.

(vi) The estimated date (month/year) in which the person intends to submit a Premanufacture Notice (PMN) for this substance if EPA informs the notice submitter that the substance is not on the Inventory.

(vii) The address of the facility under the control of the submitter at which the manufacture or processing of the substance would most likely occur. For an imported substance, the facility under the control of the importer at which processing of the substance would likely occur, if any.

(viii)(A) For substances intended to be manufactured in the United States, a description of the most probable manufacturing process that would be used by the submitter to produce the substance for non-exempt commercial purposes.

(B) For substances intended to be imported, a brief description of how the submitter is most likely to process or use the substance for a commercial purpose. If the substance is not expected to be processed or used at any facility under the importer's control, a statement to this effect must be included along with a description of how the substance will be processed or used at sites controlled by others, if this information is known or reasonably ascertainable.

(3)(i) If an importer cannot provide the chemical identity information required by paragraph (b)(2)(i) and (v) of this section because it is claimed confidential by its foreign manufacturer or supplier, the foreign manufacturer or supplier must supply the required information directly to EPA in accordance with §720.45(a)(1), (2), and (3) and reference the importer's notice. If the appropriate supporting document from the foreign party is not received within 30 days after EPA receives the importer's notice, the notice will be considered incomplete.

(ii) If a manufacturer cannot provide all of the required information in accordance with §720.45(a)(1), (2), and (3) because the new chemical substance is manufactured using a reactant that has a specific chemical identity claimed as confidential by its supplier, the notice must contain chemical identity information that is as complete as known by the manufacturer. In addition, a letter of support for the notice must then be sent to EPA by the chemical supplier of the confidential reactant, providing the specific chemical identity of the proprietary reactant. The letter of support must reference the manufacturer's notice. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the manufacturer's notice, the notice will be considered incomplete.

(4) EPA will review the information submitted by the proposed manufacturer (including importer) under this paragraph to determine whether it has a *bona fide* intent to manufacture (including import) the chemical substance. If necessary, EPA will compare this information to the information requested for the confidential chemical substance under §720.85(b)(3)(ii).

(5) If the proposed manufacturer (including importer) has shown a *bona fide* intent to manufacture (including import) the substance, and has provided sufficient unambiguous chemical identity information so EPA can make a conclusive determination of the chemical substance's inventory status, EPA will search the confidential inventory and inform the proposed manufacturer (including importer) whether the chemical substance is on the confidential inventory.

(6) If the chemical substance is found on the confidential inventory, EPA will notify the person(s) who originally reported the chemical substance that another person has demonstrated a *bona fide* intent to manufacture (including import) the substance and therefore was told that the chemical substance is on the inventory.

(7) A disclosure of a confidential chemical identity to a person with a *bona fide* intent to manufacture (including import) the particular chemical substance will not be considered a public disclosure of confidential business information under section 14 of the Act.

(8) EPA will answer an inquiry on whether a particular chemical substance is on the confidential inventory within 30 days after receipt of a complete submission under paragraph (b)(2) of this section.

(9) If the required chemical identity information has not been reported correctly or completely in the notice (except as provided under paragraph (b)(3)(ii) of this section) or if any other required data or information has been omitted or is incomplete, EPA will consider the whole notice to be incomplete. As soon as an incomplete notice is identified as such by EPA, the Agency will immediately return the notice

directly to the submitter. The submitter must then resubmit the whole, completed *bona fide* notice to EPA in order to have the Agency perform the desired Inventory search and respond to the notice.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 60 FR 16309, Mar. 29, 1995; 80 FR 42745, July 20, 2015]

§720.30 Chemicals not subject to notification requirements.

The following substances are not subject to the notification requirements of this part:

(a) Any substance which is not a "chemical substance" as defined in §720.3(e).

(b) Any mixture as defined in §720.3(u).¹

¹A new chemical substance that is manufactured or imported as part of a mixture is subject to the requirements of this part. This exclusion applies only to a mixture as a whole and not to any chemical substances which are part of the mixture.

(c) Any new chemical substance which will be manufactured or imported in small quantities solely for research and development under §720.36.

(d) Any new chemical substance which will be manufactured or imported solely for test-marketing purposes under an exemption granted under §720.38.

(e) Any new chemical substance manufactured solely for export if, when the substance is distributed in commerce:

(1) The substance is labeled in accordance with section 12(a)(1)(B) of the Act.

(2) The manufacturer knows that the person to whom the substance is being distributed intends to export it or process it solely for export as defined in §721.3 of this chapter.

(f) Any new chemical substance which is manufactured or imported under the terms of a rule promulgated under section 5(h)(4) of the Act.

(g) Any byproduct if its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)

(h) The chemical substances described below: (Although they are manufactured for commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.)

(1) Any impurity.

(2) Any byproduct which is not used for commercial purposes.

(3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(4) Any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate.

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.

(7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (ii) a chemical substance, which is intended solely to impart a specific physiochemical characteristic, functions as intended.

(8) Any nonisolated intermediate.

(i) Any chemical substance which is manufactured solely for non-commercial research and development purposes. Non-commercial research and development purposes include scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research organizations (e.g., universities, colleges, teaching hospitals, and research institutes), unless the activity is for eventual commercial purposes.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15101, Apr. 22, 1986]

§720.36 Exemption for research and development.

(a) This part does not apply to a chemical substance if the following conditions are met:

(1) The chemical substance is manufactured or imported only in small quantities solely for research and development.

(2) The manufacturer or importer notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer or importer must review and evaluate the following information to determine whether there is reason to believe there is any potential risk to health which may be associated with the chemical substance:

(i) Information in its possession or control concerning any significant adverse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer or importer by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under sections 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer or importer has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph, a laboratory is a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.)

(c)(1) The manufacturer or importer must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer or importer has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer or importer distributes a chemical substance manufactured or imported under this section to persons not in its employ, the manufacturer or importer must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer or importer.

(d) A chemical substance is not exempt from reporting under this part if any amount of the substance, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development, except where the chemical substance is processed, distributed in commerce, or used only as an impurity or as part of an article.

(e) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, state, and local regulations, or

(2) Used for the following commercial purposes:

(i) Burning it as a fuel.

(ii) Reacting or otherwise processing it to form other chemical substances for commercial purposes, including extracting component chemical substances.

(f) Quantities of research and development substances existing solely as impurities in a product or incorporated into an article, in accordance with paragraph (d) of this section, and quantities of research and development substances used solely for commercial purposes listed in paragraph (e) of this section, are not subject to the requirements of paragraphs (a), (b), and (c) of this section, once research and development activities have been completed.

(g) A person who manufactures or imports a chemical substance in small quantities solely for research and development is not required to comply with the requirements of this section if the person's exclusive intention is to perform research and development activities solely for the purpose of determining whether the substance can be used as a pesticide.

[51 FR 15102, Apr. 22, 1986]

§720.38 Exemptions for test marketing

(a) Any person may apply for an exemption to manufacture or import a new chemical substance for test marketing. EPA may grant the exemption if the person demonstrates that the chemical substance will not present an unreasonable risk to injury to health or the environment as a result of the test marketing.

(b) Persons applying for a test-marketing exemption should provide the following information:

(1) All existing data regarding health and environmental effects of the chemical substance, including physical/chemical properties or, in the absence of such data, a discussion of toxicity based on structure-activity relationships (SAR) and relevant data on chemical analogues.

(2) The maximum quantity of the chemical substance which the applicant will manufacture or import for test marketing.

(3) The maximum number of persons who may be provided the chemical substance during test marketing.

(4) The maximum number of persons who may be exposed to the chemical substance as a result of test marketing, including information regarding duration and route of such exposures.

(5) A description of the test-marketing activity, including its length and how it can be distinguished from full-scale commercial production and research and development.

(6) A fee payment identity number, as required in 40 CFR 700.45(g)(4).

(c) In accordance with section 5(h)(6) of the Act, after EPA receives an application for exemption under this section, the Agency will file with the Office of the Federal Register a notice containing a summary of the information provided in the application, to the extent it has not been claimed confidential.

(d) No later than 45 days after EPA receives an application, the Agency will either approve or deny the application. Thereafter, EPA will publish a notice in the FEDERAL REGISTER explaining the reasons for approval or denial.

(e) In approving an application for exemption, EPA may impose any restrictions necessary to ensure that the substance will not present an unreasonable risk of injury to health and the environment as a result of test marketing.

(f) When applying for a test marketing exemption, persons are subject to fees in accordance with 40 CFR 700.45.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 83 FR 52719, Oct. 17, 2018]

Subpart C—Notice Form

§720.40 General.

(a) *Use of the notice form; electronic submissions.* (1) Each person who is required by subpart B of this part to submit a notice must complete, sign, and submit a notice containing the information in the form and manner specified in this paragraph. The information submitted and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) All notices must be submitted on EPA Form 7710-25. Notices, and any support documents related to these notices, may only be submitted in a manner set forth in this paragraph.

(i) *Submission via CDX.* TSCA section 5 notices and any related support documents must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710-25 using e-PMN software. The CDX shall allow for timely communication between EPA and the submitter or the submitter's designee regarding the status of the submission throughout the entire review period. Communications between the submitter and EPA should serve to advance EPA's timely review of the new chemical substance. Non-CBI information provided to the submitter via CDX shall include, but not limited to, analogs and models relied upon by EPA; the conditions of use EPA has identified are relevant to the submission; and reports or assessments developed by EPA pertaining to the submission. The submitter shall have an opportunity to provide timely feedback to EPA regarding the information provided to the submitter by EPA pertaining to the submission.

Commented [A6]: EPA Form 7710-25 should be updated to ensure that more than one individual can have access to CDX regarding the submission.

(ii) You can access the e-PMN software as follows:

(A) *Website.* Go to EPA's TSCA New Chemicals Program website at <http://www.epa.gov/oppt/newchemicals> and follow the appropriate links.

(B) *Telephone.* Call the EPA CDX Help Desk at 1-888-890-1995.

Commented [A7]: This new paragraph is aimed at ensuring that CDX is used as a vehicle for timely and efficient communication between both the submitter and EPA throughout the PMN review period.

(C) *E-mail, HelpDesk@epacdc.net.*

(b) *When to submit a notice.* Each person who is required to submit a notice must submit the notice at least 90 calendar days before manufacture or import of the new chemical substance for commercial purposes begins.

(c) *Where to submit a notice or support documents.* For submitting notices or support documents via CDX, use the e-PMN software.

(d) *General notice requirements.* (1) Each person who submits a notice must provide the information described in §720.45 and specified on the notice form, to the extent such information is known to or reasonably ascertainable by the person. In accordance with §720.50, the notice must also include any test data in the person's possession or control, and descriptions of other data which are known to or reasonably ascertainable by the person and which concern the health and environmental effects of the new chemical substance.

(2) If information is claimed as confidential pursuant to §720.80, a person who submits a notice to EPA in the manner set forth in §720.40(a)(2)(i), (ii), or (iii) must also provide EPA with a sanitized copy.

(e) *Agency or joint submissions—*(1) A manufacturer (including importer) may designate an agent to assist in submitting the notice. If so, only the manufacturer (including importer), and not the agent, signs the certification on the form.

(2) A manufacturer or importer may authorize another person, (e.g., a supplier or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. The manufacturer or importer should indicate in a cover letter accompanying the notice which information will be supplied by another person and must identify that other person as a joint submitter where indicated on their notice form. The other person supplying information (i.e., the joint submitter) may submit the information to EPA using either the notice form or a Letter of Support, except that if the joint submitter is not incorporated, licensed, or doing business in the United States, the joint submitter must submit the information to EPA in a Letter of Support only, not in a notice form. The joint submitter must indicate in the notice or Letter of Support the identity of the manufacturer or importer. Any person who submits a notice form or Letter of Support for a joint submission must sign and certify the notice form or Letter of Support.

(3) Only the Authorized Official (AO) of a submitting company can certify initial notices and submit all TSCA section 5 documents.

(i) An AO can authorize other persons to be non-certifying AOs who may conduct all section 5 business on behalf of the submitting company except for certifying and submitting initial notices to EPA via CDX.

(ii) An AO may grant access to a support registrant to edit section 5 documents.

~~(f) *New information.* During the notice review period, if the submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must submit that information via CDX per paragraph (a)(2)(i) of this section to the address listed on the notice form or via CDX within ten days of receiving the new information, but no later than five days before the end of the notice review period. The new submission must clearly identify the submitter and the notice to which the new information is related. If the new information becomes available during the last five days of the notice review period, the submitter must~~

Commented [A8]: This paragraph has been moved to section 720.50 regarding disposition of notices.

~~immediately inform its EPA contact for that notice by telephone and or via CDX per paragraph (2)(a) of this section.~~

(g) *Chemical substances subject to a section 4 test rule.* (1) Except as provided in paragraph (g)(3) of this section, if (i) A person intends to manufacture or import a new chemical substance which is subject to the notification requirements of this part, and (ii) The chemical substance is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with §720.50. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in §720.65.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the submitter may not submit a notice until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

- (i) The name, title, and address of the person who submitted the test data to EPA.
- (ii) The date the test data were submitted to EPA.
- (iii) A citation for the test rule.
- (iv) A description of the exemption and a reference identifying it.

(h) *Chemical substances subject to a section 5(b)(4) rule.* (1) If a person (i) intends to manufacture or import a new chemical substance which is subject to the notification requirements of this part and which is subject to a rule issued under section 5(b)(4) of the Act; and (ii) is not required by a rule issued under section 4 of the Act to submit test data for the substance before the submission of a notice, the person must submit to EPA data described in paragraph (h)(2) of this section at the time the notice is submitted.

(2) Data submitted under paragraph (h)(1) of this section must be data which the person submitting the notice believes show that the manufacture, processing, distribution in commerce, use and disposal of the substance, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 60 FR 16309, Mar. 29, 1995; 75 FR 784, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013; 80 FR 42746, July 20, 2015]

§720.45 Information that must be included in the notice form.

Each person who submits a notice must include the information specified in the notice form to the extent it is known to or reasonably ascertainable by the submitter. However, no person is required to include information which relates solely to exposure of human or ecological populations outside of the United States. The notice form requires the following information relating to the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance:

(a)(1) The specific chemical identity of the substance that the person intends to manufacture or import, which includes the following:

(i) The currently correct Chemical Abstracts (CA) name for the substance, based on the Ninth Collective Index (9CI) of CA nomenclature rules and conventions, and consistent with listings for similar substances in the Inventory. For each substance having a chemical composition that can be represented by a specific, complete chemical structure diagram (a Class 1 substance), a CA Index Name must be provided. For each chemical substance that cannot be fully represented by a complete, specific chemical structure diagram (a Class 2 substance), or if the substance is a polymer, a CA Index Name or CA Preferred Name must be provided (whichever is appropriate based on CA 9CI nomenclature rules and conventions). In addition, for a Class 2 substance, the notice must identify the immediate chemical precursors and reactants by specific chemical name and Chemical Abstracts Service Registry Number (CASRN), if the number is available. Tradenames or generic names of chemical precursors or reactants are not acceptable as substitutes for specific chemical names.

(ii) The currently correct CASRN for the substance if a CASRN already exists for the substance.

(iii) For a Class 1 substance and for any Class 2 substance for which a definite molecular formula is known or reasonably ascertainable, the correct molecular formula.

(iv) For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

(2) For a polymer, the submitter must also report the following:

(i) The specific chemical name and CASRN, if the number is available, of each monomer and other reactant used, at any weight percent, to manufacture the polymer. Tradenames or generic names of chemical reactants or monomers are not acceptable as substitutes for specific chemical names.

(ii) The typical percent by weight of each monomer and other reactant in the polymer (weight of the monomer or other reactant expressed as a percentage of the weight of the polymeric chemical substance manufactured), and the maximum residual amount of each monomer present in the polymer.

(iii) For monomers and other reactants used at 2 weight percent or less (based on the dry weight of the polymer manufactured), indicate on the PMN form any such monomers and other reactants that should be included as part of the polymer description on the Inventory, where the weight percent is based on either (A) the weight of monomer or other reactant actually charged to the reaction vessel, or (B) the minimum weight of monomer or other reactant required in theory to account for the actual weight of monomer or other reactant molecules or fragments chemically incorporated (chemically combined) in the polymeric substance manufactured.

(iv) For a determination that 2 weight percent or less of a monomer or other reactant is incorporated (chemically combined) in a polymeric substance manufactured, as specified in paragraphs (a)(2)(iii)(B) of this section, analytical data or appropriate theoretical calculations (if it can be documented that analytical measurement is not feasible or not necessary) to support this determination must be maintained at the site of manufacture or import of the polymer.

(v) Measured or estimated values of the minimum number-average molecular weight of the polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight, with a description of how the measured or estimated values were obtained.

(3) The person must use one of the following two methods to develop or obtain the specified chemical identity information reported under paragraphs (a) (1) and (2) of this section and must identify the method used in the notice:

(i) *Method 1.* Obtain the correct chemical identity information required by paragraphs (a) (1) and (2) of this section directly from the Chemical Abstracts Service (CAS), specifically from the CAS Registry Services Inventory Expert Service, prior to submitting a notice to EPA. A copy of the chemical identification report obtained from CAS must be submitted with the notice.

(ii) *Method 2.* Obtain the correct chemical identity information required by paragraphs (a) (1) and (2) from any source. The notice will be incomplete according to § 720.65(c)(1)(vi) if the person uses Method 2 and any chemical identity information is determined to be incorrect by EPA.

(4) If an importer submitting the notice cannot provide all the information specified in paragraphs (a) (1) and (2) of this section because it is claimed as confidential by the foreign supplier of the substance, the importer must have the foreign supplier follow the procedures in paragraph (a)(3) of this section and provide the correct chemical identity information specified in paragraphs (a) (1) and (2) of this section directly to EPA in a joint submission or as a letter of support to the notice, which clearly references the importer's notice and PMN User Fee Identification Number. The statutory review process will commence upon receipt of both the notice and the complete, correct information.

(5) If a manufacturer cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because the new chemical substance is manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CAS number, if available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN User Fee Identification Number. The statutory review period will commence upon receipt of both the notice and the letter of support.

(b) The impurities anticipated to be present in the substance by name, CAS Registry number, and weight percent of the total substance.

(c) Known synonyms or trade names of the new chemical substance.

(d) A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance.

(e) The estimated maximum amount to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any 12-month period during the first three years of production.

(f) A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new substance in the formulation for each commercial or consumer use.

(g) For sites controlled by the submitter:

(1) The identity of sites where the new substance will be manufactured, processed, or used.

(2) A process description of each manufacture, processing, and use operation which includes a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the new chemical substance.

(3) Worker exposure information, including worker activities, physical form of the new substance to which workers may be exposed, the number of workers, and the duration of activities.

(4) Information on release of the new substance to the environment, including the quantity and media of release and type of control technology used.

(h) For sites not controlled by the submitter, a description of each type of processing and use operation involving the new chemical substance, including identification of the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new chemical substance will occur, the number of workers exposed and the duration of exposure, and controls which limit worker exposure and environmental release.

[48 FR 21742, May 13, 1983, as amended at 60 FR 16310, Mar. 29, 1995; 83 FR 52719, Oct. 17, 2018]

§720.50 Submission of test data and other data concerning the health and environmental effects of a substance.

(a) *Test data on the new chemical substance in the possession or control of the submitter.* (1) Except as provided in paragraph (d) of this section, each notice must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities. This includes test data concerning the new chemical substance in a pure, technical grade, or formulated form.

(2) A full report or standard literature citation must be submitted for the following types of test data:

(i) Health effects data.

(ii) Ecological effects data.

(iii) Physical and chemical properties data.

(iv) Environmental fate characteristics.

(v) Monitoring data and other test data related to human exposure to or environmental release of the chemical substance.

(3)(i) If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4)(i) If a study, report, or test is incomplete when a person submits a notice, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected; significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the notice review period ends, the person must submit the study, report, or test to the address listed on the notice form or via CDS, as specified in paragraph (a)(3)(i) of this section, within ten days of receiving it, but no later than five days before the end of the review period. If the test or experiment is completed during the last five days of the review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within ten days of the request, but no later than five days before the end of the review period.

(6) All test data described by paragraph (a) are subject to these requirements, regardless of their age, quality, or results.

(b) *Other data concerning the health and environmental effects of the new chemical substance that are known to or reasonably ascertainable by the submitter.* (1) Except as provided in paragraph (d) of this section, any person who submits a notice must describe the following data, including any data from a health and safety study, if the data are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance, of any mixture or article containing the new chemical substance, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the substance.

(2) Data that must be described include data concerning the new chemical substance in a pure, technical grade, or formulated form.

(3) The description of data reported under this paragraph must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not contained in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described by this paragraph are subject to these requirements, regardless of their age, quality, or results, and regardless of whether they are complete at the time the notice is submitted.

(c) ~~Reserved~~ Analog data. A submitter may submit any relevant data pertaining to an analog chemical that is structurally similar to the new chemical substance and which will facilitate the review of the new chemical substance. EPA shall use the analog information provided by the submitter unless EPA can demonstrate to the submitter that the best available science supports the use of another analog. If the analog identity is CHI, EPA shall provide to the submitter redacted copies of studies, reports or other information on the analog EPA relies upon to clearly demonstrate that EPA's choice of an analog represents the best available science.

(d) ~~Data that need not be submitted—(1) Data previously submitted to EPA.~~ (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the notice includes the office or person to whom the data were submitted, the date of submission, and, if appropriate, a standard literature citation as specified in paragraph (a)(3)(ii) of this section.

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the notice and any claim of confidentiality, under §720.80.

(2) *Efficacy data.* This part does not require submission of any data related solely to product efficacy. This does not exempt a person from submitting any of the data specified in paragraph (a), (b), or (c) of this section.

(3) *Non-U.S. exposure data.* This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

(4) *Other information.* A person may submit other information, not otherwise required in this section, to facilitate EPA's review of the notice.

(5) *Use of data.* In conducting reviews of new chemical substances, and to the extent feasible, EPA shall rely on data rather than models; models shall not replace data, unless EPA can demonstrate why the use of models in place of data represents the best available science.

(i) Data provided to EPA by the submitter shall be relied upon by EPA unless EPA can demonstrate that it does not represent the best available science.

(ii) To the extent EPA relies on conservative assumptions to assess either hazard or exposure during the review of a new chemical substance, such conservative assumptions shall be grounded in the TCCR principles referred to in §720.60(a).

[48 FR 21742, May 13, 1983, as amended at 51 FR 15102, Apr. 22, 1986]

Commented [A9]: This new paragraph makes clear that EPA must rely on the analog information provided by the submitter unless EPA can demonstrate that another analog represents the best available science.

Commented [A10]: This new paragraph makes clear that data provided by the submitter should be relied upon rather than models, unless EPA can demonstrate that models represent the best available science. This paragraph also recognizes that EPA relies on conservative assumptions, but those assumptions must comport with the TCCR principles within the Risk Characterization Handbook, referred to in section 720.60(a).

§720.57 Imports.

(a) Except as otherwise provided in this section, the provisions of this subpart C apply to each person who submits a notice for a new chemical substance which he or she intends to import for a commercial purpose. In addition, each importer must comply with this section.

(b) EPA will hold the principal importer, or the importer that EPA determines must submit the notice when there is no principal importer under §720.22(b)(2), liable for complying with this part, for completing the notice form and for the completeness and truthfulness of all information which it submits.

Subpart D—Disposition of Notices

§720.60 General.

This subpart establishes procedures that EPA will follow in reviewing notices.

(a) EPA shall conduct reviews of new chemical substances in a fit for purpose manner by which EPA tailors risk assessment components to be commensurate with the conditions of use specific and relevant to the chemical substance undergoing review. Reviews of chemical substances shall be consistent with the risk characterization TCCR principles of transparency, clarity, consistency, and reasonableness as described in EPA's Risk Characterization Handbook, December 2000. EPA shall ensure that EPA employees and EPA contractors who are engaged in reviewing new chemical substances possess the requisite expertise and knowledge to proficiently conduct reviews. Reviewers shall include, but not be limited to, certified industrial hygienists and risk assessors with industry experience, if feasible. At a minimum, EPA shall provide public access via the Internet to all contractor training manuals, procedures and other related information contractors rely upon to perform new chemical reviews. In conducting reviews of any new chemical substance EPA staff and contractors shall presume compliance with applicable legal standards, unless there is clear evidence to the contrary.

(b) EPA must conduct a review of the notice, make a determination and take the required actions associated with the determination within the applicable review period. Generally, submissions will be reviewed in the order in which they are submitted, unless the submission qualifies for expedited review as described in paragraph (d).

(c) EPA shall review the notice and determine that:

(i) the new chemical substance or significant new use presents an unreasonable risk of injury to human health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use;

(ii) the information on the new chemical substance or significant new use is insufficient to make a reasoned evaluation of the health and environmental effects;

(iii) in the absence of sufficient information to permit EPA to evaluate the new chemical substance, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use.

Commented [A11]: This new paragraph mandates that reviews of new chemical substances must be "fit for purpose," in which the review is commensurate with the specific circumstances applicable to the new chemical substance. Reviews also must adhere to the principles of transparency, clarity, consistency, and reasonableness as described in the EPA Risk Characterization Handbook, December 2000. In addition, EPA must ensure that EPA staff and contractors conducting new chemical reviews possess the necessary skills and knowledge to proficiently conduct those reviews. Training manuals and other relevant information relied upon by contractors performing reviews must be publicly accessible via the Internet, but may be provided to the public by other means as well.

Commented [A12]: This new paragraph requires new chemical review submissions to be reviewed in the order in which they are submitted to EPA. Under this provision, there is no ability for a review to occur out of order, unless that submission qualifies for expedited review as described in new paragraph (d).

Commented [A13]: This new language reflects amended TSCA section 5(a)(3)(A).

Commented [A14]: This new language reflects amended TSCA section 5(a)(3)(B)(i).

Commented [A15]: This new language reflects amended TSCA section 5(a)(3)(B)(F)(i).

(iv) The new chemical substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, or

Commented [A16]: This new language reflects amended TSCA section 5(a)(3)(B)(i)(ii).

(v) The new chemical substance or significant new use is not likely to present an unreasonable risk of injury to human health or the environment without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use.

Commented [A17]: This new language reflects amended TSCA section 5(a)(3)(C).

(d) EPA may designate categories of submissions that are subject to expedited review. Categories of submissions shall include, but not limited to, those submissions that comport with the Sustainable Futures Program. EPA shall render a determination on a new chemical substance undergoing expedited review within 60-45 days of EPA initiating its review. For expedited reviews, EPA shall generate a single report that provides a summary of how EPA conducted its assessment and made its determination.

Commented [A18]: This new paragraph mandates that new chemical submissions that fall within the Sustainable Futures Program receive expedited review, determinations are to be rendered within 45 days of submission. EPA may designate other categories for expedited review.

(e) Each determination under paragraph (c) shall be accompanied by a brief written statement identifying the basis for the determination, including the identification of foreseeable uses that were the basis for any determination under subparagraph (c)(i) or (iii). A preliminary determination shall be communicated to the submitter 45 days from the date the review period commences and in advance of a final determination giving the submitter an opportunity to review and comment within 15 days of receipt of the preliminary determination.

Commented [A19]: This new paragraph describes the information to accompany a determination made under paragraph (c). EPA must make a preliminary determination on the chemical substance within 45 days of having initiated EPA's review of the chemical substance.

(f) New information. During the notice review period, if the submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must submit that information via CDX, per paragraph §720.40 (a)(2)(i), within ten days of receiving the new information, but no later than five days before the end of the notice review period. The new submission must clearly identify the submitter and the notice to which the new information is related. If the new information becomes available during the last five days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone and via CDX per paragraph §720.40 (a)(2)(ii).

(6c) Evaluating Unreasonable Risk.

(i) In determining under paragraph (c)(v) whether a chemical substance is unlikely to present an unreasonable risk, the probability of an unreasonable risk materializing under the conditions of use must be less likely than not. In determining under paragraph (c)(ii) whether a chemical substance may present an unreasonable risk, the probability of an unreasonable risk materializing under the conditions of use must be more likely than not. In determining under paragraph (c)(i) whether a chemical substance presents an unreasonable risk, the probability of an unreasonable risk materializing under the conditions of use must be a reasonable certainty.

Commented [A20]: This new paragraph attaches probabilities to each unreasonable risk determination of paragraph (c).

(ii) EPA shall not make risk determinations under paragraph (c) using worst case scenarios involving unreasonable assumptions. EPA shall take into consideration the effect of representations concerning the conditions of use described in a PMN or SMDN, applicable laws and regulations, including the reasonably anticipated effect of future laws and regulations (including SNURs and Part 704 sentinel notification rules), the expected time frame in which any identified unreasonable risk is reasonably likely to arise under the conditions of use, reasonable assumptions of potential environmental releases of the chemical substance, and any other health risks created by proposed PPE.

Commented [A21]: This new paragraph makes clear that EPA should not evaluate unreasonable risk based on worst case scenarios involving unreasonable assumptions. Instead, this paragraph sets forth other considerations that EPA should take into account.

(iii) EPA is not bound to take actions required by section 5(e) of the Act until it makes a final determination for a chemical substance under paragraph (c) of this section. Before making a final determination, EPA may make a preliminary determination under paragraph (c) and, in its discretion, take actions or receive additional information that may change the reasonably anticipated conditions of use and make its final determination based on the revised conditions of use.

§720.61 Actions on Determinations.

(a) If EPA makes a final affirmative determination each determination under paragraph (c) shall be accompanied by a brief written statement identifying the basis for the unreasonable risk determination, including the identification of foreseeable uses that were the basis for any determination under subparagraph (c)(i) or (iii).

(b) If the Administrator makes an affirmative finding under (c)(ii), (iii) or (iv), the Administrator shall, to the extent necessary to protect against an unreasonable risk under the conditions of use, issue an Order, to take effect at the expiration of the applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of such substance or to prohibit or limit any combination of such activities. The Administrator shall not be obligated to issue an Order where, notwithstanding a determination under (c)(ii), (iii) or (iv), an Order issued to the submitter is, in the EPA's discretion, is not necessary to protect against an unreasonable risk under the reasonably anticipated conditions of use, including circumstances where the unreasonable risk may be adequately and timely addressed by a significant new use rule, sentinel reporting rule, or other means.

(c) Absent good cause, an Order issued under section 5(e) of the Act shall terminate when the Order is no longer necessary to protect against the unreasonable risk under the conditions of use that was the basis for the Order, including where such unreasonable risk is addressed by a significant new use rule applicable to the Submitter.

(d) If the Administrator makes an affirmative finding under (c)(ii), (iii) or (iv), and determines to address the identified unreasonable risk with a significant new use rule, the notice submitter is obligated to comply with the manner of manufacture, processing and use described in its PMN until such time as the SNUR is issued. EPA may accept PMN amendments at any time to conform the PMN to expected SNUR terms.

§720.62 Notice that notification is not required.

When EPA receives a notice, EPA will review it to determine whether the chemical substance is subject to the requirements of this part. If EPA determines that the chemical substance is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture or import of the substance and that the submission is not a notice under this part.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993]

§720.65 Acknowledgement of receipt of a notice; errors in the notice; incomplete submissions; and false and misleading statements.

(a) *Notification to the submitter.* EPA will acknowledge receipt of each notice by sending a letter via CDX or U.S. mail to the submitter that identifies the premanufacture notice number assigned to the new chemical substance and date on which the review period begins. The review period will begin on the date the notice is received by the Office of Pollution Prevention and Toxics Document Control Officer. The

Commented [A22]: This new paragraph provides EPA with alternative actions EPA may take other than TSCA section 5 (e) Orders. These actions would be based on a preliminary determination under paragraph (c) of section 720.60.

Commented [A23]: This new paragraph requires EPA to provide a written explanation for an unreasonable risk determination under paragraph (c). Based on this determination and accompanying written explanation, a Submitter may pursue an administrative appeal pursuant to section 720.71.

Commented [A24]: These new paragraphs bound the circumstances under which an Order may be issued and when such an Order terminates.

Commented [A25]: This new paragraph makes the PMN terms binding on the submitter until an intended SNUR is issued, thus potentially avoiding the need for Orders for issues of concern both (1) in the PMN and (2) not intended by submitter, but reasonably foreseeable to EPA.

acknowledgment does not constitute a finding by EPA that the notice, as submitted, is in compliance with this part.

(b) *Errors in the notice.* (1) Within 15 ~~30~~ days of receipt of the notice, EPA ~~shall~~ ~~may~~ request that the submitter remedy errors in the notice. The following are examples of such errors:

- (i) Failure to date the notice form.
- (ii) Typographical errors that cause data to be misleading or answers to any questions to be unclear.
- (iii) Contradictory information.
- (iv) Ambiguous statements or information.

(2) In the request to correct the notice, EPA will explain the action which the submitter must take to correct the notice.

(3) If the submitter fails to correct the notice within 15 days of receipt of the request, EPA may extend the notice period under section 5(c) of the Act, in accordance with §720.75(c).

(c) *Incomplete submissions.* (1) A submission is not complete, and the notification period does not begin, if:

- (i) The wrong person submits the notice form.
- (ii) The submitter does not sign the notice form.
- (iii) Some or all of the information in the notice or the attachments are not in English, except for published scientific literature.
- (iv) The submitter does not submit the notice in the manner set forth in §720.40(a)(2).
- (v) The submitter does not provide information that is required by section 5(d)(1)(B) and (C) of the Act and §720.50.
- (vi) The submitter does not provide information required on the notice form and by §720.45 or indicate that it is not known to or reasonably ascertainable by the submitter.
- (vii) The submitter does not submit a second copy of the submission with all confidential information deleted for the public file, as required by §720.80(b)(2).
- (viii) The submitter does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by §720.40(g).
- (ix) The submitter does not submit data which the submitter believes show that the chemical substance will not present an unreasonable risk of injury to health or the environment, if EPA has listed the chemical substance under section 5(b)(4) of the Act, as required in §720.40(h).

Commented [A26]: This new language shortens the time for EPA to alert the submitter of errors in the submission that require correction.

(x) The submitter does not include an identifying number and a payment identity number as required by 40 CFR 700.45(e)(3).

(xi) The submitter does not provide a description of any health and safety study concerning the PMN in progress at time of the PMN submission in CDX.

(2)(i) If EPA receives an incomplete submission, the Director, or his or her delegate, will notify the submitter within 1540 days of receipt that the submission is incomplete and that the notice review period will not begin until EPA receives a complete notice.

(ii) If EPA obtains additional information during the notice review period that indicates the original submission was incomplete, the Director, or his or her delegate, may declare the submission incomplete within 1540 days after EPA obtains the additional information and so notify the submitter.

(3) The notification that a submission is incomplete under paragraph (c)(2) (i) or (ii) of this section will include:

(i) A statement of the basis of EPA's determination that the submission is incomplete.

(ii) The requirements for correcting the incomplete submission.

(iii) Information on procedures under paragraph (c)(4) of this section for filing objections to the determination or requesting modification of the requirements for completing the submission.

(4) Within ten days after receipt of notification by EPA that a submission is incomplete, the submitter may file written objections requesting that EPA accept the submission as a complete notice or modify the requirements necessary to complete the submission.

(5)(i) EPA will consider the objections filed by the submitter. The Director, or his or her delegate, will determine whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within ten days of receiving the objections.

(ii) If the Director, or his or her delegate, determines, in response to the objection, that the submission was complete, the notice review period will be deemed suspended on the date EPA declared the notice incomplete, and will resume on the date that the notice is declared complete. The submitter need not correct the notice as EPA originally requested. If EPA can complete its review within 90 days from the date of the original submission, the Director, or his or her delegate, may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(iii) If the Director, or his or her delegate, modifies the requirements for completing the submission or concurs with EPA's original determination, the notice review period will begin when EPA receives a complete notice.

(d) *Materially false or misleading statements.* If EPA discovers at any time that person submitted materially false or misleading statements in the notice, EPA may find that the notice was incomplete from the date it was submitted, and take any other appropriate action.

[48 FR 21742, May 13, 1983, as amended at 75 FR 785, Jan. 6, 2010]

Commented [A27]: This new language makes clear that the submitter must provide EPA with a description of any health and safety study ongoing, relevant to the PMN submission, but not yet completed at the time of the PMN submission via CDX.

Commented [A28]: The new, shorter time period mirrors the change in paragraph (b).

§720.70 Notice in the Federal Register.

(a) *Filing of FEDERAL REGISTER notice.* In accordance with section 5(d)(2) of the Act, after EPA receives a notice, EPA will file with the Office of the Federal Register a notice including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific chemical identity listed in the notice will be published in the FEDERAL REGISTER unless the submitter has claimed chemical identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with §720.85(a)(3).

(2) The categories of use of the new chemical substance will be published as reported in the notice unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under §720.87(b) will be published.

(3) A list of information ~~data~~ submitted in accordance with §720.50(a) will be published. In addition, for test data submitted in accordance with §720.40(g), a summary of the data will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

§720.75 Notice review period.

(a) *Length of notice review period.* The notice review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete notice, or the date EPA determines the notice is complete under §720.65(c), unless the Agency extends the period under section 5(c) of TSCA and paragraph (c) of this section. EPA may for good cause extend the review period for additional periods not to exceed in the aggregate 90 days.

(i) If notice is submitted on a weekend or Federal holiday, Day 1 of review period starts on the following work day.

(ii) Review period resets to Day 1 if the submitter substantially amends the original submission after EPA has initiated review. Any extension of review periods for any submission shall not impact the timely review of any other submission by any submitter.

(b) *Suspension of the running of the notice review period.* (1) A submitter may voluntarily suspend the running of the notice review period if the Director or his or her delegate agrees. If the Director does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the notice review period. The suspension must be for a specified period of time and shall not exceed 90 days, unless good cause can be shown for greater exceedance.

(2) ~~Oral requests.~~ A request for a suspension shall be made via CDX using e-PMN software, or 15 days or less may be made orally, including by telephone, to the submitter's EPA contact for that notice. Any request for a suspension exceeding 15 days must be submitted in the manner set forth in paragraph (b)(2)(ii) of this section. The running of the notice review period will be suspended upon approval of the oral request by the Director or her or his delegate.

(ii) ~~Written requests.~~ Requests for suspensions exceeding 15 days must be submitted electronically to EPA via CDX using e-PMN software. Requests for suspensions of 15 days or less may also be submitted electronically to EPA via CDX using e-PMN software. See §720.40(a)(2)(i) for information on how to

Commented [A29]: This change reflects amended TSCA.

Commented [A30]: This new language caps the amount of time EPA may extend the review period.

Commented [A31]: This language clarifies when the first day of the review period commences.

Commented [A32]: This new paragraph resets the review period if the submitter substantially amends the original submission. This paragraph also clarifies that changes to the review period for one submission should not impact the review of any other submission.

Commented [A33]: This new language allows a submitter to extend the suspension period for a period greater than 90 days but only for good cause.

Commented [A34]: This new language requires submitters to use the CDX to request a suspension.

access the e-PMN software. The running of the notice review period will be suspended upon approval of the written request by the Director or her or his delegate.

(c) *Extension of notice review period.* (1) At any time during the notice review period, EPA may determine that good cause exists to extend the notice review period specified in paragraph (a) of this section. ~~If EPA extends the review period the total period of extensions exceeds 90 days for any given notice and (4)(i)-(iv) do not apply, EPA shall reimburse the submitter 50% of the notice fee paid by the submitter.~~

(2) If EPA makes such a determination, EPA will:

(i) Notify the submitter that EPA is extending the notice review period for a specified length of time, and state the reasons for the extension.

(ii) Issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the notice review period and gives the reasons for the extension.

(3) The initial extension may be for a period of up to 90 days. If the initial extension is for less than 90 days, EPA may make additional extensions ~~subject to paragraph (a). However, the total period of extensions may not exceed 90 days for any notice. If the total period of extensions exceeds 90 days for any given notice and (4)(i)-(iv) do not apply, EPA shall reimburse the submitter 50% of the notice fee paid by the submitter.~~

(4) The following are examples of situations in which EPA may find that good cause exists for extending the notice review period:

(i) EPA has reviewed the notice and determined that there is a significant possibility that the chemical substance will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial 90-day period.

(ii) EPA has reviewed the submission and is seeking additional information ~~that is necessary for EPA to complete its review.~~

(iii) EPA has received significant additional information during the notice review period.

(iv) The submitter has failed to correct a notice after receiving EPA's request under §720.65(b).

(d) *Notice of expiration of notice review period.* EPA will notify the submitter that the notice review period has expired or that EPA has completed its review of the notice. Expiration of the review period does not constitute EPA approval or certification of the new chemical substance, and does not mean that EPA may not take regulatory action against the substance in the future. ~~Submitter may not proceed to manufacture or import of the chemical substance until EPA has made one of the determinations in 720.66.~~

(e) *Withdrawal of a notice by the submitter.* (1)(i) A submitter may withdraw a notice during the notice review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt by EPA of the CDX submission.

(ii) *Submission of withdrawal notices.* EPA will accept statements of withdrawal only if submitted in accordance with this paragraph. Statements of withdrawal must be generated, completed, and submitted to

Commented [A35]: This new language requires EPA to reimburse the submitter 50% of the notice fee if the review period extension does not fall under the good cause exemption as described in paragraph (4).

Commented [A36]: This new language clarifies that the total aggregate extensions requested by the EPA shall be no greater than 90 days.

Commented [A37]: This language clarifies that additional information sought by EPA must be necessary for EPA to complete the review.

Commented [A38]: This new language reflects amended TSCA.

EPA (via CDX) using e-PMN software. See §720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(2) If a manufacturer (including importer) which withdrew a notice later resubmits a notice for the same chemical substance, a new notice review period begins.

(f) Constructive withdrawal. (1) EPA will deem a submitter to have constructively withdrawn the notice if the submitter fails to provide a response to any EPA request within 30 days of EPA having sent the request. (2) Notwithstanding (1), a submitter's response received by EPA after 30 days shall be deemed to be timely submitted if the submitter made a good faith effort to respond within 30 days.

(2) EPA shall provide notification to submitter that the submitter's notice is constructively withdrawn and will be closed out in CDX.

§720.76 Major Amendments to Notices

(a) Major amendments are those that would result in EPA substantially revising either risk assessment or risk management actions and prevent EPA from making a determination within the applicable review period.

(b) If EPA informs the submitter that a submission is deemed a major amendment to the original submission, the submitter shall take one of the following actions: (1) accept amendment as new notice subject to a new TSCA fee for section 5 activity under \$700.45 and reset of review period to Day 1, (2) accept EPA determination based on information submitted with original notice, or (3) voluntarily withdraw the original submission.

§720.77 Pre and Post Submission Meetings

(a) Meetings between the submitter and EPA serve to advance EPA's review of the new chemical substance. Generally, EPA will grant a presubmission meeting request by the submitter. In requesting a meeting with EPA via CDX, the submitter shall indicate the issues for discussion.

(b) During the meeting or no later than five business days after the meeting, EPA shall to the extent practicable, and consistent with the TCCR principles as described in EPA's Risk Characterization Handbook, address the issues raised by the submitter and clearly convey to the submitter the anticipated data needs identified by EPA to facilitate EPA's review of the submission.

(c) All discussions during the meeting shall be made of record.

(d) Post submission meeting requests via CDX will be granted by EPA if EPA reasonably believes a meeting will advance the disposition of the submission. A post submission meeting shall be conducted pursuant to paragraph (a).

[48 FR 21742, May 13, 1983, as amended at 53 FR 12523, Apr. 15, 1988; 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006; 75 FR 786, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013; 80 FR 42746, July 20, 2015]

Commented [A39]: These new paragraphs make clear that failure of a submitter to respond to any EPA request within 30 days will constitute constructive withdrawal, and unless the submitter can show a good faith effort to respond within 30 days, the submitter's notice will be closed out in CDX.

Commented [A40]: This new paragraph describes the nature of an amendment deemed to represent a major amendment, and if so designated by EPA, presents three options that the submitter of the major amendment shall choose from.

Commented [A41]: This new paragraph makes clear that presubmission meetings requested by the submitter generally will be granted by EPA, and that EPA shall address the issues raised by the submitter no later than five business days after the meeting, and consistent with the TCCR principles.

§720.78 Recordkeeping.

(a) Any person who submits a notice under this part must retain documentation of information in the notice, including (1) other data, as defined in §720.50(b), in the submitter's possession or control; and (2) records of production volume for the first three years of production or import, the date of commencement of manufacture or import, and documentation of this information. This information must be retained for five years from the date of commencement of manufacture or import.

(b)(1) Persons who manufacture or import a chemical substance under §720.36 must retain the following records:

(i) Copies of, or citations to, information reviewed and evaluated under §720.36(b)(1) to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under §720.36(c)(1) including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under §720.36(b)(2).

(iv) The names and addresses of any persons other than the manufacturer or importer to whom the substance is distributed, the identity of the substance to the extent known, the amount distributed, and copies of the notifications required under §720.36(c)(2). These records are not required when substances are distributed as impurities or incorporated into an article, in accordance with paragraph (d) of this section.

(2) A person who manufactures or imports a chemical substance under §720.36 and who manufactures or imports the substance in quantities greater than 100 kilograms per year must retain records of the identity of the substance to the extent known, the production volume of the substance, and the person's disposition of the substance. The person is not required to maintain records of the disposition of products containing the substance as an impurity or of articles incorporating the substances.

(3) Records under this paragraph must be retained for 5 years after they are developed.

(c) Any person who obtains a test-marketing exemption under this part must retain documentation of information in the application and documentation of compliance with any restrictions imposed by EPA when it granted the application. This information must be retained for five years from the final date of manufacture or import under the exemption.

§720.79 Administrative Appeal

A submitter who disagrees with an EPA determination pursuant to 720.60 (c)(1) – (5), may appeal such determination to the Senior Science Advisor (SSA) or comparable scientist within the Office of Chemical Safety and Pollution Prevention. The appeal shall be filed via CDX within 15 days of EPA's determination and shall provide the scientific rationale for the submitter's disagreement, to the extent practicable and the rationale for an alternative determination. The SSA shall review the basis for the appeal within 15 days of receipt to ensure its completeness, and shall promptly convene a panel of three EPA senior scientists who can objectively conduct a *de novo* review of the new chemical substance considering all the information provided by the submitter and EPA, and based on a simple majority vote, render a determination pursuant to 720.60(c)(1) – (5) within 60 days of receipt of the submitter's appeal.

Commented [A42]: This new paragraph provides the submitter with the option of administratively appealing an EPA determination. The review of the determination shall be *de novo* and conducted by three EPA senior scientists who can objectively render a determination based on a simple majority vote within 60 days of receipt of the appeal.

[48 FR 21742, May 13, 1983; 48 FR 33872, July 26, 1983, as amended at 51 FR 15102, Apr. 22, 1986; 58 FR 34204, June 23, 1993]

Subpart E—Confidentiality and Public Access to Information

§720.80 General provisions.

(a) A person may assert a claim of confidentiality for any information which he or she submits to EPA under this part.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1)(i) For information submitted on the notice form, the claim(s) must be asserted on the form in the manner prescribed on the notice form.

(ii) When a person submits information in an attachment, the claim(s) must be asserted in the attachment as described on the notice form.

(2) If any information is claimed as confidential, the person must submit, in addition to the copies specified by §720.40, a sanitized copy of the notice form (or electronic submission) and any attachments.

(i) The notice and attachments must be complete. The submitter must designate that information which is claimed as confidential in the manner prescribed on the notice form, via EPA's e-PMN software. See §720.40(a)(2)(iv) for information on how to obtain e-PMN software.

(ii) The sanitized copy must be complete except that all information claimed as confidential in the original must be deleted. EPA will place this sanitized copy in the public file.

(iii) If the person does not provide the sanitized copy, or information in a health and safety study (except information claimed as confidential in accordance with §720.90), the submission will be deemed incomplete and the notice review period will not begin until EPA receives the sanitized copy or the health and safety study information is included, in accordance with §720.65(c)(1)(vi).

(c) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent permitted by the Act, this subpart, and part 2 of this title.

(d) If a notice submitter does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public and place it in the public file without further notice to the submitter.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 60 FR 16311, Mar. 29, 1995; 75 FR 786, Jan. 6, 2010]

§720.85 Chemical identity.

(a) *Claims applicable to the period prior to commencement of manufacture or import.* (1)(i) A person who submits information to EPA under this part may assert a claim of confidentiality for the chemical identity of the new chemical substance. This claim will apply only to the period prior to the commencement of manufacture or import for commercial purposes. A submitter may assert this claim only if the submitter

believes that public disclosure prior to commencement of manufacture or import of the fact that anyone intends to manufacture or import the specific chemical substance for commercial purposes would reveal confidential business information.

(ii) If the notice includes a health and safety study concerning the new chemical substance and if the claim for confidentiality with respect to the chemical identity is denied in accordance with §720.90(c), EPA will deny a claim asserted under this paragraph.

(2) Any person who asserts a claim of confidentiality for chemical identity under this paragraph must provide one of the following items at the time the notice is submitted:

(i) The generic name which was accepted by EPA in the prenotice consultation conducted under paragraph (a)(3) of this section.

(ii) One generic name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible. The generic name will be subject to EPA review and approval at the time a notice of commencement is submitted.

(3)(i) Any person who intends to assert a claim of confidentiality for the chemical identity of a new chemical substance may seek a determination by EPA of an appropriate generic name for the substance before submitting a notice. For this purpose, the person should submit to EPA:

(A) The chemical identity of the substance.

(B) A proposed generic name(s) which is only as generic as necessary to protect the confidential chemical identity of the new chemical substance. The name(s) should reveal the chemical identity of the substance to the maximum extent possible.

(ii) Within 30 days, EPA will inform the submitter either that one of the proposed generic names is adequate or that none is adequate and further consultation is necessary.

(4) If a submitter claims chemical identity to be confidential under this paragraph, and if the submitter complies with paragraph (a)(2) of this section, EPA will issue for publication in the FEDERAL REGISTER notice described in §720.70 the generic name proposed by the submitter or one agreed upon by EPA and the submitter.

(b) *Claims applicable to the period after commencement of manufacture or import.* (1) Any claim of confidentiality under paragraph (a) of this section is applicable only until the substance is manufactured or imported for commercial purposes and becomes eligible for inclusion on the Inventory. To maintain the confidential status of the chemical identity when the substance is added to the Inventory, a submitter must reassert the confidentiality claim and substantiate the claim in the notice of commencement of manufacture required under §720.102. A submitter may not claim the chemical identity confidential for the period after commencement of manufacture or import unless the submitter claimed the chemical identity confidential for the period prior to commencement of manufacture or import under paragraph (a) of this section.

(2)(i) A person who believes that public disclosure of the fact that anyone manufactures or imports the new chemical substance for commercial purposes would reveal confidential business information may assert a claim of confidentiality under this paragraph.

(ii) If the notice includes a health and safety study concerning the new chemical substance, and if the claim for confidentiality with respect to the chemical identity is denied in accordance with §720.90(c), EPA will deny a claim asserted under this paragraph.

(3) Any person who asserts a confidentiality claim for chemical identity must:

(i) Comply with the requirements of paragraph (a)(3) of this section regarding submission of a generic name.

(ii) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the chemical substance the fact that the particular chemical substance is included on the confidential Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available for the particular chemical substance, and agree to furnish to EPA upon request:

(A) An elemental analysis.

(B) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the chemical substance.

(iv) Provide a detailed written substantiation of the claim, by answering the following questions:

(A) What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance? How could a competitor use such information given the fact that the identity of the substance otherwise would appear on the Inventory of chemical substances with no link between the substance and your company or industry? How substantial would the harmful effects of disclosure be? What is the causal relationship between the disclosure and the harmful effects?

(B) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the Inventory?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?

(E) Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public, e.g., in technical journals or other publications, in libraries, or in State, local, or Federal agency public files?

(F) What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?

(G) To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public or to competitors?

(H) In what form does this particular chemical substance leave the site of manufacture, e.g., as part of a product, in an effluent or emission stream? If so, what measures have you taken to guard against discovery of its identity?

(I) If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?

(J) For what purpose do you manufacture or import the substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.

(L) If the notice includes a health and safety study concerning the new chemical substance, the submitter must also answer the questions in §720.90(b)(2).

(4) If the submitter does not meet the requirements of this paragraph, EPA will deny the claim of confidentiality.

(5)(i) EPA will publish a generic name on the public Inventory if:

(A) The submitter asserts a claim of confidentiality in accordance with this paragraph.

(B) No claim for confidentiality of the specific chemical identity as part of a health and safety study has been denied in accordance with part 2 of this title or §720.90.

(ii) Publication of a generic name on the public Inventory does not create a category for purposes of the Inventory. Any person who has a *bona fide* intent to manufacture or import a chemical substance which is described by a generic name on the public Inventory may submit an inquiry to EPA under §720.25(b) to determine whether the particular chemical substance is included on the confidential Inventory.

(iii) Upon receipt of a request described in §720.25(b), EPA may require the submitter which originally asserted confidentiality for a chemical substance to submit to EPA the information listed in paragraph (b)(3)(iii) of this section.

(iv) Failure to submit any of the information required under paragraph (b)(3)(iii) of this section within ten days of a request by EPA under this paragraph is a waiver of the original submitter's confidentiality claim. In this event, EPA may place the specific chemical identity on the public Inventory without further notice to the original submitter.

(6) If a submitter asserts a claim of confidentiality under this paragraph, EPA will examine the generic chemical name proposed by the submitter.

(i) If EPA determines that the generic name proposed by the submitter is only as generic as necessary to protect the confidential identity of the particular chemical substance, EPA will place that generic name on the public inventory.

(ii) If EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, EPA will propose in writing, for review by the submitter, an alternative generic name that will reveal the chemical identity of the chemical substance to the maximum extent possible.

(iii) If the generic name proposed by EPA is acceptable to the submitter, EPA will place that generic name on the public inventory.

(iv) If the generic name proposed by EPA is not acceptable to the submitter, the submitter must explain in detail why disclosure of that generic name would reveal confidential business information and propose another generic name which is only as generic as necessary to protect the confidential identity. If EPA does not receive a response from the submitter within 30 days after the submitter receives the proposed name, EPA will place EPA's chosen generic name on the public inventory. If the submitter does provide the information requested, EPA will review the response. If the submitter's proposed generic name is acceptable, EPA will publish that generic name on the public inventory. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of EPA's choice of a generic name. Thirty days after this notification, EPA will place the chosen generic name on the public inventory.

§720.87 Categories or proposed categories of uses of a new chemical substance.

(a) A person who submits information to EPA under this part on the categories or proposed categories of use of a new chemical substance may assert a claim of confidentiality for this information.

(b) A submitter that asserts such a claim must:

(1) Report the categories or proposed categories of use of the chemical substance.

(2) Provide, in nonconfidential form, a description of the uses that is only as generic as necessary to protect the confidential business information. The generic use description will be included in the FEDERAL REGISTER notice described in §720.70.

(c) The person must submit the information required by paragraph (b) of this section in the manner specified in the notice form.

§720.90 Data from health and safety studies.

(a) *Information other than specific chemical identity.* Except as provided in paragraph (b) of this section, EPA will deny any claim of confidentiality with respect to information included in a health and safety study, unless the information would disclose confidential business information concerning:

(1) Processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(3) Information which is not in any way related to the effects of a substance on human health or the environment, such as the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of confidentiality in accordance with §720.80.

(b) *Specific chemical identity*—(1) *Claims applicable to period prior to commencement of manufacture.* A claim of confidentiality for the period prior to commencement of manufacture or import for the chemical identity of a chemical substance for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under §720.85(a).

(2) *Claims applicable to period after commencement of manufacture or import for commercial purposes.* To maintain the confidential status of the chemical identity of a chemical substance for which a health and safety study was submitted after commencement of manufacture or import, the claim must be reasserted and substantiated in conjunction with a claim under §720.85(b). In addition to the questions set forth in §720.85(b)(3)(iv) of this part, the submitter must answer the following questions:

(i) Would disclosure of the chemical identity disclose processes used in the manufacture or processing of a chemical substance or mixture? Describe how this would occur. In responding to the question in §720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this process information.

(ii) Would disclosure of the chemical identity disclose the portion of a mixture comprised by any of the substances in the mixture? Describe how this would occur. In responding to the question in §720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this information.

(iii) Do you assert that disclosure of the chemical identity is not necessary to interpret any of the health and safety studies you have submitted? If so, explain how a less specific identity would be sufficient to interpret the studies.

(c) *Denial of confidentiality claim.* EPA will deny a claim of confidentiality for chemical identity under paragraph (b) of this section, unless:

(1) The information would disclose processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the information would disclose the portion of the mixture comprised by any of the substances in the mixture.

(3) The specific chemical identity is not necessary to interpret a health and safety study.

(d) *Use of generic names.* When EPA discloses a health and safety study containing a specific chemical identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the chemical substance by the generic name selected under §720.85.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993]

§720.95 Public file.

All information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential. In addition, EPA may add materials to the public file, subject to subpart E of this part. Publicly available docket materials are available at the addresses in §700.17(b)(1) and (2) of this chapter.

[48 FR 21742, May 13, 1983, as amended at 53 FR 12523, Apr. 15, 1988; 60 FR 16311, Mar. 29, 1995; 60 FR 34464, July 3, 1995; 77 FR 46292, Aug. 3, 2012]

Subpart F—Commencement of Manufacture or Import

§720.102 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences the manufacture or import of a new chemical substance for a nonexempt commercial purpose for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement of manufacture or import.

(b) *When to report.* (1) If manufacture or import for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on, or no later than 30 calendar days, after the first day of such manufacture or import.

(2) If manufacture or import for commercial purposes began or will begin before the effective date of this rule, the submitter must submit the notice by the effective date of this rule.

(c) *Information to be reported on form.* (1) The notice must be submitted on EPA Form 7710-56, which is available as part of EPA's e-PMN software. See §720.40(a)(2)(iv) for information on how to obtain e-PMN software. The form must be signed and dated by an Authorized Official (AO). All information specified on the form must be provided. The notice must contain the following information:

(i) The specific chemical identity of the PMN substance.

(ii) A generic chemical name (if the chemical identity is claimed as confidential by the submitter).

(iii) The premanufacture notice (PMN) number assigned by EPA.

(iv) The date of commencement for the submitter's manufacture or import for a non-exempt commercial purpose (indicating whether the substance was initially manufactured in the United States or imported). The date of commencement is the date of completion of non-exempt manufacture of the first amount (batch, drum, etc.) of new chemical substance identified in the submitter's PMN. For importers, the date of commencement is the date the new chemical substance clears United States customs.

(v) The name and address of the submitter.

(vi) The name of the authorized official.

(vii) The name and telephone number of a technical contact in the United States.

(viii) The address of the site where commencement of manufacture occurred.

(ix) Clear indications of whether the chemical identity, submitter identity, and/or other information are claimed as confidential by the submitter.

(2) If the submitter claims the chemical identity confidential, and wants the identity to be listed on the confidential portion of the Inventory, the claim must be reasserted and substantiated in accordance with §720.85(b). Otherwise, EPA will list the specific chemical identity on the public Inventory. Submitters who did not claim the chemical identity, submitter identity, or other information to be confidential in the PMN cannot claim this information as confidential in the notice of commencement.

(d)(1) *Where to submit.* All notices of commencement must be submitted to EPA on EPA Form 7710-56. Notices may only be submitted in a manner set forth in this paragraph.

(2) *Submission of notice of commencement.* EPA will accept notices of commencement only if submitted in accordance with this paragraph. All notices of commencement must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices of commencement must be generated and completed using e-PMN software. See §720.40(a)(2)(ii) for information on how to obtain e-PMN software.

[48 FR 21742, May 13, 1983, as amended at 48 FR 41140, Sept. 13, 1983; 51 FR 15103, Apr. 22, 1986; 53 FR 12523, Apr. 15, 1988; 60 FR 16311, Mar. 29, 1995; 60 FR 34464, July 3, 1995; 65 FR 39304, June 26, 2000; 71 FR 33641, June 12, 2006; 75 FR 786, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013]

Subpart G—Compliance and Inspections

§720.120 Compliance.

(a) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(b) A person who manufactures or imports a new chemical substance before a notice is submitted ~~and the notice review period expires~~ is in violation of section 15 of the Act even if that person was not required to submit the notice under §720.22.

Commented [A43]: This deletion reflects amended TSCA.

(c) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of this rule is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(e) Failure or refusal to permit entry or inspection as required by section 11 is a violation of section 15 of the Act (15 U.S.C. 2614).

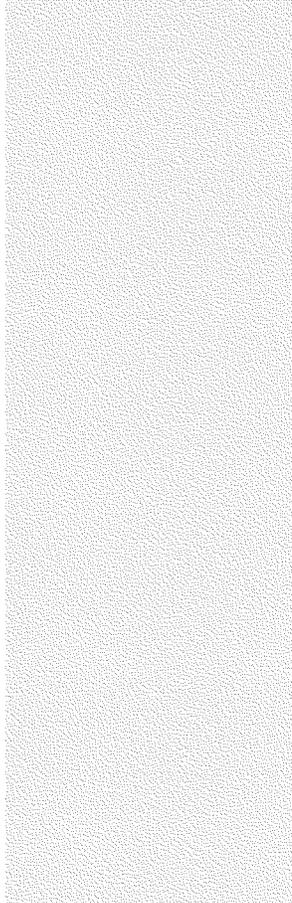
(f) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this rule may be subject to penalties calculated as if they never filed their notices.

(g) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this rule or act to seize any chemical substance manufactured or processed in violation of this rule or take other

actions under the authority of section 7 of this Act (15 U.S.C. 2606) or section 17 of this Act (15 U.S.C. 2616).

§720.122 Inspections.

EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 of the Act and this rule, to verify that information submitted to EPA under this rule is true and correct, and to audit data submitted to EPA under this rule.



Senator MERKLEY. Yes, thank you very much, Mr. Fischer.

As you were testifying, I was taken back to the extensive bipartisan discussions we had a couple years ago when we were kind of reformulating TSCA and trying to make it work more effectively. I imagine there will be future hearings like that. It seems to be a challenging process.

I want to begin with some questions for you, Ms. Lassiter. I am trying to understand the impact of this chemical. When I was growing up in Oregon, we never saw raptors. The hawks disappeared; the eagles disappeared; the osprey disappeared. I say disappeared; I never saw them, and now they are abundant. The cause was a particular pesticide, Dichlorodiphenyltrichloroethane (DDT), which caused the shells of the eggs to be so weak that they would get crushed.

What is the death mechanism here? What is this chemical doing to the fish that is killing them? Is it interfering with their brain, is it causing liver disease? What is going on?

Ms. LASSITER. Thank you for that question, Senator. As you know, we just, in 2020, discovered that 6PPD-Q is so toxic to coho salmon and other fish, and so we are still learning. We are conducting research in Washington.

We are funding research at other agencies, like USGS, to study fish and to figure out what is happening with them. We have a number of agencies looking into fish tissue studies to get a closer look at what is happening in the fish themselves, but we are working toward developing monitoring now.

Senator MERKLEY. In short, we do not really know yet?

Ms. LASSITER. That is right.

Senator MERKLEY. Okay. Are we finding that it is toxic to eggs, the fish eggs?

Ms. LASSITER. We do not know that yet, either.

Senator MERKLEY. Is it toxic only to adult fish, or also to the small fry?

Ms. LASSITER. It seems to be toxic to returning salmon, so it is pre-spawn mortality, so they are coming back in the streams to spawn, and that is when we see the mass mortality events.

Senator MERKLEY. They are dying before they spawn?

Ms. LASSITER. Correct.

Senator MERKLEY. Well, that would have a big impact.

In the Washington State area where you have these streams running into ocean inlets and so forth, and salt water, are we finding that it is also killing the salmon? Because I saw a reference to the impact on the orcas. Is it also affecting the adult fish when they are still in ocean water?

Ms. LASSITER. We do not know that yet. What we have seen is where they are dying in mass quantities where they are coming back to spawn, and there are hotspots that we are still identifying, but often in urban streams.

Senator MERKLEY. When it comes to salmon, I keep hearing the coho mentioned, but we have many types of salmon. What about other types of salmon?

Ms. LASSITER. We know that there are impacts to other fish, like rainbow trout. But the instant mortality, the within hours from exposure, that is specifically coho salmon. The impact is not the same

on other salmon, like Chinook, which, as you know, are the primary food source for our resident orca whales.

Senator MERKLEY. OK, so a lot to be learned in terms of what is the mechanism that is killing them, and what other fish are affected. But you do not think it is having the same impact on Chinook?

Ms. LASSITER. That is right.

Senator MERKLEY. That is really interesting, but for another moment.

Ms. Norberg, when this chemical was introduced to affect the oxygenation deterioration, did it, I think I saw a reference somewhere to, it increases the wear by about 20 percent. Is that accurate, or how would you characterize the extension of life of the tire?

Ms. NORBERG. Yes, in general terms, it is at least, tires are lasting at least two-thirds longer than they would without 6PPD. Before 6PPD became widespread in its use, other waxes were used to protect the tire, and they do not protect the tire from dynamic wear and ozone exposure.

Senator MERKLEY. Crudely, are we talking about a tire that, with 6PPD, is a 50,000-mile tire, and it becomes a 30,000-mile tire?

Ms. NORBERG. I think it would be much more severe than that.

Senator MERKLEY. Well, 30,000 to 50,000 would be a two-thirds increase of 20,000 on top. I am trying to get a general characteristic we can put our hands around.

Ms. NORBERG. Maybe the best way to say is that a tire would last a third as long.

Senator MERKLEY. One-third as long?

Ms. NORBERG. Yes, typically. I may have misspoke, yes. Typically, a tire now, average lifespan of a tire is somewhere in the 40,000 mile range. We would expect a tire to last a third of that time on the outside.

Senator MERKLEY. That is a dramatic change.

Ms. NORBERG. It is very dramatic, yes.

Senator MERKLEY. For sure. I really appreciate the cooperation of the tire industry in tackling this challenge, because not every industry says yes, we recognize it is an issue, and we want to be partners and try to find a solution. That is very, very helpful.

So, as I understand it, you presented that there were 70 chemicals or so that were being analyzed, and now, sort of that ballpark, 60 or 70, and now 7 of those are promising? Do those seven chemicals, do we know that they do not have the same lethal impact on trout and coho that 6PPD-Q has?

Ms. NORBERG. In the alternatives analysis that we are conducting, we have identified that understanding toxicity to coho and other salmonids is really critical to identifying an alternative. The seven materials that we have moved forward to stage two have met our initial screening for hazard criteria, but we have not fully evaluated all of those chemicals for sensitivity to coho and other salmonids. That will be part of the stage two analysis, not only for those seven chemicals, but beyond that, as we get more toxicity and hazard data for other chemicals. We may be evaluating additional materials as we move forward.

Senator MERKLEY. My time has expired, so I am going to turn this over to our co-chair, and then I will have some additional questions. Thank you.

Senator MULLIN. Did you call me co-chair? Did I get upgraded?

Senator MERKLEY. Absolutely. Vice-chair, co-chair. Any title you want, Senator Mullin.

[Laughter.]

Senator MULLIN. Thank you. My wife has some nicknames for me too, and they are not always good.

Thank you guys, once again, for being here. I do appreciate your time. This is something somewhat new to me until we started actually recognizing this hearing. I had not really heard this problem with the coho, even though I am Cherokee, and I meet with the tribes on a very regular basis. Obviously, it is a concern to them.

Typically, what we hear about is the habitat, that they are having a hard time spawning, going back upstream, because of dams and infrastructures put in place. That, I totally understand, so this is kind of new to me.

I have some questions for you, Ms. Lassiter. Is that right?

Ms. LASSITER. Yes.

Senator MULLIN. When they are doing the test for the 6, what is it, 699? I am looking at my notes here. What is it?

Ms. LASSITER. 6PPD-Q.

Senator MULLIN. 6PPD-Q. Thank you. When they are doing the tests on that, what was the concentration rate of it? Was it tested in open streams, was it tested in concentrated pools? Then what was the mixture rate that we are looking at?

Ms. LASSITER. We have tested at concentrations that are found in the environment. I do not have the exact numbers in front of me. I do not know how meaningful they would be.

Senator MULLIN. Was it tested in the environment or in a moving body of water, or was it a concentrated pool?

Ms. LASSITER. Mostly, we have been testing in labs. There has been a lot of different testing happening, not just at my agency, so I can not speak to that. But we have tested in the lab at concentrations that have been found in the environment.

Senator MULLIN. But not in the environment. We have not actually tested this in the moving water environment to see how fast this actually diluted inside the moving water, and then what is the concentration rate per acreage of water per fish.

Ms. LASSITER. Okay. We have sampled for 6PPD-Q in our moving waterways, but when we are doing the tests on fish, that is happening in a laboratory environment.

Senator MULLIN. Listen, I am all about finding alternatives, I really am, but we also need to understand the impact of it, too.

Ms. LASSITER. Absolutely.

Senator MULLIN. Mr. Chairman, I think what Ms. Norberg was referring to by a third less, remember, this is affected by oxygen when it interacts with it. You can not just look at the tire based on the miles because it is the exposure rate, it is the dry rot.

It is the same thing if a car is sitting there in the environment for 4 years, 5 years, even though it is not driven, it can be a brand new tire that will create dry rot, which makes it not safe to drive

any more. It is the amount of time it can be exposed, and I think that is what we need to be looking at here.

If people that are, today, just used to look at the tread rate on it, then you are not going to understand the dry rot, the cracking, that is happening on the sidewalls, which is where the dangerous part happens. It blows out on the front axle; you have all types of issues. Then, it is the effect that happens not just to the driver, but then everyone around the vehicle.

I do feel very strongly that we need to find the alternatives, but we also need to find the true impact of this. As the industry is looking for an alternative, we need to actually understand the science and the impacts of it, too, and the cost to consumers. My Lord, we are all dealing with massive inflation rate, the way that we are dealing with today, and that is no, I am not making a political point, I am just telling you, that is the fact of the matter, and this would just add to it if we do not understand the cost.

When Congress first set this up, we had to have a reasonable impact of what it was going to be to the consumer moving forward. All this needs to be understood.

Mr. Fischer, you talked about something I was talking about with the EPA and the fact that they are not able to get these approvals done, to actually make the change we need to. Can you elaborate a little bit more on that?

Mr. FISCHER. Yes. As I mentioned in my testimony, the statute says 90 days to 180 days. I would say, on average, if you have a Premanufacture Notice (PMN) going under review at EPA and the review concludes and there is a consent order, attached to that review, we are talking up to a year and a half, maybe longer. If you then add a SNUR to it, a Significant New Use Rule that would follow that approval process, then you are adding on another, probably, 2 years.

It has now become sort of a multi-year endeavor, versus the 90 days to 180 days that was in the statute. Even when Congress amended the statute in 2016, it did not change those timelines. Congress still assumed EPA would meet the 90 days to 180 days. As you mentioned, or what was mentioned earlier today, is a rare event. Most of the time, submitters need to anticipate it taking at least a year. In fact, I advise folks, do not expect anything under a year.

Senator MULLIN. Mr. Chairman, I think this leads to something that we should be looking at too, that maybe we need to have a hearing with EPA to hold their feet to the fire, so to say, for getting these out. This is important for safety perspectives. This is important to the tribes. This is important to the consumer, and there is no reason why they can not do this.

I know they talked about not having enough money, but my Lord, it seems like every year we are raising their budget to begin with. They are just not prioritizing the way that Congress has asked them to do.

With that, I yield back.

Senator MERKLEY. Thank you very much. I will get you a new nameplate, if you would like.

[Laughter.]

Senator MULLIN. Thank you.

Senator MERKLEY. I want to turn back to this question of the coho being affected. You say in the laboratory, so where is this laboratory where the fish are being tested against the chemical?

Ms. LASSITER. We are doing the studies in Washington, I believe, at the Washington Stormwater Center, so associated with WSU, and we have researchers at UW as well.

Senator MERKLEY. I will followup, because I want to come see the testing, obviously, close by in Oregon. We talk about salmon so much, and we talk about how much we are spending to move the small fry over the dams or around the dams and all sorts of challenges, obviously. This issue is really a significant new addition to the discussion of the challenge we are facing.

I am wondering if we are seeing similar impacts, say, that are being reported from Alaska or from the east coast or from Norway, or other places where there are salmon runs. Has this identification of a challenge occurred in Washington State, really a diligent observation that the fish were dying after a rainstorm, and what is going on? But are we seeing hints of this happening in other areas where there are salmon?

Ms. LASSITER. Certainly, actually being able to see the mass mortality events has been most dramatic in Washington. We do have researchers across the Country with USGS studying this phenomenon and studying it on other fish, and there is research underway in Europe, as well.

Senator MERKLEY. What made it easier to detect in Washington? Is it because the streams are shorter, so the adult coho are concentrated, and in an urban area, where they can be easily observed, as opposed to 1,000 miles up the Columbia River, or so forth? What, why?

Ms. LASSITER. That is such a good question, and that is why we are conducting research and monitoring now. We do not have those answers.

Senator MERKLEY. Okay. I will really want to followup with this question of the kill mechanism, why it is killing. If we do not understand why it is killing them, I mean, it must be something that is common to the rainbow trout and the coho and the brook trout, I think you mentioned lake trout, that is something different if it is not affecting the Chinook.

Have we had Chinook in the laboratory and these aquariums and they are not affected?

Ms. LASSITER. Yes, they have been tested in the same way.

Senator MERKLEY. That is really fascinating.

Ms. NORBERG, I wanted to turn to the question of whether the tire industry in other countries is also doing research on this.

Ms. NORBERG. Yes, we are working as a global tire industry on both this issue, and then the broader issue of tire and road wear particles. There is a global industry organization called the Tire Industry Project that is based in Switzerland. It is part of the World Business Council for Sustainable Development. They have been studying tire and road wear particles for many years and continue that work.

Because 6PPD, really the issue originated here, we are at the tip of the spear when it comes to the 6PPD specific issues, but we are coordinating as a global industry on this issue.

Senator MERKLEY. Is the primary research on this issue happening in Switzerland?

Ms. NORBERG. Broadly, on tire and road wear particles, they continue that work, yes. Then, we on 6PPD and 6PPD-Q are really in the lead here in the U.S., but coordinating with our global counterparts.

Senator MERKLEY. The scientific research that took this many dozens of chemicals, 60, 70 chemicals, and reduced it to 7 promising, that research happened in Switzerland?

Ms. NORBERG. No, that research happened here in the U.S., and I led that project. It is ongoing.

Senator MERKLEY. Okay. When you get down to those seven chemicals, and the question is, do these chemicals also have an impact on fish, are you transporting those chemicals to Ms. Lassiter's Washington State laboratories to be tested, or how are you determining the impact?

Ms. NORBERG. The work that we have been doing is pursuant to the California regulatory requirements as part of the Safer Consumer Products regulations. That regulation is a very rigorous, very prescribed process for evaluating alternatives to identify safer chemicals in products.

The stage one, which we have completed, is basically a screening step, and then we will continue to do more in-depth research of not only those seven chemicals, but any others where we can garner additional research. The ones we are moving forward do not have indications of negative impacts on salmonids or other species yet to date, but we will continue that evaluation as we move forward.

Senator MERKLEY. That screening process—cloakroom needs us to vote, I am informed.

Senator MULLIN. I guess so. I can make my last question very quick.

Senator MERKLEY. I am going to stop and turn it over to our Vice Chair, co-chair, Ranking Member, all of the above, and then we will adjourn the hearing. I really appreciate you all bringing your information to bear, because this situation where the high lethality of this particular chemical in regards to the coho is a super big deal, and we have to solve it.

Thank you.

Senator MULLIN. Thank you once again.

Just real quick, Ms. Norberg, how many other things is 6PPD found in? Are there other products?

Ms. NORBERG. I am sorry, I missed the last part of your question.

Senator MULLIN. What other products is 6PPD found in, other than just tires?

Ms. NORBERG. I do not think I can give you the full list. I am most familiar with tires, but other rubber products most likely contain 6PPD.

Senator MULLIN. Ms. Lassiter, do you know? I am just curious; I do not know the answer either. I am just asking.

Ms. LASSITER. Oh, right. No, that is certainly Ms. Norberg's area of expertise.

Ms. NORBERG. Yes, I am aware of one study in Washington State that looked at seals for water systems, but I could not—we are happy to followup.

Senator MULLIN. I would assume so. I would assume they would be in seals.

Mr. Fischer, do you know? I think that is something we need to find out, too, other places it is found.

My last question that I have, real quick, what steps, Mr. Fischer, what steps do you recommend the EPA could do administratively to improve their timeline?

Mr. FISCHER. Thank you for that question.

In my written submission, I included a fairly lengthy petition for rulemaking, where we basically took Part 720, which are the regulations that govern new chemical reviews, and made a lot of substantive changes.

But a couple would be sort of requiring EPA to take a much more reasonable approach when they are reviewing a new chemical submission. For example, if they do not have data, their defaults should be reasonable. Right now, they tend to be worst-case scenarios, which are completely unrealistic, implausible, et cetera. I think EPA needs to sort of bring that thinking back into more reasonable areas.

The concept of reasonableness, I think, should be really instilled in how EPA reviews new chemicals.

There are a lot of other suggestions as well in the petition that you now have as part of the record. Another one I would like to mention is, there should be much more of a collaborative exchange between the submitter and EPA staff. There should be an understanding of, if EPA needs more data, if there are issues with the data that have been submitted. That should be conveyed to the submitter on a more timely approach or basis.

Right now, it tends to, you submit, and it tends to go in a bit of a black box. I think that can both frustrate the submitter, and it also may prolong the review process if EPA could have obtained answers to its questions a lot earlier. I really believe there should be much more of a collaborative approach to getting new chemicals reviewed and hopefully approved.

Senator MULLIN. Thank you. Thank you guys for being here.

Senator MERKLEY. Ms. Lassiter, is it appropriate for me to say that 6PPD is to coho as DDT was to eagles? A very short answer. Fair or unfair?

Ms. LASSITER. It is fair. It is considered highly toxic.

Senator MERKLEY. Given that we are supposed to be voting, I have to run.

Ms. LASSITER. Thank you, Senator.

Senator MERKLEY. Before we adjourn, I ask unanimous consent from all of the members present to submit for the record a variety of materials that includes letters from stakeholders and other materials related to today's hearing.

[Laughter.]

Senator MERKLEY. Hearing no objection, so approved.

[The referenced information follows:]

**The Yurok Tribe, the Port Gamble S’Klallam Tribe, and the Puyallup Tribe of Indians
Letter for the Record**

**Senate Committee on Environment and Public Works
Subcommittee on Chemical Safety, Waste Management,
Environmental Justice, and Regulatory Oversight**

Understanding the Potential Environmental Impacts of the Chemical 6PPD

August 16, 2024

The Yurok Tribe, Port Gamble S’Klallam Tribe, and Puyallup Tribe of Indians (collectively, the “Tribes”) submit this letter to the record for the Senate Committee on Environment and Public Works Subcommittee on Chemical Safety, Waste Management, Environmental Justice, and Regulatory Oversight’s July 31, 2024, hearing on “Understanding the Potential Environmental Impacts of the Chemical 6PPD.”

The Tribes share the Subcommittee’s concern over the devastating effects of 6PPD and its degradation product, 6PPD-Q, on populations of salmon, steelhead, and other aquatic life. Indeed, the Tribes have a unique perspective on and stake in addressing this crisis given the profound importance of healthy salmon populations to the Tribes’ cultures and economies. As elaborated below, the Tribes respectfully urge the Subcommittee members and their colleagues in Congress to support and resource the critical work of the Environmental Protection Agency (“EPA”) to expeditiously promulgate regulations mandating a phaseout of 6PPD in tires under the Toxic Substances Control Act (“TSCA”) as well as initiatives to identify alternatives to 6PPD that are safe for salmon, for other aquatic life, and for people. In all of these efforts, it is imperative that members of Congress and federal and state regulators center the perspectives and expertise of Tribal Nations to ensure that collectively we develop real solutions to the 6PPD-Q contamination crisis—*i.e.*, solutions that will: protect and restore vital populations of salmon, steelhead, and other wildlife that are harmed by the toxic effects of 6PPD and 6PPD-Q; avoid adoption of “regrettable substitutions” for 6PPD that likewise pose significant threats to human health or the environment and therefore represent false solutions; and advance tribal sovereignty and environmental justice.

1. Federal and State Efforts to Address the 6PPD-Q Contamination Crisis Must Center Tribal Perspectives and Expertise

While the Tribes appreciate the Subcommittee’s convening of a hearing to raise awareness about the devastating ecological impacts of 6PPD use in tires and the urgent need for solutions, the Subcommittee’s failure to include the perspectives of tribal leadership or tribal experts in the hearing is not acceptable. The health, wellbeing, and cultures of the Yurok, Port Gamble S’Klallam, and Puyallup Tribes and their members are inextricably linked to the viability and vitality of salmon populations—as is true for many Tribal Nations in the Pacific Northwest. The precipitous declines in salmon and steelhead populations resulting from ubiquitous 6PPD-Q contamination harm the physical and spiritual health and welfare of tribal

members. Further, Tribal Nations have unique sovereign interests in and rights to viable populations of salmon, steelhead, and other fish species within their ancestral territories.

Accordingly, Tribal Nations have singular perspectives on and expertise regarding the ecological, economic, cultural, and political impacts of 6PPD use and the resulting harm to salmon and other aquatic life. Further, consistent with their unique stake in addressing this crisis, Tribal Nations have played a vital leadership role in driving solutions—including but not limited to the Tribes’ successful petition to EPA demanding TSCA risk management regulations that will address the unreasonable risks to the environment from 6PPD use in tires by compelling a phase-out of that use.¹ We urge you to ensure that future initiatives concerning 6PPD by the Subcommittee, and by your colleagues in Congress, respect and incorporate the expertise and perspectives of Tribal Nations.

2. Expeditious, Well-Resourced Federal Regulatory Action is Needed to Address the 6PPD-Q Contamination Crisis

As the Subcommittee heard, “6PPD-Q is among the most toxic chemicals known for aquatic organisms,” with particularly devastating effects on coho salmon.² Indeed, the only chemical shown to be more toxic to aquatic species is the widely banned chemical war agent parathion.³ Due to the ubiquitous use of 6PPD in tires, 6PPD-Q is now ubiquitous in urban stormwater runoff and surface waters,⁴ where it has been measured repeatedly at concentrations above the lethal levels for coho salmon, rainbow trout, brook trout, and white spotted char.⁵ And

¹ Yurok Tribe, Port Gamble S’Klallam Tribe, and Puyallup Tribe of Indians, *Citizen Petition Under TSCA Section 21 to Prohibit 6PPD in Tires* (Aug. 1, 2023); see also Letter from Michal Freedhoff, EPA Assistant Administrator for Chem. Safety and Pollution Prevention, to Elizabeth Forsyth and Katherine O’Brien, Earthjustice, Re: Petition ID No. 001845: Toxic Substances Control Act Section 21 Petition Regarding N-(1,3-Dimethylbutyl)-N’-phenyl-p-phenylenediamine (CASRN 793-24-8, aka 6PPD) in Tires – Final EPA Response to Petition (Nov. 2, 2023) (granting petition).

² Zhenyu Tian et al., *6PPD-Quinone: Revised Toxicity Assessment and Quantification with a Commercial Standard*, 9 *Env’t Sci. & Tech. Letters* 140, 143 (2022).

³ *Id.*, Table 1; see U.S. Env’t Prot. Agency, *R.E.D. Facts Ethyl Parathion* 4 (Sept. 2000), https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-057501_1-Sep-00.pdf.

⁴ Lixi Zeng et al., *Widespread Occurrence and Transport of p-Phenylenediamines and Their Quinones in Sediments Across Urban Rivers, Estuaries, Coasts, and Deep-Sea Regions*, 57 *Env’t Sci. & Tech.* 2393, 2397 (2023); see also Cassandra Johannessen et al., *Detection of Selected Tire Wear Compounds in Urban Receiving Waters*, 287 *Env’t Pollution* 117659, at 1, 6, 8 (2021); Jenifer K. McIntyre et al., *Treading Water: Tire Wear Particle Leachate Recreates an Urban Runoff Mortality Syndrome in Coho But Not Chum Salmon*, 55 *Env’t Sci. & Tech.* 11767, 11772 (2021).

⁵ Zeng et al. 2023 at 2394; Kyoshiro Hiki & Hiroshi Yamamoto, *The Tire-Derived Chemical 6PPD-quinone is Lethally Toxic to the White-Spotted Char *Salvelinus leucomaenis pluvius* But Not to Two Other Salmonid Species*, 9 *Env’t Sci. & Tech. Letters* 1050, 1052–53 (2022); McIntyre et al. 2021 at 11768, 11771–72; Cassandra Johannessen et al., *The Tire Wear*

as the Subcommittee heard, 6PPD-Q has been identified as the primary causal agent responsible for “urban runoff mortality syndrome,” which kills up to 100% of coho returning to spawn in urban streams.

Thus, there is no question that real-world levels of 6PPD-Q in the environment are devastating critical populations of coho salmon and other aquatic life. Peer-reviewed scientific research tells us that “[w]ild coho populations cannot withstand the high rates of mortality that are now regularly occurring in urban spawning habitats,”⁶ and that “it will be difficult, if not impossible to reverse historical coho declines” without eliminating this toxic threat.⁷ In turn, the devastation of salmon and steelhead populations due to 6PPD-Q contamination threatens entire ecosystems, as at least 138 other wildlife species—including southern resident orca whales, eagles, bears, wolves, and seals—depend upon salmon and steelhead for food.⁸

The dramatic suppression of salmon populations in the Pacific Northwest also has major economic consequences. Communities that depend upon the fishing economy have been devastated by the precipitous declines in salmon runs. Indeed, in recent years numerous tribal and non-tribal salmon fisheries along the West Coast have been hit so hard by exceptionally low catches that the U.S. Secretary of Commerce has declared them eligible for federal disaster relief.⁹ In contrast, the estimated economic value of a restored salmon fishery *in California alone* is \$5.676 billion, which would support more than 94,000 jobs.¹⁰ Even at current suppressed levels, and without considering associated economic benefits, commercial revenue from salmon fishing in the Pacific region (comprising Oregon, Washington, and California) reached

Compounds of 6PPD-Quinone and 1,3-Diphenylguanidine in an Urban Watershed, 82 Archives of Env't Contamination & Toxicology 171, 175 (2021); J.K. Challis et al., *Occurrences of Tire Rubber-Derived Contaminants in Cold-Climate Urban Runoff*, 8 Env't Sci. & Tech. Letters 961, 961 (2021); Zhenyu Tian et al., *A Ubiquitous Tire Rubber-Derived Chemical Induces Acute Mortality in Coho Salmon*, 371 Sci. 185, 186–88 (2021).

⁶ Julann A. Spromberg et al., *Coho Salmon Spawner Mortality in Western U.S. Urban Watersheds: Bioinfiltration Prevents Lethal Storm Impacts*, 53 J. Applied Ecology 398, 398 (2016).

⁷ Blake E. Feist et al., *Roads to Ruin: Conservation Threats to a Sentinel Species Across an Urban Gradient*, 27 Ecological Applications 2382, 2393 (2018); see also Julann A. Spromberg & Nathaniel L. Scholz, *Estimating the Future Decline of Wild Coho Salmon Populations Resulting From Early Spawner Die-offs in Urbanizing Watersheds of the Pacific Northwest, USA*, 7 Integrated Env't Assessment & Mgmt. 648, 655 (2011).

⁸ Mary F. Willson & Karl C. Halupka, *Anadromous Fish as Keystone Species in Vertebrate Communities*, 9 Conservation Biology 489 (1995); Marie Fazio, *Northwest's Salmon Population May be Running Out of Time*, New York Times (Jan. 20, 2021); Dukes Seafood and Chowder, *Environmental Impact of Salmon Decline: This Isn't Just About Fish*, Seattle Times (Jan. 26, 2018).

⁹ See NOAA Fisheries, *Fishery Resource Disaster Determinations*, <https://www.fisheries.noaa.gov/national/funding-financial-services/fishery-resource-disaster-determinations> (last visited Aug. 15, 2024).

¹⁰ Mem. from Rob Southwick, Southwick Assocs., to Richard Pool, Golden Gate Salmon Ass'n, at 4 (Aug. 9, 2012) (attached as **Exhibit 1**).

approximately \$29.9 million in 2020.¹¹ Commercial salmon-fishing revenue in Alaska totaled \$449 million in 2020.¹² Increased salmon sport-fishing opportunities associated with a restored fishery would also have major economic benefits. Between 2012–2015, the average total economic impact of the salmon sport fishing industry was \$394 million in Washington and \$153 million in Alaska.¹³ These figures, too, reflect the economic benefits associated with severely depressed salmon stocks. Indeed, salmon and steelhead runs are so depleted that Washington State has been forced to close streams or runs to sport fishing, sometimes for entire seasons.¹⁴

In short, the cultural, ecological, and economic impacts of 6PPD use in tires are profound and they demand an urgent and well-resourced federal regulatory response; non-regulatory, industry-driven initiatives will not suffice. Despite knowing for years of the link between 6PPD use, the generation of 6PPD-Q, and urban runoff mortality syndrome, the tire industry has made little progress in developing viable alternatives. The U.S. Tire Manufacturer’s Association (“USTMA”) touts as significant progress its development of a stage 1 alternatives analysis for the California Department of Toxic Substances Control, but four of the seven potential 6PPD alternatives identified in the recently revised version of that report are other PPD compounds that are closely related to 6PPD,¹⁵ and—according to the USTMA’s own screening criteria—three of those four chemicals present similar overall hazards to 6PPD, while the fourth has only “somewhat lower” hazard scores.¹⁶ This emphasis on alternatives that are structurally similar to 6PPD and present similar hazards raises serious concerns about a “regrettable substitution” for 6PPD that will itself perpetuate serious environmental harm, as well as concerns about the time industry will take to identify and commercialize a truly viable alternative if left to operate without a regulatory deadline. As such, we urge the Subcommittee and your colleagues in Congress to support and resource EPA’s current TSCA risk management rulemaking for 6PPD—a process that, if carried out in conformity with TSCA’s substantive mandate and timelines, has

¹¹ Nat’l Marine Fisheries Serv., *Fisheries Economics of the United States*, 2020 at 44 (2020).

¹² *Id.* at 32.

¹³ Gordon Gislason et al., *Economic Impacts of Pacific Salmon Fisheries*, Pacific Salmon Comm’n, at 18–23 (2017), <http://www.psc.org/download/333/special-reports/9337/economic-impacts-of-pacific-salmon-fisheries.pdf>.

¹⁴ See, e.g., Wash. Dep’t of Fish & Wildlife, *Wenatchee River Salmon Season Will Not Open in 2024* (July 26, 2024), <https://wdfw.wa.gov/fishing/regulations/emergency-rules/wenatchee-river-salmon-season-will-not-open-2024-2024-07-0>; Wash. Dep’t of Fish & Wildlife, *Fishing to Close in the Nooksack River, Including All Forks* (May 21, 2024), <https://wdfw.wa.gov/fishing/regulations/emergency-rules/fishing-close-nooksack-river-including-all-forks-2024-05>.

¹⁵ U.S. Tire Manufacturers Ass’n, *Q&A: Stage 1 Alternatives Analysis for 6PPD in Tires*, <https://www.ustires.org/qa-stage-1-alternatives-analysis-6ppd-tires> (last visited Aug. 15, 2024).

¹⁶ U.S. Tire Manufacturers Ass’n, *Preliminary (Stage 1) Alternatives Analysis Report, Motor Vehicle Tires Containing N-(1,3-dimethylbutyl)-N’-phenyl-p-phenylenediamine (6PPD)* 60–61, Gradient (2024), https://www.ustires.org/sites/default/files/2024-03/USTMA%20Consortium%206PPD%20AA%20Preliminary%20Report_3-25-24.pdf.

the capacity to ensure uniform, nationwide regulations that will compel a transition away from 6PPD on the most expeditious timeline practicable.

We appreciate the Subcommittee's attention to this vital issue and look forward to ongoing engagement in efforts to support the urgently needed phaseout of 6PPD in tires.

Respectfully submitted,

Katherine O'Brien
Earthjustice
(212) 284-8036
kobrien@earthjustice.org

*Counsel for the Yurok Tribe,
the Port Gamble S'Klallam Tribe,
and the Puyallup Tribe of Indians*

Exhibit 1



August 9, 2012

Mr. Richard Pool
Golden Gate Salmon Association
1370 Auto Center Drive
Petaluma, CA 94952

Dear Mr. Pool:

We looked into updating our previous economic impact estimates associated with recreational salmon fishing in California. Please accept this letter as a presentation of the best estimates available along with a description of the methodology and data sources used.

As described below, our data sources were the U.S. Department of Commerce's National Marine Fisheries Service and the California Department of Fish and Game. We sought to update our 2006 estimates to 2010/2011, but the data necessary to estimate the economic impacts of salmon harvests were not available for these years. Therefore, we will stick with the 2006 estimates which are summarized as:

	Sales Impact ¹	Jobs Impact
	-----	-----
Total 2004-2006 Commercial and Recreational Activity	\$1.4 billion	23,000
Estimate of the Future Returns if Salmon were Restored to their Full Potential	\$5.7 billion	94,000

Commercial Fisheries:

To estimate the potential impacts from a restored commercial salmon fishery, average landings for 2004 and 2005 were used as they represent rather steady harvests. Harvests began to decrease rapidly in 2006 down to practically nothing in 2008 and 2009. In 2004 and 2005, salmon on average represented 12% of the total value of California's commercial fisheries landings. Assuming the mark-ups and value added from salmon processing, distribution and retail were the same as for all other commercial fisheries in California as reported by NOAA, then the economic impacts for commercial salmon harvests at 'normal' 2004 and 2005 levels would have been:

¹ Sales impacts = Sales by California businesses.



Sales impacts (total sales that occur in the CA economy): \$1.17 billion
 Income impacts (salaries/wages/benefits, sole proprietor earnings): \$608 million
 Employment (full and part time): 21,480

All data for these commercial salmon impacts were not produced by Southwick Associates but instead were obtained directly from the National Marine Fisheries Service's (NMFS) annual report *Fisheries Economics of the United States, 2006* (Economic and Sociocultural Analysis Division, National Marine Fisheries Service, NOAA, Silver Spring, MD. 2007). The 2006 impacts provided in my estimates were not changed in any way as reported by NMFS. This source provided information on the number of fish harvested, the dollars per pound received by fishermen, and the economic impacts of these dollars, including the multiplier effects. These data were produced by NOAA Fisheries economists and statisticians. The commercial impact calculations were produced in a straightforward fashion. We assumed the impacts per fish would be the same as in 2006, and simply matched the impacts per pound with the total pounds harvested in 2004-05.

Looking back, salmon landings in 2004 and 2005 (6.06 million lbs) were well under historic landings from previous decades. If salmon can be re-established to historic levels, annual commercial harvests could realistically reach 25 million pounds. At such levels, assuming no change in the economic impacts per pound of fish landed from current levels, economic impacts from commercial salmon landings could reach:

Sales impacts (total sales that occur in the CA economy): \$4.83 billion
 Income impacts (salaries/wages/benefits, sole proprietor earnings): \$2.51 billion
 Employment (full and part time): 88,672

Recreational Fisheries:

Recreational impacts were produced using several sources. The number of salmon fishing trips in California in 2006 was measured by the California Department of Fish and Game via its *California Recreational Fisheries Survey* (CRFS). This same data source reported the total number of recreational fishing trips for salmon and all other species combined. With these data, we estimated the percentage of all California marine recreational fishing attributable to salmon.

The economic impacts generated by each marine sportfishing trip in California were also obtained directly from the National Marine Fisheries Service's (NMFS) *Fisheries Economics of the United States, 2006*. Just like the

P.O. Box 6435 Fernandina Beach Florida 32035
 904-277-9765 904-261-1145 (fax)
 Rob@southwickassociates.com www.southwickassociates.com



commercial fisheries data, the impact information including multipliers obtained from NMFS were not changed in any way. We matched the two data sources to estimate impacts attributable to recreational salmon fishing.

Economic impacts were not available specifically for salmon fishing. Instead, they were only available by fishing method such as fishing from a boat or from shore. Considering most salmon fishing is done from boats, we first determined the impacts generated by California marine anglers using boats. Next, an adjustment was made to account only for boat trips targeting salmon. According to CRFS, in 2004 and 2005, 14.82% of California's marine boat fishing trips targeted salmon. Assuming the economic impacts per trip are consistent regardless of species targeted, the economic impacts associated with salmon trips would have been expected to average approximately:

Total sales impacts (total sales that occur in the CA economy): \$204.8 million

Value-added impacts (salaries/wages/benefits, proprietors & property income, dividends, excise & sales taxes): \$107.2 million

Employment (full and part time): 1,345

Just like the commercial fisheries analysis presented earlier, the recreational analysis is based on 2004-2005 data. A healthy, well-managed fishery would reasonably be expected to allow for additional recreational fishing trips. If recreational fisheries could also increase by the same amount as commercial landings as described above (4.13 times greater than 2004-05 levels), and assuming the impacts for the additional trips remain consistent, the economic impacts could reach up to:

Total sales impacts (total sales that occur in the CA economy): \$845.8 million

Value-added impacts (salaries/wages/benefits, proprietors & property income, dividends, excise & sales taxes): \$442.7 million

Employment (full and part time): 5,555

Combined Commercial and Recreational Impacts:

By adding the result for the commercial and recreational analyses above, California had nearly 23,000 jobs related to salmon, and nearly \$1.4 billion in economic activity:



	<u>Sales Impacts</u>	<u>Jobs:</u>
Commercial	\$ 1.170 billion	21,480
Recreational	\$ 205 million	1,345
	-----	-----
Total	\$1.375 billion	22,825

If historical salmon harvests could be reached again, the impacts would increase significantly:

	<u>Sales Impacts</u>	<u>Jobs:</u>
Commercial	\$ 4.830 billion	88,672
Recreational	\$ 846 million	5,555
	-----	-----
Total	\$5.676 billion	94,227

We expect the former 2004-05 levels to be more realistic, but the latter results may hopefully encourage California to strive for greater habitat restoration goals.

If you have any questions, please do not hesitate to let me know. Thank you.

Sincerely,

Rob Southwick,
President

Senator MERKLEY. Additionally, Senators will be allowed to submit questions for the record through the close of business on Wednesday, August 14th, 2024. We will compile those questions, send them out to all of you, and we will ask for a reply, if possible, by Wednesday, August 28th, 2024.

With that, the hearing is adjourned. I apologize, we will not be coming down to say hello, because I am running out the door. Take care, and thank you.

[Whereupon, at 3:16 p.m., the hearing was adjourned.]

