U.S. D4 Monitoring Program FAQs

Why did the silicones industry and EPA collaborate on a D4 environmental monitoring program?
For several years, EPA had been trying to develop a better understanding of the potential effects of substances in the environment, including D4. To further this understanding, the silicones industry worked with EPA to design a monitoring program that would produce the exposure data the agency needed to conduct a thorough and scientifically sound evaluation of D4.

What is the Enforceable Consent Agreement (ECA)?
The ECA is an agreement between the silicones industry and EPA that provided the agency with monitoring data to characterize sources and pathways of release of D4 to the environment. The agreement established an environmental monitoring program, designed with EPA, that was conducted at specific D4 manufacturing, processing, and formulating facilities, and select municipal wastewater treatment plants that treat D4.

When did the program begin?
The agreement (ECA) between SEHSC and EPA was finalized in April 2014. In March 2016, after the industry and EPA agreed to the study's parameters (including a detailed Study Plan and Quality Assurance Project Plan) and the sample sites, SEHSC began its environmental monitoring program. Scientists collected the first samples in May 2016.

Who paid for the program?
The silicones industry covered the full cost of the D4 environmental monitoring program.

How many sites were sampled?
The study was comprised of 14 sites located around the U.S. Ten sites were municipal wastewater treatment plants that treat D4 in the wastewater from residential areas and industrial facilities. The final four sites were "direct discharge" sites, where manufacturers or processors of D4 discharge wastewater, following on-site water treatment facilities, directly into surface waters.

How were the municipal sites chosen?
The 10 municipal wastewater treatment plant locations were selected to represent the universe of more than 16,000 wastewater treatment plants in the U.S. These include five municipal sites that primarily receive wastewater from residential customers and five municipal sites that receive wastewater from at least one industrial discharger that processes or formulates with D4.

What was sampled and analyzed?
During two separate events, scientists sampled and analyzed influent and biosolids within the municipal wastewater treatment facilities. Effluent at the permitted sampling location point for each facility, and surface water, sediment, fish, and sediment-dwelling invertebrates where the effluent and river are mixed (typically referred to as the "mixing zone") were sampled and analyzed for all sites.

What is the mixing zone?
According to EPA, a mixing zone "is a limited area or volume of water where initial dilution of a discharge takes place and where certain numeric water quality criteria may be exceeded." In these

designated areas where effluent from a facility mixes with the receiving water (e.g., river or lake), the level of certain substances is allowed to be higher than the acceptable concentration for the general body of water.

What can be concluded from the data?
The silicones industry is pursuing an independent, peer-reviewed environmental risk evaluation of the data. It is important to note that a preliminary assessment of the data – derived from 10 wastewater treatment plants that represent the treatment of more than 99 percent of silicones in use in the U.S. – suggests that no regulatory restrictions are needed.

Is this data comparable to data collected from other D4 environmental monitoring programs?
The data produced in this D4 monitoring program are generally consistent with those reported for similar wastewater treatment sites in other environmental monitoring programs conducted throughout the world.

How might EPA use this data?
EPA has indicated that it will use this robust data set to conduct its environmental risk assessment of D4. These real-world data will help ensure the agency can rely on more accurate exposure data, rather than modeling estimations, to evaluate D4.

Why is it important that EPA use this monitoring data in its assessment of D4?
Real-world monitoring data provide evidence of actual levels of a given substance in the environment. While modeling may be appropriate in certain circumstances, real-world data allow scientists to assess actual exposure levels, and these data can be used to refine and better calibrate predictive models that may not be appropriate to use for silicone materials.

What will be the silicones industry's role in the evaluation of D4?
The silicones industry stands ready to continue to work with EPA in its assessment of D4, and provide additional technical support to the agency as it contemplates the risk evaluation process for D4.