Petroleum substances from a regulatory perspective

Feedback from ECHA and outlook

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ECHA key facts

- Started on 1 June 2007
- 600 staff from 27 countries

- Originally REACH
- Since 2009 Classification and Labelling
- Now also Biocides and Prior Informed Consent

Implementing European chemicals legislation

- **REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals – 2007**
- **CLP – Classification, Labelling and Packaging – 2009**
- **BPR** – Biocidal Products Regulation – 2013
- **PIC** – Prior Informed Consent – 2014

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.

Risk = Hazard * Exposure

R for Registration and Responsibility

- Responsibility for the management of the risks of substances lies with industry;
- Registration provisions requires industry to collect and generate data (where needed);
- Risks related to these substances should be assed by industry
- Appropriate risk management measures should be developed by industry and communicated to users;
- To ensure that industry meet these obligations in a transparent manner, industry is required to submit a dossier containing all this information to the Agency;
- Most of the information in the dossier is published on ECHA's website (non-confidential part);
- Registered substances are allowed to circulate on the internal market.

Concawe's role in Registration

- Concawe
  - Supported companies in the successful registration of ~ 4000 dossiers representing 200-300 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.

Classification and labelling

- Classification and labelling is the first step to define the hazards of chemical substances and mixtures to facilitate safety
  - Downstream consequences: e.g. no carcinogenic chemicals as such or in mixtures provided to consumers

- CLP Regulation
  - Implementation of agreed UN-wide system
  - Transitional period 2010-2015: both classification systems used
  - Harmonised classifications in Annex VI

Risk management: restrictions

- When unacceptable risks to humans or the environment have been identified;
- Member State competent authorities can submit dossiers proposing restrictions (or European Commission instructing ECHA);
- European Commission Decision based on an ECHA Opinion;
- Annex XVII of REACH lists all restrictions.

Risk management: authorisation

- Substances of very high concern (SVHCs): CMRs, PBT/vPvB or 'equivalent concern';
- Identification by Member States (or European Commission instructing ECHA) onto the 'Candidate List';
- Some transferred onto the 'Authorisation List' , Annex XIV;
- Once on the Authorisation List, the substance can only be marketed or used after 'sunset date' if authorised by the European Commission. It decides based on an ECHA opinion.

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

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
  - so far these groups have been omitted from screening 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.

Substances addressed (3/3)

What makes an SVHC 'relevant'?

- The substance is registered, i.e. used in the EU;
- Uses are within the scope of authorisation;
  - e.g. low priority if only registered as intermediate or fuel;
- Risks are already known → start restriction process;
- Uses are not already regulated by specific EU legislation that provides a (similar) pressure for substitution (as authorisation).

Screening: to identify substances of concern

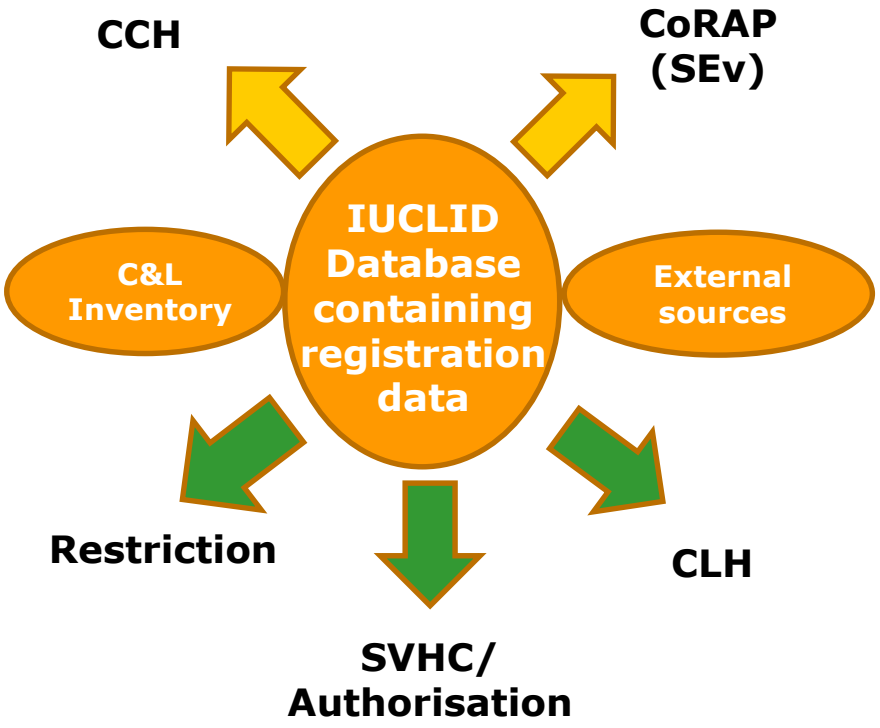
- Use of all available data
- Allocate identified substances to the appropriate process:

Further information generations

- Substance evaluation (SEv)
- Compliance check (CCH)

Regulatory risk management

- Harmonised classification and labelling (CLH)
- Identification of SVHCs (possibly leading to Authorisation)
- Restriction



Analysis of Petroleum substances so far

- Difficult to assess petroleum substances in a similar way as other registered substances:
  - Registration data does not allow to conclude whether and what **volume** of the registered substance is in the scope of authorisation (intermediate and fuel volumes not known) and the type of **uses** in the scope of authorisation;
  - Substances are registered with **unspecific Substance Identification** information, making it difficult to identify the actual constituents that make the substance of concern;
  - The information on the **hazard profile** of the substance is aggregated in such a way, that it's difficult to understand which substance in the category has which hazard profile.

Analysis of Petroleum substances

- Observations so far:
  - Most (if not all products) are of potential concern
    - Unclear hazard (CMR, PBT);
    - Unclear use (potential exposure).

- Work ongoing by ECHA and Member States
  - ECHA is analysing these substances in a more systematic way;
    - Including developing methods for (de-)prioritisation based on use/potential exposure;
  - Provide a starting point for the further work on these substances under the SVHC Roadmap.

- Some Member States are already analysing other ways of addressing constituents of concern, e.g. PBT and/or CMR impurities.

Next steps for ECHA and Member States

- To finalise ongoing ECHA project by Q1 2015
  - Analyse the difficulties to be overcome to make practical; progress for (a group of) petroleum substances,
  - Prioritise which difficulties to tackle first ;
  - to extent possible consider the use/tonnage data provided by companies.
- The report will serve as (one of) starting point(s) for the "PetCo co-ordination group" (CG) to establish a systematic approach to assess petroleum substances.
- To set up PetCo CG together with Member States,
  - the first meeting involving stakeholders foreseen in Q2 /Q3;
  - invitation to nominate participants (probably April).

Suggested next steps for industry

- Further collaborate with Concawe in providing relevant use information;
  - Use information was identified as a realistic mechanism for prioritisation in a short term in meeting between Concawe and ECHA in February 2015;
  - Enables to focus activities on substances that (might) matter.

- Further assess the substances for presence of:
  - CMR substances (full Annex VI list).
  - PBT substances.

- Concawe is an important discussion partner for ECHA and Member States for this activity.

Thank you!

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