

Human health; the practical challenges for petroleum UVCB substances

Online workshop on testing and assessment of petroleum UVCB substances

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disclaimer

- This presentation does not present a formal view of ECHA on the compliance of any Substance
- This presentation is informal, and not intended to present a definitive view on all of ECHA's positions
- Please consult the ECHA Guidance and website for definitive advice

Background

- Serious concerns
 - Potential for CMR properties
- Need for information on Substances
 - No data, no market !
 - Major ECHA goal
 - Opportunity for providing information to maximise benefits for hazard/ risk assessment

UVCBs

- Unknown, variable composition...
 - How to account for hazardous properties associated with unknown or variable composition ?
- Adaptations (grouping and read-across)
 - A prerequisite for read-across is the demonstration of structural similarity
 - For UVCBs, this requires characterisation of the composition
 - The basis for prediction of properties for read-across
 - Case-specific, but requires substantiation

Example hypothesis

- A generic approach for UVCBs
 - Structural similarity to predict similar properties in a category
 - Requires comprehensive information on composition
 - Requires substantial information on the properties
 - Testing proposals for higher-tier tests
- Note the requirement for information!
 - Insufficiency of supporting information can invalidate the read-across or increase the higher-tier testing required

Future developments

- “Structural similarity for UVCB substances shall be established on the basis of similarities in the structures of the constituents, together with the concentration of these constituents and variability in the concentration of these constituents. If it can be demonstrated that the identification of all individual constituents is not technically possible or impractical, the structural similarity may be demonstrated by other means, to enable a quantitative and qualitative comparison of the actual composition between substances.”
 - Having effect from ~January 2022

Involvement of Registrants

- ECHA's tools
 - Compliance check
 - ECHA requires all the missing information for every substance in a category
 - Testing proposal evaluation
 - ECHA can take account of testing strategies, for example with read-across in a category
- Registrants have the ability to propose adaptations and corresponding testing strategies

Thank you!

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