Inneke Claes
REACH Advocacy Manager

Maintaining REACH registrations up-to-date: The petroleum industry's approach



Overview



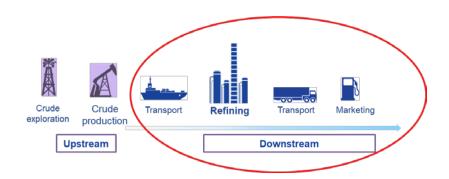
European Petroleum Refiners Association

Concawe

Carries out research on environmental, health and safety issues relevant to the oil industry

FuelsEurope

Represents with the EU Institutions the interests of companies conducting refinery operations in the EU



FuelsEurope represents 40 Member Companies ≈ 100% of EU Refining







Our REACH journey since 2010

- 2010: Completed registration phase, dossier assembly and submission
- 2019: Concawe (consortium and SIEF manager) in charge of 184 registered petroleum substances with in total 4500 registrations

Since 2010, Concawe **kept registration dossiers up-to-date**. Examples:

- Together with authorities and companies, help to address significant challenges in regulatory assessment of highly complex (petroleum) UVCB substances
 - Development/optimisation of Concawe strategies and methods (Petrorisk, Petrotox, Cat App)
 - Extensive analytical, human health and environmental work programs, incl. guideline testing
 - **Transparency**: Results discussed in scientific fora and with legislators, published in peer reviewed journals and other public channels
- Generated data submitted into dossiers updates
- Dossier clean up

Since 2016, systematic yearly update program of dossiers for 31 March

- Updated information from co-registrants (tonnages, uses) by 30 November (Y-1)
- Other new information from work programs and following dossier evaluations

Moving to **evaluation phase**: addressing ECHA/MSCA challenges on our dossiers and data





Going forward - Concawe REACH strategy

Consensus on aligned way forward will help both authorities and industry to facilitate the regulatory assessment of petroleum UVCBs at a relatively short timeframe, lowest cost for industry (competitiveness & minimizing animal testing) while not underestimating hazard and risks (i.e., addressing all 3 aims of REACH)



Underpin Hazard and Risk assessments



Current and future activities

Development and optimisation of Concawe REACH strategies to address the significant challenges in the regulatory assessment of highly complex (petroleum) UVCB substances

- Address "Dual UVCB REACH Challenge" together with authorities
 - Deviations from standard information requirements (analytical, human health and environment)
 - Are practically necessary
 - Need to be pragmatic
 - And in consensus between authorities and industry
 - Read-across and categories
 - Rationalise number of registered substances
- Methodologies agreed with authorities
 - Provide certainty for industry
 - Minimise animal tests and complete dossiers faster across all petroleum substances
 - Allow to move forward with regulatory assessment of petroleum substances

Some other topics

- Implementing regulation mandatory dossier updates
- Poison centre notifications FuelsEurope

More information

- REACH Roadmap for Petroleum Substances 2019 update
 - An informed REACH strategy will shorten the time and reduce cost to fully assess all petroleum substances. It will also significantly minimise the use of laboratory animals, by developing and applying alternative methods for a more sustainable approach to toxicology testing.
 - https://www.concawe.eu/publication/reach-roadmap-petroleum-substances/
- Cat App
 - New Technologies to Underpin Category Approaches and Read-across in Regulatory Programmes
 - https://www.concawe.eu/cat-app/
- Petrotox
 - A spreadsheet model developed by Concawe designed to calculate the toxicity of petroleum products to aquatic organisms
 - https://www.concawe.eu/reach/petrotox/
- Petrorisk
 - A spreadsheet tool, developed by Hydroqual for Concawe, that performs environmental risk assessments for petroleum substances using principles provided by the European Chemical Agency (ECHA) for fulfilling stakeholder obligations under the EU REACH regulation.
 - https://www.concawe.eu/reach/petrorisk/



THANK YOU FOR YOUR ATTENTION

This document was presented by Inneke Claes

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