No. 25-158
Consolidated with Nos. 25-572 and 25-573

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
and LEE ZELDIN, in his official capacity as
Administrator of the United States Environmental Protection Agency,

Respondents.

On Petitions for Review of a Final Agency Action of the
United States Environmental Protection Agency
89 Fed. Reg. 102,773 (December 18, 2024)

PETITIONERS' OPENING BRIEF

October 17, 2025

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RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Ninth Circuit Rule 26.1-1, Petitioners Alaska Community Action on Toxics and Environmental Defense Fund state that they are non-profit corporations, have no parent corporation, and no publicly held corporation owns 10% or more of their stock.

DATED: October 17, 2025

/s/ Michael Youhana
Michael Youhana

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INTRODUCTION

Alaska Community Action on Toxics and Environmental Defense Fund challenge a final regulation that unlawfully fast tracks the approval of some of the most dangerous chemicals—persistent, bioaccumulative, and toxic chemicals ("PBTs")—allowing them onto the market so long as they meet arbitrary criteria that do not protect health or the environment.

PBTs are among the worst of the worst: an insecticide known as DDT brought bald eagles to the brink of extinction; lead used in paint and gasoline continues to poison the brains of young children, decades after those products were banned; and today, so-called forever chemicals, per- and polyfluoroalkyl substances ("PFAS"), are found in municipal water systems, farmlands, and the bodies of 99% of adults. The danger of PBT chemicals lies in the fact that they persist and accumulate in the environment, making them incredibly difficult to clean up once they are released into the world.

In 2016, Congress amended the Toxic Substance Control Act ("TSCA")[1] to prevent such calamities from reoccurring. TSCA sets up a system of individualized review for every new chemical before it can be manufactured, which is designed to

[1] This acronym is typically pronounced "Tosca."

catch dangerous new chemicals and regulate them before they are introduced onto the market and cause harm.

However, in the challenged rulemaking, the Environmental Protection Agency ("EPA" or "Agency") thwarts Congress's intent by expressly exempting new PBT chemicals from the premanufacture review system for the first time ever. EPA's novel fast-track provision allows any new PBT chemical onto the market based on a cursory review, so long as the chemical meets arbitrary limits on production, release, or exposure that do not ensure the chemical is safe.

Fast tracking the approval of new PBTs is unlawful. TSCA only allows EPA to create such fast-track exemptions if the terms of the exemption regulation ensure, in advance, that new chemicals are safe—*i.e.* "will not present an unreasonable risk." 15 U.S.C. § 2604(h)(4). EPA has not met that standard here, as even EPA recognizes that the limits on production, releases, and exposures in its exemption regulations fail to ensure that new PBTs will not present unreasonable risk. That alone renders the rule unlawful. Furthermore, EPA's justification for its new rule—that there may be some hypothetical PBTs that do not release into the environment and cause no exposure—is arbitrary. It is doubtful that any such PBTs exist; indeed, EPA failed to identify a single one. And even if such PBTs did exist,

the rule sweeps far more broadly, allowing decidedly unsafe new PBTs to be manufactured.

Petitioners are non-profit organizations with members in fenceline communities near PBT-manufacturing facilities and in Alaska Native communities particularly at risk from PBTs. Petitioners seek to reduce their members' exposure to new PBTs in the air they breathe, the water they drink and fish in, the food they eat, and the products they use. Accordingly, Petitioners seek an order from this Court vacating the portion of EPA's new regulation that makes new PBTs eligible for fast-track review.

JURISDICTIONAL STATEMENT

The Courts of Appeals have exclusive jurisdiction to review rules issued under TSCA. 15 U.S.C. § 2618(a)(1)(A).

On December 18, 2024, EPA published the rule that is the subject of the consolidated petitions. ACAT-ER-004 (89 Fed. Reg. 102,773 (Dec. 18, 2024)) ("Final Rule"); *see also* 40 C.F.R. § 23.5 (specifying promulgation date for purposes of judicial review is two weeks from date of Federal Register publication). Petitioner Alaska Community Action on Toxics ("ACAT") timely petitioned this Court for review of the Final Rule on January 9, 2025. Petition for Review, No. 25-158, Dkt. No. 1.1; *see* 15 U.S.C. § 2618(a)(1)(A) (establishing 60-

day deadline to petition for review of TSCA rules). Venue is proper in this Circuit because ACAT's principal place of business is located within this Circuit. Miller Decl. ¶ 3; 15 U.S.C. § 2618(a)(1)(A).

On January 9, 2025, Petitioner Environmental Defense Fund ("EDF") timely petitioned the Second Circuit for review of the Final Rule, and the petition was subsequently transferred to this Court and consolidated with the other petitions challenging the Final Rule. Notice, No. 25-158, Dkt. No. 9.2; Consolidation Order, No. 25-158, Dkt. No. 9.3.

ISSUES PRESENTED

1. EPA found that new PBTs are inherently risky even if they comply with the terms of the low volume ("LVE") and low release and exposure ("LoREX") exemptions. Did EPA violate TSCA or act arbitrarily and capriciously by refusing to make new PBTs categorically ineligible for these exemptions to the more rigorous standard review process when EPA could not determine that new PBTs "will not present unreasonable risk" even when they comply with the terms of the exemption? 15 U.S.C. § 2604(h)(4).

2. EPA promulgated a new provision making every new PBT presumptively eligible for approval under the LVE and LoREX exemptions unless EPA affirmatively determines that the PBT will likely cause serious injury. 40

C.F.R. § 723.50(d)(2)(ii) ("PBT Fast-Track Provision" or "Fast-Track Provision"). Was EPA's promulgation of the PBT Fast-Track Provision in violation of TSCA and arbitrary and capricious because it makes PBTs eligible for the LVE and LoREX exemptions, even though the terms of the exemptions fail to ensure new PBTs "will not present an unreasonable risk" as required by 15 U.S.C. § 2604(h)(4)?

3. In a prior rulemaking, EPA made a category of chemicals ineligible for an exemption because EPA could not determine the category "will not present an unreasonable risk" under the terms of the exemption. Was EPA's promulgation of the Fast-Track Provision arbitrary and capricious because EPA failed to explain this departure from Agency precedent?

4. EPA sought to justify the PBT Fast-Track Provision by speculating that the LVE and LoREX exemptions could be used to safely manage new PBTs that result in zero releases and zero exposures. Was the promulgation of the Fast-Track Provision arbitrary and capricious because this hypothetical zero-release-zero-exposure rationale ignored Petitioners' contrary comments, was unsupported by evidence, and was unconnected to the regulatory text?

5. EPA claimed that the PBT Fast-Track Provision codified a 1999 policy governing the review of new PBTs. Was the Fast-Track Provision arbitrary

and capricious because EPA failed to respond to comments demonstrating that the Provision is inconsistent with the 1999 policy or to explain the Agency's departure from the policy?

STATUTES AND REGULATIONS

Pertinent statutes, regulations, and legislative history appear in the accompanying addendum.

STATEMENT OF THE CASE

I. Exposure to PBT Chemicals Endangers Human Health and the Environment.

Persistent, bioaccumulative, and toxic—or "PBT"—chemicals are amongst the most harmful and notorious chemicals. The pesticide DDT decimated bald eagle populations, bringing them to the brink of extinction, until it was banned. Polychlorinated Biphenyls ("PCBs") released by a General Electric plant over 50 years ago have contaminated a 200-mile stretch of the Hudson River, creating the largest Superfund site in the United States that continues to cause problems 20 years after cleanup began. Decades after bans on leaded gasoline and lead paint,

lead from those products remains in the environment, resulting in ongoing damage to the developing brains of young children.[2]

A. PBTs are more dangerous than other chemicals because of their persistence (P) and their bioaccumulative (B) properties.

What differentiates PBTs from other toxic chemicals is their persistence and potential to bioaccumulate. Persistence (P) means PBTs "remain in the environment for long periods of time." 84 Fed. Reg. 36,728, 36,731 (July 29, 2019). And bioaccumulation (B) means they "build up or concentrate in [the] body tissue" of people and other organisms exposed to them. *Id.*

As a result, EPA recognizes that PBTs are of special concern because: "(1) their persistence in the environment increases the likelihood of exposure of biological systems to those chemicals; [and] (2) their bioaccumulative potential increases the probability that they will move vertically through and become embedded in trophic chains"—*i.e.* food chains. ACAT-ER-248. Once a PBT

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[2] EPA, *Endangered Species: Save Our Species Information – Bald Eagle*, https://www.epa.gov/endangered-species/endangered-species-save-our-species-information-bald-eagle (last updated Aug. 6, 2025); ACAT-ER-262 ("Prominent examples of PBT chemical substances include the insecticide DDT and polychlorinated biphenyls (PCBs)."); NOAA, *Hudson River*, https://darrp.noaa.gov/hazardous-waste/hudson-river (last updated Apr. 11, 2025); EPA, *Third Five-Year Review of the Upper Hudson River Cleanup* (Jan. 2025), https://www.epa.gov/system/files/documents/2025-01/hudson_final3rdfyr_factsheet_english_2.pdf; EPA, *Learn about Lead*, https://www.epa.gov/lead/learn-about-lead (last updated Sept. 9, 2025).

chemical is released into the environment, it can be dangerous even "at low concentrations, [because] the combination of persistence and bioconcentration in organisms can result in residues high enough to approach a toxic dose." ACAT-ER-267; *see* ACAT-ER-248 (similar). Indeed, because of these characteristics, PBTs "can cause adverse health and ecological consequences for . . . years to decades or more." EPA, *Economic Analysis for Final Regulation of Decabromodiphenyl ether (DecaBDE) Under TSCA Section 6(h)* at 1-1 (Dec. 16, 2020), https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0080-0641.

B. It is critical to identify and manage the risks of PBTs before they enter commerce.

PBT chemicals are ubiquitous in modern society, and past experience demonstrates that, once PBT chemicals enter into commerce, they are likely to cause environmental contamination and harm people for years, or even decades, with the harm often not being recognized until years after.

1. Once PBT chemicals enter commerce, they can cause releases and exposures throughout their lifecycle—from initial manufacture, to processing into other products, distribution in commerce, and use, through ultimate disposal.

When PBTs are manufactured or processed at industrial sites, they release into local water and air, and as a result will quickly reach the communities that immediately surround the sites. *See, e.g.,* Agency for Toxic Substances and Disease

Registry, *Toxicological Profile for Perfluoroalkyls* at 648, 650–51 (May 2021), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf (summarizing documented groundwater and drinking water exposures of people living near chemical plants to a PBT PFAS); 84 Fed. Reg. at 36,740–41 (describing releases of PBT flame retardant from manufacturing and processing).

PBTs are also in widespread use in consumer products, resulting in exposure in the home. Brominated flame retardants are widely used in many household products—including televisions, computers, textiles, mattresses, and children's toys—which can then release these flame retardants into homes. 86 Fed. Reg. 880, 884–85 (Jan. 6, 2021); 84 Fed. Reg. at 36,734–35, 36,741. PFAS—known as "forever chemicals" because of how long they persist—are found in everyday household products like nonstick cookware and stain resistant furniture. EPA, *PFAS National Primary Drinking Water Regulation Fact Sheet* at 1 (Apr. 9, 2024), https://www.epa.gov/system/files/documents/2024-04/pfas-npdwr_fact-sheet_general_4.9.24v1.pdf.

Eventually, PBT-containing products reach the end of their useful life and have to be disposed of; and once sent to a landfill, recycler, or incinerator, they can cause significant environmental releases. *See* ACAT-ER-159; EPA, *Learn About Polychlorinated Biphenyls (PCBs)*, https://www.epa.gov/pcbs/learn-about-

polychlorinated-biphenyls (last updated Mar. 28, 2025) (discussing ongoing releases from landfills and incinerators); 84 Fed. Reg. at 36,740–41 (describing releases resulting from disposal of a PBT flame retardant).

2. These releases can lead to widespread environmental contamination and human exposure, which can cause harm long after a PBT is released. Repeated small releases of PBTs can build up over time, serving as a reservoir for the chemical and a source of ongoing exposure to plants, animals and humans, impacting whole ecosystems and the communities that live in and depend on these areas. And attempts at cleanup may fail, meaning people will continue to be exposed. As EPA recognizes: "Once PBT chemicals are released into the environment, they are often difficult or impossible to remediate." ACAT-ER-248 (emphasis added).

Thus, even as releases decrease—for example, because a chemical has been regulated or discontinued—harmful exposures can increase over time. *See* EPA, *Learn About Dioxin*, https://www.epa.gov/dioxin/learn-about-dioxin (last updated Jan. 18, 2025) ("In fact, a large part of current exposures to dioxins in the United States is due to releases that occurred decades ago."); *see also* EPA, *Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals* at 109 (Dec. 2020), https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0202-

0004/content.pdf (Environmental releases of decaBDE from ongoing use, recycling, and disposal of materials containing it "are likely to increase over time until the stock of available materials with decaBDE is depleted." (emphasis added)).

Although the use of PCBs was banned under TSCA almost 50 years ago, 15 U.S.C. § 2605(e) (1976), the chemical continues to release into the environment from existing products, landfill leaks, and waste incineration. EPA, *Learn About Polychlorinated Biphenyls (PCBs)*. For example, a portion of the Hudson River contaminated by PCBs from a General Electric plant is still in the process of being restored more than four decades after the area was listed as a Superfund site. NOAA, *Hudson River*. PCBs also persist throughout the Great Lakes and continue to present risks of exposure to people who might eat contaminated fish, such as lake trout or walleye. EPA, *Great Lakes Open Lakes Trend Monitoring Program: Polychlorinated Biphenyls (PCBs)*, https://www.epa.gov/great-lakes-monitoring/great-lakes-open-lakes-trend-monitoring-program-polychlorinated-biphenyls (last updated Nov. 27, 2024).

Difficulty remediating environmental releases of PBTs is not unique to PCBs. A now-shuttered lead-battery recycling plant in Los Angeles has required the cleanup of thousands of nearby homes, and the cleanup has been ongoing for

more than two decades. Cal. Dep't of Toxic Substances Control, *Exide Home*, https://dtsc.ca.gov/exide-home/(last visited Oct. 15, 2025). PFAS chemicals threaten the drinking water of at least 100 million U.S. residents, and "nearly all people in the U.S. have PFAS in their blood." EPA, *Biden-Harris Administration Finalizes First-Ever National Drinking Water Standard to Protect 100M People from PFAS Pollution* (Apr. 2024), https://www.epa.gov/newsreleases/biden-harris-administration-finalizes-first-ever-national-drinking-water-standard; Agency for Toxic Substances and Disease Registry, *Fast Facts: PFAS in the U.S. Population* (Nov. 12, 2024), https://www.atsdr.cdc.gov/pfas/data-research/facts-stats/index.html. One widely-used flame retardant has been detected in human blood, umbilical cord blood, and breast milk, as well as in fish, amphibians, birds, mammals, and invertebrates. EPA, *Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals*, at 60–69, 72–88, 108–109.

Because PBTs are so ubiquitous, people are typically not exposed to a single PBT in isolation, "but rather to a complex mixture of multiple [PBTs]" and their combined effects may be more harmful than the sum of the individual chemicals. *See, e.g.,* Stockholm Convention on Persistent Organic Pollutants, *Report of the Persistent Organic Pollutants Review Committee on the Work of its Tenth Meeting; Addendum: Risk Profile on Decabromodiphenyl Ether*

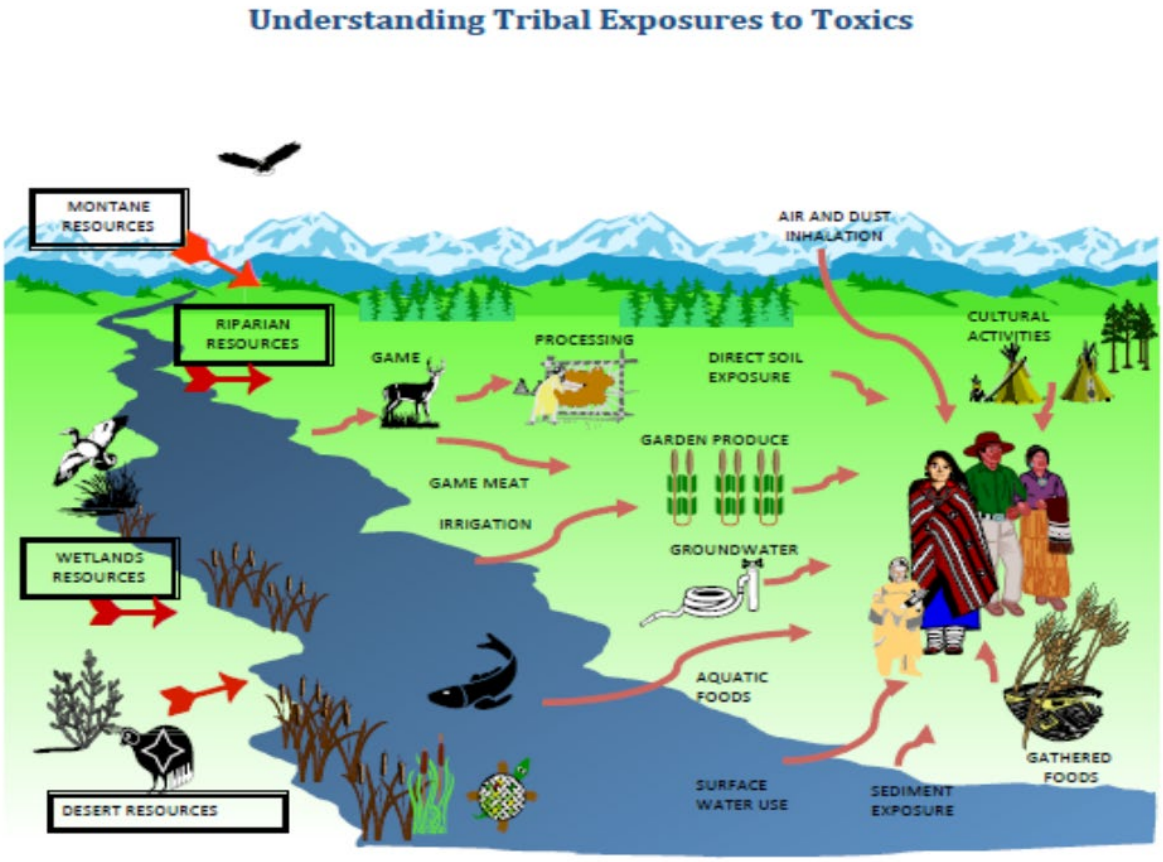
(Commercial Mixture, c-decaBDE) at 27–28 (Oct. 2014), https://chm.pops.int/TheConvention/POPsReviewCommittee/Reports/tabid/2301/ctl/Download/mid/7538/Default.aspx?id=17&ObjID=19072.

4. As demonstrated by the history of multiple PBTs—lead, PFAS, PCBs, and brominated flame retardants—the public, policy makers, and regulators often do not learn about the severe harm of PBT chemicals until years after the substances have exposed humans and the environment, with the widespread chemicals' toxic effects likely to continue for many years into the future. Thus, it is vital to appropriately regulate PBT chemicals before they get onto the market and then out into the world, when it is too late to prevent them from causing harm.

C. In order to protect Native Alaskans, it is necessary to manage the risks of new PBTs before they enter commerce.

Petitioner ACAT represents Native Alaskans, Indigenous people living in Alaska, whose health and way of life are threatened by widespread PBT contamination. *See generally* Miller Decl. PBTs manufactured and used in the mainland United States migrate thousands of miles on oceanic and atmospheric currents to Alaska in a process known as "global distillation." *Id.* ¶ 11. Once there, PBTs contaminate the traditional foods that Native Alaskans rely on for subsistence, including fish, marine mammals, and wild plants. *Id.* ¶¶ 11–13, 15; Waghiyi Decl. ¶ 4; Jemewouk Decl. ¶¶ 3–4. Whale and walrus meat relied upon by

some Native Alaskans have become so contaminated with PBTs that EPA recommends eating not more than one serving per month. Miller Decl. ¶ 15. These communities are uniquely exposed to PBTs through multiple additional pathways, as illustrated by EPA's tribal partnership group on toxic chemicals:



Nat'l Tribal Toxics Council, Understanding Tribal Exposures to Toxics at 8 (June 2015), https://nttc.sfo3.cdn.digitaloceanspaces.com/Docs/NTTC-Understanding_Tribal_Exposures_to_Toxics-2015-06-19.pdf.

As a result, Native Alaskans are among the world's most chemically contaminated populations, and are particularly overburdened by PBTs. Miller Decl. ¶ 15. PBTs are especially harmful to children and pregnant women in these communities, who have the some of the world's highest levels of PBT contamination in their blood and breast milk. *Id*. For example, women of child-bearing age in Alaska's Yukon-Kuskokwim Delta have the highest levels of toxic polybrominated diphenyl ethers of any population in the circumpolar Arctic. *Id*.

As one ACAT declarant states: "We cannot give up our traditional practices just to avoid exposure to POPs and other PBTs—it is our way of life as intended by our Creator. However, we are being contaminated without our consent." *See* Waghiyi Decl. ¶ 16. So long as PBTs are manufactured and released into the environment without proper regulation, these communities will continue to be contaminated without their consent. *Id*.

II. TSCA Establishes a System of Premanufacture Review to Prevent New Chemicals, Including New PBTs, from Causing Harm and Contamination.

A. Congress enacted TSCA to prevent chemical companies from experimenting on the public with dangerous new chemicals.

1. When Congress enacted TSCA in 1976, it sought to "assure that chemicals receive careful premarket scrutiny before they are manufactured," ending the status quo in which new chemicals "c[ould] be marketed without

notification of any governmental body and without any requirement that they be tested for safety." S. Rep. No. 94-698 at 3 (1976). To that end, Congress enacted a system of premanufacture review, recognizing that:

> [t]he most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest.

Id. at 5. This premanufacture review system was meant to prevent the all-too-common occurrence in which a toxic chemical becomes ubiquitous before its toxicity is apparent. *See id.* at 4–5 (noting a number of such PBT chemicals). These premanufacture review provisions would prevent "the public or the environment [from being] used as a testing ground for the safety of these products." *Id.* at 3.

2. TSCA established a Standard Review Process, requiring chemical companies to apply to EPA before they could begin manufacturing a new chemical in the United States, by submitting a premanufacture notice ("Premanufacture Notice" or "PMN").[3] 15 U.S.C. § 2604(a)(1) (1976). EPA was required to review each Premanufacture Notice to determine the risk posed by the new chemical and to regulate it as necessary—up to and including blocking market access—to

[3] Petitioners refer to the process for reviewing Premanufacture Notices as "the Standard Review Process" for simplicity.

prevent potential harm to human health or the environment. *Id*. § 2604(a), (e), (f) (1976).

The Premanufacture Notice had to include, among numerous categories of information, a description of reasonably ascertainable data relating to the new chemical's health and environmental effects. *Id.* § 2604(b), (d) (1976). EPA had 90 days to complete its review of the Premanufacture Notice, but could extend the review period by another 90 days "for good cause." *Id*. § 2604(a), (b), (c) (1976). However, if EPA failed to take action on an application within the review period, the manufacturer was free to commence manufacture. *Id*. § 2604(g) (1976).

3. Congress recognized that there might not be enough information about a new chemical to make an accurate and "reasoned" evaluation of how much risk it poses. *Id*. § 2604(e)(1)(A)(i) (1976). Precisely because new chemicals are new, there might not be "[]sufficient" information about their health effects, *id.,* for example, because no studies have been conducted. In situations where information is lacking, a new chemical "may present an unreasonable risk," and Congress authorized EPA to: (1) issue an order to regulate the new chemical; and (2) require more testing by the applicant to enable EPA "to evaluate the health and environmental effects of [the] chemical." *Id.* § 2604(e)(1)(A), (2)(D) (1976).

B. TSCA established a high bar for EPA to exempt a category of chemicals from the standard premanufacture review process.

As relevant here, Congress authorized EPA to issue "rule[s]" that create exemptions from the Standard Review Process, and these exemption rules may cover a category of chemicals.[4] *Id.* §§ 2604(h)(4), 2625(c) (1976) (authorizing regulation by "category"). "[U]pon application and by rule" EPA may exempt a category of chemicals from the Standard Review Process if EPA determines the terms of the exemption ensure the category "will not present an unreasonable risk of injury to health or the environment." *Id.* § 2604(h)(4) (1976) (emphasis added).

When creating or modifying an exemption rule, EPA must find that the category of "new chemical substances eligible for the exemptions will not present an unreasonable risk . . . under the terms of the exemption[]." 60 Fed. Reg. 16,336, 16,345 (Mar. 29, 1995) (describing statutory test for exempting a category of chemicals). In other words, the terms of an exemption rule must create safeguards sufficient for EPA to determine, in advance, that a category of new chemicals will not present unreasonable risk. *Id.*

[4] TSCA established a limited set of statutory exemptions from the Standard Review Process as well. *See, e.g.,* 15 U.S.C. § 2604(h)(1) (1976) (test marketing exemption), § 2604(h)(3) (1976) (research and development exemption).

That is a high bar. EPA may create an exemption with less rigorous, expedited review procedures, but only if the Agency is certain that the exemption rule contains substantive limits that will keep people and the environment safe from a chemical approved under the exemption. If EPA cannot make this determination, it cannot create an exemption and chemicals must instead go through the Standard Review Process, where they will receive comprehensive, individualized review and regulation, if warranted. That fulfills TSCA's overarching purpose to "prevent the general environment from becoming the laboratory in which harmful effects of chemicals are discovered." *Dow Chem. Co. v. EPA*, 605 F.2d 673, 676 (3d Cir. 1979).

C. EPA created the LVE and LoREX Exemption rules to fast track the approval of new chemicals if specified limits on production, release, and exposure are met.

1. Following TSCA's enactment, EPA created the Low Volume Exemption ("LVE") and Low Release and Exposure Exemption ("LoREX") (together, the "Exemptions"). These Exemptions allow EPA to fast track the approval of new chemicals that meet specific production, release, or exposure criteria. 50 Fed. Reg. 16,477, 16,478 (Apr. 26, 1985); 60 Fed. Reg. at 16,336–38.

A new chemical is eligible for the LVE if it is "manufactured in quantities of 10,000 kilograms or less per year." 40 C.F.R. § 723.50(c)(1) (1995). A new

chemical is eligible for the LoREX if it meets criteria relating to release and exposure, such as: no dermal exposure; no inhalation exposure (except from certain air releases from incineration); and drinking water exposure and surface water concentrations under specified thresholds. *Id.* § 723.50(c)(2) (1995).

Under these Exemptions, a chemical manufacturer submits a "notice[]" (*i.e.* an application) to EPA before manufacturing a new chemical. *Id.* § 723.50(a)(2) (1995). The Agency then has just 30 days to review the application and determine whether the application meets the term of an Exemption, rather than the full 90-to-180-day timeframe in the Standard Review Process. *See id.* § 723.50(g)(1) (1995).[5]

2. As EPA recognizes, the 30-day review under the Exemptions is less "detailed and comprehensive" than the 90-to-180-day review for the Standard Review Process. ACAT-ER-006; *see also* ACAT-ER-016. Additionally, unlike the Standard Review Process, EPA does not "require testing or impose additional restrictions [by order]" for a chemical approved under the Exemptions. *Id.* Together, those deficiencies can make it difficult to "address . . . uncertainties" regarding the risk of a particular a new chemical. *Id.*

[5] The relevant limits on production volumes, releases, and exposures, as well as the 30-day length of the review period, remain unchanged even after issuance of the challenged Final Rule. *Compare* 40 C.F.R. § 723.50 (1995) *with* 40 C.F.R. § 723.50.

3. The chemical industry uses the Exemptions to avoid the Standard Review Process in order to get toxic chemicals quickly approved by EPA. For example, chemical industry attorneys have stated that obtaining an exemption is an "attractive option for high-toxicity substances," because "[i]f submitted as a [Premanufacture Notice], the same substance might well wind up being regulated" by EPA. Keller & Heckman LLP, *The Constantly Pending PMN: Low Volume Exemption Applications Are Living Documents*, Martindale (Mar. 16, 2011), https://www.martindale.com/chemicals/article_Keller-Heckman-LLP_1255440.htm. The industry also sees "advantage[s]" because of the shortened "30-day review." *Id.*; *see also* ACAT-ER-016 (noting "the shortened 30-day review period . . . is one of the major benefits of these [E]xemptions as it allows companies to introduce new chemical substances more quickly into commerce.").

Consequently, chemical manufacturers submit hundreds of applications per year to manufacture new chemicals under the Exemptions. *See* EPA, *Exemptions Table*, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/exemptions-table (last updated Oct. 14, 2025) (identifying, in the "Case Number" field, LVE applications with an "L" and LoREX applications with an "X").

Indeed, for fiscal year 2025, applications under the LVE Exemption, alone, outnumber applications under the Standard Review Process. *Compare id.* (identifying 196 LVE applications submitted in FY2025 with "L-25") *with* EPA, *Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) Table*, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and (last updated October 14, 2025) (identifying 154 PMN applications submitted in FY2025 with "P-25").

D. After EPA created the LVE and LoREX Exemptions, it recognized that new PBTs are a category of chemicals that are uniquely risky and difficult to review.

1. In 1999, EPA first established new PBTs as a category of chemicals for conducting premanufacture review. ACAT-ER-260 ("1999 PBT Policy") (establishing "a category of persistent, bioaccumulative, and toxic (PBT) new chemical substances"); *see* 15 U.S.C. § 2625(c) (1976) (authorizing EPA to regulate by "category"). EPA recognized that PBTs were "priority pollutants and potential risks to humans and ecosystems" and that establishing new PBTs as a distinct category "is a major element in the Agency's overall strategy to further reduce risks from PBT pollutants." ACAT-ER-262.

2. Central to the 1999 PBT Policy was a recognition that additional testing was vitally important for new PBTs. First, the Policy contemplated that

applications to manufacture new PBTs would go through the Standard Review Process. *See* ACAT-ER-268-69. After completing that review, EPA would issue orders for new PBTs, requiring additional testing to develop more information about their risks (which is not an option under the Exemptions). *Id.*; *see* 15 U.S.C. § 2604(e) (1976) (authorizing testing). Indeed, new PBTs would be barred from manufacture if they were very persistent and very bioaccumulative—*i.e.* exceeded certain numerical persistence and bioaccumulation criteria. ACAT-ER-268-69. In those cases, companies would be required to submit test data before any manufacture could begin. *Id.* (describing the "Ban Pending Testing" approach).

E. In 2016, Congress overhauled TSCA and strengthened the premanufacture review process for new chemicals.

1. Congress significantly revised the unreasonable risk standard and thereby raised the bar for creating exemption rules and approving exemption applications. First, Congress mandated that EPA consider risks faced by "potentially exposed or susceptible subpopulations"—communities who are more susceptible to exposure to toxic chemicals, such as children, pregnant women, or communities already overburdened by pollution—not just the risks faced by the general population. 15 U.S.C. § 2604(a)(3), (h)(4) (mandating specific consideration of risks to such "potentially exposed or susceptible subpopulation[s]"); *id.* § 2602(12) (defining "potentially exposed or susceptible

subpopulation"); *cf.* 40 C.F.R. § 702.33. EPA has recognized that this definition can cover "[t]ribal communities where reliance on subsistence fishing results in increased chemical exposure via ingestion." 89 Fed. Reg. 37,028, 37,040 (May 3, 2024).

Second, Congress redefined the meaning of unreasonable risk—prohibiting the consideration of "costs and other non-risk factors." *E.g.,* 15 U.S.C. § 2604(a)(3). Assessing the risks posed by new chemicals is now a strictly scientific endeavor.

2. Congress also required EPA to make an affirmative determination on each new chemical application before manufacture could begin, thereby prohibiting the automatic approval of applications where EPA had failed to timely act. *See* 15 U.S.C. § 2604(a)(1)(B)(ii); ACAT-ER-005 (summarizing amendments); *see also* Kevin McLean, Harv. L. Sch., *Three Years After—Where Does Implementation of the Lautenberg Act Stand?* at 19–20 (Feb. 26, 2020), https://eelp.law.harvard.edu/wp-content/uploads/2025/05/McLean-TSCA.pdf. Previously, if EPA did not render a determination within the review period, the application was automatically deemed approved and the applicant could begin manufacturing the new chemical. *See supra* at 17 (citing 15 U.S.C. § 2604(g) (1976)). Consequently, "EPA issued risk determinations for approximately 20% of

new chemical submissions. In 80% of cases, EPA 'dropped' the chemical from further review and allowed it to go to market." EPA, *Statistics for the New Chemicals Program Under TSCA* (Aug. 4, 2025), https://web.archive.org/web/20250812181743/https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-program. Similarly, applications under the LVE and LoREX Exemptions were deemed approved if EPA did not act within the applicable 30-day review period. *See* 40 C.F.R. § 723.50(g)(2) (1995).

Congress put a stop to approvals based on the expiration of the review period, which had undermined the new chemicals review system and endangered public health, allowing manufacturers to commence production of chemicals before EPA had evaluated their risks and decided whether regulation was necessary.

III. The Final Rule Expressly Fast Tracks the Approval of New PBTs under the LVE and LoREX Exemptions for the First Time.

1. In 2023, EPA proposed to amend the regulations governing new chemicals review to "align" the regulations to the 2016 TSCA Amendments. ACAT-ER-234, ACAT-ER-250 ("Proposed Rule"). EPA repeatedly recognized the need to ensure the regulations—including the exemption rules issued under Section

2604(h)(4)—reflect the new requirements to protect "potentially exposed or susceptible subpopulation[s]." *See, e.g.,* ACAT-ER-237.

In light of the 2016 Amendments, EPA recognized a need to modify the LVE and LoREX Exemptions. *See* ACAT-ER-246-49. EPA proposed to end the practice where, if the 30-day review period expired, approval of an application resulted. Under the Proposed Rule, before an applicant could begin manufacture of a new chemical, EPA would be required to make a determination that the chemical complies with the terms of an Exemption. *See* ACAT-ER-258 (third column). EPA also proposed to make the category of PFAS chemicals categorically ineligible for the Exemptions due, in part, to their "longevity and persistence in the environment." ACAT-ER-247; *see also* ACAT-ER-247-49.

2. EPA also recognized the need to restrict the eligibility of new PBTs under the LVE and LoREX Exemptions because PBTs are inherently risky. EPA found that "[w]hen exposure of the environment or biological organisms (including humans) to a PBT chemical is expected, one or more of the conditions above (*i.e.*, serious acute or chronic effects or significant environmental effects) is generally likely to occur, often making the PBT chemical ineligible for the exemptions." ACAT-ER-249.

But EPA took a different approach than what it proposed for PFAS. Instead of proposing to make all new PBTs ineligible for the Exemptions, EPA's proposal would only make a subset ineligible: those new PBTs for which EPA affirmatively determined there would be "anticipated environmental releases and potentially unreasonable exposures." ACAT-ER-258. EPA claimed the newly proposed eligibility criteria reflected long-standing EPA practices that implemented the Agency's 1999 PBT Policy. ACAT-ER-249.

3. Petitioners submitted extensive comments objecting to this proposal. These comments explained that the limits in the LVE and LoREX Exemptions do not protect against the inherent risks posed by PBTs, and therefore, EPA must make new PBTs categorically ineligible for the Exemptions. *See* ACAT-ER-157-60 ("ACAT Comments"); ACAT-ER-225-32 ("EDF Comments"). Furthermore, Petitioners noted that while EPA's proposal referenced the 1999 PBT Policy, it misstated the Policy's scope and effects and failed to codify the core of the Policy: that new PBTs would go through the Standard Review Process and be subject to orders for additional testing. *See* ACAT-ER-231.

Commenters urged EPA to simply make all new PBTs categorically ineligible for expedited approval under the Exemptions and to require new PBTs to be evaluated under the Standard Review Process. ACAT-ER-157-60; ACAT-ER-

225-32. Commenters noted that the 30-day review process for the Exemptions was likely insufficient to carry out a careful, individualized review to assess the risks posed by each new PBT. *See* ACAT-ER-231. Such individualized review is necessary to ensure that EPA does not mistakenly allow the next DDT or PCB onto the market.

4. Largely ignoring these comments, EPA issued the Final Rule, for the first time expressly authorizing the expedited approval of new PBT chemicals under the LVE and LoREX Exemptions. ACAT-ER-029 (Final Rule) (codifying 40 C.F.R. § 723.50(d)(2)(ii)). Under this new Fast-Track Provision, every new PBT is eligible for approval under the Exemptions, unless EPA affirmatively determines that an individual new PBT will result in "anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms." *Id.*

SUMMARY OF ARGUMENT

In promulgating the PBT Fast-Track Provision, 40 C.F.R. § 723.50(d)(2)(ii), EPA violates TSCA. The Provision allows EPA to expedite approval of new PBT chemicals under the LVE and LoREX Exemptions, even though the terms of those Exemptions fail to ensure that the PBT chemicals "will not present an unreasonable risk . . . including . . . to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(h)(4). Circumventing the Standard Review

Process in this manner violates that statutory standard and is arbitrary and capricious.

I.A. In this rulemaking EPA itself recognized that new PBTs are inherently risky and that the terms of the Exemptions—*i.e.* the numerical limits on production (LVE) or releases and exposure (LoREX)—do not sufficiently protect against that risk. Indeed, EPA has never determined that those limitations ensure that the category of new PBT chemicals "will not present an unreasonable risk," as the statute requires. 15 U.S.C. § 2604(h)(4). Accordingly, EPA cannot say that the Exemptions protect subpopulations—like those living at the fenceline of chemical manufacturing plants or Native Alaskans who rely on foods likely to be contaminated by new PBTs—let alone the general population. Thus, in this rulemaking, EPA was required to make new PBTs ineligible for approval under the Exemptions. EPA's refusal to do so violates TSCA and is arbitrary.

I.B. The Fast-Track Provision turns the statute on its head, for the first time affirmatively authorizing the approval of dangerous new PBTs under the Exemptions. Under the Provision, every new PBT is presumptively eligible for expedited approval unless EPA affirmatively determines that a chemical potentially results in unreasonable exposure, which even EPA acknowledges will likely cause serious injury—*i.e.* death, incapacitation, or disfigurement. That violates TSCA

Section 2604(h)(4), which requires EPA to determine, with certainty, that the terms of an exemption rule will prevent such injuries before making a category of chemicals eligible. Instead, the terms of the new Provision now require EPA to prove such injuries will occur in order to reject an application for a new PBT.

I.C. EPA's action is also arbitrary because it is inconsistent with prior EPA precedent where EPA did make a category of new chemicals ineligible for another exemption.

II.A. EPA's justification confirms the arbitrary nature of its action. The Agency claims that the Fast-Track Provision could be used to manage hypothetical PBTs used in closed-loop systems with no releases and no exposures. But this hypothetical is an unsupported fiction: EPA simply ignored evidence that even when used in a closed-loop, new PBTs will eventually have to be disposed of, resulting in some releases and some exposures, which will contaminate the environment and cause injury to people and other organisms. Because of this reality, EPA was unable to identify a single real-world example that matched its zero-release-zero-exposure hypothetical. Moreover, even if this fanciful scenario was not purely hypothetical, the Fast-Track Provision would still not be justified, because the plain text of the Provision authorizes approval of new PBTs with some

exposures. If EPA's goal was to allow for the approval of only zero-release-zero-exposure PBTs, it needed to write a different, narrower provision.

II.B. Finally, EPA claims the Fast-Track Provision codifies the Agency's 1999 PBT Policy, but as Petitioners pointed out in comments, the new Provision conflicts with that policy and EPA failed to respond to those comments.

III. The Court should partially vacate the Fast-Track Provision—excising the language requiring EPA to affirmatively determine that there are "anticipated environmental releases and potentially unreasonable exposures"—and thereby make new PBTs categorically ineligible for approval under the Exemptions. Here, vacatur will ensure that if a company applies to manufacture a new PBT, the chemical will go through the Standard Review Process. In that review, the new PBT will receive individualized scrutiny, individualized regulations tailored to its unique risks, as appropriate, and likely additional ongoing testing. Such individualized review is fully supported by EPA's own findings, and is the default mandate of TSCA.

IV. Doing so would remedy the harm the Fast-Track Provision will inflict on Petitioners and their members, because the Provision threatens them with increased exposure to new PBTs and denies them useful information that EPA would otherwise have to disclose to them.

STANDARD OF REVIEW

TSCA's judicial review provision incorporates the Administrative Procedure Act's standard that requires courts to set aside an EPA action that is "arbitrary, capricious, an abuse of discretion . . . otherwise not in accordance with law[, or] in excess of statutory . . . authority." 5 U.S.C. § 706(2)(A), (C); 15 U.S.C. § 2618. Agency action is arbitrary and capricious when "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Judicial review, while "deferential," must be "thorough, probing, [and] in-depth." *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric.*, 415 F.3d 1078, 1093 (9th Cir. 2005) (citation modified).

ARGUMENT

I. The Final Rule Violates TSCA and Is Arbitrary Because it Fast Tracks the Approval of Inherently Risky New PBTs.

A. EPA's refusal to make PBTs categorically ineligible for the LVE and LoREX Exemptions violates TSCA and is arbitrary.

TSCA requires EPA to make a chemical category ineligible for an exemption where the category may present unreasonable risks of injury even when complying with the terms of the exemption. *See* 15 U.S.C. §§ 2604(h)(4), 2625(c). The record, including EPA's own findings, establishes that the category of new PBTs may—indeed, will likely—present unreasonable risk even when complying with the terms of the LVE and LoREX Exemptions. Thus, EPA was required to make new PBTs categorically ineligible for the Exemptions, and its refusal to do so in the Final Rule is unlawful and arbitrary. *See* ACAT-ER-004 (Final Rule) (making only "certain… PBT… chemical substances . . . ineligible for these [E]xemptions.") (emphasis added).

1. Where the terms of an exemption fail to ensure a category of chemicals "will not present an unreasonable risk," EPA must make the category ineligible for fast-track approval.

1. TSCA authorizes EPA to create a rule exempting new chemicals from the Standard Review Process but only if EPA determines the terms of the exemption rule ensure that chemicals approved under the exemption "will not" present unreasonable risk. 15 U.S.C. § 2604(h)(4); *see* 50 Fed. Reg. at 16,487

("EPA has determined that substances manufactured under the terms of this exemption rule will not present an unreasonable risk." (emphasis added)).[6]

2. If, after EPA has created an exemption, EPA determines that the terms of the exemption no longer ensure that a particular category of chemicals "will not present an unreasonable risk," EPA must make that category ineligible for approval under the exemption. *See* 15 U.S.C. §§ 2604(h)(4), 2625(c). EPA has acknowledged that obligation, stating where "EPA can no longer conclude that [a category of new chemicals] will not present an unreasonable risk to human health or the environment under the terms of [an] exemption rule," EPA must make the category ineligible under the exemption. 75 Fed. Reg. 4,295, 4295 (Jan. 27, 2010) (citation modified) (describing this as "the determination necessary to support an exemption under TSCA [Section 2604(h)(4)]"); *see id.* 4,299–301 ("excluding" a category of polymers from eligibility under a different exemption to the Standard Review Process).

[6] EPA itself also recognized in this rulemaking that "EPA may exempt a chemical substance from section 5 requirements upon application and by rule only if EPA determines the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk." ACAT-ER-249.

3. In other words, EPA must make a category of chemicals ineligible for an exemption if chemicals in the category may present unreasonable risk, even when manufactured in compliance with the terms of an exemption.

Unlike other provisions governing the review of new chemicals, the "will-not-present" standard of Section 2604(h)(4) requires certainty. For example, TSCA establishes different standards for different EPA regulatory actions on a new chemical under the Standard Review Process, all of which incorporate uncertainty, including: (1) finding that the information available to EPA is "insufficient to permit a reasoned evaluation of the health . . . effects" of the new chemical; (2) finding that the EPA only has enough information to say a new chemical "may present" unreasonable risk, but not enough information to make a definitive determination; and (3) finding that a chemical is "not likely" to present unreasonable risks. 15 U.S.C. § 2604(a)(3)(B)(i), (ii), (a)(3)(C), (e).

If EPA cannot be certain in advance that the terms of an exemption ensure a category meets the will-not-present standard, the Agency must make the category ineligible. *See Secs. Exch. Comm'n v. McCarthy*, 322 F.3d 650, 656 (9th Cir. 2003) ("It is a well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a

different meaning for those words." (citing *Russello v. United States,* 464 U.S. 16, 23 (1983))).

4. When EPA makes a category ineligible under a particular exemption, chemicals in the category can still be approved for manufacture, but they must go through the Standard Review Process (or some other exemption, if eligible). This ensures that each new chemical will receive a "more detailed and comprehensive review and analysis" of the distinct risks posed by the chemical than is possible in the rushed, 30-day exemption review period. ACAT-ER-016. Moreover, under the Standard Review Process, if regulation is necessary, each chemical will receive regulations tailored to their unique risks, rather than simply having to comply with the generic terms of an exemption. Equally important, if EPA finds the risks of the chemical are uncertain, EPA must require more testing, an option that is not available under an exemption. 15 U.S.C. § 2604(e); ACAT-ER-016 (EPA does not "require testing" under its Exemption regulations.).

2. EPA found that the terms of the LVE and LoREX Exemptions do not protect against the inherent risks of new PBTs, but refused to make new PBTs ineligible.

EPA's findings in the Final Rule confirm that the terms of the LVE and LoREX Exemption rules—*i.e.* the numerical limits they place on production volumes and chemical releases—fail to ensure that the category of new PBT

chemicals "will not present an unreasonable risk." 15 U.S.C. § 2604(h)(4). Accordingly, EPA was required to make new PBTs ineligible for approval under those Exemptions. EPA's refusal to do so is unlawful.

1. EPA's own findings and the record, as a whole, establish that new PBTs inherently may present unreasonable risk. By EPA's definition, new PBTs are chemicals that inherently "result[] in potential risks to humans and ecosystems" because such substances persist in the environment, accumulate in organisms, and are toxic—*i.e.* because they are PBTs. *See* 40 C.F.R. § 723.50(b)(12) (emphasis added). EPA also found that "[w]hen exposure of the environment or biological organisms (including humans) to a PBT chemical is expected . . . serious acute or chronic effects or significant environmental effects . . . [are] generally likely to occur." ACAT-ER-249 (emphasis added).

EPA concluded that new PBTs "are of special concern" because "their persistence and bioaccumulation potential, coupled with toxicity concerns, can result in risk to biological systems." ACAT-ER-248 (emphasis added). Those potential risks and likely serious or significant effects mean that new PBTs inherently may present unreasonable risk.

2. The terms of the Exemptions do not protect against those inherent risks—*i.e.* they fail to ensure that new PBTs "will not present an unreasonable

risk" as TSCA requires. 15 U.S.C. § 2604(h)(4). The LVE and LoREX Exemptions authorize the manufacture of chemicals either where: (1) production quantities are below 10,000 kilogram per year, 40 C.F.R. § 723.50(c)(1) (the LVE); or (2) releases of the chemical into the environment and exposures are below certain thresholds (*e.g.* no incinerator releases above 1 microgram per cubic meter maximum annual average concentration), 40 C.F.R. § 723.50(c)(2) (the LoREX).

Those limitations on production and exposure fail to ensure that new PBTs "will not present an unreasonable risk" including to "potentially exposed or susceptible subpopulation[s]." 15 U.S.C. § 2604(h)(4). When EPA established and updated the Exemptions in 1985 and 1995, the Agency did not analyze whether the Exemptions' numeric thresholds protected people or the environment from PBTs. *See, e.g.,* 60 Fed. Reg. at 16,336 (absence of any discussion of PBTs); 50 Fed. Reg. at 16,477 (similar). The Agency could not have been expected to do so because EPA did not even identify new PBTs as a distinct chemical category until 1999. *See* ACAT-ER-260 (1999 PBT Policy).

Similarly, EPA never analyzed whether the terms of the LVE and LoREX Exemptions protect relevant subpopulations—like children, Native Alaskans who rely on traditional foods, or communities at the fenceline of chemical plants. The obligation to protect such subpopulations was only established by Congress in the

2016 Amendments, long after the Exemptions were established. *Compare* 15 U.S.C. § 2604(h)(4) (requiring protection of subpopulations) *with id.* § 2604(h)(4) (1976) (no such requirement).

In other words, EPA has never analyzed and determined that the LVE's 10,000 kilogram production limit protects a community from a new PBT manufactured at a nearby plant. Similarly, EPA has never analyzed or determined that the LoREX's limits on consumer, worker, and general population exposures protect a Native Alaskan from eating fish or whale contaminated by dangerous levels of a new PBT. Indeed, EPA has never analyzed these limits with respect to PBTs at all.

And in the challenged rulemaking, EPA conducted no analysis to remedy these deficiencies.

3. Accordingly, in the Final Rule, EPA was required to make new PBTs ineligible for approval under the Exemptions because the Agency could not (and did not) determine that communities and the environment would be safe if new PBTs were manufactured under the terms of the Exemptions. *See* 15 U.S.C. § 2604(h)(4). Doing so was necessary to achieve EPA's stated goal "to align the regulatory text" of the Exemptions "with the amendments to TSCA's new

chemicals review provisions" and with the Agency's own findings about the inherent risks of PBTs. ACAT-ER-234; *see also* ACAT-ER-248-49.

EPA itself recognized the need to limit the eligibility of new PBTs under the Exemptions. For example, EPA noted that the existing Exemption terms "do not expressly disqualify" the category of new PBTs, despite the fact that new PBTs "often" may present unreasonable risks. ACAT-ER-249; *see also id.* ("EPA's specific concerns for PBT chemicals as they relate to [the Exemptions] are not separately codified in the existing regulations.").

4. EPA's refusal to make PBTs categorically ineligible violates TSCA, 15 U.S.C. § 2604(h)(4), and is arbitrary and capricious, *see State Farm*, 463 U.S. at 43 (an action is arbitrary if there is not a "rational connection between the facts found and the choice made") (citation modified).

B. The Fast-Track Provision affirmatively authorizes the approval of new PBTs under the LVE and LoREX Exemptions without safeguarding health or the environment, which violates TSCA and is arbitrary.

1. The Fast-Track Provision requires EPA to prove a new PBT is unsafe to be ineligible for the Exemptions, which violates the will-not-present standard.

The terms of the Fast-Track Provision turn the statute on its head, making each and every new PBT eligible for expedited review under the Exemptions unless EPA affirmatively determines that a specific PBT is unsafe. In effect, the

rule treats an absence of evidence as a reason to expedite the approval of a new PBT chemical, rather than a reason to deny an exemption application and require the new PBT to go through the Standard Review Process.

1. By its plain terms, the Fast-Track Provision greenlights the approval of any new PBT under the Exemptions, unless EPA makes an affirmative determination that a specific PBT is associated with both "anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms." 40 C.F.R. § 723.50(d)(2)(ii) (emphasis added). Unless EPA makes both findings, a new PBT "can[] be manufactured" under either Exemption. *Id.* § 723.50(d). Thus, if EPA lacks exposure or release information that would allow it to make these twin determinations—as is often the case for novel new PBTs that are not currently manufactured or in use—a new PBT would be eligible under the Fast-Track Provision.

In effect, the rule treats an absence of evidence on releases and exposures as a reason to approve an exemption for a new PBT chemical, rather than a reason to deny the application. Given that new PBTs may present unreasonable risk—even when meeting the Exemptions' limits on production or release and exposure—requiring EPA to make these additional affirmative findings violates TSCA's will-not-present standard. 15 U.S.C. § 2604(h)(4). On this record, EPA was required to

make new PBTs categorically ineligible for the Exemptions, without the need for any further affirmative findings.

2. Moreover, requiring EPA to determine that there are releases and exposures is tantamount to requiring EPA to determine that a new PBT likely presents unreasonable risk. This is because, as EPA acknowledged, if there are "exposure[s]" to a PBT chemical, "serious acute or chronic effects or significant environmental effects [are] generally likely to occur"—such as "death, severe or prolonged incapacitation, [or] disfigurement." ACAT-ER-249 (emphasis added); 40 C.F.R. § 723.50(b)(6)–(8) (defining "serious acute," "serious chronic," and "significant environmental" effects). In other words, the Fast-Track Provision establishes that a new PBT is only ineligible for expedited review if EPA affirmatively determines the chemical "likely" presents an unreasonable risk of injury. ACAT-ER-249. Every other new PBT is eligible for the Exemptions.

That is the precise opposite of what TSCA demands. Instead of requiring EPA to determine, with certainty, that a new PBT is safe (*i.e.* "will not present an unreasonable risk") before granting an Exemption application, the terms of the Provision require EPA to prove that a new PBT is unsafe in order to reject it. 15 U.S.C. § 2604(h)(4).

2. The Fast-Track Provision hinges on a nonsensical "unreasonable exposure" standard, which is arbitrary.

1. The Fast-Track Provision ties exemption eligibility to whether there are "potentially unreasonable exposures" to a new PBT, 40 C.F.R. § 723.50(d)(2)(ii), but that neologism "is nonsensical" within the context of TSCA. *Idaho Power Co. v. Fed. Energy Reg. Comm'n*, 312 F.3d 454, 461 (D.C. Cir. 2002), as amended on reh'g (Mar. 5, 2003).

Under TSCA, whether an exemption can be granted is based on "risk," which is a function of hazard and exposure. 15 U.S.C. § 2604(h)(4); 60 Fed. Reg. at 16,345 ("Risk is the combination of the hazard presented by a chemical substance or category of chemical substances and the exposure of humans or the environment to the substances or category.") Thus, to determine risk to people, the Agency must compare (1) the estimated amount of the chemical people take in through air, water, etc. (exposure) with (2) scientific information about the harms the chemical causes and the dose at which the chemical causes harm (hazard). *See* 60 Fed. Reg. at 16,345. By integrating these two assessments to see whether the level of exposure exceeds the dose that causes harm, the Agency determines whether there is risk of injury.

Under this statutory framework, the concept of an "unreasonable exposure" is nonsensical because it only assesses one element of risk, exposure, while

ignoring the other, hazard. Ingesting one liter of water and one liter of gin will have vastly different effects even though the exposure is the same, because they have different hazards. It would be nonsensical to refer to ingesting one liter of liquid as either a reasonable or an unreasonable exposure without specifying the liquid. So too for new PBTs.

2. To the extent the Fast-Track Provision uses "unreasonable exposure" as shorthand to mean that EPA will assess the potential exposures of each new PBT and compare those exposures to the PBT's potential hazard, the Provision fares no better. In that case, by comparing hazard and exposure, EPA is assessing risk, and "unreasonable exposure" is just a euphemism for "unreasonable risk." And under that reading, the Fast-Track Provision makes new PBTs ineligible only if EPA affirmatively determines they have "potentially unreasonable exposures"—*i.e.* potentially unreasonable risks. 40 C.F.R § 723.50(d)(2)(ii). That would violate TSCA's will-not-present standard, which instead requires that EPA prove a new chemical is safe before approving it under an exemption, not find it is unsafe as a prerequisite for rejecting it. 15 U.S.C. § 2604(h)(4).

3. Commenters raised these very points, yet EPA did not acknowledge them, let alone respond, rendering the rule arbitrary and capricious. ACAT-ER-231-32 (EDF Comments) (raising issue); ACAT-ER-120-25 ("Response to

Comments") (failing to respond); *see Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) ("An agency must consider and respond to significant comments."); *also Ohio v. EPA*, 603 U.S. 279, 293–94 (2024) (An agency that offers "no reasoned response" to comments "fail[s] to supply a satisfactory explanation," and thereby, acts arbitrarily. (citation modified)).

C. The Fast-Track Provision contravenes EPA's prior precedents and practices, which is arbitrary.

Finally, the Fast-Track Provision is arbitrary because it "fails to follow [EPA's] own precedent [and] fails to give a sufficient explanation for failing to do so." *Andrzejewski v. Fed. Aviation Admin.*, 563 F.3d 796, 799 (9th Cir. 2009); *Kentucky Mun. Energy Agency v. Fed. Energy Reg. Comm'n*, 45 F.4th 162, 178 (D.C. Cir. 2022) (similar).

The Fast-Track Provision contradicts EPA's prior precedent making a category of chemicals ineligible for exemptions based on the fact that the category is persistent, bioaccumulative, and toxic. In 2010, EPA made a category of "polymers containing PFAS or PFAC" ineligible for an exemption based on EPA's expectation that this category would degrade and release residual chemicals that would "persist in the environment, may bioaccumulate, and may be highly toxic"—*i.e.* may be PBTs. 75 Fed. Reg. at 4,296. Given that finding, EPA determined it could "no longer make the determination that . . . [the category] 'will

not present an unreasonable risk'" and therefore made the entire category ineligible for the exemption. *Id.* (quoting 15 U.S.C. § 2604(h)(4)).

EPA departs from that prior precedent here by maintaining the eligibility of new PBTs under the Exemptions, despite EPA's conclusions that: (1) they are inherently risky because they are persistent, bioaccumulative, and toxic; and (2) the terms of the Exemptions do not sufficiently protect against those inherent risks. EPA did not recognize nor explain why it was departing from its prior precedent, which is arbitrary. *Andrzejewski*, 563 F.3d at 799; *see* ACAT-ER-120-25 (Response to Comments) (absence).

II. EPA's Explanations for Promulgating the Fast-Track Provision Confirm that its Action Is Arbitrary.

A. Unsupported speculation about possible zero-release-zero-exposure PBTs cannot justify the Fast-Track Provision, which authorizes approval of PBTs with some exposure.

EPA argues that PBTs should be eligible under the Exemptions because there may be some hypothetical PBTs for which there are no releases and no exposures. Specifically, EPA speculates "that there are instances where PBT chemical substances can be managed under [the LVE or LoREX] exemption[s]" because the chemical "will not result in worker, general population, or consumer exposure and . . . is not expected to result in releases to the environment." ACAT-ER-017 (Final Rule).

That explanation fails. First, EPA offers no evidence that there are PBT chemicals that do not release to the environment or do not cause exposure. Second, even if there were such zero-release-zero-exposure PBTs, the plain terms of the Fast-Track Provision sweep far broader than EPA's purported justification, making new PBTs eligible even if they result in some exposure. Thus, EPA has failed to make "a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (citation modified).

1. EPA's claim—that some PBTs can be manufactured, processed, distributed in commerce, used in products, and ultimately disposed but then never release to the environment or cause human exposure—is fanciful.

EPA simply had no response to Petitioner's comments that new PBTs will eventually be released into the environment, cause exposures, and thereby result in serious injury. ACAT-ER-120-25 (Response to Comments) (absence); *see Ohio*, 603 U.S. at 293 (An agency that offers "no reasoned response" to comments acts arbitrarily.). Petitioner's comments demonstrated that, according to the best available science, releases of a new PBT are inevitable and once a PBT is released, exposures will result. *See* ACAT-ER-158-60 (ACAT Comments) (summarizing "ample evidence that PBT chemicals release into the environment at some point under the conditions of use."). These comments noted that all chemicals eventually

have to be disposed; thus, "when products containing PBTs are disposed of . . . they cause significant environmental releases." *See* ACAT-ER-159. Given EPA's acknowledgment in the proposed rule that releases result in exposures and that exposures result in "'serious'" injury, the comments argued serious injury was inevitable. ACAT-ER-159-60 (quoting 88 Fed. Reg. at 34,114–15).

EPA did not acknowledge or respond to the scientific evidence presented about the inherent likelihood that PBTs will be released and cause exposure. *See* ACAT-ER-120-25 (Response to Comments) (absence). Instead, EPA baldly asserted that there are PBTs that do not result in releases and exposure. ACAT-ER-122. "EPA's response does not meaningfully address [these] comment[s]," and its action is therefore arbitrary. *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1146 (9th Cir. 2015); *see State v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) ("Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decisionmaking." (citation modified)).

Indeed, EPA failed to identify a single real-world example of a PBT for which there are no releases and exposures; such "speculation" is arbitrary. *Sinclair Wyoming Refining Company LLC v. EPA*, 114 F.4th 693, 713–14 (D.C. Cir. 2024) (finding EPA action arbitrary when the Agency provided "no studies or data" but rested on "sheer speculation" (citation modified)).

2. Even if such zero-release-zero-exposure PBTs exist, EPA's justification fails on its own terms because the Fast-Track Provision plainly authorizes the approval of PBTs with some exposures, so long as the exposures are not "unreasonable." 40 C.F.R. § 723.50(d)(2)(ii). The disconnect between the "agency's explanation" for the Provision and what it "actually does" is arbitrary. *EDF v. EPA*, 922 F.3d 446, 454 (D.C. Cir. 2019) (citing *State Farm*); *Goldstein v. Secs. and Esch. Comm'n*, 451 F.3d 873, 882–83 (D.C. Cir. 2006) (noting that a broad regulation was based on an agency "conclusion [that] does not follow from its premise" and that the rule should be "tailored" to the premise).

If EPA intended to limit the eligibility under the Fast-Track Provision to zero-release-zero-exposure PBTs, it could have codified that limitation. Instead, the Provision goes "beyond what the [Agency's] justification supported—raising doubts about whether the solution lacks a rational connection to the problem described." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania,* 591 U.S. 657, 708 (2020) (Kagan, J., concurring) (citation modified). Here, "the rule's overbreadth causes serious harm" and is arbitrary. *Id.*

B. The Fast-Track Provision's focus on "unreasonable exposures" does not codify and is inconsistent with the Agency's 1999 PBT Policy.

EPA also seeks to justify the Fast-Track Provision by arguing that it merely "codif[ies] EPA's long-standing practice" of rejecting Exemption applications for new PBTs with "anticipated environmental releases and potentially unreasonable exposures," which EPA claims reflects its 1999 PBT Policy. ACAT-ER-249 (Proposed Rule) (section "Codifying EPA's Policy Concerning PBT Chemicals"); ACAT-ER-017 (Final Rule) (similar).

1. That explanation is arbitrary because it fails to respond to Petitioner's comments pointing out that there was no such long-standing practice and that the Fast-Track Provision is inconsistent with the 1999 PBT Policy. *See Ohio*, 603 U.S. at 293. Petitioner's comments noted that the Policy made no mention of "unreasonable exposures," let alone suggested that new PBTs without "unreasonable exposure[s]" were eligible for the Exemptions. ACAT-ER-227, ACAT-ER-229 (EDF Comments).

Instead, the 1999 PBT Policy contemplated that new PBTs would go through the Standard Review Process and thus made no mention of the LVE or LoREX Exemptions. ACAT-ER-226-29 (EDF Comments); *see* ACAT-ER-268-69 (1999 PBT Policy). Additionally, the Policy contemplated that EPA would

typically order limits on new PBTs—particularly new testing of the chemical—reflecting that EPA lacked information to accurately determine their risk. *See* ACAT-ER-268-69; *see also* ACAT-ER-264 (discussing EPA's testing authority under Section 5(e)—*i.e.* 15 U.S.C. § 2604(e)). Indeed, for very persistent, very bioaccumulative new PBTs, the Policy contemplated that EPA would require testing to be completed before manufacture could begin. ACAT-ER-268-69; *see* ACAT-ER-228-29 (discussing the Policy's "Ban Pending Testing" approach).

Moreover, Petitioner's comments noted that EPA categorically rejected all LVE applications for all new PBTs for a period of several years, undermining EPA's claim of a long-standing approach. ACAT-ER-226 (n. 120). The comment asked EPA to codify the 1999 PBT Policy in the updated regulations, thereby making new PBTs categorically ineligible for the Exemptions. ACAT-ER-225-32.

EPA offered no response, simply reiterating its incorrect position that its new Fast-Track Provision codifies EPA's preexisting policy. *See* ACAT-ER-017 (Final Rule); ACAT-ER-120-25 (Response to Comments) (failing to respond). That failure to respond to Petitioner's comments is arbitrary. *Ohio*, 603 U.S. at 293–95.

2. EPA's departure from the actual 1999 PBT Policy is also arbitrary and capricious because it is unexplained. EPA erroneously claimed the Fast-Track

Provision codifies the 1999 PBT Policy and thus failed to "display awareness that it [was] changing position" from its Policy. *California Pub. Utilities Comm'n v. Fed. Energy Reg. Comm'n*, 879 F.3d 966, 977 (9th Cir. 2018) (citation modified) (holding agency action arbitrary where it departed from a "longstanding policy . . . without acknowledgement or explanation").

III. The Court Should Vacate the Unlawful Language in the Fast-Track Provision that Makes New PBTs Eligible for the Exemptions.

1. The Court should vacate the unlawful portion of the Final Rule to ensure that new PBTs are categorically ineligible for approval under the LVE and LoREX Exemptions, thereby ensuring EPA's regulations satisfy the will-not-present standard of Section 2604(h)(4). Specifically, the Court should vacate the text stricken below:

> A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraph (c)(1) or (2) of this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance . . . is… A PBT chemical substance ~~with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.~~

ACAT-ER-029 (Final Rule) (codifying the Fast-Track Provision at 40 C.F.R. § 723.50(d)(2)(ii)).

2. Partially vacating the Provision in this manner is appropriate because when faced with invalid regulations courts should "try to limit the solution to the

problem." *See Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 81–82 (D.C. Cir. 2020) (quoting *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 328–29 (2006)); *Finnbin, LLC v. Consumer Prod. Safety Comm'n*, 45 F.4th 127, 136 (D.C. Cir. 2022) (stating that partial vacatur is presumptively the appropriate remedy when only one aspect of a rule is challenged).

Here, EPA recognized that it needed to restrict the LVE and LoREX exemptions to protect against the inherent risks posed by new PBTs to comply with the amended TSCA. ACAT-ER-017 (Final Rule); *see also* ACAT-ER-248-49 (Proposed Rule). Striking the unlawful fast-track language achieves that goal. And partial vacatur is fully supported by the record, in which EPA has acknowledged the unreasonable risks associated with PBT releases and exposures.

Partial vacatur is supported by ordinary severability principles and EPA's expressed preference for severability of the Final Rule. *See Cmty. for Creative Non-Violence v. Turner*, 893 F.2d 1387, 1394 (D.C. Cir. 1990) (Noting that a court's "presumption [regarding a regulation] is always in favor of severability."); ACAT-ER-018 (stating the Final Rule is severable). And partial vacatur is preferable to full vacatur of the entirety of the Provision, 40 C.F.R. § 723.50(d)(2)(ii), because "there is no reason to think that [EPA] . . . would have

preferred no new rules at all" given EPA's recognition of the need to limit the eligibility of PBTs. *Finnbin,* 45 F.4th at 136; *see* ACAT-ER-248-49.

3. Partially vacating the Fast-Track Provision would not prohibit the manufacture of new PBTs, but rather would require applicants seeking to make a new PBT chemical to apply through the Standard Review Process. The Standard Review Process would ensure that each new PBT receives: individualized scrutiny of its risks; regulations tailored to any specific unreasonable risks found; and, if EPA needs more information on the chemical, a requirement for testing.

4. If this Court disagrees that vacatur is the appropriate remedy, remand of the Provision back to EPA for reconsideration per the Court's ruling would be an appropriate alternative remedy. *A Cmty. Voice v. EPA*, 997 F.3d 983, 988 (9th Cir. 2021) (remanding, without vacatur, an insufficiently protective TSCA rule).

IV. Petitioners Have Standing.

Petitioners have associational standing to challenge the Fast-Track Provision on behalf of their members and the individual supporters whom Petitioners represent. *See Am. Unites for Kids v. Rousseau*, 985 F.3d 1075, 1096–97 (9th Cir. 2021). Petitioners also have standing based on informational injuries caused by the rule. *Animal Legal Def. Fund v. United States Dep't of Agric.*, 935 F.3d 858, 865–68 (9th Cir. 2019).

1. Petitioners' members and the people they represent are harmed by the manufacture, processing, distribution, use, and disposal of new PBT chemicals. ACAT serves and has members who are Native Alaskans whose way of life is being threatened by the cumulative exposure of Arctic wildlife to PBT chemicals. *See* Miller Decl. ¶¶ 3–6, 11–18. These individuals fish, hunt, and gather traditional foods—like fish or whale—and therefore will be exposed to new PBTs that will migrate to the arctic and contaminate their traditional foods. *Id*. ¶¶ 12–16, 18; Waghiyi Decl. ¶¶ 8–18; Jemewouk Decl. ¶ 4. Similarly, EDF's members are likely to be exposed to new PBTs as a result of the Fast-Track Provision in light of the fact that EPA has recently approved the manufacture of such new PBTs near their homes and workplaces. *See generally* Anglin Decl.; Deferrante Decl.; Vultaggio Decl.; *also* Doa Decl. ¶¶ 39–41.

As individuals within overburdened Native Alaskan communities and fenceline communities, ACAT's and EDF's members are "a potentially exposed or susceptible subpopulation," which Congress required EPA to take special care to protect from exposure to new chemicals. 15 U.S.C. §§ 2602(12), 2604(h)(4).

2. These individuals face a "credible threat" from the PBT Fast-Track Provision because it weakens the standards designed to protect them from new PBTs. *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 879 (9th Cir. 2013); *Ass'n of*

Irritated Residents v. EPA, 10 F.4th 937, 943 (9th Cir. 2021); *see also Safer Chems., Healthy Fams. v. EPA*, 943 F.3d 397, 421 (9th Cir. 2019) (finding standing to challenge regulation that arguably "threatens [petitioners'] concrete interest in the health protections provided by TSCA").

3. Petitioners and their members are also harmed because the Fast-Track Provision denies them information on new PBTs that EPA would have been required to disclose if the chemicals were ineligible for the Exemptions and instead subject to the Standard Review Process. *Animal Legal Def. Fund*, 935 F.3d at 867 ("A plaintiff sustains a cognizable informational injury in fact when agency action cuts her off from information which must be publicly disclosed pursuant to a statute." (citation modified)).

TSCA mandates that EPA disclose information on a new PBT that is submitted or generated during the Standard Review Process. *See* 15 U.S.C. § 2604(b)(3), (d)(1). And if EPA had codified the 1999 PBT Policy, companies seeking to manufacture new PBTs ordinarily would be required to develop additional test data that EPA would be required to publicly disclose. *Id.* § 2604(b)(3), (e); *see supra* at 22–23 (describing testing obligations under 1999 PBT Policy). This information would be helpful to Petitioners' "advocacy, which often involves presenting scientific data about chemicals to regulatory bodies at the

state and federal level," Miller Decl. ¶ 25, and would help Petitioners' members remain informed about the risks associated with new chemicals entering their environment, Waghiyi Decl. ¶¶ 7, 20. *See also* Doa Decl. ¶¶ 43, 44 (describing informational injuries to EDF).

4. This Court can remedy those harms by vacating the unlawful portions of the Fast-Track Provision or remanding the Provision back to the Agency to reconsider its unlawful action. *See, e.g., Nat. Res. Def. Council*, 735 F.3d at 873 (finding standing and vacating rule); *Nw. Requirements Utilities v. Fed. Energy Reg. Comm'n*, 798 F.3d 796, 807 n. 8 (9th Cir. 2015) (holding an injury is redressable by remand back to the agency to reconsider even if the agency may decide not to alter course after remand).

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Court declare the PBT Fast-Track Provision unlawful and partially vacate the portions of the Provision that make PBTs ineligible for the LVE and LoREX Exemptions only on a determination of "anticipated environmental releases and potentially unreasonable exposures." 40 C.F.R. § 723.50(d)(2)(ii).

Respectfully submitted this 17th day of October, 2025.

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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9th Cir. Case Number(s) 25-158, 25-572, 25-573

I am the attorney or self-represented party.

This brief contains 11,599 **words,** including 37 words manually counted in any visual images, and excluding the items exempted by FRAP 32(f). The brief's type size and typeface comply with FRAP 32(a)(5) and (6).

I certify that this brief *(select only one)*:

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Signature s/Michael Youhana **Date** 10/17/2025
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No. 25-158
Consolidated with Nos. 25-572 and 25-573

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
and LEE ZELDIN, in his official capacity as
Administrator of the United States Environmental Protection Agency,

Respondents.

On Petitions for Review of a Final Agency Action of the
United States Environmental Protection Agency
89 Fed. Reg. 102,773 (December 18, 2024)

PETITIONERS' STATUTORY AND REGULATORY ADDENDUM

October 17, 2025

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5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (6462)

5 U.S.C.A. § 706, 5 USCA § 706
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United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2602

§ 2602. Definitions

Currentness

As used in this chapter:

(1) the [1] term "Administrator" means the Administrator of the Environmental Protection Agency.

(2)(A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including--

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and

(ii) any element or uncombined radical.

(B) Such term does not include--

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(3) The term "commerce" means trade, traffic, transportation, or other commerce (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, transportation, or commerce described in clause (A).

(4) The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(5) The terms "distribute in commerce" and "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture mean to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(6) The term "environment" includes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

(7) The term "guidance" means any significant written guidance of general applicability prepared by the Administrator.

(8) The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter.

(9) The term "manufacture" means to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture.

(10) The term "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 that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and 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.

(11) The term "new chemical substance" means any chemical substance which is not included in the chemical substance list compiled and published under section 2607(b) of this title.

(12) The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

(13) The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce--

(A) 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

(B) as part of an article containing the chemical substance or mixture.

(14) The term "processor" means any person who processes a chemical substance or mixture.

(15) The term "protocols and methodologies for the development of information" means a prescription of--

(A) the--

(i) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which information for a chemical substance or mixture are to be developed and any analysis that is to be performed on such information, and

(B) to the extent necessary to assure that information respecting such effects and characteristics are reliable and adequate--

(i) the manner in which such information are [2] to be developed,

(ii) the specification of any test protocol or methodology to be employed in the development of such information, and

(iii) such other requirements as are necessary to provide such assurance.

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

(17) The term "United States", when used in the geographic sense, means all of the States.

CREDIT(S)

(Pub.L. 94-469, Title I, § 3, Oct. 11, 1976, 90 Stat. 2004; Pub.L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 100-418, Title I, § 1214(e)(1), Aug. 23, 1988, 102 Stat. 1156; Pub.L. 114-92, Div. A, Title III, § 315, Nov. 25, 2015, 129 Stat. 791; Pub.L. 114-182, Title I, §§ 3, 19(c), June 22, 2016, 130 Stat. 448, 505.)

Notes of Decisions (5)

Footnotes

1 So in original. Probably should be capitalized.

2 So in original. Probably should be "is".

15 U.S.C.A. § 2602, 15 USCA § 2602
Current through P.L. 119-36. Some statute sections may be more current, see credits for details.

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publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5. This subsection shall not take effect until two years after January 1, 1977.

(g) Petition for standards for the development of test data

A person intending to manufacture or process a chemical substance for which notice is required under section 2604(a) of this title and who is not required under a rule under subsection (a) of this section to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 2613 of this title, in the Federal Register the reasons for such denial.

(Pub. L. 94-469, § 4, Oct. 11, 1976, 90 Stat. 2006.)

REFERENCES IN TEXT

The Occupational Safety and Health Act of 1970, referred to in text, is Pub. L. 91-596, Dec. 29, 1970, 84 Stat. 1590, which is classified generally to chapter 15 (§ 651 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 651 of Title 29 and Tables volume.

EFFECTIVE DATE.

Section effective Jan. 1, 1977, except as provided in subsec. (f) of this section, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 2604, 2606, 2607, 2611, 2613, 2614, 2617 to 2620, 2623, 2625, 2626, 2630 of this title.

§ 2604. Manufacturing and processing notices

(a) In general

(1) Except as provided in subsection (h) of this section, no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title, or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d) of this section, of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b) of this section.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(b) Submission of test data

(1)(A) If (i) a person is required by subsection (a)(1) of this section to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 2603 of this title before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule at the time notice is submitted in accordance with subsection (a)(1) of this section.

(B) If—

(i) a person is required by subsection (a)(1) of this section to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 2603(c) of this title from the requirements of a rule promulgated under section 2603 of this title before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) of this section or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B) of this section.

(2)(A) If a person—

(i) is required by subsection (a)(1) of this section to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule promulgated under section 2603 of this title before the submission of such notice to submit test data for such substance,

such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1) of this section.

(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A) of this section, the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B) of this section, the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 2613 of this title, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2) of this section, would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).

(c) Extension of notice period

The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) of this section before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 2613 of this title, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) Content of notice; publications in the Federal Register

(1) The notice required by subsection (a) of this section shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 2607(a)(2) of this title, and

(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 2613 of this title, for examination by interested persons.

(2) Subject to section 2613 of this title, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) of this section or of data under subsection (b) of this section, the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or data has been received;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (b) of this section, describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) of this section or a rule under section 2603 of this title.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) of this section and for which the notification period prescribed by subsection (a), (b), or (c) of this section has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

(e) Regulation pending development of information

(1)(A) If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a) of this section; and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, 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, or

(II) such 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,

the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c) of this section, 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.

(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c) of this section, and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a) of this section, the Administrator makes the determination described in paragraph (1)(A) and if—

(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,

the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction 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).

(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a) of this section; and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, 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, or

(II) such 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.

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) of this section to the manufacturing or processing of such substance may expire before such proceeding can be completed.

(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 2605(a) of this title respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) Protection against unreasonable risks

(1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a) of this section, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 2605 of this title can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) of this section to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 2605(a) of this title to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 2605(a) of this title, or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 2605(d)(2)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may—

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) of this section to the manufacture or processing of such substance.

(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 2605 of this title can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance or to prohibit any combination of such activities.

(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) of this section shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) of this section shall apply with respect to an injunction issued under subparagraph (B).

(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C) of this section, the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.

(g) Statement of reasons for not taking action

If the Administrator has not initiated any action under this section or section 2605 or 2606 of this title to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b) of this section, before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) Exemptions

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) of this section to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) of this section to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b)(2) of this section, and

(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2) of this section for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order

the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) of this section to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(3) The requirements of subsections (a) and (b) of this section do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 2605(c) of this title.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) of this section inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) Definitions

For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(Pub. L. 94-469, § 5, Oct. 11, 1976, 90 Stat. 2012.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 2603, 2606, 2607, 2611 to 2613, 2614, 2616 to 2620, 2623, 2625, 2630 of this title.

§ 2605. Regulation of hazardous chemical substances and mixtures

(a) Scope of regulation

If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements:

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2604

§ 2604. Manufacturing and processing notices

Currentness

(a) In general

(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may--

(i) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title, or

(ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use.

(B) A person may take the actions described in subparagraph (A) if--

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and

(ii) the Administrator--

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including--

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) Review and determination

Within the applicable review period, subject to section 2617 of this title, the Administrator shall review such notice and determine--

(A) that the relevant chemical substance or significant new use presents 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, in which case the Administrator shall take the actions required under subsection (f);

(B) that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, 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; or

(II) such 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,

in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to 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, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(4) Failure to render determination

(A) Failure to render determination

If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 2625(b) of this title, and the Administrator shall not be relieved of any requirement to make such determination.

(B) Limitations

(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) Article consideration

The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(b) Submission of information

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit information for such substance pursuant to a rule, order, or consent agreement under section 2603 of this title before the submission of such notice, such person shall submit to the Administrator such information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If--

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 2603(c) of this title from the requirements of a rule or order under section 2603 of this title before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(A)(ii).

(2)(A) If a person--

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule, order, or consent agreement under section 2603 of this title before the submission of such notice to submit information for such substance,

such person may submit to the Administrator information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes shows that--

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A)(i), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(A)(ii), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Information submitted under paragraph (1) or (2) of this subsection or under subsection (e) shall be made available, subject to section 2613 of this title, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including--

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of Title 5.

(c) Extension of review period

The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b). Subject to section 2613 of this title, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) Content of notice; publications in the Federal Register

(1) The notice required by subsection (a) shall include--

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 2607(a)(2) of this title, and

(B) in such form and manner as the Administrator may prescribe, any information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other information concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 2613 of this title, for examination by interested persons.

(2) Subject to section 2613 of this title, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of information under subsection (b), the Administrator shall publish in the Federal Register a notice which--

(A) identifies the chemical substance for which notice or information has been received;

(B) lists the uses of such substance identified in the notice; and

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 2603 of this title.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the applicable review period has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

(e) Regulation pending development of information

(1)(A) If the Administrator determines that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, 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 subpopulation identified as relevant by the Administrator under the conditions of use; or

(II) such 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,

the Administrator shall issue an order, to take effect on 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 to the extent necessary to protect against 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, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

(B) An order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the applicable review period, and (ii) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(2) Repealed. Pub.L. 114-182, Title I, § 5(5)(D), June 22, 2016, 130 Stat. 458

(f) Protection against unreasonable risks

(1) If the Administrator determines that a chemical substance or significant new use with respect to which notice is required by subsection (a) presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Administrator shall, before the expiration of the applicable review period, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 2605(a) of this title to apply to a chemical substance with respect to which a finding was made under paragraph (1)--

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 2605(a) of this title, or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 2605(d)(3)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

(B) The provisions of subparagraph (B) of subsection (e)(1) shall apply with respect to an order issued under subparagraph (A).

(4) Treatment of nonconforming uses

Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) Workplace exposures

To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

(g) Statement on Administrator finding

If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) Exemptions

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes--

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that--

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information by the applicant on such substance would be duplicative of information which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such information on such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)--

(i) to the person who previously submitted the information on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted information for a chemical substance is a period--

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such information to the Administrator, and

(ii) ending--

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such information,

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of--

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) Definitions

(1) For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(2) For purposes of this chapter, the term "requirement" as used in this section shall not displace any statutory or common law.

(3) For purposes of this section, the term "applicable review period" means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

CREDIT(S)

(Pub.L. 94-469, Title I, § 5, Oct. 11, 1976, 90 Stat. 2012; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, §§ 5, 19(e), June 22, 2016, 130 Stat. 454, 506.)

Notes of Decisions (1)

15 U.S.C.A. § 2604, 15 USCA § 2604
Current through P.L. 119-36. Some statute sections may be more current, see credits for details.

End of Document

the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) of this section to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(3) The requirements of subsections (a) and (b) of this section do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 2605(c) of this title.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) of this section inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) Definitions

For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(Pub. L. 94-469, § 5, Oct. 11, 1976, 90 Stat. 2012.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 2603, 2606, 2607, 2611 to 2613, 2614, 2616 to 2620, 2623, 2625, 2630 of this title.

§ 2605. Regulation of hazardous chemical substances and mixtures

(a) Scope of regulation

If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements:

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use

or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

(b) Quality control

If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment—

(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and

(2) if the Administrator determines—

(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy; or

(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 554 of title 5. Any manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.

(c) Promulgation of subsection (a) rules

(1) In promulgating any rule under subsection (a) of this section with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—

(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,

(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not pro-

mulgate a rule under subsection (a) of this section to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this chapter. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this chapter and under such law (or laws), and (iii) the relative efficiency of actions under this chapter and under such law (or laws) to protect against such risk of injury.

(2) When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5 (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) provide an opportunity for an informal hearing in accordance with paragraph (3); (D) promulgate, if appropriate, a final rule based on the matter in the rulemaking record (as defined in section 2618(a) of this title), and (E) make and publish with the rule the finding described in subsection (a) of this section.

(3) Informal hearings required by paragraph (2)(C) shall be conducted by the Administrator in accordance with the following requirements:

(A) Subject to subparagraph (B), an interested person is entitled—

(i) to present such person's position orally or by documentary submissions (or both), and

(ii) if the Administrator determines that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B)(ii)) such cross-examination of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.

(B) The Administrator may prescribe such rules and make such rulings concerning procedures in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) the imposition of reasonable time limits on each interested person's oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.

(C)(i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single representative of such interests for purposes of cross-examination, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.

(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

(D) A verbatim transcript shall be taken of any oral presentation made, and cross-examination conducted in any informal hearing under this subsection. Such transcript shall be available to the public.

(4)(A) The Administrator may, pursuant to rules prescribed by the Administrator, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating in a rulemaking proceeding for the promulgation of a rule under subsection (a) of this section to any person—

(i) who represents an interest which would substantially contribute to a fair determination of the issues to be resolved in the proceeding, and

(ii) if—

(I) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

(II) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding without compensation under this subparagraph.

In determining for purposes of clause (i) if an interest will substantially contribute to a fair determination of the issues to be resolved in a proceeding, the Administrator shall take into account the number and complexity of such issues and the extent to which representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues.

(B) In determining whether compensation should be provided to a person under subparagraph (A) and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding. The Administrator shall take such action as may be necessary to ensure that the aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either—

(i) would be regulated by the proposed rule, or

(ii) represent persons who would be so regulated,

may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.

(5) Paragraph (1), (2), (3), and (4) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a) of this section.

(d) Effective date

(1) The Administrator shall specify in any rule under subsection (a) of this section the date on which it shall take effect, which date shall be as soon as feasible.

(2)(A) The Administrator may declare a proposed rule under subsection (a) of this section to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if—

(i) the Administrator determines that—

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date; and

(II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 2606 of this title granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c) of this section, for a hearing on such rule, and either promulgate such rule (as proposed or with modifications) or revoke it; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it.

(e) Polychlorinated biphenyls

(1) Within six months after January 1, 1977, the Administrator shall promulgate rules to—

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after January 1, 1977, no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B) and (C)—

(i) no person may manufacture any polychlorinated biphenyl after two years after January 1, 1977, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that—

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one half years after October 11, 1976.

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraphs (2), (3), and (4) of subsection (c) of this section.

(5) This subsection does not limit the authority of the Administrator, under any other provision of this chapter or any other Federal law,

to take action respecting any polychlorinated biphenyl.

(Pub. L. 94-469, § 6, Oct. 11, 1976, 90 Stat. 2020.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 2603, 2604, 2606 to 2608, 2611, 2612, 2614, 2616 to 2620, 2623, 2630 of this title.

§ 2606. Imminent hazards

(a) Actions authorized and required

(1) The Administrator may commence a civil action in an appropriate district court of the United States—

(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

(B) for relief (as authorized by subsection (b) of this section) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture, or

(C) for both such seizure and relief.

A civil action may be commenced under this paragraph notwithstanding the existence of a rule under section 2603, 2604, or 2605 of this title or an order under section 2604 of this title, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this chapter.

(2) If the Administrator has not made a rule under section 2605(a) of this title immediately effective (as authorized by section 2605(d)(2)(A)(i) of this title) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).

(b) Relief authorized

(1) The district court of the United States in which an action under subsection (a) of this section is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) of this section brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) of this section against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) Venue and consolidation

(1)(A) An action under subsection (a) of this section against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia, or for any judicial district in which any of the defendants is found, resides, or transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) of this section against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) of this section in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpeonas requiring attendance of witnesses in an action brought under subsection (a) of this section may be served in any judicial district.

(2) Whenever proceedings under subsection (a) of this section involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(d) Action under section 2605

Where appropriate, concurrently with the filing of an action under subsection (a) of this section or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 2605(a) of this title.

(e) Representation

Notwithstanding any other provision of law, in any action under subsection (a) of this section, the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) Definition

For the purposes of subsection (a) of this section, the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 of this title can protect against such risk.

(Pub. L. 94-469, § 7, Oct. 11, 1976, 90 Stat. 2026.)

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Proposed Legislation

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2618

§ 2618. Judicial review

Currentness

(a) In general

(1)(A) Except as otherwise provided in this subchapter, not later than 60 days after the date on which a rule is promulgated under this subchapter, subchapter II, or subchapter IV, or the date on which an order is issued under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title,, [1] any person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule or order if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(B) Except as otherwise provided in this subchapter, courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under this subchapter, other than an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(C)(i) Not later than 60 days after the publication of a designation under section 2605(b)(1)(B)(ii) of this title, any person may commence a civil action to challenge the designation.

(ii) The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this subparagraph.

(2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of Title 28 shall apply to the filing of the record of proceedings on which the Administrator based the rule or order being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

(b) Additional submissions and presentations; modifications

If in an action under this section to review a rule, or an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule or order and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule or order being reviewed or make a new rule or order by reason of the additional submissions and presentations and shall file such modified or new rule or order with the return of such submissions and presentations. The court shall thereafter review such new or modified rule or order.

(c) Standard of review

(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule or order, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of Title 5, and (ii) except as otherwise provided in subparagraph (B), to review such rule or order in accordance with chapter 7 of Title 5.

(B) Section 706 of Title 5 shall apply to review of a rule or order under this section, except that--

(i) in the case of review of--

(I) a rule under section 2603(a), 2604(b)(4), 2605(a) (including review of the associated determination under section 2605(b)(4)(A)), or 2605(e) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole; and

(II) an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such order if the court finds that the order is not supported by substantial evidence in the record taken as a whole; and

(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of Title 5 to be incorporated in the rule or order, except as part of the record, taken as a whole.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule or order reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of Title 28.

(d) Fees and costs

The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

(e) Other remedies

The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

CREDIT(S)

(Pub.L. 94-469, Title I, § 19, Oct. 11, 1976, 90 Stat. 2039; renumbered Title I and amended Pub.L. 99-519, § 3(b)(2), (c)(1), Oct. 22, 1986, 100 Stat. 2989; Pub.L. 102-550, Title X, § 1021(b)(8), Oct. 28, 1992, 106 Stat. 3923; Pub.L. 114-182, Title I, §§ 14, 19(m), June 22, 2016, 130 Stat. 498, 508.)

Notes of Decisions (17)

Footnotes

1 So in original.

15 U.S.C.A. § 2618, 15 USCA § 2618
Current through P.L. 119-36. Some statute sections may be more current, see credits for details.

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priate, and shall make available to the public such findings and recommendations.

(4) This section shall not be construed to require the Administrator to amend or repeal any rule or order in effect under this chapter.

(Pub. L. 94-469, § 24, Oct. 11, 1976, 90 Stat. 2045.)

§ 2624. Studies

(a) Indemnification study

The Administrator shall conduct a study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any such law. The study shall—

(1) include an estimate of the probable cost of any indemnification programs which may be recommended;

(2) include an examination of all viable means of financing the cost of any recommended indemnification; and

(3) be completed and submitted to Congress within two years from the effective date of enactment of this chapter.

The General Accounting Office shall review the adequacy of the study submitted to Congress pursuant to paragraph (3) and shall report the results of its review to the Congress within six months of the date such study is submitted to Congress.

(h) Classification, storage, and retrieval study

The Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than 18 months after the effective date of enactment of this chapter.

(Pub. L. 94-469, § 25, Oct. 11, 1976, 90 Stat. 2046.)

References in Text

The "effective date of enactment of this chapter", referred to in subsecs. (a)(3) and (b), probably means January 1, 1977, the effective date of the chapter prescribed by sec. 31 of Pub. L. 94-469, which is set out as a note under section 2601 of this title, rather than October 11, 1976, the date of enactment.

§ 2625. Administration

(a) Cooperation of Federal agencies

Upon request by the Administrator, each Federal department and agency is authorized—

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this chapter; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this chapter.

(b) Fees

(1) The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit data under section 2603 or 2604 of this title to defray the cost of administering this chapter. Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 2603 or 2604 of this title.

(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (1).

(c) Action with respect to categories

(1) Any action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this chapter with respect to a category of chemical substances or mixtures, any reference in this chapter to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter.

(d) Assistance office

The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this chapter applicable to such manufacturers and processors, the policy

of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

(e) Financial disclosures

(1) Except as provided under paragraph (3), each officer or employee of the Environmental Protection Agency and the Department of Health, Education, and Welfare who—

(A) performs any function or duty under this chapter, and

(B) has any known financial interest (i) in any person subject to this chapter or any rule or order in effect under this chapter, or (ii) in any person who applies for or receives any grant or contract under this chapter,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of Health, Education, and Welfare (hereinafter in this subsection referred to as the "Secretary"), as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall—

(A) act within 90 days of January 1, 1977—

(i) to define the term "known financial interests" for purposes of paragraph (1), and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements; and

(B) report to the Congress on June 1, 1978, and on June 1 of each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of Health, Education, and Welfare, which are of a nonregulatory or nonpolicymaking nature, and the Administrator and the Secretary may by rule provide that officers or employees occupying such positions shall be exempt from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of title 18.

(5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

(f) Statement of basis and purpose

Any final order issued under this chapter shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

(g) Assistant Administrator

(1) The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of data, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this chapter, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall (A) be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970, and (B) be compensated at the rate of pay authorized for such Assistant Administrators.

(Pub. L. 94-469, § 26, Oct. 11, 1976, 90 Stat. 2046.)

REFERENCES IN TEXT

Reorganization Plan No. 3 of 1970, referred to in text, is set out in the Appendix to Title 5, Government Organization and Employees.

§ 2626. Development and evaluation of test methods

(a) In general

The Secretary of Health, Education, and Welfare, in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter into contracts with public and private entities for, projects for the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 2603 of this title. The Administrator shall consider such methods in prescribing under section 2603 of this title standards for the development of test data.

(b) Approval of Secretary

No grant may be made or contract entered into under subsection (a) of this section unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require. The Secretary may apply such conditions to grants and contracts under subsection (a) of this section as the Secretary determines are necessary to carry out the purposes of such subsection. Contracts may be entered into under such subsection without regard to section 529 of title 31 and section 5 of title 41.

(c) Annual reports

(1) The Secretary shall prepare and submit to the President and the Congress on or before January 1 of each year a report of the number of grants made and contracts entered into under this section and the results of such grants and contracts.

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Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2625

§ 2625. Administration

Currentness

(a) Cooperation of Federal agencies

Upon request by the Administrator, each Federal department and agency is authorized--

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this chapter; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this chapter.

(b) Fees

(1) The Administrator may, by rule, require the payment from any person required to submit information under section 2603 of this title or a notice or other information to be reviewed by the Administrator under section 2604 of this title, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 2605(b) of this title, of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 2603, 2604, and 2605 of this title, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, including contractor costs incurred by the Administrator. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to pay such fee and the cost to the Administrator of carrying out the activities described in this paragraph. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 2603 or 2604 of this title.

(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (4).

(3) Fund

(A) Establishment

There is established in the Treasury of the United States a fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the "Fund"), consisting of such amounts as are deposited in the Fund under this paragraph.

(B) Collection and deposit of fees

Subject to the conditions of subparagraph (C), the Administrator shall collect the fees described in this subsection and deposit those fees in the Fund.

(C) Use of funds by Administrator

Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use in defraying the costs of the activities described in paragraph (1).

(D) Accounting and auditing

(i) Accounting

The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of Title 31.

(ii) Auditing

(I) In general

For the purpose of section 3515(c) of Title 31, the Fund shall be considered a component of a covered executive agency.

(II) Components of audit

The annual audit required in accordance with sections 3515 and 3521 of Title 31 of the financial statements of activities carried out using amounts from the Fund shall include an analysis of--

(aa) the fees collected and amounts disbursed under this subsection;

(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of this subchapter for which the fees may be used; and

(cc) the number of requests for a risk evaluation made by manufacturers under section 2605(b)(4)(C)(ii) of this title.

(III) Federal responsibility

The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

(4) Amount and adjustment of fees; refunds

In setting fees under this section, the Administrator shall--

(A) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

(B) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray--

(i) the lower of--

(I) 25 percent of the costs to the Administrator of carrying out sections 2603, 2604, and 2605 of this title, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, other than the costs to conduct and complete risk evaluations under section 2605(b) of this title; or

(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and

(ii) the costs of risk evaluations specified in subparagraph (D);

(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

(D) notwithstanding subparagraph (B)--

(i) except as provided in clause (ii), for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section 2605(b)(4)(C)(ii) of this title, establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 2605(b) of this title;

(ii) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section 2605(b)(4)(C)(ii) of this title, and which are included in the 2014 update of the TSCA Work Plan for Chemical Assessments, establish the fee at a level sufficient to defray 50 percent of the costs to the Administrator of conducting the risk evaluation under section 2605(b) of this title; and

(iii) apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses;

(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under chapter 10 of Title 5 or subchapter II of chapter 5 of Title 5 is applicable with respect to such meetings;

(F) beginning with the fiscal year that is 3 years after June 22, 2016, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray--

(i) approximately but not more than 25 percent of the costs to the Administrator of carrying out sections 2603, 2604, and 2605 of this title, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, other than the costs to conduct and complete risk evaluations requested under section 2605(b)(4)(C)(ii) of this title; and

(ii) the costs of risk evaluations specified in subparagraph (D); and

(G) if a notice submitted under section 2604 of this title is not reviewed or such a notice is withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

(5) Minimum amount of appropriations

Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for the Chemical Risk Review and Reduction program project of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for that program project for fiscal year 2014.

(6) Termination

The authority provided by this subsection shall terminate at the conclusion of the fiscal year that is 10 years after June 22, 2016, unless otherwise reauthorized or modified by Congress.

(c) Action with respect to categories

(1) Any action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this chapter with respect to a category of chemical substances or mixtures, any reference in this chapter to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter.

(d) Assistance office

The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this chapter applicable to such manufacturers and processors, the policy of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

(e) Financial disclosures

(1) Except as provided under paragraph (3), each officer or employee of the Environmental Protection Agency and the Department of Health and Human Services who--

(A) performs any function or duty under this chapter, and

(B) has any known financial interest (i) in any person subject to this chapter or any rule or order in effect under this chapter, or (ii) in any person who applies for or receives any grant or contract under this chapter,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of Health and Human Services (hereinafter in this subsection referred to as the "Secretary"), as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall--

(A) act within 90 days of January 1, 1977--

(i) to define the term "known financial interests" for purposes of paragraph (1), and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements; and

(B) report to the Congress on June 1, 1978, and on June 1 of each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of Health and Human Services, which are of a nonregulatory or nonpolicymaking nature, and the Administrator and the Secretary may by rule provide that officers or employees occupying such positions shall be exempt from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of Title 18.

(5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

(f) Statement of basis and purpose

Any final order issued under this chapter shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

(g) Assistant Administrator

(1) The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of information, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this chapter, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970.

(h) Scientific standards

In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable--

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

(i) Weight of scientific evidence

The Administrator shall make decisions under sections 2603, 2604, and 2605 of this title based on the weight of the scientific evidence.

(j) Availability of information

Subject to section 2613 of this title, the Administrator shall make available to the public--

(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this subchapter;

(2) any information required to be provided to the Administrator under section 2603 of this title;

(3) a nontechnical summary of each risk evaluation conducted under section 2605(b) of this title;

(4) a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies; and

(5) each designation of a chemical substance under section 2605(b) of this title, along with an identification of the information, analysis, and basis used to make the designations.

(k) Reasonably available information

In carrying out sections 2603, 2604, and 2605 of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

(l) Policies, procedures, and guidance

(1) Development

Not later than 2 years after June 22, 2016, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this chapter made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(2) Review

Not later than 5 years after June 22, 2016, and not less frequently than once every 5 years thereafter, the Administrator shall--

(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this subchapter; and

(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

(3) Testing of chemical substances and mixtures

The policies, procedures, and guidance developed under paragraph (1) applicable to testing chemical substances and mixtures shall--

(A) address how and when the exposure level or exposure potential of a chemical substance or mixture would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; and

(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this subchapter, including information relating to potentially exposed or susceptible populations.

(4) Chemical substances with completed risk assessments

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to June 22, 2016, the Administrator may publish proposed and final rules under section 2605(a) of this title that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 2605 of this title.

(5) Guidance

Not later than 1 year after June 22, 2016, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

(m) Report to Congress

(1) Initial report

Not later than 6 months after June 22, 2016, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of--

(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 2605(b)(4)(C)(i) of this title, and the resources necessary to conduct the minimum number of risk evaluations required under section 2605(b)(2) of this title;

(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 2605(b)(4)(C)(ii) of this title, the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

(C) the capacity of the Environmental Protection Agency to promulgate rules under section 2605(a) of this title as required based on risk evaluations conducted and published under section 2605(b) of this title; and

(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 2605(b) of this title.

(2) Subsequent reports

The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

(n) Annual plan

(1) In general

The Administrator shall inform the public regarding the schedule and the resources necessary for the completion of each risk evaluation as soon as practicable after initiating the risk evaluation.

(2) Publication of plan

At the beginning of each calendar year, the Administrator shall publish an annual plan that--

(A) identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion;

(B) describes the status of each risk evaluation that has been initiated but not yet completed; and

(C) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

(o) Consultation with Science Advisory Committee on Chemicals

(1) Establishment

Not later than 1 year after June 22, 2016, the Administrator shall establish an advisory committee, to be known as the Science Advisory Committee on Chemicals (referred to in this subsection as the "Committee").

(2) Purpose

The purpose of the Committee shall be to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this subchapter.

(3) Composition

The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations.

(4) Schedule

The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

(p) Prior actions

(1) Rules, orders, and exemptions

Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this chapter before June 22, 2016.

(2) Prior-initiated evaluations

Nothing in this chapter prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(3) Actions completed prior to completion of policies, procedures, and guidance

Nothing in this chapter requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule under this chapter solely because the action was completed prior to the development of a policy, procedure, or guidance pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

CREDIT(S)

(Pub.L. 94-469, Title I, § 26, Oct. 11, 1976, 90 Stat. 2046; Pub.L. 98-80, § 2(c)(2)(A), Aug. 23, 1983, 97 Stat. 485; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, §§ 17, 19(q), June 22, 2016, 130 Stat. 499, 510; Pub.L. 117-286, § 4(a)(69), Dec. 27, 2022, 136 Stat. 4313.)

Notes of Decisions (1)

15 U.S.C.A. § 2625, 15 USCA § 2625
Current through P.L. 119-36. Some statute sections may be more current, see credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter A. General
Part 23. Judicial Review Under EPA—Administered Statutes (Refs & Annos)

40 C.F.R. § 23.5

§ 23.5 Timing of Administrator's action under Toxic Substances Control Act.

Currentness

Unless the Administrator otherwise explicitly provides in promulgating a particular rule or issuing a particular order, the time and date of the Administrator's promulgation or issuance for purposes of section 19(a)(1) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is (a) for a Federal Register document, two weeks after the date when the document is published in the Federal Register, or (b) for any other document, two weeks after it is signed.

SOURCE: 50 FR 7270, Feb. 21, 1985; 53 FR 29322, Aug. 3, 1988; 70 FR 33359, June 8, 2005, unless otherwise noted.

AUTHORITY: Clean Water Act, 33 U.S.C. 1361(a), 1369(b); Clean Air Act, 42 U.S.C. 7601(a)(1), 7607(b); Resource, Conservation and Recovery Act, 42 U.S.C. 6912(a), 6976; Toxic Substances Control Act, 15 U.S.C. 2618; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136n(b), 136w(a); Safe Drinking Water Act, 42 U.S.C. 300j–7(a)(2), 300j–9(a); Atomic Energy Act, 42 U.S.C. 2201, 2239; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), 346a, 28 U.S.C. 2112(a), 2343, 2344.

Current through October 2, 2025, 90 FR 47963. Some sections may be more current. See credits for details.

End of Document

KeyCite Yellow Flag
Proposed Regulation

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 702. General Practices and Procedures (Refs & Annos)
Subpart B. Procedures for Chemical Substance Risk Evaluations (Refs & Annos)

40 C.F.R. § 702.33

§ 702.33 Definitions.

Currentness

All definitions in TSCA apply to this subpart. In addition, the following definitions apply:

Act means the Toxic Substances Control Act (TSCA), as amended (15 U.S.C. 2601 et seq.).

Aggregate exposure means the combined exposures from a chemical substance across multiple routes and across multiple pathways.

Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

EPA means the U.S. Environmental Protection Agency.

Pathways means the physical course a chemical substance takes from the source to the organism exposed.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, the elderly, or overburdened communities.

Reasonably available information means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14.

Routes means the ways a chemical substance enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Sentinel exposure means the exposure from a chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures.

Uncertainty means the imperfect knowledge or lack of precise knowledge of the real world either for specific values of interest or in the description of the system.

Variability means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population.

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017; 89 FR 37052, May 3, 2024, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

Current through October 2, 2025, 90 FR 47963. Some sections may be more current. See credits for details.

End of Document

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (where N = 1 ppb).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping requirements.* Recordkeeping requirements specified in § 721.125(a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[60 FR 11045, Mar. 1, 1995]

§ 721.9975 Zirconium(IV), [2,2-bis[(2-propenyloxy)methyl]-1-butanolato-01,02]tris(2-propenoato-O-)-.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substance zirconium(IV) 2,2-(bis-2-propenyloxy)methyl)-1-butanolato-01,02]tris 2-propenoato-*O*)-(PMN P–91–389) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(2)(iii), (a)(2)(iv), (a)(3), (a)(4), (a)(5)(xi), (a)(6)(i), (a)(6)(ii), (a)(6)(iv), (b) (concentration set at 0.1 percent), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e) (concentration set at 0.1 percent), (f), (h)(1)(i)(A), (h)(1)(i)(B), (h)(1)(i)(C), (h)(1)(vi), (h)(2)(i)(B), (h)(2)(i)(C), (h)(2)(i)(D), and (h)(2)(iii)(A).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping requirements.* Requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[57 FR 44075, Sept. 23, 1992, as amended at 58 FR 34204, June 23, 1993]

PART 723—PREMANUFACTURE NOTIFICATION EXEMPTIONS

Subpart A—(Reserved)

Subpart B—Specific Exemptions

Sec.

AUTHORITY: 15 U.S.C. 2604.

Subpart A—(Reserved)

Subpart B—Specific Exemptions

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

(i) Chemical substances manufactured in quantities of 10,000 kilograms or less per year.

(ii) Chemical substances with low environmental releases and human exposures.

(2) To manufacture a new chemical substance under the terms of this exemption a manufacturer must:

(i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under paragraph (e) of this section.

(ii) Comply with all other provisions of this section.

(b) *Definitions.* The following definitions apply to this subpart.

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

(2) *Consumer* means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

(3) *Environment* has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(4) *Environmental transformation product* means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(5) *Metabolite* means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(6) *Serious acute effects* means human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(7) *Serious chronic effects* means human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(8) *Significant environmental effects* means:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society;

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year; or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. Endangered or threatened species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(9) *Site* means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

(10) The terms *byproduct, EPA, importer, impurity, known to or reasonably ascertainable, manufacture, manufacturer, new chemical substance, person, possession or control, and test data* have the same meanings as in §720.3 of this chapter.

(c) *Exemption categories.* Except as provided in paragraph (d) of this section, this exemption applies to:

(1) Any manufacturer of a new chemical substance manufactured in quantities of 10,000 kilograms or less per year under the terms of this exemption.

(2) Any manufacturer of a new chemical substance satisfying all of the following low environmental release and low human exposure eligibility criteria:

(i) *Consumers and the general population.* For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance:

(A) No dermal exposure.

(B) No inhalation exposure (except as described in paragraph (c)(2)(iv) of this section.

(C) Exposure in drinking water no greater than a 1 milligram per year (estimated average dosage resulting from drinking water exposure in streams from the maximum allowable concentration level from ambient surface water releases established under paragraph (c)(2)(iii) of this section or a higher concentration authorized by EPA under paragraph (c)(2)(iii) of this section).

(ii) *Workers.* For exposure of workers to the new chemical substance during all manufacturing, processing, dis-

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tribution in commerce, use and disposal of the substance:

(A) No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable EPA guidance).

(B) No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable EPA guidance).

(iii) *Ambient surface water.* For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion, calculated using the methods prescribed in §§721.90 and 721.91, unless EPA has approved a higher surface water concentration supported by relevant and scientifically valid data submitted to EPA in a notice under paragraph (e) of this section on the substance or a close structural analogue of the substance which demonstrates that the new substance will not present an unreasonable risk of injury to aquatic species or human health at the higher concentration.

(iv) *Incineration.* For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration, calculated using the formula:

(kg/day of release after treatment) multiplied by (number of release days per year) multiplied by (9.68×10^{-6}) micrograms per cubic meter.

(v) *Land or groundwater.* For releases to land or groundwater, no releases to groundwater, to land, or to a landfill unless the manufacturer has demonstrated to EPA's satisfaction in a notice under paragraph (e) of this section that the new substance has negligible groundwater migration potential.

(d) *Chemical substances that cannot be manufactured under this exemption.* A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraphs (c)(1) or (c)(2) of this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance, any reasonably anticipated metabolites, environmental transformation products, or by-products of the substance, or any reasonably anticipated impurities in the substance may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance:

(1) Serious acute (lethal or sublethal) effects.

(2) Serious chronic (including carcinogenic and teratogenic) effects.

(3) Significant environmental effects.

(e) *Exemption notice.* (1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to the EPA at least 30 days before manufacture of the new chemical substance begins. The notice must be sent in writing to: TSCA Document Control Officer, (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The date of submission will be the date on which the notice is received by the TSCA Document Control Officer. EPA will acknowledge the receipt of the notice by letter. The letter will identify the date on which the review period begins. The notice shall be submitted using EPA Form No. 7710–25 ("the PMN form"), which may be obtained from EPA by writing the Environmental Assistance Division, (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC. 20460, or by calling the TSCA Assistance Information Service at (202) 554–1404; TDD (202) 554–0551; online service modem (202) 554–5603.

(2) The notice shall contain the information described below, pursuant to the referenced provisions of §720.45.

(i) Manufacturer identity.

(ii) Chemical identity (§720.45(a)).

(iii) Impurities (§720.45(b)).

(iv) Known synonyms or trade names (§720.45(c)).

(v) Byproducts (§720.45(d)).

(vi) Production volume (§720.45(e)). (A) Manufacturers submitting an exemption application under paragraph (c)(1) of this section will be assumed to be manufacturing at an annual production volume of 10,000 kilograms. Manufacturers who intend to manufacture an exempted substance at annual volumes of less than 10,000 kilograms and

wish EPA to conduct its risk assessment based upon such lesser annual production level rather than a 10,000–kilograms level, may so specify by writing the lesser annual production volume in the appropriate box on the PMN form and marking the adjacent binding option box. Manufacturers who opt to specify annual production levels below 10,000 kilograms and who mark the production volume binding option box shall not manufacture more than the specific annual amount of the exempted substance unless a new exemption notice for a higher (up to 10,000 kgs) manufacturing volume is submitted and approved pursuant to this section.

(B) Manufacturers submitting an exemption under paragraph (c)(2) of this section shall list the estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12–month period during the first 3 years of production.

(vii) Description of intended categories of use. (§720.45(f)).

(viii) For manufacturer-controlled sites, the manufacturer shall supply identity of manufacturing sites, process descriptions, and worker exposure and environmental release information (§720.45(g)); for sites not controlled by the manufacturer, processing and use operation descriptions, estimated number of processing and use sites, and worker exposure/environmental release information (§720.45(h)). A manufacturer applying for an exemption under paragraph (c)(1) of this section need not provide information on worker exposure and environmental release referenced in paragraphs (e)(2)(viii) of this section if such information is not known or not readily available to the manufacturer. To assist in reporting this information, manufacturers may obtain a copy of EPA's Guidance for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50, available from the Environmental Assistance Division at the address listed in paragraph (e)(1) of this section. Where worker exposure and environmental release information is not supplied by the manufacturer, EPA will generally apply "bounding estimates" (i.e., exposure estimates higher than those incurred by persons in the population with the highest exposure) to account for uncertainties in actual exposure and release scenarios.

(ix) Type and category of notice. The manufacturer must clearly indicate on the first page of the PMN form that the submission is a "TSCA section 5(h)(4) exemption notice," and must indicate whether the notice is being submitted under paragraph (c)(1) or (c)(2) of this section. Manufacturers of chemical substances that qualify for an exemption under both paragraph (c)(1) and (c)(2) of this section may apply for either exemption, but not both.

(x) Test data (§720.50).

(xi) Certification. In addition to the certifications required in EPA form 7710–25, the following certifications shall be included in notices under this section. The manufacturer must certify that:

(A) The manufacturer intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(D) For substances manufactured under paragraph (c)(1) of this section, the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30–day review period.

(xii) Sanitized copy of notice. (A) The manufacturer must make all claims of confidentiality in accordance with paragraph (l) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (l)(3) of this section.

(B) If the manufacturer does not provide the second copy, the submission will be considered incomplete.

(3) *Incomplete notices.* If EPA receives a submission which does not include all of the information required under this

paragraph (e) of this section, the submission will be determined to be incomplete by EPA. When a submission for a new chemical substance has been determined to be incomplete, a manufacturer reapplying for an exemption for the new chemical substance must submit a new exemption notice containing all the information required under this paragraph (e) of this section including a certification page containing an original dated signature; partial submissions sent to EPA to supplement notices declared incomplete will not be accepted. Photocopied pages from previously submitted exemption forms will be accepted provided that the certifications page contains an original dated signature.

(f) *Multiple exemption holders.* (1) A manufacturer who intends to manufacture a substance for which an exemption under this section was previously approved may apply for an exemption under paragraph (c)(1) or (c)(2) of this section; however, EPA will not approve any subsequent exemption application under paragraph (c)(1) of this section unless it can determine that the potential human exposure to, and environmental release of, the new chemical substance at the higher aggregate production volume will not present an unreasonable risk of injury to human health or the environment.

(2)(i) If EPA proposes to deny an exemption application for a substance for which another manufacturer currently holds an exemption, and that proposed denial is based exclusively on the cumulative human exposure or environmental release of the substance which precludes the EPA from determining that the subsequent applicant's activities will not present an unreasonable risk of injury to human health or the environment, the EPA will notify the first exemption holder that it must, within 21 days of its receipt of EPA's notice, either:

(A) Provide a new certification that it has commenced, or that it will commence, manufacture of the new chemical substance under this section within 1 year of the expiration of its exemption review period; or

(B) Withdraw its exemption for the new chemical substance.

(ii) If the first exemption holder does not respond to the EPA's notice under paragraph (f)(2)(i) of this section within the prescribed time period, EPA shall issue a notice of ineligibility to the first exemption holder under the provisions of paragraph (h)(2) of this section.

(g) *Review period.* (1) EPA will review the notice submitted under paragraph (e) of this section to determine whether manufacture of the new chemical substance is eligible for the exemption. The review period will end 30 days after receipt of the notice by the TSCA Document Control Officer. To provide additional time to address any unresolved issues concerning an exemption application, the exemption applicant may, at any time during the review period, request a suspension of the review period pursuant to the provisions of §720.75(b) of this chapter.

(2) Upon expiration of the 30-day review period, if EPA has taken no action, the manufacturer may consider its exemption approved and begin to manufacture the new chemical substance under the terms described in its notice and in this section.

(h) *Notice of ineligibility*—(1) *During the review period.* If the EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of this section or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30-day review period, EPA will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the reasons for the ineligibility determination. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act or submitting a new notice under paragraph (e) of this section that satisfies EPA's concerns.

(2) *After the review period.* (i)(A) If at any time after the review period specified in paragraph (g) of this section the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances ("the Assistant Administrator") makes a preliminary determination that manufacture of the new

chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms of the section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (h)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (h)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (h)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (h)(2)(i)(A) of this section may submit, within 15 days of receipt of written notification, detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (h)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that manufacture of the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 7 days of the written notification under paragraph (h)(2)(iii) of this section. The manufacturer may not resume manufacture, processing, distribution in commerce, and use of the new chemical substance until it submits a notice under section 5(a)(1) of the Act and part 720 of this chapter and the notice review period has ended.

(vi) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (h)(2)(i)(A) of this section.

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and part 720 of this chapter within 15 days of receipt of the written notification under paragraph (h)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, or 17 of the Act.

(i) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify under terms of this section, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information. If, during the notice review period specified in paragraph (g) of this section, the submitter obtains possession, control, or knowledge of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must send that information to the address listed on the notice form within 10 days of receiving the new in-

formation, but no later than 5 days before the end of the notice review period. The new submission must clearly identify the submitter and the exemption notice to which the new information is related. If the new information becomes available during the last 5 days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(j) *Changes in manufacturing site, use, human exposure and environmental release controls, and certain manufacturing volumes.* (1) Except as provided in paragraph (j)(6) of this section, chemical substances manufactured under this section must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice under paragraph (e) of this section.

(2) Where the manufacturer lists a specific physical form in which the new chemical substance will be manufactured, processed, and/or used, the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in either the same physical form described in the notice under paragraph (e), or in a physical form which will not increase the human exposure to or environmental release of the new chemical substance over those exposures or releases resulting from the specified physical form (e.g., a manufacturer which specifies that the new chemical substance will be produced in a non-volatile liquid form generally may not change to a respirable powder form).

(3) The annual production volume of chemical substances manufactured under paragraph (c)(1) of this section for which the manufacturer designated a binding annual production volume pursuant to paragraph (e)(2)(vi) of this section must not exceed that designated volume.

(4) Any person who manufactures a new chemical substance under paragraph (c)(1) or (c)(2) of this section must comply with the provisions of this section, including submission of a new notice under paragraph (e) of this section, before:

(i) Manufacturing the new chemical substance at a site that was not approved in a previous exemption notice for the substance, except as provided in paragraph (j)(6) of this section.

(ii) Manufacturing the new chemical substance for a use that was not approved in a previous exemption notice for the substance.

(iii) Manufacturing the new chemical substance without employing the human exposure and environmental release controls approved in a previous exemption notice for the substance.

(iv) Manufacturing the new chemical substance in a physical form different than that physical form approved in a previous exemption notice for the substance and which form may increase the human exposure to, or environmental release of, the new chemical substance over those exposures or releases resulting from the physical form approved in the previous notice.

(v) Manufacturing the chemical substance in annual production volumes above any volume designated by the manufacturer as binding under paragraph (e)(2)(vi) of this section in a previous exemption notice for the substance.

(5) In an exemption notice informing EPA of a change in site, use, or worker protection, or environmental release controls, the manufacturer is not required to provide all of the same information submitted to EPA in a previous exemption notice for that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and location of the new site, new worker protection or environmental release controls, and new use information. The notice must also include the EPA-designated exemption number assigned to the previous notice and a new certification by the manufacturer, as described in paragraph (e)(2)(xi) of this section.

(6)(i) A manufacturer may, without submitting a new notice, manufacture the new chemical substance at a site not listed in its exemption application under the following conditions:

(A) the magnitude, frequency, and duration of exposure of individual workers to the new chemical substance at the new manufacturing site is equal

to, or less than, the magnitude, frequency, and duration of exposure of the individual workers to the new chemical substance at the manufacturing site for which the EPA performed its original risk-assessment pursuant to the original exemption notice; and

(B) Either (*1*) at the new manufacturing site, the manufacturer does not release to surface waters any of the new chemical substance, or any waste streams containing the new chemical substance; or (*2*) at the new manufacturing site, the manufacturer maintains surface water concentrations of the chemical substance, resulting from direct or indirect discharges from the manufacturing site, at or below 1 part per billion, or at or below an alternative concentration level approved by the Agency in writing or under the procedures described in paragraph (c)(2)(iii) of this section, using the water concentration calculation method described at §§721.90 and 721.91.

(ii) The manufacturer shall notify EPA of any new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance under the exemption at the new manufacturing site as follows:

(A) The notification must contain the EPA-designated exemption number to which the notification applies, manufacturer identity, the street address of the new manufacturing site, the date on which manufacture commenced at the new site, the name and telephone number of a technical contact at the new site, any claim of confidentiality, and a statement that the notification is an amendment to the original exemption application under the terms of this section.

(B) The notification may be submitted on EPA form 7710–56 "Notice of Commencement of Manufacture;" however, the manufacturer must add the statement required under paragraph (j)(6)(ii)(A) of this section that the notification is an amendment to the original exemption.

(C) The notification must contain an original signature of an authorized official of the manufacturer.

(k) *Customer notification.* (1) Manufacturers of new chemical substances described in paragraphs (c)(1) and (c)(2) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice at paragraph (e) of this section. The manufacturer must also inform processors and industrial users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) A manufacturer of a new chemical substance described in paragraph (c)(2) of this section may distribute the chemical substance only to other persons who agree in writing to not further distribute the substance until it has been reacted, incorporated into an article, or otherwise rendered into a physical form or state in which environmental releases and human exposures above the eligibility criteria in paragraph (c)(2) of this section are not likely to occur.

(3) If the manufacturer learns that a direct or indirect customer is processing or using the new substance in violation of use restrictions or without imposing prescribed worker protection or environmental release controls, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately unless the manufacturer is able to document each of the following:

(i) That the manufacturer has, within 5 working days, notified the customer in writing that the customer has failed to comply with the conditions specified in this section and the exemption notice under paragraph (e) of this section.

(ii) That, within 15 working days of notifying the customer of the noncompliance, the manufacturer received from the customer, in writing, a statement of assurance that the customer is aware of the terms of this section and the exemption notice and will comply with those terms.

(4) If, after receiving a statement of assurance from a customer under paragraph (k)(3)(ii) of this section, the manufacturer obtains knowledge that the customer has again failed to comply with any of the conditions specified in this section or the exemption notice, the manufacturer shall cease supplying the new chemical substance to that

customer and shall report the failure to comply to EPA within 15 days of obtaining this knowledge. Within 30 days of its receipt of the report, EPA will notify the manufacturer whether, and under what conditions, distribution of the chemical substance to the customer may resume.

(l) *Confidentiality.* (1) If the manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph (l) must provide a generic chemical 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.

(ii) The generic name provided by the manufacturer will be subject to EPA review and approval in accordance with the procedures specified in §720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice with all information claimed as confidential deleted. EPA will place the second copy in the public file.

(m) *Exemptions granted under superseded regulations.* Manufacturers holding exemptions granted under the superseded requirements of this section (as in effect on May 26, 1995) shall either continue to comply with those requirements (including the production volume limit) or apply for a new exemption pursuant to this section. EPA will not accept requests to amend exemptions granted under the superseded requirements; manufacturers wishing to amend such exemptions must submit a new exemption under paragraph (e) of this section. If a new exemption for a new chemical substance is granted under this exemption to the manufacturer holding an exemption under the superseded requirements, the exemption under the superseded requirements for such substance shall be void.

(n) *Recordkeeping.* (1) A manufacturer of a new chemical substance under paragraph (c) of this section must maintain the records described in this paragraph at the manufacturing site or site of importation for a period of 5 years after date of their preparation.

(2) The records must include the following to demonstrate compliance with this section:

(i) Records of annual production volume and import volume;

(ii) Records documenting complaince with the applicable requirements and restrictions of paragraphs (c), (e), (f), (h), (i), (j), and (k) of this section.

(3) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA, permit such person at all reasonable times to have access to and to copy records kept under paragraph (n)(2) of this section.

(4) The manufacturer must submit the records listed in paragraph (n)(2) of this section to EPA upon written request. Manufacturers must provide these records within 15 working days of receipt of such request.

(o) *Compliance* . (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical

substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other action under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 1616).

[60 FR 16346, Mar. 29, 1995]

§ 723.175 Chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture and processing of new chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.

(2) To manufacture a new chemical substance under the terms of this exemption, a manufacturer of instant photographic or peel-apart film articles must:

(i) Submit an exemption notice when manufacture begins under paragraph (i) of this section.

(ii) Comply with certain requirements to limit exposure to the new chemical substance under paragraphs (e), (f), (g), and (h) of this section.

(iii) Comply with all recordkeeping requirements under paragraph (j) of this section.

(b) *Definitions.* (1) *Act* means the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*).

(2) An *article* is a manufactured item (i) which is formed to a specific shape or design during manufacture, (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (iii) 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 described in §710.2 of this chapter except that fluids and particles are not considered articles regardless of shape or design.

(3) The term *byproduct, EPA, impurities, person,* and *site* have the same meanings as in §710.2 of this chapter.

(4) The term *category of chemical substances* has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

(5) The terms *chemical substance, distribute in commerce, distribution in commerce, environment, manufacture, new chemical substance,* and *process* have the same meanings as in section 3 of the Act (15 U.S.C. 2602).

(6) *Director of the Office of Pollution Prevention and Toxics* means the Director of the EPA Office of Pollution Prevention and Toxics or any EPA employee designated by the Office Director to carry out the Office Director's functions under this section.

(7) The term *exemption category* means a category of chemical substances for which a person(s) has applied for or been granted an exemption under section 5(h)(4) of the Act (15 U.S.C. 2604).

(8) The term *instant photographic film article* means a self-developing photographic film article designed so that all the chemical substances contained in the article, including the chemical substances required to process the film, remain sealed during distribution and use.

(9) *Intermediate* means any chemical substance which is consumed in whole or in part in a chemical reaction(s) used for the intentional manufacture of another chemical substance.

(10) *Known to or reasonably ascertainable* 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, our could obtain without unreasonable burden or cost.

(11) The term *peel-apart film article* means a self-developing photographic film article consisting of a positive image receiving sheet, a light sensitive negative sheet, and a sealed reagent pod containing a developer reagent and designed so that all the chemical substances required to develop or process the film will not remain sealed within the article during and after the development of the film.

(12) *Photographic article* means any article which will become a component of an instant photographic or peel-apart film article.

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 723. Premanufacture Notification Exemptions (Refs & Annos)
Subpart B. Specific Exemptions

40 C.F.R. § 723.50

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

Currentness

(a) Purpose and scope.

(1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A)(i) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

(i) Chemical substances manufactured in quantities of 10,000 kilograms or less per year.

(ii) Chemical substances with low environmental releases and human exposures.

(2) To manufacture a new chemical substance under the terms of this exemption a manufacturer must:

(i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under paragraph (e) of this section.

(ii) Comply with all other provisions of this section.

(3) This section does not apply to microorganisms subject to part 725 of this chapter.

(b) Definitions. The following definitions apply to this subpart.

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

(2) Consumer means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

(3) Environment has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(4) Environmental transformation product means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(5) Metabolite means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(6) Serious acute effects means human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(7) Serious chronic effects means human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(8) Significant environmental effects means:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society;

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year; or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. Endangered or threatened species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(9) Site means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

(10) The terms byproduct, EPA, importer, impurity, known to or reasonably ascertainable, manufacture, manufacturer, new chemical substance, person, possession or control, and test data have the same meanings as in § 720.3 of this chapter.

(11) PFAS or per- and poly-fluoroalkyl substance means a chemical substance that contains at least one of these three structures:

(i) R–(CF2)–CF(R')R", where both the CF2 and CF moieties are saturated carbons;

(ii) R–CF2OCF2–R', where R and R' can either be F, O, or saturated carbons; or

(iii) CF3C(CF3)R'R", where R' and R" can either be F or saturated carbons.

(12) PBT chemical substance means a chemical substance possessing characteristics of persistence (P) in the environment, accumulation in biological organisms (bioaccumulation (B)), and toxicity (T) resulting in potential risks to humans and ecosystems. For more information on EPA's Policy on new chemical substances that are PBTs, see EPA's 1999 policy statement (64 FR 60194, November 4, 1999 (FRL–6097–7)).

(c) Exemption categories. Except as provided in paragraph (d) of this section, this exemption applies to:

(1) Any manufacturer of a new chemical substance manufactured in quantities of 10,000 kilograms or less per year under the terms of this exemption.

(2) Any manufacturer of a new chemical substance satisfying all of the following low environmental release and low human exposure eligibility criteria:

(i) Consumers and the general population. For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance:

(A) No dermal exposure.

(B) No inhalation exposure (except as described in paragraph (c)(2)(iv) of this section.

(C) Exposure in drinking water no greater than a 1 milligram per year (estimated average dosage resulting from drinking water exposure in streams from the maximum allowable concentration level from ambient surface water releases established under paragraph (c)(2)(iii) of this section or a higher concentration authorized by EPA under paragraph (c)(2)(iii) of this section).

(ii) Workers. For exposure of workers to the new chemical substance during all manufacturing, processing, distribution in commerce, use and disposal of the substance:

(A) No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable EPA guidance).

(B) No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable EPA guidance).

(iii) Ambient surface water. For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion, calculated using the methods prescribed in §§ 721.90 and 721.91, unless EPA has approved a higher surface water concentration supported by relevant and scientifically valid data submitted to EPA in a notice under paragraph (e) of this section on the substance or a close structural analogue of the substance which demonstrates that the new substance will not present an unreasonable risk of injury to aquatic species or human health at the higher concentration.

(iv) Incineration. For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration, calculated using the formula:

(kg/day of release after treatment) multiplied by (number of release days per year) multiplied by (9.68×10^{-6}) micrograms per cubic meter.

(v) Land or groundwater. For releases to land or groundwater, no releases to groundwater, to land, or to a landfill unless the manufacturer has demonstrated to EPA's satisfaction in a notice under paragraph (e) of this section that the new substance has negligible groundwater migration potential.

(d) Chemical substances that cannot be manufactured under this exemption. A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraph (c)(1) or (2) of this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance, any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance:

(1) May cause:

(i) Serious acute (lethal or sublethal) effects;

(ii) [1] Serious chronic (including carcinogenic and teratogenic) effects; or

(ii) [1] Significant environmental effects.

(2) Or is:

(i) A PFAS.

(ii) A PBT chemical substance with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.

(e) Exemption notice.

(1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to EPA at least 30 days before manufacture of the new chemical substance begins. Exemption notices and modifications must be submitted to EPA on EPA Form No. 7710–25 via CDX using e–PMN software in the manner set forth in this paragraph. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e–PMN software. Notices and any related support documents, must be generated and completed (via CDX) using e–PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e–PMN software.

(2) The notice shall contain the information described below, pursuant to the referenced provisions of § 720.45.

(i) Manufacturer identity.

(ii) Chemical identity (§ 720.45(a)).

(iii) Impurities (§ 720.45(b)).

(iv) Known synonyms or trade names (§ 720.45(c)).

(v) Byproducts (§ 720.45(d)).

(vi) Production volume (§ 720.45(e)).

(A) Manufacturers submitting an exemption application under paragraph (c)(1) of this section will be assumed to be manufacturing at an annual production volume of 10,000 kilograms. Manufacturers who intend to manufacture an exempted substance at annual volumes of less than 10,000 kilograms and wish EPA to conduct its risk assessment based upon such lesser annual production level rather than a 10,000–kilograms level, may so specify by writing the lesser annual production volume in the appropriate box on the PMN form and marking the adjacent binding option box. Manufacturers who opt to specify annual production levels below 10,000 kilograms and who mark the production volume binding option box shall not manufacture more than the specific annual amount of the exempted substance unless a new exemption notice for a higher (up to 10,000 kgs) manufacturing volume is submitted and approved pursuant to this section.

(B) Manufacturers submitting an exemption under paragraph (c)(2) of this section shall list the estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12–month period during the first 3 years of production.

(vii) Description of intended categories of use (§ 720.45(f)).

(viii) For manufacturer-controlled sites, the manufacturer shall supply identity of manufacturing sites, process descriptions, and worker exposure and environmental release information (§ 720.45(g)); for sites not controlled by the manufacturer, processing and use operation descriptions, estimated number of processing and use sites, and worker exposure/environmental release information (§ 720.45(h)). A manufacturer applying for an exemption under paragraph (c)(1) of this

section need not provide information on worker exposure and environmental release referenced in paragraphs (e)(2)(viii) of this section if such information is not known or not readily available to the manufacturer. To assist in reporting this information, manufacturers may obtain a copy of EPA's Guidance for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50, available from the Environmental Assistance Division at the address listed in paragraph (e)(1) of this section. Where worker exposure and environmental release information is not supplied by the manufacturer, EPA will generally apply "bounding estimates" (i.e., exposure estimates higher than those incurred by persons in the population with the highest exposure) to account for uncertainties in actual exposure and release scenarios.

(ix) Type and category of notice. The manufacturer must clearly indicate on the first page of the PMN form that the submission is a "TSCA section 5(h)(4) exemption notice," and must indicate whether the notice is being submitted under paragraph (c)(1) or (c)(2) of this section. Manufacturers of chemical substances that qualify for an exemption under both paragraph (c)(1) and (c)(2) of this section may apply for either exemption, but not both.

(x) Test data (§ 720.50).

(xi) Certification. In addition to the certifications required in EPA form 7710–25, the following certifications shall be included in notices under this section. The manufacturer must certify that:

(A) The manufacturer intends to manufacture the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(D) For substances manufactured under paragraph (c)(1) of this section, the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30–day review period.

(xii) Sanitized copy of notice.

(A) The manufacturer must make all claims of confidentiality in accordance with paragraph (l) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (l)(3) of this section.

(B) If the manufacturer does not provide the second copy, the submission will be considered incomplete.

(xiii) Safety Data Sheet (§ 720.45(i)).

(xiv) Physical and chemical properties and environmental fate characteristics (§ 720.45(j)).

(3) Incomplete notices. EPA will conduct a pre-screen of the notice, typically taking 2–3 days and according to the criteria under paragraph (e)(2) of this section. If EPA concludes that the notice is incomplete, EPA will notify the submitter and the review period will not begin. Once the submitter corrects the errors or incomplete submission according to the requirements provided by EPA and re-submits the notice to EPA, the review period will begin. If EPA does not identify errors or determine the notice to be incomplete during screening, the review period will begin on the date EPA received the complete notice.

(f) Multiple exemption holders.

(1) A manufacturer who intends to manufacture a substance for which an exemption under this section was previously approved may apply for an exemption under paragraph (c)(1) or (c)(2) of this section; however, EPA will not approve any subsequent exemption application under paragraph (c)(1) of this section unless it can determine that the potential human exposure to, and environmental release of, the new chemical substance at the higher aggregate production volume will not present an unreasonable risk of injury to human health or the environment.

(2)(i) If EPA proposes to deny an exemption application for a substance for which another manufacturer currently holds an exemption, and that proposed denial is based exclusively on the cumulative human exposure or environmental release of the substance which precludes the EPA from determining that the subsequent applicant's activities will not present an unreasonable risk of injury to human health or the environment, the EPA will notify the first exemption holder that it must, within 21 days of its receipt of EPA's notice, either:

(A) Provide a new certification that it has commenced, or that it will commence, manufacture of the new chemical substance under this section within 1 year of the expiration of its exemption review period; or

(B) Withdraw its exemption for the new chemical substance.

(ii) If the first exemption holder does not respond to the EPA's notice under paragraph (f)(2)(i) of this section within the prescribed time period, EPA shall issue a notice of ineligibility to the first exemption holder under the provisions of paragraph (h)(2) of this section.

(g) Review period.

(1) EPA will review the notice submitted under paragraph (e) of this section to determine whether manufacture of the new chemical substance is eligible for the exemption. The review period will run for 30 days from the date EPA receives a complete notice. To provide additional time to address any unresolved issues concerning an exemption application, the exemption applicant may, at any time during the review period, request a suspension of the review period pursuant to the provisions of § 720.75(b) of this chapter.

(2) No person submitting a notice under paragraph (e) of this section may manufacture the new chemical substance until EPA notifies the submitter that the new chemical substance meets the terms of this section.

(h) Notice of ineligibility—

(1) During the review period. If the EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of this section or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30–day review period, EPA will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the reasons for the ineligibility determination. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act or submitting a new notice under paragraph (e) of this section that satisfies EPA's concerns.

(2) After the review period.

(i)(A) If at any time after the review period specified in paragraph (g) of this section the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention ("the Assistant Administrator") makes a preliminary determination that manufacture of the new chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms of the section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (h)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (h)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (h)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (h)(2)(i)(A) of this section may submit, within 15 days of receipt of written notification, detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (h)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that manufacture of the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Agency determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 7 days of the written notification under paragraph (h)(2)(iii) of this section. The manufacturer may not resume manufacture, processing, distribution in commerce, and use of the new chemical substance until it submits a notice under section 5(a)(1) of the Act and part 720 of this chapter and EPA has made one of the five determinations as set forth in section 5(a)(3) of the Act and taken the action required in association with that determination.

(vi) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (h)(2)(i)(A) of this section.

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and part 720 of this chapter within 15 days of receipt of the written notification under paragraph (h)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, or 17 of the Act.

(i) Additional information. If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify under terms of this section, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information. If, during the notice review period specified in paragraph (g) of this section, the submitter obtains possession, control, or knowledge 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 to EPA within ten days of receiving the new information, but no later than five days before the end of the applicable review period. The new information must be submitted electronically to EPA via CDX and must clearly identify the submitter and the exemption notice to which the new information is related. If the new information becomes available during the last 5 days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone or e-mail and submit the new information electronically to EPA via CDX.

(j) Changes in manufacturing site, use, human exposure and environmental release controls, and certain manufacturing volumes.

(1) Except as provided in paragraph (j)(6) of this section, chemical substances manufactured under this section must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice under paragraph (e) of this section.

(2) Where the manufacturer lists a specific physical form in which the new chemical substance will be manufactured, processed, and/or used, the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in either the same physical form described in the notice under paragraph (e), or in a physical form which will not increase the human exposure to or environmental release of the new chemical substance over those exposures or releases resulting from the specified physical form (e.g., a manufacturer which specifies that the new chemical substance will be produced in a non-volatile liquid form generally may not change to a respirable powder form).

(3) The annual production volume of chemical substances manufactured under paragraph (c)(1) of this section for which the manufacturer designated a binding annual production volume pursuant to paragraph (e)(2)(vi) of this section must not exceed that designated volume.

(4) Any person who manufactures a new chemical substance under paragraph (c)(1) or (c)(2) of this section must comply with the provisions of this section, including submission of a new notice under paragraph (e) of this section, before:

(i) Manufacturing the new chemical substance at a site that was not approved in a previous exemption notice for the substance, except as provided in paragraph (j)(6) of this section.

(ii) Manufacturing the new chemical substance for a use that was not approved in a previous exemption notice for the substance.

(iii) Manufacturing the new chemical substance without employing the human exposure and environmental release controls approved in a previous exemption notice for the substance.

(iv) Manufacturing the new chemical substance in a physical form different than that physical form approved in a previous exemption notice for the substance and which form may increase the human exposure to, or environmental release of, the new chemical substance over those exposures or releases resulting from the physical form approved in the previous notice.

(v) Manufacturing the chemical substance in annual production volumes above any volume designated by the manufacturer as binding under paragraph (e)(2)(vi) of this section in a previous exemption notice for the substance.

(5) In an exemption notice informing EPA of a change in site, use, or worker protection, or environmental release controls, the manufacturer is not required to provide all of the same information submitted to EPA in a previous exemption notice for that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and location of the new site, new worker protection or environmental release controls, and new use information. The notice must also include the EPA-designated exemption number assigned to the previous notice and a new certification by the manufacturer, as described in paragraph (e)(2)(xi) of this section.

(6)(i) A manufacturer may, without submitting a new notice, manufacture the new chemical substance at a site not listed in its exemption application under the following conditions:

(A) the magnitude, frequency, and duration of exposure of individual workers to the new chemical substance at the new manufacturing site is equal to, or less than, the magnitude, frequency, and duration of exposure of the individual workers to the new chemical substance at the manufacturing site for which the EPA performed its original risk-assessment pursuant to the original exemption notice; and

(B) Either (1) at the new manufacturing site, the manufacturer does not release to surface waters any of the new chemical substance, or any waste streams containing the new chemical substance; or (2) at the new manufacturing site, the manufacturer maintains surface water concentrations of the chemical substance, resulting from direct or indirect discharges from the manufacturing site, at or below 1 part per billion, or at or below an alternative concentration level approved by the Agency in writing or under the procedures described in paragraph (c)(2)(iii) of this section, using the water concentration calculation method described at §§ 721.90 and 721.91.

(ii) The manufacturer shall notify EPA of any new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance under the exemption at the new manufacturing site as follows:

(A) The notification must contain the EPA-designated exemption number to which the notification applies, manufacturer identity, the street address of the new manufacturing site, the date on which manufacture commenced at the new site, the name and telephone number of a technical contact at the new site, any claim of confidentiality, and a statement that the notification is an amendment to the original exemption application under the terms of this section.

(B) The notification must be submitted electronically to EPA via CDX as a support document to the original notification. Prior to submission to EPA via CDX, such notices must be generated and completed using the e–PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e–PMN software.

(k) Customer notification.

(1) Manufacturers of new chemical substances described in paragraphs (c)(1) and (c)(2) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice at paragraph (e) of this section. The manufacturer must also inform processors and industrial users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) A manufacturer of a new chemical substance described in paragraph (c)(2) of this section may distribute the chemical substance only to other persons who agree in writing to not further distribute the substance until it has been reacted, incorporated into an article, or otherwise rendered into a physical form or state in which environmental releases and human exposures above the eligibility criteria in paragraph (c)(2) of this section are not likely to occur.

(3) If the manufacturer learns that a direct or indirect customer is processing or using the new substance in violation of use restrictions or without imposing prescribed worker protection or environmental release controls, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately unless the manufacturer is able to document each of the following:

(i) That the manufacturer has, within 5 working days, notified the customer in writing that the customer has failed to comply with the conditions specified in this section and the exemption notice under paragraph (e) of this section.

(ii) That, within 15 working days of notifying the customer of the noncompliance, the manufacturer received from the customer, in writing, a statement of assurance that the customer is aware of the terms of this section and the exemption notice and will comply with those terms.

(4) If, after receiving a statement of assurance from a customer under paragraph (k)(3)(ii) of this section, the manufacturer obtains knowledge that the customer has again failed to comply with any of the conditions specified in this section or the exemption notice, the manufacturer shall cease supplying the new chemical substance to that customer and shall report the failure to comply to EPA within 15 days of obtaining this knowledge. Within 30 days of its receipt of the report, EPA

will notify the manufacturer whether, and under what conditions, distribution of the chemical substance to the customer may resume.

(l) Confidentiality. Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

(m) Exemptions granted under superseded regulations. Manufacturers holding exemptions granted under the superseded requirements of this section (as in effect on May 26, 1995) shall either continue to comply with those requirements (including the production volume limit) or apply for a new exemption pursuant to this section. EPA will not accept requests to amend exemptions granted under the superseded requirements; manufacturers wishing to amend such exemptions must submit a new exemption under paragraph (e) of this section. If a new exemption for a new chemical substance is granted under this exemption to the manufacturer holding an exemption under the superseded requirements, the exemption under the superseded requirements for such substance shall be void.

(n) Recordkeeping.

(1) A manufacturer of a new chemical substance under paragraph (c) of this section must maintain the records described in this paragraph at the manufacturing site or site of importation for a period of 5 years after their preparation.

(2) The records must include the following to demonstrate compliance with this section:

(i) Records of annual production volume and import volume.

(ii) Records documenting compliance with the applicable requirements and restrictions of paragraphs (c), (e), (f), (h), (i), (j), and (k) of this section.

(3) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA, permit such person at all reasonable times to have access to and to copy records kept under paragraph (n)(2) of this section.

(4) The manufacturer must submit the records listed in paragraph (n)(2) of this section to EPA upon request. Manufacturers must provide these records within 15 working days of receipt of such request.

(o) Compliance.

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

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other action under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 1616).

(p) Subject to a significant new use rule or listed on TSCA Inventory. If a significant new use rule is proposed or finalized in part 721 of this chapter for a chemical substance described by a generic chemical name or if the specific chemical identity of a chemical substance is listed on the confidential portion of the TSCA Inventory, EPA may make reasonable efforts to notify any persons who may also manufacture the same chemical substance under the terms of this section. A disclosure to a person with an approved exemption under this section that the chemical substance is subject to a proposed or final rule in part 721 of this chapter or is listed on the confidential portion of the TSCA Inventory will not be considered public disclosure of confidential business information under section 14 of the Act. The notification will inform manufacturers subject to the terms of this section that the chemical substance is subject to a proposed or final significant new use rule under section 5(a)(2) of the Act or is listed on the TSCA Inventory, and identify the proposed or final section in subpart E of part 721 of this chapter that pertains to the chemical substance or the generic name for that substance listed on the public portion of the TSCA Inventory, as applicable.

Credits

[50 FR 16488, April 26, 1985; 53 FR 12523, April 15, 1988; 60 FR 16346, March 29, 1995; 60 FR 34465, July 3, 1995; 62 FR 17932, April 11, 1997; 64 FR 31989, June 15, 1999; 71 FR 33642, June 12, 2006; 75 FR 787, Jan. 6, 2010; 77 FR 46293, Aug. 3, 2012; 78 FR 72828, Dec. 4, 2013; 80 FR 42746, July 20, 2015; 87 FR 39769, July 5, 2022; 87 FR 47103, Aug. 2, 2022; 88 FR 37173, June 7, 2023; 89 FR 102798, Dec. 18, 2024]

SOURCE: 51 FR 6414, Feb. 24, 1986, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2604.

Current through October 2, 2025, 90 FR 47963. Some sections may be more current. See credits for details.

Footnotes

1 So in original; there are two subsections (d)(1)(ii). See 89 FR 102798.

1 So in original; there are two subsections (d)(1)(ii). See 89 FR 102798.

End of Document

S. REP. 94-698, S. Rep. No. 698, 94TH Cong., 2ND Sess. 1976, 1976 U.S.C.C.A.N. 4491, 1976 WL 13880 (Leg.Hist.)

****4491** P.L. 94-469, TOXIC SUBSTANCES CONTROL ACT

Senate Report (Commerce Committee) No. 94-698,
Mar. 16, 1976 (To accompany S. 3149)
House Report (Interstate and Foreign Commerce Committee) No. 94-1341,
July 14, 1976 (To accompany H.R. 14032)
House Conference Report No. 94-1679,
Sept. 23, 1976 (To accompany S. 3149)
Senate Conference Report No. 94-1302,
Sept. 24, 1976 (To accompany S. 3149)
Cong. Record Vol. 122 (1976)
DATES OF CONSIDERATION AND PASSAGE
Senate March 26, September 29, 1976
House August 23, September 28, 1976

The Senate bill was passed in lieu of the House bill. The Senate Report and the House Conference Report are set out.

(CONSULT NOTE FOLLOWING TEXT FOR INFORMATION ABOUT OMITTED MATERIAL. EACH COMMITTEE REPORT IS A SEPARATE DOCUMENT ON WESTLAW.)

SENATE REPORT NO. 94-698

Mar. 16, 1976

***1** The Committee on Commerce having considered the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, reports favorably thereon and recommends that the bill do pass.

PURPOSE AND BRIEF DESCRIPTION

The purpose of S. 3149 is to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances. The bill is designed to fill a number of regulatory gaps which currently exist. They are:

1. PREMARKET REVIEW

While certain environmental health statutes may be used to protect health and the environment from chemical substances, only pesticides, drugs, and food additives undergo premarket scrutiny prior to first manufacture. The Clean Air Act (77 Stat. 392), the Federal Water Pollution Control Act (66 Stat. 755), the Occupational Safety and Health Act (84 Stat. 1590), and the Consumer Product Safety Act (86 Stat. 1207), do not provide for this type of premarket scrutiny.

2. DIRECT REGULATION OF CHEMICALS

While air and water laws authorize limitations on discharges and emissions, the Occupational Safety and Health Act authorizes the ****4492** establishment of ambient air standards for the workplace, and the Consumer Product Safety Act authorizes standards with respect to ***2** consumer products, there are no existing statutes which authorize the direct control of industrial chemicals themselves for their health or environmental effect (except section 211 of the Clean Air Act, which authorizes the regulations of fuel additives).

While these other authorities will in many cases be sufficient to adequately protect health and the environment, the alternative of preventing or regulating the use of the chemical in the first instance may be a far more effective way of dealing with the hazards. If expensive sewage treatment facilites can be avoided, for example, through removing dangerous materials from household and industrial wastes, the authority to do so ought to be provided.

3. CONSIDERATION OF ALL THE RISKS

While individual agencies may be authorized to regulate occupational, environmental, or direct consumer hazards with respect to a chemical substance, there is no agency which has the authority to look comprehensively at the hazards associated with the chemical. Existing authority allows the agencies to only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical. The bill would grant the Environmental Protection Agency the authority to look at the hazards in total.

4. COLLECTION OF TEST DATA

The committee bill also provides a mechanism whereby information with respect to health and environmental effects can be collected from manufacturers and processors of chemical substances. While other statutes provide regulatory authority, they do not place the responsibility for gathering information in support of the regulatory program squarely with persons who are responsible for the manufacture or processing of the chemical substance or mixtures.

Specifically, the bill provides:

(1) That manufacturers of new chemical substances give notification to EPA 90 days in advance of first manufacture and that test data accompany that notification if required by EPA. The provision is not applicable to research chemicals unless EPA specifically includes any such chemical.

(2) That the EPA Administrator require manufacturers to test or have tested those chemical substances which he determines may present an unreasonable risk of injury to health or the environment or those for which significant human or environmental exposure takes place or will take place. The provision is applicable both to new and existing chemical substances.

(3) Manufacturers and processors of chemical substances are required to maintain certain records and reports to better enable the Administrator to determine if unreasonable risks exist. Importantly, manufacturers must maintain with the Administrator lists of health and safety studies conducted, whether or not they have been conducted as a result of this legislation. The Administrator ****4493** is authorized to require the submission of any study on the list.

***3** (4) Citizens are authorized to bring suits to enjoin certain violations and to require the Administrator of EPA to perform his mandatory duties. A citizens' petition provision is also provided whereby citizens may receive judicial review of petitions to EPA which were denied or not acted upon.

BACKGROUND AND NEEDS

The last century has witnessed the ever-accelerating growth of the chemical industry. Sales now exceed $100 billion a year. This industry has developed a vast new array of chemicals. In fact, it is estimated that there are presently 2 million recognized chemical compounds in existence with nearly 250,000 new compounds produced each year. While most of these compounds will never be commercialized, the Environmental Protection Agency estimates that approximately 1,000 new chemical each year will find their way into the marketplace and subsequently into the environment through use or disposal.

As the industry has grown, we have become literally surrounded by a man-made chemical environment. We utilize chemicals in a majority of our daily activities. We continually wear, wash with, inhale, and ingest a multitude of chemical substances. Many of these chemicals are essential to protect, prolong, and enhance our lives. Yet, too frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers.

In 1971, the Council on Environmental Quality in a report entitled ‘Toxic Substances‘ concluded that regulatory mechanisms to control toxic chemicals were ‘inadequate.‘ This report was the impetus for the original Toxic Substances Control Act legislation.

After 15 days of hearings and extensive analysis over the last 5 years, the Toxic Substances Control Act has evolved into a comprehensive measure to protect the public and the environment from exposure to hazardous chemicals. The legislation would assure that chemicals receive careful premarket scrutiny before they are manufactured or distributed to the public. This provision would end the present situation where chemicals can be marketed without notification of any governmental body and without any requirement that they be tested for safety. Thus, this provision would no longer allow the public or the environment to be used as a testing ground for the safety of these products.

In a recent speech supporting toxic substances control legislation, Russell E. Train, the Administrator of the Environmental Protection Agency, pointed out that--

Most Americans had no idea, until relatively recently, that they were living so dangerously. They had no idea that when they went to work in the morning, or when they ate their breakfast-- that when they did the things they had to do to earn a living and keep themselves alive and well-- that when they did things as ordinary, as innocent and as essential to life as eat, drink, breathe or touch, they could, in fact, be laying their lives on the line. They had no idea that, without their knowledge or consent, they were often engaging in a grim game of chemical roulette whose result they would not know until many years later.

Dr. Train's view is a reflection of the fact that in the last few years the list of commonly utilized and widely dispersed chemicals that ***4 **4494** have been found to be potentially significant health and environmental dangers has been constantly growing. A partial list includes:

(1) Kepone, which has been implicated in causing brain damage and other nervous system disorders;

(2) vinyl chloride, arsenic, and asbestos, all found to be potentially extremely potent cancer-causing agents in man;

(3) mercury, lead, and other heavy metals;

(4) PCB's which have been found to cause liver cancer in rats and to have contaminated numerous fish stocks throughout the United States; and

(5) fluorocarbons, propellants in aerosols and coolants in refrigerators and air-conditioners, suspected of depleting the Earth's ozone layer which protects humans from excessive ultraviolet radiation that can cause skin cancer.

Furthermore, the interaction of chemical substances in some cases, makes these dangers multiplicative rather than additive. Dr. Irving Selikoff, of the Mount Sinai Medical School, for example, pointed out that asbestos workers who are nonsmokers do not have an appreciably higher lung cancer rate than the population at large. However, Dr. Selikoff noted that if an asbestos worker smokes, his chances of getting lung cancer are eight times greater than the average cigarette smoker and are 92 times greater than an individual who is neither an asbestos worker or a smoker. Thus, the risks appear to be multiplied by these interactions.

Russell Peterson, Chairman of the Council on Environmental Quality, after analyzing these chemical dangers concluded at last year's hearings, ‘Toxic substances legislation is probably the most important environmental legislation now before the

Congress.' Many doctors and scientists concur with Dr. Peterson noting that controlling toxic chemicals in the environment is one of the crucial health requirements facing this Nation. Dr. David Rall, Director of the National Institute of Environmental Health Sciences of the National Institutes of Health, has stated, for example:

Recent experience with vinyl chloride, bischloromethyl ether, methylbutyl ketone, and sulphuric acid mist indicate that these compounds are not theoretical threats, but known causes of illness and death. Many of these compounds are toxic to man in relatively low concentrations. Man is assaulted by these compounds alone and in combination from multiple sources. This problem constitutes possibly the major health hazard of this decade.

Cancer, which was projected to kill as many Americans in 1975 as all the battle deaths in Vietnam, Korea, and the Second World War combined, appears particularly susceptible to a preventive approach through control of toxic substances in the environment. The National Cancer Institute, for example, estimates that 60 to 90 percent of the cancers occurring in this country are a result of environmental contaminants. Furthermore, the National Cancer Institute has plotted the incidence of cancer around the industrial centers of the United States. Almost without exception the industrial centers, where industrial chemicals are obviously found in largest concentrations, had the highest incidence of cancer. Thus, the Toxic Substances Control Act, which provides authority for increased testing of chemicals for their cancer-causing effects, can serve as an early warning system to signal potential dangers before products are widely dispersed and irretrievable societal danger has been unleashed.

***5 **4495** Toxic chemicals have also been implicated in causing birth defects and genetic damage. The National Foundation-March of Dimes recently wrote to Senator Magnuson in support of toxic substances legislation stating:

More than 200,000 infants are born with physical or mental damage each year, a staggering 7 percent of all births * * * A total of 15 million Americans have birth defects serious enough to drastically affect their daily lives * * * It is with alarm that our attention is drawn to some aspects of modern technology which work counter-productive to our aims. Each year billions of pounds of chemicals which are virtually untested and unregulated are produced in industrial processes and used in commercial products. Experience with vinylchloride has shown it to be a highly toxic substance which experimentally can cause cancer and birth defects; but this experience came only with its burden of proof on the public. We look now to preventative testing of toxic substances in industrial production prior to manufacture or distribution as one critical means to reduce exogenous causes of birth defects.

In order to protect against these dangers, the proposed Toxic Substances Control Act would close a number of major regulatory gaps, for while certain statutes, including the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act, may be used to protect health and the environment from chemical substances, none of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances. Under these other statutes, the Government regulator's only response to chemical dangers is to impose restrictions after manufacture begins.

The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest. Frequently, it is far more painful to take regulatory action after all of these costs have been incurred. For example, the hazards associated with vinyl chloride have made headlines in recent months. Vinyl chloride has been implicated as causing liver cancer in industrial workers. At the same time the country has grown extremely reliant on the plastics which are produced from the chemical. In fact, 1 percent of our gross national product is associated with the vinyl chloride industry. Obviously, it is far more difficult to take regulatory action against this chemical now, than it would have been had the dangers been known earlier when alternatives could have been developed and polyvinyl chloride plastics not become such an intrinsic part of our way of life in this country.

The proposed Toxic Substances Control Act also provides a far more effective mechanism to protect against dangerous chemical materials contained in consumer and industrial products. While air and water pollution laws authorize limitations on

discharges and emission and the Occupational Safety and Health Act authorizes workplace ambient standards, there are no statutes (except the fuel additives provisions of the Clean Air Act) which authorize the direct control of such chemicals for their health or environmental effects.

The regulation of the discharge of excessive levels of mercury into the environment is an example of the need for such controls. Recently, there has been growing concern about mercury pollution due to industrial discharges. Yet, testimony has indicated that an even greater ***6** threat of pollution may be posed by the presence of mercury in such consumer products as paint, home thermometers, sponges, and a variety of other products. Industrial pollution often can be pinpointed and corrective action rapidly taken; however, it is nearly impossible to prevent an individual householder from disposing of products containing toxic substances either down the drain or out with the garbage. While many dangerous materials can be removed from municipal sewage, many others cannot, therefore, it seems far more prudent to provide authority to limit the amounts of dangerous materials in consumer products than to allow them to escape into a municipal sewage plant or to vainly ask the householder not to dispose of them. A prime purpose of the proposed Toxic Substances Control Act is to provide authority for such regulatory controls.

Another important provision would provide regulators timely access to information regarding health and safety studies concerning chemicals covered by the Act. The importance of this provision was demonstrated in hearings of the Subcommittee on the Environment of the Senate Commerce Committee, where witnesses made detailed allegations that certain groups within the chemical industry had knowledge of the cancer-causing potential of vinyl chloride well in advance of the time that this information was released to the Government or the public. Similar charges were made that data was suppressed which suggested that industrial workers exposed to the chemical BCME were experiencing unusually high lung cancer rates. This legislation will provide the authority for EPA to gather this kind of information with respect to existing studies as well as studies which may be begun in the future.

The time has passed where human health and the environment is protected only after serious injury has occurred. As Russell Train has stated:

It is time we started putting chemicals to the test, not people. It is time we gave the people of this country some reason to believe that every time they take a breath or eat or drink or touch, they are not taking their life into their hands.

The Committee bill, which contains provisions to regulate chemical hazards, will help provide this needed assurance.

DESCRIPTION

1. TESTING OF CHEMICAL SUBSTANCES

There are two multi-part bases under which the Administrator must require that testing be conducted on a chemical substance or mixture. First, if the manufacturer, processing, distribution in commerce, use, or disposal (a) may present an unreasonable risk. (b) there are insufficient data or experience upon which to judge the effects upon health and the environment, and (c) testing is necessary to develop data, the Administrator must require testing.

Second, if the Administrator finds that the chemical substance or mixture may present significant human or environmental exposure because it is or will be produced in substantial quantities or for other reasons, and that the substance or mixture may perhaps present an adverse effect on health and the requirements of (b) and (c) above are ***7** ****4497** met, the Administrator must require testing. The finding with respect to an adverse effect is to be presumed if the Administrator has no reliable data or experience available to him.

In addition, the Administrator must consider the reasonably ascertainable costs and other burdens associated with conducting tests in light of the possible risks of injury to health or the environment. These findings are to be published in the Federal Register.

An eight member Federal advisory committee is established to develop a priority list of chemicals which it recommends to the Administrator for testing. The members of the committee are made up of Federal officials who either have regulatory responsibility in the area of chemical substances or have expertise with respect to testing needs.

Within 12 months after the date of inclusion of a chemical substance or mixture on the priority list, the Administrator is required to either (a) initiate a rulemaking proceeding to require testing or (b) publish in the Federal Register his reasons for not initiating such a proceeding.

2. PREMARKET NOTIFICATION

At least 90 days prior to the first manufacture (for commercial purpose) of a new chemical substance, manufacturers are to give notice to the Administrator. The notice is to contain information with respect to the identity of the substance, uses, estimates of amount to be produced, description of byproducts, a list of test data, and estimates of the number of employees who will be exposed to the substance.

If a testing requirement applicable to the new chemical has been established (see discussion of ‘Testing of Chemical Substances‘ above) the notification must be accompanied by the test data required.

The 90-day premarket notification period may be extended by the Administrator for an additional 90 days for good cause shown.

During the premarket notification period, the Administrator is authorized to issue an order which may restrict or prohibit the manufacturer of a new chemical substance on either of two bases:

(a) that a test requirement is necessary (or should be revised or added to); or

(b) that a restrictive rule is appropriate.

Orders issued during the premarket notification period are to be immediately effective and will trigger the appropriate rulemaking provisions under section 6 (restrictions) or section 4 (testing requirement). A provision to expedite rulemaking under these provisions is provided.

If the Administrator determines that orders during the premarket notification period are inappropriate or that action should not be taken under the imminent hazards authority of section 7, he must publish a statement of his reasons in the Federal Register.

The premarket notification provisions would also apply to significant new uses of existing chemical substances.

Premarket notification would not take place with respect to mixtures or experimental or research chemicals unless the Administrator specifically includes any such chemical for purposes of the premarket notification.

The Administrator is also authorized to exempt persons from premarket notification for test marketing purposes or specially limited ***8 **4498** purposes or with respect to chemical substances which are intermediate reaction products formed during the manufacture of other chemical substances and for which there is no exposure to human beings or the environment.

3. RESTRICTIVE AUTHORITY

Restrictive requirements may be prescribed for any chemical substance or mixture which presents or is likely to present an unreasonable risk of injury to health or the environment. Remedies available to the Administrator range from outright prohibitions to simple labeling requirements.

In promulgating rules, the Administrator is to consider all relevant factors and make findings with respect to them. Included are the risks to human beings and to the environment, the benefits of the substance or mixture, and the reasonably ascertainable economic consequences of the rule.

The Administrator is also authorized to seek orders in the district courts to protect against imminent hazards. Imminent hazards are defined as substances or mixtures which present an unreasonable risk of death, serious illness, or serious personal injury, or serious environmental harm prior to the completion of an administrative hearing or other proceeding authorized under the bill.

4. REPORTING AND RETENTION OF INFORMATION

The bill authorizes the Administrator to collect information which will prove extremely valuable in gathering information necessary to assess and take action against chemicals causing unreasonable risks. Manufacturers or processors may be required to submit pertinent information with respect to the identity, uses, amounts produced, byproducts, health effects, and exposure levels of chemical substances.

In addition, lists of health and safety studies conducted by, initiated by, or known to persons within the chemical industry must be submitted to the Administrator. The Administrator may then require the submission of any study appearing on the list. This will be valuable in avoiding the situations that have occurred in the past with chemicals like vinyl chloride and BCME where allegations have been made that the industry and trade associations withheld information which would have revealed hazards associated with these chemicals at a much earlier date.

In addition, persons within the chemical industry, and liability insurers of these persons, are required to submit any information to the Administrator which supports the conclusion that an unreasonable risk to health or the environment is presented.

5. RELATIONSHIP TO OTHER FEDERAL LAWS

If an unreasonable risk may be prevented or reduced sufficiently by other Federal laws, the Administrator must request the agency administering the law to issue an order declaring whether or not ***9 **4499** such a risk is presented. If the agency agrees that such a risk is presented, it must determine if the risk can be prevented or reduced to a sufficient extent by action taken under the law administered by it.

If the other Federal agency issues the order declaring that there is no unreasonable risk or initiates action under the other law, the Administrator may not take action under this authority to prevent the unreasonable risk.

With respect to other laws administered by the Administrator, the Administrator is directed to coordinate his actions with actions taken under those Federal laws and to use the authority contained in those laws unless this authority would be more appropriate.

In order to insure that information is gathered and premarket notification takes place, the restriction on the Administrator's authority would not apply to section 4 (testing), section 5 (premarket notification), or section 8 (reporting and information gathering).

6. CITIZENS PARTICIPATION

The bill contains a citizen's suit provision which authorizes suits against the Administrator where he has failed to perform a nondiscretionary duty and against others who are alleged to be in violation of sections 4 (testing), 5 (premarket notification), or 6(a) (restrictive rules). The provision is modeled after similar provisions in the Safe Drinking Water Act (88 Stat. 1660) Consumer Product Safety Act, Clean Air Act, Federal Water Pollution Control Act, and Noise Control Act.

In addition, citizens are authorized to petition the Administrator to take action the purpose of which is to protect against unreasonable risks of injury to health or the environment. If the Administrator fails to take action within 90 days on such a petition, or denies it, judicial review of the denial or failure is authorized. After gathering evidence in a de novo procedure, the courts would be authorized to require the initiation of the action requested if the petitioner has shown that the action requested is justified. The citizen's petition provision is similar to that contained in the Consumer Product Safety Act.

7. EMPLOYEE PROTECTION

Discrimination against any employee who participates in proceedings, testifies in a proceeding, or participates in any other action necessary to carry out the purposes of the legislation is prohibited.

A procedure is provided whereby the Secretary of Labor would conduct a proceeding and may order the reinstatement of the employee if violations are found.

In addition, the Administrator is required to continually evaluate the effects on employment which may result from the issuance of rules or orders under the bill. If requested by an employee whose employer has acted against him or her because of any rule or order issued under this bill, or when such actions are threatened, the Administrator is required to investigate the matter and to make findings of fact with respect to such allegations.

***10 **4500** RESPONSES TO ARGUMENTS

1. The bill does not contain excessive authority for EPA.

In the major regulatory provisions, section 4 (relating to test requirements) and section 6 (relating to restrictive authority), the Administrator is directed to consider costs and benefits when deriving appropriate rules.

Under section 6, the Administrator is required to make findings with respect to all relevant factors and to publish them in the Federal Register. This includes the risks to health and the environment, the benefits of the substance or mixture to be regulated, and the reasonably ascertainable economic consequences of the rule.

Under section 4, the Administrator is required to consider the reasonably ascertainable costs and other burdens associated with conducting the tests in light of the possible risks of injury to health or the environment and is required to publish these considerations in the Federal Register.

The rulemaking provisions of sections 4 and 6 provide an additional means to prevent improper action by EPA. Under section 4(b)(4) the Administrator is required to give interested persons an opportunity for the oral presentation of data, views, or arguments in addition to the opportunity to make written submissions.

Under the rulemaking provisions of section 6, an informal hearing must be provided with rights of cross-examination granted in appropriate instances.

Of course, judicial review of rules issued is available.

Finally, section 2(c) specifically states that it is the intent of Congress that the Administrator be reasonable and prudent in his administration of the bill, and that he is to consider the environmental, economic, and social impact of actions taken thereunder.

2. The premarket notification provisions are not too broad.

If hazards are to be discovered and prevented prior to the first manufacture of new chemical substances or prior to the imposition of significant new uses of existing substances, premarket notification is an essential provision.

Other alternatives to the committee bill now pending in the House of Representatives, would restrict premarket notification only to those chemical substances for which a finding of risk could be made. Thus, the EPA Administrator would be placed in the position of predicting not only what new chemical substances might be produced, but their level of hazard as well. The unpredictable new chemical substance would be completely missed by this procedure as would those substances for which hazards information does not exist. Thus, the premarket notification provisions of the committee bill forms the backbone of the preventive aspects of health protection sought by this legislation.

While the EPA Administrator must be given the authority to act during the premarket notification period to gather more data or to take appropriate restrictive action, the notification burden itself should not be onerous. Unless testing has been other wise required, notification only consists of reporting routine information which should be in the hands of the manufacturer in the first place. Included ***11** is information as to the identity of the product, categories of use, estimates of the amount to be produced and, insofar as reasonably ascertainable, to be produced for each of the categories of use, a description of byproducts, lists of existing test data, and estimates of the number of persons who will be exposed in their places of employment.

Estimates of the number of new chemicals to which this requirement will be applicable range from several thousand (Manufacturing Chemists' Association) to around 1,000 (EPA). This is contrasted with registration of pesticides by EPA, for example, which numbered nearly 8,000 in 1975.

3. The Committee bill does not extensively overlap with other Federal authorities and authority within EPA.

Section 9 of the Committee bill requires the Administrator of EPA to utilize other Federal laws which he administers unless he determines that the risk may be more appropriately protected against by utilizing this authority. The right to use this authority is an alternative that would be extremely important in certain instances. For example, EPA should be allowed to regulate a dangerous chemical substance contained within a consumer product, rather than being required to control it later through an effluent standard or emissions standard, which may be a far more inefficient and expensive method of regulation.

This relationship must exist if this legislation is to address the issue of controlling industrial chemicals as a means of preventing environmental degradation as an alternative to other forms of control.

With respect to statutes not administered by EPA, the Administrator is directed to give notice to other relevant Federal agencies if the risk associated with a chemical may be prevented or reduced to a sufficient extent by action taken under the other Federal laws not administered by EPA. The other agency is required to respond to the notice of the Administrator, but in not less than 90 days. If the other agency issues an order declaring that there is no unreasonable risk of injury to health or the environment, or initiates appropriate action under its own authority, the Administrator has no authority to take restrictive action under this Act.

In order to ensure that the vital premarket notification, testing, and reporting requirements are retained, nothing contained in the provision is to effect that authority or requirements.

Finally, the Administrator of EPA is required to consult and coordinate with the Secretary of Health, Education, and Welfare, and the heads of other appropriate Federal agencies for the purpose of achieving the maximum enforcement under this Act while imposing the least burdens of duplicative requirements.

The entire provision is designed to minimize duplication and overlap in the regulation of toxic chemicals, while providing EPA with sufficient authority to alert other agencies of chemical dangers where those other agencies have sufficient regulatory authority to eliminate these dangers.

4. The bill minimizes burdens on small business.

The bill contains a number of provisions which provide assurance that small business will not be overburdened by its requirements. First, it should be noted that small chemical manufacturers in gen-

***12 **4502** do not synthesize large numbers of new chemicals. Synthesis of new chemicals takes place primarily within the major companies which have the financial capability to engage in this kind of research. Therefore, most small chemical companies should not be subject to the premarket notification requirements of section 5.

There are also provisions which will serve to limit the small companies' financial obligations when testing is required. A cost-sharing procedure, for example, is provided where a chemical company that wishes to produce a chemical discovered by someone else shares the cost of developing the test data. One of the explicitly stated bases for determining how these costs are to be apportioned is the market shares of the company which is required to provide reimbursement. A small company will usually have a smaller market share and therefore the reimbursement requirements will be minimized.

Also, in each case where restrictive rules are authorized, the Administrator is required to protect against ‘unreasonable risks.‘ In determining what is an ‘unreasonable‘ risk a balancing of risks and benefits is required. The effect of a rule on small business, of course, is one of the things that the Administrator must weigh in balancing risks and benefits.

The legislation also allows the Administrator to exclude substances from any or all provisions of the Act, if such substance does not present an unreasonable risk. The products developed by small businesses may be excluded by the Administrator utilizing this provision if such risks are not presented.

Under the rulemaking procedures of this legislation, compensation is available to pay attorneys' fees and other costs of representing persons before EPA who could not otherwise afford it. Small businessmen could well be eligible for such help. Also an amendment accepted by the committee provides authority to require replacement or repurchase by manufacturers or processors of banned or restricted products. This provision will prevent small retailers and wholesalers from being saddled with large inventories of otherwise unusable products.

5. There is precedent for the de novo procedures contained in the citizens' petitions provisions and such procedures are necessary.

The citizens petitions provision in the legislation is analogous to a provision contained in the Consumer Product Safety Act. This section will assure that the Environmental Protection Agency is forced to focus on the provisions of the bill directed at protecting health and the environment from the dangers of toxic chemicals. The citizens' petitions provision is limited to petitions ‘the purpose of which (are) to protect against an unreasonable risk of injury to health or the environment.‘ If a citizen can show by a preponderance of the evidence that the action requested in a citizen's petition conforms to the applicable requirements, then EPA should be required to initiate an action. It should be noted that in reviewing a denial of the citizen's petition by the Environmental Protection Agency the court can only require EPA to initiate an action. The court would not be allowed in this situation to determine the content of a rule or outcome of such a proceeding.

The court, if petitioned, shall conduct a de novo review of any denial or failure to act on a citizen's petition by the Environmental Protection Agency. In a judicial review of the Administrator's denial of ***13 **4503** a citizen's petition or failure to act, there would be no record upon which the review could be based, and therefore a de novo procedure is essential to provide the opportunity to develop such a record.

The responsiveness of government is a critical concern and the citizens' petition provision will help to protect against lax administration of the bill.

6. The economic burdens that may be imposed as a result of this legislation are not substantial particularly when considered in the context of the economic, health, and other benefits.

There have been widely varying estimates from the chemical industry of the total cost to the industry of the legislation. The Dow Chemical Co., for example, has estimated that the legislation would cost the chemical industry $2 billion per year. The Manufacturing Chemists Association estimated that these costs would range from $340 million to $1.3 billion per year. The Environmental Protection Agency, however, estimates that the annual total cost to the chemical industry from the enactment of this legislation will be far lower and will range from $80 to $140 million per year.

In order to analyze the accuracy of these studies, the committee requested the General Accounting Office to examine these estimates. The General Accounting Office report to the committee seriously questioned the high estimates of the Dow and Manufacturing Chemists' Association studies, and stated that EPA's estimates were more reliable and realistic and that the legislation, if enacted, would cost the chemical industry between $100 to $200 million a year.

It is important to note that in the testing and key regulatory provisions of the legislation, it is specifically required that the Administrator evaluate the risks and the benefits of his actions before taking regulatory action. Thus, costs are not to be incurred unless they are offset by benefits of at least the same magnitude. In comparing risks, costs, and benefits, however, it is important to recognize that one is weighing noncommensurates, and it is not feasible to reach a decision just on the basis of quantitative comparisons. The burdens of human suffering and premature death are extraordinary and must be given full consideration in such decisions.

LEGISLATIVE BACKGROUND

S. 3149 had its genesis in the 92d Congress. On February 10, 1970, the Administrator of the Environmental Protection Agency transmitted by executive message a legislative proposal which was introduced by Senators Hart and Magnuson, by request, as S. 1478, the ‘Toxic Substances Control Act of l971.‘

Eight days of hearings were held in the 92d Congress on S. 1478 and amendment No. 338 which proposed major changes in the legislation. The Senate passed the bill on May 30, 1972, following Committee action. The House of Representatives acted late in the session but there was insufficient time to reconcile the differences between the Senate and House bills.

In the 93d Congress, S. 426 was introduced on January 18, 1973 by Senators Magnuson, Tunney, and Hart. Three days of hearings were held on S. 426 and S. 888, the Administration's bill.

***14 **4504** Following Committee action, the Senate passed S. 426 on July 18, l973.The House of Representatives passed S. 426 with amendments in lieu of H.R. 5356 on July 23, 1973. However, as in the 92d Congress, the conference was unable to resolve the differences between the House and Senate bills.

In the 94th Congress, S. 776 was introduced on February 20, 1975, by Senators Tunney, Hart, and Magnuson. Hearings were held on March 3, 5, 10, April 5, and October 24, 1975.

The Subcommittee on Consumer Protection and Finance of the Interstate and Foreign Commerce Committee of the House of Representatives reported H.R. 10318 on December 3, 1975. The Senate Committee on Commerce met in executive session on February 3, 4, and 17, 1976, to consider a substitute text offered by Senators Hartke, Tunney, and Hart which conforms quite closely to H.R. 10318. The Committee unanimously ordered the substitute text reported favorably with amendments as an original bill, S. 3149.

SECTION-BY-SECTION ANALYSIS

SECTION 1-SHORT TITLE AND TABLE OF CONTENTS

The short title of the proposed Act is the 'Toxic Substances Control Act.' A table of contents is provided.

SECTION 2-FINDINGS, POLICY, AND INTENT

Subsection (a) puts forth congressional findings that humans and the environment are exposed to a large number of chemical substances and mixtures and that some may cause an unreasonable risk of injury to health or the environment. The findings also state that the regulation of chemical substances and mixtures in intrastate commerce is necessary to the effective regulation of interstate commerce in such substances and mixtures.

Subsection (b) sets forth the policy of the United States that adequate data should be developed with respect to chemicals and mixtures and that manufacturers should have the responsibility of developing the data. The subsection further states that adequate authority should exist to appropriately regulate substances and mixtures and that authority should not impede or unduly create unnecessary economic barriers to technological innovation.

Importantly, subsection (c) states that it is the intent of Congress that the Administrator 'shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator proposes to take under this Act.' While this section of the bill is not an operative section, the intent of Congress as stated in this subsection should guide each action the Administrator takes under other sections of the bill.

SECTION 3-DEFINITIONS AND EXCLUSIONS

Subsection (a) sets forth the definitions which are used in the bill.

Of particular importance is the definition of a 'chemical substance.' The term means any substance of a particular molecular identity including a combination of substances occuring as a result of a chemical reaction, or any element or uncombined radical.

***15 **4505** The term does not include any mixture, which is a combination of chemical substances which do not react chemically with each other and the combination is not the result of a chemical reaction, or combination of chemicals occurring in nature. Mixtures may be addressed under the provisions of the Act, but is excluded from the definition of chemical substance so that automatic premarket notification does not take place under section 5. As the term 'mixture' includes 'articles containing chemical substances', the use of the latter term has been deleted throughout the bill.

In addition, the term does not include pesticides, tobacco, or tobacco products, nuclear material (as defined in the Atomic Energy Act), firearms and ammunition (to the extent subject to taxes imposed under section 4181 of the Internal Revenue Code), or food, drugs, cosmetics, or medical devices (as defined in the Federal Food, Drug, and Cosmetic Act). The term food also

means food as defined in the Poultry Products Inspection Act, the Federal Meat Inspection Act, and the Egg Products Inspection Act. With respect to the explicit exclusion of nuclear materials, nothing in the bill should be construed as an implicit exclusion of such materials from related Acts which contain no explicit exclusion, such as the Federal Water Pollution Control Act.

Subsection (b) authorizes the Administrator to exclude from coverage under this Act or any provision of the Act, any substance or mixture if the Administrator determines, by rule, that an unreasonable risk of injury to health or the environment is not presented. The exclusion under this subsection would not apply to the imminent hazards authority of section 7 or the mandatory reporting of unreasonable risk information under section 8(e). Rules under this subsection are to be promulgated in accordance with the rulemaking provisions of section 6(c) which are similar to the rulemaking provisions of the Magnuson-Moss Warranty Federal Trade Commission Act (88 Stat. 2183).

Exclusions under this subsection must be carefully drawn so that unreasonable risks associated with the chemical substance or mixture which may occur subsequent to the time of the exclusion are avoided as well as risks known at the time of the exclusion. The situation must be avoided where new unpredictable uses, for example, of a chemical substance, may not be properly controlled under the provisions of this Act because of the existence of an exclusion under this subsection.

SECTION 4-TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Subsection (a) sets forth the conditions under which the Administrator must require testing of a chemical substance or mixture.

First, if a chemical substance or mixture (a) may present an unreasonable risk of injury to health or the environment, (b) there are insufficient data or experience to reasonably determine or predict the effects, and (c) testing is necessary to develop data, then the Administrator must require testing.

Second, if a chemical substance or mixture may present a significant human or environmental exposure because of production in substantial quantities or for other reasons, and the substance or mixture may perhaps present an adverse effect on health and the environment, the Administrator must require testing if the two other criter ((b) and (c) above) are also satisfied. If there is no reliable data or experience available to the Administrator, the finding required with respect ***16 **4506** to presentation of an adverse effect on health or the environment shall be presumed.

With respect to mixtures, an additional finding must be made that testing of components of the mixture is not a more reasonable and efficient means of determining the effects on health and the environment.

In requiring testing, the Administrator is to consider the reasonably ascertainable costs and other burdens associated with conducting tests in light of the possible risk of injury to health or the environment and shall publish this information in the Federal Register.

Of course, any judicial review of these considerations shall take place at the time the final rule is reviewed in accordance with section 19. There will be no separate review of these considerations as a procedural matter separate and apart from the review of the final rule.

Subsection (b) sets forth the requirements with respect to the content of the testing rule under subsection (a). An illustrative list of the kinds of health and environmental effects for which testing may be required is provided.

The administrator is required, at intervals of not less than 12 months, to review the adequacy of the rules developed under subsection (a) and to make appropriate revisions, if necessary.

Rules developed under subsection (a) shall be promulgated in accordance with the informal rulemaking procedures of section 553 of title 5, United States Code. The administrator is required to give interested persons an opportunity for the oral presentation

of data, views, or argument and to make a transcript of the oral presentation. Any such oral presentation will be informal and not subject to many of the delays associated with more formal hearings.

Subsection (c) provides an exemption from the testing requirements so that the submission of duplicative data may be avoided. If an exemption takes place, a cost sharing procedure is provided so that the person granted the exemption provides fair and equitable reimbursement to the person who develops the data. So that small businessmen do not get assessed an undue proportion of the costs, the subsection requires that among the relevant factors to be considered by the Administrator in determining fair and equitable reimbursement, that he consider the effect on competition within the chemical industry and the share of the market for such substance or mixture of the person required to provide reimbursement. Any exemptions provided under this subsection, or under section 5(g), are expected to be made available to the public in accordance with the confidentiality provisions of section 14 without delay. The most appropriate way would be to publish notice of the exemption in the Federal Register.

The reimbursement period lasts from 2 years after the date of submission or at the expiration of the period which the Administrator determined was necessary to develop the data, whichever is later.

Provision is also made for the sharing of data cost which is in the process of being developed.

Subsection (d) requires that the Administrator publish information received in response to a testing requirement and make the data available to the public (in accordance with the Freedom of Information Act provisions of section 14), within 15 days of receipt.

Subsection (e) establishes a Federal agency advisory committee to advise the Administrator with respect to testing priorities. Eight ***17** members are provided including ****4507** members from the Department of Commerce, EPA, the Department of Labor, Council on Environmental Quality, the National Institute for Occupational Safety and Health, the National Institute of Environmental Health, Sciences, the National Cancer Institute, and the National Science Foundation.The members of the advisory committee are those Federal officials who either have regulatory responsibilities in the area of chemical substances or mixtures, or have expertise with respect to testing needs. In accordance with this principle, it is anticipated that the member from the Department of Commerce would represent the National Oceanic and Atmospheric Agency, or the National Bureau of Standards, or some other agency within the Department of Commerce which has expertise with respect to testing needs.

Within 12 months after the inclusion of a chemical on the list, the Administrator shall either initiate a rulemaking under subsection (a) or publish reasons for not initiating the proceeding. It is expected that the Administrator's statement in the Federal Register will be specific and will explain in some detail why the conditions for testing under subsection (a) are absent.

Subsection (f) specifies required actions of the Administrator in response to test data or other information which indicates that a substance or mixture has the potential to induce: (1) cancer; (2) gene mutations; or (3) birth defects. The Administrator must take appropriate action under the regulatory provisions of section 5(e), 6(a), or 7 within 180 days after the date of receipt of such data or information or publish in the Federal Register his finding that no unreasonable risk of injury is presented and his reasons for making such a finding. He is only required to take this action when the substance or mixture has a potential to induce these health effects at levels for which human exposure exists, or will exist, with appropriate safety margins.

So that the Administrator may gear up for making these kinds of determinations following the date of enactment, he is not required to take action, or publish his reasons for failing to take action, until 2 years after the date of enactment of the Act.

SECTION 5-PREMARKET NOTIFICATION OF CHEMICAL SUBSTANCES

Subsection (a) requires that manufacturers of new chemical substances give notice to the Administrator at least 90 days prior to the first manufacture of a new chemical substance. The notification is to be accompanied by all of the pertinent information referred to in section 8(a)(2) regardless of whether he had or has not otherwise required its submission under that section.

Included would be the identity of the chemical substance, uses anticipated, amounts to be produced, amounts anticipated for each category of proposed use, by-products, lists of existing data concerning environmental or health effects, and estimates of the number of persons who will be exposed to the substance in their places of employment. If unreasonable risks are not presented, the Administrator is authorized to shorten the 90-day mandatory notification requirement.

In addition, if the chemical substance is covered by a testing requirement under section 4(a), the manufacturer is also required to submit the data developed in accordance with that requirement.

***18 **4508** Subsection (c) requires that the information submitted be published in the Federal Register within 15 days of receipt, subject to the provisions relating to confidentiality under section 14. The 90-day pre-market notification period would begin upon publication in the Federal Register.

Subsection (d) authorizes the Administrator to extend the initial 90-day period for an additional 90 days for good cause shown. While the majority of chemicals may be adequately screened during the initial 90-day period, there are instances in which an additional 90 days may be necessary to adequately screen the substances. If a completely new substance is being examined, for example, more time to adequately review the information and take appropriate action would be necessary. Thus, if the Administrator has not had sufficient opportunity to review the premarket notification information, and to make a judgment as to whether further action is necessary, he would have the authority to postpone the manufacture of the substance for up to an additional 90 days.

Subsection (e) authorizes the Administrator is issue orders during the premarket notification period.

If the Administrator finds that a section 4(a) testing requirement should be established (or should be added to or revised) he is required to issue an order prohibiting or restricting the chemical substance pending the completion of a rulemaking proceeding under section 4(a) and the submission of any data required thereunder. The order is to be immediately effective and shall contain a proposed rule (or amendment or revision thereof) under section 4(a).

If the Administrator finds during the premarket notification period that a rule is appropriate under section 6(a), he shall issue an order which appropriately prescribes requirements authorized under section 6(a). The order is to be immediately effective and must contain a proposed rule under section 6(a).

The Administrator is directed to conclude the rulemaking procedures under section 4(a) or section 6(a) as expeditiously as practicable. If the oral presentation of data, views, or arguments, is requested under section 4(a) or the opportunity to make written submissions has been requested, the Administrator must begin this procedure within 30 days after such request. The same is true with respect to a rulemaking under section 6(a). If an informal hearing under that section is requested, the Administrator must comply within 30 days. In either case, the Administrator must affirm, modify, or revoke the order issued within 10 days after the conclusion of the submissions or oral presentation under section 4 or an informal hearing under section 6.

Subsection (f) requires the Administrator to publish in the Federal Register his reasons if he decides not to issue an order under subsection (e) or to take action under the imminent hazards authority of section 7 during the premarket notification period. The Administrator's failure to issue such an order or take action under section 7 is judicially reviewable in accordance with section 19. It is anticipated that the Administrator's statement in the Federal Register will be specific and contain sufficient information explaining why there are no unreasonable risks which should have been protected against or a need for more test data.

***19 **4509** Subsection (g) provides exemptions to avoid the submission of duplicative data which is similar to the procedure described under section 4(c), described above.

Subsection (h) also provides for premarket notification procedures with respect to significant new uses of existing chemical substances. If a new use of an existing substance has been specified by the Administrator in accordance with this subsection,

all of the premarket notification procedures and authority during the premarket notification procedures and authority during the premarket notification period apply to such new use of an existing substance.

Subsection (i) creates special exemptions which authorize the Administrator to exempt from the premarket notification provisions persons who wish to engage in test marketing or specially limited purposes for chemical substances upon a showing that no unreasonable risks of injury to human health or the environment would result. Appropriate restrictions may be imposed by the Administrator.

In addition, premarket notification for those new chemical substances formed through intermediate reactions within reaction vessels or in other instances in which there is no exposure to human beings or, the environment may be avoided through exemptions issued by the Administrator.

Subsection (j) authorizes the Administrator to specify any mixture which may be subject to any provision of the premarket notification procedures.

There are mixtures such as, adhesives, paints and inks, which can produce chemical substances upon end use. Chemical substances produced upon end use of such mixtures should not be considered new chemical substances automatically subject to the premarket notification provisions of this section. Manufacture is defined under section 3(a)(7) to mean to ‘import, produce, or manufacture for commercial purposes.‘ These types of substances would not be covered under the premarket notification provisions because they are not manufactured for commercial purpose, per se. Similarly, minor reactions occurring incidental to the mixing process or upon storage of a mixture, such as the cross-linking of polymers, would not constitute a basis for subjecting such mixtures to the premarket notification provisions intended for new chemical substances because the resulting substances are not manufactured for commercial purpose.

Such chemical substances arising during the formulation, storage or use of such mixture should be considered as byproducts of the precursor substance or substances. The responsibility for reporting and testing such byproducts under the provisions of this legislation would then fall upon the manufacturer of the precursor substance. Of course, the Administrator may specifically subject any mixture to the premarket notification provisions.

Subsection (k) specifically exempts from the premarket notification provisions chemical substances which are manufactured or intended to be manufactured in small quantities solely for scientific experimentation or analysis or for chemical research. The Administrator is authorized to include those kinds of chemical substances when they may result in an unreasonable risk of injury to human health or the environment.

***20 **4510** SECTION 6-REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES

Subsection (a) requires the Administrator is issue rules to protect against chemical substances or mixtures which present or are likely to present an unreasonable risk of injury to health or the environment. A number of remedies are available to the Administrator ranging from outright prohibitions to labeling requirements. A procedure is provided whereby production, processing, and distribution quotas may be developed in those instances where a rule of the Administrator specifies a total amount that may be produced, processed, or distributed and for Federal supervision of any voluntary agreements that might be entered into by persons who are the object of these rules and for adequate protection against anticompetitive practices.

The authority of section 6(a) is broad enough to authorize the control of those chemical substances or mixtures which may not be the sole cause of an unreasonable risk. For example, if a number of products are responsible for an unreasonable risk, the Administrator would be authorized to move against all of them even though no single one of them can be shown to be the sole cause. The authority is also broad enough to reach those chemical substances which may enhance the toxic properties of other substances or mixtures through the processes known as synergism or potentiation.

Subsection (b) authorizes the Administrator to define the manner in which a substance may be manufactured or processed if he has good cause to believe that such manufacturing or processing causes the adulteration of a chemical substance. A substance is considered adulterated if it contains another molecular identity, uncombined radical element, or any combination thereof which, through the manner in which it is manufactured or processed, causes or contributes to an unreasonable risk of injury to human health or the environment. Rules of this type would be developed in accordance with section 554 of title 5, United States Code.

Subsection (c) requires the Administrator to consider the relevant factors when issuing rules under subsection (a) and to make findings with respect to them. Included are the risks presented to humans and the environment, the benefits of the substance or mixture, and the reasonably ascertainable economic consequences of the rule, including the consideration of the effect on the national economy, innovation, and public health. As is the case in other instances under the legislation where the costs to the chemical industry of a rule are to be considered, it is expected that the chemical industry will come forward with data bearing on the actual costs of compliance.

Findings required to be made shall be published in the Federal Register. As is the case with respect to section 4(a) rules, and other rules issued under the bill, findings of this type are not to be judicially reviewed as a matter separate and apart from the final rule. Thus, the findings published in the Federal Register are informational and will not become the object of a separate judicial review.

This subsection also specifies the rulemaking procedures which are to be followed in promulgating subsection (a) rules. The rulemaking procedures are to be informal and in accordance with section 553 of title 5, United States Code. Interested persons are entitled to orally present their position and to present documentary submissions. In ***21 **4511** addition, if the Administrator determines that there are disputed issues of material fact, he must provide interested persons with the opportunity to make rebuttal submissions and to conduct such cross-examination as he determines to be appropriate and required for a full and true disclosure with respect to the issues. Appropriate procedures for limiting the extent of cross-examination are provided.

The Administrator is authorized to provide compensation for reasonable attorneys fees, expert witness fees, and other costs of participating in rulemaking proceedings to those persons who would not otherwise be adequately represented in such proceedings if representation of these interests are necessary for a fair determination or such persons are unable to effectively participate in the proceeding because such persons cannot afford to pay the cost of participating. Thus, the provision will help insure that the interest of consumers, public interest organizations, and others are represented by the rulemaking procedures of this section. No more than $1 million per year may be paid under the provisions of this section.

The rulemaking procedures of this subsection are virtually identical to those contained in the Magnuson Moss Warranty Federal Trade Commission Act.

Subsection (b) requires the Administrator to specify in a rule issued under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible. The relevant provisions of the Administrator to waive certain notice and procedural requirements when these requirements are impracticable unnecessary, or contrary to the public interest.

SECTION 1-IMMINENT HAZARDS

Subsection (a) defines an imminent hazard to be a situation involving an unreasonable risk of death, serious illness or serious personal injury, or serious environmental harm which will occur prior to the completion of an administrative hearing or other proceedings authorized under any other section of this bill.

Subsection (b) authorizes the district courts to take action against imminently hazardous chemical substances, mixtures, or articles containing the substance or mixture or against persons who manufacture, process, distribute in commerce, use, or dispose of these substances, mixtures, or articles, or to take action against both the substance, mixture, or article and any such person.

Subsection (c) authorizes the courts to grant such relief as may be necessary. The subsection includes a number of illustrative examples.

Subsection (d) contains venue and consolidation provisions with respect to suits brought under this section.

Subsection (e) requires the Administrator, where appropriate, to initiate a rulemaking under section 6(a).

Subsection (f) authorizes the representation of the Administrator by attorneys of the Environmental Protection Agency with respect to suits brought under this section.

SECTION 8-REPORTING AND RETENTION OF INFORMATION

Subsection (a) requires the Administrator to issue rules which require each person who manufactures or processes, or proposes to manufacture or process, a chemical substance to maintain those records ***22 **4512** and to make such reports as the Administrator may reasonably require. In addition, the Administrator is required to promulgate rules which require manufacturers or processors of mixtures or chemical substances produced in small quantities solely for scientific experimentation or analysis, or for chemical research or analysis, to maintain records and to submit to the Administrator reports only to the extent that it is necessary for the effective enforcement of the legislation.

This subsection also contains an illustrative list of the kind of information which the Administrator may require of manufacturers or processors of chemical substances. Included are the identity of substances, categories or proposed categories of use, estimates of the amount to be produced, and estimates of the amount which will be produced for each of its categories or proposals of use, a description of byproducts, all existing data concerning the environmental and health effects of the substance or mixture, and estimates of the number of workers who will be exposed to the chemical substance.

To determine which substances are new chemical substances for the purpose of the premarket notification provisions of section 5, subsection (b) requires the Administrator to publish an inventory of existing chemical substances not later than 270 days after the date of enactment of the Act. Substances not appearing on that inventory will be considered new chemical substances for the purposes of section 5. Of course, any information the Administrator receives under subsection (a) with respect to chemicals proposed to be manufactured shall not be included in the inventory until premarket notification occurs.

Subsection (c) requires persons who manufacture, process, or distribute in commerce chemical substances, or those intending to engage in these activities, to maintain records of adverse reactions to health or the environment alleged to have been caused by the substance or mixture. These kinds of records shall be maintained for 5 years from the date the information was reported to the person, except that reports dealing with occupational reactions shall be retained for 30 years.

Subsection (d) requires persons who manufacture, process, or distribute in commerce chemical substances or mixtures to maintain lists of health and safety studies conducted by them of for them with the Administrator. The Administrator is authorized to require the submission of any study appearing on the list. The Administrator is authorized to exclude certain types of categories of studies if they are unnecessary to carry out the purposes of the Act.

Subsection (e) requires persons who manufacture, process, or distribute chemical substances or mixtures in commerce, and liability insurers thereof, to inform the Administrator when they receive information which supports the conclusion that unreasonable risks or injurys to health or the environment are caused or contributed to by a substance or mixture.

The Committee is concerned that any allegations of risks or other information presented to the Administrator by employees of the chemical industry receive proper attention by EPA. The situation that existed with respect to the Kepone plant at Hopewell, Va., whereby an employee complaint to the Department of Labor allegedly was insufficiently attended to, should not occur. EPA

should respond properly ***23 **4513** to complaints received in the context of this authority, and the Comptroller General may be asked by the committee to oversee EPA's procedures with respect to employee complaints.

SECTION 9-RELATIONSHIP TO OTHER LAWS

This section is intended to minimize overlap and duplication between this act and other Federal laws while assuring protection from environmental and health dangers.

Subsection (a) deals with the action the Administrator is to take when he determines that a law administered by another agency could be used to prevent or sufficiently reduce an unreasonable risk to health or the environment presented by a chemical substance or mixture. In such a case the Administrator is to request that agency to (1) issue an order declaring whether or not such a risk is presented, and (2) if an order is issued declaring that an unreasonable risk is presented, to determine if the risk may be prevented or sufficiently reduced under the law administered by that agency. The agency is to respond to a request from the Administrator within 90 days and publish its findings and conclusions in the Federal Register.

The Administrator may not take action under sections 6 or 7 of this act if the agency to which the request was addressed either issues an order declaring there is no unreasonable risk or initiates action under the law which it administers within 90 days of the publication of its report.

Subsection (b) directs the Administrator to use the authorities under other laws he administers to prevent or reduce risks to health or the environment presented by chemical substances or mixtures unless he determines that such risks may more appropriately be protected against under this act.

Subsection (c) specifies that the exercise of authority by the Administrator under this act shall not constitute any limitation upon the authority of the Occupational Safety and Health Administration to prescribe or enforce standards or regulations affecting occupational safety and health.

Subsection (d) directs the Administrator to consult and coordinate his activities under this act with the Secretary of Health, Education, and Welfare and the heads of other appropriate Federal agencies in order to achieve maximum enforcement of this act while imposing the least burden of duplicative requirements on those subject to the act. The Administrator is to report annually to the Congress on these efforts.

Subsection (e) specifies that nothing in this section shall limit any requirement of section 4, 5 (other than sec. 5(e), or 8, or rules promulgated thereunder.

SECTION 10-RESEARCH, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA

Subsection (a) directs the Administrator to conduct research and monitoring as is necessary to carry out the purposes of the act in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other heads of appropriate Federal agencies.

Subsection (b) directs the Administrator to establish and administer ***24 **4514** an interagency committee to (1) construct within the Environmental Protection Agency an efficient system for the collection, dissemination to other Federal agencies, and use of data submitted to the Administrator under this act, and (2) coordinate the regulation of chemical substances among Federal agencies. In consultation with the Secretary of Health, Education, and Welfare and the heads of appropriate agencies, the Administrator is to design, establish and coordinate a system for the retrieval of toxicological and other scientific data useful to the Administrator in carrying out this Act.

Subsection (c) authorizes the Administrator, in consultation with the Secretary of Health, Education, and Welfare, to make grants and enter into contracts to carry out his responsibilities under this section.

SECTION 11-INSPECTIONS AND SUBPOENAS

Subsection (a) authorizes the Administrator or his designee to inspect any establishment or facility in which chemical substances or mixtures are manufactured, processed, or stored, or any conveyance used to transport chemical substances or mixtures for their distribution in commerce. Such inspections shall require the presentation of appropriate credentials and a written notice to the owner or agent in charge of the premises or conveyance to be inspected, and shall be conducted in a reasonable manner. An inspection shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this act that are applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

Subsection (b) authorizes the Administrator to require, by subpoena, the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, or other information the Administrator deems advisable. In the event of controversy, failure, or refusal of any person to obey such order, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply therewith. Failure to obey an order of the court is punishable by the court as a contempt.

SECTION 12-EXPORTS

Subsection (a) exempts from the provisions of this Act (other than sec. 8) any chemical substance, mixture or article containing a chemical substance, mixture or article that (1) is manufactured, processed, sold, or held for sale solely for export from the United States, and (2) is labeled so as to show that it is intended for export. This exemption shall not apply to any substance, mixture or article that the Administrator finds would cause or contribute to an unreasonable risk to the health of persons within the United States or to the environment of the United States. This would provide control of substances exported to Canada, for example, which may impact the Great Lakes or substances to be disposed of by ocean dumping.

Subsection (b) requires that any person who exports or intends to export a chemical substance or mixture shall notify the Administrator of such exportation or intent to export if the chemical substance or mixture is one (1) for which data is required under section 4 or 5, ****4515 *25** (2) for which a rule has been proposed or promulgated under section 5 or 6, or (3) with respect to which an action is pending or relief has been granted under section 7. The Administrator shall furnish the appropriate information pertaining to the application of this act to the government of the foreign country for which the export is intended.

SECTION 13-ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

Subsection (a) requires the Secretary of the Treasury to refuse entry into the customs territory of the United States of any chemical substance, mixture, or article containing a chemical substance or mixture offered for entry if (1) it fails to conform with any requirement of this act or any rule in effect thereunder, or (2) it is otherwise prohibited pursuant to this act from being distributed in commerce. The subsection details the procedures the Secretary of the Treasury is to follow in the event of an entry refusal.

Subsection (b) directs the Secretary of the Treasury, after consultation with the Administrator, to issue rules for the enforcement of subsection (a) of this section.

SECTION 14-DISCLOSURE OF DATA

This section specifies that information obtained by the Administrator under this Act shall be subject to the Freedom of Information Act which establishes the availability of information received by Federal officials to the public. However, this section specifies that all information received shall be disclosed (1) upon request, to officers or employees of the United States in connection with their official duties under laws protecting human health or the environment or the specific law enforcement purposes; (2) to contractors of the United States when necessary in the performance of a contract; (3) health or the environment; or (4) to any duly authorized committee of the Congress upon written request. While information is not required to be disclosed in proceedings under this Act in order to prevent parties from joining such a proceeding just to get access to data, the Administrator is expected to release information, as he may do under the Freedom of Information Act, in proceedings when it will be used for legitimate purposes in the proceeding.

SECTION 15-PROHIBITED ACTS

This section sets forth those acts that shall be unlawful under this act. Such unlawful acts are (1) failure or refusal to comply with any rule or order promulgated under section 4, 5, or 6 or any requirement prescribed by section 5, (2) the use or disposal of a chemical substance or mixture by such person who knew or had reason to know it was manufactured, processed, or distributed in commerce in violation of section 5 or a rule or order under section 6, (3) failure or refusal to maintain records, submit reports, notices, or other information, or permit access to or copying of records as required by this act or a rule thereunder, or (4) failure or refusal to permit entry or inspection as required by section 11. ****4516**

***26** SECTION 16-PENALTIES

Subsection (a) provides civil penalties of up to $25,000 per day for any person who violates this Act. Such civil penalty shall be assessed by the Administrator after the opportunity for an adjudicative hearing. In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation as well as the violator's ability to pay, his ability to continue to do business, his history of prior violations, and his degree of culpability. The Administrator may compromise, modify, or remit any civil penalty imposed under this subsection.

Any person who requests an adjudicative hearing for the assessment of a civil penalty and is aggrieved by an order assesing a civil penalty may file a petition for judicial review of such order with the U.S. Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business.

If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, the Attorney General is directed to recover the amount assessed, plus interest, in any appropriate district court.

Subsection (b) provides criminal penalties of up to $25,000 per day, in addition to or in lieu of a civil penalty, for any person who knowingly (having actual knowledge) or willfully violates this Act.

SECTION 17- SPECIFIC ENFORCEMENT AND SEIZURE

Subsection (a) grants the U.S. district courts jurisdiction over civil actions sought by the Administrator or Attorney General, to restrain violations of this Act, to compel actions required by this Act, or to require manufacturers or processors of chemical substances or mixtures not in compliance with orders or rules issued under certain provisions of this Act to give notice of such fact and to either repurchase or replace such substances or mixtures. Such a civil action may be brought in the appropriate district court.

In the Committee's deliberations on the legislation, it was determined that the language of amendment No. 21 (sponsored by Senators Philip A. Hart, Nelson, and Percy) defining the burden a plaintiff must sustain in order to gain relief under laws administered by EPA, or relief sought by the Administrators, should not be incorporated in this committee bill. The amendment

attempted to rectify a three-judge panel decision of the 8th circuit concerning relief sought against the Reserve Mining Co. As decisions reached by the courts in subsequent appeals are consistent with the requirements of amendment No. 21, the amendment is unnecessary.

Subsection (b) makes any chemical substance or mixture manufactured, processed, or distributed in commerce in violation of this Act or any article containing such substance or mixture liable to seizure and condemnation within the jurisdiction of any district court in which such substance, mixture, or article is found.

SECTION 18-PREEMPTION

Subsection (a) asserts that, except for certain specified limitations, nothing in this Act shall affect any State's authority to regulate chemical ***27 **4517** substances, mixtures, or any article containing such substances or mixtures. The limitations are (1) if the Administrator has required by rule the testing of a chemical substance or mixture under section 4, no State or political subdivision may subsequently require testing for purposes similar to those required under the rule, and (2) if the Administrator prescribes a requirement under section 5 or 6 of this act to protect against an unreasonable risk presented by a chemical substance, mixture, or article containing a chemical substance or mixture, no State or political subdivision may subsequently regulate such substance, mixture, or article unless the regulation is identical to that prescribed by the Administrator or unless the State or political subdivision bans the use or distribution of such substance, mixture, or article within the territorial jurisdiction of the State or political subdivision.

Subsection (b) specifies conditions under which the Administrator may by rule exempt a State or subdivision from the limitations imposed in subsection (a). A State or subdivision may be exempted if their requirements would not cause a violation of this act, a significantly higher degree of protection is afforded, and undue burdens on interstate commerce would not result.

SECTION 19-JUDICIAL REVIEW

Subsection (a) specifies that not later than 60 days after the promulgation of any rule under this Act or an order under section 5(e), any person may file a petition for judicial review of such rule. The Administrator shall transmit to the Attorney General, who shall file in the court, the record of the proceedings on which the Administrator based such rule or order as provided in section 2112 of title 28, United States Code. The term ‘record‘ means such rule or order, any transcript required of any oral presentation, any written submission of interested parties, and any other information the Administrator considers relevant and with respect to which the Administrator, on or before the date of promulgation of such rule or order, published a notice in the Federal Register identifying such information. Of course, the record need not contain written documentation of each and every widely accepted scientific principle or fact which may support the rule or order issued. In these cases, it should be presumed that agency expertise is definitive so that an extensive record need not be developed or judicial review result with respect to widely accepted scientific principle.

Subsection (b) authorizes petitioners to apply to the courts for leave to adduce additional data, views, or arguments. If the petitioner satisfies the court that such additional information would be material and that there are reasonable grounds for the petitioner's failure to adduce such information in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity for oral presentation and written submissions. Upon the basis of the additional information, the Administrator may modify the findings or determinations upon which the rule or order reviewed by the court was based. Modified or new findings together with the Administrator's recommendation, if any, for modifying or setting aside such rule or order shall be filed with the court.

***28 **4518** Subsection (c) grants the courts jurisdiction, upon the filing of a petition under subsection (a), (1) to review the rule or order involved in accordance with chapter 7 of title 5, United States Code, and (2) to grant appropriate relief, including interim relief, as provided in such chapter. This subsection explicitly states that any rule promulgated by the Administrator

under section 5 or 6 and reviewed under this section shall be affirmed unless the rule is not supported by the substantial evidence on the record taken as a whole. Review of all other actions taken (or inaction) shall be on an 'arbitrary or capricious' basis in accordance with chapter 7 of title 5, United States Code.

Any considerations or findings required of the Administrator in the process of developing a rule or order under this Act shall not be reviewable apart from the review of the final rule or order.

Subsection (d) specifies that remedies provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

SECTION 20-CITIZEN'S CIVIL ACTION

The provisions of this section are intended to provide a remedy if the Administrator is lax in carrying out his duties under this Act. Subsection (a) authorizes any person to commence a civil action against persons alleged to be in violation of this act or any rule prescribed under section 4 (testing), section 5 (premarket notification), or section 6 (restrictive rules) to restrain such violation. In addition, actions are authorized against the Administrator to compel him to perform any duty which is not discretionary under this Act. Actions shall be brought in the appropriate district court.

Subsection (b) specifies certain limitations on the announcement of a civil action. No action may be commenced before the expiration of a specified time period after proper notice has been given of an alleged violation or failure of the Administrator to perform a duty under this act. Also, no action may be commenced if the Administrator, or Attorney General on his behalf, has commenced and is diligently prosecuting a civil action to require compliance with this Act.

Subsection (c) authorizes the Administrator to intervene in any civil action under this section to which the Administrator is not a party. The court is authorized to award costs of suit and reasonable fees for attorneys and expert witnesses, if appropriate.

Nothing in this section shall restrict the right of any person under any statute or common law to seek enforcement of this Act, or any rule under this Act, or to seek any other relief.

Subsection (d) authorizes a court, upon application of the defendant, to consolidate two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations when such actions are pending in two or more judicial districts.

SECTION 21-CITIZEN'S PETITIONS

This provision provides a means to initiate procedures for issuance of a rule or order under this act to protect against unreasonable risk of injury to health or the environment. Included, for example, would be a testing requirement under section 4(a), a restrictive rule under ***29 **4519** section 6(a), or a modification of a section 3(b) rule which would have the effect of further protecting against unreasonable risks by reducing the extent to which a chemical substance or mixture is excluded from coverage under the Act. Subsection (a) authorizes any person to petition the Administrator to issue such a rule or order.

Subsection (b) requires the Administrator to either grant or deny a petition within 90 days after filing. If a petition is granted, the Administrator shall promptly commence an appropriate proceeding to comply with such petition. If a petition is denied, the Administrator shall publish in the Federal Register the reasons for such denial.

If the Administrator denies a petition (or fails to act within the 90-day period), the petitioner may commence a civil action with 60 days, in a U.S. district court to compel the Administrator to initiate the action requested. Because of the absence of an adequate record for the court to review in such a case, the opportunity is granted to the petitioner for a judicial review based

on a preponderance of the evidence in a de novo proceeding. If the petitioner can satisfy the court by a preponderance of the evidence in such a proceeding that the action requested in the petition conforms to the applicable requirements of this act, the court shall order the Administrator to initiate the action requested by the petitioner.

SECTION 22-NATIONAL DEFENSE WAIVER

The Administrator is directed to waive compliance with any provision of this Act upon request of the Secretary of Defense and upon a determination by the President that the requested waiver is necessary in the interest of national defense.

SECTION 23-EMPLOYEE PROTECTION

Subsection (a) prohibits an employer from discharging or otherwise discriminating against any employee because the employee, or any person acting pursuant to a request of the employee, participates or intends to participate in any way in any proceeding or action for the purposes of carrying out the intent of this Act.

Any employee who believes that he or she has been discharged or otherwise discriminated against is authorized by subsection (b) to file a complaint with the Secretary of Labor within 30 days of the alleged violation. The Secretary is to investigate such an alleged violation and shall, within 90 days, issue an order either providing relief or denying the complaint, unless the Secretary and the person alleged to have committed such violation agree to a settlement. The forms of relief which the Secretary can provide are prescribed in this subsection.

Subsection (c) authorizes judicial review of an order issued under subsection (b) upon petition by any person adversely affected or aggrieved by such order.

Whenever a person has failed to comply with an order issued under subsection (b), subsection (d) directs the Secretary of Labor to file a civil action in the appropriate district court to enforce such action. In such civil actions the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages.

***30 **4520** Subsection (e) excludes from the protection of subsection (a) any employee who, acting without direction from the employee's employer or any agent of the employer, deliberately causes a violation of any requirement of this Act.

Subsection (f) directs the Administrator to conduct continuing evaluations of the potential loss or shifts of employment which may result from the issuance of any rule or order under this act. Any employee who is discharged or threatened with discharge or otherwise discriminated against by any person because of the results of any rule or order issued under this act may request the Administrator to conduct a full investigation of the matter. The Administrator shall thereupon investigate the matter, and, at the request of any interested party, shall hold a public hearing. Upon receiving the report of any such investigation, the Administrator shall make findings of fact as to the effect of such rule or order on employment and shall make recommendations as he deems appropriate, which report, findings, and recommendations shall be available to the public. Nothing in this subsection shall be construed to require the Administrator to modify or withdraw any rule or order issued under this Act.

SECTION 24-STUDIES

Subsection (a) directs the General Accounting Office to conduct a study of all Federal laws for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of action taken by the Administrator under any such law. The study shall include the probable cost and means of financing any recommended indemnification and be submitted to the Congress not less than 2 years from the date of enactment of this Act.

Subsection (b) directs the Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal agencies to coordinate a study of the feasibility of establishing (1) a standard classification for chemical substances, and (2) a standard means for storing and retrieving information respecting such substances.

SECTION 25-ADMINISTRATION OF ACT

Federal agencies are authorized in subsection (a) to cooperate with the Administrator by making their services, personnel, and facilities available to assist in the administration of this act and by making available to the Administrator information necessary for the administration of this Act.

Subsection (b) authorizes the Administrator to require, by rule, the payment of a reasonable fee, not to exceed $2,500, from any person required to submit data under section 4 or 5 to defray the cost of administering the Act.

Subsection (c) authorizes the Administrator to take action with respect to categories of chemical substances or mixtures as well as individual chemical substances or mixtures. For purposes of defining a category, chemical substances or mixtures may be grouped by virtue of similarities in their chemical structure, physical, chemical or biological properties, use, mode of entry into the human body or environ- ***31** ment, ****4521** or in some other way suitable for purposes of this Act. This authority is given to the Administrator to facilitate the efficient and effective administration of this act and is not to be used in any way that would frustrate the intent of any provision of this Act. Thus, for example, categories might be appropriately used for purposes of compiling the inventory of section 8(b) so that every variation in the distribution of a polymer chain length would not be automatically subject to the premarket notification requirement. However, categories are not to be used in the section 8(b) inventory so as to effectively provide exemptions for new chemical substances intended to be covered under the premarket notification provision.

Subsection (d) specifies that any proposed or final rule or order issued under this Act shall be accompanied by a statement of purpose and justification. This statement shall identify the sources and precise nature of the most important information used in deciding upon the rule or order and shall indicate the weight or importance the Administrator gave to the various elements of information in arriving at his decision. Such a statement shall be considered part of the ‘record of the proceedings‘ for purposes of judicial review under section 19(a).

Subsection (e) directs the President, by and with the advice and consent of the Senate, to appoint as Assistant Administrator of the Environmental Protection Agency an individual who by reason of background and experience is especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for the efficient collection and analysis of data necessary for making well-informed regulatory decisions and the development of a spectrum of regulatory options available to the Administrator.

SECTION 26-AUTHORIZATION FOR APPROPRIATIONS

Subsection (a) authorizes to be appropriated to the Administrator for carrying out this act $11 million for the fiscal year ending June 30, 1976; $2,600,000 for the transition quarter, July 1, to September 30, 1976; and $10 million for the fiscal year ending September 30, 1977. No part of these funds are to be used for the construction of research laboratories.

Subsection (b) requires that whenever any budget request, supplemental budget request, supplemental budget estimate, legislative recommendation, prepared testimony for congressional hearings or comments on legislation relating to this act is sent to the President or to the Office of Management and Budget, the Administrator shall concurrently transmit a copy to the Congress. This subsection further prohibits any officer or agency of the United States from requiring the Administrator to

submit this information to him prior to its submission to Congress. The provision is virtually identical to that contained in the Consumer Product Safety Act.

SECTION 27-ANNUAL REPORT

The Administrator is required to submit to the President and the Congress a comprehensive annual report on the administration of this Act. A list of items to be included in the report is presented.

***32** * * * *

****4522** ESTIMATED COSTS

Pursuant to the requirements of section 252 of the Legislative Reorganization Act of 1970, the Committee estimates the cost of the bill for each of the first 5 fiscal years as follows:

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

The Committee knows of no cost estimates made by any Federal agency which differs from those tabulated above. The estimates were derived from information submitted by EPA.

RECORD VOTES IN COMMITTEE

1. On the motion by Senator Hartke to require that 'reasonably ascertainable economic consequences' of section 6(a) rates be considered, that findings be made with respect to all relevant factors considered, and that such findings be published in the Federal Register.

YEAS (17)

Magnuson Tunney

Pastore Stevenson

Hartke Ford

Hart Pearson

Cannon Baker

Long Beall

Moss Weicker

Hollings Buckley

Inouye

NAYS (1)

Durkin

2. On the motion of Senator Hartke to report the bill favorably:

YEAS (20)

Magnuson Stevenson

Pastore Ford

Hartke Durkin

Hart Pearson

Cannon Griffin

Long Baker

Moss Stevens

Hollings Beall

Inouye Weicker

Tunney Buckley

NAYS (0)

* * * *

***73 **4523** AGENCY COMMENTS

ENVIRONMENTAL PROTECTION AGENCY,
OFFICE OF THE ADMINISTRATOR,
Washington, D.C., June 23, 1975.

Hon. WARREN G. MAGNUSON,

Chairman, Committee on Commerce,

U.S.Senate,

Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of March 6, 1975, for the views of the Environmental Protection Agency on S. 776, the Toxic Substances Control Act.

We are in accord with the objectives of S. 776 and the general approach taken in the bill to control toxic substances. As we testified before your Subcommittee on the Environment on March 10, 1975, the bill contains the authorities which we believe

are essential for effective toxic substances control legislation. We urged the enactment of toxic substances control legislation and indicated that we would have suggestions on some of the specific provisions of S. 776 when we submitted our report.

We note that S. 776 contains significant improvements over some of the toxic substances control bills that have been before the committee the past 4 years. Many of these improvements are consistent with past EPA recommendations. It is not our intention in our report by concentrating on suggested revisions to the bill to detract from or fail to recognize the effort and improvements already evident in S. 776.

We have already stated in our testimony our objection to the provision that would preclude the Administrator from forwarding any budget estimates, legislative proposals, comments on legislation, or testimony to the Office of Management and Budget prior to the transmission of these same materials to the Congress. We also stated in our testimony that to designate by statute the specific responsibility of an Assistant Administrator may tend to create a problem of internal management.

We will discuss below a number of additional areas in S. 776 where we have particular problems and where we believe amendments are in order. These proposed amendments are set out in an attachment to ***74** this letter along with a number of important additional amendments and brief explanations of each. We urge that all of these amendments be favorably considered by the committee.

This report on S. 776, including the attached proposed amendments were jointly developed with the other concerned Federal departments and agencies and represents the views of the administration on S. 776.

Policy of Administration

We are proposing that the Declaration of Policy section of the bill include recognition of the role of this legislation in complementing and supplementing a number of present Federal programs that deal with various aspects of toxic substance control. We are also proposing that the general requirement of the bill for consultation and coordination ***4524** make specific reference to this policy statement. Such amendments would be of great assistance in the day to day administration of this legislation, both by assuring due regard for the responsibilities of other agencies, and by helping to establish the atmosphere of cooperation and interchange which is vital to the successful operation of comprehensive toxic substances legislation.

In line with this policy, and because of the special role of the Occupational Safety and Health Act of 1970 in providing workers with protection from unsafe or unhealthful working conditions which may be created through the manufacture, distribution or use of toxic substances, we are also proposing some language for the bill and some question about the respective regulatory jurisdictions of EPA and the Department of Labor.

Definitions

We are proposing that the definition of ‘chemical substance‘ be amended to provide the Administrator with some flexibility to exclude, in appropriate situations, certain substances from the definitions and thus from the requirements of the act or from particular provisions of the act. It would be almost impossible to draft the bills to exempt certain substances from the act or, as more likely the case, from certain provisions of the act in each situation where such is necessary. Scientific laboratory reagents are an example. Here it may very well be appropriate to exclude such products from the testing and regulatory provisions, but not necessarily the reporting and adverse effects provisions when they are used by certain research or scientific laboratories; on the other hand, we would not likely wish to exclude high school laboratories from any labeling requirements. An exclusion may also be in order for a substance not manufactured in commercial quantities. An excessive burden and inconvenience to the industry or the user would be averted with this flexibility in the act.

We anticipate that the Administrator would exercise his discretion to exclude from the definition of chemical substances most substances manufactured in less than commercial quantities for the purpose of testing. Thus, most substances manufactured in less than commercial quantities would be exempt from the testing provisions of the bill. The proposed amendment would however enable EPA to require testing in those cases where the potential threat to health and the environment showed such testing to be necessary.

***75** We are also proposing to add to the act a definition for a 'new chemical substance.' This is necessary in order that chemical substances which were used in previous years for some purpose, and such use discontinued, do not become classified as existing chemicals, and thus exempt from certain requirements relating to new substances.

Testing

The testing provisions provide that standards for test protocols would be promulgated, rather than the test protocol itself. Testing would be required only for substances which the Administrator determines may present an unreasonable risk to health or the environment, where there are insufficient data to conclude that such a risk does or does not exist, and where testing would assist in making such a determination.

****4525** There is a provision in the testing requirement of the bill that we foresee as an undue burden upon the Administrator. While we agree that provision should be made for the sharing of testing costs in the event that there is more than one manufacturer of a substance for which testing is required, we are very reluctant to become involved in designating which manufacturer-- or possibly a third party-- should conduct the tests if the parties cannot reach an agreement. We are therefore recommending deletion of the provisions authorizing the Administrator to designate which party should do the testing.

A further amendment we are proposing with regard to the testing provisions is a specific requirement that the Administrator must consider alternative methods for meeting the standards for test protocols proposed by a manufacturer, such as one that might be less costly or more effective. This would insure that industry is allowed to use the best test protocols in meeting the testing standards.

Premarket screening

We are proposing an amendment which will delete the authority in the bill to treat a rule proposed under section 6 during the premarket review period of a product as a final rule. Thus a chemical substance of product may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision of the act. The substance or product, however, remains subject to all other provisions of the act and a rule proposing restrictions on the substance or product may be proposed immediately during the premarket review period under section 6 and the rulemaking proceedings initiated at that time.

If it appears that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to the completion of the rulemaking proceedings, action may be taken to restrict or ban it under the imminent hazard provisions of the bill, thus preventing it from becoming a threat to health or the environment.

Quotas

Another difficulty we have with S. 776 concerns the requirement that the Administrator provide for the assignment of quotas in any regulation limiting the amount of a substance which may be manufactured, imported, or distributed. The mandatory requirement of a quota system would make the regulatory process vastly more cumbersome and difficult to administer. Thus, we recommend that the quota provi- ***76** sion be deleted. The act already provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent

requirement practicable, consistent with protection of health and the environment. In our view, restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would seldom be necessary. Nevertheless, we strongly recommend against becoming involved in the establishment of quotas for various manufacturers, even in such limited situations.

**4526 Economic impact

S. 776 would require that the Administrator consider a number of relevant factors in promulgating rules with respect to a chemical substance.We are proposing that a specific provision be added that he also must consider the economic impact of such action, including, but not limited to, consideration of the effects on business, employment, and the national economy. Consideration of these factors are already inherent in the requirement that he consider all relevant factors. This amendment is submitted in lieu of other proposals that have already been made for the mandatory preparation of detailed economic impact statements at the time a regulation is promulgated.

Health and safety studies

We are proposing a revision of the requirement for the submission of health and safety studies, or lists of such studies, in order to provide some flexibility in this requirement. This should lessen the burden to industry in compiling the lists or submitting the studies, and to EPA in not being overburdened with information it does not need or cannot effectively use. The amendment would require submission of lists of ongoing and new studies, rather than the study, with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of studies to be included on the lists and the number of years for which prior studies must be listed. The amendment would also provide that a person would list studies which he knows are being made or have been made.

Confidential information

We are recommending that the confidentiality provision, section 15 of S. 776, be amended in several respects. First, the substantive criterion for withholding data as confidential should be the test established by the Freedom of Information Act, 5 U.S.C. 552(b)(4). Our proposed amendment would have the effect of requiring nondisclosure of information obtained under the Toxic Substances Control Act which may be withheld under 5 U.S.C. 552(b)(4), that is, ‘trade secrets and commercial or financial information obtained from a person and privileged or confidential.‘ This will make the confidentiality standard more definite (because there exists a body of case law interpreting 5 U.S.C. 552(b)(4), and will promote uniformity.

In addition to the exemption for disclosure to Federal officers and employees, a separate provision should allow disclosure to EPA contractors and their employees, under appropriate safeguards and after appropriate EPA findings that disclosure is necessary. EPA accom-

*77 a great deal of its investigatory and analytical tasks by contract. If contractors are not allowed access to information under this bill, EPA could not perform its duties satisfactorily without substantial manpower increases. The recently enacted Privacy Act, 5 U.S.C. 552a, provides that, for purposes of the section of the Privacy Act which imposes penalties on Government employees for wrongful use or disclosure of information entitled to confidentiality, Government contractors and their employees are to be considered Government employees (5 U.S.C. 552a(m)). We recommend inclusion of such a provision in the toxic substances bill. Our proposed amendments allow **4527 disclosure to contractors and include a penalty for wrongful disclosure of information by Government employees (including contractors and their employees).

We also believe that the provisions relating to qualified scientists and individual names are not necessary. The term ‘qualified scientists‘ would be difficult to interpret, and in any event a scientist would have no greater rights under the subsection than

would any person under our (proposed) basic confidentiality criterion. We believe that the Federal Privacy Act and the Freedom of Information Act provide ample protection of the rights of individuals whose names appear in health and safety records.

Finally, with regard to access of information by Congress, we believe that such confidential information should be made available upon written request.

Exemption from Federal preemption

We do not recommend the provisions of S. 776 which would allow State and local agencies to petition the Administrator for exemption from the Federal preemption requirements. State and local agencies would be allowed to regulate any toxic substance until such time as the Administrator puts into effect regulations for testing or restricting a substance. Thereafter, they could impose only a total ban on a substance. In view of the fact that the bill authorizes the Administrator to regulate with respect to geographic areas there would appear to be no need for a State or local agency to duplicate any regulations with respect to a substance after Federal regulations are in effect.

Interagency cooperation and coordination

Several amendments are being proposed to the act to provide for the maximum cooperation and coordination among the several agencies of the Federal Government which have programs and responsibilities concerned with toxic substances. These amendments also would clarify that the act is intended to complement and supplement existing laws and regulations such as the occupational health and safety requirements.

A number of Federal agencies, particularly the Department of Health, Education, and Welfare and the Occupational Health and Safety Administration of the Department of Labor have extensive responsibilities relating to toxic substances and human health and would stand to benefit from various provisions of the act. For example, test results and other data generated in this area would, of course, be valuable to them and should be made available to all agencies concerned.

***78** We are also recommending that the provision contained in previous bills before the Congress directing the Council on Environmental Quality to coordinate a study on the feasibility of establishing a standard classification system for chemical compounds and means of obtaining rapid access to information on such substances be restored to the act. This section provides CEQ the lead in establishing information systems in a manner currently being initiated. This is being done in conjunction with the agencies that would have been represented on the interagency committee as set out in the provision proposed to be deleted.
****4528**

Appropriations

We wish to make clear that our budget requests over the past several years have included funds to handle work anticipated to be required under toxic substances legislation, in the expectation that it would by now have been a reality. Consequently, considerable groundwork has been laid and we anticipate that activities during fiscal year 1976 can be met within the $8 million requested in the President's budget. Furthermore, we would point out that EPA wishes to remain in accord with the President's stated policy of holding new spending to an absolute minimum. Consequently we would point out that the authorization levels in S. 776 are in excess of amounts required to implement its provisions.

We have outlined above in our letter a number of the proposed amendments to the act which we consider important; the attachment contains both these and additional amendments which we believe are of equal importance. We strongly believe that the adoption of these amendments would improve and strengthen the legislation and enable EPA to protect the health and the environment to the greatest practical extent while at the same time relieving the industry as well as the Government of some burdensome requirements.

With the favorable consideration of these proposed amendments, we would urge the enactment of S. 776.

My staff and I stand ready to assist your committee in any way possible.

We are advised by the Office of Management and Budget that there is no objection to the submission of this report from the standpoint of the program of the President.

Sincerely yours,

JOHN R. QUARLES, Jr.,
Acting Administrator.

TOXIC SUBSTANCES CONTROL ACT

PROPOSED AMENDMENTS BY EPA AND OTHER FEDERAL AGENCIES TO S. 776

1. Definitions

a. Page 4, lines 1 and 2, delete the language ‘or in some other way suitable for formation of a group for the purposes of this Act‘.

Explanation.-- This amendment would delete the open-ended authority to designate almost any grouping as a ‘category of chemical substances‘.

***79** b. Page 4, line 5, delete paragraph (3) and insert new paragraph (3):

(3) ‘Chemical substance‘ means any chemical substance which (A) has an organic or inorganic particular molecular identity; (B) is any combined or uncombined radical or element; or (C) is any mixture; Provided, however, the Administrator may by regulation exclude from this definition as it applies to this Act, or to any provision of this Act, certain categories of chemical substances such as scientific laboratory reagents and samples, or chemical substances not manufactured in commercial quantities.

****4529** Explanation.-- This amended definition of a ‘chemical substance ‘ would provide the Administrator with flexibility to exclude, in appropriate cases, substances from the requirements of the Act, or a particular provision, where it does not need to be regulated, cannot be effectively regulated, or where meeting the requirements might be an undue burden. Scientific laboratory reagents, samples, and other chemical substances manufactured in less than commercial quantities are examples.

We urge the following language be included in the committee report with respect to this definition:

Chemical substance would be defined to permit the Administrator the flexibility to provide by regulation for exempting chemical substances in certain categories or in less than commercial quantities from certain provisions of the bill. With respect to those chemical substances, it is anticipated that the Administrator will exercise his discretion to exclude, and thereby exempt, most of them from the testing provisions of the bill. The Administrator retains the authority to require testing in those cases where he finds a potential threat to health and the environment which indicates that such testing is necessary.

c. Page 5, line 2, delete the period and insert a semicolon after ‘studies ‘ and delete remainder of paragraph; and on line 12, delete ‘study‘ and insert ‘study, including health and safety data developed pursuant to such study,‘.

Explanation.-- Correspondence relating to alleged adverse effects on health and similar reports are already required to be maintained in the section 8(d) regarding records, and an amendment is proposed to authorize the Administrator to require

submission of such records. There is no need to include unconfirmed complaints and notices in the definition of health and safety data and confusion results when this is attempted. It is also proposed to specifically provide that a health and safety ‘study‘ includes health and safety data developed pursuant to such study.‘.

d. Page 6, insert after line 14 the following and renumber other paragraphs accordingly.

(15) ‘new chemical substance‘ means any chemical substance which has not been manufactured or imported in commercial quantities into the United States during the 18-month ***80** period immediately prior to the effective date of this Act, regardless of its commercial production or importation in the United States prior to such time.

Explanation.-- A definition of ‘new chemical substance‘ is necessary in order that chemical substances that were used in prior years and were discontinued do not become classified as existing chemicals for purposes of this Act.

****4530** Testing

a. Page 9, after line 8, insert new paragraph (4) as follows:

(4) The Administrator will consider alternative methods for meeting the standards for test protocols proposed by any person or governmental entity which is a manufacturer, processor, or importer of such chemical substance.

Explanation.-- This amendment would specifically direct the Administrator to consider alternative methods for meeting the standards for test protocols proposed by a manufacturer, such as less costly or more effective test protocols.

b. Page 9, line 14, delete the last two sentences in paragraph (1) beginning with ‘If‘, and insert in lieu thereof: ‘If such an arrangement is made the Administrator shall be notified and the remaining such persons shall be exempted from requirements to perform tests.‘

Explanation.-- We do not believe that the Administrator should become involved in designating which party (or a third party) should perform tests if the parties cannot agree among themselves. If a cost-sharing arrangement is made for one of the parties to do the testing, however, provision should be made to exempt the other parties from the testing requirements.

c. Page 11, line 15, insert after ‘arguments,‘ the following: ‘and permit cross-examination to such extent and in such manner as in his discretion he determines is necessary and appropriate in view of the nature of the issue involved, the number of the participants and the nature of the interests of such participants.‘

Explanation.-- This amendment would permit limited cross-examination as is provided in the section 6 rulemaking procedures to restrict toxic chemicals.

3. Premarket screening; imminent hazard

a. Page 12, line 3, after ‘substance‘ add the following sentence:

Subsequent submission or request for submission of additional information shall not be regarded as changing the date of such notice.

Page 13, line 4, delete entire subsection (c); on line 25, delete beginning with ‘Unless‘ through ‘90 days‘ on line 2, page 14, and insert in lieu thereof ‘Ninty days‘; renumber following subsections accordingly.

Page 14, line 10, after ‘substance‘ insert ‘before or‘.

Page 22, line 13, after ‘environment,‘ insert ‘that should be corrected immediately, and‘.

Explanation.-- These amendments will delete the authority in the bill to treat a rule proposed under section 6 during the premarket review period of a product as a final rule.

***81** Thus a chemical substance or product may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision of the Act. The substance or product, however, remains subject to all other provisions of the Act and a rule proposing restrictions on the substance or product may be proposed immediately during the premarket review period under section 6 and the rule-making proceedings initiated at that time.

****4531** If it appears that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to the completion of the rule-making proceedings, action may be taken to restrict or ban it under the imminent hazard provisions of the bill, thus, preventing it from becoming a threat to health or the environment.

The other amendments would clarify the date premarket notice commences, that restrictive rules under section 6 may be promulgated before or after manufacture or distribution of a substance, and that an imminent hazard is a risk that should be corrected immediately.

4. Restrictions on hazardous chemical substances.

a. Page 17, line 23, delete ‘condition‘ and insert in lieu thereof ‘circumstances‘, and insert the following language in the committee report with respect to section 6 of the bill:

The provisions of section 6 of S. 776 provide EPA with regulatory authority which will complement and supplement existing authority to control hazardous substances but not to preempt authority already vested by statute in other Federal departments or agencies. Proposed new section 9(b) would preclude EPA from taking action under sections 6 and 7 which the Secretary of Labor could take under the Occupational Safety and Health Act. Thus, for example, the Administrator of EPA could not, under section 6(a)(3) require that a substance be labeled so as to prescribe requirements for its safe and healthful use which apply solely to workers in their place of employment. The Department of Labor, pursuant to the Occupational Safety and Health Act of 1970, already has authority to prescribe safe and healthful working conditions. Similarly, section 6(b)(2) shall not be construed to allow the Administrator of EPA to establish occupational safety and health standards.

Explanation.-- The clarification to paragraph 6(a)(2), together with the addition of legislative history with respect to paragraphs 6(a)(3) and 6(b)(2), will assist in implementation of the bill's policy to ‘complement and supplement‘ existing authority. These changes will assist in avoiding overlap between EPA and the Department of Labor's workplace safety and health authority.

b. Page 18, line 17, page 20, line 23, page 21, lines 6 and 12, delete ‘adulterated‘ (or ‘adulteration‘) and insert in lieu thereof ‘contaminated‘ (or contamination‘).

Explanation.-- We believe that the term ‘contaminated‘ (or ‘contamination ‘) would more clearly express the intent of these provisions instead of ‘adulterated‘ which is often understood or defined as an intentional act.

***82** c. Page 19, line 11, delete entire paragraph (3).

Explanation.-- We believe that the Administrator should not become involved in assigning quotas to industry. The mandatory requirement of a quota system would make the regulatory process vastly more cumbersome and difficult to administer. The Act already provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator ****4532** shall select the least stringent requirement practicable consistent with protection of the health and the environment. It is expected that the establishment of quotas could seldom, if ever, be necessary as such would be a most stringent requirement. Nevertheless, we strongly recommend against becoming involved in the establishment of quotas.

d. Page 20, after line 15, insert the following:

(4) the economic impact of such action, including, but not limited to, consideration of the effects on business, employment, and the national economy.

Explanation. This amendment would specifically require the Administrator to consider economic impact in promulgating regulations, already inherent in the requirement that he consider all relevant factors. This would be in lieu of proposals that have been made for the mandatory preparation of detailed economic impact statements for issuance at the time any regulation is promulgated.

5. Suits by U.S. attorneys instead of by Administrator

Page 22, line 17, delete all after ‘may‘ through ‘so,‘, line 19 and insert in lieu thereof: ‘request a United States Attorney to petition an appropriate district court of the United States‘

Page 39, line 3, delete ‘Administrator or the‘.

Page 46, line 7, delete ‘Administrator (or Attorney General on his behalf) ‘ and insert in lieu thereof ‘Attorney General‘.

Page 46, line 8, after ‘commenced‘ delete ‘and is diligently prosecuting‘ on lines 8 and 9.

Explanation.-- These amendments would carry out the long-time policy of having the Justice Department responsible for litigation instead of each Agency. In the citizen suit provisions, we believe that it is sufficient if the Attorney General has commenced an action and that it is not necessary to impose a further requirement that he be diligently prosecuting it, a concept which is at best difficult to litigate and at worst could lead to counter-productive court action.

6. Submission of records; health and safety studies

a. Page 25, line 3, add at end of sentence:

The Administrator may require copies of such records pursuant to his responsibilities under sections 4, 5, 6, and 7 of this Act.

Explanation.-- While the bill provides that records of adverse health effects caused by chemical substances are required to be maintained, no provision is made to require submission of such records. This amendment would correct that omission.

b. Page 25, line 4, delete subsection (e) and insert in lieu thereof:

(e) Health and Safety Studies. The Administrator shall promulgate regulations under which he may require any person ***83** son who manufactures, processes, or distributes in commerce any chemical substance (or with respect to paragraph (3), any person who has possession of a study) to submit to him--

(1) lists of health and safety studies in progress on or initiated after the date of enactment of this Act, conducted by or for such person, or known to such person;

**4533 (2) lists of health and safety studies conducted by or for such person, or known to have been made by any person, prior to the date of enactment of this Act;

(3) copies of any such studies appearing on a list submitted pursuant to paragraphs (1) or (2), or otherwise known by him.

Explanation.-- This amendment would revise the provision requiring industry to report on or submit all health and safety studies. It would require submission of lists of ongoing and new studies rather than the study, with a right to require submission of studies. It would authorize the Administrator to provide by regulation for the types of studies to be included on the lists, and the number of years of prior studies for particular types of studies; and would require a person to also list studies which he knows are being made or have been made.

7. Additional exemption: additional limitation on authority

a. Page 26, line 8, delete 'or'; line 10, after 'Act)' insert a comma and add 'cosmetics (as such term is defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act),'; line 18, replace the period with a semicolon, and add the following:

(3) any source material, special nuclear material or byproduct material as defined in the Atomic Energy Act of 1954 (42 U.S.C. 2011), as amended, and regulations issued pursuant thereto; or

(4) tobacco and tobacco products.

Explanation.-- We believe that cosmetics should also be exempted and materials regulated under the AEC Act, and do not believe that tobacco products should be regulated under the Toxic Substances Control Act.

b. Page 26, after line 18, add new subsection (b) as follows, and renumber other subsections accordingly:

(b) Notwithstanding any provision of this Act, the Administrator shall have no authority under sections 6 and 7 of this Act to take any action which the Secretary of Labor is authorized to take pursuant to the Occupational Safety and Health Act. In exercising authority pursuant to this Act, the Administrator shall not, for the purposes of applying section 4(b)(1) of the Occupational Safety and Health Act, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

Explanation.-- The purpose of these changes is to eliminate the possibility of jurisdictional conflicts between EPA and the Department of Labor where actions taken by one authority might otherwise preclude or duplicate action of the other.

*84 8. Interagency cooperation and coordination

Page 3, after line 17, add the following new paragraph:

(5) such authority over chemicals be exercised in such a manner as to complement and supplement existing Federal policies, regulations, and public laws regarding the protection **4534 of health and the environment, including occupational health, consumer safety, food, drug, and cosmetic authorities.

Page 28, line 3, delete the sentence after 'coordination.-- ' and insert in lieu thereof:

In administering the provisions of this Act, the Administrator shall consult and coordinate with the relevant agencies and instrumentalities of the Federal Government in accordance with the policies set forth in section 2(b) of this Act.

Page 30, line 2, delete the last sentence of subsection (a) and insert in lieu thereof:

The Administrator is authorized to make contracts and grants for research and monitoring as necessary to carry out the purposes of this Act in consultation with the Secretary of Health Education, and Welfare on such contract and grant programs.

Page 30, line 7, delete entire subsection (b) and insert new subsection (b) as follows:

(b) The Council on Environmental Quality in consultation with the Administrator, the Secretary of Health, Education and Welfare, the Secretary of Commerce, and the heads of other appropriate departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical compounds and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such materials. A report on such study shall be published within 18 months after enactment of this Act.

Explanation.-- These proposed amendments are intended to clearly set forth that it is the policy of the Act that there be the maximum cooperation and coordination among the several agencies of the Federal toxic substances; that the Act is intended to complement and supplement existing laws and regulations such as the Federal occupational health and safety requirements; and that appropriate provisions are made to establish and to have access to information relating to chemical compounds.

A number of Federal agencies, particularly the Occupational Health and Safety Administration of the Department of Labor have extensive responsibilities relating to toxic substances and human health and would stand to benefit from various provisions of the Act. The testing of chemicals as they relate to the programs of these agencies and the test results and other information and data generated by the legislation would, of course, be valuable to them and must be made available.

***85** One of these amendments specifically provides that the EPA Administrator will consult with the Secretary of Health, Education, and Welfare on any contract and grant programs for carrying out the research and monitoring activities under the Act, but not necessarily on each individual contract or grant.

****4535** We are also recommending that the provision contained in the previous bills before the Congress directing the Council on Environmental Quality to coordinate a study on the feasibility of establishing a standard classification system for chemical compounds and means of obtaining rapid access to the information on such substances be restored to the Act. This section provides CEQ to have the lead in establishing information systems in a manner currently being initiated. This is being done in conjunction with the agencies that would have been represented on the interagency committee as set out in the provision proposed to be deleted.

9. Additional assistant administrator

Page 28, line 15, delete subsection (a), renumber subsections (b) and (c) accordingly.

Explanation.-- This amendment would delete the provision for a special category Assistant Administrator for Toxic Substances.

10. Administrative inspections

Page 31, line 6, insert ‘(a)‘ after ‘Sec. 12‘, and after line 21 insert new subsection (b):

(b) Notwithstanding the provisions of subsection (a), the Administrator shall have authority to inspect financial data records pertaining to testing costs when he orders contribution or reimbursement for the costs of performing tests in connection with the provisions of sections 4(c) and 5(f).

Explanation.-- Section 4(c) and 5(f) authorize the Administrator to determine the equitable contribution or reimbursement of testing costs where more than one person benefits from the testing. This amendment would authorize access to financial data on testing costs in order for the Administrator to carry out the requirement to apportion the costs among those benefits from the testing.

11. Disclosure of confidential information

Page 34, line 18, delete entire section 15 and insert in lieu thereof the following revised section:

CONFIDENTIALITY

SEC. 15. (a) CENTRAL.-- Any information reported to, or otherwise obtained by, the Administrator or his representative under this Act, which is exempt from mandatory disclosure by reason of section 552(b)(4) of title 5, United States Code, shall be entitled to confidential treatment and shall not be disclosed by the Administrator or by any officer or employee of the United States except that such information may be disclosed.

(1) to officers and employees of the United States in connection with their official duties;

(2) to contractors with the United States and employees of such contractors, if in the opinion of the Ad-

***86** such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the effective ****4536** date of this Act for the performance of work in connection with this Act;

(3) when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding; or

(4) to the extent that the Administrator determines it is necessary to protect health or the environment.

(b) ACCESS BY CONGRESS.-- Notwithstanding any limitation contained in subsection (a) or any other provision of law, all information reported to or otherwise obtained by the Administrator or his representative under this Act shall be made available upon written request of any duly authorized committee of the Congress.

(c) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.-- (1) Any officer or employee of the United States, who by virtue of his employment or official position has obtained possession of, or has access to, material which is entitled to confidential treatment under subsection (a), and who knowing that disclosure of the specific material is prohibited by this section, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.

(2) For the purposes of this subsection (c), any contractor with the United States who is furnished information pursuant to subsection (a)(2), and any employee of any such contractor, shall be considered to be an employee of the United States.

Explanation.-- This section should be amended in several respects First, the substance criterion for withholding data as confidential should be the test established by the Freedom of Information Act. 5 U.S.C. 552(b)(4). Our proposed amendment would have the effect of requiring nondisclosure of information obtained under the Toxic Substance Control Act which may

be withheld under 5 U.S.C. 552(b)(4). i.e., ‘trade secrets and commercial or financial information obtained from a person and privileged or confidential. ‘ This will make the confidentiality standard more definite (because there exists a body of case law interpreting 5 U.S.C. 552(b)(4), and will promote uniformity.

In addition to the exemption for disclosure to Federal officers and employees, a separate provision should allow disclosure to EPA contractors and their employees, under appropriate safeguards and after appropriate EPA findings that disclosure is necessary. EPA accomplishes a great deal of its investigatory and analytical tasks by contract. If contractors are not allowed access to information under this bill, EPA could not perform its duties satisfactorily without substantial manpower increases. The recently-enacted Privacy Act, 5 U.S.C. 552a, provides that, for purposes of the section of the Privacy Act ***87** which imposes penalties on Government employees for wrongful use or disclosure of information entitled to confidentiality, Government contractors and their employees are to be considered Government employees ****4537** (5 U.S.C. 552a(m)). We recommend inclusion of such a provision in the toxic substances proposed bill. Our amendments allow disclosure to contractors, and include a penalty for wrongful disclosure of information by Government employees (including contractors and their employees).

We also believe that the provisions relating to qualified scientists and individual names are not necessary. The term ‘qualified scientists‘ would be difficult to interpret, and in any event a scientist would have no greater rights under the subsection than would any person under our (proposed) basic confidentiality criterion. We believe that the Federal Privacy Act and the Freedom of Information Act provide ample protection of the rights of individuals whose names appear in health and safety records.

Finally, with regard to access of information by Congress, we believe that release of such confidential information should be upon written request.

12. State exemption from Federal preemption

Page 42, line 14, delete subsection (b).

Explanation.-- This amendment would delete the provision that would allow State and local governments to petition to be exempted from Federal preemption requirements.

13. Citizen suits for discretionary action

Page 45, line 13, delete language after ‘Act‘ through line 16, and insert in lieu thereof: ‘which is not discretionary with the Administrator.‘.

Explanation.-- This amendment would make the provision conform with the usual citizen suit provision and not authorize suits against the Administrator for discretionary acts. It would thus prevent the possibility of every decision of the Administrator from being redecided in the district courts.

14. Indemnification study

Page 52, line 17, delete all of section 25 and renumber section 26 accordingly.

Explanation.-- This amendment would delete the requirement for a study on Federal indemnification under laws administered by EPA. We believe sufficient information already exists to recommend against indemnification under programs administered by EPA.

15. Submissions of budgets and testimony to Congress

Page 54, line 15, delete all of subsection (c).

Explanation.-- This amendment would delete the requirement that Agency budget requests, testimony and comments on legislation must not be submitted to OMB prior to submission to Congress. We continue to object to this provision.

16. Additional miscellaneous amendments

Page 2, line 16, add after ‘substances‘: ‘which may present an unreasonable risk to health or the environment.‘

***88** Page 3, line 8, insert after ‘to‘ the following: ‘ensure that adequate testing is conducted by those persons who manufacture, import or process, to‘.

****4538** Page 5, line 17, after ‘ecological studies‘ insert ‘monitoring studies,‘.

Page 8, line 4, delete ‘proscribed‘ and insert ‘prescribed‘.

Page 8, line 20, insert after ‘that‘ ‘one or more of the following‘.

Page 8, line 24, insert after ‘synergistic properties,‘ ‘persistence,‘.

Page 10, line 6, delete ‘section 5(g)‘ and insert ‘section 5(f)‘.

Page 22, line 12, delete ‘any‘.

Page 22, line 13, delete ‘threat‘ and insert in lieu thereof ‘risk‘.

Page 29, line 15, delete the period and add ‘if appropriate.‘.

Page 33, line 20, delete ‘delivery‘ and insert in lieu thereof ‘release ‘; line 22, delete ‘three months‘ and insert in lieu thereof ‘90 days‘; and on line 25, delete ‘deliver‘ and insert in lieu thereof ‘release‘.

Page 34, line 1, after ‘decision‘ insert ‘by the Administrator‘; line 4, delete ‘article, together with the‘ and insert in lieu thereof ‘article as set forth in the Customs entry plus the estimated‘; line 5, delete ‘forfeiture of ‘ and insert in lieu thereof ‘liability for assessment of liquidated damages equal to‘; line 6 delete ‘refusal‘ and insert in lieu thereof ‘failure‘; line 10, delete ‘delivery‘ and insert in lieu thereof ‘release‘; line 11, insert a comma after ‘payment‘ and delete ‘of‘ and the comma after ‘charges‘; and on line 16, delete ‘of subsection (a)‘.

Page 39, line 5, ‘section 17,‘ should read ‘section 16,‘.

Explanation.-- These amendments are technical corrections or are otherwise self-explanatory

***89** ADDITIONAL VIEWS OF MR. BAKER

In my view, the Toxic Substances Control Act which is the subject of this Committee Report represents a considerable improvement over past efforts to develop legislation in this field, and I support the bill. There is clearly a need for regulatory authority which can, where possible, identify and control the introduction of harmful substances into the environment before

damage to health or the environment occurs. This bill permits regulation of toxic chemicals at points in the chain of manufacture and use that are impossible to reach under existing laws. In addition, the concept of premarket screening will, in some cases, prove a boon to industry by providing a mechanism whereby a harmful substance can be halted before a manufacturer has invested a great deal of time and money in marketing and distributing it.

While I opposed some of the amendments which were added to the measure during the Committee's mark-up, I will confine these views to a discussion of one section of the bill which was the subject of an amendment I offered. Unfortunately, that amendment was rejected by the Committee.

Section 4(e)(1) of the bill as reported creates an interagency advisory committee to advise the Administrator as to those chemicals which should be priorities for testing. The priority list is required to be published in the Federal Register, and the Administrator is required to institute a rulemaking procedure to develop testing requirements on these chemicals within 1 year or publish his reasons for not doing so.

These requirements pose several problems for both the industry and the Administrator which I believe the Committee has neglected to address adequately. First, publication of a priority list in the Federal ****4539** Register is likely to generate a good deal of publicity in the media which will inevitably result in a perception by the public that chemicals on the list are harmful, even though they will not, at this point, have undergone testing for toxicity.This ‘blacklisting‘ effect will, in my opinion, work a substantial unfairness on manufacturers of products which contain a chemical appearing on the list.

While I feel strongly that the public should be advised of harmful chemicals in the marketplace, I see little or no benefit in mandatory disclosure of the advisory committee's list prior to any decision by the Administrator that those chemicals do, in fact, meet the criteria for testing established by the bill. Other sections of the bill provide for disclosure to the public of test data received by the Administrator, as well as information received when a chemical undergoes premarket screening. Moreover, section 14 of the bill requires the Administrator to disclose any information he has if he determines it is necessary to protect human health or the environment. These provisions insure continuing dissemination to the public through the Federal Register of information pertaining to the administration of the Act.

***90** Secondly, I do not believe that requiring the Administrator to take action on the advisory committee's list within 12 months or publish his reasons for not taking action is consistent with the proper role of an advisory committee. This requirement effectively removes the decision on whether to require testing from the Administrator and places it in the hands of the advisory committee-- an entity not responsible for administration of the Act. The priority list developed by the committee should be received and evaluated by the Administrator as a recommendation. By requiring that he act on the advisory committee's recommendation, the bill removes from the Administrator the flexibility which he will need to make responsible decisions on the testing of chemicals.

HOWARD H. BAKER, Jr.

(Note: 1. PORTIONS OF THE SENATE, HOUSE AND CONFERENCE REPORTS, WHICH ARE DUPLICATIVE OR ARE DEEMED TO BE UNNECESSARY TO THE INTERPRETATION OF THE LAWS, ARE OMITTED. OMITTED MATERIAL IS INDICATED BY FIVE ASTERISKS: *****. 2. TO RETRIEVE REPORTS ON A PUBLIC LAW, RUN A TOPIC FIELD SEARCH USING THE PUBLIC LAW NUMBER, e.g., TO(99-495))

S. REP. 94-698, S. Rep. No. 698, 94TH Cong., 2ND Sess. 1976, 1976 U.S.C.C.A.N. 4491, 1976 WL 13880 (Leg.Hist.)

End of Document

No. 25-158
Consolidated with Nos. 25-572 and 25-573

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
and LEE ZELDIN, in his official capacity as
Administrator of the United States Environmental Protection Agency,

Respondents.

On Petitions for Review of a Final Agency Action of the
United States Environmental Protection Agency
89 Fed. Reg. 102,773 (December 18, 2024)

PETITIONERS' ADDENDUM OF DECLARATIONS

October 17, 2025

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DECLARATION OF JANICE ANGLIN
IN SUPPORT OF PETITIONERS' OPENING BRIEF

I, Janice Anglin, declare as follows:

1. My name is Janice Anglin, and I live in Endicott, New York. My husband I lived here in the same house for over 40 years, where we raised our three children. Since recently losing my husband, I live here with my King Charles spaniel.

2. I have retired from my career as a reading specialist, and hope to volunteer in the schools soon. I spend free time with my children and five grandchildren, who come to visit as often as possible. One of my children still lives in Endicott. I am active, and play tennis outside when I can.

3. I am interested in environmental issues, particularly as they pertain to toxic substances, and that interest has also led me to a deep interest in nutrition. I have been a member of Environmental Defense Fund (EDF) for over five years.

4. Here in Endicott, people have dealt with various environmental issues. For example, IBM – which was here for years – was known to have caused pollution. More recently, a company from New Jersey began emitting visible pollution at nighttime. Community members, including a committee at my church, spoke up and passed around information about this, and Endicott's mayor learned about these challenges and the visible emissions eventually stopped.

5. I have been concerned for many years about drinking water quality and toxicity. I installed a filtration system for my whole house, and have given my children water filters to use instead of drinking tap water. I have done research to try to determine what contaminants – including carcinogens – are in Endicott's town water, along with doing research for my friends' areas, but have not been sure that I've gotten full information about what is in these water systems.

6. Concern about my children's health was heightened when my son began exhibiting symptoms of leukemia many years ago. After he was finally diagnosed, he had to undergo many difficult treatments, including a bone marrow transplant. He still has side effects from his treatments.

7. I have recently been made aware of the problems of persistent, bioaccumulative, toxic ("PBT") chemicals and about the fact that EPA has issued a regulation that does not protect people from new PBTs that companies make. I have also learned of a facility near me in Endicott, on Wayne Street, which appears to go by the name of Chrysta-Lyn Chemical Company, and the fact that this company has asked EPA to be able to make new types of PBT chemicals without going through a standard review process. I have also learned that, based on the limited information available to the public, these chemicals can cause health effects for people exposed to them and at least one of them can be toxic to aquatic life.

8. This company is a mile from my house. I am worried that the chemicals enter my drinking water. Even though I have a filtration system, I do not know if it is able to filter these particular chemicals out. I am worried about serious health harms and illness from the PBT chemicals to me, my family, and future family members, including to my son who is already dealing with leukemia.

9. I am concerned about the possible impact of these toxic chemicals on the value of my home here in Endicott.

10. I also understand that I may be exposed to other PBTs from other facilities in town or from products in my home, which could make the effects from PBTs from the facility on Wayne Street worse for me and my family.

11. I understand that the regulation EPA issued last year, unless it is fixed, will lead to companies making unsafe chemicals because EPA will not fully ensure their safety. Instead, the regulation should be changed, and EPA should not allow new PBTs to be approved unless it fully reviews the chemicals and makes sure they will not harm my community.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 13 October, in 2025 in Endicott, New York.

Janice Anglin

Janice Anglin

DECLARATION OF ROBERT DEFERRANTE
IN SUPPORT OF PETITIONERS' OPENING BRIEF

I, Robert Deferrante, declare as follows:

1. My name is Robert Deferrante, and I live in Endicott, New York. I am retired from my career, and I enjoy spending some of my free time now driving a school bus. I also stay educated about environmental issues, and support environmental work.

2. For example, I support Environmental Defense Fund (EDF), because I feel it is an effective organization that does a variety of activities while keeping their overhead low. I have been a contributing member of EDF for 28 years, and have gotten involved with various EDF campaigns and calls to action.

3. I have been concerned about harms to the environment for decades, since I was a child. My father was a staunch environmentalist who also supported work in defense of the environment. He raised his kids to care about the environment as well.

4. For many years, I have been focused on pollution and its harm to people. For example, when I lived in Los Angeles, I learned of abandoned, improperly capped oil wells in areas of lower socioeconomic status. I was concerned about both the environmental and justice and safety issues of that issue, and got involved in calls to action like petitioning to clean up these areas.

5. Though my involvement with EDF, I have learned about issues of toxic chemicals in this country.

6. I have also been made aware of the problems of persistent, bioaccumulative, toxic ("PBT") chemicals and about the fact that EPA has issued a regulation that does not protect people from new PBTs that companies make.

7. I have also been made aware of a facility near me in Endicott, which appears to go by the name of Chrysta-Lyn Chemical Company, and the fact that this company has made PBTs before, and that they did not undergo a full review by EPA before they were made. I have also been made aware that, based on the limited information available to the public, these chemicals can cause health effects for people exposed to them and at least one of them can be toxic to aquatic life.

8. This company is located in walking distance from my house. I was disturbed to learn these facts, and I am concerned that these - and other PBT chemicals that this company may make in the future without a full review - will harm my health and the surrounding environment, including the river that I live two blocks from, are not fully understood. Since moving to Endicott, I go to the river about five days a week, and often take my dog on walks there. I also bike on the Two Rivers Greenway path.

9. I also understand that I may in addition to environmental exposure to the PBTs being produced at the local facility, I may be exposed to other PBTs, like through flame retardant chemicals in products in my home, and that harms from PBTS from the facility could be compounded by the harms through my daily exposures from these other sources.

10. I have two daughters. One daughter lives less than four miles away from me here in Endicott, and another goes to college in Philadelphia and comes back to visit often. I am concerned about their exposures and harm, as well as to any family – including children – they will have one day. In short, I am worried about serious health harms and illness from the PBT chemicals to me, my family, and future family members.

11. I understand that the regulation EPA issued last year, unless it is fixed, will lead to the making and using of unsafe chemicals because EPA will not fully ensure their safety. Instead, the regulation should be changed, and EPA should not allow new PBTs to be approved unless it fully reviews the chemicals and makes sure they will not harm communities like Endicott.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 16 October, in 2025 in UNION, New York.

Robert Deferrante

DECLARATION OF MARIA DOA

I, Maria J. Doa, declare and state as follows:

1. I am the Senior Director, Chemicals Policy, at the Environmental Defense Fund. I hold a Bachelor of Science in chemistry and a Ph.D. in organic chemistry. Before joining Environmental Defense Fund, I worked at the U.S. Environmental Protection Agency ("EPA"), where for twenty-two years I held various leadership positions focused on the regulation of toxic chemicals and the management of the application of scientific research and data to regulatory decisions. A copy of my CV is attached as **Exhibit 1**.

2. The Environmental Defense Fund is a non-profit organization that works to protect the public from toxic chemicals, including chemicals that are reviewed and regulated under the Toxic Substances Control Act (TSCA).

Personal Experience at EPA and in the TSCA New Chemicals Program

3. Before joining the Environmental Defense Fund in November 2021, I held leadership positions at EPA, most recently as the director of the Science Policy Division in EPA's Office of Research and Development. The Science Policy Division coordinates scientific advice on regulatory activities and coordinates science and technology issues, such as public access to data, across the Agency.

4. Before I joined the Office of Research and Development in 2018, I served for seven years as Director of the Chemical Control Division in the Office of Chemical Safety and Pollution Prevention. The Chemical Control Division was responsible for the development and implementation of regulations and programs for the testing, data development and collection, and risk management functions for most industrial, commercial, and consumer chemicals subject to TSCA.

5. As part of my role as the Director of the Chemical Control Division, I led the TSCA risk management programs for new chemicals, which is intended to ensure that these chemicals are appropriately regulated before they enter the marketplace and cause harm to humans and the environment. This included managing the review of premanufacture notices (PMNs); exemption applications including low volume exemptions (LVE) and low releases and low exposures exemptions (LoREX); significant new use notices; and the development of any regulation of the new chemicals including through TSCA section 5(e) orders.[1] I

[1] 15 U.S.C. § 2604(e). One outcome of EPA's review of a premanufacture notice for a new chemical substance or a significant new use is a TSCA section 5(e) order. Most TSCA section 5(e) orders issued by EPA are Consent Orders that are negotiated with the submitter of the notification. EPA must issue an order when the Agency determines the substance may pose an unreasonable risk to health or the environment, there is insufficient information to allow the Agency to make a reasoned evaluation of the health and environmental effects of the new chemical substance or significant new use or the chemical substance is or will be produced in substantial quantities and will either enter the environment in substantial quantities or there may be significant or substantial human exposure to the

also led the development of significant new use rules[2] and regulations that apply to the review of new chemicals. In my time in this role, the program reviewed thousands of new chemicals. I directly made decisions for a substantial sub-set of those, including the PMNs regulated by TSCA section 5(e) orders and certain LVE submissions.

6. I worked closely with the Risk Assessment Division, which developed the risk assessments that were the basis for determining whether the risks presented by a new chemical were unreasonable. These risk assessments consisted of an evaluation of the toxicity and "environmental fate" (persistence, bioaccumulation, environmental transport) of the chemical and the ways people and the environment could be exposed to them. These risk assessments were also the basis for determining the most effective risk management requirement(s) to mitigate the unreasonable risks presented by the chemical.

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substance. A section 5(e) order prohibits or limits the chemical's manufacture, processing, distribution, or use to protect against that risk. The orders can include requirements for testing, protective equipment, hazard communication, restrictions on releases to air, water and/or land, and recordkeeping.

[2] TSCA section 5(a)(2) significant new use rules can be used to require notice to EPA before a chemical substance is used in a way that changes the type or form of exposure to humans or the environment to a chemical substance, increases the magnitude and duration of exposure of humans or the environment to a chemical substance, increases the quantity of the chemical substance or changes the manner and methods of manufacturing, processing, distribution in commerce and disposal of a chemical.

The Problem of PBT Chemicals

7. Persistent, bioaccumulative, and toxic chemicals ("PBT") are an especially pernicious category of chemicals. PBTs are defined by their: (1) persistence, meaning the length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes; (2) potential for bioaccumulation, meaning the process by which organisms may accumulate certain chemicals in their bodies. The term refers to both uptake of chemicals from water and from ingested food and sediment residues; and (3) toxicity, meaning the deleterious or adverse biological effects elicited by a chemical, physical, or biological agent. Persistent chemicals can take months to years to break down in the environment, and so even small, repeat releases of such chemicals will build up in the environment, increasing their potential exposure to humans and wildlife.

10. Even small releases of these toxic chemicals that can remain in the environment for a significant amount of time and can bioaccumulate have the potential to present greater risks to human health and the environment than toxic chemicals that do not. In other words, for any given level of release to the environment, a toxic chemical that is a PBT is far riskier than a chemical of equivalent toxicity due to PBTs' persistence and potential for bioaccumulation. Thus, even relatively small amounts of PBTs present outsized risks. PBT chemicals may be released to the environment at any point throughout their

lifecycle, i.e. when they are manufactured, distributed in commerce, processed into other products, or used. And once a product containing a PBT chemical reaches the end of its useful life, it must be disposed of—for example, in a landfill or incinerator—at which point there is a high likelihood the PBT chemical will be released. This is the case even for products where the PBT is "enclosed," like a capacitor containing a PBT chemical. During use or treatment and disposal at the end of its life, the PBT will likely come out of the product. In other words, once manufactured, the release of a PBT chemical at some point in its lifecycle is a near certainty. Once a PBT chemical is released into the environment, people and other organisms are likely to be exposed. Toxic chemicals that are both persistent and bioaccumulative also have the potential to pose significant exposures to humans and ecosystems over a longer period of time, years to decades. Repeated small releases of these chemicals can build up over time, serving as a reservoir for the chemical and a source of ongoing exposure to plants, animals and humans. This can impact whole ecosystems and the communities that live and depend on these areas.

11. A well-known example that illustrates this is polychlorinated biphenyls or "PCBs" in the Great Lakes. They were used in coolants, hydraulic fluids, heat transfer fluids, paints and rubber due to their stability, non-flammability and electrical insulating properties. They were also used in

"enclosed" applications such as capacitors and electrical transformers. The manufacture of these industrial chemicals was banned under TSCA in 1977,[3] but their legacy uses, including the many in so-called "enclosed systems," continued providing a source of releases. PCBs have been found throughout the Great Lakes in sediments, water, and aquatic organisms. PCBs persist in lake sediments, and almost 50 years after manufacturing stopped they are a continuing source of exposure. Human exposure to PCBs in the Great Lakes region comes from the food pathway, primarily via sport and subsistence fish (such as lake trout and walleye), which bioaccumulated these chemicals and from drinking water.

12. Toxic chemicals that persist and bioaccumulate can pose significant exposures to communities and ecosystems both near and far. They can pose risks to those that immediately surround industrial sources because the PBTs will reach those communities first. In addition, many PBTs are known to undergo regional and long-range transport and will impact communities farther away from their origin of release. Results from an EPA study of chemicals in lake fish found that PCBs as well as dioxins and furans, also PBTs, were widely distributed in lakes

[3] 15 U.S.C. § 2605(e).

and reservoirs in the lower 48 states.[4] They have also been found in the Arctic and there has been little evidence that levels there have been decreasing.[5]

13. PBT chemicals present a distinct risk to indigenous communities living in Arctic regions like Alaska. Once released into the environment, PBTs that are mobile undergo long range transport, including via a process called global distillation, also known as the "grasshopper effect," that causes them to migrate from the warmer regions where they are released, leapfrogging into polar regions, where they then accumulate over time.[6] As an example, global ocean current patterns represent a significant pathway for this long-range transport of PBTs. And once in the Arctic, the colder environment further slows the breakdown of PBT chemicals, which then accumulate over time in the Arctic environment and in

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[4] EPA. The National Study of Chemical Residues in Lake Fish Tissue. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.epa.gov/sites/default/files/2018-11/documents/national-study-chemical-residues-lake-fish-tissue.pdf

[5] MacDonald, RW, LA Barrie, TF Bidleman, ML Diamond, DJ Gregor, RG Semkin, et al. 2000. Contamination in the Canadian Arctic: 5 years of progress in understanding sources, occurrence and pathways. *The Science of the Total Environment* 254(2-3):93-234. PMID: 10885446.

[6] Rigét, F. A Bignert, B Braune, J Stow, S Wilson. 2010. Temporal trends of legacy POPs in Arctic biota, an update. *The Science of the Total Environment* 408:2874-2884. (available at www.amap.no/documents/download/1116).

biological organisms, including plants and animals.[7,8] These plants and animals are then consumed by indigenous populations, resulting in greater exposures to the chemical than those experienced by the general population.[9]

14. Thus, PBT chemicals can pose a heightened risk to many subpopulations, including to indigenous communities in the Arctic, communities that live near plants that make or use PBTs ("fenceline communities"), and subsistence fishers.

Statutory and Regulatory Background

15. Section 5 of TSCA establishes a comprehensive system of review by EPA before a new chemical can be manufactured in the United States (defined to include import into the country).[10] This system of premanufacture review is designed to ensure chemicals that may present or present an unreasonable risk are

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[7] de Wit, CA. D Herzke, K Vorkamp. 2010. Brominated FRCs in the Arctic environment—trends and new candidates. *The Science of the Total Environment* 408(15):2885-2918. PMID: 19815253. (available at http://www.ncbi.nlm.nih.gov/pubmed/19815253);

[8] AMAP 2015. Summary for Policy-makers: Arctic Pollution Issues 2015. *Arctic Monitoring and Assessment Programme (AMAP)*, Oslo, Norway. 12 pp. (available at www.amap.no/documents/doc/sum-mary-for-policy-makers-arctic-pollution-issues-2015/1195).

[9] AMAP 2014. Trends in Stockholm Convention Persistent Organic Pollutants (POPs) in Arctic Air, Human media and Biota.

[10] 15 U.S.C. § 2604.

appropriately regulated before they can be commercialized and cause harm to humans and the environment. These protections are particularly important for safeguarding against the threat posed by PBT chemicals.

16. Under the standard process for premanufacture review, a chemical manufacturer must submit a premanufacture notice ("PMN") to EPA, and EPA must review the PMN to determine the risk posed by the chemical, and then based on the results of that review make a determination of whether to regulate the new chemical's manufacture.[11] EPA may "upon application and rule" exempt a new chemical or category of new chemicals from PMN review if EPA determines the terms of the exempting rule ensure new chemicals "will not present an unreasonable risk of injury," including that it will not present such risk to potentially exposed and susceptible subpopulations.[12] EPA has created four rules-based exemptions to the standard PMN process. As relevant here, EPA has maintained two rules-based exemptions to PMN review for several decades, the Low Volume Exemption (LVE) and the Low Release and Exposure Exemptions (LoREX) (collectively, "the Exemptions").[13]

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[11] *See generally* 15 U.S.C. § 2604.

[12] 15 U.S.C. §§ 2604(h)(4), 2625(c).

[13] 40 C.F.R. § 723.50(c)(1), (c)(2).

The Standard PMN Process

17. As part of the PMN, the manufacturer must include information pertaining to the chemical's properties, including information on health and safety, production volume and how the chemical will be produced and used. Based on the information the company submits along with other information available to the Agency, EPA can make one of five possible determinations as to the potential risk of the new chemical:

(i) The chemical substance presents an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(A) of the Act.

(ii) Information available to EPA is insufficient to permit a reasoned evaluation of the health and the environmental effects of the relevant chemical substance, as set forth in section 5(a)(3)(B)(i) of the Act.

(iii) In the absence of sufficient information to permit EPA to make such an evaluation, the chemical substance may present an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(B)(ii)(I) of the Act.

(iv) The 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, as set forth in section 5(a)(3)(B)(ii)(II) of the Act.

(v) The chemical substance is not likely to present an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(C) of the Act.

EPA must regulate the new chemical unless EPA determines that the new chemical "is not likely to 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."[14] If EPA makes one of any of the four other determinations, it must regulate the chemical before it can be manufactured. These regulations may include options like further testing or limitations on the chemical's manufacture. Under TSCA, the manufacturer cannot manufacture the chemical until EPA has rendered a determination on the PMN. TSCA sets out a general timeframe of 90-180 days to complete PMN review, but EPA may take longer given the complexities of many cases. The only consequence of a longer review is that the applicant's fees are returned.[15]

18. Thus, EPA's adequate evaluation of the risks posed by new chemicals is necessary and fundamental to carrying out this system of premanufacture review and ensuring that new chemicals do not harm people or the environment. EPA cannot fulfill its mission if it does not adequately assess the risk of a new chemical. If EPA underestimates risk, it likely cannot effectively manage the risks presented by the chemical. EPA may erroneously conclude that the new chemical is not

[14] 15 U.S.C. § 2604(a)(3)(C).

[15] 15 U.S.C. § 2605(a)(4), (c).

likely to present unreasonable risk and, thus, does not need to be regulated. Or, having underestimated the true magnitude of risk, EPA is likely to issue under-protective regulations to safeguard against the new chemical's risks. This is of particular concern for PBTs because even small amounts used and released can have long-term impacts on human health and the environment.

19. Simplistically, "risk" is a function of estimated or assessed hazard and exposure. *See* 15 U.S.C. § 2605(b)(4)(F). Hazard is an assessment of the potential harms caused by the chemical and the levels at which the harms occur. And exposure is an assessment of how much of a chemical an individual (or ecological receptor like an animal or a tree) encounters. Integrated together, hazard and exposure inform how likely a harmful outcome is anticipated to occur. Persistence and bioaccumulation influence risk, because persistence may lead to higher and longer sources of exposures and bioaccumulation may lead to an increase in body burden.

20. EPA is required to use the "best available science" in assessing the risk posed by new chemicals. 15 U.S.C. § 2625(h). Consistent with the best available science mandate, an evaluation that accurately represents the risks presented by the chemical requires consideration of the type of harm(s) caused by the chemical, the toxicity level of the chemical (how much exposure to the chemical is expected to cause that harm), and a picture of the ways an individual is

exposed to the chemical and the magnitude of that exposure. This picture should include all the ways the general population, more highly exposed or susceptible subpopulations, and the environment are exposed during the manufacture, processing, distribution in commerce, use and disposal of the chemical—that is, from the sum of what is referred to in TSCA as the chemical's "conditions of use."[16] This picture must also reflect that a person may be exposed via multiple conditions of use of the chemical and through multiple pathways of exposure, including by inhalation, drinking water, and dermal contact. Finally, this picture must reflect that exposure can come from multiple environmental sources, including the air, water, and land. It is the consideration of the sum of the exposures during the lifecycle of the chemical that is the basis of an accurate determination of the types and magnitude of the risks the chemical presents.

21. Again, this is a more complicated analysis in the context of new chemicals and relevant information needed to determine the risk posed by a new chemical is likely to be lacking precisely because they are new, requiring EPA to order the development of more information about the chemical to gain an adequate picture of it.

22. EPA is also required to consider risks to potentially exposed and susceptible subpopulations, whom Congress, in 2016, specifically required EPA to

[16] 15 U.S.C. § 2602(4).

consider when assessing the risk posed by new chemicals.[17] Subpopulations such as fenceline communities or people who rely on subsistence diets are often more highly exposed than the general population. These subpopulations are often at greater risk than the general population even at the same level of exposure because they may be exposed to a chemical from multiple conditions of use of the chemical. For example, the community may be exposed to releases from one or more industrial facilities, some of which manufacture the chemical, others which process it, and still others where the chemical is disposed. Members of the community may also be additionally exposed because they work at one of the facilities and/or are exposed to the chemical in products they use at home. The number and type of potentially exposed and susceptible subpopulations will often be greater for PBTs than for non-PBTs. Subsistence and sport fishers are one example of more highly exposed subpopulations. They will be exposed to higher levels of PBT chemicals in fish and other aquatic life, given the demonstrated ability of PBTs to bioaccumulate in these species.

23. Further, fenceline communities are often more susceptible to a given new chemical because they are already exposed to multiple chemicals that are produced and released together. Some of these may cause the same harm, such as cancer, and even attack the same part of the body. For example, members of the

[17] 15 U.S.C. § 2604(a)(3).

community exposed to one of these chemicals may be more susceptible to liver cancer based on their co-exposure to similar chemicals also associated with liver cancer already released into their environment. In assessing a chemical, the failure to consider the cumulative exposures for each of the chemicals for that community would likely significantly underestimate to its members the actual risk of liver cancer.

24. Assessing the risks from PBT chemicals is more complicated given the effect of persistence and bioaccumulation on estimating exposure. This complication is compounded because the exposure models EPA uses in the TSCA New Chemicals Program are not designed for chemicals that are persistent and bioaccumulative. Rather, they are designed for a simpler screening analysis targeted to chemicals that readily degrade and have a low potential for bioaccumulation. For example, for routine releases of a chemical that readily biodegrades and is thus not persistent, the potential for exposure dissipates rapidly. Thus, the daily exposure for that chemical is directly based on the daily release. In contrast, calculating exposure from daily releases of a chemical that is persistent requires a consideration of the amount released each day plus the amount that remains from the previous day and the amount that remains from the day before that, etc. For example, consider a daily 100-pound release of a chemical with a

half-life of 3 months.[18] For each daily release of 100 pounds, after 3 months, one half—or 50 pounds—of the chemical will remain. After another 3 months, half of that—or 25 pounds—will remain. In this situation a daily release of 100 pounds of the chemical will quickly build up in the environment and the analysis of the daily exposure becomes more complicated. Compare this with a non-PBT chemical that has a half-life of 3 hours. Twenty-four hours after the release of the chemical, less than 1% of the chemical remains. Thus, conducting a rapid exposure assessment on a PBT chemical using models developed for non-PBT chemicals is inconsistent with using the best available science. This chemical-degradation differential also illustrates that for PBTs that are highly persistent and highly bioaccumulative, there is no release threshold below which exposure is safe.

25. Similarly, evaluating exposure across a PBT chemical's lifecycle can be more complicated for PBTs given that releases from uses, disposal of products, and treatment of industrial and commercial wastes containing PBTs may add to environmental levels and the levels already accumulated in humans, animals and plants, thus becoming a source for long-term exposure. Careful attention must be given to releases associated with production processes, effectiveness of

[18] A half-life of 3 months means that half of the quantity of the chemical will be destroyed (transformed) in 3 months, with half of the original quantity of the chemical remaining.

engineering controls, wastewater treatment removal efficiencies, disposal release, and more to assess these additional contributors to PBT exposures.

26. In sum, having a robust system of premanufacture review for new PBT chemicals is incredibly important and cannot effectively be done during an abbreviated exemption review.

27. Recognizing the outsized risks posed by PBT chemicals and the difficulty of assessing them, EPA officially designated new PBT chemicals as a distinct category of new chemicals for purposes of premanufacture review in 1999.[19] The 1999 PBT Policy consisted of two primary components: regulation under a TSCA section 5(e) consent order and testing requirements.[20]

28. For chemicals that EPA found were PBT chemicals, the policy provided that EPA would issue a section 5(e) order regulating the chemical and requiring testing (typically once specified production levels were reached). And for those new PBT chemicals that were "very persistent" (half-life in soil, sediment or water greater than 6 months) and "very bioaccumulative" (fish bioconcentration factor or bioaccumulation factor greater than 5000), the 1999 PBT Policy provided

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[19] EPA. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances; Policy Statement, 64 Fed. Reg. 60196, Nov. 4, 1999. (1999 PBT Policy)

[20] 15 U.S.C. § 2604(e).

that EPA would ban the manufacture of the chemical pending further health and safety testing.[21] In essence, EPA recognized in the 1999 PBT Policy that there is too much uncertainty regarding new PBTs to effectively safeguard the public through premanufacture review, and so established a policy that would result in: (1) the regulation of new PBTs that go through premanufacture review; and (2) the ongoing development of new test data after the premanufacture review ended so that the regulations could be strengthened if needed or for very persistent and very bioaccumulative toxic chemicals test data could be developed before commercialization to determine the extent to which it could cause harm and build up in the environment and plants, animals and people.

29. As applied to the Exemptions, when I was the director of the Chemical Control Division, from 2014 to 2017 any LVE exemption application identified as meeting the criteria of the 1999 PBT Policy was required to be raised to me for review. This procedure for review of PBT LVEs by the Chemical Control Division director was reflected in a 2017 New Chemical Program standard operating procedure. Essentially all LVE exemption applications for new PBTs were denied because they were PBTs, which meant the manufacturer would have to apply under the full PMN review, triggering the testing and regulation requirements mandated by the 1999 PBT Policy.

[21] 1999 PBT Policy at 60202.

2024 Exemptions as Fast-Tracking PBT Approval

30. In the 2024 rule establishing framework rules for new chemicals, EPA—for the first time—expressly authorized new PBT chemicals to be approved under expedited approval processes established by the Exemptions. The rule fast-tracks the approval of new PBTs, expressly making any new PBT eligible for the Exemptions unless EPA finds a specific new PBT has "anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms."[22] The term "potentially unreasonable exposures" is not defined and has no relationship to the 1999 PBT Policy.

31. The LVE exemption requires an applicant manufacturer to establish that its new chemical will be "manufactured in quantities of 10,000 kilograms or less per year."[23] The LoREX exemption requires an applicant manufacturer to establish that the new chemical will meet eligibility criteria establishing "low environmental release and low human exposure," including criteria pertaining to: specific groups—consumers, the general population, and workers; surface water concentrations; incinerators releases; and land and groundwater releases.[24]

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[22] 40 C.F.R. § 723.50(d)(2).

[23] 40 C.F.R. § 723.50(c)(1).

[24] 40 C.F.R. § 723.50(c)(1).

32. To establish eligibility of a new chemical for approval under one of the Exemptions, a manufacturer must file a notice with EPA containing specified information.[25] And the review period for an application under the Exemptions is significantly truncated, only 30 days, as compared to the 90-180 day review period for a PMN.

33. Exemptions differ from full new chemical reviews in numerous ways, including that there are no testing provisions for exemptions. TSCA's section 5(e) — "Regulation Pending Development of Information" —provides for the development of testing in the absence of sufficient information,[26] but there is no corollary regulatory provision authorizing testing for approved LVEs. Also, unlike PMN reviews, multiple LVEs may be granted for the same chemical because multiple different companies can apply under the LVE to manufacture the same chemical. Multiple exemptions associated with a single new PBT can result in quantities of that PBT that exceed the 10,000 kilogram exemption limit for an applicant to manufacture an individual PBT under that exemption.

34. This new fast-track regulation is dangerous, because it short-cuts the standard PMN process for new PBT chemicals and is contrary to EPA's recognition in the 1999 Policy that PBTs should be subject to regulation and

[25] 40 C.F.R. § 723.50(e).

[26] 15 U.S.C. § 2604(e).

additional testing. The terms of the Exemptions do not protect against the unique risks posed by new PBT chemicals and thus do not ensure that a new PBT chemical will not present unreasonable risk.

35. It is unlikely that EPA can conduct a comprehensive release and exposure assessment for new PBTs in the expedited 30-day review period for the LVEs and LoREX exemptions. For example, multiple different companies at different times may have applied for LVEs to manufacture the same new PBT chemical. An adequate assessment of whether the new PBT chemical may present unreasonable risk, particularly to potentially exposed and susceptible subpopulations, would examine releases and exposures resulting from all of the LVE applications, if granted. But that is typically not done in the LVE analysis; indeed, the individuals within EPA responsible for reviewing a new exemption application may not be aware that other Exemption applications have previously been granted for the same PBT chemical given the speed of the process. Even when they are aware of other LVEs for the same PBT chemical, it is likely not possible to conduct such an assessment adequately within the 30-day review period. This is because of the complications of the analysis and the need to consider the potential for the impacts from the individual LVEs for the new PBT to build on each other.

36. New PBTs approved under the Exemptions will threaten health—particularly the health of subpopulations like indigenous people living in the Arctic and fenceline communities—and the environment, because the terms of the Exemptions do not sufficiently protect against their risks.

PBT LVEs Recently Issued by EPA

37. Based on a screening-level review of a large sample of LVE applications submitted to EPA between 2016 and 2025, it is apparent that companies regularly apply to manufacture new PBTs under the Exemptions.

38. To identify potential LVE PBTs, I worked with colleagues to develop an approach to identify PBT LVEs. We reviewed 1,458 LVEs from 2016 to 2025. Of these, 344 LVEs had non-confidential chemical identities.[27] Knowing the specific chemical identity is critical to assessing its properties. Using the identity of the chemical, we then searched EPA's CompTox Chemicals Dashboard Resource

[27] Under TSCA, a company that submits an application to manufacture a new chemical may claim that the specific chemical identify constitutes confidential business information (CBI), pursuant to 15 U.S.C. § 2613. In practice, once a submitter has claimed that the specific identity is CBI, EPA will not release the specific identity to the public, but instead will release a generic identifier. Without the specific identity, it is difficult for members of the public to gain relevant information about the new chemicals. The vast majority of manufacturers claim specific chemical identity to be CBI. For the sample we reviewed, EPA revealed the specific identity of less than 25% of the chemicals.

Hub[28] for information, including physical-chemical properties, chemical degradation (to estimate persistence), bioconcentration factors (to estimate bioaccumulation) and toxicity of the chemicals. For toxicity, we also looked at the Safety Data Sheets (SDS)[29] for the chemical or existing information developed by another government agency, e.g., the European Union Chemicals Agency. Additionally, we used EPA's EPI Suite to estimate persistence, bioaccumulation and aquatic toxicity.[30] EPI Suite is a suite of programs for screening-level estimates of physical-chemical properties and environmental fate (including chemical degradation and bioconcentration/bioaccumulation). EPI Suite also includes the ECOSAR program, which estimates ecotoxicity. EPA developed EPI Suite with Syracuse Research Corp. and routinely uses EPI Suite in its evaluation

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[28] EPA. CompTox Chemicals Dashboard Resource Hub. https://www.epa.gov/comptox-tools/comptox-chemicals-dashboard-resource-hub. "EPA developed the CompTox Chemicals Dashboard ("Dashboard") to provide public access to chemistry, toxicity, and exposure data. This information includes chemical structures, experimental and predicted physicochemical and toxicity data, hazard and bioassay data, and additional links to relevant websites and applications."

[29] A Safety Data Sheet or SDS is a document that provides essential information about the hazards, properties, and safe handling practices for chemicals used in the workplace.

[30] EPA. EPI Suite™-Estimation Program Interface. https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

of TSCA new chemicals. We then compared the estimates for persistence and bioaccumulation with the criteria for these properties in the 1999 PBT Policy.

39. We identified 30 chemicals that meet the 1999 PBT Policy persistence and bioaccumulation criteria. The 1999 PBT Policy's lowest criterion for persistence is a transformation half-life of greater than 2 months and lowest criterion for bioaccumulation is a bioconcentration factor or bioaccumulation factor greater than 1,000. For aquatic toxicity, we considered chronic toxicity values of less than 10 milligrams/liter, which is consistent with the aquatic toxicity criteria in EPA's Points to Consider When Preparing TSCA New Chemical Notifications.[31] For the human health toxicity criterion, we considered indications of "hazard endpoints," including genotoxicity, indications of systemic toxicity in any organism, identification of toxicity in SDS and/or by other government agencies, also consistent with EPA's stated criteria.[32]

40. The 30 LVEs included LVEs EPA granted to Crysta-Lyn of Endicott, NY for two chemicals. These chemicals have been characterized as causing skin

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[31] EPA. Points to Consider When Preparing TSCA New Chemical Notifications. p. 19. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/points-consider-when-preparing-tsca.

[32] Id. p. 12, "The human health score is typically based on qualitative considerations such as hazard endpoints."

sensitization and are toxic to aquatic life.[33] Further, these chemicals are similar to each other and have similar properties[34] and the cumulative exposures from both to the community and environment near the production and use of these PBT chemicals would even further increase potential risks.

41. Given the regularity with which manufacturers have applied under the Exemptions for approval to manufacture new PBTs in the recent past, it is almost certain they will continue to do so now that EPA has expressly fast-tracked their approval under these Exemptions. It is likely these reviews will be further expedited given EPA's recently announced initiative to accelerate the review of LVEs.[35]

42. These harms would be remedied if new PBTs were made ineligible for approval under the Exemptions. These new PBT chemicals would instead have

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[33] EPA. ChemView, https://chemview.epa.gov/chemview/ Submission information for L-23-0187 (CASRN 162093-35-8) and L-23-0199 (CASRN 864666-05-7).

[34] The similarity of the chemical structures which inform their similar properties can be seen in EPA. CompTox Chemicals Dashboard Resource Hub. See https://comptox.epa.gov/dashboard/chemical/details/DTXSID401386102 for information on L-23-0199 and https://comptox.epa.gov/dashboard/chemical/details/DTXSID001387039 for information on L-23-0187.

[35] EPA. *EPA Accelerates Review of New Chemicals used in Low Volumes and Slashes Backlog of these Submissions* (Aug. 11, 2025), https://www.epa.gov/chemicals-under-tsca/epa-accelerates-review-new-chemicals-used-low-volumes-and-slashes-backlog.

to go through full review under the standard PMN process, and EPA would be required to adequately evaluate their risks and impose restrictions individually tailored to each chemical to ensure they do not present an unreasonable risk. That would safeguard EDF members and the broader public—including fenceline communities, and indigenous people living in the Arctic— from risks posed by new PBT chemicals.

Informational Injuries

43. Additionally, if EPA codified its 1999 PBT Policy for new PBTs in the regulations, that would benefit EDF directly, by disclosing information on new PBT chemicals that would be helpful to EDF. If the policy were codified and new PBTs made ineligible for the Exemptions, when EPA receives an application to manufacture a new PBT under an Exemption, the applicant would be required to instead submit a PMN application for the chemical. TSCA mandates that the PMN application file be made publicly available and those application files are useful to EDF. In turn, the 1999 PBT Policy envisions that EPA would either ban the production pending testing or issue a TSCA section 5(e) order requiring testing. TSCA mandates the disclosure of such test data, and EDF would utilize that test data in its research and advocacy.

44. This information would be useful to EDF in accomplishing the mission of protecting people from dangerous chemicals. Our efforts rely on EPA

disclosing information about new chemicals, as it is obligated to do under TSCA. For example, EDF submits comments on rulemakings implementing TSCA, including rules related to the new chemicals program, which requires EDF to review new chemical submissions. Additionally, information from new chemical submissions and EPA decisions on these submissions is useful in educating our members and the general public about the chemicals EPA is allowing onto the market and the restrictions EPA imposes on them. EPA sends out action alerts, publishes blog posts, and communicates through other channels to inform members and the public of whether EPA is adequately protecting them. Finally, EDF engages in advocacy work at the national, state, and local level to protect their members from potentially dangerous classes of chemicals. EPA needs information about whether EPA is adequately and lawfully implementing the system of premanufacture review to educate policy makers and effectively engage in this advocacy.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on October 15, 2025.

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Maria J. Doa, Ph.D.

EXHIBIT 1

Maria J. Doa, Ph.D.

4223 38th Street, N.W., Washington, DC 20016
202.286.3020; mariajdoa@gmail.com

Summary

- Extensive experience in the integration of science and public policy
- Effective communicator of complex interdisciplinary scientific issues at the national and international levels
- Focus on developing risk assessment and risk management practices that consider the impacts of chemicals wholistically
- Expertise in modern risk-management practices
- Experience working with international organizations

Employment History

Environmental Defense Fund, Washington, DC

Senior Director, Chemical Policy November 2021 – Present

I lead efforts to reduce exposures to toxic chemicals, primarily through health-protective implementation of the nation's primary chemical safety law – the Toxic Substances Control Act. My efforts focus on encouraging more robust, inclusive, and transparent decisions that consider the impacts chemicals can have throughout their lifecycle on communities, particularly those most at risk.

U.S. Environmental Protection Agency, Office of Research and Development, Washington, DC

Director, Science Policy Division October 2019 – October 2021

I led the synthesis of the Office of Research and Development's scientific support for EPA regulatory activities and coordinated cross-EPA science and technology policy issues.

Accomplishments

- Led the coordination and synthesis of the Office of Research and Development's scientific contributions to the development of more than 40 significant EPA regulations and regulatory-related scientific assessments.
- Developed metrics and an information system to evaluate the impact of the Office of Research and Development's contributions to the development of EPA regulations.
- Improved the cross-EPA coordination of science and technology policy issues, such as peer review, risk assessment guidelines, and reproducibility of information.

Senior Science Advisor April 2018 – October 2019

In this position, I led evaluations on the impact of EPA's Office of Research and Development's science on decision making at the national, regional, state, and local level.

U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, Washington, DC

Director, Chemical Control Division May 2011 – April 2018

In this position I developed and implemented incentive-based and regulatory risk management approaches to significantly reduce risks from industrial, commercial and consumer chemicals. Many actions involved complex scientific, technical and policy issues and were done under tight legislative deadlines.

Accomplishments

- Improved EPA's approach on established chemicals through leadership on the prioritization of more than 1,000 candidate chemicals for risk evaluation. The prioritization methodology I developed was subsequently included by Congress as a key component in the 2016 amendments to the Toxic Substances Control Act.
- Annually, completed pre-market regulatory evaluations for 1,000 chemicals.
- Successfully led the development of the first proposed regulations in 25 years to protect the public and workers from exposures to highly toxic chemicals.
- Improved the quality, timeliness and consistency of regulations on industrial, commercial and consumer chemicals by collaboratively leading cultural change, identifying critical solutions and empowering managers and staff resulting in the elimination of a backlog of 400 chemical cases within 2 years and timely completion of 100 chemical cases annually.

- Provided leadership at the international level representing the United States environmental policies to the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials, chairing international expert meetings on nanomaterials, and leading bilateral negotiations on nanomaterials with Canada and the European Union.
- Increased access to, usability of, and transparency of scientific and regulatory information on more than 15,000 chemicals and nanomaterials through the development of ChemView, a modern Web-based information system available to industry, the public, and government.

Director, National Program Chemicals Division July 2003 – May 2011

I led EPA's lead paint program, resulting in major progress toward eliminating lead poisoning in children; risk-reduction programs on polychlorinated biphenyls (PCB) and mercury; and the asbestos in schoōls program. This work required strong scientific and policy backgrounds and involved working with a wide range of international and domestic public, industry, and government stakeholders.

Accomplishments

- Created a strong community of collaboration to coordinate scientific and regulatory activities with partners across EPA, the Federal Government (including the Centers for Disease Control and Prevention, the Consumer Products Safety Commission, the National Institute of Standards and Technology (NIST), the Department of Housing and Urban Development), with states, the Environmental Council of States (ECOS), the Quicksilver Caucus, industry, and environmental, public health and community public interest groups.
- Chaired the United Nations Environment Program – World Health Organization Global Alliance to Eliminate Lead in Paints and the United Nations Environment Program Global Mercury Partnership Mercury-Containing Products Partnership Area.
- Reduced children's exposure to lead paint from residential renovations by leading the development and implementation of regulatory renovation standards, through innovative collaborative outreach strategies, including with the Ad Council, and by the creation of a new grant program supporting local efforts to reduce lead poisoning. These lead poisoning prevention efforts have resulted in more than $1.5 billion in benefits.

U.S. Environmental Protection Agency, Office of Environmental Information

Director, Toxics Release Inventory Program Division October 1999 - July 2003

I led the multi-media Toxics Release Inventory (TRI) Program - a key community right- to-know program about toxic chemicals.

Accomplishments

- Created a modern data management approach to TRI data including development of intelligent reporting tools, annual receipt and processing of 100,000 plus submissions, quality control, and working with community and environmental groups on the use of the data
- Expanded TRI by completing hazard determinations for and adding to TRI more than 300 chemicals and 5 industry sectors, significantly increasing publicly available information on toxic chemical releases and industry's environmental performance.
- Chaired the OECD Task Force on Pollutant Release and Transfer Registers and represented the Agency in other international fora, including the North American Commission for Environmental Cooperation, and the Inter-Organization Programme for the Sound Management of Chemicals.
- Represented EPA in the United Nations Economic Commission for Europe negotiations on the development of a Pollutant Release and Transfer Register protocol under the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.

Education

University of Pittsburgh, Pittsburgh, Pennsylvania; Ph.D., Organic Chemistry

University of Michigan, Ann Arbor, Michigan; B.S., Chemistry

DECLARATION OF JASMINE JEMEWOUK
IN SUPPORT OF PETITIONERS' OPENING BRIEF

I, Jasmine Jemewouk, declare as follows:

1. I am a descendant of the Native Village of Elim, one of over 200 federally recognized native communities in Alaska, as well as an enrolled member of the Eastern Band of Cherokee Indians. I grew up in Elim, Alaska, a village of roughly 300 people on the Seward Peninsula. I currently live in Anchorage, Alaska, with my husband and my daughter, who is about one-and-a-half years old.

2. I am a member and supporter of Alaska Community Action on Toxics ("ACAT") and currently work as ACAT's Water Quality and Community Health Protection Coordinator. I served on the board of directors of ACAT from 2016 until 2023. I first became in involved in ACAT when I was in high school. I participated in the National Institute of Health's STEP UP Program, through which I secured an internship with ACAT, doing research on public health issues facing Alaskans, including Alaska Native people.

3. Through my work at ACAT and my service as a board member, I have learned a great deal about the problems that persistent, bioaccumulative, toxic ("PBT") chemicals cause for Alaskans, particularly Alaska Native people. Because the Arctic is a hemispheric sink, I am aware that PBT chemicals travel to Alaska from other parts of the country and then concentrate in our environment and our

traditional foods. I am gravely concerned about the contamination of our traditional foods and its impact on me and my family.

4. Traditional foods, such as birds, fish, seal, caribou, berries, and greens, are of great importance to our community, as they are integral part of our way of life and identity. When I return home to Elim, I join my family to go out hunting for beluga whales, gather the eggs of wild birds, fish, and pick berries. Traditional foods represent one of the only regular and reliable sources of food for many Alaska Native people. It takes two plane rides to get to my village, so it is difficult and costly to transport food from outside. Eating these traditional foods is one of the only ways to get vital calories and nutrients. My grandmother has four freezers stocked full of these traditional foods and makes sure to feed me whenever I am home. Accordingly, I, my young daughter, and the rest of my family, regularly consume these traditional foods and will continue to eat them foods going forward.

5. I am aware that the Environmental Protection Agency issued a rule that allows it to fast-track the approval of applications to manufacture new PBT chemicals. I am concerned about my exposure and my daughter's exposure to toxic new PBT chemicals approved under this new rule. I want EPA to prohibit new PBTs from being approved under these rushed procedures.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 9 October, in 2025.

JASMINE JEMEWOUK

DECLARATION OF PAMELA MILLER

I, Pamela K. Miller, hereby declare as follows:

1. I am the Executive Director of Alaska Community Action on Toxics ("ACAT"). I helped found ACAT in 1997 and have served as Executive Director since its founding. In this capacity, I am familiar with all aspects of ACAT's mission, purpose, membership, and activities. I submit this declaration in support of ACAT's petition challenging provisions of the 2024 New Chemicals Rule related to persistent, bioaccumulative, and toxic chemical substances ("PBTs") issued by the United States Environmental Protection Agency ("EPA") to implement provisions of the Toxic Substances Control Act ("TSCA"). *See* EPA, *Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)*, 89 Fed. Reg. 102773 (December 18, 2024) ("New Chemicals Rule").

2. My background is as a biologist. I have a bachelor's degree in biology from Wittenberg University (1978) and a master's degree from Miami University in environmental science with a specialty in aquatic biology (1981). I have over thirty years of experience in research, policy, advocacy, and training programs focused on environmental health, justice, and marine ecology. Since 2005, I have served as a principal investigator for community-based research projects supported by the National Institute of Environmental Health Sciences ("NIEHS") with Indigenous communities and have served as author or co-author of a dozen papers

concerning our community-based participatory research, published in the peer-reviewed scientific literature. In 2016, I was elected to serve as the co-chair of the International POPs Elimination Network ("IPEN"), a global network of more than 500 environmental health and justice organizations working for a toxics-free future. A true and correct copy of a recent Biographical Sketch (which identifies select publications and recent research projects) is attached.

3. ACAT is a 501(c)(3) non-profit public interest environmental health research and advocacy organization. ACAT is incorporated and has its headquarters in Alaska. ACAT works on behalf of Alaska communities that are concerned about environmental health issues arising from pollution, with a particular emphasis on Alaska Native communities. ACAT's mission is to advocate for environmental and community health for our members by protecting their rights to clean air, clean water, toxics-free food, and a toxic-free environment, as well as the rights of their communities to know about the toxic chemicals in their environment, products and food. ACAT empowers communities to eliminate exposure to toxics through collaborative research, shared science, education, organizing, and advocacy. Upon request, we assist individuals, tribes, and communities to implement effective strategies to prevent or reduce their exposures to toxic substances, protect the ecosystems that sustain them, and hold accountable those responsible for the contamination. Because existing remedies are so often

inadequate to address Alaskans' concerns, we also work to achieve systemic policy change at the marketplace, local, state, national, and international levels.

4. Much of our work is done in collaboration with Alaska Natives, who make up 20% of the state's population and are disproportionately exposed to toxic chemicals because of contamination of their traditional food sources. As a result, these communities face unique and serious environmental challenges. We support community-based environmental health research and train village leaders to conduct their own environmental sampling though our Community-Based Environmental Health Research Institute. We also work with coalitions to advocate for state policies that will protect Alaska's people, wildlife, and the environment. Our role is to listen to the voice and priorities of communities and be available to support initiatives to improve community health and provide helpful resources.

5. We currently have eight board members. Six of our eight board members are Alaska Native women representing the diverse communities that we serve (including Yupik, Inupiaq, Gwich'in Athabascan, Kaagwaantaan Tlingit, and Sugpiaq). One other board member is an Alaska resident, and the eighth and final member lived in Alaska for many years and now resides in Colorado. ACAT's board of directors is responsible for the governance of the organization, including approval of the organizational budget, organizational priorities, financial policies, and personnel policies; supervising the executive director; and fundraising. The

officers are two co-chairs, the treasurer, and secretary. All board members make personal financial contributions and work with our development director on fundraising from individuals.

6. ACAT is supported financially by its 800 non-voting members, who contribute financially to ACAT, and has 12,000 supporters, who respond to action alerts, attend events, or engage in workshops or meetings. The overwhelming majority of our members and supporters live in Alaska.

7. ACAT actively worked for the 2016 reform of TSCA. Our hope was that under a reformed TSCA, EPA would prioritize, evaluate, and then regulate chemicals that are found in high levels in Alaska communities.

8. Since TSCA was amended in 2016, ACAT has continued to push EPA to implement TSCA in a way that centers public health and protects overburdened communities, like Alaska Natives. To that end, ACAT advocates for EPA to conduct robust risk evaluations of new and existing chemicals that consider all sources of exposure and the higher risks faced by overburdened communities, as well as to adopt strong, health-protective risk management rules. ACAT's advocacy includes submitting comments to EPA on proposed rules, as well as bringing legal challenges when EPA fails to comply with an environmental law.

Chemical Contamination in Alaska

9. Most people think of Alaska as pristine and unpolluted, but this is not correct. Though largely undeveloped, Alaska has more than its share of contaminants. Toxic chemicals from many sources, both local and global, are showing up in Alaska's land, water, fish, wildlife, and people.

10. Far from pristine, Alaska has more than 2,000 known toxic waste sites from military and industrial operations.

11. In addition to these local sources of pollution, Alaska is contaminated by persistent organic pollutants ("POPs")—which are within the category of PBTs—that originate thousands of miles away travel to, and concentrate in, the Arctic in a process known as "global distillation." In the process of global distillation, POP chemicals that are emitted to the air or enter into the water from polluting sources in Europe, Asia, and North America are picked up by oceanic and atmospheric currents and deposited in the Arctic. Once there, their deterioration is slowed by low temperatures and sunlight and they remain available for uptake into biological systems (including plants and animals) for far longer than they would in other environments.

12. In the Arctic ecosystem, these POPs can bio-magnify in the food chain and reach extremely high concentrations in marine mammals, such as ringed seals and polar bears, which contain some of the highest levels of these chemicals

on the planet. These animals are integral components of the diets and lifestyles of indigenous peoples of Alaska and the Arctic. Their consumption has long provided basic nutrition as well as social, cultural, spiritual, and economic well-being.

13. The presence of POP chemical contaminants in traditional foods means that Indigenous Peoples, including Alaska Natives, regularly ingest chemicals that are harmful to human health. In response, many have shifted away from their ancient diets and lifestyles. This shift has resulted in rising rates of obesity, diabetes, and cardiovascular disease.

14. The study of Arctic contamination has been the focus of initiatives such as the Northern Contaminants Program that was initiated in 1991 by the Canadian government and the multi-country circumpolar Arctic Monitoring and Assessment Programme. These programs have provided solid evidence that the concentrations of many legacy existing and new chemicals, particularly POPs, are increasing in Arctic ecosystems and peoples due to long-range transport, and that current levels represent a hazard to human health. POPs, such as brominated and chlorinated flame retardants, perfluorinated chemicals, and dioxins, are among the chemicals of greatest concern.[1]

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[1] *See e. g.* AMAP 2015. Summary for Policy-makers: Arctic Pollution Issues 2015. *Arctic Monitoring and Assessment Programme (AMAP)*, Oslo, Norway. 12 pp. (available at www.amap.no/documents/doc/sum-mary-for-policy-makers-arctic-pollution-issues-2015/1195); MacDonald, RW, LA Barrie, TF Bidleman, ML Diamond, DJ Gregor, RG Semkin, et al. 2000. Contamination in the Canadian Arctic: 5 years of progress in understanding sources, occurrence and

15. The end result is that the indigenous peoples of Alaska and the Arctic are among the world's most chemically contaminated populations. Children, pregnant women, and Alaska Natives are particularly vulnerable and experience disproportionate exposures. The developing brains and bodies of babies and infants are exquisitely sensitive to very low levels of toxic chemicals passing through the placenta or breast milk. Alaska Natives are particularly vulnerable because of their reliance on traditional foods such as fish and marine mammals (which are near the top of the food web and concentrate PBTs in their fatty tissue). Arctic Indigenous populations have levels of contamination in blood and breast milk higher than those found anywhere else on Earth [2,3]. Women of child-bearing age in the Alaska's Yukon-Kuskokwim Delta have the highest levels of toxic polybrominated diphenyl ethers ("PBDEs") of any population in the circumpolar Arctic. This is

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pathways. *The Science of the Total Environment* 254(2-3):93-234. PMID: 10885446. (available at http://www.ncbi.nlm.nih.gov/pubmed/10885446); Rigét, F. A Bignert, B Braune, J Stow, S Wilson. 2010. Temporal trends of legacy POPs in Arctic biota, an update. *The Science of the Total Environment* 408:2874-2884. (available at www.amap.no/documents/download/1116); de Wit, CA. D Herzke, K Vorkamp. 2010. Brominated FRCs in the Arctic environment—trends and new candidates. *The Science of the Total Environment* 408(15):2885-2918. PMID: 19815253. (available at http://www.ncbi.nlm.nih.gov/pubmed/19815253); AMAP 2014. Trends in Stockholm Convention Persistent Organic Pollutants (POPs) in Arctic Air, Human media and Biota. AMAP Technical Report to the Stockholm Convention. AMAP Technical Report. No. 7 (2014), Arctic Monitoring and Assessment Programme (AMAP), Oslo, Norway (available at http://www.amap.no/documents/search/ ISBN – 978-82-7971-084-4).

[2] AMAP 1998. Assessment Report: Arctic Pollution Issues 1998. ISBN 82-7655-061-4. www.amap.no/documents/doc/amap-assessment-report-arctic-pollution-issues/68

[3] AMAP 2015. Summary for Policy-makers: Arctic Pollution Issues 2015. Arctic Monitoring and Assessment Programme (AMAP), Oslo, Norway. 12 pp. www.amap.no/documents/doc/summary-for-policy-makers-arctic-pollution-issues-2015/1195.

concerning because prenatal exposure to PBDEs is associated with lower IQ and higher hyperactivity scores in children. Whale and walrus meat, the mainstay of the people of St. Lawrence Island in the Northern Bering Sea, is so contaminated with PCBs that EPA recommends eating not more than one serving per month.

ACAT's Work on Chemical Contamination in Alaska

16. ACAT works to eliminate environmental contaminants that affect the water, traditional foods, health, and cultures of the Indigenous peoples and other residents of Alaska in several ways:

a. Advocating at the local, state, national, and international levels for protective policies that reduce and eliminate exposures to toxic chemicals.

b. Working directly with Alaska communities to prevent industry and the military from conducting polluting activities;

c. Working with school boards to pass policies that will protect children and workers from toxic exposures at school and with health care facilities to reduce the use of harmful chemicals in the healthcare setting; and

d. Raising awareness of existing pollution, such as educating mine workers and people living downstream from Red Dog Mine in northwest Alaska, the single largest polluter in the nation, about the chemicals that are released into the air, water, and land as a result of mining activities.

17. ACAT also provides workshops, public lectures and other educational programs to inform physicians, nurses, teachers, environmentalists, and other professionals as well as the general public about the link between pollutants and adverse effects on human health. For example, ACAT:

a. Established the Collaborative on Health and the Environment ("CHE")-Alaska, which advances knowledge and effective action to address concerns about the links between human health and environmental factors. CHE-Alaska sponsors monthly seminars and other public events featuring scientists, health care professionals, and policy experts who are working to improve environmental health.

b. Organized the first-ever Alaska Children's Environmental Health Summit to bring together scientists, Alaska Native community and Tribal leaders, health care professionals, policy makers, parents, teachers, and children's advocates to discuss the latest science and develop recommendations to protect the health of children in the Arctic.

18. ACAT conducts health surveys, environmental sampling, biomonitoring studies, and other community-based participatory research to enhance our understanding of the threats faced by our members, so we know where to focus our efforts. ACAT also trains tribal village leaders to conduct their

own environmental sampling through our Community-Based Research Field Institute. For example, we are working with the Yupik people of St. Lawrence Island on a traditional foods study to determine levels of PCBs and other contaminants in subsistence foods such as fish and marine mammals. ACAT and our research partners have published 20 papers in the peer-reviewed scientific literature based on our community-based-research in the Arctic concerning persistent contaminants, endocrine disruption and other biomarkers associated with health outcomes. These research activities consume a significant share of our budget.

The Role of TSCA in Protecting Human Health and the Environment in Alaska and the Arctic

19. Given the unique vulnerability of our members' communities to harm from toxic chemicals, ACAT and its members have a particular interest in ensuring that the revised TSCA is implemented in the most health-protective manner that the law permits.

20. When Congress revised TSCA in 2016, ACAT was hopeful that it would provide an effective means to protect our members and Alaska's communities because it contains a number of provisions that require EPA to identify potentially exposed or susceptible subpopulations, such as our members, and protect them from the risks posed by toxic chemicals. Of particular importance

is TSCA's requirement that EPA review all new chemicals before they are manufactured in or imported to the United States, and regulate those chemicals as necessary to protect potentially exposed or susceptible subpopulations. The requirement that EPA assess the risk to at-risk subpopulations is critically important to protecting Alaska Natives, who are at-risk from POPs. If properly implemented, TSCA's premanufacture review system can protect our members from the hazards of chemical exposure.

21. ACAT has long been concerned that EPA has exempted potentially dangerous chemicals from the standard premanufacture review process in a way that threatens Alaskans and Alaska Natives. TSCA establishes a standard review procedure in which chemical manufacturers must submit a premanufacture notice ("PMN") that EPA must review before a new chemical can be manufactured. During PMN review, EPA must restrict a chemical from being manufactured unless it finds that the chemical will not present an unreasonable risk. EPA has established a number of problematic exemptions to the PMN review process, particularly under the Low Volume Exemption (LVE) and the Low Release and Exposure Exemption (LoREX). These exemptions allow expedited review and approval of toxic new chemicals that meet certain production or release criteria, even though these criteria are not stringent enough to protect people, particularly at-risk subpopulations like Alaskans and Alaska Natives, from the risks posed by

POPs. Given these concerns, ACAT has advocated that EPA to restrict these exemptions. For example, in 2021 ACAT signed a petition to EPA requesting that EPA make Per- and Polyfluoroalkyl Substances ("PFAS"), a highly dangerous subcategory of POPs, ineligible for these exemptions.

22. In 2024, EPA issued a final rule to update the regulations governing premanufacture review. Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 102773 (December 18, 2024) ("New Chemicals Rule").

23. The final New Chemicals Rule stated that new PBTs (and thus, new POPs) are eligible for LVE and LoREX exemptions, unless EPA determines the manufacture of a new PBT results in "anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms." *See* 89 Fed. Reg. at 102,1798. Thus, the New Chemical Rule allows EPA to approve the manufacture of new PBTs, including new POPs, that may pose an unreasonable risk—including an unreasonable risk to subpopulations like Native Alaskans—under the LVE and LoREX exemptions, thereby bypassing a full and rigorous PMN review. In addition, the New Chemicals Rule adopted a vague definition of "PBT chemical substance" that failed explain EPA's process for identifying these substances. *See id*. This creates the risk that EPA will fail to identify POPs that should be ineligible, even under EPA's deficient criteria.

24. ACAT's members and the people we serve will be harmed by the above provisions of the New Chemicals Rule because those provisions weaken TSCA's protections against new POP chemicals to which they are exposed.

25. Finally, EPA's failure to codify its 1999 Policy harms ACAT, denying ACAT information about dangerous new PBTs that would be helpful to ACAT. If EPA codified the 1999 Policy, applications to manufacture new PBTs would have to go through the standard PMN review process and would presumptively result in section 5(e) orders requiring additional testing. That test data would have to be publicly disclosed under TSCA. Such test data would be helpful to ACAT's advocacy, which often involves presenting scientific data about chemicals to regulatory bodies at the state and federal level, and to meetings of the Stockholm Convention.

26. A court order could remedy this injury, for example by vacating the unlawful provisions that fast-track the approval of new PBTs or by remanding the rule to the agency, thus giving it an opportunity to cure the deficient rule.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on 12 October, in 2025.

Pamela K. Miller

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Pamela K. Miller**

eRA COMMONS USER NAME (credential, e.g., agency login): pamelamillerpi

POSITION TITLE: **Executive Director, Alaska Community Action on Toxics**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Wittenberg University (Springfield, Ohio)	B.S.	06/1978	Biology
Miami University (Oxford, Ohio)	M.En.	06/1981	Environmental Science

A. Personal Statement

I have twenty-four years of experience in conducting and supervising research among communities, multiple researchers, and health care institutions, as well as experience in coordinating field research programs in remote locations of Arctic Alaska. In collaboration with the Yupik people of Sivuqaq (a/k/a St. Lawrence Island), I oversee community-based participatory research (CBPR) as a Principal Investigator, implement community educational programs and interventions, health fairs, workshops for health care providers, meetings with community youth and leadership, research translation, and evaluation. As a public environmental health scientist, I understand that any efforts I make to bring about positive policy changes and public health interventions must be backed by scientific information. My work is directed toward advancing scientific knowledge and policy with an emphasis on understanding the effects of environmental contaminants and improving the health and wellbeing of the indigenous peoples of Alaska and the circumpolar Arctic.

On-Going Research Support from the past three years that I would like to highlight:

NIEHS 2R01ES019620-06A1 (Miller, PI) [with 2 no-cost extensions] 09/20/17 – 06/20/24
Role: Principal Investigator
Protecting the Health of Future Generations: Assessing and Preventing Exposures to Endocrine- Disrupting Flame-Retardant Chemicals & PCBs in Two Alaska Native Arctic Communities on St. Lawrence Island. (PFG II)
Purpose: We used minimally invasive methods to assess the body burden of PCBs and select flame retardant chemicals and their relationships to health outcomes in SLI children aged 2-12. We have collected resident stickleback fish to assess mechanisms of developmental disruption due to exposure to PCBs and select flame retardant chemicals, using transcriptomic, epigenetic, endocrine, and histological approaches. We are developing measures to prevent and mitigate exposure of SLI children to PCBs and select flame retardant chemicals.

NIEHS 1R01ES032392-01 (Miller, PI) 05/20/21 – 02/28/26
Role: Principal Investigator
Restoring Northeast Cape for the Health and Well-Being of the Yupik Communities of St. Lawrence Island, Alaska (NEC)
Purpose: We collected blood and hair samples from 200 adult residents of Sivuqaq (traditional name for St. Lawrence Island), Alaska, including a sub-sample of people who use the Northeast Cape (NEC), formerly used defense site, as a subsistence food gathering site and/or use it as a seasonal or temporary camp. In addition, all 200 participants wore passive silicone wristband monitors for 72 hours. We will analyze the samples to estimate exposure to contaminants such as PCBs (polychlorinated biphenyls), pesticides, and mercury. We assessed markers of health, such as thyroid and diabetes risk.

Related publications I would like to highlight:

1) Babayev, M., Capozzi, S.L., **Miller, P.K.**, McLaughlin, K.R., Seguinot-Medina, S., Byrne, S.C., Zheng, G., Salamova, A. PFAS in drinking water and serum of the people of a southeast Alaska community: A pilot study, *Environmental Pollution*, Volume 305, 2022, 119246, ISSN 0269-7491, https://doi.org/10.1016/j.envpol.2022.119246
2) Jordan-Ward R., von Hippel, F.A., Zheng, G., Salamova, A., Dillon, D., Gologergen, J., Immingan, T, Dominguez, E., **Miller**, P.K., Carpenter, D.O., Postlethwait, J.H., Byrne, S., and Buck, C.L. 2022. Elevated mercury and PCB concentrations in Dolly Varden (*Salvelinus malma*) collected near a formerly used defense site on Sivuqaq, Alaska. *Science of the Total Environment* 826:154067. https://doi.org/10.1016/j.scitotenv.2022.154067
3) **Miller, P.K**. 2023. Protecting the health of future generations in the Arctic through community-based participatory research and action. *Explore* 19(2):271-272. https://doi.org/10.1016/j.explore.2022.12.008
4) Jordan-Ward, R., von Hippel, F.A., Wilson, C.A., Maldonado, Z.R., Dillon, D., Contreras, E., Gardell, G., Minicozzi, M.R., Titus, T., Ungwiluk, B., **Miller**, P.K., Carpenter, D.O., Postlethwait, J.H., Byrne, S., Buck, C.L. 2024. Differential gene expression and developmental pathologies associated with persistent organic pollutants in sentinel fish in Troutman Lake, Sivuqaq, Alaska. *Environmental Pollution* 340:122765. https://doi.org/10.1016/j.envpol.2023.122765

B. Positions, Scientific Appointments, and Honors

Positions

1997- present Executive Director, Alaska Community Action on Toxics (ACAT)
Founded ACAT and served as Executive Director since then for this statewide, nonprofit environmental health organization. Won multiple federal research grants for ACAT (since 2000), serving as research team leader for the first four years, and as principal investigator since 2005.

1990-1997 Research Biologist, Greenpeace Alaska, Anchorage
Conducted advocacy-based campaigns concerning environmental issues such as energy, climate change, and contaminants affecting human health. Worked with Alaska communities to solve environmental problems. Lobbied Congress and state legislators for marine environmental protection. Co-founded Cook Inlet Keeper program to protect the Cook Inlet watershed and served on the Keeper board from 1994 - 2002.

1986-1990 Technical Coordinator, Ocean Issues, State of Washington Department of Ecology
Served as Governor's representative on Regional Technical Working Group for the continental shelf program of the U.S. Department of Interior. Worked within the State's federally funded Coastal Zone Management Program to establish the Olympic Coast National Marine Sanctuary. Coordinated the efforts of federal and state agencies on marine issues. Organized major conference on ocean environmental issues. Organized and managed bird rescue program after large offshore oil spill. Edited monthly newsletter published by the Department of Ecology for policy makers and the public: *Coastal Currents.*

1987-1990 Director, Nisqually Reach Nature Center
Directed volunteer-based marine education center in the south Puget Sound region of Washington State. Led marine education programs youth, teachers, and the public.

1985-1986 Instructor, Florida Keys Community College
Taught biology and botany courses as an adjunct instructor.

1984-1985 Research Biologist, National Marine Fisheries Service
Collected biological data for NMFS aboard fishing vessels in Bering Sea.

1982-1984 Research Biologist, Harbor Branch Institution
Designed and conducted marine ecological and botanical studies in the Florida Keys.

1981-1982 Instructor, Newfoundland Harbor Marine Institution
Taught marine science workshops for teachers, students, and adults in the Florida Keys.

Honors

2023 *Alaska Conservation Foundation's Lifetime Achievement Award* for protecting and enhancing Alaska's natural greatness

2016 - present Elected to Steering Committee and Co-Chair of the International Pollutants Elimination Network

2015 - present Invited to participate with prominent scientists and public health advocates on the newly formed Project TENDR (Targeting and Neuro-Developmental Risks).

	Coordinated working groups focused on PBDE flame retardants (polybrominated diphenyl ethers) and plastics. Co-Authored TENDR Consensus Statement (July 2016) http://ehp.niehs.nih.gov/ehp358/
2013	Selected as Board Member, Groundswell Fund
2013-2016	Served as mentor to teams of fellows in the Reach the Decision Makers program from the University of California San Francisco, Reproductive Health and Environment Program. (First invited to be a fellow for the 2011 cohort and later asked to mentor fellows)
2012	*Meritorious Service Award* by the Board of Regents of University of Alaska for service to the community
2009-2010	Advisory Group for Centers for Disease Control and Prevention
2010	White House Advisory Forum
2001	*Olaus Murie Award for Outstanding Professional Contribution* to protecting Alaska's natural environment
1990	*Washington State Governor's Environmental Excellence Award* for establishing the Olympic Coast National Marine Sanctuary

C. Contributions to Science

Alaska has more than 2,000 known toxic waste sites from military and industrial operations, and the health of Alaska residents is also affected by the long-range transport of persistent pollutants to the north as well as toxic chemicals in consumer products.

1. Amchitka Island. As a research biologist, I led a research expedition in 1996 to Amchitka in the Aleutian Islands of Alaska. We collected biological samples to determine radiation levels associated with underground nuclear tests conducted in the 1960s-70s. Our research revealed plutonium-239/240 and americium-241 in freshwater plants at the edge of the Bering Sea. We concluded that the underground nuclear explosions on Amchitka were the source of the observed radiation. I wrote two public reports in collaboration with physicist Norm Buske describing our findings: *Nuclear Flashback: Return to Amchitka* (1996) and *Nuclear Flashback Part II: The Threat of the U.S. Nuclear Complex* (February 1998). These offer our methods and results to allow future scientists to replicate our findings. http://www.akaction.org/media-center/publications/

As a result of our research, the Clinton Administration agreed to begin the first health assessment of the Amchitka workers' occupational exposures. The Amchitka Project was established in 2000 as a non-profit organization located at the offices of Laborer's Local 341; I served on the advisory committee for the Project until 2005. As of December 2015, $97 million dollars had been distributed to provide medical evaluation and compensation to workers and their families.

2. Stockholm Convention on Persistent Organic Pollutants. When I founded ACAT in 1997, one of my first tasks was to support an international effort by the United Nations to negotiate a binding treaty to eliminate persistent organic pollutants (POPs) worldwide. The Arctic is a hemispheric sink for POPs that travel north on air and ocean currents, where they are "trapped" in the cold environment through a process known as global distillation. The POPs enter the food chain and eventually make their way into marine mammals. Indigenous peoples of the Arctic are particularly vulnerable because of their reliance on traditional foods which include marine mammals.

Because of my scientific and technical expertise about the effects of POPs in the Alaska Arctic, ACAT was instrumental in the negotiation, signing, and implementation of the Stockholm Convention on Persistent Organic Pollutants (POPs Treaty). Since the POPs Treaty was ratified and activated in 2004, ACAT has participated in biennial meetings in Geneva with delegates to the Conference of Parties (COP); and in annual meetings in Europe of the POPs Review Committee (POPRC). The POPRC is comprised of scientists who advise COP delegates to ensure the treaty's implementation. POPRC scientists and COP delegates work to continue adding specific POPs to the list for global elimination.

I am an official observer through IPEN at meetings of the POPRC and the COP. Each of the six observers from IPEN takes one to three of the nominated chemicals to shepherd through the POPRC's process for consideration. I participate in subcommittees and provide them with the most recent science to help them decide whether to pass the POP to the next stage for consideration. We also prepare reviews of scientific literature intersessionally and prepare an analysis for "our" POPs and send them to the secretariat for the POPRC for distribution to other stakeholders to rebut. These intersessional scientific "debates" are held every three months. To date, thirty-four chemicals have been listed for global elimination. The first "Dirty

Dozen" were listed in 2004: aldrin, endrin, dieldrin, chlordane, heptachlor, hexachlorobenzene, mirex, toxaphene, polychlorinated biphenyl, DDT, dioxins, and furans.

My contribution to science for the POPRC is to review scientific literature and prepare technical comments. The POPRC scientists sent to the POPRC by various nations can arrive at consensus precisely because they have solid, up-to-date research to support their decisions provided by my IPEN colleagues andmyself.

3. Sivuqaq (a/k/a St. Lawrence Island). In 1998 I connected with faculty researchers who were interested in using science to shed light on the links between military toxics and health conditions observed by a Yupik elder and health aide (Annie Alowa) in her remote village on Sivuqaq. We began a series of collaborative research projects on Sivuqaq with ACAT's first NIEHS (National Institute of Environmental Health Sciences) grant in 2000 and continue this research to present. Each of our research projects on Sivuqaq is more than a collaboration among scientists and health organizations; everything we do is in full partnership with the Yupik Tribes and people who live on Sivuqaq. My tasks are to oversee all the planning, research, and advocacy we conduct on the Island. Here is a selection of publications of twenty published in peer-reviewed journals:

1) **Miller, P.K.**, Waghiyi, V., Welfinger-Smith, G., Byrne, S.C., Kava, J., Gologergen, J., Eckstein, L., Scrudato, R., Chiarenzelli, J., Carpenter, D.O., Seguinot-Medina, S. 2013. Community-based participatory research projects and policy engagement to Protect Environmental Health on St. Lawrence Island, Alaska. *International Journal of Circumpolar Health; Circumpolar Health Supplement* 72: 21656. http://dx.doi.org/10.3402/ijch.v72i0.21656
2) Byrne S.C., **Miller, P.K.**, Seguinot-Medina S., Waghiyi, V., Buck, C.L., von Hippel, F.A., Carpenter, D.O. 2018. Associations between serum polybrominated diphenyl ethers and thyroid hormones in a cross-sectional study of a remote Alaska Native population. *Scientific Reports*. 2018. Feb 2;8(1):2198. http://doi:10.1038/s41598-018-20443-9
3) Byrne S.C., **Miller, P.K.**, Seguinot-Medina, S., Waghiyi, V., Buck, C.L., von Hippel, F.A., and Carpenter, D.O. Exposure to perfluoroalkyl substances and associations with serum thyroid hormones in a remote population of Alaska Natives, *Environmental Research*, Volume 166, 2018, pp. 537-543, https://doi.org/10.1016/j.envres.2018.06.014
4) Byrne S.C., Seguinot-Medina, S., Waghiyi, V., Apatiki, E., Immingan, T., **Miller, P.K.**, Buck, C.L., von Hippel, F.A., and Carpenter, D.O. 2022. PFAS and PBDEs in traditional subsistence foods from Sivuqaq, Alaska. *Environmental Science and Pollution Research* 29, 77145–77156 (2022). https://doi.org/10.1007/s11356-022-20757-2
5) **Miller, P.K.** 2023. Protecting the health of future generations in the Arctic through community-based participatory research and action. Explore 19(2):271-272 (2023). https://doi.org/10.1016/j.explore.2022.12.008

DECLARATION OF RICHARD VULTAGGIO
IN SUPPORT OF PETITIONERS' OPENING BRIEF

I, Richard Vultaggio, declare as follows:

1. My name is Richard ("Rich") Vultaggio. I was born and raised in Endicott, New York, and lived there until recently. My family's history in Endicott goes back numerous generations, and we hold land there.

2. I am a member and supporter of Environmental Defense Fund, for almost 20 years now, along with other environmental organizations. For over two decades, I have been supporting environmental work and teaching myself about environmental issues.

3. I really enjoy learning about people who are finding ways to fix our environmental problems, and I believe strongly that this is what our government should be doing as well.

4. I have been concerned about toxic pollution since I was a child. My grandparents originally lived on a street in Endicott that was developed into the IBM campus. IBM, along with a shoe company that used to exist in Endicott, was known to pollute the area with chemicals, including the river here, the Susquehanna.

5. From EDF, I have learned about a type of chemicals called persistent, bioaccumulative, toxic ("PBT") chemicals. I also understand that there is a company in Endicott, the Chrysta-Lyn Chemical Company located on Wayne Street, that has made these types of chemicals, and that these chemicals have been

"exempted" from being fully reviewed for safety by the Environmental Protection Agency. I have also been made aware that that these chemicals could harm people who come into contact with them and that at least one of them could be toxic to river life. I am concerned about how this could have harmed the health of me and my family.

6. I also understand that the Environmental Protection Agency has a regulation that could allow companies including Chrysta-Lyn to make PBTs that are not vetted and safe. I am concerned about the health of the community, and also about the reputation of the community. Like with the toxic contamination from IBM and others, this could make people fear staying in and moving to the Endicott area. The facility is less than two miles from some of my family's area property, some of which is by the river; our property value could be significantly lessened.

7. The government regulation allowing these toxic chemicals to be put onto the market should be changed, and EPA should not approve them unless it fully reviews the chemicals and makes sure they will not harm Endicott or any other places.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 12 October, 2025.

Rich Vultaggio

Rich Vultaggio

I, VIOLA WAGHIYI, declare and state as follows:

1. My name is Pangunnaaq Vi Waghiyi, I am a Sivuqaq Yupik grandmother and citizen of the Native Village of Savoonga, one of 229 federally recognized tribes in Alaska.

2. I was born and raised on Sivuqaq ("the Island"), an island in the Northern Bering Sea, which has been the home for my people for thousands of years.[1] I moved to Nome, Alaska, when I was eight years old so I grew up in both communities. Now, my work at Alaska Community Action on Toxics ("ACAT") also brings me home to the Island. I currently reside in Anchorage, Alaska, with my husband, our four sons, and their families. My husband and I are raising our six-year-old grandson.

3. I am a member and supporter of ACAT, as well as its Environmental Health and Justice Program Director. ACAT is a women-led, non-profit advocacy organization headquartered in Anchorage, Alaska, with a board comprised primarily of Arctic Indigenous women. I have been a member and supporter of ACAT for over 23 years.

4. I first learned about ACAT in October 2002, when I read a press release in the *Anchorage Daily News* about the extremely high levels of polychlorinated biphenyls ("PCBs"), which are a type of persistent,

[1] Sivuqaq is also known as St. Lawrence Island.

bioaccumulative, and toxic ("PBT") chemical, in my people's blood. My people were exposed to PCBs as a result of the release of toxic chemicals from two former Cold War-era military bases established on Sivuqaq. The two former bases were the eyes and ears of the North during the Cold War, but they also poisoned our lands, waters, fish, plants, and berries with legacy military toxics abandoned and buried at the two former bases, leading to significant health harms. The press release really touched me, because it highlighted a reality that I knew, that there were very high rates of cancer in our people who lived on the Island, particularly those whose families lived, worked, or camped at the Northeast Cape down gradient from the military site.

5. My own family who live (or lived) on the Island have experienced high rates of cancer. My dad, John Waghiyi, Sr., died of cancer; my mom, Della Waghiyi, had cancer and many other health harms including heart disease, strokes, diabetes, a stillborn child and mental health harms which we now attribute to the toxic chemicals the military left on our Island. We buried my eldest brother, Fritz Waghiyi, three years ago due to cancer. I am also a cancer survivor and have had 3 miscarriages, which I attribute to military toxics. Cancer treatment can be a life sentence in itself. We now believe it is not a matter of *if I will get cancer* but *when*. I decided, after reading the ACAT press release, that the Creator had plans for me to fight to hold the military accountable and to work to protect our people from

exposure to toxic chemicals. Soon after I read the press release, I was offered a position with ACAT, which I had to think about before I accepted, since I had no experience in this field. Now I can't see myself doing anything else as much as I've come to learn.

6. As the Environmental Health and Justice Program Director for ACAT, I am an advocate for Arctic Indigenous peoples. I have traveled to Geneva, Switzerland five times to participate in meetings of the Conference of the Parties at the United Nation's Stockholm Convention on Persistent Organic Pollutants ("POPs"), an international, legally binding treaty ratified by 182 countries to eliminate the production and use of POPs, which are a subcategory of PBTs. More recently, I've traveled twice for the Intergovernmental Negotiating Committee for the Plastics Treaty. In this role, I represent my people and other Arctic Indigenous peoples by delivering testimony on their behalf. I am motivated by my desire to protect current and future generations from environmental contamination and its associated health harms. As a Global Indigenous Peoples Caucus leader, my role is to lead an Arctic Indigenous Peoples delegation to these conventions and negotiations, to train our delegates, and to be the conscience of the conventions by reminding all convention delegates why the convention began—to protect Arctic Indigenous Peoples from being contaminated by POPs and microplastics without our consent.

7. ACAT hires and trains Sivuqaq community health researchers to ensure that citizens of tribal nations are partners in our work and trained to combat the release of toxic chemicals into the Arctic. I am currently co-leading our Sivuqaq project *Protecting Future Generations: Assessing and Preventing Exposures to Endocrine Disrupting Chemicals on St. Lawrence Island*, which aims to research the effect of endocrine disrupting chemicals on children's ability to learn in Sivuqaq communities. This phase of the *Protecting Future Generations* project began after parents, grandparents, and leadership in our tribal nation grew concerned about children's low test scores and asked us to determine the role that PCBs and toxic flame retardants played in this complex issue. I was also part of a research team that found that the congener BDE-209, which is associated with decaBDE, another PBT, was present in 100% of traditional food samples from Sivuqaq.

8. Through this work I have learned that I and my Yupik people are being contaminated without our consent in our homes, workplaces, and through our traditional foods. I became aware that POPs and other PBTs originate in other parts of the world and travel into the Arctic, placing burdens on us we did not create. I do this work with ACAT because I am a mother and grandmother and want to make sure there are measures in place to protect our most vulnerable, our children and future generations of Arctic Indigenous people and protect our ability

to safely eat our traditional foods, which are a significant part of our identity, spirituality and culture.

9. My people have inhabited Sivuqaq for thousands of years. Our elders refer to the ocean as our farm, and we continue to live off the land and ocean like we have for centuries, as our Creator intended. Seventy to eighty percent of our Sivuqaq families eat only a subsistence diet. Like most Sivuqaq families, my children, grandchildren, and I regularly consume traditional subsistence foods, known as neqipik. Our elders can go no more than three days without eating our traditional foods, because their digestive systems will become irritated from western diet.

10. On Sivuqaq, neqipik includes: bowhead whales, walrus, seals, reindeer, birds, fish, crabs, clams, and sea bird eggs. If it is on our Island, we eat it, always making sure to take only what we need as we believe the marine mammals give themselves up so our people can continue to survive. Walrus in particular is an important part of our diet and supports us during our long winters. Historically the women in our community hand sew the female walrus hides to make skin boats, and our hunters use the tusks for tools and other carvings to make a living.

11. I am a mother of four sons, and my children have eaten neqipik since birth. Our people used frozen whale blubber when our infants are teething. Our mothers also chewed fish and subsistence foods for our babies when they did not

have teeth to chew for themselves. I am currently helping to raise my grandson, who lives with me, and we are feeding him the same traditional diet. My granddaughters were born in Anchorage but lived for a period of time in the village of Shageluk, also eat a subsistence diet, and help their grandfather when he goes fishing and trapping rabbits.

12. In my community, mothers and grandmothers encourage us to eat significant amounts of neqipik when pregnant. My mother made sure that I regularly ate neqipik during my pregnancies. I continued to eat traditional foods when I was breastfeeding. We receive our intake of Vitamin D from marine mammals and view them as superfoods, which can help to maintain a healthy pregnancy.

13. Hunting and fishing for our traditional foods is often a shared experience with family and friends on and off the Island. It takes the entire community to harvest marine mammals during our Spring Hunt. This is often because hunting large marine mammals is difficult, and the climate can change suddenly and become harsh. One example of communal hunting is whaling. Our whaling captains come together to hunt for whales in 18-foot open aluminum skiffs in the Northern Bering Sea, with the utmost respect for the ocean which our elders call our farm, it can now be unforgiving due to rapid climate change. This hunting practice is a way of life that has passed down through the generations and has

sustained our people for many centuries. Once the group strikes a whale, all of the hunters work together to tow the whale to shore. Once it is towed to shore, all the hunters are involved in the harvest of the whale. The whales can be up to 60 feet long.

14. Thewhaling captain who struck the whales then shares food with all the whaling captains who then share it with family members. It is through this communal sharing of food that I now generally receive neqipik. My family members from the Island——make sure that I have traditional foods to eat. My brother recently brought me freshly harvested whale, which is currently in my freezer. He and my other family also brings me fish and other traditional foods which are caught on our Island. In southcentral Alaska, my niece goes fishing and brings me some of the fish she catches. I fish and hunt less now that I am older, but I go berry picking, pick medicinal plants, and harvest local greens.

15. I understand that my traditional diet could expose us to PBTs, since PBT pollution that originates elsewhere is contaminating our neqipik which I, my family, and my people rely on. I am also concerned that the harms to me are compounded by potential exposures in my daily life. I have two televisions in my home, a laptop computer for work, upholstered furniture, and my grandson plays with plastic toys. I bring these items into my home without any way to know whether they can cause toxic exposures which can harm my family's health and

wellbeing. I understand that PBTs could be present in all these items but now try to make informed decisions. I am concerned that my subsistence diet of neqipik, combined with these other sources of exposure, could cause me and my people serious health harms and illness.

16. We cannot give up our traditional practices just to avoid exposure to POPs and other PBTs—it is our way of life as intended by our Creator. However, we are being contaminated without our consent. POPs and other PBTs do not break down readily in the environment. As a result, they end up in our traditional foods and our bodies. I also know that they can be passed from mothers to children during pregnancy and through breast milk.

17. These exposures cause damage to our children's developing brains, affect their immune systems, and can cause cancer and other serious health harms. It affects our children's ability to learn our language, our creation stories, our songs and dances, our culture, and our traditional knowledge including on how to predict the weather and of the migration patterns of the wildlife that sustains us. As a grandmother with seven young Indigenous grandchildren, I am greatly concerned about what this contamination means for their future and our future generations.

18. Our ability to conceive and carry our children and bring them to a healthy term are threatened by the assault from PBTs in our bodies and wombs, our children's first environment. We are witnessing illnesses never seen before in our

people due to military contamination and the greed of multinational corporations that manufacture toxic chemicals without taking our human health, our environment, and our traditional foods into account.

19. Through my work, I am aware that the Toxic Substances Control Act ("TSCA") contains provisions to protect us from some of these harms. I understand that the U.S. Environmental Protection Agency ("EPA") is generally required to review new chemicals before they enter the market, in a process known as premanufacture review. Where a new chemical presents or may present unreasonable risk, including risks to at-risk subpopulations like our Arctic Indigenous people, EPA must regulate the chemical to protect against the risks it poses.

20. I understand that EPA issued a rule last year, which allows EPA to fast-track the review and approval of new POPs and other PBT chemicals outside the standard premanufacture review process. I am concerned that the fast-track approval of new PBTs will lead to the manufacture of unsafe chemicals that regulators and the public do not fully understand and that will further contaminate our traditional foods, the environment, and the products in our homes. This rule does not protect me or my family from burdens we didn't create.

21. EPA should not be weakening the standards for approving new PBTs. I and my Yupik People would benefit from strictest rules to reduce our exposure to

PBTs through our traditional foods, the environment, and the products we bring into our homes and workplaces not knowing they are manufactured with toxic chemicals.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed this 15th day of October, 2025, in Anchorage, AK.

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Viola Waghiyi