IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA, **Plaintiff,** **v.** **DENKA PERFORMANCE ELASTOMER LLC and DUPONT SPECIALTY PRODUCTS USA, LLC,** **Defendants.**	**CIVIL ACTION NO. 2:23-cv-735** **JUDGE CARL J. BARBIER** **MAG. JUDGE MICHAEL NORTH**

AMENDED COUNTERCLAIM

NOW INTO COURT, through undersigned counsel, comes Defendant, Denka Performance Elastomer, LLC ("DPE"), which submits this Amended Counterclaim against the United States of America, acting on behalf of the United States Environmental Protection Agency ("EPA") and Michael S. Regan, Administrator of the EPA.

INTRODUCTION

1. DPE operates a manufacturing facility in La Place, Louisiana (the "Facility") that uses a chemical called chloroprene to produce Neoprene, a popular synthetic rubber that is used in a wide array of products, including cars, adhesives, medical devices, wetsuits, and other applications. The Facility is the only Neoprene-producing facility in the United States.

2. In September 2010, EPA released a Toxicological Review of Chloroprene ("2010 Review") in which EPA calculated an "inhalation unit risk" ("IUR") for human exposure to chloroprene of 5×10^{-4} per $\mu g/m^3$ for 70-years continuous exposure ("chloroprene IUR"). Based on the chloroprene IUR, EPA later declared that the chloroprene concentration associated with an incremental lifetime (*i.e.*, 70-year) cancer risk level of 1-in-10,000 was 0.2 $\mu g/m^3$.

3. As described further herein, EPA has historically recognized that IUR values should be used only as a starting point for crafting emissions limits and that, when regulators develop such limits, they must consider the uncertainty inherent in IUR values along with a broad set of health risk measures and information. In the past, EPA has not used IUR values, by themselves, as a basis for setting regulatory standards. Congress expressly endorsed EPA's multi-factor approach to determining the acceptability of risk under Section 112 in the 1990 Amendments to the Clean Air Act. *See* 42 U.S.C. § 7412(f)(2)(B). Therefore, EPA has always relied on IUR values as only one component of a broader risk assessment analysis. However, in 2022, contrary to this long-standing risk assessment protocol, EPA, without explanation, abruptly began imposing the 0.2 μg/m^3 value derived from the chloroprene IUR as a strict limit for ambient chloroprene concentrations ("0.2 μg/m^3 standard").

4. Even worse, EPA has relied upon the chloroprene IUR to derive the 0.2 μg/m^3 standard despite substantial scientific information showing that the chloroprene IUR is based on faulty science. Specifically, in setting and failing to correct the stringent chloroprene IUR, EPA (i) relied upon a default assumption that humans are as sensitive to chloroprene as the female B6C3F1 mouse; (ii) established the IUR as the upper 95 percentile of the "central tendency" for the IUR established with the most sensitive species and gender in the laboratory experiments conducted on the effects of exposure to chloroprene; (iii) applied Age Dependent Adjustment Factors based on a flawed conclusion that chloroprene has a mutagenic mode of action; and (iv) elected not to use a physiologically-based pharmacokinetic ("PBPK") model demonstrating that use of the female B6C3F1 mouse data significantly overstates the carcinogenic risk of chloroprene to humans. EPA's default assumptions are wrong.

5. EPA's establishment of the 0.2 µg/m^3 value as a bright-line standard compounds EPA's scientific errors in setting the chloroprene IUR and continues to impose real harm on DPE. EPA's unprecedented direct application of the chloroprene IUR to enforce compliance with the 0.2 µg/m^3 standard is arbitrary and capricious because EPA (i) contradicts its own risk assessment protocol; (ii) contradicts its historical policy and practice without explanation; and (iii) fails to meaningfully consider substantial scientific information that shows that the strict limit of 0.2 µg/m^3 is not necessary to protect human health or the environment. Further, EPA's establishment of the 0.2 µg/m^3 standard is *ultra vires* because EPA may only issue limits on air pollutants pursuant to procedures set forth in the Clean Air Act and the Administrative Procedure Act. *See* 42 U.S.C. § 7607(d); *see also* 5 U.S.C. §§ 552–553. EPA acted beyond its authority by directing DPE to comply with an ambient air standard without following these requirements, including notice and comment, and considering EPA's longstanding risk protocols.

6. To be very clear, DPE strongly supports effective environmental protection for the Facility's neighbors. Between 2017 and 2020, DPE reduced chloroprene emissions from the Facility by 85 percent (from 118 tons per year ("tpy") to 18 tpy) at a cost to DPE of more than $35 million. *See* EPA and LDEQ, *Summary Report: Air Monitoring for Chloroprene Concentrations near the Denka Performance Elastomer LLC (DPE) Facility in LaPlace, Louisiana, May 25, 2016, through July 16, 2020*, at 1 ("EPA Summary Report"), *available at* https://www.epa.gov/la/denka-air-monitoring-data-summaries ("Since March 2018, following the implementation of emission controls being installed by DPE, chloroprene stack emissions have been reduced by 85% and EPA air monitoring data have shown corresponding significant reductions of chloroprene concentrations in the community."). Since 2020, DPE has further reduced chloroprene emissions from the Facility through a series of emission reduction projects.

7. Rather than address the scientific information in a rulemaking proceeding—in which EPA would be required to provide a meaningful response to comments by the public, including DPE—EPA began enforcing the 0.2 µg/m^3 standard as an air quality standard. On May 18, 2022, the Director of EPA's Air Enforcement Division, acting on EPA's behalf, demanded that DPE take actions to reduce the Facility's emissions to ensure that off-site concentrations of chloroprene are lower than 0.2 µg/m^3, and threatened DPE that EPA would use "all available tools" to compel DPE to adhere to this standard. As further described herein, during the months that followed, EPA continued to demand compliance with the 0.2 µg/m^3 standard, while using "all available tools" to pressure DPE, both directly and indirectly. Consistent with EPA's threats, these actions by EPA were designed to coerce DPE to comply with the 0.2 µg/m^3 standard. These coercive actions by EPA, beginning with the May 18, 2022 directive, effectively established an ambient standard.

8. As alleged below, EPA has followed through on its threats to use "all available tools" to compel DPE to comply with the 0.2 µg/m^3 standard and continues to do so. DPE files this amended counterclaim under the Administrative Procedure Act to obtain judicial review of EPA's *ultra vires* establishment of the 0.2 µg/m^3 standard.

THE PARTIES

9. Counterclaim-Plaintiff DPE owns the Facility on land under lease from DuPont Specialty Products USA LLC ("DuPont") and operates the Facility.

10. Counterclaim-Defendant EPA is the federal agency charged with the administration of the Clean Air Act, 42 U.S.C. §§ 7401 *et seq*., and the administration of the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. §§ 6901 *et seq*.

11. Counterclaim-Defendant Michael S. Regan is the Administrator of EPA. Administrator Regan is responsible for supervising the activities of EPA, including the actions at issue in these Counterclaims. He is being sued in his official capacity.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1331 because DPE's claims arise under the laws of the United States, including the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Section 702 of the APA waives the government's defense of sovereign immunity in this matter. 5 U.S.C. § 702; *Stockman v. Fed. Election Comm'n*, 138 F.3d 144, 152 n.13 (5th Cir. 1998).

13. The relief sought herein is authorized by 5 U.S.C. §§ 704, 706(2) and 28 U.S.C. §§ 2201-02.

14. Venue is proper in this judicial district under 28 U.S.C. § 1391(e)(1) because the acts and omissions giving rise to the claims alleged herein harm only one facility in the United States—the DPE Facility—which is located within the boundaries of the U.S. District Court for the Eastern District of Louisiana.

FACTUAL BACKGROUND

A. The Facility.

15. The Facility is in St. John the Baptist Parish in Louisiana. The Facility was originally operated by DuPont beginning in 1964. In 1968, DuPont announced that it would begin Neoprene production at the Facility.

16. On November 1, 2015, DPE acquired the Neoprene manufacturing operations at the Facility from DuPont, and such operations have been owned and operated by DPE since that time.

17. Chloroprene is a key chemical used to produce Neoprene. According to EPA data, DuPont's operation of the Facility resulted in chloroprene emissions of approximately 500 tons per year in 1987. Between 1987 and 2015, chloroprene emissions from the Facility under DuPont's operation dropped to about 120 tons per year. Since DPE acquired the Neoprene manufacturing operations at the Facility in 2015, DPE has made substantial investments to further reduce chloroprene emissions.

18. Chloroprene is listed as a "hazardous air pollutant" under the Clean Air Act, and EPA has regulated chloroprene emissions from the Facility since the mid-1990s. It is undisputed that the Facility meets the emission standards for chloroprene that EPA has established under the Clean Air Act.

B. EPA's 2010 Review And Resulting IUR.

19. In September 2010, EPA released the 2010 Review in support of EPA's Integrated Risk Information System ("IRIS") assessment of chloroprene.[1] In the 2010 Review, EPA concluded that chloroprene was "likely to be carcinogenic to humans" and set one of the most stringent IURs for any hazardous pollutant. Specifically, EPA calculated an IUR for human exposure to chloroprene of 5 x 10^{-4} per $\mu g/m^3$ for 70-years exposure. Based on the chloroprene IUR, EPA issued a memorandum in 2016 stating that the chloroprene concentration associated with an incremental lifetime (*i.e.*, 70-year) cancer risk level of 1-in-10,000 was 0.2 $\mu g/m^3$, which the 2016 EPA memorandum generally described as the "upper limit of acceptability for purposes

[1] EPA, *Toxicological Review of Chloroprene: In Support of Summary Information on the Integrated Risk Information System (IRIS)* (Sept. 2010), *available at* https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf.

of risk-based decisions."[2] Until 2022, EPA had never treated this "upper limit of acceptability" as a "bright line" threshold. The fact that EPA, without explanation, is now treating the 1-in-10,000 value as a strict and enforceable standard is at sharp variance with more than 30 years of EPA risk assessment policy. Based on the available science, EPA's 0.2 $\mu g/m^3$ standard for chloroprene is entirely unnecessary to protect human health and the environment.

20. In December 2015, EPA published a National Air Toxics Assessment, or NATA, based on reported emissions from industrial facilities in 2011 ("2011 NATA"). In general, EPA uses NATAs to identify and prioritize air toxics that EPA believes contribute to health risks for further assessment and potential agency action. In the 2011 NATA, EPA relied upon the chloroprene IUR as well as on data regarding chloroprene emissions from the Facility during 2011 and other data.

C. Prior To 2022, EPA Relied Upon IUR Values As A Non-Determinative Component In Establishing Regulatory Standards.

21. EPA reviews and publishes information about the health and environmental effects of industrial chemicals in its IRIS assessments, which provide toxicity values for health effects resulting from exposure to chemicals. For many chemicals, one part of this assessment is an IUR value, which is intended to be an estimate of the increased cancer risk from continuous inhalation exposure to a concentration of a particular chemical of 1 $\mu g/m^3$ for a lifetime. In theory, an IUR can be multiplied by an estimate of lifetime exposure (in units of $\mu g/m^3$) to estimate a person's lifetime risk of developing cancer as a result of chemical exposure.

[2] *See* Memo from Kelly Rimer, Leader, Air Toxics Assessment Group, Health & Env't Impacts Div., OAQPS, to Frances Verhalen, P.E., Chief, Air Monitoring/Grants Section, EPA Region 6, Re: Preliminary Risk-Based Concentration Value for Chloroprene in Ambient Air (May 5, 2016).

22. Sections 112 and 307 of the Clean Air Act set out the procedures by which EPA regulates hazardous air pollutants. *See* 42 U.S.C. §§ 7412, 7607. In establishing air emissions standards, EPA is required to establish a rulemaking docket, publish a notice of proposed rulemaking in the Federal Register, and allow any person to submit written comments or other documentary information in response to the notice of proposed rulemaking. *Id.* § 7607(d); *see also* 5 U.S.C. §§ 552 – 553 (APA). The Clean Air Act also addresses EPA risk assessment in such rulemakings. In carrying out rulemakings pursuant to Section 112, rather than treating risk values such as IUR values as "a rigid line for acceptability," EPA considers risk level along with "a series of other health measures and factors." 54 Fed. Reg. 38044, 38045 (Sept. 14, 1989) ("Benzene Rule"). Section 112(f)(2)(B) of the Clean Air Act specifically endorsed EPA's use of risk assessment factors as set out in the 1989 Benzene Rule. 42 U.S.C. § 112(f)(2)(B) (endorsing 54 Fed. Reg. 38044).

23. In the Benzene Rule, EPA explained that there is a two-step approach to establishing emissions standards. 54 Fed. Reg. at 38045. The first step is to determine an "acceptable risk." EPA considers risk values (like IURs) that are higher than 1-in-10,000 to be presumably—but not conclusively—unacceptable. But critically, the risk value must be weighed against other factors to determine acceptability. *Id.* The second step is to set the standards that provide an "ample margin of safety" when considering all health information and other relevant factors such as costs and technological feasibility. *Id.*

24. EPA applied the risk assessment protocol as set out in the Benzene Rule in 2005, in the NESHAPs for Coke Oven Batteries, *see* 70 Fed. Reg. 19992 (2005), and in 2006, in the National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities, *see* 71 Fed. Reg. 42723 (2006). In both cases, EPA determined that estimated lifetime cancer risks greater than 1-

in-10,000 were not only acceptable, but that emission limits allowing a cancer risk of almost 3-in-10,000 (for Coke Ovens) and 2-in-10,000 (for Dry Cleaners) protected public health with an ample margin of safety.

25. Most recently, in a residual risk evaluation conducted in 2020 for Miscellaneous Organic NESHAPs or "MON," EPA relied on the Benzene Rule's risk assessment policy, explaining: "the [Clean Air Act] expressly preserves the EPA's two-step process for developing standards to address residual risk and interpret 'acceptable risk' and 'ample margin of safety' as developed in the Benzene NESHAPs.'" 85 Fed. Reg. 49084 (2020). The first step involves a determination of "acceptability" based on a "broad set of health risk measures and information." *Id.* In the second step, EPA also considers "cost and economic impacts of controls, technological feasibility, uncertainties, and many other relevant factors." *Id*.

26. In sum, prior to 2022, EPA treated IUR values as only one component in establishing regulatory standards, not as bright-line regulatory limits in and of themselves, and never imposed a regulatory limit based solely on an IUR value.

27. EPA's website contains a page describing EPA's IRIS program. It states that the IUR is a value that "estimate[s] increased cancer risk from inhalation exposure to a concentration of 1 µg/m^3 for a lifetime."[3] EPA's website further states:

> Risk assessment is a four-step process described by the National Research Council (NRC) in 1983 as 'the characterization of the potential adverse health effects of human exposures to environmental hazards.' Characterizing risk involves integrating information on hazard, dose-response, and exposure. An IRIS assessment includes the first two steps of the risk assessment process: Hazard Identification [and] Dose-Response Assessment.

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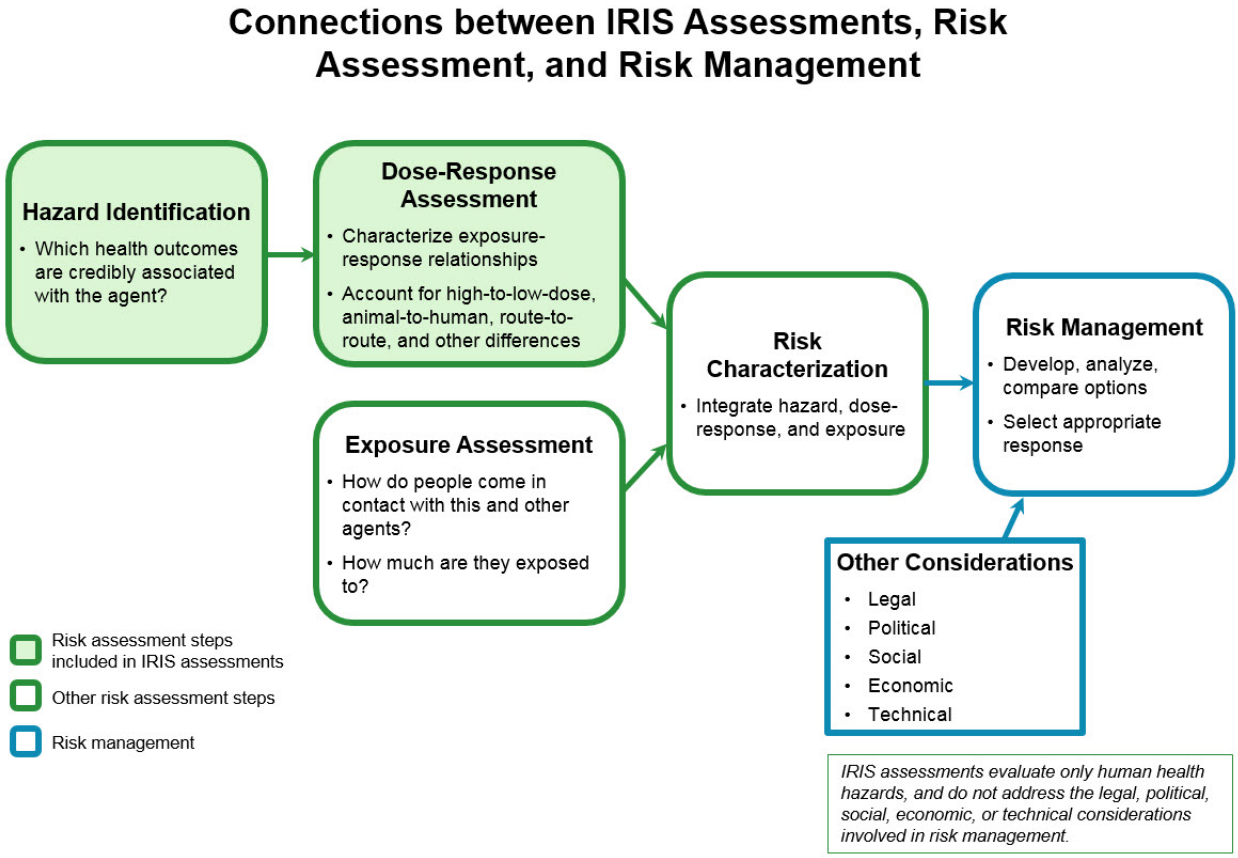
[3] *See* EPA, Basic Information about the Integrated Risk Information System, *available at* https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system; *see also* EPA, *Guidelines for Carcinogen Risk Assessment,* at 5-1 to 5-7 (Mar. 2005), *available at* https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

EPA's website also provides the following graphic showing EPA's approach to risk management, with a legend identifying which two of the five total components are included in the IRIS assessment (*i.e.,* the IUR).



Source: https://www.epa.gov/sites/default/files/2015-09/iris_rm.jpg

28. Similarly, EPA's Guidelines for Carcinogen Risk Assessment state that the risk assessment steps that include an IRIS assessment (*i.e.*, hazard identification and dose-response assessment), along with the exposure assessment component, "serve as *starting materials* for the overall risk characterization process that completes the risk assessment." EPA, *Guidelines for Carcinogen Risk Assessment*, at 1-21 (emphasis added). The Guidelines for Carcinogen Risk Assessment state that risk characterization "is an appraisal of the science that informs the risk

manager in public health decisions, as do other decision-making analyses of economic, social, or technology issues." *Id.* at 5-1 to 5-2.

29. Consistent with the above, in rulemaking, EPA has recognized that:

> IRIS is not a comprehensive toxicological database. There may be more recent relevant information available than is contained in IRIS. . . . IRIS values are not legally binding and are not entitled to conclusive weight in any rulemaking. In addition, EPA . . . should not rely exclusively on IRIS values but should consider all credible and relevant information that is submitted in any particular rulemaking. If an outside party questions IRIS values during the course of an EPA rulemaking . . . EPA considers all credible and relevant information . . . .

National Primary Drinking Water Regulations: Minor Revisions to Public Notification Rule and Consumer Confidence Report Rule, 66 Fed. Reg. 46928, 46929 (Sept. 7, 2001).

30. Consistent with that long-standing position, in the Benzene Rule, which now serves as the model for EPA's analytical framework in Section 112 rulemakings, EPA set out a flexible process, requiring consideration of a range of factors, including scientific uncertainties and weight of evidence. *See* Benzene Rule, 54 Fed. Reg. at 38,045. EPA explained that the 1-in-10,000 risk level "does not necessarily reflect the true risk, but displays a conservative risk level which is an upper-bound that is unlikely to be exceeded." *Id.* Here, the 0.2 $\mu g/m^3$ value derived from the chloroprene IUR is similarly associated with an estimated incremental lifetime cancer risk level of 1-in-10,000.

31. Until 2022, EPA's approach to the 0.2 $\mu g/m^3$ value derived from the chloroprene IUR was consistent with this approach: that is, EPA did not seek to impose the 0.2 $\mu g/m^3$ value associated with a 1-in-10,000 risk level as a bright-line and enforceable standard for chloroprene emissions.

32. For example, in June 2016, six months after publishing the 2011 NATA, EPA issued an "Action Plan" to DPE and expressed its intent to "collect and evaluate site-specific

information" regarding chloroprene emissions. *See* EPA, *Action Plan: Denka Performance Elastomer, LLC – Pontchartrain Facility (formerly the DuPont Neoprene Facility, Pontchartrain Works) LaPlace, St. John the Baptist Parish, Louisiana, June 2016*, at 1, *available at* https://www.epa.gov/sites/default/files/2016-06/documents/epa-laplace-action-plan.pdf. At that time, EPA expressly recognized that the 2011 NATA, which relied in part on the chloroprene IUR, should *not* be used "to identify actual exposures and associated risks to specific individuals." *Id.* In other words, EPA at that time took the position that there was no basis to apply 0.2 μg/m^3 as a standard for chloroprene emissions at the Facility.

33. Similarly, in September 2019, the Director of EPA's Office of Air Quality Planning and Standards informed the Louisiana Department of Environmental Quality ("LDEQ") by letter that the 0.2 μg/m^3 value for chloroprene exposure "is not based on an evaluation of current, real-world exposures, is not an air quality standard, and it is not used directly for regulatory purposes. Furthermore, the risks calculated using the [IUR], such as [1-in-10,000], is not a 'bright line' for determining whether a risk level is considered safe or acceptable." Letter from P. Tsirigotis (EPA) to Dr. C. Brown (LDEQ), at 2 (Sept. 23, 2019), *available at* https://www.epa.gov/sites/default/files/2020-09/documents/image2019-09-23-132129.pdf. In other words, as of September 2019, EPA confirmed that 0.2 μg/m^3 was *not* a "bright line" standard for determining risk, and certainly did *not* demand compliance with 0.2 μg/m^3. EPA further acknowledged that, "in setting emission standards under the Clean Air Act, risk is one factor that we need to consider, along with information on costs, energy, safety, control technologies, and other relevant factors. And there are many other factors." *Id.*

D. Starting In 2022, EPA Abruptly—And Without Explanation—Reversed Its Position Regarding IURs.

34. On May 18, 2022, EPA suddenly reversed its policy of treating IURs as only one non-determinative component in risk management. Instead, EPA began treating the 0.2 μg/m^3 value derived from the chloroprene IUR *as a bright-line standard* and ordered DPE to comply with it, without providing any explanation or providing DPE an opportunity to comment or challenge the new directive. This reversal was manifested in multiple ways.

35. On May 18, 2022, in a meeting between representatives from EPA, the Department of Justice, and DPE, EPA announced that it considered the 0.2 μg/m^3 standard derived from the chloroprene IUR to be *confirmed and final* and stated that EPA would not wait any longer for DPE to reduce chloroprene emissions below 0.2 μg/m^3. Mary Greene, the Director of EPA's Air Enforcement Division, on behalf of EPA, directed DPE to take immediate action to implement specific emission reduction projects to reduce chloroprene concentrations at the fence line of the Facility below 0.2 μg/m^3. EPA estimated that these projects would cost DPE $75 million. Director Greene stated that if DPE did not implement these projects, then EPA would use "all available tools" to compel DPE to reduce chloroprene concentration levels below the 0.2 μg/m^3 standard. Director Greene's directive was made without regard to the multiple factors in addition to risk levels addressed in EPA's risk protocols, which demonstrated to DPE that, going forward, EPA would treat the 0.2 μg/m^3 standard as a bright line. EPA provided DPE with no recourse to challenge this abrupt change in DPE's compliance obligations.

36. Under the threat of EPA employing "all available tools" against DPE, DPE continued to meet with EPA throughout the summer of 2022. EPA continually demanded that DPE take actions, all designed to ensure DPE's compliance with EPA's 0.2 μg/m^3 standard. DPE implemented many of these actions, requiring it to incur costs it would not have otherwise incurred.

In August 2022, EPA continued its directives, and made express threats to enforce the 0.2 µg/m^3 standard via emergency orders, including by specifying precise dates on which such orders would be issued if DPE did not comply with EPA's directives. Importantly, Section 303 of the Clean Air Act, 42 U.S.C. § 7603, and its parallel provision, Section 7003 of RCRA, 42 U.S.C. § 6973, permit EPA to issue administrative orders and *immediate* shutdown orders. Thus, the "tools" that EPA threatened to apply included its authority to file an emergency action that could force the Facility to shut down operations at any time. With no administrative recourse, DPE continued to respond to EPA's demands while diverting significant company resources to plan for the operational, reputational, and legal consequences of an administrative order that could shut down or effectively shut down DPE's entire operations with no notice.

37. Another "tool" available to EPA is its authority to require certain minimum elements of operating permits that are issued by the states. *See* 42 U.S.C. § 7661a(d)(1). EPA has sought, and upon information and belief is continuing to seek, to deploy this tool against DPE. On October 12, 2022, EPA sent a "letter of concern" to LDEQ and the Louisiana Department of Health ("LDH") regarding a complaint filed under Title VI of the Civil Rights Act ("October 2022 Letter"). The October 2022 Letter emphasizes LDEQ's responsibility under the Clean Air Act to issue operating permits to major stationary sources like the Facility, repeatedly referenced 0.2 µg/m^3 as the benchmark that LDEQ should require DPE to achieve in order to protect the community near the Facility, and urged LDEQ to take action on DPE's pending operating permit renewals. Thus, the October 2022 Letter further illustrated EPA's May 2022 pronouncement that EPA's deliberations on the 0.2 µg/m^3 standard derived from the chloroprene IUR were final and that, moving forward, EPA would apply the 0.2 µg/m^3 standard as a bright line, with no adjustments. The October 2022 Letter also showed that EPA was (and, upon information and

belief, still is) pressuring LDEQ to enforce the 0.2 µg/m^3 standard against the Facility via LDEQ's issuance of operating permits. Within days of a lawsuit by the State of Louisiana challenging EPA's authority to pursue the investigation under the Civil Rights Act, EPA abruptly closed the underlying investigation. However, upon information and belief, EPA continues to seek to use operating permits as a "tool" to compel compliance with the 0.2 µg/m^3 standard.

38. Also, beginning in August 2022, EPA escalated the use of its RCRA authority as a "tool" to compel reductions in chloroprene emissions below the 0.2 µg/m^3 standard. EPA's RCRA team demanded that DPE take measures to contain alleged hazardous waste at the Facility or face an emergency action under Section 7003 of RCRA. This RCRA investigation resulted in a December 2022 partial Consent Agreement in which DPE agreed to comply with EPA's demands without resolving DPE's liability and expressly reserving EPA's right to assess penalties for the alleged claims.

39. Upon information and belief, EPA's position with respect to DPE's solid waste management was predicated on the assumption that emissions associated with DPE's solid waste were contributing to chloroprene concentrations levels above 0.2 µg/m^3 near the Facility and EPA's view of 0.2 µg/m^3 as a bright-line standard. Internal EPA emails produced in response to a FOIA request indicate that, even before demanding that DPE comply with 0.2 µg/m^3, EPA was directing its staff to institute a RCRA Section 7003 emergency action based on chloroprene releases that were being detected by air monitors. Notably, one internal EPA email states that, under EPA's interpretation of Section 7003 and based on EPA's guidance for Section 7003 orders, "Denka is meeting all the check boxes for imminent and substantial endangerment, but so is just about everybody else . . . ." The same staff member suggested that actual concerns under RCRA were not driving the potential emergency action, stating there "may be RCRA concerns about the

operation of the facility but for the time being my management wants [EPA to issue an order under Section] 7003." On December 28, 2022, EPA issued a press release announcing the Consent Agreement, which makes clear that EPA relied on its RCRA authority to reduce air emissions associated with the Facility, stating that the waste at issue "contributes to emissions of chloroprene from the plant" and that the consent order would lead to "emissions reductions."[4]

40. EPA's efforts to impose 0.2 μg/m^3 as a bright-line standard continued in this lawsuit alleging an "imminent and substantial endangerment" ("ISE Action"), in which EPA seeks to use its emergency authority under Section 303 of the Clean Air Act as another "tool" to compel DPE to comply with the 0.2 μg/m^3 standard. The chloroprene concentration level at which EPA alleges the emergency will be abated is the same level EPA demanded DPE meet during the May 18, 2022 meeting: 0.2 μg/m^3. Relying entirely upon the 0.2 μg/m^3 standard, EPA's ISE Action seeks a permanent injunction requiring DPE to "immediately cease chloroprene and Neoprene production" until DPE "can demonstrate that it is able to maintain annual average chloroprene concentrations … at or below 0.2 μg/m^3 in the areas surrounding the Facility." EPA's "Statement of Final Relief" (Oct. 20, 2023).

41. The ISE Action is action *by EPA*. Section 303 of the Clean Air Act authorizes the "Administrator" of EPA, and not any other agency, to bring suit "on behalf of the United States." 42 U.S.C. § 7603. Having expressly authorized this action, Mr. Regan, the Administrator of EPA is represented by the Department of Justice, acting as counsel. *See* 42 U.S.C. § 7605(a) ("The Administrator shall request the Attorney General to appear and represent him in any civil action

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[4] EPA, *EPA enters into Consent Agreement and Issues Final Order to Denka Performance Elastomer in LaPlace, La., for Violation of Hazardous Waste Regulations* (Dec. 28, 2022), *available at* https://www.epa.gov/newsreleases/epa-enters-consent-agreement-and-issues-final-order-denka-performance-elastomer.

instituted under this chapter to which the Administrator is a party."). EPA agrees that it was the party that "filed this action under 42 U.S.C. § 7603 on February 28, 2023." Reply in Support of Mot. for Prelim. Injunction, R. Doc. 94, at 10. The ISE Action authorized by the EPA Administrator alleges that the Facility's emissions of chloroprene constitute an imminent and substantial endangerment and seeks a permanent injunction requiring the Facility to shut down until it can demonstrate compliance with EPA's 0.2 μg/m^3 standard for chloroprene.

42. On March 20, 2023, the United States filed a motion for preliminary injunction seeking a shutdown of the Facility unless DPE complied with EPA's host of prescriptive requirements. In its briefing in support of the motion, the United States makes no effort to hide that this unprecedented ISE Action is entirely dependent on enforcing EPA's 0.2 μg/m^3 standard as a bright line. *See, e.g.,* Mem. in Support of Mot. for Preliminary Injunction, R. Doc. 9-2, at 6 ("For the relevant health effects of breathing chloroprene, the EPA determined that the average concentration of chloroprene a person may regularly breathe over a 70-year lifetime without being expected to exceed a 1-in-10,000 risk of contracting chloroprene-linked cancers is 0.2 μg/m^3"); *id.* at 9 ("monitoring data shows that the communities surrounding Denka's Facility are being exposed to long-term average airborne chloroprene levels that are between two and over fourteen times greater than 0.2 μg/m^3"); *id.* at 11 ("Even the lowest measured average value for Denka's five closest monitors (out of the six total) is about four times greater than 0.2 μg/m^3."); Reply in Support of Mot. For Preliminary Injunction, R. Doc. 94, at 25 ("Until Denka reduces long-term average chloroprene concentrations in the ambient air surrounding the Facility to approximately 0.2 μg/m^3, there remains a substantial likelihood of irreparable harm."). Indeed, the United States purports to substantiate its claim that current levels of chloroprene at the Facility "present unacceptably high cancer risk" using an expert—Dr. John Vandenberg—who specifically bases his opinion on the

accuracy of the 2010 Review. *Id.* at 21 (citing Ex. D, Decl. of Dr. John Vandenberg). Dr. Vandenberg's first opinion is that "EPA's IRIS Assessment is scientifically accurate and concludes chloroprene is [a] likely and potent human carcinogen." *Id.* at 7 (opinion I). Dr. Vandenberg also provides a straight-forward calculation that uses the chloroprene IUR as an established quantity. *Id.* at 24 ("Cancer risks for inhaled pollutants are calculated by multiplying the ADAF-adjusted IUR [provided in the 2010 Review] by the concentration of chloroprene in the air that people are exposed to for the duration of exposure and summed across age groups to estimate lifetime cancer risk to a specified amount of a substance.").

43. In response to discovery in the ISE Action, EPA confirmed that it considers the 0.2 $\mu g/m^3$ standard to be final and that the ISE Action is predicated entirely on enforcing 0.2 $\mu g/m^3$ as a bright-line standard. EPA's response to DPE's Interrogatory No. 4 states: "EPA believes that the ambient air concentration of chloroprene that Denka needs to achieve in order to abate the imminent and substantial endangerment alleged in the PI Motion is 0.2 $\mu g/m^3$." EPA's Statement of Final Relief for the permanent injunction puts its position in the starkest of terms: DPE must shut down its Facility immediately and not return to production until 0.2 $\mu g/m^3$ can be achieved. EPA's "Statement of Final Relief" (Oct. 20, 2023). Thus, EPA reconfirmed the directive that EPA announced to DPE on May 18, 2022—*i.e.*, that EPA had determined that 0.2 $\mu g/m^3$ is a post-deliberative, final standard which EPA seeks to enforce using "all available tools."

E. <u>EPA Has Improperly Established The 0.2 $\mu g/m^3$ Standard As A Workaround To Proper And Lawful Rulemaking.</u>

44. In April 2023, EPA released a proposed rule that would amend the regulations governing emissions of chloroprene. Notably, the preamble to the proposed rule recites EPA's policy that IURs and similar IRIS values are only used in the first step required in promulgating emissions standards. *See* Proposed Rule, New Source Performance Standards for the Synthetic

Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry, 88 Fed. Reg. 25080, 38044-45 (Apr. 25, 2023) ("Proposed Rule") (citing Benzene Rule). DPE has provided comments to EPA addressing the scientific flaws in the Proposed Rule as well as EPA's misapplication of its risk protocols. *See* DPE July 7, 2023 Comments to EPA Proposed Rule (Ex. 1 to DPE Opp. to Mot. for Preliminary Injunction), R. Doc. 73-1. If EPA does not correct these errors in the final rule, DPE intends to challenge the final rule in court. However, because EPA has already begun implementing "all available tools" to enforce the 0.2 μg/m^3 standard, DPE seeks review of the establishment and imposition of that standard.

45. EPA effectively admits in briefing in this case that the ISE Action is yet another workaround to allow it to impose the 0.2 μg/m^3 standard on DPE *before* EPA completes the rulemaking through the process required by Congress in the Clean Air Act and the APA, and in case its use of the 0.2 μg/m^3 standard in the rulemaking does not pass judicial scrutiny. Reply in Support of Mot. for Preliminary Injunction, R. Doc. 94, at 29 ("The Proposed Rule's current compliance deadline is not until March 2026 – two years after the yet-to-be finalized rule's effective date . . . . And Denka is sharpening its knives to entirely dismantle the Proposed Rule . . . . There is an important ongoing need for the requested preliminary injunction."). EPA doubtless also seeks to avoid the judicial review provisions of the Clean Air Act by establishing what is effectively the same standard in a clandestine and non-transparent manner, without the trouble of complying with the Clean Air Act's and APA's process requirements. The APA does not allow this *ultra vires* agency action. DPE is entitled to judicial review of EPA's establishment of the 0.2 μg/m^3 standard and EPA's use of "all available tools" in imposing that standard.

FURTHER ALLEGATIONS SUPPORTING COUNTERCLAIM

A. EPA Has Disregarded Substantial Scientific Evidence That The 0.2 µg/m^3 Standard Is Not Necessary To Protect Human Health Or The Environment.

46. EPA's sudden reversal of its policy regarding the use of IURs and enforcement of 0.2 µg/m^3 as an ambient air standard is especially troubling in light of the substantial scientific evidence available when EPA first developed the chloroprene IUR and the even more robust evidence available in 2022, when EPA began enforcing 0.2 µg/m^3 as an effective ambient air standard. That scientific evidence showed that 0.2 µg/m^3 is not necessary to protect human health or the environment. DPE was provided no meaningful opportunity to correct EPA's flawed science before or after EPA's May 18, 2022 directive.

47. In setting the stringent 0.2 µg/m^3 standard for chloroprene, EPA relied upon a default assumption that humans are as sensitive to chloroprene as the female B6C3F1 mouse. *See* EPA's Response to DPE's RFA No. 17 ("The United States further admits that the inhalation unit risk for chloroprene determined in the 2010 IRIS assessment is based on the assumption that humans are as sensitive to chloroprene exposure as the female B6C3F1 mouse."). While EPA relied entirely on female B6C3F1 mice studies, it disregarded study results of all other animal species, including male B6C3F1 mice, all of which found a dramatically lower (even zero) cancer risk. Declaration of P. Robinan Gentry ("Gentry Decl."), R. Doc. 73-5, ¶ 37, Table 1. This was a fundamental error due to the substantial toxicokinetic differences between female B6C3F1 mice and humans, resulting in EPA's 0.2 µg/m^3 value dramatically overstating human cancer risks associated with exposure to chloroprene. *Id.* Peer reviewers in the 2010 Review recognized this fundamental shortcoming and raised concerns regarding the toxicokinetic differences between humans and female B6C3F1 mice. *Id.* ¶ 39-40.

48. EPA compounded this incorrect conservative assumption with a series of other conservative assumptions. Three steps were used to translate the B6C3F1 mouse data into EPA's chloroprene IUR: (i) developing an "upper bound" composite risk estimate for all tumor sites observed in the study of 2.7×10^{-4} per $\mu g/m^3$; (ii) rounding the estimate upward to one significant digit, to 3×10^{-4} per $\mu g/m^3$; and (iii) applying the age adjustment factors to increase the IUR by 67% to 5×10^{-4} per $\mu g/m^3$. *See* 2010 Review at 137-38.

49. The 2010 peer review comments supported EPA's preference to develop a PBPK model, a specialized computer model specifically designed to adjust risk assessments due to the different toxicological effects of a chemical from one species to another—for example, the differences between female B6C3F1 mice and humans. Declaration of Michael Lumpkin ("Lumpkin Decl."), R. Doc. 73-4, ¶¶ 41-50.

50. EPA expressly acknowledged that it would be appropriate for EPA to rely upon a new and improved PBPK model for chloroprene and encouraged DPE to develop such a model. Between 2017 and 2021, DPE and EPA actively coordinated to develop a new and improved PBPK model for chloroprene. Gentry Decl., R. Doc. 73-5, ¶¶ 17-33. DPE employed a team of scientists at Ramboll US Consulting, Inc. ("Ramboll") to develop and refine this PBPK model. *Id.* Ramboll prepared a work plan for the development of a PBPK model and, in April 2018, provided the draft work plan to EPA for its review and comment. *Id.* On information and belief, EPA committed substantial resources to provide Ramboll with quality assurance guidance on the development of the PBPK model. In June 2019, to ensure that the new PBPK model was correct, Ramboll submitted the PBPK model for publication in the peer-reviewed journal Inhalation Toxicology,

and after peer review, the PBPK model was published in January 2020.[5] In October 2020, EPA itself sponsored an external peer review of an updated version of the Ramboll PBPK model. The 2020 peer review panel provided comments. By early 2021, Ramboll had substantively revised the PBPK model to address all the meaningful comments from the EPA-sponsored peer review, making technical changes in the model to provide a better fit for cross-species tumor predictions among laboratory test animals. Gentry Decl., R. Doc. 73-5, ¶ 60.

51. However, unbeknownst to DPE, EPA sponsored another independent peer review of the new Ramboll PBPK model for chloroprene in 2021. Unlike the 2020 EPA-sponsored external peer review, this follow-up peer review was conducted secretly and without giving Ramboll the opportunity to address any questions from the peer review panel. Nonetheless, the follow-up peer review demonstrated that Ramboll had successfully addressed most of the comments on prior versions of the PBPK model. On balance, the peer reviewers considered the Ramboll PBPK model to be ready for use in estimating an IUR for an IRIS review. Following the 2021 peer review sponsored by EPA, Ramboll revised the PBPK model, and the model, again, underwent journal peer review and was published a fourth time in August 2023.[6] Ramboll addressed and resolved all critical comments and questions raised by EPA-sponsored peer reviews and there are no issues that reasonably counter using the PBPK model to calculate an IUR. Gentry Decl., R. Doc. 73-5, ¶ 72.

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[5] Harvey J. Clewell 3rd, *et al.*, *Incorporation of In Vitro Metabolism Data and Physiologically Based Pharmacokinetic Modelling in a Risk Assessment for Chloroprene*, Inhal. Toxicol. 31(13-14):468-483 (Nov-Dec 2019), https://pubmed.ncbi.nlm.nih.gov/31992090/.

[6] J.L. Campbell Jr., *et al.*, *Using Available In Vitro Metabolite Identification and Time Course Kinetics for β-Chloroprene and its Metabolite, (1-Chloroethenyl) Oxirane, to Include Reactive Oxidative Metabolites and Glutathione Depletion in a PBPK Model for β-Chloroprene*, Front. Pharmacol. 14:1223808 (Aug. 17, 2023), https://pubmed.ncbi.nlm.nih.gov/37663267/.

52. In 2021, EPA personnel abruptly ceased all substantive communications with DPE regarding the Ramboll PBPK model or any appropriate revisions to the IUR based on that model.

53. The 2010 peer review also strongly criticized EPA's misuse of the relevant epidemiological data in the 2010 Review. The most important and comprehensive epidemiological studies of chloroprene that were available in 2010 were studies of U.S. chloroprene workers prepared in 2007 by Dr. Gary Marsh, Ph.D.[7] Dr. Marsh's 2007 studies involved, among other things, an analysis of chloroprene exposure at the Facility and showed no relationship between worker exposure to chloroprene and lung or liver cancer mortalities.[8]

54. DPE provided EPA with a major new follow-up epidemiological study conducted by Dr. Marsh in 2021. Dr. Marsh's new study provided an update through 2017 regarding the cohort of U.S. chloroprene workers that was the subject of Dr. Marsh's 2007 study. The updated 2021 Marsh study showed *no increase* in cancer mortalities among U.S. chloroprene workers.

55. Further, DPE provided EPA with data from the Louisiana Tumor Registry, which indicated lower cancer incidence rates in St. John the Baptist Parish compared to the state average. Data from the Louisiana Tumor Registry continues to show no increase in cancer incidence rates in the community surrounding DPE's Facility. Like Dr. Marsh's updated epidemiological data,

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[7] *See* Gary M. Marsh, *et al.*, *Mortality Patterns Among Industrial Workers Exposed to Chloroprene and Other Substances. II. Mortality in Relation to Exposure*, Chem. Biol. Interact. 166(1-3):301-16 (Mar. 20, 2007), https://pubmed.ncbi.nlm.nih.gov/17007827/.

[8] As discussed further below, Dr. Marsh performed a major follow-up epidemiological study in 2021, which provided an update through 2017 regarding the cohort of chloroprene workers that was the subject of Dr. Marsh's 2007 study. The updated 2021 Marsh study showed *no increase* in cancer mortalities among U.S. chloroprene workers. *See* Garry M. Marsh, *et al.*, *Mortality Patterns Among Industrial Workers Exposed to Chloroprene and Other Substances: Extended Follow-Up*, J. Occup. Environ. Med. 63(2):126-138 (Feb. 1, 2021), https://pubmed.ncbi.nlm.nih.gov/33234876/.

the Louisiana Tumor Registry data strongly support the conclusion that chloroprene does not pose a meaningful risk to humans.

56. DPE submitted this scientific data to EPA in formal petitions for correction and reconsideration of the 2020 Review, including (i) a June 26, 2017 Request for Correction; (ii) a July 23, 2018 Request for Reconsideration of the denial of the 2017 Request for Correction (which DPE withdrew after working with EPA to develop the PBPK model); (iii) a July 15, 2021 Request for Correction; and (iv) a June 10, 2022, DPE Request for Reconsideration of the denial of the 2021 Request for Correction. EPA denied DPE's 2022 Request for Reconsideration on October 19, 2022, thereby affirming EPA's denial of the 2021 Request for Correction. Notably, when EPA denied the 2021 Request for Correction and the 2022 Request for Reconsideration, it did *not* base its decisions on concerns about the quality or relevance of the scientific information presented by DPE. Rather, the agency simply said that it was not required to update the 2010 IRIS Assessment and that it did not have enough resources to do so. Thus, EPA denied these requests without even considering the new scientific studies submitted by DPE.

B. EPA's Establishment And Enforcement Of The 0.2 µg/m^3 Standard Is Reviewable By This Court.

57. EPA did not meaningfully consider the substantial scientific evidence that the 0.2 µg/m^3 standard derived from the chloroprene IUR does not accurately reflect the risk of cancer associated with chloroprene emissions or undertake a comprehensive risk characterization and risk management process based on EPA's established policies and procedures. Instead, in 2022, EPA undertook agency action that doubled down on these errors by establishing the 0.2 µg/m^3 as a regulatory standard, equivalent to a rule, and directly applying that standard against DPE under the threat of using "all available tools" to force full compliance.

58. On May 18, 2022, EPA communicated its position that the science behind the 0.2 μg/m^3 standard was settled and that the 0.2 μg/m^3 standard was applicable and enforceable. Since May 18, 2022, EPA has relentlessly reinforced this position, and threatened DPE with emergency actions if it did not reduce emissions enough to ensure that off-site concentrations of chloroprene are below 0.2 μg/m^3. Director Greene's directive on May 18, 2022, was followed by EPA actions designed to coerce DPE's adherence to the 0.2 μg/m^3 standard more quickly—(i) the October 2022 Letter seeking to have LDEQ enforce 0.2 μg/m^3 via emissions permits, (ii) the use of EPA's RCRA authority to reduce ambient air concentrations, and, most recently, (iii) the ISE Action seeking to enforce the 0.2 μg/m^3 standard. These overlapping coercive actions demonstrate that EPA was not bluffing when it directed DPE to comply with 0.2 μg/m^3 as a standard and that EPA will not stop enforcing the 0.2 μg/m^3 standard until it is achieved.

59. The establishment of the 0.2 μg/m^3 standard satisfies both conditions for finality. "First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up).

60. The establishment of the 0.2 μg/m^3 standard is final and not subject to further decision-making by EPA. EPA has rejected DPE's administrative challenges to the chloroprene IUR and rejected or ignored calls to revisit the 0.2 μg/m^3 standard. As a policy matter, after denying DPE's 2021 Request for Correction, EPA could have revisited the 0.2 μg/m^3 standard in response to these requests. Instead, EPA convened the May 18, 2022 meeting to announce to DPE that the possibility of revisiting the 0.2 μg/m^3 standard was foreclosed, that EPA had finalized its position, and that EPA would seek to enforce the standard using "all available tools." EPA made

clear that the position it was communicating was not "merely tentative." *Bennett v. Spear*, 520 U.S. 154, 178 (1997).

61. As to the second *Bennett* prong, the establishment of the 0.2 μg/m^3 standard has led to legal consequences and determined rights and obligations because (i) it binds EPA and its staff, *Texas v. EEOC*, 933 F.3d 433, 441 (5th Cir. 2019), and (ii) has led to substantial negative consequences for DPE. It is clear from Director Greene's directive at the May 18, 2022 meeting, from the face of the October 2022 Letter, and from the complaint, motion for preliminary injunction, and Statement of Final Relief in the ISE Action that EPA has applied—and will continue to apply—the 0.2 μg/m^3 standard as a bright line, with no adjustments. Indeed, the very purpose of the May 18, 2022 meeting was to disabuse DPE of any notion that EPA would revisit the 0.2 μg/m^3 standard and to direct DPE to meet that standard or face the full force of EPA's enforcement tools.

62. After the May 18, 2022 meeting, DPE faced a choice—and still does—to either comply with EPA's order to comply with the 0.2 μg/m^3 standard or face a battery of EPA actions, including emergency actions under the Clean Air Act and RCRA. These provisions permit EPA to issue *immediate* shutdown orders, before the opportunity for judicial review. *See* 42 U.S.C. § 7603 (no judicial review for 60 days); *id.* § 6973 (no judicial review requirement). EPA retains its ability to bring a RCRA Section 7003 action predicated on 0.2 μg/m^3 at any time. "The APA's final agency action requirement prevents this strong-arming of regulated parties into 'voluntary compliance' without the opportunity for judicial review . . . ." *San Francisco Herring Ass'n v. Dep't of the Interior*, 946 F.3d 564, 582 (9th Cir. 2019) (quoting *Sackett v. EPA*, 566 U.S. 120, 131 (2012)).

63. EPA's establishment of the 0.2 μg/m^3 standard has had severely negative consequences for DPE beyond defending the ISE Action (though those costs have been substantial). DPE has poured extensive resources into investigating and implementing emissions reduction projects demanded by EPA. Because of EPA's establishment of the 0.2 μg/m^3 standard, DPE is effectively precluded from expanding chloroprene and neoprene production and from implementing other business decisions that would lead to increased chloroprene emissions. DPE employees have spent thousands of hours innovating ways to further reduce chloroprene emissions and engaged multiple third-party consultants for the same purpose, all at great cost to DPE.

64. Based on the October 2022 Letter, and upon information and belief, EPA will require LDEQ to issue operating permits that seek to limit chloroprene concentrations near DPE's Facility to 0.2 μg/m^3, even after having withdrawn the civil rights investigation underlying the October 2022 Letter.

65. Further, the emission reduction measures demanded by EPA during the May 18, 2022 meeting and demanded by EPA in the ISE Action—with the express purpose of meeting the 0.2 μg/m^3 standard—would require DPE to invest substantial time and capital in further emissions reductions projects. In addition, the Statement of Final Relief sought by EPA in the ISE Action would require DPE to immediately shut down the Facility, depriving DPE of its only source of revenue, forcing employees and contractors out of work, harming DPE's reputation, and impairing its ability to meet contractual obligations.

66. As alleged above, the establishment of the 0.2 μg/m^3 standard constitutes "final" agency action under *Bennett.* However, regardless of whether these allegations establish "final" agency action under *Bennett*, this Court may review the Agency's imposition of an *ultra vires*

standard limiting DPE's air emissions. *See Apter v. Dep't of Health & Human Servs.*, 80 F.4th 579, 591 (5th Cir. 2023).

AMENDED COUNTERCLAIM FOR RELIEF

(Counterclaim-Defendants' Establishment of a Chloroprene Standard Using an Unadjusted IUR in Bright-Line Fashion Is Arbitrary, Capricious, an Abuse of Discretion, and Contrary to Law)

67. DPE incorporates paragraphs 1 – 66 as if fully set forth herein.

68. EPA's establishment of the 0.2 μg/m^3 standard through its actions beginning in 2022—*i.e.*, the senior EPA official's May 2022 threat, the October 2022 Letter seeking to have LDEQ enforce the 0.2 μg/m^3 standard via emissions permits, the use of EPA's RCRA authority predicated on the 0.2 μg/m^3 standard, and the ISE Action seeking to enforce the 0.2 μg/m^3 standard—is arbitrary, capricious, an abuse of discretion, and contrary to law. The 0.2 μg/m^3 standard is a substantive rule that should have been subject to the notice and comment requirements of the APA and the Clean Air Act. 5 U.S.C. § 552–553; 42 U.S.C. §§ 7412, 7607. EPA has not completed its rulemaking process and does not have the authority to promulgate ambient air standards outside of this process.

69. Further, EPA's abrupt and unexplained about-face in policy is arbitrary and capricious, in violation of the APA. EPA has arbitrarily and capriciously reversed 30 years of EPA risk assessment policy without reasoned explanation by treating a value based on the chloroprene IUR in a strict, "bright line" fashion. "Where an agency changes its policy, the agency must show awareness that it is changing a policy and give a reasoned explanation for the adoption of the new policy." *FCC v. Fox Television Stations*, 556 U.S. 502, 515–16 (2009). Here, EPA for the first time adopted a risk value based on a maximum plausible IUR value to impose that value as a standard, without considering the other factors required by Section 112(f)(2)(A) of the Clean Air Act, 42 U.S.C. § 7412(f)(2)(A), including "costs, energy, and other relevant factors." EPA

has failed to undertake the two-step analysis described in the Benzene Rule and endorsed by Congress in Section 112 of the Clean Air Act. Instead, EPA has simply determined, based on its view of the "maximum plausible risk," that a 1-in-10,000 lifetime cancer risk from chloroprene is unacceptable without any consideration of the other factors. This departure from policy is particularly egregious in light of EPA's refusal to consider substantial, relevant scientific information, including the Ramboll PBPK Model, the Marsh epidemiology studies, and the Louisiana Tumor Registry data.

70. EPA was obligated to conduct a formal rulemaking that provides a "reasoned explanation" for its change in policy with respect to IUR values. EPA's failure to do so, resulting in the 0.2 $\mu g/m^3$ standard, was arbitrary, capricious, an abuse of discretion, and not in accordance with law, in violation of the APA.

RELIEF REQUESTED

For the reasons set forth above, DPE respectfully requests that the Court grant the following relief:

71. A judicial declaration that EPA's establishment of the 0.2 $\mu g/m^3$ standard for chloroprene was arbitrary, capricious, an abuse of discretion, and not in accordance with law, because EPA contradicted decades of EPA practice and policy by relying on an unadjusted IUR value in creating an ambient air standard without consideration of other relevant factors, through notice and comment, while failing to provide a reasoned explanation for this departure, in violation of the APA.

72. A judicial declaration that EPA's establishment of the 0.2 $\mu g/m^3$ standard for chloroprene, was arbitrary, capricious, an abuse of discretion, and not in accordance with law, because EPA failed to consider substantial scientific evidence showing that this standard is unnecessary to protect human health or the environment.

73. An order enjoining EPA from enforcing the 0.2 µg/m^3 standard for chloroprene until EPA complies with the notice and comment provisions of the APA and the Clean Air Act and EPA provides a reasoned explanation for its departure from decades of EPA practice and policy regarding risk assessment.

74. An order permanently enjoining EPA from applying the 0.2 µg/m^3 standard for chloroprene unless and until EPA has fully considered the scientific evidence regarding the potential risk of chloroprene to humans.

75. An order granting all such other relief as the Court deems appropriate.

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Respectfully submitted,

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