



Frequently Asked Questions: EU's D4, D5, D6 Authorization Draft Recommendation

What is authorization?

Authorization is a procedure conducted under rules established by the European chemicals management law, known as REACH. If a substance is subject to authorization, some uses will be banned in the European Union (EU) unless the EU government grants specific permission.

What is the EU proposing with respect to silicone substances?

D4, D5, and D6 are proposed as candidates for authorization because European authorities have concluded that these substances have met existing PBT or vPvB criteria under REACH and have designated them as substances of very high concern (SVHC). Following standard REACH procedure, the European Chemicals Agency (ECHA) compiles every second year, at least, a list with substances it recommends prioritizing for authorization.

Is an authorization determination for D4, D5, and D6 in the EU currently final?

No. The process to prioritize D4, D5, and D6 for authorization initially seeks to determine whether or not a ban is necessary and does not mean that the authorization recommendation is currently final. The review process will last about 12 months, with the potential to add D4, D5, and D6 to a list of banned substances (Annex XIV) coming at a later stage.

What are the next steps?

A consultation has been launched to gather information on whether these substances should be prioritized for authorization. Comments can be submitted on this proposal until June 5, 2020. The ECHA Member State Committee will prepare an opinion on ECHA's draft recommendation taking into account the comments received during this consultation. Based on the opinion of the Committee and the consultation, ECHA will provide its final recommendation to the European Commission in the Spring of 2021. The Commission then will decide which of the substances to include in the Authorization List and the respective conditions applicable for each substance.

What countries would be affected by authorization?

Should an authorization requirement for D4, D5, and D6 be adopted, it would apply to products produced in *and* imported into the EU. In addition, the silicones industry expects that a ban of some uses of the substances by the EU would pose practical challenges for the use of the materials in global supply chains that would likely create barriers to trade. This EU action would also complicate the effective implementation of risk-based science policy in regions that are developing chemicals management systems.

Does the silicones industry believe the authorization procedure is justified?

No. The silicones industry contends that an authorization requirement for D4, D5, and D6 by the EU would be inconsistent with sound science and out of step with regulatory outcomes for the substances in other regions of the world, including Australia and North America. The EU proposal for authorizing D4, D5, and D6 is an unfortunate consequence of the EU's flawed

regulatory evaluation for these silicone materials. The EU's assessment of D4, D5, and D6 did not consider all available evidence and ignored technical input from leading academic experts.

What previous regulations has the EU levied on D4, D5, and D6?

The EU is the only regulatory authority in the world that has imposed restrictions on the use of any silicone material in commerce. It has imposed a wash-off personal care products restriction on D4, D5, and D6 and listed D4, D5, and D6 as SVHCs. The EU is also proposing a restriction for D4, D5, and D6 in leave-on personal care applications and consumer and professional use applications. These regulations are the direct result of the EU's flawed hazard-based approach for assessing the environmental risks associated with chemicals in commerce and its failure to consider exposure in its evaluation of silicone materials.

Does the silicones industry support the EU's restrictions on wash-off and leave-on products or the SVHC designation for D4, D5, and D6?

No. The silicones industry has consistently and unequivocally opposed both EU restrictions and its SVHC designation because there is no underlying scientific justification for these regulations. The Global Silicones Council (GSC) has long maintained that the abundance of scientific data confirms that D4, D5, and D6 are safe for the environment. The silicones industry firmly believes that the EU's evaluation of these substances did not adequately consider all the available information, and as a result, the GSC has filed legal challenges in the EU against both the wash-off restriction and the SVHC designation.

What is the expected environmental benefit of authorization in the EU?

Similar to the regulatory restrictions and SVHC designation imposed on the materials in the EU, the GSC believes that authorization of D4, D5, and D6 would not provide any meaningful environmental benefit and would needlessly jeopardize innovation and economic growth.

How do other countries view the risks posed by D4, D5, and D6?

No country or region outside of the EU has imposed product restrictions on D4, D5, or D6. Australia and Canada conducted their own risk assessments of D4, D5, and D6 using a weight of evidence approach and found that environmental concentrations of these substances did not warrant regulatory restrictions on any products.