UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
AIR QUALITY PLANNING
AND STANDARDS

SEP 23 2019

Dr. Chuck Carr Brown, Secretary
Louisiana Department of Environmental Quality
602 N. Fifth Street
Baton Rouge, LA 70802

Dear Secretary Brown:

As follow-up on recent conversations between the Louisiana Department of Environmental Quality and EPA's Office of Air and Radiation, I wanted to provide you an update on the status of ongoing activities and next steps regarding the United States Environmental Protection Agency's (EPA) efforts related to the request for reconsideration (RFR #17002A) submitted by Denka Performance Elastomer LLC (DPE) on the *2010 Integrated Risk Information System (IRIS) Toxicological Review of Chloroprene*. In its initial 2017 request for correction (and its 2018 request for reconsideration), DPE claimed that "the 2010 IRIS Review provides conclusions and advice to the public that do not reflect the "best available science" or "sound and objective scientific practices" required under the EPA Guidelines." Furthermore, DPE claimed that the agency's updated human inhalation unit risk estimate (URE) is too high and should be replaced with a suggested lower value.

DPE and its contractor have been working to develop a new physiologically-based pharmacokinetic (PBPK) model for potential use in improving estimates of how chloroprene is absorbed, distributed, metabolized, and excreted by the human body. EPA's Office of Research and Development has been providing guidance regarding procedures for validating new models and their potential application to the IRIS program.

In a June 12, 2019, meeting between representatives from DPE and EPA, DPE, via its contractor Ramboll Environ, agreed to provide the new PBPK model to EPA. Consistent with standard EPA procedures, EPA will then quality assure the model and conduct a peer review focused on the code within the Ramboll Environ-developed model and model parameters.

In a letter dated July 17, 2019, the agency notified DPE that it was pausing reconsideration of the company's request until after the results of the peer review mentioned above have been fully assessed. EPA estimates it will take a minimum of nine months to complete the IRIS quality assurance and peer review processes. In accordance with EPA's Information Quality Guidelines (IQG), EPA will then review and assess the results of these reviews and convene an IQG Executive Panel to reconsider EPA's response to DPE's original

request for correction. Under EPA's IQG, this Executive Panel will make the final decision on the request for reconsideration.

Finally, as you know, chloroprene is one of 187 pollutants that Congress classified as "hazardous air pollutants," also called "air toxics." The Clean Air Act instructs EPA to regulate air toxics by setting limits on the amount of pollution that industrial sources can *emit* to the air, rather than by setting *ambient standards*, which are limits on the amount of a pollutant that is allowed in the outdoor air. The IRIS URE, which is not based on an evaluation of current, real world exposures, is not an air quality standard and it is not used directly for regulatory purposes. Furthermore, the risk calculated using the IRIS URE, such as 100-in-1-million, is not a "bright line" for determining whether a risk level is considered safe or acceptable. Other health risk measures and information such as risk estimation uncertainty are important in making a determination of risk acceptability. Finally, please note that in setting emission standards under the Clean Air Act, risk is one factor that we need to consider, along with information on costs, energy, safety, control technologies, and other relevant factors.

I look forward to our continued collaboration to address this matter. If you have any questions, please contact Erika Sasser, the director of the Health and Environmental Impacts Division at EPA's Office of Air Quality Planning & Standards, at Sasser.Erika@epa.gov, or (919) 541-3889.

Sincerely,

Peter Tsirigotis

Director