January 17, 2017

Memorandum to: EPA Transition Team

From: Denka Performance Elastomer, LLC

Subject: Urgent Need for EPA Technical Correction of EPA IRIS Quantitative Exposure Risk Value for Chloroprene

I. Executive Summary

The Environmental Protection Agency (EPA) is using faulty and highly inflated risk data from the EPA's 2010 Integrated Risk Information System (IRIS) Toxicological Review of Chloroprene (2010 Chloroprene Review) to seek extraordinary emission reductions from Denka Performance Elastomer, LLC (DPE), at its Neoprene production plant located in Laplace, Louisiana. EPA is seeking emission reductions that do not appear to be technically feasible. EPA has organized a public meeting to advise the public of its concerns about DPE's emission, and it has set up a website to keep the public informed about the issue. https://www.epa.gov/la/laplace-louisiana-background-information. EPA has also used the IRIS data to target DPE for an enforcement investigation by EPA's National Environmental Investigations Center (NEIC). These actions threaten DPE's ability to keep the Neoprene plant, the only Neoprene production facility in the United States, in operation.

The problem is that the IRIS risk value for the chemical of interest, chloroprene, is faulty, and EPA's IRIS office has advised DPE that it has no interest in reviewing or resources to review the risk value. The chloroprene risk value is faulty because EPA developed it in 2010 in a process that made one default risk assumption after another, ending up with a risk value that is, according to DPE's highly regarded toxicological consultants at Ramboll Environ, at least a hundred times too high. Moreover, the IRIS risk value was theoretically estimated based on laboratory animal data and it is not supported by occupational epidemiological data. Because the IRIS value is faulty, EPA's request for emission reductions is misguided and the information EPA is providing the public is misleading and is unnecessarily creating public fears.

Specifically, EPA's flawed IRIS program has undermined the sole Neoprene production facility in the United States, owned and operated by Denka Performance Elastomer LLC (DPE) located in LaPlace, Louisiana (the Facility). Specifically, EPA's decision to avoid peer-reviewed science that engages all stakeholders undermines three of the key principles stressed by the President-elect:

- *Employment Concerns:* These studies will result in unwarranted compliance costs that pose a *direct* threat to DPE's ability to keep its facility open and to keep jobs in Louisiana. The Transition Team should consider how the potential scientific inaccuracy in the IRIS quantitative risk values for chloroprene threaten the economic vitality of DPE, as well as DPE's downstream supply chain customers. EPA's actions affecting Neoprene production threaten significant *indirect* job losses. Neoprene is utilized in a wide variety of applications, such as laptop sleeves, orthopedic braces, electrical insulation, liquid and sheet applied elastomeric membranes or flashing, and automotive fan belts. Many of these products rely on

domestic Neoprene production. If IRIS sets inaccurate and inflated toxicity values, this can threaten the supply chain utilized by many industries. The President-elect has stressed maintaining productive manufacturing capacity in the United States. The correction of the 2010 Chloroprene Review is consistent with that concern. And,

- *Sound Scientific Process:* The President-elect has stressed the need for transparent, fair, and predictable regulatory processes based upon sound scientific information. The 2010 Chloroprene Review used unsupported assumptions, it failed to give appropriate weight to the most important epidemiological study, and it gave full weight to outdated and/or poor quality epidemiological studies from Russia and China. When used as the basis for standard-setting, prioritizing, or in the context of litigation, mistakes in IRIS can result in harm to the regulated community while failing to provide the accuracy necessary to serve the public interest. Correcting the IRIS value as it relates to Neoprene production is a case study on the importance of using sound scientific processes.

The following memorandum provides further information on EPA's treatment of DPE, outlining the technical flaws of the process and what is needed to rectify the situation. Ultimately, we believe program officials are imposing unnecessary regulatory requirements based on scientifically flawed technical analysis, and we hope your team would be willing to review the situation at EPA.

II. Introduction

On November 1, 2015, DPE acquired the Louisiana Neoprene production. Immediately after acquiring the facility, DPE learned of the imminent publication of the Environmental Protection Agency's 2011 National-Scale Air Toxics Assessment (2011 NATA study), which was released to the public on December 17, 2015. The 2011 NATA study identifies the DPE facility as creating the greatest offsite risk of cancer of any manufacturing facility in the United States. DPE's highly respected toxicological consultants at Ramboll Environ have concluded that the NATA conclusion is incorrect for two basic reasons: (1) It is based on scientifically unwarranted assumptions in the 2010 Chloroprene Review, and (2) the 2010 Chloroprene Review is outdated and needs to be updated to account for more recent peer reviewed studies.

The EPA IRIS program provides a database for toxicological information and human health effects data, it identifies the health hazards of chemicals found in the environment, and it provides quantitative risk assessment metrics for standard setting purposes. While the program's intended purposes are laudable, it is clear the EPA has departed from sound science in implementing the IRIS program by using questionable assumptions and analysis, outdated data, and other examples of disputed methodology. DPE's toxicological and epidemiological consultants at Ramboll Environ believe that the 2010 Chloroprene Review used a series of highly conservative assumptions that are scientifically unsupported concerning the risk of cancer from human exposure to chloroprene. Further, these scientists believe that the 2010 Chloroprene Review disregarded the negative conclusions of the most rigorous epidemiological study available, which had concluded that there was no showing of linkage between workplace

exposure to chloroprene and cancer. Instead of using the conclusions of this study, EPA used a small part of the data – "cherry picked" the data -- to support its own opposite conclusions.

EPA is currently relying on the 2011 NATA study and the 2010 Chloroprene Review to seek massive emission reductions by DPE.

III. Background and Introduction to Denka Performance Elastomer, LLC

DPE was formed by two Japanese companies, Denka Company Limited and Mitsui & Co., Ltd., to acquire and enhance the Neoprene manufacturing operation in Louisiana. The Neoprene facility has been operating at that location since 1973. The base feedstock for Neoprene is chloroprene, the subject of the IRIS 2010 Chloroprene Review.

DPE is investing in and upgrading the facility, including new measures to reduce its environmental footprint and improve its productivity and competitiveness. In addition, DPE has recently opened a new corporate headquarters office building at the LaPlace site. With an annual payroll of $33 million, the facility directly employs 200-250 people in manufacturing jobs and regularly employs between 400 and 600 contractors. DPE has also created 16 new corporate jobs. The facility is a commercial mainstay of the area.

On December 17, 2015, EPA released the 2011 NATA study. The NATA study involves a nationwide air modeling review of U.S. manufacturing facilities, the results of which it combines with IRIS risk values. After multiplying the air modeling estimates of chloroprene concentrations by the extraordinarily high chloroprene risk value in the 2010 Chloroprene Review, the 2011 NATA study concluded that the DPE facility created the highest offsite cancer risk of any manufacturing facility in the United States. In an unprecedented use of the screening quality risk assessment in the 2011 NATA study, within days after releasing the study, EPA propounded Clean Air Act Section 114 information requests to DPE, and EPA immediately began an intense process of scrutinizing DPE's emissions.

IV. The Scientific Flaw in EPA's Initiative Against DPE

The specific IRIS value that is driving the chloroprene risk assessment is the inhalation Unit Risk Estimate (URE) set forth in the 2010 Chloroprene Review. The IRIS chloroprene URE is at least a hundred times higher than current peer-reviewed studies justify. EPA staff have expressed an unwillingness to reconsider the 2010 Chloroprene Review to incorporate the more recent peer-reviewed findings and to correct methodological errors contained in the 2010 Chloroprene Review. We recognize that the IRIS review process is technically challenging and resource intensive, but in DPE's case the IRIS "science" is the pivotal factor driving huge agency and DPE environmental costs.

DPE's toxicological and epidemiological consultants have reviewed the 2011 NATA study and the 2010 Chloroprene Review and have concluded that EPA's assessment of the cancer risk associated with chloroprene conflicts with the preponderance of underlying toxicological and epidemiological studies and data. The chloroprene URE is too high because of overly

conservative calculations in applying laboratory toxicological data from mice, the most sensitive species in the laboratory studies, to humans. The 2010 Chloroprene Review made extremely conservative URE calculations from female mouse laboratory exposure data, and then it simply assumed that humans have the exact sensitivity to chloroprene as female mice. This analysis is flawed because the data demonstrate a large difference in sensitivity among laboratory test species (mice, rates, and hamsters), and large differences are expected between mice and humans.

There are well-documented toxicological reasons why the mouse is much more sensitive than other species. The standard technique to adjust for these differences in species is a physiologically based pharmacokinetic ("PBPK") model. IRIS has used this technique in other chemical risk assessments, but did not use this technique in the chloroprene risk assessment. The 2010 Chloroprene Review acknowledged that its quantitative risk values would be more accurate if PBPK models were applied, but said that no validated PBPK models for chloroprene were available at that time. As DPE has called to EPA's attention, a peer-reviewed PBPK model for chloroprene was published in 2014 (Allen, *et al.*). The application of the Allen-derived URE for chloroprene would reduce the URE by two orders of magnitude. At a minimum, EPA should revise its estimates to incorporate the 2014 PBPK values.

In addition, the chloroprene URE is premised on an erroneous review of the epidemiological evidence. The leading epidemiological study of chloroprene (Marsh, *et al.* (2007)) examined data from 20,000 workers in the U.S. and Europe, including 1400 from the Pontchartrain Neoprene Facility, and concluded that the data did not demonstrate a link between worker exposure to chloroprene and cancer. However, the 2010 Chloroprene Review disregarded the overall weight of the data, and instead relied on very small and statistically limited subgroups in the data to reach the opposite conclusion from that of the study authors. It also relied on outdated and poor quality Russian and Chinese studies. DPE's consultants believe that a "weight-of-evidence" review of the epidemiological data shows no link between chloroprene exposure in workers and cancer. This comports with Louisiana cancer statistics which show that St. John the Baptist Parish, where the facility is located, has one of the lower cancer rates in Louisiana. In short, these "real world" results demonstrate the gross inaccuracy of the theoretically-based IRIS chloroprene URE.

Even EPA would agree that the IRIS group has great difficulty in applying consistent toxicological principles among the various chemicals. The chloroprene URE is extraordinarily high when compared to the IRIS UREs for similar chemicals. The 2010 IRIS Review classified chloroprene only as a "probable" human carcinogen. Yet, the URE for vinyl chloride, a "known" human carcinogen, is 57 times lower, and the URE for benzene, another "known" human carcinogen, is 75 times lower. Manufacturing facilities emitting these substances would find it difficult to survive had IRIS used comparable URE methodology in evaluating those chemicals. Furthermore, the discrepancy between "known" human carcinogens and chloroprene, which is only categorized as a "probable" carcinogen, further shows the inconsistencies in the IRIS review process.

These conclusions about the 2010 Chloroprene Review are consistent with scientific and congressional criticism of IRIS. In particular, the National Academy of Sciences' National

Research Council ("NRC") recommended an extensive overhaul of the IRIS toxicity evaluation methodology in 2011 and again in 2014, and Congress instructed EPA to change the IRIS methodology to address the NRC recommendations. EPA has advised Congress that it is implementing these changes. But, the 2010 Chloroprene Review was completed prior to these changes and has not been updated to be consistent with these changes. Accordingly, if EPA aims to abide by Congressional intent and its past statements to Congress, it should revise its 2010 IRIS review to incorporate the best available science.

DPE has shared its concerns about the science underlying the chloroprene URE with IRIS. On August 9, 2016, DPE's \consultants with Ramboll Environ met with a large group of IRIS scientists at Research Triangle Park, North Carolina. Among other things, the IRIS scientists told Ramboll Environ that there is no room on the agency's schedule for an evaluation of the 2010 Chloroprene Review. From DPE's perspective, however, the scientific resources it would require to correct the chloroprene URE are miniscule in comparison with the high level of EPA (and LDEQ) resources devoted to the enforcement, technical review, and standard setting unleashed by the chloroprene URE, much less the massive financial impact on DPE's facility. This highlights the weakness of the IRIS process as it relates to both the facility and the process writ large.

V. EPA (and LDEQ) Actions to Reduce DPE's Chloroprene Emissions

Based on the 2011 NATA and the 2010 Chloroprene Review, EPA and the Louisiana Department of Environmental Quality (LDEQ) are requesting DPE to reduce emissions. DPE is currently in compliance with its air permits, and its emissions easily comply with the current ambient air standard for chloroprene of 857 $\mu g/m^3$ on an eight-hour basis. However, based on the 2010 Chloroprene Review, the agencies have told DPE and the public that DPE should meet an exposure level of 0.2 $\mu g/m^3$ on an annual average basis, more than a thousand-fold reduction in the applicable standard. Even after the application of the most advanced air pollution controls available, DPE's studies do not indicate that the facility can achieve such a value. Thus, DPE remains under a threat of continued and new agency pressure to further reduce emissions – even beyond the point of what is feasible.

Over the past year, DPE has worked unceasingly with EPA and LDEQ to address every facet of the facility's chloroprene emissions. For example:

- In December 2015, EPA propounded a series of Clean Air Act Section 114 information requests to DPE;
- Beginning with a week-long inspection of the facility in June 2016, EPA's National Environmental Investigation Center ("NEIC") is in the process of conducting an extensive multi-media review of the facility's regulatory compliance. The NEIC review was triggered by the 2011 NATA.
- The agencies, including EPA Headquarters, EPA Region 6, and LDEQ, have conducted several facility inspections, and DPE has had at least 14 major meetings and conferences with the agencies over this time.

- The agencies are conducting vicinity air monitoring and requiring DPE to conduct additional air monitoring;

These actions have placed a substantial strain on DPE's limited resources. In addition, the intense agency scrutiny has resulted in multiple news reports that have increased concerns in the local community. Environmental activists and plaintiffs lawyers have had numerous meetings in the community about DPE, all based on the assumption that 0.2 $\mu g/m^3$ is the "safe" level of chloroprene. Again, all of these actions are based on the 2010 Chloroprene Review.

VI. DPE's Voluntary Commitment to and Investment in Air Pollution Controls

Notwithstanding DPE's good environmental compliance record and its concerns about the science behind the 2010 Chloroprene Review, DPE is making extraordinary efforts to meet the agency demands. On January 6, 2017, DPE and LDEQ entered into an Administrative Order on Consent for an 85% chloroprene emission reduction in the next 12 months. DPE estimates that the capital cost of these emission reduction devices is approximately $18 million, and the devices will cost hundreds of thousands of dollars per year to operate. The majority of DPE's capital budget is devoted to environmental compliance measures. For a manufacturing facility of its size, this is an extraordinarily large investment in pollution control technology.

VII. DPE Requests that EPA's IRIS Group Commit to a Speedy and Technically Rigorous Update of the Chloroprene URE

DPE requests that EPA's IRIS group update the 2010 Chloroprene Review to reflect the new peer-reviewed studies and correct the unwarranted assumptions in the 2010 evaluation. Any one of a series of possible scientific corrections would give DPE sufficient relief to comply with agency requirements and to prosper as a company. The Company urgently requests that EPA commit to the application of sound and updated toxicological science to the chloroprene URE and the use of that updated information in the Clean Air Act evaluation of the facility. If the URE is corrected, the agency and public concerns about the air pollution health risks from the facility will be mitigated. Without this relief, it is not certain that the facility can survive which imperils the sole domestic source of Neoprene. Given this threat, we respectfully request that the Trump Transition Team consider directing IRIS to devote sufficient resources for a prompt reconsideration of the 2010 URE for chloroprene.