

The REACH End Game?

Risk Management for Petroleum Substances as REACH Evolves

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Outline

- Context
- Petroleum substances of very high concern?
- Moving forward

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





Some principles of REACH

- Industry responsible for safe manufacture and use:
 - Registration and dissemination for transparency;
 - Not an approval system.
- Deal with the 'burden of the past' with a systemic program for registration of old chemicals
 - Get adequate information on hazards while minimising the unnecessary use of experimental animals;
 - Risk management at company level by supply chain communication;
 - Risk management at European level by regulatory means.

$$\text{Risk} = \text{Hazard} * \text{Exposure}$$

Concawe's role in Registration

- Concawe
 - Supported companies in the successful registration of ~ 4000 dossiers representing ~200 substances;
 - Coordinated a number of actions to improve the quality of the information (e.g. intermediate use information and substance identity);
 - Keeps the 'master dossiers' up to date;
 - Has multiple programs to further develop and improve the information in the dossiers and the information that needs to be communicated through the supply chain.

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 (1/3)

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 (2/3)

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;
 - ECHA recognises the differences in markets and chemistry between coal and petroleum 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 address these substances to be **established by 2015**, to be able to **start identifying substances from 2016** onwards -> **PETCO Working Group**

Substances addressed (3/3)

What makes an SVHC 'relevant'?

- High priority substances
 - Being registered, i.e. used in the EU
 - Having uses within the scope of authorisation (common screening talks more about within the scope of regulatory action under REACH/CLP)
- Lower priority to those substances only registered as intermediate or fuel

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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 in for environment and higher tier human health
 - New approach methods for hazard assessment are not ready (yet)
 - Many challenges that require scientific sound (development) work

Petroleum substances of high concern - exposure?

- Initially focus on a 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

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Next steps

- Short term (2017-2018):
 - Member states will work on a small number high priority substances to analyse whether further generation of data is needed before analysing possible Risk Management Options
 - Concawe will submit updated dossiers with improved use information and clarification of compositions
- Mid term (2017-2019):
 - Based on new compositional information Concawe committed to review the hazard assessment and risk assessment where relevant
 - Inclusion of new approach toxicology information to revise and strengthen the approaches taken
 - Further utilisation of non-standard analytical techniques
 - Testing proposals to be done where needed
- Long term (2019 and beyond):
 - Concawe to keep dossiers up to date and integrate new information and new science
 - Further regulatory work by authorities on substances of priority

Need for collaboration

- Your substances are under attention:
 - Urgency because of possible CMR and PBT properties
 - Political willingness (need?) 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 extended
- This work is also relevant in the future:
 - Although fossil sourcing has an end, substitutes will have the same/similar challenges
 - Data, information and knowledge now generated, can also be applied for generations to come

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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