No. 25-384

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

FOOD AND WATER WATCH, *et al.*
Plaintiffs-Appellees,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Defendants-Appellants.

Appeal from the United States District Court for the Northern District of California
No. 3:17-cv-02162 (Hon. Edward M. Chen)

OPENING BRIEF FOR DEFENDANTS-APPELLANTS

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GLOSSARY

EPA	Environmental Protection Agency
NTP	National Toxicology Program
SDWA	Safe Drinking Water Act
TSCA	Toxic Substances Control Act

INTRODUCTION

Fluoride is a common mineral that exists naturally in groundwater. For many decades, many municipal water suppliers nationwide have also added fluoride to drinking water as a public health measure to prevent tooth decay. Also for many decades, the Environmental Protection Agency (EPA) has imposed limits on the amount of fluoride in drinking water under the Safe Drinking Water Act (SDWA).

Unsatisfied, Plaintiffs Food & Water Watch et al. petitioned EPA in 2016 to ban adding fluoride to drinking water under Section 21 of the Toxic Substances Control Act (TSCA). EPA denied the petition, and Plaintiffs filed suit under Section 21's judicial review provision. After seven years and two bench trials, the district court held that Plaintiffs had shown that adding fluoride to drinking water presents an unreasonable risk to human health and ordered EPA to manage that risk in accordance with TSCA.

The judgment of the district court should be reversed. As a threshold matter, Plaintiffs have failed to carry their burden on standing. The drinking water for Plaintiffs' only relevant standing declarant naturally contains fluoride, and the remedy Plaintiffs seek would not require the water utility to remove that naturally occurring fluoride. Thus, the injury to Plaintiffs is not caused by the addition of fluoride to drinking water, and no remedy available in this case will redress it.

Even if Plaintiffs had established standing, reversal is warranted on at least two independent legal grounds. First, the district court violated TSCA Section 21 by permitting Plaintiffs to rely on evidence not first presented to EPA in the petition and reviewed by EPA in denying the petition. The court's final merits ruling overwhelmingly relied on voluminous evidence that did not even *exist* at the time of the original petition, and which was therefore not presented in the petition to EPA. The court's approach of allowing the consideration of new evidence on a rolling basis throughout the proceedings is contrary to statutory text and frustrates the purpose of TSCA Section 21's mandatory exhaustion requirement. If allowed to stand, the court's approach would transform Section 21 from a citizen petition provision into the driving force of the entire statutory scheme. Such a boundless approach to Section 21 would undermine EPA's ability to meet TSCA's prioritization, risk-evaluation, and risk-management deadlines, and it would require EPA to proceed to risk management with a record insufficient to satisfy TSCA's rigorous scientific and regulatory standards.

Second, the district court abused its discretion by commandeering the trial and administrative proceedings in violation of the party-presentation principle. In particular, the court refused to rule after the close of evidence at the first trial—notwithstanding the parties' insistence that the case was ready for resolution, and in the face of the court's repeated acknowledgment that it had "serious concerns" about

Plaintiffs' standing. This, and the court's determination to accumulate more evidence that it, rather than the parties, thought proper, transformed the court from a neutral arbiter into an advocate, and transformed TSCA Section 21 from a citizen-petition provision into a license for judicial rulemaking.

To be sure, EPA continues to disagree with the district court's merits order purporting to apply TSCA's scientific standards. But rather than ask this Court to review the district court's factual findings on the technical, complex scientific issues litigated below, this appeal instead presents more straightforward legal grounds for reversal.

This Court should reverse.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. § 1331 and 15 U.S.C. § 2620(b)(4)(A). 6-ER-1172. As explained in Argument Part I, the court lacked Article III jurisdiction because Plaintiffs failed to prove their standing.

This Court has appellate jurisdiction under 28 U.S.C. § 1291. The district court issued an order addressing the merits of Plaintiffs' case on September 24, 2024, and entered judgment on November 20, 2024. 1-ER-3. Defendants timely filed a notice of appeal on January 17, 2025, 58 days later. 6-ER-1192; *see* 28 U.S.C. § 2107(b); Fed. R. App. P. 4(a)(1)(B).

STATEMENT OF THE ISSUES

(1) Whether Plaintiffs failed to establish standing to assert a claim to compel EPA to regulate fluoride added to drinking water under TSCA Section 21.

(2) Whether the district court violated TSCA Section 21 by ruling on an evidentiary record overwhelmingly different than the one in the petition presented to and reviewed by EPA.

(3) Whether the district court abused its discretion after the first trial by taking over the case in violation of party presentation principles.

PERTINENT STATUTES AND REGULATIONS

All pertinent statutes and regulations are set forth in Appellant's Addendum.

STATEMENT OF THE CASE

I. Legal Background: Toxic Substances Control Act

Congress enacted TSCA in 1976 and amended it in 2016. The statute directs EPA to assess and manage any unreasonable risks chemicals pose to health and the environment. *See generally Envtl. Def. Fund v. Reilly*, 909 F.2d 1497, 1498 (D.C. Cir. 1990). To that end, TSCA authorizes EPA to, among other things: (1) identify chemicals in use in commerce and gather information about their production, use, and possible adverse effects; (2) conduct risk evaluations to determine whether chemicals present an unreasonable risk of injury to health or the environment, under the given chemical's conditions of use; and (3) regulate the import, manufacture,

processing, distribution in commerce, use, or disposal of chemicals that pose an unreasonable risk to health or the environment.

A. TSCA Section 6

TSCA Section 6 authorizes EPA to evaluate and regulate unreasonable risks posed by existing chemicals in commerce. 15 U.S.C. § 2605. Section 6(a) permits EPA to regulate in a variety of ways to the extent necessary to address an unreasonable risk identified by the Agency: For example, EPA may ban a chemical's manufacture or distribution in commerce, or may take lesser steps, such as limiting the amount of the chemical that can be manufactured, processed, or distributed in commerce or prohibiting particular uses of the chemical. *Id.* § 2605(a)(1)-(7). When considering how to regulate a chemical, EPA must consider the benefits of the chemical, the economic consequences of any regulation, and other factors. *Id.* § 2605(c)(2). Prior to regulating a chemical, EPA must undertake notice and comment rulemaking. *Id.* § 2605(c)(3).

Because of the immense authority Section 6(a) confers on EPA to regulate chemicals, prior to undertaking a Section 6(a) rulemaking, TSCA requires that EPA first make a formal determination that the manufacturing, processing, distribution in commerce, use, or disposal of a chemical presents an "unreasonable risk." TSCA does not define "unreasonable risk," but Section 6(b) prescribes the process, called a "risk evaluation," that EPA must undertake in making an "unreasonable risk"

determination, *id.* § 2605(b)(4), and directs EPA to establish, by rule, a process for conducting risk evaluations, *id.* § 2605(b)(4)(B). EPA has done so: 40 C.F.R. §§ 702.31-702.51.[1] Critically, the unreasonable risk identified by EPA in a risk evaluation affects the content of any resulting risk-management rule in a number of ways specified by the statute.

Under TSCA, a risk evaluation is a prescribed set of steps for analyzing the health and environmental hazards of a chemical under its conditions of use, the human and environmental exposures to the chemical under those conditions of use, the integration of the hazards and exposures to determine the risk to people or the environment under the conditions of use, and the determination of whether that risk is "unreasonable." *See* 15 U.S.C. § 2605(b)(4)(A), (F).[2] A Section 6 risk evaluation consists of scoping, hazard assessment, exposure assessment, risk characterization, and risk determination. 40 C.F.R. § 702.39(a).

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[1] This Brief cites the Risk Evaluation regulation currently in effect. 89 Fed. Reg. 37,028 (May 3, 2024). A different version was in effect when Plaintiffs sued, 82 Fed. Reg. 33,726 (July 20, 2017), but the steps of a risk evaluation described above are consistent across both versions. The differences between the two versions are not relevant to the issues raised on appeal.

[2] The 2016 amendments substantially revised Section 6 to require EPA to take more aggressive action to assess and, as necessary, regulate existing chemicals. EPA now has mandatory requirements to prioritize chemicals as high priority substances and conduct a certain number of risk evaluations on high priority substances on an ongoing basis. 15 U.S.C. § 2605(b)(3)(C). Further, EPA must conduct these risk evaluations in line with new statutory deadlines. *Id.* § 2605(b)(4)(G).

At hazard assessment, EPA evaluates the reasonably available scientific literature on the target chemical (e.g., human epidemiological studies, laboratory studies, human clinical studies, ecological field data). *See id.* § 702.39(c)(3). EPA uses this literature for multiple purposes. The first purpose—called hazard identification—is to determine whether the target chemical is associated with a particular adverse effect or hazard (e.g., cancer, respiratory problems, neurotoxic effects). *Id.* § 702.39(c)(4). After EPA has identified plausible hazards, EPA next evaluates the literature for a second purpose: to identify the strengths, limitations, and uncertainties associated with the literature. *Id.* § 702.39(c)(6). In this assessment, for each human health or environmental hazard endpoint, EPA determines whether the weight of the scientific evidence supports moving to a "dose-response analysis," that is, whether the science is clear enough to determine the level of exposure at which the target chemical triggers a particular hazard (referred to as a "point of departure"). *See id.* § 702.39(c)(5).

If the weight of the scientific evidence does not support selecting a hazard level or point of departure, the assessment on that specific hazard ends and EPA does not make a finding of unreasonable risk regarding that specific health endpoint. If the weight of the evidence supports a hazard level or point of departure, EPA conducts an exposure assessment, where it evaluates the duration, intensity, frequency, and number of exposures to the target chemical under the relevant

conditions of use. 40 C.F.R. § 702.39(d)(1). EPA then proceeds to risk characterization, where the agency integrates the hazard and exposure assessments to characterize the risk from the target chemical under the relevant conditions of use. *Id.* § 702.39(e). EPA then makes a formal determination whether the risk presented is unreasonable within the meaning of TSCA. *Id.* § 702.39(f). If EPA makes a determination of unreasonable risk, then EPA promulgates a rule to manage that risk under Section 6(a). 15 U.S.C. § 2605(a).

B. TSCA Section 21

1. Petition Process

Section 21 of TSCA permits "any person" to petition EPA to "initiate a proceeding" for the "issuance, amendment, or repeal" of "a rule under" TSCA Sections 4, 6, or 8, "or an order under" Sections 4, 5(e), or 5(f). 15 U.S.C. § 2620(a). The petition must "set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal" the requested rule or order. *Id.* § 2620(b)(1).

In considering whether to grant a Section 21 petition, EPA has 90 days to assess whether to grant the petition. *Id.* § 2620(b)(3). During this 90-day period, EPA "may hold a public hearing or may conduct such investigation or proceeding as [EPA] deems appropriate in order to determine whether or not such petition should be granted." *Id.* § 2620(b)(2). Whether or not it holds a public hearing, EPA

evaluates whether petitioners have demonstrated that "it is necessary to issue" the requested rule or order. *Id.* § 2620(b)(1), (b)(2).

The "necessary" language in Section 21(b)(1) refers to the statutory standards that apply to the relevant section of TSCA that the petitioner has invoked. In other words, the facts establishing that it is "necessary" to commence a proceeding under Section 21 mirror those that EPA must "find" before issuing a rule or order on its own initiative. For instance, if a petitioner requests the initiation of a proceeding for the issuance of a rule or order under TSCA Section 4, the petitioner must show it is "necessary" to issue a Section 4 rule or order by demonstrating the existence of the factors in Section 4(a) that EPA must find before issuing such a rule or order. *See Ctr. for Envtl. Health v. Regan*, 103 F.4th 1027, 1037-38 (4th Cir. 2024). Similarly, if (as here) a petitioner requests the initiation of a proceeding for the issuance of a risk management rule under TSCA Section 6(a), the petitioner must show it is "necessary" for the agency to undertake a Section 6(a) rulemaking by demonstrating that the chemical presents an "unreasonable risk" under the relevant conditions of use. Although the petitioner need not produce a risk evaluation that comports with all the requirements of Section 6(b) or EPA's risk evaluation regulation, the petitioner nonetheless must provide EPA with information that is reasonably comparable, in quality and scope, to the information EPA would assess when

conducting its own risk evaluation, so that EPA may evaluate the petition within the 90 days allotted.

As noted above, within 90 days of receiving the petition, EPA must "either grant or deny the petition." 15 U.S.C. § 2620(b)(3). If EPA grants a Section 21 petition, it must "promptly commence an appropriate proceeding" in accordance with the relevant TSCA section. *Id.* If, however, EPA denies a Section 21 petition, the agency must publish the reasons for its denial in the Federal Register. *Id.*

2. Judicial Review

Persons whose petitions have been denied may commence a civil action in federal district court within 60 days of EPA's denial "to compel [EPA] to initiate a rulemaking proceeding as requested in the petition." 15 U.S.C. § 2620(b)(4)(A).

In a suit seeking to compel EPA to initiate a rulemaking for a new Section 6(a) rule, the petitioner "shall be provided an opportunity to have such petition considered by the court in a de novo proceeding." *Id.* § 2620(b)(4)(B). The petitioner must "demonstrate[] to the satisfaction of the court by a preponderance of the evidence that" the petitioned chemical "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors…under the conditions of use." *Id.* If the petitioner meets that burden, the court may order EPA to "initiate" the requested proceeding. *Id.*

II. Factual Background

A. Fluoride and Regulation of Fluoride in Drinking Water

Fluoride is a common mineral that is released into the environment when rocks or soil are dissolved by water. Fluoride is naturally present in virtually all rivers, lakes, and surface waters, but the level varies by location. Fluoride is also naturally present in foods, including tea, coffee, fish, and other seafood products. *See* 50 Fed. Reg. 20,168 (May 14, 1985).

Since the early 1900s, fluoride has been estimated to lower the incidence of dental cavities by making teeth stronger and more resistant to decay. Too much fluoride, however, may cause dental and skeletal fluorosis. *See, e.g.*, 65 Fed. Reg. 25,982-01, 26,009 (May 4, 2000) (discussing dental fluorosis); *but see* 2-ER-301-03 ("The prevalence of severe enamel fluorosis is very low (near zero) at fluoride concentrations below 2 mg/L.").

Citing fluoride's benefits to oral health, beginning in the 1960s, the U.S. Public Health Service has recommended that community water providers add fluoride to tap water to reduce the risk and severity of tooth decay, especially in children. 2-ER-283-84. The U.S. Public Health Service has no regulatory authority over water fluoridation, and consequently its recommendation is advisory only. States and municipalities decide whether to follow the recommendation. As of 2024, approximately two-thirds of the U.S. population receives water with added fluoride.

At present, the recommended level for community water fluoridation is 0.7 mg/L. 2-ER-74. Some communities have water sources with naturally occurring fluoride at concentrations greater than 0.7 mg/L. 80 Fed. Reg. 24,936, 24,936-37 (May 1, 2015); 2-ER-284, 5-ER-1021.

EPA has regulatory authority over public drinking water systems under SDWA. 42 U.S.C. §§ 300f et seq. Pursuant to SDWA, EPA sets enforceable and recommended safe levels of certain substances, including fluoride, in drinking water. 42 U.S.C. §§ 300f et seq. Under SDWA, EPA has set an enforceable maximum allowable concentration of fluoride in drinking water at 4 mg/L (the standard is set based on naturally occurring fluoride but applies to any fluoride levels in the water to be served in the public water system). 40 C.F.R. § 141.62. Drinking water facilities regulated by SDWA must remove fluoride above these levels. EPA also has a recommended drinking water standard for fluoride of 2.0 mg/L; while this standard is not enforceable, EPA requires public water systems to notify the public if and when water sample levels exceed this threshold.[3] *Id.* §§ 143.1, 143.3; *id.* § 141.208.

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[3] The Department of Health and Human Services announced in April 2025 that it is reconvening the Community Preventative Health Services Task Force to make a new recommendation on fluoridation of drinking water. EPA simultaneously announced that it will prepare an updated health effects assessment for fluoride that will inform any potential revisions to EPA's fluoride drinking water standard. "EPA Will

B. 2016 Petition and EPA's Denial

On November 23, 2016, Plaintiffs filed a Section 21 petition requesting that EPA exercise its authority under TSCA Section 6(a) to prohibit the artificial fluoridation of U.S. drinking water. 2-ER-202-81 (2016 petition). The petition contended that a significant body of scientific evidence, comprised primarily of testing on rodents and studies of health effects on humans in China, India, and Iran, demonstrated fluoride's risk of neurotoxic harm. *E.g.*, 2-ER-211. The central cited studies were not from the United States or countries with comparable levels of fluoride exposure and exposure to other potential neurotoxic chemicals, and none measured an effect at levels of 0.7 mg/L, the level of fluoride added to water in the United States. *Compare* 2-ER-210-12, *with* 2-ER-192-94.

On February 27, 2017, EPA denied the petition and published its denial in the Federal Register. 2-ER-188-200 (denial). EPA's denial explained that the petition had not set forth a scientifically defensible basis to conclude that fluoridated water presented a risk of neurotoxic harm. 2-ER-192. EPA individually discussed several of the studies relied upon by the petition, explaining that those studies had significant data quality issues and did not establish a link between neurotoxic harms and fluoridation at levels present in the United States. 2-ER-192-95. EPA also observed

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Expeditiously Review New Science on Fluoride in Drinking Water," https://www.epa.gov/newsreleases/epa-will-expeditiously-review-new-science-fluoride-drinking-water (April 7, 2025).

that "[t]he petition itself concedes that the actual existence of [neurotoxic] effects [of fluoridation at levels present in U.S. drinking water] is unestablished." 2-ER-193.

III. Procedural History

A. Initial Judicial Proceedings

Plaintiffs filed suit under TSCA Section 21 in April 2017. 6-ER-1168. EPA moved for a protective order to limit the scope of the court's review. 6-ER-1212. EPA explained that Plaintiffs were not entitled to discovery or to introduce information (including studies) not presented to EPA in their administrative petition. Doing so would be inconsistent with Section 21's limitation of the district court's review to "such petition," and with Section 21's exhaustion requirement.

In February 2018, the court denied EPA's motion. 1-ER-53-69. In the court's view, Section 21's "de novo proceeding" language and statutory context suggested that Plaintiffs may introduce evidence and take open-ended discovery far beyond the materials identified in the petition. 1-ER-53-69. While the court acknowledged EPA's argument that an open record would render the "requirement to present an administrative petition setting forth the 'facts' requiring a rule meaningless," the court suggested that it "might impose limits on new evidence" and thus "afford significance to the exhaustion requirement" under TSCA Section 21. 1-ER-66-67. As discussed below, it ultimately did not do so.

As a consequence of the court's order, extensive fact and expert discovery ensued. Towards the end of discovery, the parties disagreed about whether and how to introduce a soon-to-be released draft monograph from the National Toxicology Program (NTP).[4] The draft NTP monograph systematically reviewed and evaluated the association between exposures to fluoride and human neurodevelopment and cognition. Ultimately, the parties agreed not to present the draft NTP monograph at the first trial.[5]

The parties also spent a considerable amount of time shaping the record concerning jurisdiction. In May 2019, Plaintiffs stipulated that they would "rely exclusively on" declarations of several named individuals "to establish the factual basis in support of the claims of standing." 4-ER-682. "This stipulation is intended to limit evidence Plaintiffs may introduce to establish the factual basis that supports their claims of standing at each stage of the litigation, including trial." 4-ER-683.

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[4] NTP, within the National Institute of Environmental Health Sciences, works to build knowledge and advance toxicological sciences to protect and promote human health.

[5] EPA moved to extend discovery to accommodate the anticipated release of the draft document, 6-ER-1161-66, but Plaintiffs opposed extending discovery, 6-ER-1153-69, and the court sided with Plaintiffs, 6-ER-1150-52. Later, after the close of discovery and before trial, Plaintiffs disclosed the draft NTP monograph as a standalone exhibit they intended to introduce. EPA moved in limine to exclude the draft monograph. 6-ER-1143-49. Plaintiffs later withdrew their opposition to that motion and withdrew the proposed exhibit. *See, e.g.*, 5-ER-1092, 4-ER-779-81, 5-ER-1081.

The declarations asserted the declarants' concerns about a variety of physical harms from fluoride, including headaches, dementia, bone cancer, ADHD, and hypothyroidism, as well as their financial expenditures to avoid these harms. *See, e.g.*, 3-ER-355-595, 4-ER-598-680. None of the declarations alleged that they planned to become pregnant or were caring for young infants, or that they were incurring costs to avoid IQ decrements. The court entered the stipulation as an order. 3-ER-351-53.

In the fall of 2019, the parties cross-moved for summary judgment. EPA argued, among other things, that Plaintiffs had not met their burden to demonstrate standing. EPA argued that none of Plaintiffs' alleged harms were supported by evidence, nor were they related to the harms asserted in the petition (i.e., neurotoxic harm during pregnancy or to very young children). 4-ER-795. In December 2019, the court denied both parties' motions. 6-ER-1106. As to standing, the court held that Plaintiffs' allegations of neurotoxic harm in the form of headaches were sufficient, at the summary judgment stage, to "rise above the purely speculative, albeit perhaps barely, for standing purposes." 6-ER-1114.

B. First Trial

In June 2020, the court held a bench trial on Plaintiffs' claim that fluoridated drinking water presents an "unreasonable risk" of injury to human health. The

parties presented voluminous evidence—including 55 exhibits and seven expert witnesses—about fluoride's potential neurotoxic effects on children.

The evidence about the neurotoxic harm focused on the risk of fluoride to unborn and young children, and included results of experimental animal studies (the most important of which was published in 2018), prospective human cohort studies (with the focus primarily on cohort studies published after 2017), and a variety of cross-sectional studies conducted in developing countries. *See* 5-ER-1055-56 (court order identifying studies for parties to discuss); 5-ER-1034, 5-ER-1043-45, 5-ER-1001-03, 5-ER-1010, 5-ER-1013-14. In Plaintiffs' words, the "most important studies" in the case were those based on the human cohort studies published after 2016. 4-ER-778, 5-ER-997, 5-ER-1001. Of course, the 2016 petition had not cited these yet-to-be-published studies. *See* 1-ER-27.

EPA argued that the animal studies did not support a finding of unreasonable risk; the human cohort studies did not demonstrate a consistent, adverse association between fluoride exposure and neurotoxic harms; and the cross-sectional studies were all conducted in places with much higher overall exposures to other chemical substances (and much higher levels of fluoride exposure), rendering their results unhelpful in the context of the specific condition of use in the United States. *See, e.g.*, 2-ER-335-40. As EPA's expert declared in summarizing this evidence, "the overall weight of scientific evidence does not establish that neurodevelopmental

harm is likely to be a hazard of community water fluoridation in the U.S." in part because the evidence is not "strong, consistent, coherent, or biologically plausible." 2-ER-333. Plaintiffs, by contrast, contended that the court could find an unreasonable risk despite "conflicting and inconclusive evidence" because of TSCA's "'overriding purpose' of preventing harm before it occurs." 5-ER-1015.

As it had been at the summary judgment stage, standing was squarely at issue during the first trial. 6-ER-1131, 6-ER-1139, 5-ER-1024-30. EPA contended that Plaintiffs' declarants asserted injuries they attributed to fluoride, but the evidence at trial did not establish that fluoride caused the harms they complained of (e.g., headaches, dementia). 6-ER-1131, 6-ER-1140, 5-ER-1024-30; *see also* 3-ER-351-53. Instead, the evidence at trial focused on the risk of neurodevelopmental harm to unborn and young children. But "[g]iven the ages of the individual Plaintiffs and standing declarants, none can establish a real threat of neurodevelopmental injury, reduced loss of IQ or ADHD from early, developmental exposure to community water fluoridation." 5-ER-1029, 5-ER-1050-53.

Immediately after closing arguments, the court sua sponte raised concerns about the evidence presented, cast doubt on Plaintiffs' standing, encouraged the parties to resolve the suit through the administrative process, and suggested staying the case. *See* 1-ER-28-52. The court acknowledged, "obviously, we've gone well beyond the administrative record because so much has changed since that record,

that petition was filed with the EPA…There have been two significant series of studies, prospective cohort studies, which everybody agrees is the best methodology." 1-ER-28. "[W]hat is before this Court is an entirely different body of evidence—not entirely, but a substantially different body of evidence that was presented to the EPA." 1-ER-30. The court asked the parties: "[d]oesn't it make sense to have the agency take a second look [at the evidence]? Take a look now that the evidence has been produced by both sides…And it's going to be informed, hopefully, soon by the [final] NTP [monograph]. There may be some other things [i.e., new studies]. There is the pooled study that Dr. Lanphear is hoping to—I don't know how long that's going to be. And you've got the Spain study that is not in published form, not been peer reviewed yet." 1-ER-30. Given that most of the evidence presented at trial was not in the petition, as well as its concerns about Plaintiffs' standing, the court encouraged the parties to "reboot" the case, with Plaintiffs filing a new petition and the court holding the case "in abeyance and give the agency a chance to relook." 1-ER-31, 1-ER-35.

Both parties resisted the court's belated suggestion to channel the case into a new administrative process or await new studies. Plaintiffs' counsel expressed frustration with the idea of once again returning the process to EPA, rather than obtaining a court ruling. 1-ER-35, 1-ER-44. Plaintiffs' counsel told the court that Plaintiffs had "presented sufficient evidence to demonstrate a risk under the proper

standard under Section 6," and expressed concern about waiting years for a ruling. 1-ER-42, 1-ER-44.

For its part, EPA's counsel informed the court that TSCA did not provide for the type of administrative process that the court was suggesting. 1-ER-33-34. EPA explained that Plaintiffs could file a new petition, but that new petition would have to meet the burden required under Section 21. 1-ER-39-41. The court pushed back, suggesting that what it was "hoping for" was "a substantive review" of the new evidence. 1-ER-41-42. The court also emphasized that, were EPA to reject Plaintiffs' request in this new administrative proceeding, "[t]hat doesn't mean this case goes away. I still have this case. I could rule on this case." 1-ER-36.

Notwithstanding the parties' pushback, the court emphasized that it was hoping that the parties would meet-and-confer, that Plaintiffs would file an updated petition, and that EPA would engage in a "substantive review" of that petition. 1-ER-42. The court informed the parties that it would call a status conference in a few months to discuss the matter further. 1-ER-45. Regardless, it closed the trial record. 1-ER-51.

Subsequently, in anticipation of a ruling on the trial record, the parties submitted supplemental briefing on standing and filed post-trial proposed findings of facts and conclusions of law. But, at the court's insistence, the parties also engaged in extended discussions regarding the potential for Plaintiffs to file a new

or an amended petition. 5-ER-988-89. Plaintiffs proposed to submit to EPA a petition that included the evidence presented at the first trial. Plaintiffs insisted "that they have already presented sufficient evidence to demonstrate an unreasonable risk under the statute." 5-ER-989. EPA informed Plaintiffs—consistent with its defense at trial—that simply repackaging the evidence presented at trial would be insufficient for EPA to find unreasonable risk. 5-ER-988.

C. The court orders its "reboot" through a supplemental petition, an amended complaint, and an abeyance to allow science to "evolve."

The court held a status conference on August 6, 2020. 4-ER-738-77 (transcript). The court again encouraged the parties to resolve their dispute through an administrative process. It reiterated the points it had raised at the end of trial, namely, that Plaintiffs likely lacked standing and that EPA should administratively consider the evidence presented at trial, and that the court would put the case in abeyance for the parties to resolve their differences. 4-ER-757 ("The standing issues are very serious, and it raises some—some significant questions, and frankly, doubts about standing…I think there are grave questions about standing."); 4-ER-770-71 (reiterating concerns about standing); 4-ER-758 ("[I]t's obviously my hope that with the new evidence, that the Agency, the EPA, would take a second look, and not sort of just prejudge this."). The court also made clear, however, that should the administrative process not result in the outcome the court sought, the court would

continue to "hold the case in abeyance" pending "intervening developments, intervening studies, intervening things. And if necessary, to resolve any standing or jurisdictional issues." 4-ER-772. Further, the court invited Plaintiffs to amend their complaint to cure Plaintiffs' standing deficiency. 4-ER-767, 4-ER-770-71.

At the hearing, EPA and Plaintiffs again expressed concern with this approach. EPA expressly "object[ed] to holding this case in abeyance or staying it. My client would like the Court [to] go forward on the trial record, and issue a decision." 4-ER-768. Plaintiffs stated that they believed that on standing, "the case law is—is strongly on our side for having met our burden." 4-ER-771. As to the new petition, Plaintiffs stated, "I can tell you it's not something that our clients want to do. We're not keen on submitting a new petition, to be frank." 4-ER-749. And they encouraged the court to rule, noting that "[P]laintiffs do have concern, Your Honor, about—you know, science is never complete. You know. I wish we could, you know, know that there's the final study to definitively resolve everything….But I think it's—that's obviously not the burden, under TSCA[.]" 4-ER-755. In short, the parties agreed that the case was ready for a ruling on the trial record as they had developed it.

On August 10, 2020, the court issued an order putting the case in abeyance. 1-ER-23-27. The order laid out the court's doubts about whether Plaintiffs had met their burden on standing by a preponderance of the evidence. 1-ER-23-27. "The

evidence presented by Plaintiffs at trial focused overwhelmingly, if not exclusively, on the contention that fluoride poses a risk of *neurodevelopmental* harm." 1-ER-23. "None of the standing Plaintiffs in this case claim to be subject to that risk of harm; there are no allegations that the named Plaintiffs are pregnant, planning to become pregnant, or caring for infants." 1-ER-24. The court explained, "Plaintiffs have not shown any relationship between the evidence presented" at trial "and the harms alleged by the named Plaintiffs, [so] it is doubtful they have carried their burden of demonstrating" standing. 1-ER-25. In part to address these issues, the court "direct[ed] Plaintiffs to file a new petition with EPA" including "as much underlying data and as many calculations as possible." 1-ER-26-27.

The court reiterated that an abeyance would not only permit Plaintiffs to cure their standing deficiency but would also allow EPA to consider the scientific developments since the original petition was filed, including the yet-to-be published final NTP monograph, along with other studies. 1-ER-26-27. The court observed that: "the evidence contained in Plaintiff's underlying petition to the EPA (from 2016)" was "very different from the evidence that was presented to the Court at trial." 1-ER-26. The court further noted that it expected that additional new studies "would shed important light on the issues contested in this case." 1-ER-26. The court warned that: "[s]hould the EPA deny the new petition, the Court will permit amendment of the complaint herein and consider permitting supplementation of the

record in this case to account for, e.g., new evidence contained in the new petition or new studies published since the trial in this case." 1-ER-27.

In October 2020, EPA filed a motion for relief from the abeyance order. 5-ER-979-987. The motion argued that Plaintiffs had failed to carry their burden on standing at trial, and the court was required to dismiss the case rather than continue to keep the case in abeyance. 5-ER-983, 5-ER-943-51. As for amendment, EPA contended that granting a do-over on standing would violate their binding agreement embodied in the standing stipulation and unfairly prejudice EPA. 5-ER-984-85.

Plaintiffs opposed EPA's motion, 5-ER-952-60, and, as directed by the court, submitted to EPA the evidence identified by the court's abeyance order, along with the findings of the draft NTP monograph, as a "supplement" to their 2016 petition, 5-ER-962-78. On January 13, 2021, the court denied EPA's motion to vacate the abeyance order and dismiss the action. 1-ER-22.

On January 19, 2021, EPA sent a letter declining to reopen its decision in light of Plaintiffs' purported "supplemental petition." 5-ER-936-42. EPA reiterated its view that the evidence presented did not satisfy Plaintiffs' burden of demonstrating the risk of neurotoxic effects from exposure to fluoride. 5-ER-937, 5-ER-939 (finding "the evidence of effects" at relevant exposures "is inconsistent and unclear, and, therefore, insufficient to reach and support a hazard conclusion").

Following EPA's letter and as permitted by the court's order denying in part EPA's motion, Plaintiffs moved to supplement their complaint to add additional information on: (1) standing; (2) the court's post-trial orders; and (3) new scientific studies on fluoride and neurotoxicity that were published after the trial. 5-ER-910-34. As to standing, Plaintiffs did not identify any member of their organizations who was pregnant or seeking to become pregnant at the time of the original complaint or even trial, but asserted that, after trial, they identified one member, Jessica Trader, who was pregnant and concerned about fluoride's impacts on her child's health. 5-ER-915. Plaintiffs argued that the new facts about Trader cured their standing defect. 5-ER-916. Plaintiffs asserted that they moved for leave "so that this case, which has already gone to trial, may be resolved on the merits rather than a technicality." 5-ER-916. EPA opposed the motion to supplement on the grounds that (1) it violated the terms of the stipulation Plaintiffs entered with EPA concerning evidence Plaintiffs could present to demonstrate standing and (2) it discussed draft scientific papers post-dating the trial. 5-ER-899-909.

In April 2021, the court held a hearing on Plaintiffs' motion to supplement. 4-ER-716-37 (transcript). The court repeated its intention to permit amendment. The court also took the opportunity to reiterate that it would not rule on the trial record until it saw the final NTP monograph. 4-ER-722. In the court's words, it would "not adjudicate, to reach a final adjudication, frankly, until I see the final NTP

report….Gotta have to [sic] the NTP; that is critical." 4-ER-722. The court continued, "I think the focus [in a phase two trial] is going to be on, you know, what we were focused on, given the enhancement of some more data now. And hopefully we'll get some more—these two other studies…so we'll have a more complete record." 4-ER-723, 4-ER-729 ("[T]he NTP final monograph….is just something that is going to be important."). When questioned by counsel if the court really intended to hold the case in abeyance pending the further development of scientific evidence, rather than to rule on the trial record, the court confirmed that its "intent, is to allow the science to develop….And then if it doesn't get resolved [administratively by EPA], we resume here, and we'll pick up where we left off…. But given the development of the science, I think it is the right thing to do." 4-ER-731-32.

A month later, the court issued a written order granting Plaintiffs' motion to supplement. 1-ER-4-18. The court permitted Plaintiffs to amend their complaint on standing, relieving Plaintiffs from the standing stipulation they had entered. In the court's view, Plaintiffs would "suffer manifest injustice" if held to their stipulation "because that would likely require this Court to dismiss their case." 1-ER-11. The court also permitted supplementation as to the new studies, stating that "evolving science warrants reopening of expert discovery and trial evidence." 1-ER-14. The court explained it would "continue to hold the case in abeyance at least until the final

NTP monograph is released and possibly until the Canadian, Mexican, and Spanish cohorts are peer-reviewed." 1-ER-15; *see also* 4-ER-701 ("[O]ne of the reasons why I stayed everything, besides the standing issue, is because I knew that there were all these things that we learned about at trial, these studies that hadn't been peer-reviewed."); 4-ER-705.

The case remained in abeyance for the next year and a half awaiting new studies, including the final NTP monograph. Then, in September 2022, notwithstanding the lack of a final NTP monograph, Plaintiffs moved to take the case out of abeyance and schedule new expert discovery and a second trial to present evidence published since the prior trial. 5-ER-879-98. EPA filed an opposition, along with a Cross-Motion to Lift Stay to Decide Merits on Trial Record. 5-ER-868. EPA argued that the court should only take the case out of abeyance to decide it based on the existing trial record. 5-ER-875-78. In response, Plaintiffs explained that they "would *not* object to the Court issuing its determination without taking further evidence" (other than on standing). 5-ER-854. EPA specifically emphasized for the court that "**the parties agree that the Court should lift the abeyance and decide the merits of this case based *only* on the trial record**." 5-ER-844 (emphasis in original).

The court granted Plaintiffs' request to lift the abeyance, but it rejected EPA's request to decide the case on the trial record. 5-ER-841, 4-ER-709-13. That ruling sent the case to a new, contentious round of discovery.

D. Second trial

In January 2024, the court held a second bench trial. Over the course of ten days, the parties presented evidence on studies published since 2020. 2-ER-81. The primary dispute at trial concerned how to interpret these new studies. There was no dispute that these studies offered inconsistent results about the association between low doses of fluoride and childhood IQ, but the parties disputed the weight to give each study and what conclusions to draw about the inconsistency of the evidence. *See, e.g.*, 2-ER-94-97, 2-ER-109.

In particular, the parties focused on various cohort studies as well as new analyses of earlier cohort studies. For example, EPA relied in-part on studies conducted in Spain (2021) and Denmark (2023) of populations with similar levels of fluoride exposure as the United States, which did not show an association between fluoride and reduced IQ. 2-ER-171-72, 2-ER-175-84; *see also* 2-ER-109 (district court citing various studies from 2019, 2021, 2022, 2023 supporting this proposition, including cohort studies). Plaintiffs relied heavily on analyses of cohort studies in Canada and Mexico, particularly various analyses of that information published in

2022 and 2023. 2-ER-161-64, 2-ER-109, 2-ER-113-16 (district court relying on these studies).

The second trial also focused on three systematic reviews, including two draft documents from the NTP published in 2022 and a systematic review from Canada published *during the second trial* in 2024.[6] NTP released both a draft qualitative review of the scientific literature (draft "NTP monograph") and a draft quantitative assessment of data from over fifty studies (both studies were finalized and published in 2024 after the second trial). The draft NTP monograph concluded with moderate confidence that higher estimated fluoride exposures (above 1.5 mg/L) are associated with lower IQ in children, but also concluded that associations at low levels remain unclear and that "[m]ore studies are needed to fully understand the potential for lower fluoride exposure to affect children's IQ." 2-ER-319; *see also* 2-ER-316 ("Associations between lower total fluoride exposure [e.g., lower than 1.5 mg/L of fluoride]…and children's IQ remain unclear.").

EPA argued that the weight of the evidence—accounting for the new studies issued since the last trial—did not establish that fluoride was neurotoxic at levels of community fluoridation (i.e., 0.7 mg/L). *See generally* 2-ER-168-76. To the

[6] Taher (2024) was published online on February 6, 2024. 2-ER-306. The trial was held January 31, 2024, through February 20, 2024. *See* 6-ER-1285-93. The district court's merits order cites Taher 2024. *See* 2-ER-96, 2-ER-99.

contrary, EPA contended, the new evidence published since the last trial further muddied the picture by providing more null results. 2-ER-171-73. Plaintiffs, by contrast, maintained their position that the science was sufficiently robust and consistent to make a finding of unreasonable risk.

On September 24, 2024, the court issued its findings of fact and conclusions of law. 2-ER-72-151. The court's order purported to evaluate the evidence under the same general framework EPA would use when conducting a TSCA risk evaluation. 2-ER-84-85. Notwithstanding ongoing controversy within the scientific community on the question of fluoride's neurotoxic harm at low levels, the court construed the evidence before it as consistent enough to demonstrate fluoride's neurotoxic harm at low levels. 2-ER-106-11. After moving through each of the remaining risk evaluation steps, the court ultimately concluded that Plaintiffs had demonstrated by a preponderance of the evidence that fluoride in drinking water presents an unreasonable risk of injury to health. 2-ER-150. The court "order[ed] the Administrator to initiate rulemaking pursuant to Subsection 6(a) of TSCA," but it correctly did not attempt to dictate the outcome of such rulemaking or how EPA must proceed in the rulemaking. 2-ER-150.

SUMMARY OF ARGUMENT

1. Plaintiffs lack standing. Their sole relevant standing declarant is Jessica Trader, who resides in Leawood, Kansas. Trader's drinking water naturally contains

fluoride at levels of 0.24-0.4 mg/L, and her water utility adds only as much fluoride as necessary for her tap water to reach a concentration of 0.7 mg/L.

Even if Trader has demonstrated harm from her expenditures to avoid drinking fluoridated water, she cannot demonstrate causation or redressability because the relief available under TSCA Section 6(a) would not require Trader's drinking water utility to *remove* the naturally occurring fluoride from her water. This naturally occurring fluoride exceeds levels the district court found harmful. The remedy Plaintiffs seek under TSCA Section 6(a) would not require Trader's water utility to remove naturally occurring fluoride. Accordingly, Trader will continue to incur the harm she seeks to avoid even if she wins this suit. Plaintiffs lack standing to pursue their claim.

2. The court erred in interpreting Section 21 to permit Plaintiffs to use discovery to build a trial record comprised of scientific evidence never presented to EPA in a Section 21 petition. Section 21 does not contemplate—much less permit—a petitioner using the judicial process and the tools of discovery to update the evidentiary basis for its claim once in court. At a minimum, it does not permit the court to build the petition, with evidence not marshalled in the first instance by petitioners, on a rolling basis over many years.

Section 21 directs the court to consider "such petition," which consists of "the facts which it is claimed establish that it is necessary" to issue the relevant rule or

order. Thus, Section 21 requires petitioners to bring forth all their evidence in their petition, so that EPA may pass on it. If EPA denies the petition, the petitioner may go to court—but the object of the court's "consider[ation]" in an action under Section 21 for a Section 6(a) rule is not whether a chemical presents an unreasonable risk in the abstract but "such petition," which necessarily includes the facts contained in the petition to demonstrate it is "necessary to issue" the requested "rule." Otherwise, plaintiffs could file a bare-bones petition with EPA only to develop the facts and evidence over years of discovery in district court. In short, the court is considering the evidence set forth by the plaintiff in its petition.

This understanding of Section 21 also makes sense of Section 21's structure. In marked contrast to Sections 19 and 20, TSCA's other judicial review provisions, Section 21 sets forth a scheme of required administrative exhaustion; that is, it details both substantive and procedural steps a petitioner and EPA must follow before a petitioner may initiate suit. EPA must evaluate the petition and issue a decision within 90 days, and, in the event of denial, must publish the reasons for denial in the Federal Register. 15 U.S.C. § 2620(b)(3). Within this 90-day period, EPA "may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted." *Id.* § 2620(b)(2). These requirements would be meaningless if the plaintiff could introduce different evidence in court than its petition presented to

EPA. *Id.* § 2620(b)(1). Even if Section 21 allows for *some* additional evidence, here the district court encouraged Plaintiffs to present a case built *overwhelmingly* on new evidence that did not exist at the time of the petition, contrary to the statutory requirement that petitioners set forth the facts for EPA to consider *before* proceeding to court. That approach was erroneous.

3. The district court's takeover of the case after closing arguments in the first trial violated the party presentation principle. Rather than act as a neutral arbiter of the parties' dispute following the presentation of evidence, the court commandeered the proceedings and directed Plaintiffs how to proceed with their claims. Rather than rule on the merits—as the parties expected and as was appropriate following a full bench trial—the court instead directed the parties into an administrative process that both parties insisted was unnecessary (and that EPA asserted was unlawful). When that administrative process failed to resolve the parties' dispute to the court's satisfaction, the court again refused to rule on the issues before it—notwithstanding the court repeatedly expressing that Plaintiffs likely had not carried their burden on standing and despite the parties' repeated insistence that the case was ready for adjudication. Instead, the court maintained an abeyance to allow further development of evidence that the court believed would be useful to addressing the broader science about fluoride. The court then lifted the abeyance solely to allow Plaintiffs to provide the evidence that the court believed was necessary for Plaintiffs

to prove their standing. And the court then conducted a second trial on evidence that, in its view, was relevant and appropriate. This constituted an impermissible "takeover" of the case and an abuse of discretion. The Court should reverse on this basis as well.

STANDARD OF REVIEW

Standing is a question of law reviewed de novo. *Hartman v. Summers*, 120 F.3d 157, 159 (9th Cir. 1997). The district court's interpretation of TSCA Section 21 is a question of law reviewed de novo. *See United States v. Salazar*, 61 F.4th 723, 726 (9th Cir. 2023). The district court's conformance with the party presentation principle is reviewed for an abuse of discretion. *United States v. Sineneng-Smith*, 590 U.S. 371, 375 (2020).

ARGUMENT

I. Plaintiffs lack Article III standing to bring this action.

"To establish constitutional standing, a plaintiff must show it has suffered an 'injury in fact,' that the injury is 'fairly traceable' to the conduct at issue in the plaintiff's claim, and that 'it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.'" *CBD v. Export-Import Bank*, 894 F.3d 1005, 1012 (9th Cir. 2018) (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180-81 (2000)). "The party invoking federal jurisdiction bears the burden of establishing these elements…with the manner and degree of evidence

required at the successive stages of the litigation." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Because Plaintiffs request forward-looking relief, they must face "a real and immediate threat of repeated injury." *Murthy v. Missouri*, 603 U.S. 43, 58 (2024) (citation omitted). As the district court stressed: "At trial, Plaintiffs were required to prove the elements of standing by a preponderance of *evidence*." 1-ER-24 (emphasis in original).

As described above, Plaintiffs chose to prove standing at trial based on the declarations attached to a court-approved stipulation. 3-ER-351-53. This included declarations from a handful of individual members of Plaintiff groups, all of whom purported to suffer from (or feared they would eventually suffer from) various ailments, including headaches, cancer, and dementia. *See* 3-ER-355-595, 4-ER-598-680 (original declarations). As the court correctly observed, "the evidence" that these ailments were related to fluoridated water "was practically non-existent at trial." 1-ER-25. Instead, "the evidence at trial focused on whether fluoride poses a threat of neurotoxic harm during critical developmental periods, such as the gestational and neonatal periods." 1-ER-23. But "[n]one of the standing Plaintiffs in this case claim to be subject to that risk of harm." 1-ER-24.

There was thus a misalignment between the harm Plaintiffs alleged that they suffered and the evidence they introduced at trial. *See supra* at pp.15-18, 22-23; 4-ER-757 (district court expressing "doubts about standing" with "respect to the

current named plaintiffs and those who filed the original petition, because as we know, none of them present the kind of risk that is the—the topic of trial, and the focus of all the evidence"). Because Plaintiffs provided virtually no evidence that water fluoridation caused any of their asserted injuries, Plaintiffs did not carry their burden of establishing that EPA's failure to regulate it under TSCA caused their injuries or that regulation would redress them. *See, e.g.*, *Murthy*, 603 U.S. at 59-62 (finding no standing when plaintiffs fail to provide sufficient evidence linking challenged conduct to harms); *Diamond Alternative Energy, LLC v. EPA*, 145 S. Ct. 2121, 2138 (2025) ("Article III's redressability requirement serves to align injuries and remedies."); *Wash. Env't Council v. Bellon*, 732 F.3d 1131, 1142-46 (9th Cir. 2013) (finding no standing to challenge failure to regulate certain refineries' emissions "without any plausible scientific or other evidentiary basis that the refineries' emissions are the source of their injuries").

At the end of the first trial and repeatedly thereafter, the district court made clear that Plaintiffs had a standing problem. *See, e.g.*, *supra* at pp.21-23, 26; 1-ER-34-35; 1-ER-23-25; 1-ER-22. It should have dismissed at that point. *See* Fed. R. Civ. P. 12(h)(3) (court "must dismiss the action" if it "determines at any time that it lacks subject-matter jurisdiction"); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) ("Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and

dismissing the case.") (quoting *Ex parte McCardle*, 7 Wall. 506, 514 (1868)). But instead, it sua sponte indicated, in violation of a court-approved joint stipulation, that it would permit Plaintiffs to amend their complaint. *See supra* at pp.18, 21-24; 4-ER-757-58, 4-ER-767; *see also* 1-ER-27. And in 2023, Plaintiffs brought forward a new declaration from Jessica Trader, one of their previous standing declarants. 3-ER-345; 3-ER-593-95. Trader is the only individual that the district court identified as supporting Plaintiffs' standing. 2-ER-82-83.

Trader's first declaration stated that she was a resident of San Francisco, asserted she had dental fluorosis which caused her social anxiety and embarrassment, and asserted generalized concerns about the harms fluoride might cause on her bones, thyroid, and brain. 3-ER-593-95. She averred that she avoided drinking tap water and instead purchased bottled water and had installed a filtration system to remove fluoride. 3-ER-594. But Plaintiffs had not provided evidence that fluoride exposure at the level of artificial fluoridation of public drinking water (0.7 mg/L) causes these harms. *See also, e.g.*, 2-ER-301-03 ("[S]evere enamel fluorosis is very low (near zero) at fluoride concentrations below 2 mg/L.").

The second Trader declaration relays that Trader moved to Leawood, Kansas, in August 2020, and that the "public water supply in Leawood" is fluoridated. 3-ER-343-50. The declaration states that, in August 2021, Trader gave birth to a child and hopes to become pregnant again in the near future. 3-ER-343-44. The

declaration also states that, due to her concerns about fluoride's effects on childhood IQ, Trader actively avoids drinking tap water or giving her infant tap water and "strive[s] to provide [her child] only non-fluoridated, or defluoridated, water." 3-ER-344. She purchases bottled water and relies on filters to remove fluoride, at a substantial financial cost. 3-ER-345. She states that "[a]s long as fluoridation chemicals are added to my city's water supply, I will continue incurring these costs." 3-ER-345.

Trader's second declaration fails to establish standing. Assuming Trader could prove injury from the self-imposed cost of buying water and water filters, Trader's injury is not caused by EPA, nor is it redressable by an order in this suit.

The tap water in Leawood, Kansas is provided by WaterOne, a public water utility. WaterOne Service Area, https://www.waterone.org/344/WaterOne-Service-Area (last visited July 18, 2025).[7] WaterOne fluoridates the water it provides to its customers to 0.7 mg/L. Fluoride, https://www.waterone.org/203/Fluoride (last visited July 18, 2025). Even without fluoridation, however, a significant portion of the fluoride in Trader's drinking

[7] As explained in Defendants-Appellants' Motion for Judicial Notice, we request that this Court take judicial notice of facts disclosed in three publicly available documents posted to the internet by this public utility that speak to standing and thus this Court's jurisdiction. We cite to the internet for the pages and have attached screenshots or downloaded PDF copies to the Motion for Judicial Notice.

water (0.24-0.4 mg/L, or about 35-60 percent of the total fluoride in WaterOne's drinking water) is *not* from added fluoride, but is attributable to natural sources.[8] Fluoride, https://www.waterone.org/203/Fluoride (last visited July 18, 2025); *see also* Water Quality Report 2025 at pp.5-6, 8-9, 2025, https://www.waterone.org/339/Water-Quality-Reports (last visited July 18, 2025). In some of its findings (largely adopting some of Plaintiffs' arguments), the district court found that fluoride at these naturally occurring levels presents an unreasonable risk of injury to children.[9]

Thus, there is also no dispute (for standing purposes) that Trader's tap water, *even without community fluoridation*, would contain levels of fluoride above what the district court found to present an unreasonable risk. And there is also no dispute

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[8] For purposes of neurotoxicity, Plaintiffs have never contended there is any difference between naturally occurring fluoride and fluoride artificially added to drinking water.

[9] The court found that 0.28 mg/L, measured in maternal urinary fluoride, was a point of departure for neurotoxic effects. *See, e.g.*, 2-ER-113-22. In doing so, the court largely adopted some of Plaintiffs' proposed findings of fact. *See* 2-ER-165-66, 2-ER-186. "Maternal urinary fluoride" is a biomarker of fluoride, not an intake metric that reflects only the effects of fluoridated drinking water. Nonetheless, the district court held that "it is appropriate to infer conservatively that approximately half of the maternal urinary fluoride observed in a pregnant woman's urine is attributed to community water fluoridation." 2-ER-135. Pursuant to the court's conclusions—which EPA accepts *solely* for purposes of the standing analysis—concentrations as low as 0.14 mg/L of fluoride in drinking water could result in maternal urinary levels of 0.28 mg/L. Similarly, Plaintiffs argued for a point of departure of 0.179 mg/L in drinking water. 2-ER-186. Naturally occurring fluoride concentrations in Trader's drinking water exceed this level.

that a TSCA Section 6(a) rulemaking banning community water fluoridation would not require WaterOne to remove this naturally occurring fluoride—indeed, Plaintiffs only seek for EPA to regulate the addition of fluoride, not to address naturally occurring fluoride. 2-ER-207, 2-ER-232-34; 5-ER-821, 5-ER-835. Accordingly, even with a favorable decision, Trader will be in the same position she was in before this suit: her tap water will contain fluoride, and she will continue to incur the expense of provisioning her family with bottled or filtered water to avoid fluoride.

Plaintiffs have provided no evidence that Trader would change her purchasing decisions if she continues to be exposed to naturally occurring fluoride. *Cf. In re Coca-Cola Prods. Mktg. & Sales Pracs. Litig.*, 2021 WL 3878654, at *2 (9th Cir. Aug. 31, 2021) (no standing to pursue injunctive relief without evidence plaintiffs would actually purchase product if manufacturer made requested changes).

At best, her declaration states that she will continue to incur costs "[a]s long as fluoridation chemicals are added to my city's water supply" (3-ER-345), but she did not declare that she would start using the public water supply absent artificial fluoridation or that she would even consider drinking the water with its naturally occurring levels of fluoride. Thus, similar to *Coca-Cola*, her declaration does not provide evidence she would actually use the public water if the change were made. *See* 2021 WL 3878654, at *2.

Indeed, based on her declarations, Trader would be unlikely to start drinking from the public water supply given its naturally occurring fluoride levels and thus would continue to incur costs to avoid the fluoride in that water. Trader's second declaration emphasizes that she has "done everything within my power to protect [my daughter] from fluoridation chemicals" and that she strives to provide "only non-fluoridated, or defluoridated, water." 3-ER-344 (Decl. ¶¶ 11, 13). And Trader's *first* declaration emphasizes that Trader has other reasons to avoid fluoride and does "whatever I reasonably can to limit my ingestion of fluoride" including by purchasing bottled water. 3-ER-594 (Dec. ¶ 7). Given her goals and documented aversion to fluoride, and given the naturally occurring fluoride in her community drinking water, it is likely Trader will continue to spend her money to filter her tap water or buy bottled water.

Plaintiffs have thus not met their burden of proving that Trader's injury is caused by EPA or would be redressed by winning this suit. *See, e.g.*, *Lujan*, 504 U.S. at 571 ("The short of the matter is that redress of the only injury in fact respondents complain of requires action...by the individual funding agencies; and any relief the District Court could have provided in this suit against the Secretary was not likely to produce that action."); *California v. Texas*, 593 U.S. 659, 678-80 (2021) (where injury is attributable to something *other than* challenged provision, redressability is lacking); *Gonzales v. Gorsuch*, 688 F.2d 1263, 1267 (9th Cir. 1982)

("The focus [of the redressability inquiry], however, is always upon the ability of the court to redress the injury suffered by the plaintiff…if the court is unable to grant the relief that relates to the harm, the plaintiff lacks standing.").

Trader's asserted injury is that "[p]eriodically purchasing filter cartridges and regularly purchasing bottled water…has been a substantial expense," 3-ER-345, but as explained, natural fluoride will remain in her public drinking water regardless of EPA action under TSCA. Thus, the only asserted injury supporting Plaintiffs' standing is not caused by EPA's denial of Plaintiff's petition and cannot be redressed by this suit. This Court should reverse and remand with instructions to dismiss for lack of Article III standing.

II. Section 21 does not permit petitioners to use a Section 21 lawsuit to build a functionally new petition.

In a district court suit such as this one, seeking to compel a TSCA Section 6 rulemaking, TSCA Section 21 limits a plaintiff to presenting to the court the facts, including the issues and evidence, presented by the petition; it does not permit a plaintiff to use the judicial process to build an entirely new petition and case. Even if Section 21 allows a plaintiff limited leeway to present new evidence to the court, it does not allow the plaintiff to continually update the evidentiary basis for its petition even as trial is ongoing. A contrary interpretation is at odds with the text and structure of Section 21, which contemplates that the court will review the "petition," and inconsistent with the provision's exhaustion requirement.

In contrast to other TSCA judicial review provisions, Section 21 details both the substantive and procedural steps a petitioner must follow before filing suit. *Compare* 15 U.S.C. § 2620(a), *with id.* §§ 2618 (judicial review), § 2619 (citizen suit). Section 21 requires a person to identify in their petition whether they seek a rule or order, and under what particular section or sections of TSCA. *Id.* § 2620(a). Section 21 also requires the petition to "set forth the facts which it is claimed establish that it is necessary to issue" the relevant rule or order. *Id.* § 2620(b)(1). As explained above (pp.9-10), the "facts which it is claimed establish it is necessary" is a high bar, although the particular showing required varies based on the section of TSCA the petition invokes (e.g., Sections 4, 5, 6, or 8) and the type of relief requested (i.e., issuance of a rule or order versus amendment or repeal of a rule or order).

In the case of a petitioner seeking issuance of a Section 6(a) rule, the petitioner must demonstrate that the subject chemical presents an "unreasonable risk" by proffering the scientific evidence to support such a determination by the agency. *See supra* at pp.5-8 (discussing risk evaluations). Because EPA has only 90 days to evaluate the petition, a petition to initiate a Section 6(a) rulemaking cannot be granted based merely on the assertion that "Chemical X presents an unreasonable risk because it causes adverse effects."

Congress anticipated that EPA's review of Section 21 petitions would be meaningful, as it expressly provided that EPA may "hold a public hearing or may conduct such investigation or proceeding as [EPA] deems appropriate in order to determine whether or not" to grant the petition. *Id.* § 2620(b)(2). In short, Congress intended the petitioner to bring forth relevant information, and for EPA to expeditiously evaluate this evidence, along with any other evidence the agency deems relevant, in the first instance.

If EPA denies the petition, the petitioner may of course go to court. *Id.* § 2620(b)(4)(A). But the object of the court's inquiry in this context is not whether a chemical presents an unreasonable risk in the abstract. To the contrary, the focus of the court's "consider[ation]" is "such petition." *Id.* § 2620(b)(4)(B). The phrase "such petition," which is used six times in Section 21, encompasses the facts and evidence petitioners identify as "establish[ing] it is necessary to issue" the requested "rule or order." The judicial proceeding thus concerns whether the *petition* has established that the requested action is necessary under the statute.

Put differently, Congress consciously decided in Section 21 to require petitioners to seek relief from EPA and to meet certain requirements in doing so before going to court. *Id.* § 2620(b)(1). Section 21 does not just require notice; if Congress had intended to limit the Section 21 requirement to a notice requirement, it would have limited the plaintiffs' obligation to providing "notice" as it did in

Section 20 (as well as in citizen-suit provisions in many other environmental statutes). *Id.* § 2619. But in Section 21, Congress expressly required petitioners to exhaust their administrative remedies before proceeding to court, as indicated by the fact that the suit for a new rule or order contemplated by Section 21 concerns "such petition." *Id.* § 2620(b)(4)(A).

To the limited extent there may be flexibility under Section 21 for a court to consider evidence developed after the denial of the petition, that flexibility does not extend to the situation here. The district court's approach eviscerated the statutory exhaustion requirements and transformed Section 21's administrative exhaustion requirement into a mere notice provision as in regular citizen suits. *Cf. id.* § 2619(b)(2). The court allowed Plaintiffs to present voluminous, extensive evidence well beyond that presented to EPA in the first instance in 2016. *See* 1-ER-30 (describing evidence at end of *first* trial as "what is before this Court is an entirely different body of evidence—not entirely, but a substantially different body of evidence that was presented to the EPA"). Indeed, much of the evidence did not exist even when petitioners filed their "supplement" in 2020. Plaintiffs' petition did not (and could not have) "set forth…facts" based on evidence that did not exist at the time they filed the petition, and EPA could not have erred in denying the petition when the evidence that both Plaintiffs and the court later considered crucial to a finding of unreasonable risk did not exist when EPA published its denial. An

examination of the court's final merits order reveals that the court relied overwhelmingly on studies that post-date the original 2016 petition, and even the later "supplement." For example, in the hazard identification section of the decision, the court focused extensively on the NTP monograph finally published in 2024, and the vast majority of the studies the court discussed in detail post-date 2016 and 2020. 2-ER-86-105. When identifying points of departure or hazard levels, the court relied on publications from 2022 and 2023. 2-ER-113-122. The court even relied upon a paper (Taher 2024) that was published *during* the trial. *See supra* at p.29 n.6.

The facts here highlight why Congress opted for a robust exhaustion requirement. As in other contexts, Congress here required exhaustion to ensure that EPA would have "a fair and full opportunity" to consider the matter in the first instance. *See Woodford v. Ngo*, 548 U.S. 81, 90 (2006). That is especially relevant here, where the petition raises a complex scientific question and must set forth facts that establish a rule is necessary. Congress also required EPA to publish its "reasons" for any denial. 15 U.S.C. § 2620(b)(3). As the Supreme Court explained in *Woodford*, such exhaustion requirements only work if courts require "proper exhaustion," by declining to overturn agency decisions unless the challenging party raised the relevant issues and objections at the appropriate time before the agency. *See* 548 U.S. at 90 (citing *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952)).

The district court allowed Plaintiffs to introduce a rolling evidentiary record based on newly emerging studies—not even limited by what was published at the start of trial. That approach rendered Section 21's exhaustion provision essentially meaningless. *See, e.g.*, 1-ER-31 (expressing confusing view that "even if there is no formal doctrine of administrative exhaustion, and I don't see anything in the TSCA that requires it, other than having petition and going through the process"—that is the very process requiring exhaustion). It is implausible that Congress expressly required a plaintiff to exhaust and EPA to quickly respond to a petition but silently sanctioned an open-ended, costly, and resource-intensive process for developing the evidence through years of discovery and multiple trials.

As explained below in Part III, the court not only allowed Plaintiffs to effectively bypass the exhaustion requirement but took on an inquisitorial approach more akin to that of EPA in its role as an executive agency. That conduct amplified the court's legal error when interpreting Section 21. The court mistakenly believed that because the statute requires a "de novo proceeding," all the evidence that *could* be put before the court must be evaluated, even if the parties disclaimed their interest in that evidence. *See* 4-ER-702 ("[S]ince, under the act, the Court has to make a de novo determination, I really wanted to get the latest and the most available evidence possible. And that's still my goal."). Thus, the court concluded that the entire case

should be placed in abeyance post-trial to allow it to review relevant studies. *See supra* at pp.22-27.

The court indulged this process at least in part because of its wrongful interpretation of Section 21. Section 21's text requires the court to consider "such petition" and to make a discrete judgment on whether the "*petitioner* demonstrates" that an unreasonable risk exists. 15 U.S.C. § 2620(b)(4)(B) (emphasis added). Section 21 does not contemplate the court overriding the parties' judgments about what evidence should be collected to decide that question. Nor does it authorize the court to step into the role of EPA and conduct an open-ended, years-long process to allow scientific evidence to develop and then to revisit the question, effectively detached from the original petition. The court's misunderstanding of the statute and the role of exhaustion in this context led it down the troubling path it took here.

The court erroneously based its liberal approach to the evidence on Section 21's reference to a "de novo proceeding." *Id.* But a "de novo proceeding" is not license for Section 21 plaintiffs to introduce any evidence whatsoever, regardless of whether it existed at the time of the original petition. Rather, read in the context of Section 21 overall, a "de novo proceeding" is a new judicial proceeding rather than a continuation of any "investigation or proceeding" conducted by EPA in evaluating the petition. *Id.* § 2620(b)(2). "De novo proceeding" also means that the court conducts the proceeding without deference to the findings and reasons in EPA's

denial of the petition. Put differently, it is a fresh proceeding that does not defer to EPA's administrative findings; it is not an invitation to the Section 21 plaintiff to build a new petition, unbounded by the facts and evidence set forth in the original petition.

To the extent the court thought *Kappos v. Hyatt*, 566 U.S. 431 (2012) supported the notion that petitioners may circumvent Section 21's administrative exhaustion requirement (1-ER-63), the court was mistaken. In *Kappos*, the Supreme Court found that in suits brought under Section 145 of the Patent Act, "principles of administrative exhaustion do not apply." 566 U.S. at 438. But both textually and structurally, 35 U.S.C. § 145 differs from TSCA Section 21. Unlike Section 145 of the Patent Act, TSCA Section 21 expressly sets forth the petition process and then expressly limits the court's consideration to "such petition." *Compare* 15 U.S.C. § 2620, *with* 35 U.S.C. § 145. Moreover, in concluding that Section 145 does not place limits on a patent applicant's ability to introduce new evidence, the Supreme Court relied heavily on the long history of patent law prior to the statute's enactment, which had allowed patent applicants to introduce new evidence. *Kappos*, 566 U.S. at 439-46. No similar history supports such an approach with respect to TSCA Section 21. Furthermore, *Kappos* involved the validity of patent applications. The TSCA context is quite different; as this case demonstrates, new studies are continuously published concerning chemical risks.

Finally, EPA's interpretation of Section 21 makes eminent sense. If new evidence arises that is relevant to a chemical of concern, persons may always file a new petition, triggering a new 90-day review window by EPA. That is the correct approach to newly developed science, not a court holding onto a case for seven years, conducting two trials, refusing to rule on Plaintiffs' standing, and badgering EPA into revisiting the petition to consider new studies in the midst of proceedings.

The district court erred by interpreting Section 21 to permit Plaintiffs to introduce voluminous materials that did not exist at the time of the administrative proceeding into the record and by basing its ruling on those materials.

III. The district court's takeover of the case and participation as advocate and self-directed inquisitor was an abuse of discretion.

Federal courts function in an adversarial system of adjudication whereby they "rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present." *United States v. Sineneng-Smith*, 590 U.S. 371, 375 (2020). This system is "designed around the premise that the parties know what is best for them, and are responsible for advancing the facts and arguments entitling them to relief." *Greenlaw v. United States*, 554 U.S. 237, 244 (2008) (quotation omitted). Thus, "courts do not sit as self-directed boards of legal inquiry and research, but essentially as arbiters of legal questions presented and argued by the parties before them." *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983) (Scalia, J.). This constraint on judicial review—referred to as the party-

presentation principle—promotes "fundamental interests" that "exist, at their shared core, to protect and ensure judicial neutrality and humility." *United States v. Campbell*, 26 F.4th 860, 894-97 (11th Cir. 2022) (en banc) (Newsom and Jordan, JJ., dissenting).

While *Sineneng-Smith* involved a court violating the party-presentation principle when it decided legal issues not presented by the parties, courts may also violate the party-presentation principle by overstepping their role in other ways, including by improperly shaping the facts and evidence presented to the court. *Sineneng-Smith*, 590 U.S. at 375-76 ("But as a general rule, our system 'is designed around the premise that parties represented by competent counsel know what is best for them, and are responsible for advancing *the facts* and argument entitling them to relief.'") (quoting *Castro v. United States*, 540 U.S. 375, 386 (2003) (Scalia, J., concurring part and concurring in the judgment)) (emphasis added). The party-presentation principle is animated by the proper role of parties and courts in the adversarial system: "courts are essentially passive instruments of government. They do not, or should not, sally forth each day looking for wrongs to right. They wait for cases to come to them, and when cases arise, courts normally decide only questions presented by the parties." *Id.* at 376 (cleaned up and citation omitted). In short, it is no less inappropriate to shape the evidence and contours of a proceeding than it is to shape the legal claims presented. *See Duncan et al. v. Bonta*, 133 F.4th

852, 889-90 (9th Cir. 2025) (Berzon, J., concurring) (discussing applicability of party presentation principle to situation where judge was alleged to have improperly shaped the factual record).

The district court violated the party-presentation principle. After the close of the first trial, the court's conduct confirmed that it believed the court, not the parties, "kn[e]w what [wa]s best for them." *Sineneng-Smith*, 590 U.S. at 375 (quotation omitted). In particular, the court repeatedly refused to rule on the first trial record despite the parties' repeated requests that it should. It insisted on curing Plaintiffs' standing problem even when Plaintiffs believed they had met their burden and both sides teed the issue up for resolution. And it subsequently shaped the second trial record by holding the case in abeyance while an additional study the parties had agreed not to admit was completed. In doing so, the court inappropriately stepped into the role of advocate and inquisitor rather than neutral arbiter.

After the first trial, both sides considered the case ready for a decision and repeatedly conveyed as much to the court. EPA asked the court to rule on Plaintiffs' standing. EPA argued in closing—consistent with its position before trial—that Plaintiffs had not submitted evidence demonstrating that they had a member who had suffered the type of neurotoxic harm that was the overwhelming focus of the scientific evidence presented at trial. 5-ER-1058-59. And the court agreed, both at the August 6, 2020 hearing and in its order putting the case in abeyance. The latter

order found it "doubtful" that Plaintiffs "have carried their burden of demonstrating that [their asserted injuries] would likely be redressed by a favorable ruling from the Court." 1-ER-25, 1-ER-25 ("Plaintiffs' standing is also problematic because the evidence of the harm alleged by the named Plaintiffs was practically non-existent at trial."); 1-ER-34-35.

For their part, Plaintiffs agreed with EPA that standing was ready for adjudication. They asserted after the close of trial that they wanted to brief standing on the evidence presented, 1-ER-48-49, submitted post-trial briefing on the issue, and during the August 6, 2020 hearing, reiterated their view that "the case law is—is strongly on our side for having met our burden," 4-ER-771. Rather than rule on the issue—which the parties contended could be resolved on the trial record—the court placed the case in abeyance, explaining why Plaintiffs had failed to meet their burden, and directing Plaintiffs to file a new petition to "enable Plaintiffs to address the serious standing issues" identified by the court. 1-ER-26-27.

Beyond the jurisdictional issue, both parties repeatedly informed the court that the case was ready for adjudication on the merits. *See, e.g.*, 1-ER-33-34; *supra* at pp.19-22, 27. For instance, both parties presented proposed findings of fact and conclusions of law following trial—with the obvious intent that the court issue ultimate findings of fact and conclusions of law. EPA objected to putting the case in abeyance and requested a ruling. 4-ER-768. The parties again offered the court

an opportunity to decide the case on the trial record in Fall 2022, two years after the court entered its abeyance. EPA's filing clearly communicated that *both* parties agreed the court should decide the case based on the first trial record. 5-ER-844 (EPA); 5-ER-854 (Plaintiffs); *supra* at p.27.

From the close of the first trial onward, the court instead pushed the parties into a process shaped by the court's own judgment about both strategy and evidence. Rather than rule on the evidence from the first trial, the court demanded that the parties enter into an administrative process. 1-ER-26-27. The court directed Plaintiffs to supplement their petition and told EPA that it should consider it—notwithstanding EPA's protest that there was no legal basis to supplement a petition—at the close of the first trial, again at a status conference in August, and in its order putting the case in abeyance. *See, e.g.*, 1-ER-33-37; 4-ER-772; 1-ER-26-27. But the court did not merely express interest or suggest the parties pursue this course of action; rather, the court "*direct[ed]* Plaintiffs to file a new petition with EPA," and repeatedly urged EPA to consider the new petition and warned that the court would allow in new evidence including "new studies published since the trial in this case." 1-ER-26-27 (emphasis added).

When that administrative process did not resolve the parties' dispute, however, the court did not reconsider ruling on the trial record. Instead, the court insisted upon a fresh judicial proceeding where Plaintiffs could cure their standing

defect. It permitted Plaintiffs to amend their complaint to cure this defect, twice overruling EPA's objections, 5-ER-984-85, 5-ER-899-909, that doing so was improper in light of the parties' stipulation limiting the evidence that could be presented on standing "throughout this litigation, including trial," 3-ER-352.

The court was not satisfied merely to fix Plaintiffs' jurisdiction problems; it also apparently believed Plaintiffs' evidence on the merits was also insufficient. In fact, the court insisted on seeing the NTP monograph that the parties had ultimately *agreed* not to present at the first trial. *See supra* at p.15 & n.5; 5-ER-1092, 4-ER-779-81, 5-ER-1081. Both parties believed that their case was sufficient without it. Yet at the close of trial, the court indicated that it wished to see the NTP monograph, notwithstanding the parties' agreement otherwise. As the court explained, "the parties came to an agreement not to introduce [the draft NTP monograph], for whatever reason. So it's fine. So it hasn't come in. But the Court is aware that this is a significant study. It's coming from the NTP…But it is obviously an important piece of evidence." 1-ER-29. The court reaffirmed this view in its abeyance order, asserting that the monograph's "findings are likely to add substantially to the body of scientific analysis relevant to the precise questions before this court." 1-ER-26. It repeated this view in the hearing on the motion to supplement, noting that its "[g]otta have to [sic] the NTP" monograph before ruling. 4-ER-722. And in granting Plaintiffs' motion to supplement, the court ruled that the abeyance would

continue "at least until the final NTP monograph is released and possibly until the Canadian, Mexican, and Spanish cohorts are peer-reviewed." 1-ER-15.

It is not surprising, then, that the court waited for new studies more than a year, until Plaintiffs informed the court that they wished to wait no longer. At that point, the court permitted another year of fact and expert discovery on new evidence—despite both parties insisting that the court already had the evidence necessary to resolve the case before it.

The court's conduct after the first trial's closing arguments was inappropriate, and it was also prejudicial to the United States. It resulted in (1) Plaintiffs being allowed to cure their jurisdictional defect with new standing evidence, notwithstanding the parties' agreed-upon stipulation and Plaintiffs' failure to meet their standing burden; (2) a second round of invasive, expensive, and disputatious discovery; (3) a second trial; and (4) a ruling on the merits based nearly entirely on evidence developed during (and to some extent even after) the court-imposed abeyance.

Following the first trial, the court cannot reasonably be said to have played a "modest initiating role" of a neutral arbiter, deciding the facts and issues put before it. To the contrary, the court improperly stepped into the role of inquisitor, seeking to correct the perceived strategic missteps of Plaintiffs' counsel and to investigate the facts of the case and gather evidence itself, rather than as a neutral

arbiter. *McNeil v. Wisconsin,* 501 U.S. 171, 181 n. 2 (1991) ("What makes a system adversarial rather than inquisitorial is...the presence of a judge who does not (as an inquisitor does) conduct the factual and legal investigation himself, but instead decides on the basis of facts and arguments pro and con adduced by the parties.").

To be clear, the United States does not dispute that the court acted with good intentions. Regardless of the court's intentions, however, its conduct transformed the court from a neutral arbiter into an advocate. The court improperly refused to reach either jurisdictional or merits issues after the first trial (despite acknowledging "serious concerns" about Plaintiffs' standing), and the court decided to hold the case for evidence that *the court* deemed appropriate and necessary (despite the parties' assertions that the record was sufficient for a ruling). The court effectuated a "takeover" of the case that was inconsistent with the party presentation principle and amounted to abuse of discretion. This Court has not hesitated to reverse on party-presentation grounds where, as here, the court disregards a case presented by competent counsel. *See Todd R. v. Premera Blue Cross Blue Shield of Alaska*, 825 Fed. App'x. 440, 442 (9th Cir. 2020) (noting that the presumption that parties represented by competent counsel know what is best for them "naturally applies all the more in a case such as this, involving a specialized area of civil law and competent, highly experienced counsel on both sides").

* * * * *

This Court should reverse the court's findings of fact and conclusions of law, which were based overwhelmingly on evidence developed after the first trial, and rewind the case to the close of the first trial. Alternatively, this Court may reverse and remand with instructions to dismiss, because Plaintiffs' standing at the time of the first trial is a legal issue, and they plainly did not meet their burden. As the district court explained at that time: "[n]one of the standing Plaintiffs in this case claim to be subject to [the] risk of harm" that the evidence at trial could have established flowed from fluoridation in drinking water. 1-ER-24. Alternatively, the Court should remand to the district court for a ruling based on the evidence presented at the first trial.

CONCLUSION

For the foregoing reasons, the Court should reverse.

Respectfully submitted,

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STATEMENT OF RELATED CASES

Counsel for Appellants is aware of no related cases within the meaning of Circuit Rule 28-2.6 that are currently pending in this Court.

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Form 8. Certificate of Compliance for Briefs

9th Cir. Case Number(s) 25-384

I am the attorney or self-represented party.

This brief contains 13,825 words, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

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Date July 18, 2025

ADDENDUM

making the substitution for "notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c)" to reflect the probable intent of Congress.

Pub. L. 114–182, § 5(5)(B)(i), substituted "An order" for "A proposed order".

Subsec. (e)(1)(C). Pub. L. 114–182, § 5(5)(C), struck out subpar. (C) which read as follows: "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."

Subsec. (e)(2). Pub. L. 114–182, § 5(5)(D), struck out par. (2) which related to injunctions to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance.

Subsec. (f)(1). Pub. L. 114–182, § 5(6)(A), substituted "determines that a chemical substance or significant new use with" for "finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with", ", 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," for "before a rule promulgated under section 2605 of this title can protect against such risk," and "applicable review period" for "notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance" and struck out ", or that any combination of such activities," after "required by subsection (a)" and "or will present" after "presents".

Subsec. (f)(2). Pub. L. 114–182, § 5(6)(B), substituted "Section 2605(d)(3)(B)" for "Section 2605(d)(2)(B)" in concluding provisions.

Subsec. (f)(3)(A). Pub. L. 114–182, § 5(6)(C)(i), substituted "Administrator may" for "Administrator may—", struck out cl. (i) designation before "issue", substituted "an order to prohibit or limit the" for "a proposed order to prohibit the" and "under paragraph (1). Such order shall take effect on the expiration of the applicable review period." for "under paragraph (1), or", and struck out cl. (ii) and concluding provisions which read as follows:

"(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) to the manufacture or processing of such substance."

Subsec. (f)(3)(B), (C). Pub. L. 114–182, § 5(6)(C)(ii), (iii), redesignated subpar. (C) as (B), substituted "subparagraph (B)" for "subparagraphs (B) and (C)", struck out "clause (i) of" after "order issued under" and "; and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B)" after "subparagraph (A)", and struck out former subpar. (B) which read as follows: "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."

Subsec. (f)(3)(D). Pub. L. 114–182, § 5(6)(C)(iv), struck out subpar. (D) which read as follows: "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), 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."

Subsec. (f)(4), (5). Pub. L. 114–182, § 5(6)(D), added pars. (4) and (5).

Subsec. (g). Pub. L. 114–182, § 5(7), amended subsec. (g) generally. Prior to amendment, text read as follows: "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), 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."

Subsec. (h)(1)(A). Pub. L. 114–182, § 5(8)(A), inserted ", 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" after "health or the environment".

Subsec. (h)(2). Pub. L. 114–182, § 5(8)(B), substituted "information" for "data" wherever appearing.

Subsec. (h)(4). Pub. L. 114–182, § 5(8)(C), substituted "environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use" for "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".

Subsec. (i). Pub. L. 114–182, § 5(9), amended subsec. (i) generally. Prior to amendment, text read as follows: "For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes."

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

§ 2605. Prioritization, risk evaluation, and regulation of chemical substances and mixtures

(a) Scope of regulation

If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk:

(1) A requirement (A) prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such sub-

stance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting or otherwise restricting 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 minimum 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 minimum 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 or 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 determination 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 determination, 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) Risk evaluations

(1) Prioritization for risk evaluations

(A) Establishment of process

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

(B) Identification of priorities for risk evaluation

(i) High-priority substances

The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

(ii) Low-priority substances

The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

(C) Information request and review and proposed and final prioritization designation

The rulemaking required in subparagraph (A) shall ensure that the time required to make a priority designation of a chemical substance be no shorter than nine months and no longer than 1 year, and that the process for such designations includes—

(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided;

(ii) a requirement that the Administrator publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90

days for public comment on each such proposed designation; and

(iii) a process by which the Administrator may extend the deadline in clause (i) for up to three months in order to receive or evaluate information required to be submitted in accordance with section 2603(a)(2)(B) of this title, subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

(2) Initial risk evaluations and subsequent designations of high- and low-priority substances

(A) Initial risk evaluations

Not later than 180 days after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.

(B) Additional risk evaluations

Not later than three and one half years after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

(C) Continuing designations and risk evaluations

The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with this subsection at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

(D) Preference

In designating high-priority substances, the Administrator shall give preference to—

(i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and

(ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(E) Metals and metal compounds

In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(3) Initiation of risk evaluations; designations

(A) Risk evaluation initiation

Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

(B) Revision

The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

(C) Ongoing designations

The Administrator shall designate at least one high-priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

(4) Risk evaluation process and deadlines

(A) In general

The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance 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 to the risk evaluation by the Administrator, under the conditions of use.

(B) Establishment of process

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

(C) Requirement

The Administrator shall conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B), for a chemical substance—

(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

(D) Scope

The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

(E) Limitation and criteria

(i) Percentage requirements

The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subparagraph (C), the number of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is—

(I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and

(II) not more than 50 percent.

(ii) Requested risk evaluations

Requests for risk evaluations under subparagraph (C)(ii) shall be subject to the payment of fees pursuant to section 2625(b) of this title, and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations.

(iii) Preference

In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

(iv) Exceptions

(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) shall not be subject to section 2617(b) of this title.

(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

(F) Requirements

In conducting a risk evaluation under this subsection, the Administrator shall—

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

(v) describe the weight of the scientific evidence for the identified hazard and exposure.

(G) Deadlines

The Administrator—

(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates the risk evaluation under subparagraph (C); and

(ii) may extend the deadline for a risk evaluation for not more than 6 months.

(H) Notice and comment

The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.

(c) Promulgation of subsection (a) rules

(1) Deadlines

If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator—

(A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

(C) may extend the deadlines under this paragraph for not more than 2 years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed 2 years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

(2) Requirements for rule

(A) Statement of effects

In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, including consideration of—

(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

(B) Selecting requirements

In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

(C) Consideration of alternatives

Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

(D) Replacement parts

(i) In general

The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

(ii) Definitions

In this subparagraph—

(I) the term "complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

(II) the term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

(E) Articles

In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

(3) Procedures

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) promulgate a final rule based on the matter in the rulemaking record; and

(D) make and publish with the rule the determination described in subsection (a).

(d) Effective date

(1) IN GENERAL.—In any rule under subsection (a), the Administrator shall—

(A) specify the date on which it shall take effect, which date shall be as soon as practicable;

(B) except as provided in subparagraphs (C) and (D), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);

(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and

(E) provide for a reasonable transition period.

(2) VARIABILITY.—As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.

(3)(A) The Administrator may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 2605(a) of this title or until the Administrator revokes such

proposed rule, in accordance with subparagraph (B), 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 without consideration of costs or other non-risk factors; 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 in accordance with subsection (c), and 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 paragraph (3) of subsection (c).

(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.

(f) Mercury

(1) Prohibition on sale, distribution, or transfer of elemental mercury by Federal agencies

Except as provided in paragraph (2), effective beginning on October 14, 2008, no Federal agency shall convey, sell, or distribute to any other Federal agency, any State or local government agency, or any private individual or entity any elemental mercury under the control or jurisdiction of the Federal agency.

(2) Exceptions

Paragraph (1) shall not apply to—

(A) a transfer between Federal agencies of elemental mercury for the sole purpose of facilitating storage of mercury to carry out this chapter; or

(B) a conveyance, sale, distribution, or transfer of coal.

(3) Leases of Federal coal

Nothing in this subsection prohibits the leasing of coal.

(g) Exemptions

(1) Criteria for exemption

The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific condition of

use of a chemical substance or mixture, if the Administrator finds that—

(A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

(B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or

(C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

(2) Exemption analysis and statement

In proposing an exemption under this subsection, the Administrator shall analyze the need for the exemption, and shall make public the analysis and a statement describing how the analysis was taken into account.

(3) Period of exemption

The Administrator shall establish, as part of a rule under this subsection, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary.

(4) Conditions

As part of a rule promulgated under this subsection, the Administrator shall include conditions, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

(h) Chemicals that are persistent, bioaccumulative, and toxic

(1) Expedited action

Not later than 3 years after June 22, 2016, the Administrator shall propose rules under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments—

(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 2603 of this title, prior to June 22, 2016; and

(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) No risk evaluation required

The Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

(3) Final rule

Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

(4) Selecting restrictions

In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable.

(5) Relationship to subsection (b)

If, at any time prior to the date that is 90 days after June 22, 2016, the Administrator makes a designation under subsection (b)(1)(B)(i), or receives a request under subsection (b)(4)(C)(ii), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

(i) Final agency action

Under this section and subject to section 2617 of this title—

(1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order; and

(2) a final rule promulgated under subsection (a), including the associated determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

(j) Definition

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

(Pub. L. 94–469, title I, § 6, Oct. 11, 1976, 90 Stat. 2020; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 109–364, div. A, title III, § 317(a), Oct. 17, 2006, 120 Stat. 2142; Pub. L. 110–414, § 3, Oct. 14, 2008, 122 Stat. 4342; Pub. L. 114–182, title I, § 6, June 22, 2016, 130 Stat. 460.)

AMENDMENTS

2016—Pub. L. 114–182, § 6(1), substituted "Prioritization, risk evaluation, and regulation of chemical substances

and mixtures'' for ''Regulation of hazardous chemical substances and mixtures'' in section catchline.

Subsec. (a). Pub. L. 114–182, § 6(2)(A)–(D), in introductory provisions, substituted ''determines in accordance with subsection (b)(4)(A)'' for ''finds that there is a reasonable basis to conclude'' and ''so that the chemical substance or mixture no longer presents such risk'' for ''to protect adequately against such risk using the least burdensome requirements'', struck out ''or will present'' after ''presents'', and inserted ''and subject to section 2617 of this title, and in accordance with subsection (c)(2),'' after ''shall by rule''.

Subsec. (a)(1)(A), (2)(A). Pub. L. 114–182, § 6(2)(E), inserted ''or otherwise restricting'' after ''prohibiting''.

Subsec. (a)(3). Pub. L. 114–182, § 6(2)(F), inserted ''minimum'' before ''warnings'' in two places.

Subsec. (a)(4). Pub. L. 114–182, § 6(2)(G), substituted ''or monitor or conduct tests'' for ''and monitor or conduct tests''.

Subsec. (a)(7). Pub. L. 114–182, § 6(2)(H), substituted ''such determination'' for ''such unreasonable risk of injury'' in subpar. (A) and for ''such risk of injury'' in subpar. (B).

Subsec. (b). Pub. L. 114–182, § 6(3), amended subsec. (b) generally. Prior to amendment, subsec. (b) related to quality control procedures in the manufacturing or processing of a chemical substance or mixture to prevent unreasonable risk of injury to health or the environment.

Subsec. (c). Pub. L. 114–182, § 6(4), amended subsec. (c) generally. Prior to amendment, subsec. (c) related to promulgation of subsection (a) rules.

Subsec. (d)(1), (2). Pub. L. 114–182, § 6(5)(B), added pars. (1) and (2) and struck out former par. (1) which read as follows: ''The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.'' Former par. (2) redesignated (3).

Subsec. (d)(3). Pub. L. 114–182, § 6(5)(A), redesignated par. (2) as (3).

Subsec. (d)(3)(A). Pub. L. 114–182, § 6(5)(C)(i)(I), in introductory provisions, substituted '', and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 2605(a) of this title or until the Administrator revokes such proposed rule, in accordance with subparagraph (B), if'' for ''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''.

Subsec. (d)(3)(A)(i)(I). Pub. L. 114–182, § 6(5)(C)(i)(II), inserted ''without consideration of costs or other non-risk factors'' after ''effective date''.

Subsec. (d)(3)(B). Pub. L. 114–182, § 6(5)(C)(ii), substituted ''in accordance with subsection (c), and either promulgate such rule (as proposed or with modifications) or revoke it.'' for '', provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), 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.''

Subsec. (e)(4). Pub. L. 114–182, § 6(6), substituted ''paragraph (3)'' for ''paragraphs (2), (3), and (4)''.

Subsecs. (g) to (j). Pub. L. 114–182, § 6(7), added subsecs. (g) to (j).

2008—Subsec. (f). Pub. L. 110–414 added subsec. (f).

2006—Subsec. (e)(3)(A). Pub. L. 109–364, § 317(a)(1), (b), temporarily substituted ''subparagraphs (B), (C), and (D)'' for ''subparagraphs (B) and (C)'' in introductory provisions. See Termination Date of 2006 Amendment note below.

Subsec. (e)(3)(B). Pub. L. 109–364, § 317(a)(2), (b), temporarily substituted ''but not more than 1 year from the date it is granted, except as provided in subparagraph (D)'' for ''but not more than one year from the date it is granted'' in concluding provisions. See Termination Date of 2006 Amendment note below.

Subsec. (e)(3)(D). Pub. L. 109–364, § 317(a)(3), (b), temporarily added subpar. (D) which read as follows: ''The Administrator may extend an exemption granted pursuant to subparagraph (B) that has not yet expired for a period not to exceed 60 days for the purpose of authorizing the Secretary of Defense and the Secretaries of the military departments to provide for the transportation into the customs territory of the United States of polychlorinated biphenyls generated by or under the control of the Department of Defense for purposes of their disposal, treatment, or storage in the customs territory of the United States if those polychlorinated biphenyls are already in transit from their storage locations but the Administrator determines, in the sole discretion of the Administrator, they would not otherwise arrive in the customs territory of the United States within the period of the original exemption. The Administrator shall promptly publish notice of such extension in the Federal Register.'' See Termination Date of 2006 Amendment note below.

TERMINATION DATE OF 2006 AMENDMENT

Pub. L. 109–364, div. A, title III, § 317(b), Oct. 17, 2006, 120 Stat. 2142, provided that: ''The amendments made by subsection (a) [amending this section] shall cease to have effect on September 30, 2012. The termination of the authority to grant exemptions pursuant to such amendments shall not effect the validity of any exemption granted prior to such date.''

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 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)) 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 determination under section 2604 or 2605 of this title, a rule under section 2603, 2604, or 2605 of this title or subchapter IV, an order under section 2603, 2604, or 2605 of this title or subchapter IV, or a consent agreement under section 2603 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)(3)(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).

§ 2619. Citizens' civil actions

(a) In general

Except as provided in subsection (b), any person may commence a civil action—

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this chapter or any rule promulgated under section 2603, 2604, or 2605 of this title, or subchapter II or IV, or order issued under section 2603 or 2604 of this title or subchapter II or IV to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this chapter which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) Limitation

No civil action may be commenced—

(1) under subsection (a)(1) to restrain a violation of this chapter or rule or order under this chapter—

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 2615(a)(2) of this title to require compliance with this chapter or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this chapter or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such proceeding or action;

(2) under subsection (a)(2) before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 2606 of this title, before the expiration of ten days after such notification, except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 2617(f)(3)(B) of this title; or

(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to section 2617(f)(3)(B) of this title, after the date that is 60 days after the deadline specified in section 2617(f)(3)(B) of this title.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) General

(1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this chapter or any rule or order under this chapter or to seek any other relief.

(d) Consolidation

When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in—

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

(Pub. L. 94–469, title I, § 20, Oct. 11, 1976, 90 Stat. 2041; renumbered title I and amended Pub. L. 99–519, § 3(b)(3), (c)(1), Oct. 22, 1986, 100 Stat. 2989; Pub. L. 102–550, title X, § 1021(b)(9), Oct. 28, 1992, 106 Stat. 3923; Pub. L. 114–182, title I, §§ 15, 19(n), June 22, 2016, 130 Stat. 498, 509.)

AMENDMENTS

Subsec. (a)(1). Pub. L. 114–182, § 19(n), substituted "order issued under section 2603 or 2604 of this title" for "order issued under section 2604 of this title".

Subsec. (b)(2), (3). Pub. L. 114–182, § 15, substituted ", except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 2617(f)(3)(B) of this title; or" for period at end of par. (2) and added par. (3).

1992—Subsec. (a)(1). Pub. L. 102–550 substituted "subchapter II or IV" for "subchapter II" in two places.

1986—Subsec. (a)(1). Pub. L. 99–519 inserted references to subchapter II of this chapter.

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

§ 2620. Citizens' petitions

(a) In general

Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title.

(b) Procedures

(1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title.

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with section 2603, 2604, 2605, or 2607 of this title. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4)(A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the 90-day period) the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

(B) In an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title, the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 2603 of this title or an order under section 2603 or 2604(e) of this title—

(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and

(II) in the absence of such information, the substance may present an unreasonable risk to health or the environment, or the substance is or will be produced in substantial quantities and it 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 it; or

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 2605(a) or 2607 of this title or an order under section 2604(f) of this title, the chemical substance or mixture to be subject to such rule or order 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, under the conditions of use.[1]

the court shall order the Administrator to initiate the action requested by the petitioner. If the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this chapter and there are insufficient resources available to the Administrator to take the action requested by the petitioner, the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

(Pub. L. 94–469, title I, § 21, Oct. 11, 1976, 90 Stat. 2042; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114–182, title I, § 19(*o*), June 22, 2016, 130 Stat. 509.)

AMENDMENTS

2016—Subsec. (a). Pub. L. 114–182, § 19(*o*)(1), substituted "order under section 2603 or 2604(e) or (f) of this title" for "order under section 2604(e) or 2605(b)(2) of this title".

Subsec. (b)(1). Pub. L. 114–182, § 19(*o*)(2)(A), substituted "order under section 2603 or 2604(e) or (f) of this title" for "order under section 2604(e), 2605(b)(1)(A), or 2605(b)(1)(B) of this title".

Subsec. (b)(4)(B). Pub. L. 114–182, § 19(*o*)(2)(B)(i), substituted "order under section 2603 or 2604(e) or (f) of this title" for "order under section 2604(e) or 2605(b)(2) of this title" in introductory provisions.

Subsec. (b)(4)(B)(i). Pub. L. 114–182, § 19(*o*)(2)(B)(ii), substituted "order under section 2603 or 2604(e) of this title" for "order under section 2604(e) of this title" in introductory provisions.

Subsec. (b)(4)(B)(ii). Pub. L. 114–182, § 19(*o*)(2)(B)(iii), substituted "section 2605(a) or 2607 of this title or an order under section 2604(f) of this title, the chemical substance or mixture to be subject to such rule or order 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, under the conditions of use" for "section 2605 or 2607 of this title or an order under section 2605(b)(2) of this title, there is a reasonable basis to conclude that the issuance of such a

[1] So in original. The period probably should be a semicolon.

rule or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment''.

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

§ 2621. National defense waiver

The Administrator shall waive compliance with any provision of this chapter upon a request and determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this chapter. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the President, the Administrator determines to omit such publication because the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

(Pub. L. 94–469, title I, § 22, Oct. 11, 1976, 90 Stat. 2044; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989.)

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

§ 2622. Employee protection

(a) In general

No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this chapter;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this chapter.

(b) Remedy

(1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within 30 days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the ''Secretary'') alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2)(A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) Review

(1) Any employee or employer adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) Enforcement

Whenever a person has failed to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages.

(e) Exclusion

Subsection (a) of this section shall not apply with respect to 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 chapter.