GSC EU Legal Action against SVHC listing - FAQ

Who are the applicants involved in the legal action?
The Global Silicones Council (GSC) and six individual silicone manufacturers – Dow Silicones UK Limited, Elkem Silicones France S.A.S., Evonik Nutrition & Care GmbH, Momentive Performance Materials GmbH, Shin-Etsu Silicones Europe B.V, and WACKER CHEMIE AG – have filed an action for annulment of the decision of the European Chemicals Agency (ECHA) to identify D4, D5, and D6 as Substances of Very High Concern (SVHCs) and to include these substances in the candidate list under the EU Reach Regulation 1907/2006 ("REACH" or "the REACH Regulation").

When and where was the legal action filed?
The action was filed on September 3, 2018, with the Court of Justice of the European Union (General Court).

What ECHA decision is being contested?
On June 27, 2018, ECHA included the siloxanes D4, D5 and D6 in the "Candidate List of substances of very high concern for Authorisation", published on its website. The legal action contests the basis for ECHA's decision to identify D4, D5 and D6 as persistent, bioaccumulative, and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances, the purported grounds for their identification as SVHCs.

On what basis did ECHA identify D4, D5, and D6 as SVHCs?
ECHA concluded that these substances meet the current numerical criteria of REACH ANNEX XIII defined primarily in accordance with laboratory-derived data.

Why has industry lodged this action?
GSC members believe that ECHA failed to follow the REACH requirements to consider all the available evidence and properly assess it. The REACH Regulation requires a robust weight of evidence evaluation which in this case has not been carried out. Had it been done, such an assessment would have not supported a conclusion of PBT/vPvB, or the SVHC listing. It is important for all stakeholders – both industry and the decision-makers – that regulatory decisions are evidence-based. D4, D5, and D6 are 'data-rich' substances which have been extensively studied for potential effects in the environment. GSC maintains that ECHA failed to take all relevant scientific evidence into account and did not properly assess it, undermining the decision-making process for these substances.

On what grounds was the industry's action filed?
The GSC contends that in identifying D4, D5, and D6 as SVHCs, ECHA did not consider the full range of relevant evidence that demonstrates these substances are not persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB) and did

not properly assess the information at hand. Among others, the GSC contends that ECHA relied primarily on laboratory models and failed to consider newer, more accurate field data that show that the identified siloxanes do not pose a risk to the environment. Consequently, the SVHC listing of those substances is not justified.

In addition, the GSC contends that, by identifying D4, D5 and D6 as SVHCs, ECHA infringed the principle of proportionality embedded in European Union (EU) law, as the candidate-listing decision exceeds what is appropriate and necessary to achieve the objective of the regulation.

Why did industry decide to take this action now?
The Global Silicones Council has always maintained that the abundance of scientific data demonstrates that D4, D5, and D6 do not meet the criteria as PBT/vPvB substances. Before bringing this action, the GSC communicated its position openly and transparently to all stakeholders, including ECHA. Therefore, the action re-states and is wholly in line with GSC's long-held position.

Have other countries considered real-world data as part of their assessment of D4/D5/D6?
In both Canada and Australia, governmental authorities have evaluated the impact of D4, D5, and D6 on the environment. In each instance, regulators relied on all relevant scientific evidence and risk-based evaluations of these substances, and concluded that these substances do not pose a risk to the environment or human health. As a result, each decided not to impose any restrictions on the use of these substances in commerce. The U.S. Environmental Protection Agency (EPA) is also considering an evaluation of D4 and has worked collaboratively with industry to produce exposure data that the EPA requested for its planned assessment.

What additional information did the Australian and Canadian countries consider that ECHA did not?
In both Canada and Australia, governmental authorities have evaluated the impact of D4, D5, and D6 on the environment, and in each instance, regulators relied on all available information and an assessment that properly weighed all relevant scientific evidence (i.e. other bioaccumulation data including laboratory and field metrics, and metabolism studies as well as monitoring data assessing actual environmental concentrations).

What are D4, D5 and D6? Where are they used?
D4, D5, and D6 are critical building blocks (monomers) used primarily to produce a wide range of silicone polymers which provide unique product performance characteristics that engender innovation in thousands of products that benefit key segments of the global economy, including: transportation, building and construction, health care, alternative energy technologies, and electronics. Because of their unique attributes, some D4 (except in the EU), D5 and D6 are used as ingredients in specific types of cosmetic products and D5 is used in dry-cleaning as an alternative to perchloroethylene.

How does this case compare with the other GSC's legal challenge?
An action for annulment was filed against the Commission's Regulation restricting the use of cyclic siloxanes in 'wash-off' cosmetic products such as shampoos and shower gels. The current action is filed against ECHA's decision to designate D4, D5, and D6 as SVHCs.

What additional information does ECHA need to consider?
Regulatory decisions need to be evidence-based. D4, D5, and D6 are 'data-rich' substances which have been extensively studied for potential effects in the environment for many years. GSC maintains that, under the EU's own regulatory standards, ECHA must consider all relevant scientific information in a robust weight of evidence approach, and failed to do so in the case of D4, D5 and D6.

When do you expect the conclusions of this legal challenge will be available?
An action for annulment before the Court of Justice of the European Union typically takes one to two years.