

AmCham EU position on the Weight of Evidence

Calling for legal certainty surrounding the definition and a broader application of Weight of Evidence

Executive summary

AmCham EU calls for greater legal certainty regarding the definition of Weight of Evidence (WoE) as a key component of decision making in identification and risk management measures for chemicals in the EU.

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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 €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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Introduction

The American Chamber of Commerce to the EU (AmCham EU) takes the opportunity to contribute to the ongoing discussions on the Substances of very high concern (SVHC) roadmap implementation and related chemicals assessment developments and provide input into the debate on the role of Weight of Evidence (hereafter WoE) in identification and risk management measures for chemicals in the EU.

As an introductory remark, we fully support a science-based approach to legislation and were pleased to read the conclusions of the May 29-30 Competitiveness Council that reinforce the need for evidence-based regulations ‘by means of a robust impact assessment’.

AmCham EU would like to share the following comments related to the WoE approach:

- The WoE approach and its application within the EU regulatory environment has been a topic of discussion within The European Chemicals Agency (ECHA), the EU Scientific Committees, including EFSA; regulatory authorities outside Europe (e.g. US EPA) and the broader scientific community (e.g. ECETOC).
- ‘Weight of Evidence’ is a term often used in safety assessments to describe a risk-based approach to assess the likelihood of adverse effects having an impact on human health or the environment. The WoE approach is a framework which, rather than using a checklist approach of standard toxicological testing or numeric criteria, uses instead a tiered assessment strategy, incorporating many different types of safety data in an objective way to ensure all relevant information - including negative results and results that contradict one another - is available for consideration.
- Within the REACH legislation, the WoE approach is a component of the decision-making procedure on substance properties and thus an important part of the chemical safety assessment. In the texts, WoE can be used for the identification of substances and for the determination of risk management measures.
- Following ECHA guidance¹, the term ‘Weight of Evidence’ constitutes neither a scientifically well-defined term nor an agreed formalised concept characterised by defined tools and procedures.
- In the EU, formal procedures and consistent terminology for WoE processes are unfortunately lacking. Guidance on a WoE methodology by ECHA is still pending. This situation is particularly problematic in terms of legal certainty as several legal chemical legislation texts refer to WoE but are not correctly implemented given the lack of definition of WoE. We also understand that Member States do not feel confident in applying WoE given this gap. We find

¹ ECHA Practical Guide 2: How to report Weight of Evidence?, p. 2, See also Weed, Douglas, L., *Weight of Evidence: a Review of Concept and Methods*. *Risk Analysis*, Vol. 25, no° 6, pp. 1545-1557, December 2005.

that this is particularly the case in, for example, the implementation of Annex XIII of REACH for the Identification of PBTs and vPvBs in CLP, and we believe this will soon be the case for the assessment of endocrine disruptors.

- In our experience, today in Europe (see case study below) WoE is used only to confirm a classification, not to challenge a classification based on numeric values. This is an interpretation of the texts that we believe is not by the letter of the text and not appropriate, as it is not based on sound science.
- The issue of WoE also raises questions in the context of REACH's Substance Evaluation process. The different interpretations and expectations of how the WoE applies to a specific substance can lead to unnecessary disagreements between registrants and their evaluating Member State Authority (eMSCA.) In the case of suspected PBTs Annex XIII lays out how registrants should apply WoE to their substance. However, this does not bind eMSCAs in their evaluation of potential concerns. This disparity of understanding, in the absence of guidance, can lead to unreasonable or unnecessary requests for additional testing, or worse still, to unnecessary appeals of evaluation final decisions².
- One of the practical consequences of that situation is that under REACH and the SVHC roadmap agenda, many chemicals are likely to be classified against numeric values that do not reflect the reality of those chemicals' behaviour in the environment, meaning that they end up on candidate listing and therefore being de facto banned from the EU. This is of great concern given the importance of global trade in chemicals and the fact that this is strongly deviating from a risk-based approach to chemicals management that REACH is supposed to have. Additionally, classification against numerical values can discourage the generation of data to more accurately classify substances and ultimately could result in cases of under or over classification.

Case Study: Weight of Evidence in PBTs assessment REACH annex XIII

Annex XIII states that when a WoE approach is warranted, it should be conducted using expert judgment to compare all relevant and applicable data to the criteria for P, B, and T. Annex XIII also indicates that in a WoE determination "the quality and consistency of the data shall be given appropriate weight." The purpose of including WoE in Annex XIII is not to circumvent the established criteria for P, B, and T, nor to allow inclusion of low quality data. However, it is not yet clear exactly how WoE will be used in PBT determinations under Annex XIII. In fact, the European Chemical Agency's (ECHA) guidance on making PBT determinations now embraces WoE judgment without providing indications of how WoE should be employed. Therefore the WoE is not applied by Member States and ECHA in this context.

² For more on AmCham EU's position on how to improve REACH's Substance Evaluation Process please see XXX

AmCham EU requests

In light of all the above, we request that the Commission and ECHA take action to:

- Recognise the role of WoE for evaluation, identification of substances and for the definition of risk management measures.
- Clearly define what a WoE approach is and enshrine the definition in an ECHA guidance document.
- Ensure the WoE approach is applied by all Member States in their chemical safety assessment prioritisation exercises including evaluations for PBT/vPvB and endocrine.
- Ensure consistent application of the WoE approach throughout EU chemicals legislation (ECHA guidance, EU Scientific Committees) by clearly defining methods and procedures for applying the WoE approach in a guidance document.
- With regard to PBT/vPvB and ED assessment, ensure that regulatory decisions about chemicals that have potential PBT/vPvB /ED properties are based on risk-based WoE decision making that takes into consideration all available data, including that generated by industry, at the earliest stage of decision making, including evaluations of data reliability and relevance.