



## **GSC EU Legal Action FAQ**

### **Who are the applicants involved in the legal action?**

The Global Silicones Council (GSC) and four individual silicone manufacturers – Wacker Chemie AG, Momentive Performance Materials GMBH, Shin-Etsu Silicones Europe B.V., and Elkem Silicones France S.A.S. – have filed an action for annulment of the REACH Restriction contained in Annex XVII, which prohibits the presence of D4 and D5 in wash-off cosmetic products at a concentration of 0.1% or more.

### **Which REACH decision is being contested?**

On January 11, 2018, Regulation (EU) 2018/35 was published in the Official Journal of the European Union. Regulation 2018/35 updated Annex XVII of the REACH Regulation – to include a new REACH Restriction on certain cosmetic products containing D4 and D5 (entry 70), on the basis that D4 has been assessed as Persistent, Bioaccumulative and Toxic (PBT)/very Persistent and very Bioaccumulative (vPvB) and D5 as vPvB. This restriction prohibits placing on the market wash-off cosmetic products in which either substance is present at a concentration of 0.1% or greater. The restriction applies across the European Economic Area (EEA), which consists of the 28 Member States of the European Union and Norway, Lichtenstein and Iceland.

### **Why has industry lodged this action?**

It is important for all stakeholders – both industry and the decision-makers – that regulatory decisions are evidence-based. D4 and D5 are ‘data-rich’ substances, i.e. they have been extensively studied for potential effects in the environment. If all available scientific evidence is not taken into account to support a particular decision – it undermines the credibility and confidence in the decision-making itself. The action lodged by industry is not just about the impact of the restriction as such, but about the legal criteria that underpin the decision for a restriction. The legal criteria under REACH have led D4 and D5 to be considered as very bioaccumulative, despite the broad evidence that D4 and D5 do not behave as PBT/vPvB in the environment. As a result, the law itself appears to have prevented a robust conclusion based on the full body of science from being reached. By bringing this case, the GSC hopes that the Court has the full opportunity to re-state the importance of robust, evidence-based scientific decision-making.

### **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 and D5 do not behave as PBT/vPvB substances in the environment and therefore are safe for the environment. Before bringing this action, the GSC had communicated its position openly and transparently to all stakeholders. The action is therefore wholly in line with, and re-states, GSC’s long-held position. Parties affected by the REACH

restriction had only a limited time frame following publication of the Commission's determination in the Official Journal of the European Union to file a legal action. Having done so, the Court now has the opportunity to exercise its power of judicial review.

### **On what grounds was the industry's action filed?**

The action has been filed predominantly on the basis that the legal criteria under REACH for deciding whether a substance is bioaccumulative or very bioaccumulative effectively omit certain factors critical to understanding the real behavior of D4 and D5 in the environment, namely trophic magnification and biomagnification. Although these critical factors are considered under REACH when "screening" or "assessing" whether a substance is a potential PBT/vPvB, they are effectively omitted from the legal criteria used in deciding whether a substance is a PBT/vPvB under EU law (*i.e.*, Section 1 Annex XIII REACH) – particularly where the numeric values for bioconcentration are regarded as satisfied.

### **On what basis did the EU make its PBT/vPvB determinations for D4 and D5?**

The REACH criteria to assess bioaccumulation were intended only to be used for organic (carbon-based) substances, not inorganic substances. D4 and D5 have an inorganic backbone. Therefore, the legal criteria used to assess whether D4 and D5 are bioaccumulative, do not reflect the unique chemistry of siloxanes. Further, the criteria for bioaccumulation assessment focuses on one factor only, namely bioconcentration. As a result, the weight and importance attributed to the bioconcentration factor data was more than that attributed to the non-bioconcentration data – for example, the trophic magnification data (data measuring the average relative increase (decrease) in concentration of a substance over an entire food chain). By not applying a robust scientific weight-of-evidence determination, weighing all available data and taking the unique properties of siloxanes into account, the scientific assessment of D4 and D5 was effectively distorted. As a matter of fact, recent scientific studies have concluded that these legal criteria are not appropriate for estimating the behavior of siloxanes in the environment.

### **Have other countries considered real-world data as part of their assessment of D4/D5?**

In both Canada and Australia, governmental authorities have evaluated the impact of D4 and D5 on the environment, and in each instance, regulators relied on all available science and risk-based evaluations that consider weight-of-evidence. As a result, each decided not to impose any restrictions on the use of these substances in commerce. The U.S. is also considering an evaluation of D4 and has worked collaboratively with industry to produce exposure data that the EPA requested for its assessment.

### **What are D4 and D5? Where are they used?**

D4 and D5 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. Some D4 (except in the EU) and D5 is used as an ingredient in specific types of cosmetic products because of their unique attributes.