

Cefic reflections on the current process suggesting to identify Substances of Very High Concern (SVHC) based on their Equivalent Level of Concern (ELoC) to PBT/vPvB substances

This paper aims to share Cefic's general considerations on the process and approach proposed to identify SVHCs based on equivalent level of concern related to human and environmental effects, in order to protect ground and drinking water.

Beside other regulatory actions, an industry commitment exists already towards the protection of drinking water resources from chemical contamination.

SVHC identification is one route under REACH to target chemicals based on specific hazardous properties. However, considering the direct impact on the market, regulatory consequences, etc. SVHC identification should remain a case-by-case assessment based on well-defined criteria – which is currently not the case for the use of Article 57f addressing ELoC for environmental purposes.

1. Process transparency and predictability

In order to ensure **transparency and predictability** in the REACH process, all requirements needed to fulfil the identification assessment should be clearly identified and defined **before** any dossier development.

Art 57f of REACH allows the identification of SVHC, based on the Equivalent Level of Concern (ELoC) route. However, the way to determine this equivalence is open to interpretation.

For human health effects - with regard to the identification of sensitisers as ELoC - discussions with Member State Competent Authorities, the Commission and ECHA resulted in an ECHA authored paper in 2012 entitled "Identification of substances as SVHC due to equivalent level of concern to CMRs (Article 57f) – sensitisers as an example".

https://echa.europa.eu/documents/10162/13657/svhc_art_57f_sensitisers_en.pdf/a50728cc-6514-486c-9108-193a88b4bc9e

This discussion paper **elaborated on factors** to consider when assessing whether a substance with those properties could be identified as a sensitiser with ELoC to CMRs, was the outcome of a yearlong discussion in the RiME meeting (Risk Management Expert meeting), the CARACAL and the MSC (Member State Competent Authority meeting).

For the environmental effects, a similar approach, including stakeholder consultation, is **requested** to develop a number of key elements on the basis of which it may be determined, whether they may be regarded as giving rise to an "equivalent level of concern" to those of PBT/vPvB substances.

- ⇒ A policy paper doesn't exist yet for environmental effects. Currently, creating uncertainty in the approach proposed.
- ⇒ A paper should be developed and discussed together with stakeholders well before any application in Annex XV dossier proposal.

2. ELoC conditions to be fulfilled

In 2016, the European Court of Justice concluded in an appeal case (C-323/15P) that “In order for a substance to be classified as SVHC, REACH Art 57f requires that two conditions be fulfilled:

- There must be a scientific evidence of probable serious effects to human health or the environment and
- Those effects must give rise to an equivalent level of concern to those of other substances listed in point (a) to (e) of that article.”

Meaning “the condition relating to the serious effects to which the substances in question give rise is not sufficient for the substances in question to be identified as substances of very high concern. There must also be scientific evidence (such as exposure, emission, normal risk assessment, etc) that those serious effects give rise to an equivalent level of concern to CMR/PBT/vPvB listed in Article 57(a-e) of REACH”.

The hazard assessment as indicated in the guidance to prepare Annex XV dossier for ELoC to CMRs, should consider the seriousness of the effect, the irreversibility of the effect, the nature of the effect, the consequences for the society and the difficulty to perform concentration based risk assessment.

- ⇒ A list of parameters to consider should also be developed to prepare Annex XV dossier for ELoC to PBT/vPvB before an SVHC proposal is submitted.

The assessment should include

- The development of clear ELoC parameters to fulfil.
- A demonstration of the serious effect caused on human health and/or the environment by the substance
- A scientific evidence supporting that these serious effects provide equivalent level of concern to CMRs, PBT or vPvB substances.
- An assessment of the real exposure
- An assessment of the reversibility/irreversibility of the effect
- A thorough risk management option analysis (RMOA) based on all available information.

- ⇒ Defining intrinsic properties and criteria giving rise to the equivalent concern to PBT/vPvB require further scientific and regulatory discussion¹.

Once agreed, the set of criteria proposed for consideration to identify SVHC based on ELoC for environmental purposes should be combined. All available data should contribute to determine the hazard profile. Indeed, an isolated assessment doesn't provide information on potential exposure in an environmental compartment, nor does it inform on the type of and severity of adverse effects to humans nor to the environment.

¹ Cefic developed supporting material opening discussion on the proposed properties tabled so far by Authorities. This second document aims to trigger some ideas and feed into upcoming multi-stakeholder discussions on how an equivalent level of concern to PBT/vPvB could be best envisaged and demonstrated.

The ELoC approach should not be used as a last resort to ensure data gathering for further assessment, to address new groups of chemicals, or implement fast regulatory action.

- ⇒ Further discussion is needed to fine-tune the identification step and ensure implementation of effective risk management actions.

3. Conclusion

While sharing the ambition for safe ground- and drinking water, Cefic is of the opinion that applying a regulatory route without any agreement on the elements needed to fulfil the SVHC identification route based on ELoC for environmental purposes, is premature and may end up as using inadequately this regulatory route.

- ⇒ There is a request for more clarification and transparency in the process applied to propose a SVHC identification based on ELoC for environmental purposes, knowing that required information to support such identification has not been defined yet.

The European Chemical Industry Council remains ready and willing to discuss and share further ideas on the SVHC identification process based on Equivalent Level of Concern having serious effect to the environment.

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of 29,000 large, medium and small chemical companies in Europe, which provide 1.2 million jobs and account for 17% of world chemicals production.