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September 8, 2017

Via Federal Express and Electronic Mail (quality@epa.gov)
Information Quality Guidelines Staff
U.S. Environmental Protection Agency
William Jefferson Clinton North
1301 Constitution Avenue N.W.
OEI Quality Staff, Suite 5315
Washington, DC 20004

Re: Objection to Denka Performance Elastomer LLC's ("Denka")
Request for Correction (EPA RFC 17002) ("RFC")
Toxicological Review of Chloroprene (CAS No. 126-99-8)

Dear Sir or Madam:

Please find enclosed an Objection to the RFC recently submitted by Denka. The Objection was prepared by Dr. Karl Roberts, Ph.D. in conjunction with and including responses by Dr. Marco Kaltofen, Ph.D., P.E. and Dr. Barry S. Levy, M.D., M.P.H., P.C. These experts were asked to respond to Denka's RFC by representatives of a group of concerned residents and leaders in a community which continues to be adversely affected by the harmful contaminants emitted by Denka in the area surrounding its chemical plant in Laplace, Louisiana.

Sincerely,

Hugh P. Lambert, Esq.

Enclosures

cc: *Via Federal Express and/or Electronic Mail*
Dr. Tina Bahadori, Director
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OBJECTION TO DENKA PERFORMANCE ELASTOMER LLC (Denka)
REQUEST FOR CORRECTION (EPA RFC 17002) OF –
TOXICOLOGICAL REVIEW OF CHLOROPRENE (CAS No. 126-99-8)

Summary of Objections for Rejecting Denka's Request

EPA should reject Denka's Request for Correction (RFC) in its entirety.[1] The Request fails to meet Denka's burden of proof established by the Information Quality Act (IQA) and EPA's IQA Guidelines (EPA's Guidelines).[2] Denka's RFC meets none of the foundational requirements established by EPA's Guidelines.[3]

Denka's Request provides no new peer-reviewed scientific information that was not available to and considered by EPA during the 2010 IRIS Assessment of chloroprene.[4] Denka seeks to undermine the agency's responsibility to maintain scientific integrity by injecting impermissible, irrelevant economic, political, and feasibility arguments into the RFC process. Denka's RFC distorts the scientific process established by the IQA, EPA's Guidelines, and the Clean Air Act (CAA) by substituting its self-interested arguments for peer-reviewed science.[5]

Scientific information developed in EPA's IRIS Assessment of chloroprene and incorporated into EPA's 2011 National Air Toxics Assessment of chloroprene emissions meets the relevant requirements for actionable science.[6] Both EPA and the Louisiana Department of Environmental Quality (LDEQ), the state environmental agency to which EPA delegated CAA permitting at Denka's LaPlace facility, have properly begun to incorporate the IRIS Assessment's

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[1] Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), dated June 26, 2017.
[2] Treasury and General Government Appropriations Act Fiscal Year 2001, Pub. L. No. 106-554 § 515 (Information Quality Act); 44 U.S.C. § 3516 (notes); EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (Oct. 2002) (EPA's Guidelines).
[3] *See* EPA's Guidelines, §§ 8.2, 8.4, 8.5, pp 30-33.
[4] *See* U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010 (2010 IRIS Assessment).
[5] *See* Clean Air Act, 42 U.S.C., chapter 85; *Mississippi v. EPA,* 744 F.3d 1334 (D.C. Cir. 2013).
[6] *See* Marco Kaltofen, Ph.D., PE, (Civil, Mass.), Boston Chemical Data, Worcester Polytechnic Institute, Review of Denka Performance Elastomer, LLC (Denka) request to US EPA to reassess the Toxicological Review of Chloroprene, dated September 7, 2017 (Attachment A); *see also* Barry S. Levy, M.D., M.P.H, P.C., Comments on Chloroprene and Cancer, dated September 6, 2017 (Attachment B).

scientific information into permits that limit chloroprene emissions to protect human health and the environment.[7]

Denka's RFC simply re-argues the regulatory impact of available peer-reviewed scientific information already fully considered by EPA's 2010 IRIS Assessment. Denka has already unsuccessfully used its opportunity provided by the EPA's Guidelines to obtain a "quick and efficient resolution of [its] questions about information quality."[8] EPA National Center for Environmental Assessment (NCEA) scientists who prepared the 2010 IRIS Assessment declined Denka's August 2016 request to reconsider the agency's chloroprene research methodology and conclusions.[9] Denka's RFC offers no new scientific data or methodology not presented to NCEA in 2016. Denial of Denka's informal reconsideration request now imposes an even heavier evidentiary burden, which this RFC fails to meet. Denka's RFC fails to meet the "the burden of demonstrating that the [challenged] information does not comply with EPA or OMB guidelines *and* that a particular corrective action would be appropriate."[10]

EPA's Guidelines direct the agency to reject a RFC that presents only arguments and evidence that "could have been submitted during the comment period of a rulemaking or other action."[11] Denka, a producer of chloroprene distributed in global markets for many years, did not participate in the public comment phase of the IRIS Assessment.[12] Other chloroprene producers participated in EPA's IRIS process, as did interested members of the public. The EPA's Guidelines direct the agency to reject a Request, made after conclusion of a public scientific process, by a regulated party that could have, but chose not to, submit comments.[13]

Denka's RFC relies largely on its consultant report privately prepared for the company by Ramboll Environ (Environ).[14] The Environ report adds no new peer-reviewed scientific information to the body of information already fully considered by EPA's 2010 IRIS Assessment. The Environ report simply renews arguments using information that the agency has already fully considered. As the Court of Appeals for the District of Columbia Circuit observed, in

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[7] Louisiana Department of Environmental Quality, Check Permit Status, http://www1.deq.louisiana.gov/portal/ONLINESERVICES/CheckPermitStatus.aspx (accessed September 8, 2017); Letter from Chuck Carr Brown, Ph.D., Secretary, Louisiana Department of Environmental Quality, to Patrick A. Walsh, CIH, Safety, Health and Environmental Manager, Denka Performance Elastomer LLC, "Air Quality Modeling Protocol and Fenceline Monitoring Proposal for Chloroprene Emissions," dated May 27, 2016.

[8] *See* EPA's Guidelines, §§ 8.1, p 30.

[9] Letter from Kenneth A. Mundt, Ramboll Environ, to John Vandenberg, Ph.D., Director of Research at National Center for Environmental Assessment, EPA (Aug. 23, 2016).

[10] EPA's Guidelines, §§ 8.1, 8.2, pp 30-31 (emphasis added).

[11] EPA's Guidelines, § 8.5, pp 32-33.

[12] *See* U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010, Appendix A. Summary of External Peer Review and Public Comments and Disposition.

[13] EPA's Guidelines, § 8.5, pp 32-33 ("EPA generally would not consider a complaint that could have been submitted as a timely comment in the rulemaking or other action but was submitted after the comment period.").

[14] *See* Basis for Requesting Correction of the US EPA Toxicological Review of Chloroprene, Prepared by Dr. Robinan Gentry, Dr. Kenneth Mundt, and Dr. Sonja Sax of Ramboll Environ, Intended for Denka Performance Elastomer, LLC (June 2017) (Environ Report).

dismissing a complaint about EPA's use of scientific information to make Clean Air Act rules, "the challenge to EPA's use of [certain information] is no more than a claim that EPA did wrong by disagreeing with [a non-agency scientist's] interpretation of his data. . . . [N]othing in the Clean Air Act or the Information Quality Act prohibits EPA from independently analyzing the science, . . . and the only objections [petitioner] offers to EPA's independent analysis are either conclusory or require us to weigh in on what is apparently a legitimate scientific debate."[15]

Denka's RFC distorts the EPA's Guidelines' requirement that the party seeking scientific correction must include "[a]n explanation of how the alleged error affects or how a correction would benefit the requestor."[16] The RFC instead uses Environ's report to make arguments impermissible under the IAQ that simply advance Denka's self-interested desire to maintain profitability at its LaPlace chloroprene facility.[17]

Denka's RFC aims to replace EPA's peer-reviewed IRIS Assessment with Environ's proprietary science, radically altering the agency's duty to use scientific decision-making to regulate air quality to protect human health. Denka's RFC demands a new chloroprene emission limit that would dramatically increase the average amount of chloroprene vapor allowed into the ambient air breathed 365 days per year, every year, by people living near Denka's LaPlace facility.[18] If Environ's proprietary science replaces EPA's scientific justification of the 0.20 µgram/cubic meter chloroprene Inhalation Unit Risk (IUR) that will be incorporated into Denka's LaPlace permits, then Denka's success will reverberate far beyond LaPlace and surrounding communities. Granting Denka's RFC would expose the entire United States and our territories to dangerous levels of chloroprene, a known carcinogen.[19]

Denka's Environ report has not been subjected to external peer review, unlike EPA's IRIS Assessment.[20] The Environ report itself -- the only allegedly scientific argument presented by the RFC -- suffers from various fatal objections to its methodology that justify dismissal of its arguments and rejection of Denka's RFC. An RFC based on such a flawed report fails to comply

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[15] *Mississippi v. EPA*, 744 F.3d at 1347.

[16] EPA's Guidelines, § 8.2 pp 30-31.

[17] *See* Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), p. 6, dated June 26, 2017; *see also* Letter from Koki Tabuchi, President and Chief Executive Officer, Denka Performance Elastomer LLC, to Honorable Scott Pruitt, Administrator, U.S. Environmental Protection Agency, "Request to Withdraw and Correct the 2010 IRIS Review of Chloroprene," dated June 26, 2017.

[18] *See* Marco Kaltofen, Ph.D., PE, (Civil, Mass.), Boston Chemical Data, Worcester Polytechnic Institute, Review of Denka Performance Elastomer, LLC (Denka) request to US EPA to reassess the Toxicological Review of Chloroprene, dated September 7, 2017 (Attachment A).

[19] *See* Barry S. Levy, M.D., M.P.H, P.C., Comments on Chloroprene and Cancer, dated September 6, 2017 (Attachment B)

[20] *See* Environ Report; *see also* Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), pp. 1-2, dated June 26, 2017; *see also* Letter from Kenneth A. Mundt, Ramboll Environ, to John Vandenberg, Ph.D., Director of Research at National Center for Environmental Assessment, EPA (Aug. 23, 2016).

with EPA's Guidelines, the IQA, and the agency's CAA duty to safeguard public health and the environment by basing its regulatory actions on sound science.[21]

Denka's RFC undermines EPA's principles of scientific integrity and public transparency by advancing a novel, dangerous system of developing scientifically valid health risk assessments.[22] Accepting the Environ report's arguments by granting Denka's RFC would upend not only EPA's reliance on peer-reviewed scientific methods, but the scientific process used by all federal agencies to develop health-protective standards.[23]

Denka's desired regulatory outcomes to preserve profitability would not only expose the entire United States to chloroprene emissions that threaten human health, but pose especially grave threats to vulnerable populations and residents of environmental justice communities.[24] Denka's RFC fails to apply scientific methods required by the CAA that sustain EPA's environmental justice obligations to communities who live near and must breathe daily chloroprene emissions from the LaPlace facility.[25]

Denka's RFC extends the company's ongoing effort to mobilize political influence, directed to the EPA's highest levels, on behalf of its LaPlace chloroprene facility's economic profitability.[26] The agency's legal duty under the Clean Air Act and the Information Quality Act requires only

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[21] *Mississippi v. EPA*, 744 F.3d at 1339.

[22] *See* U.S. Environmental Protection Agency (2008) EPA Quality Policy, http://www.epa.gov/irmpoli8/policies/21060.pdf (accessed September 7, 2017); U.S. Environmental Protection Agency (1999) Principles of Scientific Integrity, http://www.epa.gov/osa/pdfs/scientific-integrity-principles.pdf (accessed September 7, 2017); *see also* Basic Information about Scientific Integrity, EPA, http://www.epaarchive.cc/node/38287.html, (accessed September 8, 2017); William D. Ruckelshaus, EPA Administrator, Fishbowl Memo (May 19, 1983), https://www.regulationwriters.com/downloads/EPA-Fishbowl-Memo-05-19-1983-Ruckelshaus.pdf (accessed September 8, 2017); *see also* Marco Kaltofen, Ph.D., PE, (Civil, Mass.), Boston Chemical Data, Worcester Polytechnic Institute, Review of Denka Performance Elastomer, LLC (Denka) request to US EPA to reassess the Toxicological Review of Chloroprene, dated September 7, 2017 (Attachment A).

[23] *See* Marco Kaltofen, Ph.D., PE, (Civil, Mass.), Boston Chemical Data, Worcester Polytechnic Institute, Review of Denka Performance Elastomer, LLC (Denka) request to US EPA to reassess the Toxicological Review of Chloroprene, p. 4, dated September 7, 2017 (Attachment A); *see also* Barry S. Levy, M.D., M.P.H, P.C., Comments on Chloroprene and Cancer, p. 2-3, dated September 6, 2017 (Attachment B).

[24] *See* EPA Policy on Protecting Vulnerable Populations, https://www.epa.gov/expobox/exposure-assessment-tools-lifestages-and-populations-highly-exposed-or-other-susceptible (accessed September 7, 2017).

[25] EPA defines its Environmental Justice obligations as: "Environmental justice is the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. EPA has this goal for all communities and persons across this nation. It will be achieved when everyone enjoys: the same degree of protection from environmental and health hazards, and equal access to the decision-making process to have a healthy environment in which to live, learn, and work." https://www.epa.gov/environmentaljustice; *see* EPA, Guidance on Considering Environmental Justice During the Development of Regulatory Actions, May of 2015; *see also* EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, June 2016.

[26] *See* Letter from Koki Tabuchi, President and Chief Executive Officer, Denka Performance Elastomer LLC, to Honorable Scott Pruitt, Administrator, U.S. Environmental Protection Agency, "Request to Withdraw and Correct the 2010 IRIS Review of Chloroprene," dated June 26, 2017.

agency career science professionals to make decisions about health risk.[27] EPA scientists conducting the 2010 IRIS Assessment had to use scientific methods -- and did so -- and properly consider public comments submitted during the agency's IRIS Assessment – and did so.[28]

This Objection requests the opportunity to timely supplement this RFC process with information obtained from EPA, Denka, and other sources, including the LDEQ, that may more fully demonstrate political efforts to distort and undermine EPA's scientific integrity, its duty to follow applicable laws and rules, and its scientific community's professional responsibilities.

Qualifications of the Objection's Author and Scientific Experts

Dr. Karl Brooks served as EPA's Region 7 Administrator from 2010 to 2015. In that capacity, he supervised the Region's scientific enterprise and was responsible to the Administrator to assure the scientific integrity of work done by professional career staff. After President Obama nominated him to the U.S. Senate, Dr. Brooks served from 2015 to 2016 as EPA's acting Assistant Administrator for the Office of Administration and Resources Management (OARM).

A member of EPA's senior staff, Dr. Brooks was an administrative peer of Dr. Paul Anastas and Dr. Thomas Burke, the Administrator's Science Advisors, who directed EPA's Office of Research and Development (ORD); and Ann Dunkin, the agency's Chief Information Officer, who directed EPA's Office of Environmental Information (OEI).[29] As EPA's chief human capital and chief contracting officer, Dr. Brooks was responsible to the Administrator for staffing and equipping the agency's science laboratories and facilities, including ORD's National Center for Environmental Assessment, the science professionals working in agency Headquarters and its AWBERC/Cincinnati and RTP/Research Triangle research campuses who prepared the 2010 IRIS Assessment of chloroprene.

Dr. Brooks holds a PhD (with honors) in environmental history. A tenured faculty member in the Environmental Studies Program and courtesy professor of law at the University of Kansas before joining EPA, he is now Clinical Professor of Public Leadership in the University of Texas at

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[27] EPA Guidelines § 8.1 identifies the "information owners" of the IRIS Assessment challenged by Denka's RFC as "those *who have the responsibility* for the *quality, objectivity,* utility, *and integrity* of the information product or data disseminated by EPA." EPA Guidelines § 8.1, p. 30 (emphasis added). Should an RFC be "deemed appropriate for consideration, the information owner office . . . makes a decision on the request on the basis of the information in question." EPA Guidelines § 8.4, p. 31. EPA's NCEA, composed of career scientists, is the "information owner" that will decide whether Denka's RFC is "appropriate" and will render its decision on a scientific basis. *Mississippi v. EPA* offers a recent endorsement of the CAA's obligation that EPA make health-protective regulatory decisions on the basis of the best available science, not the economic interests, or political affiliations, of affected parties such as Denka. *See* 744 F.3d at 1344-45.

[28] *See* U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010, Appendix A. Summary of External Peer Review and Public Comments and Disposition.

[29] Anastas served as ORD Assistant Administrator from 2009 until 2011. Burke, nominated to the U.S. Senate as ORD Assistant Administrator, acted in that capacity from 2013 until 2016. Both Anastas and Burke served as the Administrator's Scientific Advisor.

Austin's LBJ School of Public Policy. He taught environmental law in the University of Kansas School of Law and has published peer-reviewed monographs and articles in the fields of environmental history, environmental policy, and environmental law. A member of the Idaho State Bar and the Bar of the United States Supreme Court, Dr. Brooks held a "Top Secret" security clearance between 2010 and 2015 and the higher-level "Top Secret/Secure Compartmented Information" security clearance from 2015 to 2016. As acting Assistant Administrator for OARM, he was responsible to the Administrator for maintaining EPA's compliance with federal security protocols governing classified information.

Marco Kaltofen, PhD, PE (civil, MA), the president of Boston Chemical Data Corporation, is an affiliate research engineer in the Department of Physics, Worcester Polytechnic Institute. He is a Massachusetts Registered Professional Civil, Engineer. Dr. Kaltofen is an environmental scientist with 30 years' experience in environmental, workplace and product safety investigations. His research at WPI focuses on investigations into petroleum and nuclear releases. He has provided expert testimony and consulting as a chemist and as an engineer. Dr. Kaltofen's nuclear forensics work includes experience in the US, the Middle East, Russia, India, Japan and European Union countries. He serves as the Co-Chair of the Superfund Restoration Advisory Board at the US Army Soldier Systems Command, and founded the Citizens Environmental Laboratory, a nonprofit environmental testing laboratory. He has served on the EPA Committee on National Accreditation of Environmental Laboratories and is a member of the American Chemical Society and the American Society of Civil Engineers. He received his PhD from Worcester Polytechnic Institute in Civil Engineering.

Barry S. Levy, M.D., M.P.H., is an occupational and environmental health physician and epidemiologist with 40 years of experience in this field. He received a Bachelor of Science degree *summa cum laude* (with highest honors) from Tufts College, a Master of Public Health (M.P.H.) degree from the Harvard School of Public Health, and a Doctor of Medicine (M.D.) degree from Cornell University Medical College. He completed residencies in Internal Medicine at the University Hospital and the Beth Israel Hospital in Boston, and in Preventive Medicine at the Centers for Disease Control. He is Board-certified in both Internal Medicine and in Occupational Medicine, and licensed to practice medicine in Massachusetts and Connecticut. Dr. Levy has worked as a Medical Epidemiologist for the Centers for Disease Control, for which he received the U.S. Public Health Service Commendation Medal; as a faculty member at the University of Massachusetts Medical School, where he founded and directed the Occupational Health Program and was promoted to the rank of Professor with tenure; and in a number of other positions as an educator, researcher, practitioner, consultant, and organizational leader. He has clinically evaluated thousands of individuals who had developed, or were at risk of developing, a wide range of adverse health effects as a result of environmental and/or occupational exposure to chemical substances. Since 1993, he has been an Adjunct Professor of Public Health at Tufts University School of Medicine, where he has annually directed the Introduction to Environmental and Occupational Health Course for M.D./M.P.H. students.

Dr. Levy has written more than 200 journal articles and book chapters and edited 18 books, including six editions of the textbook now entitled *Occupational and Environmental Health:*

Recognizing and Preventing Disease and Injury and two editions of the book *Preventing Occupational Disease and Injury*.

Dr. Levy has served in leadership roles of several professional organizations, including serving as President of the American Public Health Association in 1997. He has received a number of awards and honors, including leading awards of the American Public Health Association, the Association of Teachers of Preventive Medicine, the American College of Preventive Medicine, and the New England College of Occupational and Environmental Medicine for career-long achievements.

Background: EPA's IRIS Chloroprene Assessment Developed Risk-Based Emission Limits to Protect Human Health That LDEQ Incorporated into the CAA Permit Governing Denka's LaPlace Facility

Denka's RFC requests EPA to change a peer-reviewed, finished, and final EPA document: the 2010 IRIS Assessment's "Toxicological Review of Chloroprene."[30] Denka's specific objection is that chloroprene, a toxic vapor and likely human carcinogen, manufactured at its LaPlace facility is not as dangerous as the 2010 IRIS Assessment concluded. Denka wants EPA to allow it to discharge chloroprene vapors into the ambient air in St. John the Baptist Parish to concentrations 156 times greater than the 0.20 µgrams/cubic meter currently allowed under federal and state law.

"IRIS Assessments [a]re the preferred source of toxicity information used by EPA. IRIS Assessments [a]re an important source of toxicity information used by state and local health agencies, other federal agencies, and international health organization."[31] IRIS provides impartial scientific information about toxicity to set national standards.

EPA completed the 2010 IRIS Assessment for chloroprene (CAS RN 126-99-8) on September 30, 2010, after all required public comments and replies were complete. The 2010 IRIS Assessment included oral and inhalation toxicity data, as well as a carcinogenicity assessment. The Assessment includes the 303-page Toxicological Review of Chloroprene (IRIS 2010) and the 30-page IRIS summary.[32]

EPA's most recent IRIS assessment of chloroprene, the 2010 IRIS Assessment, concluded that chloroprene is "likely to be carcinogenic to humans" through a mutagenic mode of action and that the primary exposure route of concern is the inhalation pathway.[33]

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[30] 2010 IRIS Assessment.

[31] Basic Information about the Integrated Risk Information System, EPA, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last accessed Aug. 31, 2017).

[32] Chloroprene CASRN 126-99-8, EPA, https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1021 (last accessed Aug. 31, 2017); Basic Information about the Integrated Risk Information System, EPA, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last accessed Aug. 31, 2017).

[33] Memo from John Vandenberg, Director, Research Triangle Park Division, National Center for Environmental Assessment, Office of Research and Development, EPA, to Wren Stenger, Division Director, Multimedia Planning

The IRIS Assessment was based on "a comprehensive review of the available evidence on chloroprene toxicity." This included "human epidemiological data, animal toxicology data, and evidence that chloroprene is mutagenic." The IRIS Assessment explains that "all of this evidence taken together supports the assessment conclusion that chloroprene is 'likely to be carcinogenic to humans.'"[34]

EPA's IRIS Assessment reached findings "similar to those of other highly respected, internationally recognized cancer agencies," including the congressionally mandated National Toxicology Program's 2005 Report on Carcinogens and the World Health Organization's International Agency for Research on Cancer (IARC) 1999 classification of chloroprene as "possibly carcinogenic to humans."[35]

EPA developed the chloroprene IRIS Assessment using a robust, transparent, and public process. Its establishment of an IUR (inhalation unit risk) of 0.20 µgrams/cubic meter was "also subject to a rigorous review" by other federal agencies and White House offices.[36] An independent external peer review panel that also reviewed the IRIS Assessment "unanimously concluded that chloroprene is a likely human carcinogen that acts via a mutagenic mode of action."[37]

The Clean Air Act requires incorporation of this IRIS Assessment into EPA health-based standards that control permitting of covered facilities. EPA's 2011 National Air Toxics Assessment (NATA) study, published December 17, 2015, applied the IRIS Assessment's IUR to identify Denka's LaPlace facility as a major emission source of chloroprene.[38] CAA permits issued to LaPlace by LDEQ must therefore incorporate the EPA chloroprene IUR. When its CAA permits are renewed by LDEQ, Denka will be required to control its chloroprene emissions to attain and to maintain 0.20 µgrams/cubic meter on an annual average basis. [39]

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and Permitting Division, EPA, Region 6, "EPA's Integrated Risk Information System (IRIS) Assessment of Chloroprene," dated May 25, 2016.

[34] Ibid.

[35] Ibid.

[36] National Institute of Environmental Health Sciences (NIEHS), Office of Management Budget (OMB), Council on Environmental Quality (CEQ), Department of Defense (DOD), and Agency for Toxic Substances and Disease Registry (ATSDR).

[37] Memo from John Vandenberg, Director, Research Triangle Park Division, National Center for Environmental Assessment, Office of Research and Development, EPA, to Wren Stenger, Division Director, Multimedia Planning and Permitting Division, EPA, Region 6, "EPA's Integrated Risk Information System (IRIS) Assessment of Chloroprene," dated May 25, 2016.

[38] *See* U.S. Environmental Protection Agency, (Dec. 17, 2015), 2011 National Air Toxics Assessment (NATA), https://www.epa.gov/national-air-toxics-assessment/2011-national-air-toxics-assessment; *see also* U.S. Environmental Protection Agency, 2011 NATA: Assessment Results, https://www.epa.gov/national-air-toxics-assessment/2011-nata-assessment-results (last accessed Aug. 31, 2017).

[39] Letter from Chuck Carr Brown, Ph.D., Secretary, Louisiana Department of Environmental Quality, to Patrick A. Walsh, CIH, Safety, Health and Environmental Manager, Denka Performance Elastomer LLC, "Air Quality Modeling Protocol and Fenceline Monitoring Proposal for Chloroprene Emissions," dated May 27, 2016; Memo from John Vandenberg, Director, Research Triangle Park Division, National Center for Environmental Assessment, Office of

Denka's Request Should be Rejected Because It Seeks Correction of Peer-Reviewed Scientific Information by Advancing Impermissible Economic Assertions and Technological Infeasibility Contentions

The Information Quality Act (IQA) and EPA Guidelines for the IQA require the agency only to consider material, relevant, peer-reviewed scientific data that contest EPA "scientific information." Denka did not participate in any phase of the agency's public scientific process that established the chloroprene standards. Denka now impermissibly seeks correction of scientific information by presenting immaterial, prejudicial, scientifically irrelevant assertions about costs of compliance by a single chloroprene emitting permittee. Denka's RFC should also be rejected because it impermissibly seeks correction by making irrelevant, unsupported allegations about economic impacts of Clean Air Act regulation and permitting on an entire industry category.

EPA should reject Denka's Request because it impermissibly presents irrelevant, unsupported contentions about alleged technological infeasibility of this permittee's compliance with EPA and state rules and permits. The Clean Air Act (CAA) assigns EPA authority to scientifically study and administratively regulate air toxics. The CAA bars agency consideration, in this scientific RFC proceeding as well as during EPA's IRIS chloroprene assessment, of contentions about compliance costs, industry economic effects, and technological infeasibility. Moreover, the IQA and EPA's IQA Guidelines properly confine the agency's consideration of a Correction Request to material and relevant peer-reviewed scientific data.

Denka's Correction Request Improperly Raises Arguments Previously Presented to and Rejected by EPA

The EPA Guidelines empower the agency to voluntarily consider objections to its scientific information. This discretionary method offers complainants, such as Denka, a quick and efficient means of resolving claims of incorrect scientific findings. Denka has previously presented all claims made in this Request for Correction to the EPA scientists responsible for the IRIS assessment. ORD's National Center for Environmental Assessment (NCEA), the "owner" of the challenged information, exercised its discretionary authority by meeting representatives of Environ, Denka's retained consulting firm, at RTP in August 2016. The NCEA scientists who conducted the scientific research about chloroprene toxicity considered the same Environ report that Denka has again submitted in support of this RFC.

At the RTP conference with NCEA scientists, Environ purported to present only its "draft" *Basis for Requesting Correction of the US EPA Toxicological Review of Chloroprene*. Denka now contends that its RFC provides EPA a new "final" version of the Environ report. Yet the only

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Research and Development, EPA, to Wren Stenger, Division Director, Multimedia Planning and Permitting Division, EPA, Region 6, "EPA's Integrated Risk Information System (IRIS) Assessment of Chloroprene," dated May 25, 2016.

change made to the Environ "draft" report is replacing the word "draft" with "final" and adding a more recent date. The arguments and contentions in both the "draft" and "final" Environ report were thoroughly discussed with NCEA in August 2016. Agency scientists concluded then that the Environ report offered no new material, relevant, peer-reviewed information that met Denka's burden to show that the chloroprene IRIS assessment warrants correction.

Denka's RFC now simply seeks "another bite at the apple" under the IQA. This bold gambit violates the Guidelines, threatens to erode EPA's principles of scientific integrity, and raises the dangerous prospect that Denka will obtain through political influence what it could not prove under the applicable legal standard.

The Request for Correction is Premature Because EPA Has Not reopened Its IRIS Assessment to Public Comment, as Required by the CAA and IQA.

The CAA requires EPA, should its scientists deem it necessary or advisable to reopen the IRIS process, to seek public comment. This legal obligation to be transparent affords interested members of the affected industry and the public opportunity to participate in a structured, public application of the scientific method and applicable laws. As EPA has not requested public comment on the chloroprene IRIS, Denka's RFC establishes no proper basis to reopen a process that complied with all applicable legal standards and scientific methods.

Denka's RFC is not presented to EPA as, and should not be construed as, the company's request to reopen public comment. The company and its legal counsel are likely aware of the methods required to petition EPA to commence a new public comment process under IRIS and NATA. As the agency has not commenced a new public comment process to reconsider the IRIS and NATA chloroprene standards, this Request for Correction must be rejected for the reasons presented in this Objection.

Denka's Request Should be Rejected Because It Mobilizes Political Influence on Behalf of its Economic Interests by Requesting the EPA Administrator Overturn Agency Scientific Findings For Impermissible Reasons

Since his confirmation on February 17, 2017, Administrator Scott Pruitt has held numerous non-public meetings with representatives of the affected chemical industries.[40] Denka's RFC even includes a letter to the Administrator by the company's chief executive officer, offering

[40] *See* J. Siciliano of the Washington Examiner, EPA goes on the defensive to play down Scott Pruitt's meetings with industry, BUSINESS INSIDER, Jun. 16, 2017, http://www.businessinsider.com/scott-pruitt-meetings-industry-epa-2017-6; *see also* C. Davenport and E. Lipton, Scott Pruitt Is Carrying Out His E.P.A. Agenda in Secret, Critics Say, N.Y. TIMES, Aug. 11, 2017, https://www.nytimes.com/2017/08/11/us/politics/scott-pruitt-epa.html?mcubz=3; *see also* D. Henry, GOP senator criticizes EPA head's closed-door meeting in North Dakota, THE HILL, Aug. 14, 2017, http://thehill.com/policy/energy-environment/346458-gop-senator-criticizes-pruitts-closed-door-meeting-in-north-dakota.

numerous unsupported allegations about the cost of meeting the LaPlace's facility CAA permits that incorporate the chloroprene IUR established by the 2010 IRIS Assessment.[41]

The EPA Administrator's direct involvement with regulated parties interested in this Request, and his demonstrated interest in economic effects of the IRIS Assessment and the CAA's effects on the chemical industry, may already have violated the IQA, EPA's IQA Guidelines, and EPA's applicable standards and formal principles for ensuring scientific integrity in all agency rulemaking and permitting. EPA should reject the Denka's RFC because it is tainted by obvious public and non-public political involvement in and pressure upon the agency's career scientific professionals. Denka continues to use political influence to pressure EPA's scientific professionals during this RFC process. Its retained consultant, Dr. Kenneth Mundt, was invited by the majority members to testify as their lead witness in a joint hearing about IRIS on September 6, 2017, convened by the Subcommittees on Environment and Oversight of the United States House of Representatives Committee on Science, Space, and Technology. Dr. Mundt's testimony closely tracked Denka's RFC by retailing, for this powerful political body, his Environ Report's self-interested criticism of EPA's IRIS chloroprene Assessment.[42]

It is highly probable, in my judgment and experience, that the House Science Committee's majority staff, who arranged the September 6 hearing and determined its witnesses, consulted privately in advance of the hearing with Dr. Mundt and/or Denka representatives, including legal counsel who authored the company's RFC. It is also highly probable, in my judgement and experience, that Denka representatives and/or the Science Committee's majority staff discussed this hearing, its witnesses, and their likely testimony privately in advance with EPA officials responsible to the Administrator's Office. Dr. Mundt's testimony dovetailed closely with questions by and comments from majority subcommittee members that indicate both congressional interest in, and the Administrator's support for, changing EPA's CAA air toxics regulatory effort by subjecting the IRIS process to more economic, technological feasibility, and political arguments. This harmony between Denka's science consultant and majority committee members was likely not coincidental, and demonstrates Denka's intensifying effort, in both Congress and the Administrator's Office, to apply political pressure against EPA scientific professionals responsible for preparing IRIS assessments.[43]

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[41] *See* Letter from Koki Tabuchi, President and Chief Executive Officer, Denka Performance Elastomer LLC, to Honorable Scott Pruitt, Administrator, U.S. Environmental Protection Agency, "Request to Withdraw and Correct the 2010 IRIS Review of Chloroprene," dated June 26, 2017.

[42] Hearing Charter for September 6, 2017, U.S. House of Representatives Committee on Science, Space, and Technology/Joint Subcommittees on Environment and Oversight, August 31, 2017. The Majority Staff of the Committee described the hearing's purpose as: "Examining the Scientific and Operational Integrity of EPA's IRIS Program."

[43] In my EPA experience as acting Assistant Administrator for Administration and Resources Management at agency Headquarters, an oversight hearing in Congress about an agency program would likely engage the Administrator's Office (AO) and certainly engage politically appointed staff in the Office of Congressional and Intergovernmental Affairs (OCIR) in advance discussions with congressional staff about the hearing's objectives and methods. If this happened regularly when the congressional majority was of a different political party than the President and his EPA Administrator, it is even more probable when the majority and the Administrator belong to the same party.

This Objection will be supplemented by additional information documenting the impermissible influence of politics and economic arguments on the scientific process established by the CAA and IQA.

During any consideration of the Request for Correction, all EPA decisions must be made by ORD career science professionals in compliance with EPA scientific integrity rules, guidelines, and appropriate scientific practice. Any participation in the consideration by the Administrator and/or his designees and/or EPA political appointees (confirmed or acting) violates the IQA as well as EPA scientific integrity rules and guidelines.

EPA's IRIS Assessment and NATA Determination About Chloroprene Must be Maintained During Consideration of the Request Because the LDEQ Relied on Them in Permitting LaPlace

If the Request for Correction is deemed appropriate and timely and not barred by the above instances of political involvement in and distortion of the IQA process, EPA must maintain the chloroprene IRIS, the associated NATA, and relevant permit conditions required by application of the IRIS and NATA during pendency of the Request.

No Weight Should be Accorded to the Environ Report, Prepared Solely to Assist Denka's Profitable Operation of LaPlace, Because It Has Not Been Peer Reviewed, Lacks the Required Characteristics of a Scientifically Valid Contribution, and Fails to Engage EPA's Assessment of Chloroprene's Hazardous Effects on Human Health

In addition to Denka's failure to subject the Environ report to peer review, multiple scientific objections fatally compromise the report's validity. The Environ report provides no new scientific data that challenge the EPA IRIS chloroprene Assessment's adherence to the IQA and the agency's proper implementation of its CAA air toxics duty.

The reports attached to and incorporated by reference in this Objection from Dr. Barry Levy and Dr. Marco Kaltofen detail numerous reasons why the proffered Environ Report and the Denka RFC warrant no serious consideration.[44] The Environ Report itself fails to meet the IQA and EPA Guidelines for providing relevant, new peer-reviewed scientific information, and Denka misuses the Report to make economic and political arguments outside the legal framework intended to safeguard EPA's scientific integrity and to protect the health of vulnerable populations living near the LaPlace facility and in environmental justice communities that EPA is obligated to consider in establishing health-protective chloroprene emissions standards and limits.

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[44] *See* Marco Kaltofen, Ph.D., PE, (Civil, Mass.), Boston Chemical Data, Worcester Polytechnic Institute, Review of Denka Performance Elastomer, LLC (Denka) request to US EPA to reassess the Toxicological Review of Chloroprene, dated September 7, 2017 (Attachment A); *see also* Barry S. Levy, M.D., M.P.H, P.C., Comments on Chloroprene and Cancer, dated September 6, 2017 (Attachment B).

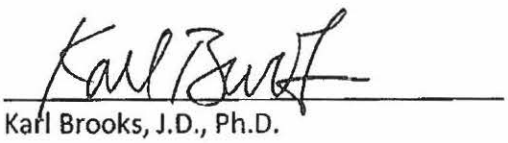
Conclusion

EPA's chloroprene Assessment properly applied the agency's duty to safeguard vulnerable populations affected by Denka's emissions. Denka's Request for Correction should be rejected because it fails to present new, peer-reviewed toxicological and epidemiological evidence demonstrating that its proposed correction to chloroprene standards will maintain required health protective standards.

EPA must reject Denka's Request for Correction to assure the primacy of science in carrying out its legal obligation to protect human health and the environment and to assure that political influence does not interfere with scientific decision-making.

Denka's Request for Correction opens a new front in a calculated political and economic campaign by this CAA permittee and affected chemical industry members to interfere with, distort, and render non-transparent decisions that governing laws and EPA policies require to be purely scientific. The IQA commands only the appropriate and qualified EPA scientific units and personnel to consider this Request. Any participation in, involvement with, or direction to these units and/or personnel by the Administrator, his Office, his appointed staff, or by appointees responsible to the Administrator violates the IQA, EPA's guidelines for implementing the IQA, and the agency's rules, procedures, and principles of scientific integrity, public transparency, and open discussion of scientific evidence, data, and arguments based thereon.

Should EPA determine that this Request for Correction complies with the IQA and EPA Guidelines, any further consideration of Denka's Request for Correction must be preceded by ORD's and/or NCEA's public notice and request for comment regarding the impact of chloroprene upon and the presence of and impact upon vulnerable populations and/or environmental justice communities located in reasonable proximity to any facility affected by the 2010 IRIS, NATA, or permits issued in response to or informed by the IRIS, NATA, and any resulting chloroprene IUR and RFC.



Karl Brooks, J.D., Ph.D.

9/8/17

Date

Boston Chemical Data
2 Summer Street, Suite 14
Natick, MA 01760
T 508-314-9334 bostonchemicaldata.com

To: John J. Cummings, Esq.
From: Marco Kaltofen, PhD., PE, (Civil, Mass.), Boston Chemical Data Corp.
Re: Review of Denka Performance Elastomer, LLC (Denka) request to US EPA to reassess the Toxicological Review of Chloroprene

Date: September 7, 2017

Denka Performance Elastomers (Denka) has requested the U.S. Environmental Protection Agency (EPA) to change a peer-reviewed, finished and final EPA document, "Toxicological Review of Chloroprene."[1] Denka's specific objection is that the company believes that its product, chloroprene, a toxic vapor and probable human carcinogen, is not as dangerous as the 2010 Integrated Risk Information System (IRIS) review states.[2] Denka wants EPA to allow it to discharge chloroprene vapors into the ambient air in St. John the Baptist Parish, to concentrations that are 156 times greater than the 0.20 micrograms per cubic meter currently allowed under federal law.

The effects of industrial chemicals on people are not often obvious, so our Federal and State governments have, through legislation, set up agencies made up of career scientists and professionals to regulate manufactured chemicals to protect our health and safety. EPA and the Louisiana Department of Environmental Quality (LDEQ) are charged with the responsibility of identifying dangerous chemicals and setting permissible limits on emissions into the environment. This reduces toxic chemical exposures to workers and residents in or near chemical manufacturing plants. It is not always possible for individuals to know whether or not chemicals from a plant are causing them harm, especially for exposures that happen over months or years. This is why the EPA and

[1] Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), dated June 26, 2017; *see* U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf

[2] Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), p. 4, dated June 26, 2017.

LDEQ have developed procedures to identify and test emissions from plants and set limits on the quantity and concentration of chemicals allowed in our air.

This scientific process includes the testing of animals that are exposed to chemicals, examining peer-reviewed literature on the effects of exposure to chemicals, historical case studies and epidemiological studies, and oversight by scientists not involved in the particular review of the chemical. These independent scientists scrutinize the process of review to make sure that it has been considered in a scientifically appropriate manner. Only after all these steps plus a public comment period are complete, are the results published and applied by regulatory agencies. Such was the case for the 2010 EPA IRIS assessment "Toxicological Review of Chloroprene."[3]

IRIS provides impartial scientific information about toxicity to set national standards. "IRIS assessments:

- Are the preferred source of toxicity information used by EPA
- Are an important source of toxicity information used by state and local health agencies, other federal agencies, and international health organizations."[4]

The IRIS Assessment for chloroprene (CAS RN 126-99-8) was completed September 30, 2010, after all required public comments and replies were complete.[5] It included oral and inhalation toxicity data, as well as a carcinogenicity assessment. The assessment includes the 303-page Toxicological Review of Chloroprene and the 30-page IRIS summary.[6]

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[3] *See* U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf

[4] Basic Information about the Integrated Risk Information System, EPA, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last accessed Aug. 31, 2017).

[5] *See* U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf

[6] *See* U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pd; *see also* U.S. Environmental Protection Agency, Chemical Assessment Summary of Chloroprene (CAS No. 126-99-8),

The Denka request was made almost seven years after the public scientific review of chloroprene was complete. Notably, chloroprene manufacturers were fully able to participate in this public process before the review was accepted by the scientific community and EPA. The changes requested by Denka would have the effect of increasing the average amount of chloroprene vapor allowed in the ambient air, meaning the air breathed by the public outside of Denka's property, 365 days a year. Denka's request would cover not just its own property, but the entirety of the United States and its territories.

A Request for Correction (RFC) may consider only new scientific data and information for review by EPA.[7] Denka's request provides no new scientific data or information other than a request to overturn the fundamental scientific basis of our regulatory system; so that Denka can avoid "burdensome" expenditures. Such an improperly-formed RFC must be denied under EPA's Information Quality Guidelines.[8]

In addition to the failure to subject the Environ report to peer review, there are also multiple scientific objections. These objections address the failure of Denka's submissions to provide new scientific data in its RFC concerning the adequacy of EPA's adherence to the Information Quality Assurance for the chloroprene IRIS document.

Animal models are reliable and routine.

In its RFC, Denka asks EPA to negate the principle of the use of animal models to determine the hazards of chemical pollutants.[9] Negating the EPA's use of animal-based data on chloroprene would disallow data that is widely accepted by the scientific community. Animal models are scientifically-reliable and are routinely used to provide data to EPA and other federal and international health agencies. This is important because it is not ethical or practical to deliberately perform toxicity tests on humans. In effect,

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Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1021_summary.pdf.

[7] *See* U.S. Environmental Protection Agency, Denial of Request for Correction by Halogenated Solvents Industry Alliance by Lek Kadeli, Acting Assistant Administrator, dated March 19, 2015.

[8] *See* EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (Oct. 2002) (EPA Guidelines), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf).

[9] Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), p. 10, dated June 26, 2017.

Denka asks the EPA to overturn a major scientific underpinning of animal-based data. It is important to remember that the only way Denka would have standing to ask for this change is if there had been, since 2010, a major change in how we use data or how we use animal models, such as the physiologically based pharmacokinetic (PBPK) model. But there has not been such a major change since then.[10]

The Denka request would require change of the entire regulatory system.

The change regarding animal data would affect not only chloroprene regulation by EPA in St. John the Baptist Parish, but would disrupt the entire system of scientific testing for the nation, and all of its health-based agencies, such as the Food and Drug Administration. One cannot request that an agency of the federal government disallow animal models of toxicity for one chemical in one place. The only way the request could be granted on this basis would be through a universal cancellation of risk values derived from animal data.

Cost and corporate benchmarks are not relevant in determining toxicity.

Denka details their spending on environmental controls and process improvements since 2014, which failed to achieve the limits on air pollution as dictated by the 2010 IRIS document.[11] This discussion is not relevant to the request for a review, because it is unrelated to the toxicity of chloroprene. To be clear, scientific data on the toxicity of chloroprene vapor is the only evidence that EPA may lawfully review in support of Denka's request to allow for increased chloroprene contamination in air. Compliance with the law is based solely on the numerical standard applicable to the United States as a whole. It is not based on comparison to a random commercial benchmark established by Denka's corporate predecessor in LaPlace, Louisiana.

Chloroprene toxicity is the only issue EPA may address.

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[10] U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, p. 17-21 September 2010, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf (PBPK 2010); Physiologically Based Pharmacokinetic Analyses — Format and Content Guidance for Industry, DRAFT GUIDANCE, U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) December 2016, Clinical Pharmacology.

[11] Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), p. 2, dated June 26, 2017

Denka expressed concerns in its request to EPA that its neighbors around its production facility publicly express dissatisfaction with Denka's environmental performance.[12] This is likewise not scientific evidence and is unrelated to the only matter at hand, the toxicity of chloroprene.

Long-term exposure limits are not comparable to short-term limits

Denka also misstates the rationale behind the IRIS values.[13] IRIS values underpin the 0.20 micrograms per cubic meter ambient air standard currently allowed under federal law. The IRIS values are based on the long-term toxicity of chloroprene. Exposure to this amount of chloroprene should cause a de minimus effect on the health of Denka's neighbors in LaPlace. The 857 micrograms per cubic meter Louisiana 8-hour standard cited by Denka is a short-term workplace standard, designed to protect healthy adult workers during their time in the Denka plant. It is not necessarily protective of children, pregnant women, the elderly, or people whose health is compromised. It is not acceptable to replace a long-term chronic exposure value with a short-term one. Long-term and ambient air exposure limits as well as limits of exposure to the general public are universally lower, often much lower, than the 8-hour values. EPA is not allowed to reverse-engineer a national IRIS value based on a short-term exposure limit for a given state.

IRIS data already include PBPK considerations.

Denka's RFC asks that EPA adjust its ambient air standard of 0.20 micrograms per cubic meter based on the PBPK model, which is used to estimate cancer risks in humans when EPA is using data from animals.[14] When EPA did its 2010 IRIS study, it produced multiple pages of small-print, single-spaced of PBPK discussion that boiled down to something like: "We've looked at this and it doesn't affect our decision."[15]

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[12] Ibid at p. 3.
[13] Ibid at p. 3.
[14] Ibid at p. 4.
[15] *See* U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, p. 17-21 September 2010, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf (PBPK 2010).

The Environ report suggests that EPA should have used a cancer risk estimate based on exposure of the human lungs to chloroprene, instead of EPA's choice of a cancer estimate based on exposure of the entire body (systemic exposure) to chloroprene.[16] Environ, on Denka's behalf, says its assumptions are more appropriate, but Environ fails to provide any new scientific evidence for its opinion. This fails the test of new scientific data required for an RFC to the EPA.

In a second example of failing to provide data on the same topic, Environ's report objects to EPA's finding that human lungs and animal lungs respond in similar ways to chloroprene vapors.[17] This is important because it means that PBPK modeling gives the same results as the original IRIS assessment would have given without PBPK modeling of the lungs. This objection was Environ's and Denka's opportunity to provide new scientific data on this issue. Once again, they did not provide any data. Once again, the RFC must be denied because new data was needed but not provided.

Since the PBPK modeling method was already examined by EPA in its 2010 IRIS assessment and since the PBPK modeling method has not changed materially since then, Denka has no reason to use any alleged flaws in the PBPK modeling method to increase the amounts of chloroprene it can discharge to the air in St. John the Baptist Parish.

The need to rely on animal studies.

Differences between human and animals species are obviously real, as is generally recognized when interpreting animal toxicity studies. The PBPK model tries to accommodate these differences, but there will always be more animal data than human data. Human studies cannot ethically expose people to toxins. Scientists rely on the best available data from human studies, even if human studies are not as controlled as animal studies. Therefore, EPA and other agencies can use a "preponderance of evidence" approach. This means that when most studies show that a chemical like chloroprene is toxic or carcinogenic, scientists and government agencies rely on that result, using the best available data, even if human data are limited. All regulators work this way in the U.S. system of government, and the results apply to everyone equally.

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[16] Basis for Requesting Correction of the US EPA Toxicological Review of Chloroprene, Prepared by Dr. Robinan Gentry, Dr. Kenneth Mundt, and Dr. Sonja Sax of Ramboll Environ, Intended for Denka Performance Elastomer, LLC, p. 27, (June 2017) (Environ Report).

[17] *See* Ibid.

In the years since the 2010 EPA IRIS process was completed, this has not materially changed. In 2016, the FDA produced an update of PBPK guidance, but this may not be used to make decisions on federal ambient air quality standards.[18]

Legal applicability alone does not allow EPA to act.

Denka's RFC provide details related solely to areas of legal applicability.[19] This portion of the evidence and argument provided by Denka does not discuss the actual toxicity of chloroprene. Since the science-based issue of toxicity is the only one that EPA can lawfully address on merits, no discussion of this section of the RFC is included here.

Denka provides misleading review of studies cited by EPA.

Denka's RFC calls EPA's use of certain studies improper because, within the study sample groups, the expected number of specific cancer deaths is sometimes less than two.[20] This neglects the critical argument that for certain more rare cancers, both the number of actual measured specific cancer deaths or incidences, and of course the overall sample size, may be much greater than two. After all the expected number of deaths is not in dispute, as this value represents an accepted standard. It is the measured value of deaths that is critical, but this statistic is not given in Denka's letter.

Denka further suggests that cancers in these chloroprene studies (as used for the IRIS determination) are related to other factors such as tobacco and alcohol use, or other environmental stressors.[21] Such factors are not new or unique the study areas or to

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[18] *See* Physiologically Based Pharmacokinetic Analyses — Format and Content Guidance for Industry, DRAFT GUIDANCE, U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) December 2016, Clinical Pharmacology – Author's (M. Kaltofen) note: This is a nonbinding document and not for implementation; it cannot be used to overturn an existing IRIS document. It is not evidence of a substantial change in science based on PBPK modeling as this guidance is not binding, and it is consistent with EPA's original 2010 IRIS approach. While used primarily by the US FDA in drug development, it is a demonstration of the state of science regarding the use of PBPK; and a clear example of how Denka's RFC overturning an existing IRIS determination affects other agencies. This is an example of how a positive EPA response to the Denka RFC based on how the PBPK analysis was used in 2010 has the effect of reopening the regulatory system in its entirety for multiple federal agencies.

[19] Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), pp. 4-7, dated June 26, 2017

[20] Ibid at p. 10.

[21] Ibid at p. 10.

Louisiana, especially in the heavily productive and industrialized lower Mississippi portion of the state. It is not conceivable that EPA was unaware of this potential when the multiyear effort to produce the IRIS document was active.

Multiple tumors are multiple occurrences, not one occurrence.

Denka's request addresses the independent nature of multiple primary cancers arising from different organs.[22] EPA makes the conservative assumption that tumors of independent organs are multiple, not singular events. (Meaning that the incidence of a case of liver cancer is a separate event from a lung cancer in the same animal). Denka opines that a condition that causes a liver cancer could conceivably also cause an entirely separate lung cancer; so this only counts as one event. Such a change in approach, beyond requiring a major leap of faith, has far reaching consequences in how regulators approach medicine and human health. The enormity of this request appears to far exceed the scarce data provided by Denka. Given that the impact of the requested action from EPA potentially affects all types of pollutants, Denka can hardly expect a favorable decision having only given limited data on one compound: chloroprene. It is understood that Denka has performed a chloroprene study of its own to provide some new data; however, the IRIS documentation process uses a preponderance of evidence approach that encompasses a large number of peer-reviewed studies, rather than a single study proffered by an interested party. [23]

Denka misstates Louisiana Tumor Registry data.

Denka may not use methods much less reliable than the EPA methods it criticizes. Denka opens its request by citing the Louisiana Tumor Registry's cancer incidence data in St. John the Baptist Parish. This registry is a respected source of aggregated cancer incidence data. These aggregated statistics are not suitable for EPA's consideration of toxicity value calculations as described in the 2010 IRIS document because there is no attempt made to discriminate among multiple cancer causes from the single numbers available in the tumor registry.

Denka did not accept EPA's use of cancer statistics, and then it provided a similar type of statistics to EPA. Denka opined in its request that other studies are poor data sources

[22] Ibid at p. 12.

[23] *See* Basis for Requesting Correction of the US EPA Toxicological Review of Chloroprene, Prepared by Dr. Robinan Gentry, Dr. Kenneth Mundt, and Dr. Sonja Sax of Ramboll Environ, Intended for Denka Performance Elastomer, LLC (June 2017) (Environ Report).

because they do not quantify all of the potential sources of cancer; then it provided a raw, anonymous, aggregated statistic that makes no attempt whatsoever to quantify any or all potential sources of cancer.[24] Denka led its case with this type of data. The data demeaned by Denka in the IRIS studies were part of a full-on peer-reviewed analysis, as opposed to Denka's data, which came from a line item found on a (granted respected and reputable) webpage.[25]

Denka misuses Tumor Registry Data by excluding many affected residents. Given the coarse nature of statistics that apply to an entire parish, Denka cannot exclude the possibility that people in neighboring St. Charles Parish received large cumulative doses of Denka's chloroprene emissions.[26] In fact, many people in St. Charles Parish live much closer to the Denka plant than do people in some parts of St. John the Baptist Parish. Denka does not examine the possibility that some residents of St. John the Baptist Parish may have lived most of their lives there, and then moved to St. Charles Parish where their cancers were diagnosed and then reported to the Registry.

St. John the Baptist tumor data is not lower for critical cancers. Looking at individual cancers in the Parish makes this issue more obvious. The Louisiana Tumor Registry age-adjusted lung cancer incidence in St. John the Baptist Parish is 60.1 versus 61.2 for the US as a whole. The human lung is a chloroprene cancer target.[27] This is hardly a significant difference given that the true (95 % confidence interval) incidence in St. John the Baptist Parish is 50.1 to 71.6. The incidence in neighboring St. Charles Parish (recall that some of these residents live closer to Denka than many St. John the Baptist Parish residents) is 67.7. The tumor registry data does not appear to say what Denka has told EPA it says.[28]

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[24] Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), p. 2, p. 10, dated June 26, 2017.

[25] Louisiana Tumor Registry, (last accessed Sept. 2017), http://sph.lsuhsc.edu/louisiana-tumor-registry/.

[26] Denka Performance Elastomer, LLC, Isopleth map, drawing number: 1132-001-B003,
2011 Air Dispersion model data drawn for Denka; Louisiana: 2010 Population and Housing Unit Counts, US Census, CPH-2-20, July 2012, (last accessed Sept. 2017), https://www.census.gov/prod/cen2010/cph-2-20.pdf.

[27] Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), dated June 26, 2017.

[28] Louisiana Tumor Registry, (last accessed Sept. 2017), http://sph.lsuhsc.edu/louisiana-tumor-registry/.

Summary of scientific evidence from Denka

Denka has not provided EPA with a scientific basis for reopening the scientific evaluation of chloroprene. Denka has certainly not provided data for pollutants other than chloroprene that would be affected by changing the methodology of EPA IRIS assessments. Denka has not provided a scientific basis for changes in how toxic compounds are evaluated by other agencies, such as the FDA, which are using methodologies identical to those used by EPA for its IRIS determinations.

Denka did provide EPA with plenty of engineering data about its own facility. These engineering data show Denka's self-interested perspective in its RFC. The information it provided describes details of why it would be expensive to comply with the ambient air standard of 0.20 micrograms per cubic meter. It is important to point out, however, that this is just information about the expense of complying with the regulation. These are not scientific data, so they are immaterial to EPA's review. Based on the scientific support (or lack of it) provided by Denka, the request for invalidation and correction of the 2010 IRIS document by EPA should be denied.

/s/ Marco Kaltofen

Marco Kaltofen, PhD., PE, (Civil, Mass.)
Boston Chemical Data Corp.

Notes:

Denka Performance Elastomer, LLC, Isopleth map, drawing number: 1132-001-B003, 2011 Air Dispersion model data drawn for Denka.

Request for Correction No. 17002, Toxicology Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), dated June 26, 2017.

Basis for Requesting Correction of the US EPA Toxicological Review of Chloroprene, Prepared by Dr. Robinan Gentry, Dr. Kenneth Mundt, and Dr. Sonja Sax of Ramboll Environ, Intended for Denka Performance Elastomer, LLC (June 2017) (Environ Report).

U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information of the Integrated Risk Information System (IRIS), Washington, DC, US EPA, September 2010, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf

U.S. Environmental Protection Agency, March 19, 2015, Denial of Request for Correction by Halogenated Solvents Industry Alliance by Lek Kadeli, Acting Assistant Administrator

U.S. Environmental Protection Agency EPA Response to Request for Correction by Halogenated Solvents Industry Alliance, Inc., RFC #16001, Nov. 4, 2016

EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (Oct. 2002) (EPA Guidelines), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf).

Roberta L. Grant, Vincent Leopold, Darrell McCant, Michael Honeycutt, Spatial and temporal trend evaluation of ambient concentrations of 1,3-butadiene and chloroprene in Texas, Chemico-Biological Interactions 166, pp. 44-51 (2007).

U.S. Environmental Protection Agency, Chemical Assessment Summary of Chloroprene (CAS No. 126-99-8), Integrated Risk Information System (IRIS), Washington, DC, US

EPA, September 2010,
https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1021_summary.pdf

Basic Information about the Integrated Risk Information System, EPA,
https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system
(last accessed Aug. 31, 2017).

Louisiana: 2010 Population and Housing Unit Counts, US Census, CPH-2-20, July 2012,
(last accessed Sept. 2017), https://www.census.gov/prod/cen2010/cph-2-20.pdf

Louisiana Tumor Registry, (last accessed Sept. 2017),
http://sph.lsuhsc.edu/louisiana-tumor-registry/

Report on Carcinogens, Fourteenth Edition, National Toxicology Program, U.S.
Department of Health and Human Services, Ninth report 2000

U.S. Environmental Protection Agency, Toxicological Review of Chloroprene (CAS No.
126-99-8) In Support of Summary Information of the Integrated Risk Information System
(IRIS), Washington, DC, US EPA, p. 17-21 September 2010,
https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf (PBPK
2010). It is also notable that the 2010 IRIS document already includes important parts of
the PBPK model, such as the chloroprene tissue to air partition coefficients for species'
livers. This data shows that interspecies variability between humans and test animals can
be smaller than the margin of error in the toxicological test results. EPA and scientific
authors in the peer-reviewed literature have said regarding the PBPK model, "Further
development of this model to explore differences in toxication/detoxification of
chloroprene across species would be useful in human risk assessment." which is not the
same as saying that the PBPK model is ready to meet the needs of the IRIS process (I.
Pagan / Chemico-Biological Interactions 166 (2007) 341–351). EPA scientists have also
opined in the scientific literature that, "The chloroprene metabolic profile appears to be
qualitatively similar across species . . ." (Ibid). Given that the PBPK model exists in part
to account for such differences, the authors are stating that the existing IRIS evaluation is
already reliable. It is also notable that the 2010 IRIS document (EPA 2010) already
includes important parts of the PBPK model, such as the chloroprene tissue to air
partition coefficients for species' livers (EPA 2010 Table 3.1). These coefficients are an
important part of the PBPK dosimetry model for target organ doses. The coefficients for
livers (an important target organ for chloroprene toxicity) are: Mouse 9.8 ± 0.9, F344 rat

11.5 ± 0.3, Wistar rat 10.9 ± 0.2, Hamster 10.5 ± 0.5 and Human 10.7 ± 1.1. These similar numbers demonstrate interspecies similarity for this part of the model, with interspecies variation (range = 1.7) less than the combined confidence limits (range = 2.9).

Physiologically Based Pharmacokinetic Analyses — Format and Content Guidance for Industry, DRAFT GUIDANCE, U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) December 2016, Clinical Pharmacology – Author's (M. Kaltofen) note: This is a nonbinding document and not for implementation; it cannot be used to overturn an existing IRIS document. It is not evidence of a substantial change in science based on

PBPK modeling as this guidance is not binding, and it is consistent with EPA's original 2010 IRIS approach. While used primarily by the US FDA in drug development, it is a demonstration of the state of science regarding the use of PBPK; and a clear example of how Denka's RFC overturning an existing IRIS determination affects other agencies. This is an example of how a positive EPA response to the Denka RFC based on how the PBPK analysis was used in 2010 has the effect of reopening the regulatory system in its entirety for multiple federal agencies.

Definition: 1 ppm = 3,620 micrograms per cubic meter

Qualifications: Marco Kaltofen, PhD, PE (civil, MA); is the president of Boston Chemical Data Corp., and is an affiliate research engineer in the Dept. of Physics, Worcester Polytechnic Institute. He is a Massachusetts Registered Professional Civil, Engineer. Dr. Kaltofen is an environmental scientist with 30 years of experience in environmental, workplace, and product safety investigations. His research at WPI focuses on investigations into petroleum and nuclear releases. He has provided expert testimony and consulting as a chemist and as an engineer. Dr. Kaltofen's nuclear forensics work includes experience in the US, the Middle East, Russia, India, Japan and European Union countries. He serves as the Co-Chair of the Superfund Restoration Advisory Board at the US Army Soldier Systems Command, and founded the Citizens Environmental Laboratory, a nonprofit environmental testing laboratory. He has served on the EPA Committee on National Accreditation of Environmental Laboratories; is a member of the American Chemical Society and the American Society of Civil Engineers. He received his PhD from Worcester Polytechnic Institute in Civil Engineering.

Comments on Chloroprene and Cancer

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September 6, 2017

Dr. Levy has been retained by John J. Cummings, III, Esq., to review materials concerning the potential of chloroprene to cause cancer and to review information concerning chloroprene exposure of people living close to the chloroprene-producing Denka Performance Elastomer plant in LaPlace, Louisiana.

Chloroprene is probably carcinogenic to humans.

The U.S. Environmental Protection Agency (USEPA) has determined that, based primarily on animal studies, chloroprene is "likely to be carcinogenic to humans."[1]

The National Toxicology Program (NTP) has also determined that chloroprene is "Reasonably anticipated to be a human carcinogen."[2]

As early as the mid-1970s, the National Institute for Occupational Safety and Health "expressed concern over the potential carcinogenicity of chloroprene."[3]

The International Agency for Research on Cancer (IARC), in 1999, stated: "There is sufficient evidence in experimental animals for the carcinogenicity of chloroprene." In addition, it stated at that time: "Chloroprene is possibly carcinogenic to humans."[4]

The above-cited determinations are based primarily on animal studies, which are widely used are a valid method to determine if a chemical is capable of causing cancer.

Experimental studies in rats, mice, and other animals have long been established as a useful method to determine the potential of chemicals to cause cancer and other adverse health effects in humans. According to a standard textbook of toxicology, "Animal bioassays are a key component of the hazard identification process."[5]

Analyses have demonstrated that chemicals that cause cancer in experimental animals are likely to cause cancer in humans.[6]

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[1] *See* U.S. Environmental Protection Agency. Toxicological Review of Chloroprene [CAS No. 126-99-8]: In Support of Summary Information on the Integrated Risk Information System [IRIS]. Washington, DC: USEPA, September 2010; *see also* Memo from John Vandenberg, Director, Research Triangle Park Division, National Center for Environmental Assessment, Office of Research and Development, EPA, to Wren Stenger, Division Director, Multimedia Planning and Permitting Division, EPA, Region 6, "EPA's Integrated Risk Information System (IRIS) Assessment of Chloroprene," dated May 25, 2016.

[2] National Toxicology Program. Chloroprene: CAS No. 126-99-8. Report on Carcinogens, Fourteenth Edition. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. Available at: https://ntp.niehs.nih.gov/ntp/roc/content/profiles/chloroprene.pdf. Accessed August 31, 2017.

[3] National Institute for Occupational Safety and Health. Current Intelligence Bulletin 1: Chloroprene. January 20, 1975.

[4] International Agency for Research on Cancer. "Chloroprene" in Re-evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide. Lyon, France: IARC. 1999, pp.227-250.

[5] Klaassen CD. Casarett and Doull's Toxicology: The Basic Science of Poisons [Eighth Edition]. New York: McGraw Hill Education, 2013, p. 129.

Chloroprene is similar to the carcinogens vinyl chloride and 1,3-butadiene, in both structure and the types of cancers that it causes in animals.

There is close similarity in the molecular structure of chloroprene and the established carcinogens vinyl chloride, and 1,3-butadiene.

There is also close similarity in the types of cancers that these three chemicals cause in animals. For example, the National Toxicology Program has reported: "Chloroprene (the 2-chloro analogue of 1,3-butadiene) caused all of the same types of tumors that 1,3-butadiene caused in mice except for lymphomas and tumors of the preputial gland and ovary."[7]

All of the epidemiological studies cited by ENVIRON had been published and were available to EPA for its IRIS assessment of chloroprene in 2010.

All of the epidemiological studies cited by ENVIRON, in its June 2017 report ("Basis for Requesting Correction of the US EPA Toxicological Review of Chloroprene"), had been published in 2007 or earlier and were available to EPA at the time that it developed its IRIS assessment of chloroprene.

There likely is, and has been, widespread exposure to chloroprene in LaPlace, Louisiana, as reflected by the presence of DHBMA, a metabolite of chloroprene, in the urine of people who live near the Denka plant.

Preliminary test results for the urine of 18 people who live close to the Denka plant in LaPlace indicate that all of them had DHBMA, one of the metabolites of chloroprene, in their urine.[8]

If further test results indicate that these people have significant amounts of chloroprene-specific metabolites in their urine and that they have lived close to the plant for significant periods of time, it would be reasonable to conclude that they are probably at increased risk of cancer.

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[6] Sanner T, Dybing E. Comparison of carcinogen hazard characterization based on animal studies and epidemiology. Basic & Clinical Pharmacology & Toxicology 2005; 96: 66-70.

[7] National Toxicology Program. Chloroprene: CAS No. 126-99-8. Report on Carcinogens, Fourteenth Edition. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. Available at: https://ntp.niehs.nih.gov/ntp/roc/content/profiles/chloroprene.pdf.Accessed August 31, 2017.

[8] Lin C-H. Analysis of chloroprene and toluene, and their metabolites in urine samples.

Cancer incidence data from the Louisiana Tumor Registry indicates that incidence of some cancers in St. John the Baptist Parish has been higher than in many other parishes.

The Louisiana Tumor Registry obtains, analyzes, and reports data on the incidence of cancer, by parish and cancer type. To the extent that people with cancer have access to medical care and are properly diagnosed, these data are reliable. The Registry participates in the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute, which has strict protocols for obtaining, analyzing, and reporting data on cancer.

Although analyses of cancer incidence data limited to people who live very close to the Denka plant are not currently available, cancer incidence data for recent years for St. John the Baptist Parish as a whole raise concerns about the higher-than-expected occurrence of various cancers in the area.

For the five-year period from 2010 through 2014, cancer incidence rates for St. John the Baptist Parish demonstrate:

1. For kidney cancer: The Parish ranks #11 overall among the 64 parishes in Louisiana, with an incidence rate of 25.9 per 100,000, which is 20% above the state average. In addition, The Parish ranks #3 among males among the 64 parishes, with an incidence rate of 37.7 per 100,000 -- 32% above the state average for males.
2. For non-Hodgkin lymphoma: The Parish ranks #6 overall among the 64 parishes in Louisiana, with an incidence rate of 25.1 per 100,000, which is 26% above the state average. In addition, the Parish ranks #1 among blacks among the 64 parishes, with an incidence rate of 23.6 per 100,000, which is 58% above the state average for blacks.
3. For female breast cancer: The Parish ranks #22 overall among the 64 parishes in Louisiana, with an incidence rate of 123.8 per 100,000, just slightly above the state average. However, the Parish ranks #9 in breast cancer among women less than 65 years of age, with an incidence rate of 91.2 per 100,000, which is 12% above the state average for women under age 65.[9]

[9] National Cancer Institute and Centers for Disease Prevention and Control. State cancer profiles. Based on Louisiana Tumor Registry data.

These findings are supported by cancer incidence data from the Louisiana Tumor Registry for St. John the Baptist Parish for the ten-year period from 2004-2013:

1. For kidney cancer: The incidence rates for the Parish were above the Louisiana average for white males, white females, and black males.
2. For non-Hodgkin lymphoma: The incidence rates for the Parish were above the Louisiana average for white and black males.
3. For female breast cancer: The incidence rates for the Parish were above the Louisiana average for white females.[10]

Given the increased rates of specific cancers in St. John the Baptist Parish that are cited above, it would be incomplete or misleading to state that St. John the Baptist Parish has one of the lower cancer rates among parishes in Louisiana.

There is a need for further analysis and epidemiological investigation of cancer incidence among people who have resided close to the Denka plant.

There is a need for further analysis and epidemiological investigation of cancer incidence among people who have lived in census tracts close to the Denka plant. Such analysis and investigation need to take into consideration that these census tracts are in both St. John the Baptist Parish as well as St. Charles Parish.

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Barry S. Levy

Barry S. Levy, M.D., M.P.H., President
Diplomat, American Board of Internal Medicine
Diplomat, American Board of Preventive Medicine
(in Occupational Medicine)
Fellow, American College of Epidemiology

[10] Louisiana Tumor Registry. Average annual incidence of the major cancers in St. John the Baptist Parish, Louisiana, and the U.S., 2004-2013: Age-adjusted rates per 100,000: Invasive Cancers Only.

Background and Experience

Barry S. Levy, M.D., M.P.H., is an occupational and environmental health physician and epidemiologist with 40 years of experience in this field. He received a Bachelor of Science degree *summa cum laude* (with highest honors) from Tufts College, a Master of Public Health (M.P.H.) degree from the Harvard School of Public Health, and a Doctor of Medicine (M.D.) degree from Cornell University Medical College. He completed residencies in Internal Medicine at the University Hospital and the Beth Israel Hospital in Boston, and in Preventive Medicine at the Centers for Disease Control. He is Board-certified in both Internal Medicine and in Occupational Medicine, and licensed to practice medicine in Massachusetts and Connecticut.

Dr. Levy has worked as a Medical Epidemiologist for the Centers for Disease Control, for which he received the U.S. Public Health Service Commendation Medal; as a faculty member at the University of Massachusetts Medical School, where he founded and directed the Occupational Health Program and was promoted to the rank of Professor with tenure; and in a number of other positions as an educator, researcher, practitioner, consultant, and organizational leader. He has clinically evaluated thousands of individuals who had developed, or were at risk of developing, a wide range of adverse health effects as a result of environmental and/or occupational exposure to chemical substances. Since 1993, he has been an Adjunct Professor of Public Health at Tufts University School of Medicine, where he has annually directed the Introduction to Environmental and Occupational Health Course for M.D./M.P.H. students.

Dr. Levy has written more than 200 journal articles and book chapters and edited 18 books, including six editions of the textbook now entitled *Occupational and Environmental Health: Recognizing and Preventing Disease and Injury* and two editions of the book *Preventing Occupational Disease and Injury*.

He has served in leadership roles of several professional organizations, including serving as President of the American Public Health Association in 1997. He has received a number of awards and honors, including leading awards of the American Public Health Association, the Association of Teachers of Preventive Medicine, the American College of Preventive Medicine, and the New England College of Occupational and Environmental Medicine for career-long achievements.

Dr. Levy regularly consults to attorneys on litigation-based issues concerning occupational and environmental exposure to potentially hazardous chemicals.