AmCham EU
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Our position

An appropriate regulatory approach to protect ground- and drinking water from contamination of chemicals

Persistent, Mobile, Toxic (PMT) and very Persistent, very Mobile (vPvM) assessments

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2017, directly supports more than 4.7 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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In November 2017 the German Environment Agency (UBA) published a paper entitled 'Protecting the sources of our drinking water',[1] targeting chemicals that could potentially end up in groundwater and drinking water. The paper recommends criteria and an assessment procedure to identify two new categories of chemical substances: (1) Persistent, Mobile and Toxic (PMT), and (2) very Persistent, very Mobile (vPvM).

The American Chamber of Commerce to the EU (AmCham EU) strongly supports the responsible care and protection of the ground and drinking water from chemical contamination. There is however concern around the current proposal and how it could be used for regulatory purposes, since the PMT/vPvM criteria are not defined under REACH. Prior to any regulatory use of the PMT/vPvM criteria, be it for REACH registration or risk management measures, an objective scientific and political discussion is required. In this respect, AmCham EU welcomes the withdrawal of the first SVHC proposal based on the PMT/vPvM concept. As highlighted by several Member States, in the absence of guidance on how to assess the equivalent level of concern to PBT/vPvB substances of PMT/vPvM substances, and more generally the environmental effects, a SVHC proposal was premature and would have created a precedent undermining the predictability and regulatory principles under REACH.

Now is however the time to have an in-depth and open discussion on the PMT/vPvM concept in order to make it a functional instrument for the protection of ground- and drinking water. Of critical and far-ranging importance is how to assess 'Equivalent Level of Concern' for the environment.

PMT/vPvM – a science-based approach?

According to the regulatory proposal brought forward by the German UBA for assessing PMT/vPvM properties, substances that have such properties should be assessed in the same manner as PBT/vPvB. However, it should be highlighted that the toxicological assessment in the UBA proposal represents a significant extension compared to the current toxic (T) criteria set out in Annex XIII of REACH. It also bases the concept of mobility on much disputed Soil Organic carbon water partitioning Coefficient (KoC) values. As a matter of fact, narrowing the evaluation of mobility to one intrinsic substance property, such as the KoC, may identify a large range of substances of no concern for groundwater exposure.

Furthermore, a direct comparison of PMT/vPvM with PBT/vPvB properties equates to comparing mobility to bioaccumulation. Mobility is a process whereby a substance is transported between environmental compartments while bioaccumulation,[2] is a process in which a chemical biomagnifies in the food chain. These are two different types of assessments, since the first informs on the potential for exposure in an environmental matrix (eg, water soil) by including key information emissions and environmental partitioning between media. While the second informs on the potential for increasing concentration in the food chain which can cause harmful concentrations in upper trophic level organisms and human beings. These assessments are therefore not informative when performed in isolation.

Indeed, when assessing persistence and mobility in isolation of each other, the results do not inform on the potential exposure in an environmental compartment, nor do they inform on the type and severity of adverse effects to humans or the environment. Taking into account the exposure and emissions data is essential when the regulatory objective is the protection of water quality.

REACH registration data may be a useful source of information in order to holistically identify potentially relevant substances for water protection based on properties and uses. Nonetheless, broad-spectrum screening based on REACH data should always be followed by a narrower assessment using more refined and higher tier data.

[1] Protecting the sources of our drinking water A revised proposal for implementing criteria and an assessment procedure to identify Persistent, Mobile and Toxic (PMT) and very Persistent, very Mobile (vPvM) substances registered under REACH, German Environmental Agency, October 2017

[2] "Bioaccumulation, a process in which the chemical concentration in an organism achieves a level that exceeds that in the respiratory medium (e.g., water for a fish or air for a mammal), the diet, or both." Gobas et al, IEAM, 2009

A thorough scientific evaluation of the approach proposed by UBA is required as it may result in the identification of a large range of substances such as PMT/vPvM and ultimately SVHC. While these substances may be of no environmental concern to ground- and/or drinking water, this could still create a potentially unnecessary burden for both authorities and industry.

A lack of ELoC guidance for environmental effects under REACH

The use of mobility properties as one of the main rationales to justify a listing as SVHC under Article 57(f) raises major concerns as chemical mobility in the environment currently lacks a precise regulatory definition. The REACH regulation moreover, does not list mobility as a substance property which can be used to identify a substance as an SVHC. Therefore, the SVHC rationale is based on Article 57(f) of REACH, namely 'Equivalent Level of Concern' to PBT/vPvB.

It should be acknowledged that the ELoC concept was agreed upon for human health effects. Comparison factors for ELoC on carcinogenic, mutagenic, reprotoxic (CMR) substances were developed to assess SVHC proposals for certain sensitising substances. This process included extensive consultation within the relevant committees, including Competent Authorities for REACH and CLP (CARACAL). This resulted in an ECHA publication on when the concept of ELoC to CMRs may apply. A similar approach has not been used when broadening the ELoC concept to include environmental effects, as in the case of PMT/vPvM assessment.

Unlike bioaccumulation, mobility criteria are not defined in REACH. Therefore, a scientific and policy discussion is needed to determine the PMT/vPvM criteria and under which conditions they may represent an ELoC to PBT/vPvB substances because of their adverse effects.

Furthermore, the concept of ELoC was subject to a European Court of Justice (ECJ) ruling (Case C 323/15 P) in which the Court defined two cumulative conditions for its application. First, it must be probable that the hazards arising from the substance's intrinsic properties have serious effects on human health or the environment. Second, there must be scientific evidence that these effects give rise to an ELoC to those of CMR, PBT or vPvB substances. Persistence and mobility relate to a substance's fate in the environment, and should not be confused with hazards. In line with the ECJ ruling, for substances with a well-documented low environmental and/or human toxicity, eligibility for SVHC status on the basis of persistent (P) and mobile (M) characteristics is therefore questionable. Moreover, any ELoC assessment should be scientific, and should include information on exposure and emissions, as is the case in a risk assessment. Failure to properly implement ELoC would create a precedent and result in legal uncertainty that could negatively impact many important substances for society and a large number of key sectors in the EU.

A more holistic approach

Specific directives are already in place in the EU to ensure ground- and drinking water protection. As it should be noted that the main sectoral substance regulations (pharmaceuticals, pesticides, biocides), require an environmental assessment, including for ground- and drinking water, as part of their substance authorisation process. This assessment takes into account substance properties, emissions and exposure data in water.

In contrast, the SVHC identification and REACH more generally is not designed to address concerns associated with the protection of ground- and/or drinking water. SVHC listings do not take emissions or exposure into consideration. REACH risk management measures are broader in scope therefore creating obligations that might not be specifically related to water protection. It could also lead to unnecessary bans or deselection of products from the market, and their uses, which could have unforeseen impacts on users and industry alike.

Conclusion

Such unnecessary regulatory activity is not aligned with the EU Better Regulation Agenda which aims for targeted regulation that goes no further than required to achieve the necessary objectives. Existing water legislation and other sectoral regulations should be viewed as the correct instruments for meeting protection goals, as they are in essence more effective and targeted in addressing water-related concerns. It should be highlighted that the Drinking Water Directive is currently going through revision in the European Parliament and Council, where the restriction of chemicals and other tools to address substances in drinking water is being discussed. In addition, the EU Water Framework Directive and related directives are currently subject to REFIT. This constitutes a propitious context for consideration of the PMT/vPvM assessment and is a more appropriate approach to address water-related concerns compared to REACH SVHC listings under ELoC for environmental concerns, the principles of which are currently not defined