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

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	**CIVIL ACTION NO. 2:23-cv-735**
v.	)	**SECTION J(5)**
DENKA PERFORMANCE ELASTOMER LLC and DUPONT SPECIALTY PRODUCTS USA, LLC,	)	**JUDGE BARBIER**
	)	**MAGISTRATE JUDGE NORTH**
Defendants.	)	

MEMORANDUM IN SUPPORT OF DENKA PERFORMANCE ELASTOMER LLC'S MOTION FOR SUMMARY JUDGMENT

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* The documents referenced herein and attached to this Memorandum as exhibits are true and correct copies of those documents as attested to in the Declaration of Kevin M. Voelkel, filed concurrently with this Memorandum. As stated in the Voelkel Declaration, in many instances, DPE has provided excerpts of the relevant portions of the exhibits. In addition, DPE has highlighted relevant portions of the exhibits for the Court's convenience.

Exhibit 25	11/13/17 Letter from Prof. Mark Squillace to EPA
Exhibit 26	12/15/17 Letter from EPA to Prof. Mark Squillace
Exhibit 27	EPA chronology
Exhibit 28	10/23/17 EPA Email
Exhibit 29	1/12/18 Letter from Prof. Mark Squillace to EPA
Exhibit 30	Petition for Section 303 action by Concerned Citizens of St. John
Exhibit 31	*Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (Oct. 1994)
Exhibit 32	Dr. Ila Cote Deposition Transcript (June 20, 2023)
Exhibit 33	2010 Toxicological Review of Chloroprene
Exhibit 34	Dr. Kristina Thayer Deposition Transcript (Dec. 14, 2023)
Exhibit 35	EPA Response to DPE's Request for Correction (Jan. 2018), Attachment 1
Exhibit 36	National Research Council, *Science and Judgment in Risk Assessment* (1994), Appendix D
Exhibit 37	Dr. Michael Lumpkin Declaration (July 7, 2023)
Exhibit 38	EPA, *Nat'l Emission Stands. for Haz. Air Pollutants: Primary Lead Smelting, Sum. of Pub. Comment and Response*, Docket No. EPA-HQ-OAR-2004-0305 (Nov. 4, 2011)
Exhibit 39	EPA, *Air Monitoring for Chloroprene Concentrations in LaPlace, LA from May 25, 2016 through July 16, 2020 Summary Report* (Sept. 2020)

I. INTRODUCTION

According to the U.S. Center for Disease Control, the average American has a 1-in-3 risk of getting cancer in their lifetime.[1] In this case, the Environmental Protection Agency ("EPA") claims that Denka Performance Elastomer LLC's ("DPE") manufacturing facility ("Facility") is causing an "imminent and substantial endangerment" because its chloroprene emissions pose a cancer risk of 5-in-10,000 to a hypothetical person who breathes in those emissions near the Facility *all day, every day for 70 years*. Even if this counterfactual assumption were true, that hypothetical person's lifetime risk of cancer due to proximity to the Facility would be increased from 1-in-3 (or 3,333-in-10,000) to 3,338-in-10,000.

EPA argues that the Facility is causing an imminent and substantial endangerment because its emissions result in off-site, ambient air concentrations of chloroprene greater than 0.2 $\mu g/m^3$—a level that EPA alleges is needed to ensure that the lifetime cancer risk due to chloroprene exposure continuously *all day, every day for 70 years* is no higher than 1-in-10,000. Thus, EPA's case is about reducing lifetime chloroprene cancer risk from 5-in-10,000 to 1-in-10,000 (a reduction in risk of 4-in-10,000). This means that a hypothetical (but completely implausible) person's lifetime cancer risk would be reduced from 3,338-in-10,000 to 3,334-in-10,000. So dire is this endangerment, according to EPA, that this Court must shut down DPE's Facility immediately. Never before has EPA made a claim like this one—and for good reason. Even under the facts alleged by EPA, there is no imminent and substantial endangerment as a matter of law.

EPA's "emergency" action here runs directly counter to the statutory program that Congress created under Section 112 of the Clean Air Act ("CAA") to address this exact situation—

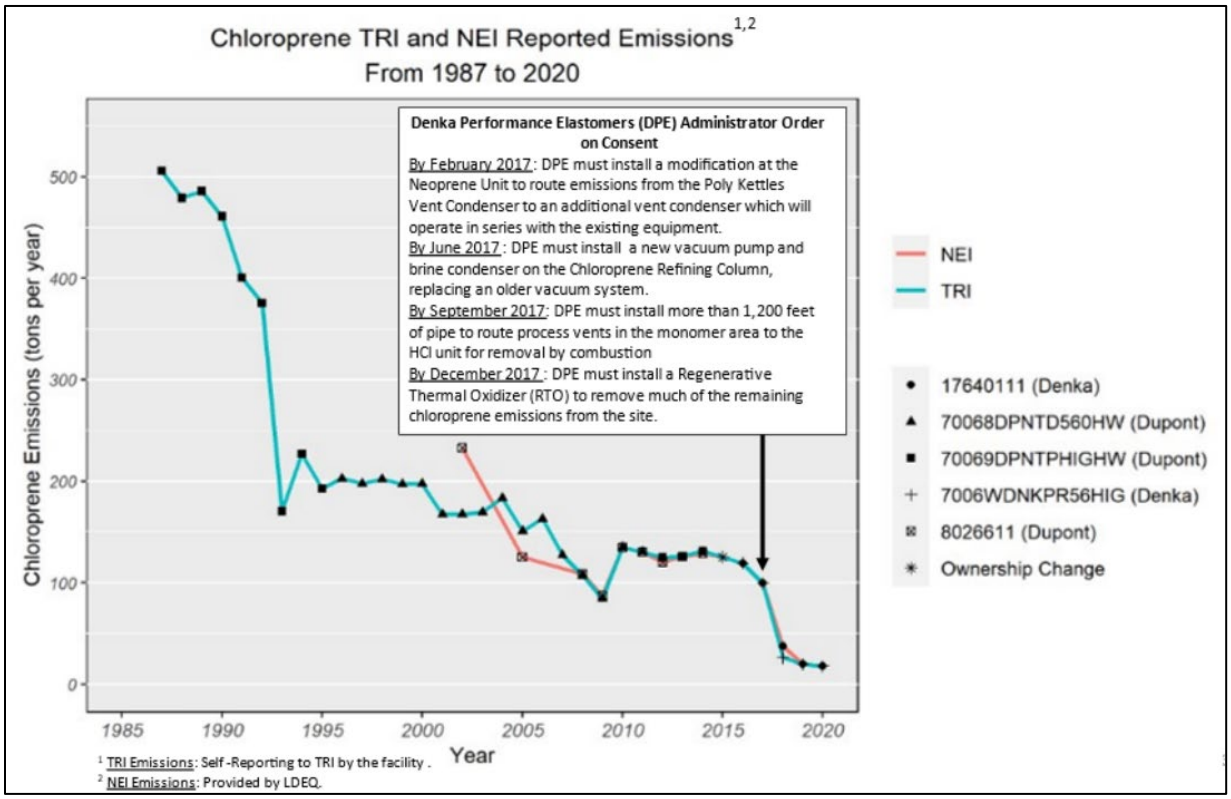
[1] *See* https://www.cdc.gov/chronicdisease/resources/publications/factsheets/cancer.htm (last checked on Dec. 19, 2023).

alleged cancer risks caused by emissions from an industrial facility. 42 U.S.C. § 7412. EPA has already issued a proposed rule for chloroprene under Section 112 that addresses the very same emissions from the very same Facility but, critically, gives DPE two to three years to comply while the Facility remains operational (instead of an immediate shutdown as EPA demands here). 88 Fed. Reg. 25,080 (April 25, 2023) ("Proposed Rule") (Ex. 1). Given that the final rule for chloroprene is due on March 29, 2024, the Court may question why it should bother holding a two-week trial only days before the final rule is issued. There is no good answer to that question.

Under Section 112, Congress required EPA to adopt rules to address the exact risks at issue here. But under the timelines adopted by Congress, risk reviews were not required until *18 years* after the statute was adopted. Surely, if Congress believed that a cancer risk above 1-in-10,000 was an imminent and substantial endangerment, it would not have given EPA 18 years to address it. Until this lawsuit, EPA had never suggested that a 1-in-10,000 risk level constitutes an imminent and substantial endangerment. To the contrary, EPA has tolerated far greater risk levels throughout its history of implementing Section 112, including a *60-in-10,000* risk in a 1989 rulemaking that EPA views as the "primary model" for Section 112 rulemaking and was specifically endorsed by Congress. Most recently, in the Proposed Rule, EPA was statutorily required to consider whether *current* chloroprene emissions *from the Facility* constitute an "imminent endangerment," and EPA determined that they do not.[2] Because those same emissions cannot constitute an "imminent *and substantial* endangerment" under Section 303, this fundamental concession alone requires dismissal of this action.

[2] As with all EPA rules, the Proposed Rule was signed by the head of EPA after sign-off from all relevant parts of EPA. In contrast, there is no such process for a Section 303 action such as this one, which requires sign-off only from lower-level officials in the enforcement office. *EPA Guidance on Use of Section 303 of the Clean Air Act* (Sept. 15, 1983) at 13 (Ex. 2).

The incongruity between this "emergency" action and the Proposed Rule is even more stark given EPA's admission that, for *seven years*, it has possessed data showing that ambient air chloroprene concentrations near the Facility far exceeded 0.2 μg/m^3. Compl. ¶¶ 44-45 (R. Doc. 1). EPA's own figure (copied below) shows the steep decline in the Facility's emissions, including during the seven years in which EPA possessed data it now relies upon to allege an emergency.



See 10/12/2022 Letter from EPA to LDEQ at 28 (Ex. 3). It defies credulity that there is suddenly an emergency now given EPA's years of inaction when emissions were far higher.

Finally, summary judgment should be granted because EPA admits it has no evidence to substantiate the 1-in-10,000 risk level, a figure that relies entirely upon a default, worst-case scenario assumption. That unsubstantiated assumption is insufficient to prove that the Facility's emissions pose an imminent and substantial endangerment to human health.

II. LEGAL STANDARD

In this action, EPA must prove that "a pollution source … is presenting an imminent and substantial endangerment to public health or welfare, or the environment." 42 U.S.C. § 7603.

Summary judgment is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In assessing if any material fact issues exist, a court considers "all of the evidence in the record but refrains from making credibility determinations or weighing the evidence." *Delta & Pine Land Co. v. Nationwide Agribusiness Ins. Co.*, 530 F.3d 395, 398 (5th Cir. 2008). A party cannot defeat summary judgment with conclusory allegations or unsubstantiated assertions. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994). If the dispositive issue is one on which the nonmoving party will bear the burden of proof at trial, the moving party may satisfy its burden by merely pointing out that the evidence in the record is insufficient with respect to an essential element of the nonmoving party's claim. *See Celotex*, 477 U.S. at 325. The burden then shifts to the nonmoving party, who must, by submitting or referring to evidence, set out specific facts showing that a genuine issue exists. *See id.* at 324. The nonmovant may not rest upon the pleadings but must identify specific facts that establish a genuine issue for trial. *See id.* at 325.

Here, summary judgment may be granted if EPA has failed to present sufficient evidence for the Court "to find that the alleged [pollution] presents a reasonable prospect of future harm and hence that it may present an imminent and substantial endangerment to health or the environment." *Simsbury-Avon Preservation Club, Inc. v. Metacon Gun Club, Inc.*, 575 F.3d 199, 211-12 (2d Cir. 2009) (applying RCRA).

III. ARGUMENT

A. In Issuing The Proposed Rule, EPA Conceded That The Facility's Emissions Are Not Causing An "Imminent Endangerment."

EPA's claim that the Facility's chloroprene emissions are causing an imminent and substantial endangerment is directly refuted by the Proposed Rule that EPA published *after* it initiated this litigation. 88 Fed. Reg. 25,080 (Ex. 1). As discussed below, in issuing the Proposed Rule, EPA was *required* by statute to assess whether the Facility's current chloroprene emissions constitute an "imminent endangerment," 42 U.S.C. § 7412(f)(4), and EPA necessarily determined they do not. Having already determined that the Facility's chloroprene emissions are not causing an "imminent endangerment," EPA cannot legitimately assert that those *same emissions* constitute an even more dire "imminent *and substantial* endangerment" under Section 303.[3]

Under Section 112(f) of the CAA, when EPA issues new pollution control requirements to address unacceptable cancer risks, there is a statutory presumption that a source must comply with those requirements within 90 days. 42 U.S.C. § 7412(f)(4). However, this default 90-day period may be extended up to two years if EPA grants a compliance "waiver." *Id.* A waiver of the 90-day compliance deadline may be extended only if EPA "finds that [additional time] is necessary for the installation of controls and that *steps will be taken during the period of the waiver to assure that the health of persons will be protected from* ***imminent endangerment***." *Id.* (emphasis added).

[3] EPA's concession that there is no imminent endangerment is an evidentiary admission. *See In re McLain*, 516 F.3d 301, 309 (5th Cir. 2008) (evidentiary admissions include a "concession made for some independent purpose" and "[s]uch admissions 'are received as substantive evidence of the facts admitted'") (quoting *Martinez v. Bally's Louisiana, Inc.*, 244 F.3d 474, 476–77 (5th Cir. 2001)); 2 McCormick On Evid. § 254 (8th ed.) (recognizing "admissions by conduct"). EPA's admission requires dismissal of this action because proving an imminent endangerment is a core element of EPA's case.

In the Proposed Rule, EPA gave DPE the full 2-year period to comply with the Section 112(f) requirements. 88 Fed. Reg. at 25,178 (Ex. 1). EPA said the 2-year period is appropriate because the "proposed provisions will require additional time to plan, purchase, and install equipment for … chloroprene control." *Id.* Section 112(f)(4) precludes EPA from granting the 2-year waiver unless it finds that (i) there is no "imminent endangerment" or (ii) steps will be taken to protect against such an endangerment. Thus, under the statute's plain language, EPA could *not have granted the waiver* in the Proposed Rule *unless it found there is no imminent endangerment*, because EPA did not include any steps to protect against any purported imminent endangerment.[4]

Indeed, EPA's grant of the 2-year waiver in the Proposed Rule is consistent with EPA's long-standing view that lifetime cancer risks above 1-in-10,000 do not constitute "imminent endangerment" and the fact that, for 30 years, EPA has routinely granted Section 112(f) compliance waivers even when cancer risks are well above this level. In fact, EPA has admitted that it has *never* found a pre-compliance risk level in a rulemaking to be an "imminent endangerment," including rulemakings where the pre-compliance risk level was greater than 1-in-10,000. *See* EPA's Response to Interrogatory No. 17 at 17 (Ex. 4). For example, in the proposed rule for Sterilization Facilities, EPA proposed an 18-month waiver where the maximum risk was *60-in-10,000* and 18,000 people faced higher than the 1-in-10,000 risk level. *See* 88 Fed. Reg. 22,790, 22,794 (4/13/23) (risk estimates) (Ex. 5); *id.* at 22,852-53 (waiver). In addition, EPA's

[4] EPA has tried to avoid this critical concession in the Proposed Rule by arguing that the preamble to the Proposed Rule is silent on whether there is no "imminent endangerment." R. Doc. 94 at 11. But that argument ignores the statutory language, which mandates that the 2-year waiver (which EPA granted) *cannot be granted* unless there is no imminent endangerment or EPA identifies steps to avoid such endangerment. Thus, the waiver could not have been granted *unless EPA found no imminent endangerment*. Under the statute's plain language, EPA cannot avoid the implications of its granting the 2-year waiver by relying on the absence of "magic words" in the preamble.

Proposed Rule proposes the same 2-year waiver for ethylene oxide sources despite those sources having risk estimates *higher* than chloroprene. *See* 88 Fed. Reg. at 25,116 (15-in-10,000 risk estimate solely for ethylene oxide pressure relief devices) (Ex. 1); *id.* at 25,178 (waiver).

Before publication, the Office of Management and Budget ("OMB") reviewed the Proposed Rule and questioned if the Facility's emissions would constitute an "imminent endangerment." OMB Review at 347 (Ex. 6). OMB asked that EPA address "what steps will be taken during the proposed 2-year period to assure that the health of people exposed to [chloroprene] emissions (including children) will receive protection from imminent endangerment[.]" *Id.* EPA declined to change the 2-year waiver and made no changes to describe steps to protect from "imminent endangerment." Instead, EPA responded that "[s]ignificant capital will need to be invested in controls here to further reduce emissions [of ethylene oxide] and chloroprene. . . . This takes significant time [to] engineer, install, and update operating procedures and staff." *Id.* Under the plain language of Section 112(f), by declining to impose any protective steps during the compliance period, EPA conceded there is no imminent endangerment.

EPA's grant of a waiver in the Proposed Rule confirms that a 1-in-10,000 risk estimate was never designed as a measure of whether emissions cause an "imminent endangerment." That is why EPA routinely—indeed, ***always*** (*see* EPA's Response to Interrogatory No. 17 at 17 (Ex. 4))—grants waivers under Section 112(f), like it has done here, because it recognizes that upper-bound lifetime cancer risks are not proof of "imminent endangerment." Indeed, EPA made this point emphatically in 2011 in response to a public comment arguing that a 2-year waiver violated Section 112(f)(4) because an "unacceptable" risk would persist during the compliance period:

> The commenter has not indicated any specific concern which presents an "imminent endangerment" that will occur during the two-year compliance period, merely making general allegations about the risks which formed the basis of the EPA's decision to promulgate regulations. Since Congress recognized that a 2-year

> compliance period may be granted despite EPA's determining to promulgate regulations to address risk, it is clear that Congress did not contemplate that any risk addressed by rules under 112(f)(2) created an imminent and substantial endangerment that would preclude a 2-year compliance date.[5]

That exact analysis applies here. But EPA is contorting itself—*in this case, and this case only*—to argue that the same "general allegations" of risks covered by Section 112(f) constitute an imminent and substantial endangerment. If the Facility's emissions do not present an "imminent endangerment," as EPA conceded in the Proposed Rule, then there is plainly no "imminent *and substantial* endangerment" for purposes of this Section 303 action.

B. The Risk Levels Alleged By EPA In This Lawsuit Do Not Constitute An Imminent And Substantial Endangerment As A Matter Of Law.

EPA's fundamental allegation in this action is that chloroprene emissions from the Facility are causing a lifetime cancer risk of greater than 1-in-10,000, which constitutes an imminent and substantial endangerment. *See, e.g.*, Compl. ¶ 58 (R. Doc. 1). While EPA's threshold for imminent and substantial endangerment is 1-in-10,000, the highest level of risk alleged by EPA equates to a 14-in-10,000 risk, based on concentrations measured at one monitoring location over a 45-month period before EPA filed the Complaint. *Id.* ¶ 48. As of December 8, 2023, however, the highest alleged concentration measured over the prior 12-months had decreased, equating to a 5.4-in-10,000 risk level as determined by EPA's expert. *See* 12/8/23 Vandenberg Decl. ¶ 10 (Ex. 7).

DPE strongly disputes EPA's claims about the cancer risk of chloroprene, but for purposes of this Motion, the Court can assume the above alleged risk levels are accurate and still grant summary judgment. The reason: The lifetime risk level alleged by EPA here—be it 1-in-10,000 or the outdated 14-in-10,000—does not constitute an imminent and substantial endangerment as a

[5] EPA, *Nat'l Emission Stands. for Haz. Air Pollutants: Primary Lead Smelting, Sum. of Pub. Comment and Response* at 21, Docket No. EPA-HQ-OAR-2004-0305 (Nov. 4, 2011) (Ex. 38).

matter of law. Congressional intent expressed in Section 112, and EPA's long-standing actions in implementing Section 112, demonstrate that a risk level of 1-in-10,000 (or 14-in-10,000) cannot be used as a threshold for an alleged imminent and substantial endangerment.

1. In Section 112, Congress made clear that the risk levels alleged by EPA here do not constitute an imminent and substantial endangerment by mandating that such risks be addressed through an *18-year* regulatory process.

In Section 112 of the CAA, Congress created a comprehensive program to address cancer risks due to emissions of hazardous air pollutants ("HAPs") from industrial facilities. In Section 112, Congress imposed deadlines by which EPA was required to take several steps:

- Within one year after the statute was signed into law in 1990, EPA was to identify "source categories"—different types of industrial facilities—that included "major sources" of such pollutants. 42 U.S.C. § 7412(c)(1).
- Within ten years (by 2000), EPA was to conduct rulemakings to set technology-based standards to reduce HAP emissions from each source category. *Id.* § 7412(d)(2).
- Within eight years of setting those standards, EPA was to conduct another rulemaking to complete a "residual risk review"—*i.e.*, to evaluate the "risk to public health remaining" after the implementation of the technology-based standards. As part of this rulemaking, EPA was *for the first time* required to consider whether more stringent standards were needed to address lifetime cancer risks higher than 1-in-10,000. *Id.* § 7412(f)(2).

This means that Congress knew that people were then exposed to lifetime cancer risks higher than 1-in-10,000 due to HAPs, yet Congress determined that it was acceptable to allow such exposure *for up to 18 years*.[6] The premise of EPA's action here—that this Court must immediately order the shutdown of the Facility to abate the risk of chloroprene—directly contradicts Congress' mandate under Section 112 that the *exact same risks* be addressed over many years under Section 112. That EPA *is currently addressing* those risks through the Proposed Rule simply underscores the incongruity of EPA's emergency action here.

[6] Congress also understood that rules promulgated under Section 112 would be subject to legal challenge, potentially extending the time before implementation. 42 U.S.C. § 7412(e)(4).

Even if Section 303 *were* an appropriate vehicle to address such long-term risks, EPA's use of the 1-in-10,000 risk level cannot be used to declare an emergency because it flatly contradicts the purpose of Section 112's 1-in-10,000 risk benchmark. Congress endorsed using the 1-in-10,000 risk level within the context of Section 112 rulemaking. Section 112(f)(2)(B) expressly endorsed EPA's use of the 1-in-10,000 risk level in a 1989 rulemaking to guide what constitutes an "acceptable risk" under Section 112. 54 Fed. Reg. 38,044 (Sept. 14, 1989) ("Benzene Rule") (Ex. 8).[7] In the Benzene Rule, EPA stated that it would "generally presume that if the risk to [the maximum exposed] individual is no higher than approximately one in 10 thousand, that risk level is considered acceptable." *Id.* at 38,045. As made clear in the Benzene Rule, this "presumptive" risk level of 1-in-10,000 is the *beginning* of EPA's framework for rulemaking, which includes significant safeguards to prevent reflexive reliance on a bare number. Here, however, EPA casts aside those safeguards and demands that this Court begin *and end* the analysis based solely on the 1-in-10,000 risk level to order an immediate shutdown of the Facility.

In the Benzene Rule, EPA set out a flexible process, requiring consideration of a range of factors, including scientific uncertainties and weight of evidence. *Id.* 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.* In establishing the 1-in-10,000 risk level in the Benzene Rule, EPA made clear that, "rather than a rigid line for acceptability, the Agency intends to weigh [the risk level] with a series of other health measures and factors." *Id.* Indeed, in the Benzene Rule, EPA expressly rejected using the 1-in-10,000 risk level as a bright

[7] As EPA acknowledges, the Benzene Rule "remains the primary model for establishing emission standards in the context of CAA Section 112(f) rulemaking. The approach developed in this rule was endorsed by Congress in the CAA's 1990 Amendments. *See* 42 U.S.C. § 7412(f)(2)(B)." EPA's Response to Interrogatory No. 6 at 12 (Ex. 9).

line. *Id.* (declining to select "Approach C" which considered only the 1-in-10,000 risk level to determine "acceptability" without incorporating consideration of other factors).

Specific to chloroprene, in 2019, EPA expressly confirmed that the 1-in-10,000 risk level "is *not based on an evaluation of current, real world exposures*," and "is *not a 'bright line'* for determining whether a risk level is considered safe or acceptable." *See* 9/23/19 Letter from EPA to LDEQ at 2 (Ex. 10) (emphasis added). But here, EPA is treating 1-in-10,000 as a "bright line" standard to shut down the Facility immediately, without giving any consideration to the uncertainties of the science, safety, and other relevant factors. Declaring an emergency and shutting down industrial facilities every time an upper-bound risk level exceeds 1-in-10,000, without bothering to consider the other relevant factors, would render meaningless the approach authorized in the Benzene Rule and endorsed by Congress. If Congress wanted to automatically deem risks above 1-in-10,000 as emergencies, then Congress easily could have included such a directive in Section 112(f)(2)(B), instead of mandating a rulemaking approach that requires full consideration of the "many relevant factors" and takes years to complete and implement.[8]

Making EPA's "emergency" action here even more inexplicable is the fact that, through the Proposed Rule, EPA is simultaneously pursuing a Section 112 rulemaking that specifically addresses chloroprene emissions from the Facility. In both the Proposed Rule and this action, EPA seeks to apply the inhalation unit risk ("IUR") for chloroprene to address the 1-in-10,000 risk level. *See, e.g.,* Compl. ¶¶ 58-59; 88 Fed. Reg. at 25,097-98 (Ex. 1). But there is a critical difference: The Proposed Rule would allow the Facility two to three years to comply, while EPA demands in

[8] Congress amended Section 303 in the *same bill* it created the Section 112 framework endorsing the Benzene Rule. *See* Pub. L. No. 101-549, 104 Stat. 2681 (Section 704 amending Section 303 of the CAA); *see also id.* 104 Stat. 2531 (Section 301 amending Section 112 of the CAA). In so doing, Congress was aware of the 1-in-10,000 risk level and plainly opted to address that risk through the rulemaking regime of Section 112 and not the emergency provisions of Section 303.

this action that the Facility immediately shut down and not return to operation until it can "demonstrate" an ability to meet the 0.2 μg/m^3 ambient air standard. *See* 88 Fed. Reg. at 25,177-78; EPA's Statement of Final Relief at 2 (Ex. 11).[9]

Further, EPA's reliance on the 1-in-10,000 risk level applicable in Section 112 rulemakings is particularly improper in this action because, while Section 112 may allow EPA to use "upper-bound" estimates of cancer risks (*i.e.*, the "maximum plausible" estimate[10]), Section 303 only allows EPA action when a facility "is presenting" an imminent and substantial endangerment. Section 303 requires EPA to show that there is an imminent risk to human health—not that there might be a risk to someone residing near the Facility continuously for 70 years. *See Me. Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 70 F.4th 582, 599 (D.C. Cir. 2023) (vacating agency action relying on "worst-case scenario" assumptions because "when the Congress wants an agency to apply a precautionary principle, it says so"). The higher standard of scientific certainty for Section 303 comports with Section 303's lack of procedural safeguards, like notice-and-comment rulemaking.

EPA has argued that the "notwithstanding" language in Section 303 provides EPA with the authority for this action. *See, e.g.,* R. Doc. 94 at 5-6. But the issue is not EPA's *authority* under Section 303, but rather one of statutory interpretation—*i.e.*, whether Congress intended to use

[9] As another example of EPA's unexplainable inconsistency, EPA alleges in this action that 15,000 to 17,000 people are exposed to a cancer risk level greater than 1-in-10,000 due to the Facility's chloroprene emissions. *See* R. Doc. 9 at 3. But in the Proposed Rule, EPA says that roughly 2,300 people are exposed to the same risk. *See* 88 Fed. Reg. at 25,107 (Ex. 1).

[10] *See, e.g.,* 88 Fed. Reg. at 25,103 ("Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk. That is, they represent a 'plausible upper limit to the true value of a quantity' (although this is usually not a true statistical confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.") (Ex. 1).

upper-bound estimates of risks higher than 1-in-10,000 as a benchmark for an imminent and substantial endangerment. The "notwithstanding" language in Section 303 plainly does not preclude this Court from looking to Section 112 to interpret statutory text, particularly when Congress simultaneously adopted the current versions of Sections 112 and 303. *See supra* n.8.

In sum, as the Proposed Rule demonstrates, Congress enacted Section 112 to deal with long-term cancer risks and expressly endorsed using that authority to address risk levels greater than 1-in-10,000. Here, EPA is short-circuiting Section 112 by simultaneously pursuing this incompatible lawsuit. If EPA were to begin addressing risks due to HAPs through emergency actions under Section 303, it would undermine the carefully calibrated process created by Congress in Section 112. Thus, this Court should find, as a matter of law, that EPA may not use Section 303 to shortcut the rulemaking procedures of Section 112 and grant this Motion.

2. The Benzene Rule addressed risk levels up to *60-times higher* than the 1-in-10,000 risk level EPA relies on here, yet EPA did not allege the facilities responsible for such risks were causing an imminent and substantial endangerment.

EPA admits that the Benzene Rule is "the primary model for establishing emission standards" under Section 112 and that "[t]he approach developed in [the Benzene] rule was endorsed by Congress in the CAA's 1990 Amendments." EPA's Response to Interrogatory No. 6 at 12 (Ex. 9). This Court need look no further than the Benzene Rule—the Congressionally endorsed "primary model for establishing emission standards" (*id.*)—to find that the risk levels alleged by EPA in this action, which are dwarfed by the risk levels addressed in the Benzene Rule, do not constitute an imminent and substantial endangerment as a matter of law.

The proposed Benzene Rule was published in July 1988 to establish emission standards for five categories of facilities, known as "source categories." 53 Fed. Reg. 28,496 (July 28, 1988) (Ex. 12). Of those five source categories, EPA determined that the "coke by-product recovery

plant" category posed the highest risk, estimating a risk level of 60-in-10,000 (or 6 x 10^{-3}), or 60 times higher than the 1-in-10,000 risk level EPA relies upon to allege an emergency here. *Id.* at 28,498. That risk level is also 10 times higher than the risk EPA attributes to the Facility in the Proposed Rule (6-in-10,000),[11] more than 10 times higher than the highest risk level EPA attributes to the Facility in the past 12 months (5.4-in-10,000),[12] and more than four times higher even than the highest risk level EPA attributed to the Facility based on outdated data (14-in-10,000).[13] Despite being far higher than any risk level alleged in this action, EPA did not assert that coke by-product recovery plants were causing an imminent and substantial endangerment prior to implementation of the final rule—even though, in the final Benzene Rule, EPA determined that the estimated risk level was actually 70-in-10,000.[14]

In addition to addressing substantially higher risk levels than EPA alleges in this action, in the Benzene Rule proposal, EPA also estimated that far more people were exposed to risks greater than 1-in-10,000. Here, EPA estimated that, as of March 2023, 16,000 residents were exposed to greater than a 1-in-10,000 risk from chloroprene. Vandenberg Decl. ¶ 59 (R. Doc. 9-6). Notably, the Proposed Rule estimates that 2,300 people (13,700 fewer than EPA alleges here) were exposed to that level of risk. 88 Fed. Reg. at 25,107 (Ex. 1). But even accepting EPA's exaggerated

[11] *See* 88 Fed. Reg. at 25,107 (Ex. 1) (Table 2 showing a Facility-wide "maximum individual cancer risk" of 600-in-1 million, or 6-in-10,000, including from non-chloroprene sources).

[12] *See* 12/8/23 Vandenberg Decl. ¶ 10 (Ex. 7) (Table 1 showing maximum average concentration level between 10/28/22 and 10/2/23 of 1.08 μg/m^3 or a 5.4-in-10,000 risk level).

[13] *See* Vandenberg Decl. ¶ 60 (R. Doc. 9-6) ("The estimated lifetime cancer risks from chloroprene concentrations detected in the air at the Active monitoring sites range from 2 to 14 per 10,000 people. . . ."). EPA relied on Dr. Vandenberg to allege a maximum risk level of 14-in-10,000 in its Complaint. *See* R. Doc. 1, ¶ 48.

[14] *See* 54 Fed. Reg. at 38,051 ("There are now 36 coke by-product recovery plants . . . . The revised baseline estimates of health risk indicate an MIR of 7x10^{-3} and an annual cancer incidence of 1 case every 6 months (2 cases/year).") (Ex. 8).

litigation number here, it is a mere fraction of the estimated *100,000 people* exposed to risks greater than 1-in-10,000 from coke by-product recovery plants. 53 Fed. Reg. at 28,498 (Table I-1 listing estimated population subject to "baseline" risk of 1 x 10^{-4} before compliance with rule) (Ex. 12).

These numbers simply cannot be squared with EPA's allegations in this case. If a 1-in-10,000 risk level constitutes an imminent and substantial endangerment, as EPA alleges here, then surely EPA would not have tolerated such risk levels for 100,000 people in the rule that serves as EPA's "primary model" for regulation of HAPs like chloroprene. Further, by explicitly endorsing the Benzene Rule (in the same legislation in which it adopted the current Section 303), Congress made clear that it did not believe that industrial plants causing lifetime cancer risks higher than 1-in-10,000 were causing an imminent and substantial endangerment. In the end, EPA lacks any legitimate basis to argue that Congress considered a 1-in-10,000 risk level to be an imminent and substantial endangerment while expressly endorsing a rule that allowed risk levels at least 60 times higher to be go unaddressed between a proposed and final rule. The risk levels alleged by EPA in this action, including the highest alleged (outdated) risk of 14-in-10,000, are well within the levels of risk that both EPA and Congress determined are properly addressed through Section 112 rulemakings—not through alleged emergency actions under Section 303 seeking an *immediate* shutdown of a facility while an applicable rule under Section 112 is pending.

3. EPA's long-standing acceptance of risk levels greater than 1-in-10,000 shows that such level of risk is not a permissible threshold for alleging an imminent and substantial endangerment.

Consistent with the Benzene Rule, EPA has—except for this lawsuit—*always* accepted risk levels over 1-in-10,000 without declaring an imminent and substantial endangerment. In the most recent example, in a Compliance Advisory published in March 2023 (*i.e.*, one month after EPA filed this lawsuit), EPA stated: "EPA estimates that *14 million people* in just 60 urban areas of the United States have more than a 1-in-10,000 lifetime risk of developing cancer caused by air

pollution."[15] Yet, EPA has not seen fit to declare an imminent and substantial endangerment as to those 14 million people. Likewise, EPA estimated that, as of 1996, 18% of children in the United States "lived in counties in which hazardous air pollutants combined to exceed the 1-in-10,000 cancer risk benchmark."[16] But instead of declaring an imminent and substantial endangerment as to those millions of children, EPA lawfully addressed the HAPs through Section 112 rulemaking.

EPA provides no estimate of actual cancer risk in this lawsuit, but the Proposed Rule (using the "maximum plausible" estimate of risk) estimates that without the further emissions controls contemplated by the Proposed Rule there will be 0.06 cancer incidences per year due to emissions from the Facility, or approximately one cancer case every 17 years. 88 Fed. Reg. at 25,120-21 (Ex. 1). Given that the Proposed Rule is anticipated to become effective beginning in just over two years (equating to less than 1/8th of a cancer by EPA's estimate), EPA's demand that the Facility shut down immediately serves no legitimate purpose in preventing cancer. Further, after the rule becomes effective, EPA estimates that cancer incidence will fall to near zero. *Id.*

If this Court were to accept EPA's truly unprecedented allegation of an emergency under the circumstances of this case, then comparable and far worse Section 303 emergencies would exist at dozens of other facilities across the country. For example, EPA admits that 23 ethylene oxide facilities pose risks greater than 1-in-10,000, but EPA has not alleged an emergency as to any of them. *See* EPA's Responses to RFA Nos. 3-4 at 6-7 (Ex. 15).[17] The Proposed Rule

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[15] EPA, *Federal Facility Compliance Under EPA's National Enforcement and Compliance Initiative to Create Cleaner Air for Communities* (Mar. 2023) (Ex. 13) (emphasis added).

[16] *See* EPA, *America's Children and the Environment Report, 2d. Ed.* (Feb. 2003) at 31 (Ex. 14).

[17] *See also* EPA, *Ethylene Oxide Risk from Commercial Sterilizers* (last updated Nov. 15, 2022) (Ex. 16). Notably, after EPA provided its responses to DPE's RFA Nos. 3-4, EPA revised its webpage to state that the information "is no longer current" and that "EPA has proposed two new

estimates that 4,200 people in communities around "HON" facilities will remain at risk above 1-in-10,000 primarily due to ethylene oxide even *after* implementation of the rule. 88 Fed. Reg. at 25,110-11 (Ex. 1). EPA estimates that there are fifteen U.S. census tracts where ethylene oxide poses a higher cancer risk than chloroprene poses here.[18] As with chloroprene, EPA has concluded that ethylene oxide operates through a "mutagenic mode of action," meaning that the alleged risks to children are higher in those fifteen tracts than in the tract in which the Facility is located. In four of those tracts the risk is more than twice as high.[19] Thus, even assuming that EPA were correct (it is not) that infants near the Facility exceed the 1-in-10,000 threshold "by their second birthday," Compl. ¶ 42, then infants in at least fifteen other tracts—near other facilities—would exceed the same threshold even faster. Yet EPA has seen fit to declare an emergency only here.

When EPA has identified a risk level greater than 1-in-10,000 in past rulemakings, EPA has *never* declared an imminent and substantial endangerment or otherwise limited emissions from the regulated facilities during the pendency of the rulemaking process or while the rule is being implemented. In fact, EPA has issued final regulations that expressly allow for lifetime cancer risks greater than 1-in-10,000.[20] In many rulemakings, EPA has identified pre-compliance cancer

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actions to address emissions of ethylene oxide from commercial sterilizers and to reduce risks for people who live, work, or go to school near these facilities." *Id.* at 2 (last visited Dec. 28, 2023). Tellingly, EPA has still not taken any action under Section 303 to address an alleged imminent and substantial endangerment relating to those facilities.

[18] *See* EPA, *2019 AirToxScreen: Assessment Results* (last updated Dec. 27, 2023) (providing access to pollutant-specific data in spreadsheet entitled 2019 AirToxScreen National Cancer Risk by Pollutant (xlsx) (Ex. 17) (excerpt of spreadsheet)).

[19] *Id.* (identifying Tracts 72123953100, 13217100300, 48141010337 and 48141010338 as having risk from ethylene oxide emissions more than twice the chloroprene risk in the Facility's tract).

[20] *See* 70 Fed. Reg. 19,992, 19,994 (April 15, 2005) (NESHAP for Coke Oven Batteries setting lifetime cancer risk from exposure to coke oven emissions at 2.7-in-10,000) (Ex. 18); 72 Fed. Reg. 25,138, 25,143 (May 3, 2007) (NESHAP for Halogenated Solvent Cleaning settings risk level of 2-in-10,000) (Ex. 19).

risks much higher than 1-in-10,000 and has never initiated an imminent and substantial endangerment action against facilities contributing to such risk. For example, EPA has identified maximum risk levels of (i) 20-in-10,000 (SOCMI source category),[21] (ii) 60-in-10,000 (commercial sterilization facilities source category),[22] and 20-in-10,000 (miscellaneous organic chemical manufacturing source category).[23] For each of these source categories, EPA estimated that more people were exposed to a risk level at or above 1-in-10,000 (87,000, 18,000, and 18,000 people, respectively) than the 16,000 people EPA alleges in this case. *Id.*

Until this case, EPA has never sought to shut down a facility based on a risk level exceeding 1-in-10,000, let alone during an ongoing rulemaking process. Facilities have always been allowed to operate during the rulemaking process and, once EPA issues a final rule, facilities typically have at least two years to make the required emission reductions.[24] Again, EPA's own rules routinely allow facilities to operate under circumstances that EPA here claims constitute an emergency. The very purpose of the 1-in-10,000 benchmark is to facilitate rulemaking under Section 112, not to circumvent it as EPA seeks to do in this unprecedented Section 303 action.

[21] 88 Fed. Reg. at 25,106 (Ex. 1) (Table 1: 2,000-in-1,000,000 risk level).

[22] 88 Fed. Reg. at 22,794-22,795 (Ex. 5) (Table 2: 6,000-in-1,000,000 risk level).

[23] 85 Fed. Reg. 49,084, 49,093 (Aug. 12, 2020) (Ex. 20) (Table 2: 18,000-in-1,000,000 risk level).

[24] For example, the Proposed Rule would give ethylene oxide sources, some of which have risk estimates *higher* than chloroprene, two years to comply. *See* 88 Fed. Reg. at 25,178 (Ex. 1).

4. EPA's decision not to take "emergency" action against the Facility for seven years simply underscores EPA's long-standing position that a 1-in-10,000 risk level does not constitute an imminent and substantial endangerment.

EPA has authority to act under Section 303 only "upon receipt of evidence" of an "imminent and substantial endangerment." 42 U.S.C. § 7603. It is undisputed that, since December 2015, EPA has possessed evidence that, *according to EPA*, shows the Facility's chloroprene emissions cause a lifetime cancer risk greater than 1-in-10,000. Yet EPA deliberately waited over seven years—until February 2023, when the Facility's chloroprene emissions had been reduced by 85% compared to 2015 levels—to bring this Section 303 action. The following undisputed facts completely undermine EPA's assertion in this action that a 1-in-10,000 risk level is a lawful threshold for an imminent and substantial endangerment:

- In December 2015, with the release of the 2011 NATA, EPA possessed evidence of what it now claims to be an imminent and substantial endangerment due to chloroprene emissions from the Facility. *See* EPA's Response to Interrogatory No. 3 at 7 (Ex. 21).

- In January 2016, EPA believed its modeling using the Facility's 2014 emissions data showed risk levels much higher than 1-in-10,000. *Id.* According to James Leathers, who verified EPA's response to Interrogatory No. 3, EPA could have declared an imminent and substantial endangerment based on that 2016 modeling. Leathers Tr. at 127:11-128:13 (Ex. 22).

- As of May and August 2016, when EPA and DPE, respectively, began air sampling at the Facility, EPA had further evidence of what it now claims is an imminent and substantial endangerment and could have brought a Section 303 action. EPA's Response to Interrogatory No. 3 at 8 (Ex. 21); Leathers Tr. at 131:9-132:10 (Ex. 22). As of August 2016, "the monitoring results [EPA was] seeing [were] pointing to a ***10^{-3} risk*** in LaPlace, or a ***1/1,000 risk*** of getting cancer in a lifetime." 8/10/16 EPA Email (Ex. 23) (emphasis added). In other words, seven years

ago, EPA observed *ten times* the risk level it now says constitutes an emergency. Mr. Leathers agreed that the monitoring data from 2016 through 2021 "showed chloroprene concentrations that were an order of magnitude higher than EPA's 2010 high risk value for chloroprene." Leathers Tr. at 140:13-141:14 (Ex. 22).

- As early as July 2016—seven years before filing this action—EPA was actively reviewing with the Department of Justice a potential Section 303 action against DPE. 7/5/16 EPA Email (Ex. 24).

- On November 13, 2017, law professor Mark Squillace demanded that EPA declare a Section 303 emergency at the Facility, arguing that residents were exposed "to chloroprene levels that far exceed the levels that EPA deems … acceptable." *See* 11/13/17 Letter from Squillace to EPA (Ex. 25); Leathers Tr. at 149:3-11 (Ex. 22). Indeed, Mr. Leathers testified that EPA had evidence of "an emergency" nine months before Prof. Squillace's demand letter, Leathers Tr. at 178:5-12, and that EPA could have declared an emergency at that time but chose not to. *Id.* at 151:13-152:6 (Ex. 22).

- Instead of pursuing a Section 303 action, EPA touted the emission reductions that the Facility agreed to make under the January 2017 Administrative Order on Consent ("AOC") reached between LDEQ and DPE, with EPA's support. *See* 12/15/17 Letter from EPA to Squillace (Ex. 26). In fact, internal EPA documents show that, when the AOC was finalized in January 2017, "EPA determined that an [imminent and substantial endangerment] order *was not the path forward*." EPA chronology at EPA_0827743 (Ex. 27) (emphasis added); *see* also 10/23/17 EPA Email (Ex. 28); Leathers Tr. at 180:3-25; 181:20-183:5 (Ex. 22). Instead of pursuing a Section 303 action, "EPA and DOJ advised and consulted LDEQ on their [AOC]," which "requires Denka to reduce chloroprene by 85% from 2014 emissions levels, most of which will be achieved through

a regenerative thermal oxidizer ["RTO"] to be installed by the end of 2017." (Ex. 28). It is undisputed this equipment was installed and achieved the anticipated emission reductions. *See* EPA Summary Report at 1 (Ex. 39) (EPA touting 85% reduction in emissions due to RTO).

- When EPA decided in January 2017 that a Section 303 action was "not the path forward," EPA knew that the emission reductions required under the AOC would *not* reduce chloroprene concentrations to the 0.2 μg/m^3 level that EPA now claims as the standard for abating an emergency. Leathers Tr. at 176:3-8; 187:9-19 (Ex. 22); *see also* 1/12/18 Letter from Squillace to EPA (Ex. 29) (noting EPA's acknowledgment that reductions required by AOC would not achieve 0.2 μg/m^3). Mr. Leathers confirmed that as of August 2020, after the RTO was running, EPA knew the Facility's chloroprene concentrations were still well above the 0.2 μg/m3 level and EPA had roughly four years of robust monitoring data. Leathers Tr. at 191:3-192:22 (Ex. 22).

- In May 2021, almost four years after Prof. Squillace's 2017 demand letter, local activists petitioned EPA to take emergency action under Section 303, alleging "a grave health emergency" due to chloroprene concentration levels "as high as 16.0 μg/m^3 in St. John." Petition to EPA at 1 (Ex. 30). EPA *still* declined to bring a Section 303 action, despite having data showing chloroprene concentrations of an order of magnitude higher than the 0.2 μg/m^3 level. Leathers Tr. at 140:13-141:14 (Ex. 22).

- EPA waited two more years, until February 2023, to bring this action—a time when the Facility's emission levels had dramatically decreased and seven years after EPA undisputedly possessed sufficient evidence of what it now claims to be an emergency. Even based on EPA's monitoring expert, fenceline concentrations during the period from October 2022 and October 2023 decreased at all active monitoring locations as compared to the period from April 2018 to

October 2023, with decreases ranging between 29% and 63%. 12/8/23 Vandenberg Decl. ¶ 10, Table 1 (Ex. 7).

In short, it is inconceivable that there is suddenly an emergency in 2023 warranting an immediate shutdown of the Facility when emissions are more than 85% lower than when EPA first received evidence supporting what it now claims to be an imminent and substantial endangerment. Why did EPA fail to assert such a claim for seven years while possessing evidence of chloroprene emissions "an order of magnitude higher" than they are today? The reason is simple: until it filed this action, EPA had never taken the position, and did not actually believe, that a 1-in-10,000 risk level constitutes a defensible threshold for a claim of imminent and substantial endangerment.

C. EPA's Chloroprene IUR Cannot Be Used As A Threshold For Alleging Imminent And Substantial Endangerment Because EPA Expressly Admits That The IUR Is Based On A Default Assumption That EPA Has No Evidence To Substantiate.

EPA claims that a lifetime of exposure to 0.2 $\mu g/m^3$ of chloroprene increases a *human's* risk of developing cancer by 1-in-10,000. This claim rests on a default assumption that humans are as susceptible to certain types of cancer as a particular species of female mice. Regardless of whether this default assumption was appropriate for the IRIS program to apply in the 2010 assessment of chloroprene ("2010 Review") (which DPE disputes), EPA has not met its burden of proof in *this* lawsuit. EPA has no evidence to substantiate this critical default assumption, which results in the unfounded use of the highest possible risk value. In this action, where EPA bears the burden of proof, it may not "rely[] upon worst-case scenarios or pessimistic assumptions" with no supporting empirical evidence. *See Me. Lobstermen's Ass'n*, 70 F.4th at 586, 599.

In the 2010 Review, EPA estimated the IUR based solely on a 1998 National Toxicology Program study ("NTP Study") of female B6C3F1 mice. *See* EPA's Response to RFA No. 17 at 18 (Ex. 15). Purely as a matter of policy, EPA estimates *human* IURs based on the IUR for the

most sensitive *animal* sex and species if (i) EPA does not identify a "clearly most relevant species" and (ii) no adequate human data are available. EPA's guidance document states:

> Although it is preferable to use human studies as the basis for the dose-response derivation, adequate human data are not always available, often forcing reliance on laboratory animal data. Presented with data from several animal studies, *the risk assessor first seeks to identify the animal model that is most relevant to humans*, based on comparability of biological effects using the most defensible biological rationale; for instance, by using comparative metabolic, pharmacokinetic, and pharmacodynamic data. *In the absence of a clearly most relevant species, however, the most sensitive species is used as a matter of science policy at the EPA*.[25]

By its terms, this policy only applies "in the absence of a clearly most relevant species" to humans. While DPE can demonstrate that a different animal in the NTP Study was the "clearly most relevant species" based on toxicokinetic data, that point need not be addressed to decide this Motion. But this Motion should be granted because there is no dispute that EPA failed to determine that the 2010 IUR is based on data most relevant to *human* risk. As the 2010 Review acknowledges, the IUR derived from female B6C3F1 mice studies was *not* based on data that allows for any adjustments to reflect the differences in risks applicable to mice versus humans:

> The calculated composite unit risk is based on the most sensitive endpoint (risk of any tumor type) in the most sensitive species and sex (female mouse). *There is no information on chloroprene to indicate that the observed rodent tumors are not relevant to humans*. Further, *no data exist to guide quantitative adjustment for differences in sensitivity among rodents and humans*.

2010 Review at 141 (Ex. 33) (emphases added).

EPA's burden in this lawsuit is to prove that there is an imminent and substantial endangerment *to humans*. Dr. Kristina Thayer, who leads the IRIS program, admitted that "EPA has . . . no idea of the true correspondence of the [B6C3F1] mouse to human response." Thayer

[25] EPA, *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (Oct. 1994) at 1-5 (Ex. 31) (emphases added). EPA's expert, Dr. Ila Cote, confirmed that, "in the absence of data to the contrary, the agency will use the most sensitive end point, which generally means the most sensitive [sex and] species." Cote Tr. 20:1-6 (Ex. 32).

Tr. 63:5-21; 154:11-14 (Ex. 34); *see also* 2010 Review at 139 (Ex. 33) (true correspondence of B6C3F1 mouse to human is "unknown"). And EPA admits that, since the 2010 Review, it has performed no *new* analysis to determine that the 2010 IUR provides a risk estimate representative of human risk, resting instead on its unsupported "default" assumption that bases the IUR on the highest possible risk level. EPA's Response to Interrogatory No. 18 at 20 (Ex. 4) ("EPA's analysis relating to its use of the B6C3F1 mouse data in calculating the IUR in the 2010 IRIS Assessment, and the analysis EPA performed to determine that the B6C3F1 mouse data was the most representative information available to understand potential human responses to chloroprene *is contained in the 2010 IRIS Assessment*....") (emphasis added).

EPA's response to Interrogatory No. 18 states that EPA's decision to rely on the B6C3F1 female mouse to calculate the IUR was "described and reflected" in EPA's decisions on three administrative appeals that DPE filed to correct the 2010 Review. *Id.* But those administrative decisions included no determination whatsoever of the sex/species most relevant to humans, but instead simply relied on the same unsubstantiated default assumption as the 2010 Review.[26]

EPA's response to Interrogatory No. 18 states that EPA's decision to rely on the B6C3F1 female mouse to calculate the IUR is "discussed" in the expert declarations of Dr. Ila Cote. *Id.* at 21. But EPA does *not* suggest that it relies on Dr. Cote for its decision to calculate the IUR using the B6C3F1 female mouse. Moreover, Dr. Cote only opines that the female B6C3F1 data is "appropriate" based on statistical suitability criteria set forth in a draft EPA document.[27] Dr. Cote

[26] *See, e.g.,* EPA Response to DPE's Request for Correction (Jan. 2018), Attachment 1 at 3 (Ex. 35) ("In accordance with the EPA Guidelines for Carcinogen Risk Assessment (2005), in the absence of data to the contrary, EPA utilizes the most sensitive species and sex in estimating cancer risk to humans, which in the case of chloroprene, is the female mouse.").

[27] *See* Cote Decl., ¶ 16 (R. Doc. 94-7) (comparing the NTP Study characteristics with criteria provided in the fourth of four elements for selecting an animal data set but failing to address the first three elements and failing to reach a judgment "based on biological criteria as to which set or

offers no determination as to "which set or sets [of data] best represents the body of data for the purpose of estimating human response." *Id.* That is the question on which EPA offers no evidence.

In contrast, DPE *has* offered evidence in support of inhalation risk estimates that are more representative of human risk than the 2010 Review IUR.[28] Such evidence is not a matter for summary judgment. But the point is, EPA offers ***no*** evidence (*e.g.*, biological or toxicokinetic data) to ***support*** using the B6C3F1 mouse as representative of ***humans***. Because EPA has failed to meet its burden of proof on this essential aspect of its claim of an imminent and substantial endangerment, this Court can grant summary judgment. *Simsbury-Avon Preservation Club*, 575 F.3d at 211-12 (affirming summary judgment where expert report failed to assess actual risk presented by contaminants at issue).

IV. CONCLUSION

For the foregoing reasons, DPE's Motion should be granted and EPA's claims dismissed.

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sets best represents the body of data for the purpose of estimating human response"). Dr. Cote represents that the incomplete criteria she evaluates is part of a National Academy of Sciences criteria, but it is in fact a draft EPA document included as an Appendix to the cited report. *See* National Research Council, *Science and Judgment in Risk Assessment* (1994) at 428-29 (Section 3.2.1 in Appendix D, "Working Paper for Considering Draft Revisions to the U.S. EPA Guidelines for Cancer Risk Assessment.") (Ex. 36).

[28] For example, DPE's expert, Dr. Michael Lumpkin, relies on toxicokinetic data to explain why the B6C3F1 female mouse is *not* representative of humans. *See, e.g.,* Lumpkin Decl. ¶ 38 (Ex. 37).

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Respectfully submitted,

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