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.	**JUDGE CARL J. BARBIER**
DENKA PERFORMANCE ELASTOMER LLC and DUPONT SPECIALTY PRODUCTS USA, LLC,	**MAG. JUDGE MICHAEL NORTH**
Defendants.	

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

NOW INTO COURT, through undersigned counsel, comes Defendant, Denka Performance Elastomer, LLC ("DPE"), which submits this Answer, Affirmative Defenses, and Counterclaims to the Complaint filed by Plaintiff, United States of America, acting at the request of Michael S. Regan, the Administrator of the United States Environmental Protection Agency ("EPA"). DPE denies each and every allegation contained in the Complaint, except as expressly admitted herein.

I. ANSWER

The unnumbered paragraph under the heading "Complaint" does not contain any allegations and does not require a response.

1. The first sentence of Paragraph 1 purports to summarize the nature of the Complaint to which no response is required. To the extent a response is required, DPE denies the allegations. In response to the second sentence of Paragraph 1, DPE admits that the Facility's address is in

LaPlace, Louisiana, but denies the remaining allegations of that sentence. DPE denies the allegations of the third sentence of Paragraph 1. The fourth sentence of Paragraph 1 purports to summarize the relief sought by the Complaint to which no response is required. To the extent a response to the fourth sentence is required, DPE denies that the United States is entitled to any relief.

2. The first sentence of Paragraph 2 purports to summarize the relief sought by the Complaint against DuPont Specialty Products USA, LLC ("DuPont"), to which no response is required. To the extent a response to the first sentence is required, DPE denies that the United States is entitled to any relief. DPE admits the allegations of the second sentence of Paragraph 2. DPE admits the allegations of the third sentence of Paragraph 2. The fourth sentence of Paragraph 2 consists of legal conclusions to which no response is required. To the extent a response to the fourth sentence is required, DPE denies the allegations. The fifth sentence of Paragraph 2 purports to reference a document, which speaks for itself and is the best evidence of its content. To the extent a response to the fifth sentence is required, DPE denies the allegations.

3. DPE admits the allegations of the first sentence of Paragraph 3. DPE admits the allegations of the second sentence of Paragraph 3. In response to the allegations of the third sentence of Paragraph 3, DPE admits only that 1,3-butadiene and chlorine are listed as hazardous air pollutants in the Clean Air Act if emitted into the atmosphere. DPE admits the allegations of the fourth sentence of Paragraph 3.

4. DPE denies the allegations of Paragraph 4, and further avers that the allegations of Paragraph 4 are based on EPA's 2010 Toxicological Review of Chloroprene ("2010 Review"), in which EPA estimated that, assuming humans are as sensitive to chloroprene as the female B6C3F1 mouse, continuously breathing chloroprene at concentrations averaging one $\mu g/m^3$ for 24 hours

per day over a 70-year lifetime—an obviously counterfactual assumption—would produce five excess cancers (that is, in excess of what is expected in unexposed populations) for every 10,000 people. Based on this, EPA alleges that continuous exposure to 0.2 μg/m^3 for 70 years increases a person's risk of developing cancer by 1-in-10,000. DPE further avers that EPA's 2010 Review and resulting 0.2 μg/m^3 value for chloroprene are fundamentally flawed because, in setting that value, EPA relied upon a default assumption that humans are as sensitive to chloroprene as a female B6C3F1 mouse, which was the most sensitive animal species and gender in the laboratory experiments conducted by EPA on the effects of exposure to chloroprene. DPE further avers that this was a fundamental error by EPA, as the peer reviewers of the 2010 Review expressly informed EPA at the time, due to the substantial toxicokinetic differences between the female B6C3F1 mouse and humans, resulting in EPA's 0.2 μg/m^3 value dramatically overstating the human cancer risks associated with exposure to chloroprene. DPE further avers that EPA—initially in setting the 0.2 μg/m^3 value for chloroprene, and now in seeking to enforce that value as the underlying driver for its Complaint—fails to consider the best available scientific information and is contrary to the weight and preponderance of scientific evidence, including (i) the use of the peer-reviewed physiologically-based pharmacokinetic ("PBPK") model, developed (with EPA's support and collaboration) by scientists at Ramboll US Consulting, Inc. ("Ramboll PBPK model"), specifically designed to make adjustments in risk assessments based upon the different toxicological effects of a chemical from one species to another, such as female B6C3F1 mice to humans; (ii) the most recent and robust, and peer-reviewed epidemiological study of chloroprene, which focused on *humans* (not female mice) who worked at chloroprene-emitting facilities, including the Facility when operated by DuPont, were exposed to substantially higher chloroprene emissions, and showed no increase in cancer mortalities; and (iii) the empirical and state-audited data from the

Louisiana Tumor Registry showing cancer incidence rates in the community surrounding the Facility that are significantly *lower* than state-wide averages despite decades of historical emissions of chloroprene from the Facility (before it was owned by DPE) that were at least an order of magnitude higher than current emissions.

5. DPE denies the allegations of Paragraph 5, including for the reasons set forth in response to Paragraph 4 above.

6. DPE denies the allegations of the first sentence of Paragraph 6. DPE admits the allegations of the second sentence of Paragraph 6.

7. Paragraph 7 consists of legal conclusions to which no response is required. Further, Paragraph 7 purports to reference federal statutes and other documents, which speak for themselves and are the best evidence of their content. To the extent a response is required, DPE denies the allegations and avers that a 1-in-10,000 cancer risk described in Paragraph 7 has never been the basis of an emergency action under Section 303 of the Clean Air Act, 42 U.S.C. 7401, *et seq.*

8. In response to the allegations of the first sentence of Paragraph 8, DPE admits only that EPA, based on EPA's 2010 Review, has estimated that breathing chloroprene at concentrations averaging 0.2 $\mu g/m^3$ over a 70-year lifetime increases a person's risk of developing cancer by 1-in-10,000, but DPE avers that EPA's 2010 Review and resulting 0.2 $\mu g/m^3$ value counterfactually assume that every resident within a 2.5 mile radius of the Facility is exposed to chloroprene 24 hours a day for 70 years. DPE further avers that EPA's 2010 Review and resulting 0.2 $\mu g/m^3$ value for chloroprene are fundamentally flawed because, in setting that value, EPA relied upon a default assumption that humans are as sensitive to chloroprene as a female B6C3F1 mouse, which was the most sensitive animal species and gender in the laboratory experiments

conducted by EPA on the effects of exposure to chloroprene, without scientific basis and merely as a default policy determination. DPE further avers that this was a fundamental error by EPA, as the majority of the peer reviewers of the 2010 Review expressly informed EPA at the time, due to the substantial toxicokinetic differences between the female B6C3F1 mouse and humans, resulting in EPA's 0.2 $\mu g/m^3$ value dramatically overstating the human cancer risks associated with exposure to chloroprene. DPE further avers that, in setting, and now seeking to enforce, the 0.2 $\mu g/m^3$ value for chloroprene as the underlying driver for its Complaint, EPA's allegations fail to consider the best available scientific information or the weight of scientific evidence as averred above in Paragraph 4. DPE denies the allegations of the second and third sentences of Paragraph 8.

9. In response to the allegations of the first sentence of Paragraph 9, DPE admits only that average concentrations of chloroprene measured at monitored locations in the vicinity of the Facility have been consistently greater than 0.2 $\mu g/m^3$ since 2016, but avers that (i) DPE emissions of chloroprene are within the limits prescribed by air permits issued by the Louisiana Department of Environmental Quality ("LDEQ") under the oversight of EPA; (ii) DPE has dramatically reduced the magnitude and scope of chloroprene concentrations outside of the Facility since it purchased the Facility in November 2015; (iii) neither set of monitors referenced in Paragraph 9 sampled ambient air on a continuous basis; and (iv) chloroprene concentrations sampled from 2016 until 2022 are not representative of present conditions. DPE admits the allegations of the second sentence of Paragraph 9. DPE admits the allegations of the third sentence of Paragraph 9, but avers that neither set of referenced monitors sampled ambient air on a continuous basis and avers that chloroprene concentrations sampled from 2016 until 2022 are not representative of present conditions. DPE admits the allegations of the fourth sentence of Paragraph 9.

10. In response to the allegations of the first sentence of Paragraph 10, DPE admits only that average concentrations of chloroprene measured at monitored locations in the vicinity of the Facility have been consistently greater than 0.2 $\mu g/m^3$ since 2016, and DPE incorporates the averments in response to the first sentence of Paragraph 9. In response to the allegations of the second sentence of Paragraph 10, DPE objects to the phrase "some of the highest" as vague, but admits that air monitors generally to the west of the Facility at times detected levels of chloroprene that were higher than levels detected in other areas. DPE further avers that EPA mistakenly and misleadingly compares intermittent 24-hour measurements to 70-year average concentrations.

11. DPE denies the allegations of Paragraph 11, including for the reasons set forth in response to Paragraph 8 above.

12. DPE denies the allegations of Paragraph 12, including for the reasons set forth in response to Paragraph 8 above.

13. DPE denies the allegations of Paragraph 13, including for the reasons set forth in response to Paragraph 8 above.

14. DPE denies the allegations of Paragraph 14, including for the reasons set forth in response to Paragraph 8 above.

15. The allegations of Paragraph 15 purport to summarize the relief requested by the Complaint, to which no response is required. To the extent a response is required, DPE denies the allegations of Paragraph 15 and denies that the United States is entitled to any relief.

16. The allegations of paragraph 16 consist of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations.

17. DPE admits the allegations of Paragraph 17.

18. The allegations of paragraph 18 consist of legal conclusions to which no response is required. Further, DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 18.

19. DPE admits the allegations of Paragraph 19.

20. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 20.

21. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of the first sentence of Paragraph 21. The second sentence of Paragraph 21 purports to reference federal statutes, which speak for themselves and are the best evidence of their content. Further, the second sentence of Paragraph 21 consists of legal conclusions to which no response is required. To the extent a response to the second sentence is required, DPE denies the allegations.

22. DPE admits the allegations of the Paragraph 22.

23. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 23.

24. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of the first and second sentences of Paragraph 24. The third and fourth sentences of Paragraph 24 purport to reference a document, which speaks for itself and is the best evidence of its content. To the extent a response to the third and fourth sentences is required, DPE denies the allegations.

25. Paragraph 25 purports to reference a document, which speaks for itself and is the best evidence of its content. Further, Paragraph 25 consists of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations.

26. Paragraph 26 consists of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations. Further, DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of the third and fourth sentences of Paragraph 26.

27. DPE admits the allegations of the first sentence of Paragraph 27. DPE admits the allegations of the second sentence of Paragraph 27. DPE denies the allegations of the third sentence of Paragraph 27. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of the fourth sentence of Paragraph 27.

28. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of the first sentence of Paragraph 28. The second sentence of Paragraph 28 purports to reference a database, which speaks for itself and is the best evidence of its content.

29. DPE admits the allegations of the first sentence of Paragraph 29. DPE admits the allegations of the second sentence of Paragraph 29.

30. Paragraph 30 purports to reference federal statutes, which speak for themselves and are the best evidence of their content. Further, the allegations of Paragraph 30 consist of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations.

31. In response to the allegations of the first sentence of Paragraph 31, DPE admits only that chloroprene can at times be emitted into the air at various stages of Neoprene manufacturing operations at the Facility and DPE incorporates the averments in response to the first sentence of Paragraph 9. In response to the allegations of the second sentence of Paragraph 31, DPE admits only that chloroprene can at times be emitted through vents from the manufacturing operations that emit into the atmosphere and avers that when DPE purchased the

Facility in 2015, the Facility had numerous pollution control devices, and since DPE purchased the Facility, it has added state-of-the-art devices to reduce more than 100 tpy of permitted chloroprene. In response to the allegations of the third sentence of Paragraph 31, DPE admits only that chloroprene can at times be emitted when tanks and other process vessels are opened, during both normal operations and maintenance work. In response to the allegations of the fourth sentence of Paragraph 31, DPE admits only that chloroprene can at times be emitted through equipment leaks and evaporative emissions from wastewater generated during neoprene manufacturing.

32. DPE denies the allegations of the first sentence of Paragraph 32. DPE denies the allegations of the second sentence of Paragraph 32. In response to the allegations of the third sentence of Paragraph 32, DPE admits only that water can at times be hosed into open grated trenches that eventually empty into the Outside Brine Pit. DPE denies the allegations of the fourth, fifth, and sixth sentences of Paragraph 32.

33. In response to the allegations of the first sentence of Paragraph 33, DPE admits only that chloroprene emissions can at times travel beyond the Facility's property line. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of the second sentence of Paragraph 33.

34. The first sentence of Paragraph 34 purports to reference a January 6, 2017 Administrative Order on Consent, which speaks for itself and is the best evidence of its content. In further response to Paragraph 34, DPE admits that in January 2017, EPA, LDEQ, and DPE worked together to facilitate the reduction of chloroprene emissions from the Facility; that on January 6, 2017, LDEQ and DPE, with EPA's guidance and support, executed an Administrative Order on Consent, pursuant to which DPE voluntarily reduced chloroprene emissions from the

Facility by 85 percent (from 118 tons per year ("tpy") to 18 tpy); that to achieve these emission reductions, DPE installed a regenerative thermal oxidizer and other emissions control equipment, at a cost of approximately $35 million, which became operational in 2018; and that in May 2020, LDEQ determined that DPE had achieved the agreed-upon 85 percent emission reductions in accordance with the Administrative Order on Consent.

35. In response to the allegations of the first sentence of Paragraph 35, DPE admits only that it reported emissions of approximately 18 tons of chloroprene during certain years and avers that it has further reduced chloroprene emissions from the Facility in the past six months. DPE denies the allegations of the second sentence of Paragraph 35. In response to the allegations of the third sentence of Paragraph 35, DPE admits only that average concentration levels at some monitoring locations within the vicinity of the Facility exceed 0.2 $\mu g/m^3$ at current emission levels.

36. Paragraph 36 purports to reference United States census data, which speak for themselves and are the best evidence of their content, but DPE avers that the referenced numbers appear to be based on an interpretation of census data rather than actual census data. Further, DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 36.

37. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 37.

38. DPE denies the allegations of Paragraph 38, including for the reasons set forth in response to Paragraph 8 above, and DPE further avers that the 2010 Review states that "[t]he proposed hypothesis is that chloroprene acts via a mutagenic mode of action."

39. DPE denies the allegations of Paragraph 39, including for the reasons set forth in response to Paragraph 8 above.

40. In response to the allegations of the first sentence of Paragraph 40, DPE admits only that EPA's Integrated Risk Information System ("IRIS") program purports to identify and characterize the health hazards of chemicals found in the environment, but DPE avers that there were fundamental flaws in EPA's 2010 Review, including for the reasons set forth in response to Paragraph 8 above. DPE denies the remaining allegations in the first sentence of Paragraph 40. In response to the allegations of the second sentence of Paragraph 40, DPE admits only that the EPA purports to develop IRIS assessments to characterize the risk to human health posed by specific environmental hazards, but DPE avers that there were fundamental flaws in the 2010 Review, including for the reasons set forth in response to Paragraph 8 above. DPE denies the remaining allegations in the second sentence of Paragraph 40. In response to the allegations of the third sentence of Paragraph 40, DPE admits only that IRIS assessments are conducted by experts in various scientific disciplines such as toxicology, epidemiology, and pharmacokinetics, but DPE avers that, as discussed in response to Paragraph 8 above, the peer reviewers of the 2010 Review raised sharp criticisms of EPA's methods and conclusions in the 2010 Review, including that basing human risk values for chloroprene on laboratory testing of the female B6C3F1 mouse would overestimate chloroprene's cancer risk to humans; that EPA should develop and utilize a PBPK model to make adjustments in risk assessments based upon the different toxicological effects of a chemical as between female B6C3F1 mice and humans; and that, according to one of two epidemiologists on the 2010 peer review panel, EPA "grossly misrepresent[ed] the evidence" regarding epidemiological studies of chloroprene workers in the United States and the United Kingdom, in particular a leading epidemiological study of chloroprene workers prepared by Dr. Gary Marsh, PhD, in 2007. DPE denies the remaining allegations in the third sentence of Paragraph 40. In response to the allegations of the fourth sentence of Paragraph 40, DPE admits

only that the 2010 Review purports to estimate cancer potency of chloroprene. DPE denies the remaining allegations in the fourth sentence of Paragraph 40 including for the reasons in the prior averments in this Paragraph.

41. In response to the allegations of the first sentence of Paragraph 41, DPE admits only that EPA published the 2010 Review in 2010, but DPE avers that there were fundamental flaws in the 2010 Review, including for the reasons set forth in response to Paragraph 8 and Paragraph 40 above. DPE denies the remaining allegations in the first sentence of Paragraph 41. The second sentence of Paragraph 41 purports to quote and reference the 2010 Review, which speaks for itself and is the best evidence of its content. To the extent a response to the second sentence is required, DPE denies the allegations, including for the reasons set forth in response to Paragraph 8 above. The third sentence of Paragraph 41 purports to quote and reference the 2010 Review, which speaks for itself and is the best evidence of its content. To the extent a response to the third sentence is required, DPE denies the allegations and DPE further avers that the "quantitative estimate of carcinogenic risk" provided by EPA was fundamentally flawed, including for the reasons set forth in response to Paragraph 8 above. DPE denies the allegations of the fourth and fifth sentences of Paragraph 41 and avers that the 2010 Review was fundamentally flawed, including for the reasons set forth in response to Paragraph 8 and Paragraph 40 above, and that the 2010 peer review raised sharp criticisms of EPA's methods and conclusions in the 2010 Review, including the criticisms identified in the response to Paragraph 40 above. DPE further avers that EPA received no comments concerning the development of the IUR from "other federal agencies and White House offices," and that public comments strongly criticized many of the scientific conclusions of the 2010 Review. DPE denies that the entire 2010 Review was "confirmed by an independent external peer review panel" and avers that EPA's response to public comments and

peer review comments, particularly as set forth in Appendix A to the 2010 Review, made gross scientific errors and improperly disregarded scientific criticism.

42. In response to the first sentence of Paragraph 42, DPE admits only that in the 2010 Review EPA purported to quantify the cancer risks associated with long-term chronic inhalation exposure due to chloroprene, but DPE avers that there were fundamental flaws in the 2010 Review, including for the reasons set forth in response to Paragraph 8 above, and that the 0.2 $\mu g/m^3$ value for chloroprene dramatically overstates the human cancer risks associated with exposure to chloroprene. DPE denies the remaining allegations in the first sentence of Paragraph 42. The second sentence of Paragraph 42 purports to reference the 2010 Review, which speaks for itself and is the best evidence of its content. To the extent a response is required, DPE denies the allegations. DPE denies the allegations of the third and fourth sentences of Paragraph 42, including for the reasons set forth in response to Paragraph 8 above.

43. DPE denies the allegations of the first sentence of Paragraph 43, including for the reasons set forth in response to Paragraph 8 above. The second sentence of Paragraph 43 purports to reference monitoring results, which data speak for themselves and are the best evidence of their content. To the extent a response to the second sentence of Paragraph 43 is required, DPE denies the allegations, and DPE further avers that the sampling method does not reflect an emissions period greater than a 24-hour period and the sampling results were completed during a time period that does not reflect emissions related to the Facility's current operations or its operations at the time the United States filed this action. DPE denies the allegations of the third sentence of Paragraph 43, including for the reasons set forth in response to Paragraph 8 above.

44. DPE admits the allegations in the first sentence of Paragraph 44. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations related to

EPA's intent in the second sentence of Paragraph 44. DPE denies the remaining allegations in the second sentence of Paragraph 44.

45. In response to the allegations of the first sentence of Paragraph 45, DPE admits only that average concentrations of chloroprene measured at monitored locations in the vicinity of the Facility have been greater than 0.2 $\mu g/m^3$ since 2016 and DPE incorporates the averments in response to the first sentence of Paragraph 9. DPE denies the allegations in the second sentence of Paragraph 45.

46. DPE admits the allegations of Paragraph 46.

47. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 47, but avers that the monitoring locations described in Paragraph 47 are approximately located within a 2.5 mile radius of the Facility.

48. In response to the allegations of Paragraph 48, DPE admits only that average concentrations of chloroprene measured at monitored locations in the vicinity of the Facility have been consistently greater than 0.2 $\mu g/m^3$ since 2016 and DPE incorporates the averments in response to the first sentence of Paragraph 9.

49. DPE admits the allegations of Paragraph 49, but avers that the 0.2 $\mu g/m^3$ value is not a probative benchmark for risk assessment, including for the reasons set forth in response to Paragraph 8 above, and the April 2018 to January 2023 time period is not representative of the Facility's current operations, including for the reasons set forth in response to Paragraph 43 above.

50. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 50.

51. In response to the allegations of Paragraph 51, DPE admits only that average concentrations of chloroprene measured at monitored locations in the vicinity of the Facility have

been consistently greater than 0.2 μg/m^3 since 2016 and DPE incorporates the averments in response to the first sentence of Paragraph 9.

52. DPE denies the allegations of Paragraph 52, including for the reasons set forth in response to Paragraph 8 above.

53. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of the first sentence of Paragraph 53. DPE lacks knowledge or information sufficient to form a belief about the truth of the allegations of the second sentence of Paragraph 53. In response to the third sentence of Paragraph 53, DPE admits that in January 2017, EPA, LDEQ, and DPE worked together to facilitate the reduction of chloroprene emissions from the Facility; that on January 6, 2017, LDEQ and DPE, with EPA's guidance and support, executed an Administrative Order on Consent, pursuant to which DPE voluntarily reduced chloroprene emissions from the Facility by 85 percent (from 118 tpy to 18 tpy); that to achieve these emission reductions, DPE installed a regenerative thermal oxidizer and other emissions control equipment, at a cost of approximately $35 million; that in May 2020, LDEQ determined that DPE had achieved the agreed-upon 85 percent emission reductions in accordance with the Administrative Order on Consent; and that, in the last 12 months, the Facility has achieved further reductions in chloroprene emissions via operational changes developed and implemented by DPE, resulting in the lowest chloroprene emission rates in the history of the Facility.

54. DPE denies the allegations of Paragraph 54, including for the reasons set forth in response to Paragraph 8 above.

55. Paragraph 55 purports to quote a federal statute, which speaks for itself and is the best evidence of its content. Further, Paragraph 55 consists of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations.

56. Paragraph 56 purports to quote a federal statute, which speaks for itself and is the best evidence of its content. Further, Paragraph 56 consists of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations.

57. Paragraph 57 purports to quote a federal statute, which speaks for itself and is the best evidence of its content. Further, Paragraph 57 consists of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations, including for the reasons set forth in response to Paragraph 8 above.

58. DPE denies the allegations of Paragraph 58, including for the reasons set forth in response to Paragraph 8 above.

59. DPE denies the allegations of Paragraph 59, including for the reasons set forth in response to Paragraph 8 above.

60. In response to Paragraph 60, DPE incorporates by reference its answers to all allegations in the Complaint.

61. The allegations of Paragraph 61 consist of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations.

62. The allegations of Paragraph 62 consist of legal conclusions to which no response is required. To the extent a response is required, DPE denies the allegations.

63. DPE denies the allegations of Paragraph 63.

64. DPE denies the allegations of Paragraph 64.

65. DPE denies the allegations of Paragraph 65.

66. DPE denies the allegations of Paragraph 66.

RESPONSE TO PRAYER FOR RELIEF

DPE denies that the United States is entitled to any relief, including the relief set forth in Subparagraphs 1-4 of its Prayer for Relief.

II. AFFIRMATIVE DEFENSES

Further answering, DPE specifically pleads the following affirmative defenses. To the extent that the following defenses appear contradictory or mutually exclusive, DPE pleads said defenses in the alternative.

First Affirmative Defense

In conducting the 2010 Review, EPA was obligated to consider the best scientific data available to EPA at the time of its decision, and its failure to do so, resulting in the setting of a 0.2 $\mu g/m^3$ value for chloroprene, was arbitrary, capricious, an abuse of discretion, and not in accordance with law, in violation of the APA.

Second Affirmative Defense

Based on numerous errors in the 2010 Review, following the procedures in EPA's Information Quality Guidelines, DPE filed a Request for Correction on June 26, 2017 ("2017 Request for Correction"). EPA denied the 2017 Request for Correction in January 2018, stating that the 2010 Review had been externally peer reviewed, and subjected to public comment and comments from other federal agencies and offices of the White House. EPA concluded that it would only update the 2010 Review based on new scientific evidence, particularly referring to the possible use of a PBPK model. EPA's denial of the 2017 Request for Correction was arbitrary, capricious, an abuse of discretion, and not in accordance with law, in violation of the APA.

Third Affirmative Defense

Following the denial of the 2017 Request for Correction, DPE submitted to EPA a Work Plan for the development of a chloroprene PBPK model to better represent human sensitivity to

chloroprene than the default assumption utilized by EPA in the 2010 Review that humans are as sensitive as the female B6C3F1 mouse. EPA worked cooperatively with DPE for more than two years on the development of a PBPK model. In October 2020, EPA sponsored through its contractor Versar, Inc. ("Versar"), a purportedly independent peer review of the PBPK model. Importantly, Versar was not an independent peer review organization, because EPA now claims that its communications with Versar are protected from disclosure to the public because Versar is part of the agency for purposes of Freedom of Information Act Exemption 5. Based on comments from the peer review panel, DPE's contractor Ramboll substantially revised the PBPK model to provide an even better predictive capacity of cross species response to chloroprene. On July 2021, with the "new scientific evidence" of a peer reviewed Ramboll PBPK model, DPE submitted its second Request for Correction ("2021 Request for Correction"). Unknown to DPE or the public, in April 2021, EPA Region 6 nominated chloroprene to EPA's IRIS program for a new toxicological review. On March 14, 2022, EPA denied DPE's 2021 Request for Correction, stating that EPA had no obligation to update prior toxicological assessments unless the chemical was nominated for toxicological review as a national or regional priority and accepted by the IRS program for further review. On June 10, 2022, utilizing an administrative appeal procedure provided by the Information Quality Guidelines, DPE filed a Request for Reconsideration of the denial of the 2021 Request for Correction ("2022 Request for Reconsideration"). On October 19, 2022, EPA denied the 2022 Request for Reconsideration. Under the Information Quality Guidelines, the agency's decision on a Request for Reconsideration is "final agency action." For many reasons, including but not limited to EPA's failure to disclose EPA Region 6's nomination of chloroprene for toxicological review, EPA's denial of the 2022 Request for Reconsideration

was arbitrary, capricious, an abuse of discretion, and not in accordance with law, in violation of the APA.

Fourth Affirmative Defense

EPA's current and ongoing application of the 2010 Review to DPE through the 0.2 μg/m^3 value for chloroprene without providing a rational basis for EPA's failure to consider the best available scientific data—including the Ramboll PBPK model, Dr. Marsh's 2021 epidemiology study, and the 2022 Louisiana Tumor Registry data—is arbitrary, capricious, an abuse of discretion, and not in accordance with law in violation of the APA.

Fifth Affirmative Defense

In denying the 2017 Request for Correction, EPA took the position that the 2010 Review (and resulting IUR) could only be changed based on the submission of new scientific evidence. In the 2021 Request for Correction, DPE did precisely that by providing the new Ramboll PBPK model for chloroprene, further analysis regarding the updated epidemiological study by Dr. Marsh, and epidemiological data from the Louisiana Tumor Registry. However, in denying the 2021 Request for Correction, EPA took the position that the purpose of the request for correction was to simply correct the analysis and data in the 2010 Review, and not to update the prior risk assessment based on new scientific evidence. In other words, after EPA faulted DPE for not providing new scientific information in the 2017 Request for Correction, EPA took the position that the 2021 Request for Correction could not be granted *because DPE had provided new scientific evidence*. EPA's rejection of the Ramboll PBPK model was an abrupt reversal of position, was not based on the evidence, data, or best scientific information available at that time, and was arbitrary, capricious, an abuse of discretion, and not in accordance with law, in violation of the APA.

Sixth Affirmative Defense

EPA has arbitrarily and capriciously reversed 30 years of EPA risk assessment policy without reasoned explanation by treating an estimated 1-in-10,000 risk based on the 2010 IUR in a strict, "bright line" fashion, and this departure from 30 years of Agency risk assessment policy without reasoned explanation was arbitrary, capricious, an abuse of discretion, and not in accordance with law, in violation of the APA.

Seventh Affirmative Defense

Under Section 112 of the Clean Air Act as amended in 1990, 42 U.S.C. § 7412, EPA must establish technology-based emission standards for hazardous air pollutants, called Maximum Available Control Technology ("MACT"), as required by Section 112(d), 42 U.S.C. § 7412(d). Following the MACT rulemaking, if the regulated category of industry poses greater than a 1-in-1,000,000 risk after the application of MACT, EPA must set "residual risk" standards under Section 112(f)(2), 42 U.S.C. § 7412(f)(2), to provide the public with an "ample margin of safety." In a significant number of residual risk evaluations, starting in 1989 (Benzene NESHAPs) and most recently in 2020 (Miscellaneous Organic NESHAPS or "MON"), EPA has established emission standards well in excess of 1-in-10,000 risk. For example, in 2005, in the NESHAPs for Coke Oven Batteries, EPA authorized a risk of 2.7-in-10,000. 70 Fed. Reg. 19992 (2005). DPE avers that as a matter of law a 1-in-10,000 risk does not constitute an "emergency" under Section 303 of the Clean Air Act.

Eighth Affirmative Defense

The relief requested in paragraph 2 of the United States' Prayer for Relief, seeking to mitigate alleged past harm to public health and welfare, is not permitted under Section 303 of the Clean Air Act, 42 U.S.C. § 7603 and should be dismissed as a matter of law.

Ninth Affirmative Defense

The relief requested in the Complaint improperly invokes "emergency" authority to circumvent Section 112 of the Clean Air Act to establish an "ambient air standard" for chloroprene in violation of Section 112(f)(2) of the Clean Air Act, 42 U.S.C. § 7412(f)(2), and to circumvent the required consideration of costs, energy, safety, control technologies and other relevant factors, such as risk estimation uncertainty, in regulating hazardous air pollutants.

Tenth Affirmative Defense

The United States' allegations of an emergency fail to consider risk estimation uncertainty in developing the IUR and the 1-in-10,000 risk estimate. EPA's denial of DPE's 2021 Request for Correction admits that the IUR is uncertain by at least a factor of two. In fact, by basing the IUR on the female B6C3F1 mouse without any scientific evidence to suggest that the female B6C3F1 mouse is more representative of human response than the male B6C3F1 mouse (one-third less sensitive than the female), the Fischer rat, the Wistar rat, or the hamster (which demonstrate up to two orders of magnitude lower sensitivity), the United States has alleged an improbable risk estimate that fails any evidentiary weight-of-evidence test or more-probable-than-not test.

DPE reserves the right to amend its answer to the Complaint and to assert additional affirmative defenses as discovery is conducted and additional defenses come to light.

PRAYER FOR RELIEF

WHEREFORE, Defendant DPE prays that this Answer and Affirmative Defenses be deemed good and proper, and that after proper proceedings had, this Court dismiss the United States' claims against DPE, with prejudice, at the United States' costs and expense.

III. COUNTERCLAIMS

DPE asserts its counterclaims 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 x 10^{-4} per $\mu g/m^3$ for 70-years continuous exposure.[1] Based on that 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 $\mu g/m^3$. In setting that stringent IUR for chloroprene, EPA relied upon a default assumption that humans are as sensitive to chloroprene as the female B6C3F1 mouse, which was the most sensitive animal species and gender in the laboratory experiments conducted on the effects of exposure to chloroprene. As discussed below, EPA's default assumption was (and remains) dead wrong, as it was directly undercut by the best scientific

[1] EPA reviews and publishes information about the health and environment effects of industrial chemicals in its Integrated Risk Information System ("IRIS"). In its "IRIS assessments," EPA provides 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 $\mu g/m^3$) to estimate a person's lifetime risk of developing cancer as a result of the chemical exposure.

information available to EPA when it performed the 2010 Review as well as the best scientific information available today.

3. As chronicled in detail below, from June 2017 through October 2022, DPE diligently pursued an administrative challenge of the 2010 Review and IUR under the Information Quality Act, pointing out the many fundamental flaws in EPA's analysis based on EPA's failure to consider the best available scientific information, including multiple lines of evidence such as epidemiology, the Louisiana Tumor Registry, and pharmacokinetics. EPA rejected those challenges, and by May 2022 was actively threatening to enforce the 0.2 $\mu g/m^3$ value for chloroprene against the Facility.

4. On January 11, 2023, DPE filed an action against EPA and EPA Administrator Regan in this Court alleging that the 2010 Review and subsequent enforcement of a 0.2 $\mu g/m^3$ value for chloroprene was arbitrary, capricious, an abuse of discretion, and not in accordance with law in violation of the Administrative Procedure Act ("APA"), because EPA failed to consider the best available scientific information (the "APA Action"). As alleged in the APA Action, EPA sought and then ignored the best available scientific information in setting the IUR. As further alleged in the APA Action, DPE diligently tried to correct EPA at every turn via the processes set forth in the Information Quality Act, but EPA ignored generally accepted science, in violation of the APA.

5. Subsequently, on February 28, 2023, EPA initiated the above-captioned action, alleging that the Facility's emissions of chloroprene constitute an "imminent and substantial endangerment" under Section 303 of the Clean Air Act ("ISE Action"). Relying entirely upon its IUR determination for chloroprene, EPA seeks an order requiring the Facility to implement emission reduction projects that would result in the Facility satisfying the 0.2 $\mu g/m^3$ value for

chloroprene and requiring DPE to immediately take all necessary measures to eliminate the alleged imminent and substantial endangerment posed by chloroprene emissions from the Facility. On March 15, 2023, the ISE Action was transferred from Section "L" to Section "J" because it is related to the APA Action. [Doc. 6.]

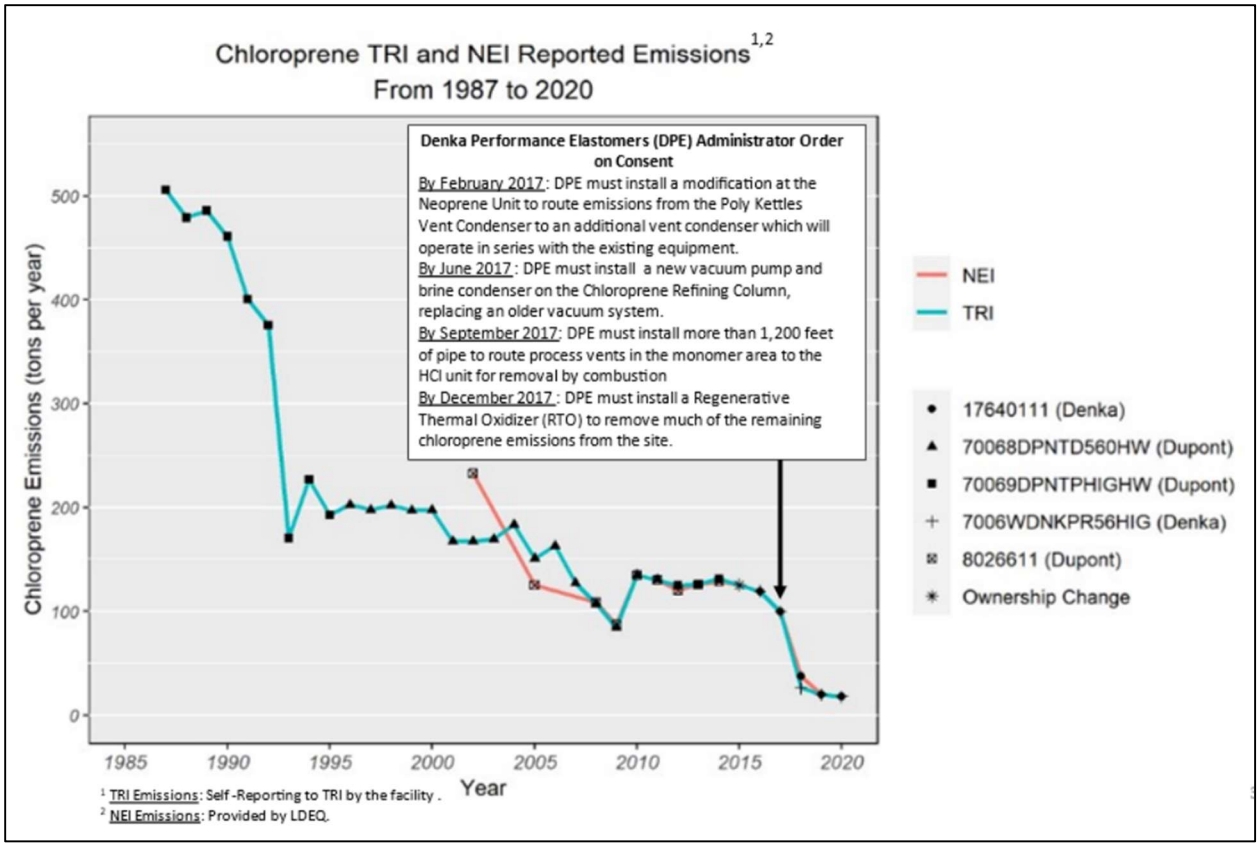
6. On March 20, 2023, EPA filed a motion for preliminary injunction seeking a shutdown of the Facility unless DPE complied with a host of prescriptive requirements not required by regulation [Doc. 9]. As discussed further below, EPA makes no effort to hide that its unprecedented action is entirely dependent on enforcing the 0.2 $\mu g/m^3$ value.

7. EPA's ISE Action compounds the Agency's scientific errors in setting the IUR and continues to impose real harm on DPE. In its crusade against chloroprene emissions, EPA's unprecedented ISE Action exacerbates the flaws in, and the harm caused by, the IUR determination because (i) EPA ignores its own risk assessment protocol, which, when properly applied, undercuts any legitimate claim of an imminent and substantial endangerment; (ii) EPA essentially disregards the most relevant epidemiological study of chloroprene, which focused on *humans* (not female mice) who worked in the chloroprene industry, were exposed to substantially higher chloroprene emissions, and showed no increase in cancer mortalities; (iii) EPA ignores the empirical data showing cancer incidence rates in the community surrounding the Facility that are substantially lower than the State averages despite decades of historical emissions of chloroprene from the Facility (before it was owned by DPE) that were at least an order of magnitude higher than current emissions; (iv) EPA ignores the significant emission reductions that DPE has implemented in the last 12 months via operational changes; and (v) EPA ignores the recent, and most relevant, fenceline monitoring data from the Facility, which shows even further reductions in chloroprene emissions.

8. DPE's counterclaims alleged herein are intended to address EPA's violations of the APA when EPA sought, and then repeatedly ignored, the best available scientific information in setting the IUR for chloroprene, including its denial of DPE's Requests for Correction, by seeking a judgment declaring that an enforceable risk assessment must consider all available scientific evidence, including updated evidence beyond a flawed 13-year old IRIS toxicological review. In assessing the potential risks of chloroprene for the past roughly thirteen years, EPA has often stressed the importance of considering and applying the best available science on risk assessment, as required by EPA's Information Quality Guidelines, EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (Oct. 2002), and the Information Quality Act, Pub. L. 106–554, §1(a)(3) [title V, §515], Dec. 21, 2000, 114 Stat. 2763 (requiring guidelines for Federal agencies to ensure and maximize "the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies"). However, in actually *setting* risk-based requirements for chloroprene, and now taking the unprecedented step of alleging in the ISE Action that emergency authority under Section 303 of the Clean Air Act (not the Agency's rulemaking or permitting authorities) should be exercised by this Court to impose further emission reductions, EPA has again refused to consider what the Agency *admits* is the best available scientific information. EPA's reason? The Agency simply declares that it is not a priority and that it has no obligation to do so. EPA is wrong. EPA's refusal to consider the full weight of available scientific evidence and to use the best available science on the potential risks of chloroprene to humans—and set appropriate risk-based requirements for chloroprene based on that science—was arbitrary, capricious, and an abuse of discretion, and was not in accordance with law, in violation of the APA.

9. Worse still, EPA *encouraged* DPE to develop the latest available scientific information and, over a multi-year period, actively collaborated with DPE in ensuring that such scientific information was complete, accurate, and up-to-date. When DPE, through substantial effort and expense, developed that scientific information, went through two rounds of external peer review overseen by EPA, and presented it to EPA, the Agency abruptly reversed course and said it had no obligation to consider the latest scientific information.

10. To be very clear, DPE strongly supports effective environmental protection for the Facility's neighbors. As noted above, it is undisputed that, just since January 2017, DPE has 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 Summary Report, Air Monitoring for Chloroprene Concentrations in LaPlace, LA from 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."). In an October 12, 2022 "letter of concern," issued under the authority of Title VI of the Civil Rights Act of 1964, sent by EPA to the Louisiana Department of Environmental Quality ("LDEQ") and the Louisiana Department of Health ("LDH"), EPA included a figure showing the significant emission reductions at the Facility since 1987, particularly the substantial reductions achieved by DPE since commencing operations at the Facility in 2015.



11. However, rather than considering all sources of relevant information and using the best available science to assure the Facility's neighbors that current levels of chloroprene emissions do not pose a meaningful risk to human health, EPA appears to be following a politically driven strategy to support the demands made by environmental activists and toxic tort litigants. This strategy has led EPA to disregard the best available science in order to catalyze permitting, rulemaking, and, ultimately, EPA's ISE Action premised on a more stringent—and undisputedly outdated—determination of the potential risks of chloroprene to humans. Upon information and belief, EPA refused to consider all sources of relevant information and use the best available scientific information on the risks of chloroprene to humans—information that EPA *encouraged* DPE to generate—predominantly because that information is inconsistent with EPA's politically expedient strategy.

THE PARTIES

12. Counterclaim-Plaintiff DPE owns the Neoprene manufacturing Facility on land under lease from DuPont Specialty Products USA LLC and operates the Facility.

13. Counterclaim-Defendant EPA is the federal agency charged with disseminating accurate information reflecting best available science concerning the toxicity of chloroprene under the Information Quality Act, Section 515 of Pub. Law 106-554 (2000), codified as 44 U.S.C. §§ 3504(d)(1) and 3516, 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*.

14. Counterclaim-Defendant Michael S. Regan is the Administrator of EPA. Administrator Regan's office is located at 1200 Pennsylvania Avenue, NW, Washington D.C. 20460. Administrator Regan is responsible for supervising the activities of EPA, including the actions at issue in this Complaint. He is being sued in his official capacity.

JURISDICTION AND VENUE

15. 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).

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

17. 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.

THE INFORMATION QUALITY ACT

18. The Information Quality Act ("IQA"), Section 515 of Pub. L. 106-554, codified in 44 U.S.C. §§ 3504(d)(1) and 3516, and implementing guidelines issued by the Office of Management and Budget ("OMB"),[2] apply to EPA's 2010 Review because that decision by EPA constitutes important scientific information disseminated by a federal agency. The IQA requires that influential scientific information disseminated by EPA be of appropriate "quality," which consists of utility, objectivity, and integrity. The 2010 Review is subject to the most demanding requirements of OMB's and EPA's IQA guidelines because it is "influential scientific information" that "present[s] information on health effects" of chloroprene. Under the IQA and implementing guidelines, EPA is required to incorporate a "high degree of transparency about the data and methods to facilitate the reproducibility of such information by qualified third parties." *See* OMB's Government-wide Data Quality Act Guidelines, 67 Fed. Reg. 8,452, 8,455 (Feb. 22, 2002).

19. EPA has established an elaborate procedure to submit requests for correction ("RFCs") and appeals of decisions on RFCs through requests for reconsideration ("RFRs"). *See* Guidelines, Section 8. The Guidelines establish substantive and procedural requirements for RFCs and RFRs. Under Guideline 8.7, an RFR is decided by a three-member "executive panel … comprised of the Science Advisor/AA for the Office of Research and Development (ORD), Chief

[2] *See* Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8,452 (Feb. 22, 2002); Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency ("Guidelines"). Available at https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.

Information Officer/AA for OEI, and the Economics Advisor/AA for the Office of Policy, Economics and Innovation (OPEI)." Further, as provided in Guideline 8.7, "[t]he executive panel makes the final decision on the RFR." As discussed further below, EPA engaged in a final agency action by denying DPE's Request for Reconsideration on October 19, 2022, and by subsequently commencing the ISE Action premised on its IUR determination for chloroprene.

FACTUAL BACKGROUND

A. The Facility.

20. 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.

21. 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.

22. 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, and current chloroprene emissions from the Facility are now below approximately 16 tons per year.

B. EPA's 2010 Toxicological Review Of Chloroprene And Resulting IUR.

23. In September 2010, EPA released the 2010 Review in support of EPA's IRIS assessment of chloroprene.[3] In the 2010 Review, EPA concluded that chloroprene was "likely to be carcinogenic to humans" and set one of its 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 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 of risk-based decisions."[4] As explained below, EPA's "upper limit of acceptability" does not constitute a "bright line" threshold and EPA's treatment of the 1-in-10,000 value as such, without explanation, is at sharp variance with more than 30 years of EPA risk assessment policy. As further explained below, EPA's 0.2 $\mu g/m^3$ value for chloroprene is both impracticable to meet and, based on the available science, entirely unnecessary to protect human health and the environment.

24. In setting that stringent 0.2 $\mu g/m^3$ value for chloroprene, EPA relied upon a default assumption that humans are as sensitive to chloroprene as the female B6C3F1 mouse, which was the most sensitive animal species and gender in the laboratory experiments conducted on the effects of exposure to chloroprene.[5] However, as the majority of experts participating in the

[3] The 2010 Review can be found at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf.

[4] *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).

[5] The B6C3F1 mouse is a hybrid strain of mouse that is produced as a cross between other specified strains of mice.

contemporaneous peer review of the 2010 Review expressly told EPA at the time, the default mouse IUR overestimates human sensitivity to chloroprene. The female B6C3F1 mouse is three times more sensitive to chloroprene than the male B6C3F1 mouse and many times more sensitive than every other type of animal that has been tested, including hamsters, Wistar rats, and Fischer rats, all of which are commonly used in laboratory studies of industrial chemicals and all of which have been utilized in laboratory experiments involving chloroprene. For example, at any given concentration, the response and estimated risk for the female B6C3F1 mouse was from *6 to 160 times* greater than the Fischer rat. Other rodent species showed *virtually no response to chloroprene*. Indeed, even the male B6C3F1 mouse showed drastically lower effects from chloroprene exposure than the female B6C3F1 mouse. No species *except* the female B6C3F1 mouse supports the 0.2 μg/m^3 value.

25. In short, because of the substantial toxicokinetic (*i.e.*, how the body handles a chemical, as a function of dose and time) differences between the female B6C3F1 mouse and humans—differences that EPA was aware of but did not account for in its calculation of the IUR—the 0.2 μg/m^3 value for chloroprene dramatically overstates the human cancer risks associated with exposure to chloroprene. Further, the most important epidemiological studies of chloroprene that were available in 2010 were studies of U.S. chloroprene workers prepared in 2007 by Dr. Gary Marsh, PhD (Marsh, et al. 2007a, 2007b).[6] Dr. Marsh's 2007 studies involved, among other things, an analysis of chloroprene exposure at the Facility and showed no relationship between

[6] *See* Marsh GM, Youk AO, Buchanich JM, Cunningham M, Esmen NA, Hall TA, Phillips ML. 2007b. Mortality patterns among industrial workers exposed to chloroprene and other substances. II. Mortality in relation to exposure. Chemico-Biological Interactions. 166(1-3):301-16.

worker exposure to chloroprene and lung or liver cancer mortalities.[7] EPA nonetheless declared in the 2010 Review that there was "evidence of an association between liver cancer risk and occupational exposure to chloroprene" and "suggestive evidence of an association between lung cancer risk and occupational exposure to chloroprene." 2010 Review at 96.

26. 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. In the 2011 NATA, EPA relied upon on the IUR for chloroprene from the 2010 Review—*i.e.*, the chloroprene risk assessment based solely on the female B6C3F1 mouse—as well as on data regarding chloroprene emissions from the Facility during 2011 and other data. In the 2011 NATA, EPA suggested that there was a high risk of cancer due to chloroprene exposure in St. John the Baptist Parish in the vicinity of the Facility. Indeed, EPA stated that "[t]he top 5 census tracts with the highest NATA-estimated cancer risks *nationally* are in Louisiana due to Denka (formerly DuPont) chloroprene emissions."[8]

[7] 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* Marsh GM, Kruchten A, Buchanich JM. Mortality Patterns Among Industrial Workers Exposed to Chloroprene and Other Substances: Extended Follow-Up. J Occup Environ Med. 2021 Feb 1;63(2):126-138.

[8] EPA, LaPlace, Louisiana – Frequent Questions (Mar. 29, 2022), available at https://www.epa.gov/la/laplace-louisiana-frequent-questions (emphasis added).

C. The 2010 Review Was Scientifically Flawed And EPA Knew It.

27. EPA's conclusions in the 2010 Review are scientifically flawed. Prior to issuing the 2010 Review, EPA consulted with a group of experts in toxicology[9] and epidemiology[10] to conduct a peer review of the 2010 Review. These experts included Dr. Herman J. Gibb, Ph.D., M.P.H., an epidemiologist; Dr. Avima M. Ruder, Ph.D., an epidemiologist; Dr. Ronald L. Melnick, Ph.D., a toxicologist; Dr. John B. Morris, Ph.D., a toxicologist; Dr. Richard B. Schlesinger, Ph.D., a toxicologist; and Dr. Dale Hattis, Ph.D., a statistician. Notably, EPA believes that the 2010 "peer review is presumptive of objectivity and 'best available' science at the time it was developed." Letter from Dr. Maureen R. Gwinn to Mr. Patrick Walsh at 1 (Mar. 14, 2022) ("2022 Request for Reconsideration Denial").

28. The peer review of the 2010 Review raised sharp criticisms of EPA's methods and conclusions in the 2010 Review. Four of the six peer reviewers raised concerns that basing human risk values on the female B6C3F1 mouse would overestimate chloroprene's cancer risk to humans. For example, Dr. Morris, a toxicologist, stated that "[i]t is my view that the mouse lung data may overestimate the risk to humans. It is recognized that exclusion of these data may be problematic, but *at a minimum* a discussion of this weakness should be provided. Because the metabolism rates in the rat appear similar to the human, the rat may offer a better species for prediction of human health risks." Final Reviewer Comments, External Peer Review Meeting on the *Toxicological Review of Chloroprene*, at 30 (Jan. 26, 2010) ("2010 Final Reviewer Comments") (emphasis

[9] The National Institutes of Health ("NIH") describes toxicology as a field of science that helps us understand the harmful effects that chemicals, substances, or situations, can have on people, animals, and the environment.

[10] NIH defines epidemiology as the branch of medical science that investigates all the factors that determine the presence or absence of diseases and disorders.

added). Dr. Ruder, an epidemiologist, observed that "[t]he text in [the 2010 Review] explains the derivation of the inhalation risk but does not explain why inhalation in mice was chosen over inhalation in rats from the same study. I assume there are physiological differences which make mice a more suitable choice, *but none were provided here*." *Id.* at 31 (emphasis added). Similarly, Dr. Schlesinger, a toxicologist, warned that EPA "may want to consider the fact that metabolic activation rate in the rat is closer to that occurring in humans than is the situation in mice." *Id*.

29. Most of the peer reviewers recognized the need to adjust the IUR for the female B6C3F1 mouse to reflect human sensitivity. Dr. Morris, a toxicologist, provided several sharply worded comments recognizing the important differences between human response and the response of the female B6C3F1 mouse:

- "[I]n my view, some skepticism is appropriate relative to the quantitative importance of mouse bronchiolar tumors. The mode of action includes metabolic activation as the first step. The metabolic activation rates in the mouse exceed those in other species by 50-fold. . . . The large differences in mouse vs. human relative to pulmonary activation raise questions as to the relevance of the mouse lesions. At the very least, this issue needs to be discussed. Exclusion of the mouse lung tumors would influence the final overall unit risk estimate indicating this is not a trivial concern." 2010 Final Reviewer Comments at 40.

- "The mouse – human comparison for lung metabolism is particularly important, a fact that was not adequately considered in the risk evaluation. The presented data indicate the activity in human lung is 50-fold lower than in mouse lung . . . . The liver activities in the mouse and man are much more similar. Since metabolic activation is the first step in the mode of action and lung tumors in mice drives the risk extrapolation, this comparison becomes particularly important. . . . [T]his type of species difference (mouse to human pulmonary metabolism) is hardly unique to chloroprene. For example, consider styrene." *Id.* at 47.

- "More detail should be provided on the metabolism kinetics for chloroprene. . . . The relative level of metabolite 1 in the humans was approximately 10-fold lower than the F344 rat and mouse. The level of metabolite in the Wistar rat and hamster was lower as well. Were these quantitative differences synthesized into a coherent explanation of species differences in response?" *Id.* at 57.

- "This section fails to include the most important species difference – the appearance of lung tumors in mice but not rats. An in situ [sic] pulmonary metabolic basis might be provided, given that the metabolic activation rate in mice appears to be 50-fold higher than the rat but that in the liver differs by only 2-fold." *Id.* at 59-60.

- "[M]agnitude of species difference in metabolism is not unique, consider styrene or naphthalene. One might convincingly argue that the enormous metabolic activation rate in the mouse coupled with the low epoxide hydrolysis rate renders this species inappropriate relative to extrapolation of lung tumors. The authors of the [2010 Review] may not agree, but a critical discussion and rationale for using the mouse data needs to be included." *Id.* at 62.

30. Notably, panel members emphasized that EPA should develop and utilize a physiologically-based pharmacokinetic ("PBPK") model, which is a specialized computer model that is specifically designed to make adjustments in risk assessments based upon the different toxicological effects of a chemical from one species to another—for example, the differences between a female B6C3F1 mouse and a human. Panel members emphasized that a PBPK model for chloroprene would allow EPA to interpret laboratory animal tumor incidence data and apply that data to human beings, while considering the significant physiological differences between mice, rats, and humans. For example, Dr. Morris, a toxicologist, stated: "[T]he toxicokinetic data is not adequately synthesized in the overall mode of action relative to potential species differences and extrapolation to man. PBPK modeling would be a highly appropriate way to incorporate kinetic data into the risk assessment." *Id.* at 6.

31. In sum, the peer reviewers of the 2010 Review raised substantial concerns that the IUR applicable to the female B6C3F1 mouse was decidedly inappropriate for assessing the risks of chloroprene exposure to humans, and that EPA should actively develop a PBPK model to correctly assess how animal risk studies translate into potential human risk.

32. In light of these criticisms by the 2010 peer reviewers, EPA should have reexamined its myopic reliance on the tumor incidence rate in the B6F3C1 female mouse and

either based its cancer risk assessment on the tumor incidence rate in the rats (as several peer reviewers suggested) or pursued the development of a PBPK model. But EPA rejected the chloroprene PBPK model that was available at that time, concluding that the model was not adequate for certain technical reasons. As explained below, although EPA subsequently encouraged DPE to develop an improved PBPK model, which DPE did in consultation with EPA, EPA ultimately refused to consider that new and improved PBPK model—not because of any shortcoming in the new PKBK model, but because EPA, under a new Administration, now took the position that the Agency was *not required* to consider the latest and best available science on chloroprene.

33. The 2010 peer review also strongly criticized EPA's misuse of the relevant epidemiological data in the 2010 Review. Dr. Gibb, one of only two epidemiologists conducting the 2010 peer review, concluded that EPA "grossly misrepresents the evidence." Referring to EPA's reliance on prior epidemiological studies in Kentucky, Louisiana, China, Russia, and Armenia, Dr. Gibb stated: "The statement [by EPA] … that there is evidence of a dose-response relationship in different cohorts in different continents (U.S., China, Russia, and Armenia) grossly misrepresents the evidence." 2010 Final Reviewer Comments at 25. For example, Dr. Gibb explained that high alcohol consumption in Russia and wide prevalence of Hepatitis B in China—both known risk factors for liver cancer mortality—were "confounding factors" that undermined the connection between chloroprene and cancer risk. *Id.* at 27.

34. Dr. Gibb also criticized EPA's attempt to justify its decision not to rely on more robust existing epidemiological studies of chloroprene workers in the United States and the United Kingdom, in particular a leading epidemiological study of U.S. chloroprene workers prepared by Dr. Gary Marsh, Ph.D., in 2007. EPA discounted these studies because it believed that the so-

called "healthy worker effect" accounted for the lack of connection between chloroprene exposure and cancer risk. EPA explained that the healthy worker effect "tends to reduce the association between an exposure [chloroprene inhalation] and the outcome [cancer mortality] because workers, as a group, are healthier than the general population comparison groups." 2022 RFR Denial, App. A, EPA Courtesy Technical Review of New Scientific Information Presented in RFC 21005, at 8. EPA used its theory on the healthy worker effect selectively to disregard existing studies that suggested that chloroprene posed little to no additional cancer risk. Dr. Gibb noted in his peer review comments that "[a]n association between liver cancer and chloroprene exposure . . . is not evident in the summary of the overall weight of evidence . . . . Furthermore, a healthy worker effect for liver cancer? With such a short life expectancy following diagnosis, I would expect the healthy worker effect for liver cancer to be minimal if it even exists." 2010 Final Reviewer Comments at 27. Finally, referring to Dr. Marsh's 2007 study of chloroprene workers in Louisville, Kentucky, Dr. Gibb noted that "[t]he largest and what appears from the [draft 2010 Review] to be the best conducted study (Marsh et al., Louisville cohort) provides little if any evidence that a liver cancer risk exists. Furthermore, the [draft 2010 Review] has not been transparent in its reasoning that there is a risk of liver cancer." *Id.*

35. In response to Dr. Gibb's peer review comments, EPA changed the language in the draft 2010 Review from "risk of liver cancer mortality is *reasonably* consistent and there is *some evidence* of an exposure-response relationship" (2009 Draft Review at 4-18 (emphasis added)) to "increased risk of liver cancer mortality is *fairly* consistent and there is some *suggestive* evidence of an exposure-response relationship." 2010 Review at 42 (emphasis added). In other words, EPA made only superficial changes to the text of the 2010 Review—none of which could have changed the IUR or the resulting 0.2 $\mu g/m^3$ value.

36. EPA attempted to respond to these comments by comparing the estimated number of excess cancer cases from the IUR to the cancer mortality rate in the leading epidemiological studies, but committed two clear errors due to simple, but consequential mistakes. *See* 2010 Review, Appendix A, page A-17. EPA purported to show that the number of lung- and liver-related cancer deaths were similar between the actual cohort in the Marsh et al., (2007a, 2007b) study (283) and an estimate based on the 2010 Review IUR, adjusted for similar exposure and population parameters (293). EPA's first error in developing its mortality estimate for the 2010 Review IUR was using the wrong IUR based on the male B6C3F1 mouse. EPA's second error was that it applied the incorrect IUR only to the occupational cohort of known causes of death (n=2,282) when all workers in the cohort **(**n=5,486) were exposed to chloroprene and should have been included in the analysis. Both of these errors resulted in a mortality estimate (purportedly based on the 2010 Review IUR) that was significantly lower than it should have been. Instead of an estimated excess cancer mortality of 293, the correct calculation should have been 927. EPA's error becomes clear when compared to the 283 cancer mortalities observed in the Marsh study cohort: the incorrect estimate of 293 provides the false appearance that the 2010 IUR is consistent with real-world, human data. But, when the corrected IUR estimate of 927 mortalities is compared to 283, it is obvious that the IUR is wildly incorrect. In other words, if the 0.2 $\mu g/m^3$ value translated to the real-world, the Marsh study should have found an additional 644 lung- and liver-related cancer deaths. EPA also committed a rudimentary error when it did not recognize that the 283 total lung and liver mortalities was below the expected number of lung and liver cancers in a non-exposed population. These calculations were not subject to peer review or to comments from other agencies or offices of the White House.

37. What EPA should have recognized in 2010 is that if the IUR were applied to the *entire* exposed worker cohort in Louisville, the female mouse IUR would have led EPA to expect that more than 70% of the workers should have contracted lung and liver cancers. In fact, the cohort of workers had a deficit of lung and liver cancer compared to an unexposed population—*i.e.*, the workers had *less* lung and liver cancer, *not* more. EPA's assertion that IRIS values represent the "gold standard" in toxicology is simply not true.

D. DPE's Initial Request For Correction And EPA's Denial Of That Request.

38. On June 26, 2017, DPE submitted a Request for Correction (numbered RFC #17002) ("2017 Request for Correction") to EPA, identifying the above-described errors in the 2010 Review and IUR. Further, DPE provided EPA with a published version of a PBPK model for chloroprene (Yang, et al., 2012). DPE also provided EPA with a substantial re-evaluation of Dr. Marsh's 2007 epidemiological study of U.S. chloroprene workers, which, as noted above, was described by one of the 2010 peer reviewers (Dr. Gibb) as "[t]he largest and what appears from the document to be the best conducted study" of chloroprene risks. 2010 Final Reviewer Comments at 27.

39. Further, DPE's 2017 Request for Correction identified data from the Louisiana Tumor Registry indicating that St. John the Baptist Parish, where the Facility is located, recorded one of the lower cancer rates of any parish in the state. The Louisiana Tumor Registry, maintained by the Louisiana State University School of Public Health, has a mission "[t]o collect and report complete, high-quality, and timely population-based cancer data in Louisiana to support cancer research, control, and prevention." LSU Health, *About the Registry*, https://sph.lsuhsc.edu/louisiana-tumor-registry/about-the-registry/.

40. On January 25, 2018, EPA denied DPE's 2017 Request for Correction on the grounds that, according to EPA, DPE had not provided any "new scientific evidence" that would alter the Agency's assessment of the risks of chloroprene to humans. In the denial, EPA stated repeatedly that in the absence of new scientific evidence, EPA would continue as a default to rely on the female B6C3F1 mouse's sensitivity to chloroprene exposure in setting the human IUR for chloroprene. EPA did acknowledge the importance of a PBPK model in assessing the risks of chloroprene to humans but concluded that the then-existing model was not sufficient due to technical issues.

41. On July 23, 2018, DPE filed a request for reconsideration (numbered RFC #17002A) ("2018 Request for Reconsideration") of EPA's denial of the 2017 Request for Correction.

E. With EPA's Support And Active Collaboration, DPE Develops A New PBPK Model.

42. In addition to filing the 2018 Request for Reconsideration, DPE embarked on a three-year project to develop an updated and peer reviewed PBPK model for chloroprene, employing a team of scientists at Ramboll US Consulting, Inc. ("Ramboll"). DPE did so to respond to EPA's conclusion in the 2018 denial of the 2017 Request for Correction that any challenge to the IUR must be based on new scientific evidence, and specifically to respond to EPA's acknowledgement that it would be appropriate for EPA to rely upon a new and improved PBPK model for chloroprene.

43. Indeed, DPE and EPA actively coordinated to develop a new and improved PBPK model for chloroprene. 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.

44. On information and belief, EPA committed substantial resources to provide Ramboll with quality assurance guidance on the development of the PBPK model. EPA even paused its review of DPE's 2018 Request for Reconsideration for more than two years to accommodate Ramboll's development of the new and improved PBPK model. At the very least, by pausing its review of DPE's 2018 Request for Reconsideration, EPA acknowledged the clear value of DPE developing a new and improved PBPK model to assess the potential risks of chloroprene to humans. Indeed, in meetings and emails between EPA and DPE and Ramboll, EPA personnel repeatedly emphasized that DPE and Ramboll should develop the PBPK model.

45. 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.[11]

46. 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 better fit for cross species tumor predictions among laboratory test animals.

47. In February 2021, EPA notified DPE that it would be resuming its review of DPE's 2018 Request for Reconsideration. By that time, with EPA's input and collaboration, including the October 2020 EPA-sponsored peer review, Ramboll had substantially updated the PBPK model for chloroprene in accordance with EPA's quality assurance comments at each stage of the

[11] Clewell HJ 3rd, Campbell JL, Van Landingham C, Franzen A, Yoon M, Dodd DE, Andersen ME, Gentry PR. 2020, *Incorporation of in vitro metabolism data and physiologically based pharmacokinetic modelling in a risk assessment for chloroprene*, Inhalation Toxicology. 31(13-14):468-483. Located at https://pubmed.ncbi.nlm.nih.gov/31992090/

development process. As such, DPE elected to withdraw its pending 2018 Request for Reconsideration. Having now developed (with EPA's cooperation and consultation) the very new scientific evidence that EPA had said was necessary, DPE was prepared to submit a new request for correction of the 2010 Review that would, among other things, highlight the new scientific information that was now available in the form of the Ramboll PBPK model for chloroprene.

F. DPE's Second Request For Correction.

48. On July 15, 2021, DPE filed its second Request for Correction (numbered RFC #21005) ("2021 Request for Correction") requesting correction of the chloroprene IUR based, in part, on Ramboll's new and improved PBPK model for chloroprene.

49. Surprisingly, given EPA's prior cooperation and quality assurance input in the development of the new Ramboll PBPK model, almost immediately after DPE submitted the 2021 Request for Correction, 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.

50. However, unbeknownst to DPE, EPA sponsored another independent peer review of the new Ramboll PBPK model for chloroprene. 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, and EPA's contractor provided Ramboll with a few additional comments that Ramboll believed it could promptly address in a final version of the model. EPA did not require a consensus recommendation for the use of the Ramboll PBPK model and none was provided. On balance, the peer reviewers considered the Ramboll PBPK model to be ready for use.

51. In addition to providing EPA with the new Ramboll PBPK model, DPE's 2021 Request for Correction also provided EPA with a major new follow-up epidemiological study conducted by Dr. Marsh (Marsh, et al. 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 (Marsh, et al. 2007a, 2007b). The updated 2021 Marsh study showed *no increase* in cancer mortalities among U.S. chloroprene workers.

52. Further, DPE provided EPA with the updated data from the Louisiana Tumor Registry, which, consistent with previous Registry data, indicated lower cancer incidence rates in St. John the Baptist Parish compared to the state average. The updated 2021 Marsh study included a figure from the Louisiana Tumor Registry website indicating that the cancer incidence rate in St. John the Baptist Parish was below the state average for the 2012-2016 period. (Marsh, et al. 2021 at 10). A study by Louisiana State University in 2020-2021 confirmed that the Louisiana Tumor Registry had not omitted relevant cancer cases in the 2009-2018 timeframe. Cancer Surveillance Project, *Cancer Reporting in St. John Parish* 3 (2021), https://louisianacancer.org/wp-content/uploads/2021/03/CRISP-Final-Report.pdf. A recent update of the Louisiana Tumor Registry for the 2015-2019 period also reported that St. John the Baptist Parish was within the bottom 25 percent of cancer incidence rates in Louisiana. LSU Health, *Louisiana Cancer Data Visualization*, https://sph.lsuhsc.edu/louisiana-tumor-registry/data-usestatistics/louisiana-data-interactive-statistics/louisiana-cancer-data-visualization/ (last visited Jan. 3, 2023).

53. Like Dr. Marsh's updated epidemiological data, the Louisiana Tumor Registry data strongly support the conclusion that chloroprene does not pose a meaningful risk to humans. Given the decades-long history of chloroprene emissions from the Facility (the vast majority of which was under DuPont's ownership and at concentrations more than an order of magnitude higher than

current emissions), if EPA's 2010 IUR were remotely accurate, then there would be a statistically significant increase in cancer rates shown in the Louisiana Tumor Registry for St. John the Baptist Parish, and there would be thousands of excess cancer mortalities in the chloroprene worker cohort covered by Dr. Marsh's updated 2021 epidemiological study. But the empirical data from the Louisiana Tumor Registry and Dr. Marsh's epidemiological study are decidedly to the contrary. The Louisiana Tumor Registry data show that the incidence of cancers near the Facility are at *or below* state-wide averages of cancers of potential concern. The updated 2021 Marsh study showed *no increase* in cancer mortalities among U.S. chloroprene workers.

G. EPA Rejects DPE's 2021 Request For Correction, But For A Different And Invalid Reason.

54. On March 14, 2022, EPA denied DPE's 2021 Request for Correction. On its face, EPA's alleged justification for denying the 2021 Request for Correction was a complete reversal from EPA's prior denial of the 2017 Request for Correction. As described above, in denying the 2017 Request for Correction, EPA had taken the position that the 2010 Review (and resulting IUR) could only be changed based on the submission of new scientific evidence. In the 2021 Request for Correction, DPE did precisely that by providing the new Ramboll PBPK model for chloroprene, further analysis regarding the updated epidemiological study by Dr. Marsh, and epidemiological data from the Louisiana Tumor Registry. Now, however, in denying the 2021 Request for Correction, EPA took the position that it had no obligation to update the 2010 Review based on new scientific evidence, arguing that new scientific information could only be considered if two conditions were met: (1) chloroprene was nominated as a national or regional priority, and (2) EPA accepted the nomination.

55. Unbeknownst to DPE at the time, in April 2021, EPA Region 6 *did* nominate chloroprene for IRIS review specifically to revisit the IUR. EPA's denial of the 2021 Request for

Correction failed to consider or disclose the nomination which could have re-opened consideration of the IUR and undermined EPA's significant policy initiatives targeting DPE. DPE was not aware of the nomination until 2023, when that information was revealed through a Freedom of Information Act request. EPA's denial of the 2021 Request for Correction is arbitrary and capricious because of EPA's failure to adequately explain, or even address, why the nomination was not accepted despite DPE's persistent actions to update the IUR based on updated information.

56. In addition, EPA's denial of the 2021 Request for Correction faults DPE for "not identifying errors in the 2010 IRIS assessment." 2022 Denial at 1. In other words, after EPA denied the 2017 Request for Correction for *not* providing new scientific information, EPA now took the position that the 2021 Request for Correction could not be granted *because DPE had provided new scientific evidence*. Quite simply, EPA created a "Catch-22" scenario where no revision of an IUR is possible without new scientific evidence, but new scientific evidence will not be permitted to change the IUR. In short, EPA arbitrarily and capriciously changed its policy for considering new scientific information as set out in the 2018 denial of the 2017 Request for Correction without reasoned explanation.

57. In denying the 2021 Request for Correction, EPA attempted to insulate itself from judicial scrutiny by providing what it characterized as a "courtesy technical review" of DPE's new scientific evidence. With a wave of the hand EPA concluded, incorrectly, that even if the new Ramboll PBPK model were appropriate for use for tumor incidence in the lung, in a full risk assessment with the consideration of multiple organs as possible tumor sites, the 2010 IUR would be reduced within a factor of two with the corrected value. EPA said, "[t]his factor of 2 difference is well within the generally accepted uncertainty for cancer risk estimation." 2022 Denial at 7. EPA apparently reasoned that the Ramboll PBPK model addresses only lung tumors, when in fact

it also provides risk values for the liver. Using the PBPK values and a full assessment, EPA would have concluded that the 2010 IUR overstates human risk by at least a factor of 35. Based on its flawed "courtesy" analysis, however, EPA stated that 2010 IUR was in reasonable agreement with potential adjustments using the Ramboll PBPK model. In addition, the 2022 denial of the 2021 Request for Correction rejected the conclusiveness of new follow-up epidemiological study by Dr. Marsh and the Louisiana Tumor Registry data.

58. On June 10, 2022, DPE submitted to EPA a Request for Reconsideration of the denial of the 2021 Request for Correction ("2022 Request for Reconsideration"). DPE reiterated all of EPA's errors in the 2010 Review and DPE's arguments and evidence set forth in the 2017 Request for Correction and the 2021 Request for Correction, and DPE urged EPA to reconsider its rejection of the highly relevant scientific information previously requested by EPA and presented in the 2021 Request for Correction, including the Ramboll PBPK model for chloroprene.

59. On October 19, 2022, EPA denied DPE's 2022 Request for Reconsideration, thereby affirming EPA's denial of the 2021 Request for Correction. In its denial, EPA reaffirmed that it has no duty to update the 2010 Review based on current scientific information, stating: "EPA's Information Quality Guidelines recognize that scientific knowledge about chemical hazards and risk changes and may need to be updated over time. However, the [request for correction] process is not a mechanism to commit EPA to undertake scientific updates of its risk assessment products, such as IRIS Toxicological Reviews." EPA's denial of the 2022 Request for Reconsideration was a final agency action because it marks the consummation of EPA's decision-making process from which legal consequences are presently impacting DPE, most acutely through EPA's ISE Action in this Court, which takes the unprecedented step of alleging that

emergency authority under the Clean Air Act (not permitting or rulemaking authority) should be exercised by the Court to impose further emission reductions.

H. EPA's Actions To Enforce The 0.2 μg/m^3 Value Against DPE.

60. EPA's position on enforcing the 0.2 μg/m^3 value as a requirement for chloroprene has undergone a clear change since EPA published the 2011 NATA in December 2015. For example, in June 2016 EPA, 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* 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. At that time, however, EPA expressly recognized that the 2011 NATA should *not* be used "to identify actual exposures and associated risks to specific individuals." *Id.* In other words, EPA at that time conceded there was no basis to apply 0.2 μg/m^3 as a requirement for chloroprene emissions at the Facility. As Judge Martin Feldman stated in *Butler v. Denka Performance Elastomer, LLC,* No. 18-CV-6685, 2020 WL 2747276, 2020 U.S. Dist. LEXIS 91998, *30-32 (E.D. La. May 27, 2020) (Feldman, J.) (quoting EPA.gov), *aff'd in part on other grounds*, 16 F.4th 427 (5th Cir. 2021), the 0.2 μg/m^3 value is "less than a federal regulation," "was not designed to pinpoint specific risk values at local levels like St. John the Baptist Parish," and that even the EPA "disclaims" it as an "absolute risk measure of a risk from air toxins."

61. From June 6-10, 2016, EPA's National Environmental Investigations Center ("NEIC") performed a compliance investigation of the Facility. *See* NEIC Focused Clean Air Act Compliance Investigation Report, October 2016, at 4. In so doing, EPA gained further information about the Facility's operations, including chloroprene emissions.

62. In January 2017, EPA, LDEQ, and DPE worked together to facilitate the reduction of chloroprene emissions from the Facility. In January 2017, LDEQ and DPE, with EPA's guidance and support, executed an Administrative Order on Consent, pursuant to which DPE voluntarily reduced chloroprene emissions from the Facility by 85 percent. To achieve these emission reductions, DPE installed a regenerative thermal oxidizer and other emissions control equipment, at a cost of approximately $35 million. In May 2020, LDEQ determined that DPE had achieved the agreed-upon 85 percent emission reductions in accordance with the Administrative Order on Consent .

63. On April 24, 2018, EPA presented its findings from the June 2016 NEIC compliance investigation, commencing negotiations between EPA and DPE to resolve such findings.

64. In September 2019, the Director of EPA's Office of Air Quality Planning and Standards informed LDEQ by letter that the 0.2 $\mu g/m^3$ 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 100-in-1-million, 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), dated Sept. 23, 2019, at 2. In other words, as of September 2019, EPA confirmed that 0.2 $\mu g/m^3$ was not a "bright line" standard for determining risk. 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.* However, EPA would soon change that position. Upon information and belief, EPA did so for political reasons, and not based on any consideration of the latest available science.

65. When President Biden took office in January 2021, he made clear that "environmental justice" was one of his Administration's highest priorities. President Biden issued Executive Order 14008, establishing the White House Environmental Justice Interagency Council, the White House Environmental Justice Advisory Council, and the "Justice40 Initiative."[12] Together, these initiatives are designed to identify and advance environmental justice priorities across numerous government agencies and ensure that 40 percent of the benefits of federal investments in clean energy are realized in environmental justice communities. The executive order also specifically orders the Administrator of EPA to "strengthen enforcement of environmental violations" throughout underserved communities. *Id.*

66. Beginning in 2016, based on the 2010 Review, EPA publicly communicated 0.2 $\mu g/m^3$ as the chloroprene concentration level associated with a cancer risk of 1-in-10,000, the risk level generally used by EPA as the "the upper limit of acceptability for purposes of risk-based decisions." *See supra* n. 4. As a result of those warnings, a group of neighborhood activists in St. John the Baptist Parish have adopted the slogan "only 0.2 will do," and numerous toxic tort lawsuits have been filed against DPE either asking the court to order DPE to ensure that off-site concentrations of chloroprene be reduced to below 0.2 $\mu g/m^3$ or seeking monetary damages to compensate the plaintiffs for the fear of contracting cancer after being exposed above the 0.2 $\mu g/m^3$ level. Notably, roughly 99% of the plaintiffs in these lawsuits do not allege contracting cancer due to chloroprene emissions from the Facility.

[12] *See* Exec. Order on Tackling the Climate Crisis at Home and Abroad (Jan. 27, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/executive-order-on-tackling-the-climate-crisis-at-home-and-abroad/.

67. On May 6, 2021, Earthjustice and other environmental activists petitioned EPA to take emergency action under Section 303 of the Clean Air Act and declare that DPE's Facility was presenting an imminent and substantial endangerment. The petition alleged that emergency action was warranted due air monitoring results showing chloroprene concentration levels in excess of 0.2 $\mu g/m^3$. Despite those allegations of an emergency made almost two years ago, EPA did not declare an imminent and substantial endangerment.

68. In November 2021, EPA Administrator Regan conducted an unprecedented and highly publicized "Journey to Justice Tour" of the American South. Administrator Regan visited St. John the Baptist Parish and communities in LaPlace, Louisiana in the vicinity of the Facility. Administrator Regan met with activists in the community who had brought toxic tort lawsuits against DPE seeking damages for alleged harms due to chloroprene emissions and/or the fear of contracting cancer. On information and belief, the local public's fear of contracting cancer has been fomented by EPA's continued public-facing statements about chloroprene emissions causing cancer and the Facility's emissions causing the "highest NATA-estimated cancer risks nationally." During his visit to the local community, Administrator Regan declined to meet with industry representatives.

69. On January 24, 2022, Administrator Regan sent a letter to the leadership of DPE's joint venture partners, but not to DPE, referring to his 2021 Journey to Justice Tour and visit to St. John the Baptist Parish. Administrator Regan referred to "the serious risks posed by the chloroprene emissions resulting from this plant's neoprene manufacturing operations," and essentially adopted the demands of environmental activists and the plaintiffs in the various toxic tort lawsuits pending against DPE. Administrator Regan insisted that DPE take actions to control

emissions of chloroprene that go far beyond what is required under EPA regulations and the air permits issued by LDEQ.

70. Shortly after the Biden Administration took office, the EPA career staff with whom DPE and Ramboll had collaborated in developing the new PBPK model abruptly ceased engaging in communications with DPE and Ramboll representatives, despite years of cooperation on the new Ramboll PBPK model. On information and belief, EPA's obvious change in posture was a politically driven decision and EPA staff were encouraged to refrain from further communications with DPE and Ramboll representatives. On information and belief, EPA is not willing to consider the new Ramboll PBPK model for chloroprene and the other updated information presented by DPE in the 2021 Request for Correction because that information undercuts EPA's public pronouncements about the alleged risks of chloroprene in the community, EPA would be criticized by environmental activists and the plaintiffs' attorneys in the toxic tort lawsuits pending against DPE, and that information refutes EPA's allegation of imminent and substantial endangerment in the ISE Action.

71. Since mid-May 2022, EPA began threatening DPE with an action under Section 303 of the Clean Air Act, which is triggered by EPA's "receipt of evidence" of an "imminent and substantial endangerment." 42 U.S.C. § 7603. Since that time, EPA has demanded DPE implement substantial emissions control projects with the goal of meeting the 0.2 $\mu g/m^3$ value.

72. In addition to the demands that EPA has made directly to DPE to meet 0.2 $\mu g/m^3$, EPA has sought to achieve that goal by pressuring LDEQ to enforce 0.2 $\mu g/m^3$ as a requirement against the Facility. On January 20, 2022, the Sierra Club and a neighborhood group filed an administrative complaint with EPA against LDEQ for alleged violations of Title VI of the Civil Rights Act, alleging that LDEQ had discriminated against Black residents of St. John the Baptist

Parish by subjecting them to disproportionate air pollution from the Facility ("Title VI Complaint"). The Title VI Complaint alleges that LDEQ has discriminated against these residents by, among other things, failing to review and strengthen the air permits issued to the Facility and failing to control chloroprene emissions from the Facility.

73. On April 6, 2022, the EPA External Civil Rights Compliance Office ("ECRCO") notified LDEQ and LDH that it was accepting for investigation the Title VI Complaint. ECRCO has implemented procedures to attempt to informally resolve the matter with LDEQ.

74. On June 3, 2022, LDEQ responded by letter to ECRCO's decision to accept the Title VI Complaint. In the letter, LDEQ stated that "neither the 0.2 $\mu g/m^3$ exposure concentration nor a cancer risk threshold of 100-in-1-million are an enforceable standard or applicable requirement under the Title V permitting program. Rather, chloroprene is regulated. . . pursuant to Section 112 of the Clean Air Act." LDEQ's letter also reminded EPA that "it is EPA that bears the responsibility to update control standards for hazardous air pollutants under Section 112 of the [Clean Air Act]. . . ."

75. On June 6, 2022, LDH responded by letter to ECRCO's decision to accept the Title VI Complaint. LDH's letter described a Parish Council meeting in November 2017 to discuss chloroprene concentrations near the Facility. In response to concerns voiced by members of the community, the LDH letter states that the Secretary of LDEQ "explained that 0.2 $\mu g/m^3$ was not an established number." The letter also states that Dr. LuAnn White of the Tulane School of Public Health convened "an Expert Panel on chloroprene, which concluded that the situation was not a public health emergency but chloroprene levels should not be as high as they were."

76. On October 12, 2022, EPA sent a "letter of concern" to LDEQ regarding the Title VI Complaint ("October 12 Letter"). The October 12 Letter "recommends" that LDEQ

immediately (i) conduct a cumulative impact analysis of the neighboring community; (ii) monitor area chloroprene concentrations based on the 0.2 µg/m^3 value; (iii) issue renewed air permits to the Facility only "after completion of the cumulative impact analysis"; and (iv) "work to establish limits in Industrial Corridor air permits [including the Facility's air permits] that, in the aggregate, limit air emissions of carcinogens that have a mutagenic mode of action, including chloroprene." The October 12 Letter further states that "[g]iven the long history of exposure in the area, the goal is to limit future air emissions of such pollutants to levels consistent with cancer risks below 100-in-1 million (based on 70 years of exposure) at sites where people live, and to reduce concentrations of such carcinogens even further if reasonably achievable." In other words, EPA's goal is to require the Facility to meet 0.2 µg/m^3 and EPA is effectively pressuring LDEQ to enforce the 0.2 µg/m^3 value against the Facility.

77. On February 28, 2023, EPA initiated the ISE Action, alleging that the Facility's emissions of chloroprene constitute an imminent and substantial endangerment. EPA seeks an order requiring the Facility to implement emission reduction projects that would result in the Facility satisfying the 0.2 µg/m^3 value for chloroprene.

78. On March 20, 2023, EPA filed a motion for preliminary injunction seeking a shutdown of the Facility unless DPE complied with EPA's host of prescriptive requirements. In the motion, EPA makes no effort to hide that its unprecedented action is entirely dependent on enforcing the 0.2 µg/m^3 value. *See, e.g.,* Mem. in Support of Mot. For Preliminary Injunction at 6, ECF No. 9-2 ("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."). Indeed, EPA 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 likely and potent human carcinogen." *Id.* at 7 (opinion I). He also provides a straight-forward calculation that uses the 2010 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.").

79. In sum, EPA's conduct here—from its denial of the 2022 Request for Reconsideration through its efforts to enforce the 0.2 μg/m^3 value for chloroprene in the ISE Action—constitutes final agency action that is having a direct and harmful impact on DPE.

FIRST COUNTERCLAIM CLAIM FOR RELIEF

(Counterclaim-Defendants' Issuance Of The 2010 Review Was Arbitrary, Capricious, An Abuse Of Discretion, And Contrary To Law In Violation Of The APA)

80. DPE incorporates paragraphs 1-79 as if fully set forth herein.

81. Counterclaim-Defendants' issuance and application of the 2010 Review setting a 0.2 μg/m^3 1-in-10,000 risk-based value for chloroprene was arbitrary, capricious, an abuse of discretion, and not in accordance with law in violation of the APA, because Counterclaim-

Defendants failed to consider the best available scientific data despite concerns raised by qualified peer reviewers.

82. In setting that IUR for chloroprene, EPA erroneously relied upon a default assumption that humans are as sensitive to chloroprene as a female B6C3F1 mouse. This was a fundamental error by EPA, as the 2010 peer reviewers of the 2010 Review expressly informed EPA at the time. Because of the substantial toxicokinetic differences between the female B6C3F1 mouse and humans—differences which EPA was aware of but did not account for in its calculation of the IUR—the IUR dramatically overstates the human cancer risks associated with exposure to chloroprene. EPA knew this and disregarded the scientific information that demonstrated it.

83. The 2010 peer reviewers emphasized to EPA that the IUR applicable to the female B6C3F1 mouse was not appropriate for assessing the risks of chloroprene exposure to humans, and that EPA should develop an accurate PBPK model to correctly assess how animal risk studies translate into potential human risk. EPA was arbitrary and capricious in failing to develop and rely upon a PBPK model in issuing the 2010 Review setting the stringent 5×10^{-4} IUR value for chloroprene and resulting 0.2 $\mu g/m^3$ value.

84. The 2010 peer review also strongly criticized EPA's misuse of the relevant epidemiological data in the 2010 Review, including the most robust epidemiological studies. EPA was arbitrary and capricious in refusing to revisit its analysis of the existing epidemiological studies or reconsidering its own analysis of the available data.

85. The above-referenced information constituted the best scientific data available to EPA at the time of its decision and relevant to assessing the potential risk of chloroprene to humans. As such, EPA was obligated to consider this information in the 2010 Review. Counterclaim-Defendants' failure to do so, resulting in the setting of a 5×10^{-4} IUR value for

chloroprene and resulting 0.2 µg/m^3 value, was arbitrary, capricious, an abuse of discretion, and not in accordance with law, because Counterclaim-Defendants failed to consider the best available scientific data in violation of the APA.

SECOND COUNTERCLAIM FOR RELIEF

(Counterclaim-Defendants' Denials Of DPE's Challenges To The 2010 Review Were Arbitrary, Capricious, An Abuse Of Discretion, And Contrary To Law In Violation Of The APA)

86. DPE incorporates paragraphs 1-85 as if fully set forth herein.

87. In DPE's 2017 Request for Correction, 2018 Request for Reconsideration, 2021 Request for Correction, and 2022 Request for Reconsideration, DPE challenged EPA's issuance of the 2010 Review resulting in the setting of a 5 x 10^{-4} IUR value for chloroprene. EPA's denial of DPE's challenges—affirming the 5 x 10^{-4} IUR for chloroprene and the resulting 0.2 µg/m^3 value—was arbitrary, capricious, an abuse of discretion, and not in accordance with law, because Counterclaim-Defendants failed to consider the best scientific data available to EPA at the time of its decision in violation of the APA.

88. In the 2017 Request for Correction and 2021 Request for Correction, DPE pointed out EPA's errors in issuing the 2010 Review and setting a 5 x 10^{-4} IUR value for chloroprene, including EPA's flawed reliance on the default assumption that humans are as sensitive to chloroprene as a female B6C3F1 mouse. DPE further pointed out the substantial criticisms of the 2010 Review by the 2010 peer reviewers, including EPA's failure to utilize a PBPK model and EPA's misuse of the relevant epidemiological data in the 2010 Review.

89. In rejecting the 2021 Request for Correction and 2022 Request for Reconsideration, Counterclaim-Defendants erred and abused their discretion by failing to consider and rely upon the new Ramboll PBPK model for chloroprene presented as part of the 2021 Request for Correction and 2022 Request for Reconsideration. The Ramboll PBPK model for chloroprene—

which was fully peer-reviewed, including by EPA's own sponsored peer review—would allow EPA to correctly assess how animal risk studies translate into potential human risk. The Ramboll PBPK study is the best available science to correctly assess how animal risk studies translate into potential human risk. Counterclaim-Defendants erred and abused their discretion by failing to fully consider and rely upon the Ramboll PBPK model and by disregarding the Ramboll PBPK model in rejecting the 2021 Request for Correction and 2022 Request for Reconsideration.

90. Further, in rejecting the 2021 Request for Correction and 2022 Request for Reconsideration, Counterclaim-Defendants erred and abused their discretion by failing to consider and rely upon the most recent and robust epidemiological data, including Dr. Marsh's 2021 epidemiological study showing no increase in cancers among U.S. chloroprene workers, and the empirical data from the Louisiana Tumor Registry showing that the incidence of cancers near the Facility are at or below state-wide averages of cancers of potential concern.

91. The above-referenced information constitutes the best available scientific data relevant to assessing the potential risk of chloroprene to humans. As such, Counterclaim-Defendants were obligated to consider and rely upon this information in the 2010 Review and should have revisited that information based on the facts and arguments set forth in the 2017 Request for Correction, the 2018 Request for Reconsideration, the 2021 Request for Correction, and the 2022 Request for Reconsideration. Counterclaim-Defendants' repeated failure to do so, resulting in the setting of a 5×10^{-4} IUR value for chloroprene, was arbitrary, capricious, an abuse of discretion, and not in accordance with law, because Counterclaim-Defendants failed to consider the best available scientific data in violation of the APA.

92. Counterclaim-Defendants' current and ongoing application of the 2010 Review to DPE through the 0.2 $\mu g/m^3$ value for chloroprene without providing a rational basis for the

Agency's failure to consider the best available scientific data—including the Ramboll PBPK model, Dr. Marsh's 2021 epidemiology study, and the 2022 Louisiana Tumor Registry data—is arbitrary, capricious, an abuse of discretion, and not in accordance with law in violation of the APA.

THIRD COUNTERCLAIM FOR RELIEF

(Counterclaim-Defendants' Abrupt Change Of Position—Refusing To Consider The Ramboll PBPK Model After Encouraging And Working With DPE To Develop It—Was Arbitrary, Capricious, An Abuse Of Discretion, And Contrary To Law In Violation Of The APA)

93. DPE incorporates paragraphs 1–92 as if fully set forth herein.

94. In denying DPE's 2017 Request for Correction, EPA stated repeatedly that DPE had failed to provide new scientific evidence to dispute, among other things, EPA's reliance on the female B6C3F1 mouse in setting the human IUR for chloroprene. Based on EPA's articulated position, DPE, through Ramboll, spent three years developing an updated and peer reviewed PBPK model for chloroprene.

95. EPA actively collaborated with DPE and Ramboll in developing the new and improved Ramboll PBPK model for chloroprene. EPA commented on Ramboll's work plan for the development of a PBPK model and, on information and belief, EPA committed substantial resources to provide Ramboll with quality assurance guidance on the development of the PBPK model. In meetings and emails between EPA and DPE and Ramboll, EPA personnel repeatedly emphasized that DPE and Ramboll should develop the PBPK model.

96. In June 2019, to ensure that the new PBPK model was correct, Ramboll subjected the PBPK model to a peer review and ultimately published the model. In October 2020, EPA itself sponsored another peer review of an updated version of the Ramboll PBPK model, resulting in further improvements to the model.

97. By early 2021, having now developed, with EPA's collaboration, the very new scientific information that EPA had said was necessary to revisit and reassess the IUR for chloroprene, DPE submitted the 2021 Request for Correction highlighting the new scientific information that was now available, including the Ramboll PBPK model for chloroprene.

98. In rejecting the Ramboll PBPK model as part of the denial of the 2021 Request for Correction and 2022 Request for Reconsideration, Counterclaim-Defendants' position regarding the model was a complete reversal from the position EPA had taken with respect to the 2017 Request for Correction. In rejecting the 2017 Request for Correction, EPA faulted DPE for not providing new scientific information. Now, in rejecting the 2021 Request for Correction and 2022 Request for Reconsideration, Counterclaim-Defendants have taken the position that EPA would not revisit the 2010 Review *because* DPE had provided new scientific evidence.

99. Counterclaim-Defendants' abrupt reversal of position was not based on the evidence, data, or best scientific information available at that time. Upon information and belief, Counterclaim-Defendants' reversal was done for political reasons, and not based on any consideration of the best science available at the time.

100. Counterclaim-Defendants' reversal of position, effectively creating Catch-22 scenario, was arbitrary, capricious, an abuse of discretion, and not in accordance with law, and resulted in Counterclaim-Defendants failing to consider the best available scientific data in violation of the APA.

FOURTH COUNTERCLAIM FOR RELIEF

(Counterclaim-Defendants' Actions To Enforce The IUR For Chloroprene Derived From The 2010 Review, And Refusing To Consider The Best Available Science, Is Arbitrary, Capricious, An Abuse Of Discretion, And Contrary To Law In Violation Of The APA)

101. DPE incorporates paragraphs 1–100 as if fully set forth herein.

102. Counterclaim-Defendants' actions to enforce the 0.2 μg/m^3 IUR value for chloroprene against the Facility, including in the pending ISE Action, is arbitrary, capricious, an abuse of discretion, and not in accordance with law in violation of the APA, because Counterclaim-Defendants have failed to consider the best scientific data available at the time.

103. In seeking to enforce the 0.2 μg/m^3 value against the Facility in the ISE Action, Counterclaim-Defendants have erred and abused their discretion by failing to consider and rely upon the new Ramboll PBPK model for chloroprene. The Ramboll PBPK study was (and remains) the best available science to correctly assess how animal risk studies translate into potential human risk. Counterclaim-Defendants erred and abused their discretion by failing to fully consider and rely upon the Ramboll PBPK model and by disregarding the Ramboll PBPK model in seeking to enforce the 0.2 μg/m^3 value against the Facility in the ISE Action.

104. Further, Counterclaim-Defendants have erred and abused their discretion by failing to consider and rely upon the most recent and robust epidemiological data, including Dr. Marsh's 2021 epidemiological study showing no increase in cancers among U.S. chloroprene workers, and the empirical data from the Louisiana Tumor Registry showing that the incidence of cancers near the Facility are at or below state-wide averages of cancers of potential concern.

105. The above-referenced information constituted the best scientific data available at the time and relevant to assessing the potential risk of chloroprene to humans. As such, Counterclaim-Defendants were obligated to consider and rely upon this information prior to engaging in efforts to enforce the 0.2 μg/m^3 value for chloroprene against the Facility, including in the ISE Action. Counterclaim-Defendants' failure to do so was arbitrary, capricious, an abuse of discretion, and not in accordance with law, because Counterclaim-Defendants failed to consider the best available scientific data in violation of the APA.

106. Further, Counterclaim-Defendants have erred and abused their discretion by failing to conduct a refined risk assessment—as required by EPA's own guidelines—before seeking to enforce the 0.2 μg/m^3 IUR value against the Facility in the ISE Action. EPA's theory of imminent and substantial endangerment relies on monitoring data that have been collected near the DPE Facility from 2016 through 2023. However, contrary to its own guidelines, EPA has failed to refine its assessment of the risk, despite almost seven years of monitoring. Instead, EPA assumes that individuals in the community will be exposed to chloroprene emissions 24 hours a day for the next 70 years. This assumption ignores decades of EPA's own risk assessment principles, as well as common sense. EPA also ignores that chloroprene concentration levels have decreased significantly compared to the historical averages it relies upon in alleging an imminent and substantial endangerment. EPA's failure to refine its risk assessment—contrary to its own guidelines—dramatically overestimates community exposure by relying upon an unrealistically conservative estimate.

107. Counterclaim-Defendants' current and ongoing application of the 2010 Review to the Facility through the 0.2 μg/m^3 IUR value for chloroprene without providing a rational basis for EPA's failure to consider the best available scientific data—including the Ramboll PBPK model, Dr. Marsh's 2021 epidemiology study, and the 2022 Louisiana Tumor Registry data—is arbitrary, capricious, an abuse of discretion, and not in accordance with law in violation of the APA.

FIFTH COUNTERCLAIM FOR RELIEF

(Counterclaim-Defendants' Reversal Of EPA's Longstanding Risk Assessment Policy Without Reasoned Explanation Was Arbitrary, Capricious, An Abuse Of Discretion, And Contrary To Law In Violation Of The APA)

108. DPE incorporates paragraphs 1–107 as if fully set forth herein.

109. Counterclaim-Defendants have arbitrarily and capriciously reversed 30 years of EPA risk assessment policy without reasoned explanation by treating an estimated 1-in-10,000 risk based on the 2010 IUR in a strict, "bright line" fashion.

110. EPA has a history of setting long-term risk standards greater than 1-in-10,000. Under Section 112 (f) of the Clean Air Act, 42 U.S.C. § 7412(f), EPA sets emission standards for hazardous air pollutants, such as chloroprene, with a statutorily required "ample margin of safety" to protect public health. EPA regulations have authorized long-term risks of greater than 1-in-10,000 in the following regulations:

- In 1989, EPA established National Emission Standards for Hazardous Air Pollutants ("NESHAPs") for benzene, 54 Fed. Reg. 38044 (Sept. 14, 1989), based on a risk assessment accepted by Congress and codified in the Clean Air Act in 42 U.S.C. § 7412(f)(2)(B). For Coke By-Product Recovery Plant, the benzene NESHAPs authorized a maximum risk of 2-in-10,000.

- In 2005, in the NESHAPs for Coke Oven Batteries, EPA authorized a risk of 2.7-in-10,000. *See* 70 Fed. Reg. 19992 (2005).

- In 2006, in the National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities, EPA authorized a risk of 2-in-10,000. *See* 71 Fed. Reg. 42723 (2006).

- In 2021, in the NESHAPs for Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, EPA authorized a risk of 2-in-10,000. *See* 85 Fed. Reg. 49084 (2020).

111. EPA's departure from 30 years of Agency risk assessment policy without reasoned explanation was arbitrary, capricious, an abuse of discretion, and not in accordance with law, in violation of the APA.

SIXTH COUNTERCLAIM FOR RELIEF

(EPA's Use Of The 2010 Review As The "Gold Standard" And As An Excuse For Ignoring Available Scientific Information In Making Air Pollution Risk Assessments Is Arbitrary, Capricious, An Abuse Of Discretion, And Contrary To Law In Violation Of The APA)

112. DPE incorporates paragraphs 1–111 as if fully set forth herein.

113. In numerous regulatory actions relating to the Facility, including but not limited to the ISE Action, the NEIC inspections, the Title VI Letter of Concern, and in numerous communications with LDEQ and others, EPA has relied on the 2010 IUR as the sole basis for action and has ignored all other available scientific information, including the Ramboll PBPK Model, the Marsh epidemiology studies, and the Louisiana Tumor Registry data.

114. Under the Clean Air Act, the Information Quality Act, and the APA, EPA has an affirmative duty to evaluate available scientific evidence in making risk determinations affecting DPE.

RELIEF REQUESTED

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

115. A judicial declaration that Counterclaim-Defendants' issuance of the 2010 Review setting a 0.2 $\mu g/m^3$ IUR value for chloroprene, was arbitrary, capricious, an abuse of discretion, and not in accordance with law, because Counterclaim-Defendants failed to consider the best scientific data available at that time in violation of the APA.

116. A judicial declaration that Counterclaim-Defendants' denial of DPE's 2017 Request for Correction, 2021 Request for Correction, and 2022 Request for Reconsideration—challenging the issuance of the 2010 Review setting a 0.2 $\mu g/m^3$ IUR value for chloroprene—was arbitrary, capricious, an abuse of discretion, and not in accordance with law, because Counterclaim-Defendants failed to consider the best scientific data available at that time in violation of the APA.

117. An order remanding the 2010 Review to EPA and requiring Counterclaim-Defendants to give full consideration to the best available scientific information regarding the

inhalation unit risk of chloroprene to humans, including the Ramboll PBPK model and the latest epidemiological data.

118. An order permanently enjoining Counterclaim-Defendants from relying upon the 2010 Review in its current form and from applying the 0.2 µg/m3 value for chloroprene unless and until EPA has fully considered the best available scientific information regarding the potential risk of chloroprene to humans.

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

Respectfully submitted,

/s/ Robert E. Holden

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CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2023, a copy of the foregoing document was filed electronically with the Clerk of Court using the Court's CM/ECF system. Notice of this filing will be sent to Plaintiff the United States of America by operation of the CM/ECF system. In addition, a copy of the foregoing has been sent to the following via email and first class U.S. Mail:

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