

Progress made with the evaluation of Petroleum Substances under REACH

A regulatory perspective

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Aims of REACH

- Ensure a high level of protection of human health and the environment
- Promote alternatives to animal testing
- Ensure the free circulation of substances on the internal market
- Enhance competitiveness and innovation



SVHC Roadmap



EU policy commitment

- **To have all relevant currently known SVHCs included in the Candidate List by 2020**
- The Commission, in consultation with the Member States and ECHA, finalised **the SVHC Roadmap** in March 2013
 - Actions needed to achieve this policy goal
- ECHA in co-operation with the Commission and Member States draw up the **Roadmap Implementation Plan** in November 2013
 - How to carry out the required actions

<http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern>

Substances addressed

Substances of very high concern (SVHC)

- **CMR:** carcinogenic, mutagenic or toxic for reproduction
 - Category 1A or 1B in accordance with the CLP Regulation (EC) 1272/2008
- **PBT, vPvB:** (very) persistent, (very) bioaccumulative and toxic for the environment (PBT or vPvB)
 - According to REACH (Annex XIII)
- **Equivalent level of concern:** identified on a case-by-case basis, cause an equivalent level of concern as with CMR or PBT/vPvB substances
 - e.g. endocrine disruptors, sensitisers

[Article 57 REACH]

Substances addressed

Special attention: Petroleum/coal stream substances

- These substances are **specifically mentioned** in the SVHC Roadmap
 - historically these groups were omitted during the further prioritisation exercises;
 - SVHC Roadmap highlights need to start working on regulatory risk management (RRM) for petroleum stream substances and coal stream substances.
- The main focus is the potential concern regarding human and environmental health due to their **CMR** and/or **PBT** properties.
- An **approach** how to prioritise these substances has been developed and agreed. PetCo now focusses on better understanding the hazard assessment and regulatory risk management possibilities for these substances

Petroleum substances of high concern - hazard?

- Because of the nature of the products, there is suspicion for CMR and/or PBT properties
- Assessing the CMR and PBT properties of petroleum substances is a challenging task
 - Complexity and variability of composition
 - Starting data-set is 'thin', specifically for environment and higher tier human health
 - New approach methods for hazard assessment are not ready (yet)
 - Many challenges that require scientifically sound (development) work

Petroleum substances of high concern - exposure?

- Initially focus on prioritisation of substances based on uses.
 - Consumer and professional use at highest priority ~ 50 substances
 - Medium priority industrial uses other than intermediate uses ~40 substances
 - Lower priority: intermediate and fuels uses only ~ 120

Progress made

- Use information was clarified leading to de-prioritisation.
- Analytical work has enhanced the understanding of the chemistry
- For Human Health, additional testing proposals have been submitted,
- For Environment, the block approach has been a good pragmatic starting point

Progress made ... but much more to come

- Use information was clarified leading to de-prioritisation. The information needs to be maintained, also in light of potential additional registrants
- Analytical work has enhanced the understanding of the chemistry, but more work is needed especially to ensure optimal testing, a solid implementation of the block approach and to substantiate read-across
- For Human Health, additional testing proposals have been submitted, but not with the density of testing we expect, and there are still quite some chemicals to work through
- For Environment, the block approach has been a good pragmatic starting point, but now that more data and information is on the table, substances will be under scrutiny. Some chemicals should already be handled as PBT because of the known PBT constituents above 0.1%

Sustainability

- Your substances are under attention:
 - Urgency because of possible CMR and PBT properties
 - Political willingness for action
- Your substances are difficult to assess:
 - Complex and variable chemistry and properties
 - The database needs to be expanded and use of (new) science needs to be discussed and used
- This work is also relevant in the future:
 - Although virgin fossil sourcing for fuels has an end,
 - some substitutes will have the same/similar challenges
 - current chemistry will continue to be used in other applications and
 - other uses might be developed
 - Data, information and knowledge now generated, can also be applied for generations to come

Need for collaboration

An open and constructive approach between industry and authorities is the most responsible way forward





Now this is not the end. It is not even the
beginning of the end. But it is, perhaps, the end
of the beginning.

(Winston Churchill)

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Thank you!

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