

Meeting with



DG GROW

*11 June 2020*

# The European petroleum refiners approach to safe use of substances

# Overview

Who are we?

Scope of the meeting

Petroleum products and REACH – Some numbers

Specifics of petroleum substances: Regulatory challenges

Substance identity for petroleum substances – UVCBs

Intelligent testing strategies for petroleum substances

PBT assessment for petroleum substances

Cocktail effect

Upcoming Commission initiatives



# European Petroleum Refiners Association

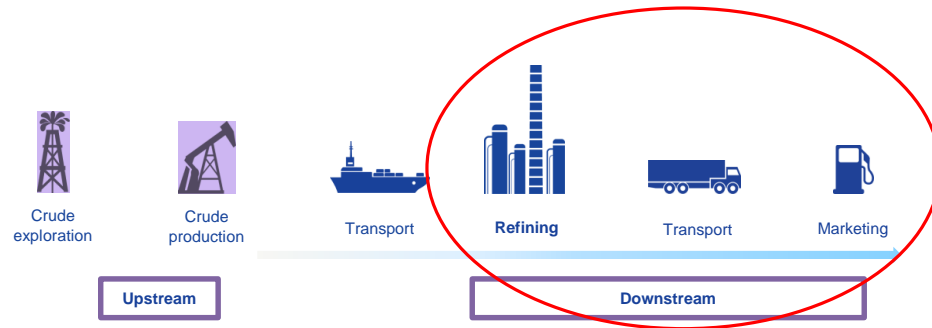
## Concawe

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

European Petroleum Refiners Association represents 40 Member Companies  
≈ 100% of EU Refining



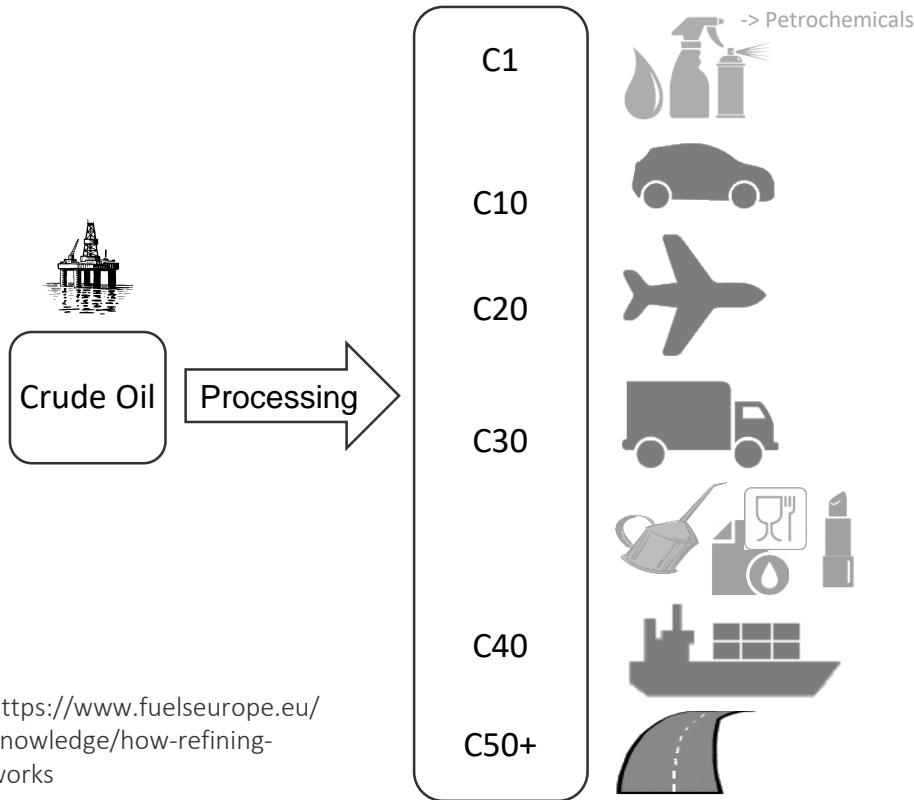
# Scope of the meeting

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## Policy guidance to find solutions for:

- Overcoming difficulties in regulating petroleum substance UVCBs
- Practically applicable experimental methods and pragmatic approaches to testing and assessments
- Interpretation of REACH legal text: moving from a hazard based to a risk based approach

# Petroleum substances and REACH – Some numbers



- Around 180 registered petroleum substances across 20 categories
- **Thousands to millions of molecules (isomers) per petroleum substance**
- **UVCB**
  - Unknown or
  - Variable composition,
  - Complex reaction products,
  - Biological materials
- About 4,500 registrations
- Yearly cycle of comprehensive dossier updates

<https://www.fuelseurope.eu/knowledge/how-refining-works>

# Specifics of petroleum substances: Regulatory challenges

## Petroleum Substances are UVCBs

- **Unknown** or
- **Variable** composition,
- **Complex** reaction products,
- **Biological** materials

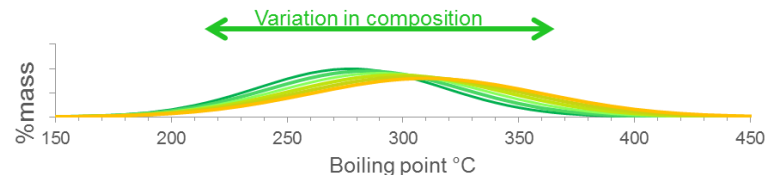
- The chemical composition of petroleum UVCBs can never be fully characterized analytically

C number	Boiling point °C (n-alkanes) (*)	Number of isomers (alkanes only!)
3	-42	1
4	-1	2
5	36	3
6	69	5
7	98	9
8	126	18
10	174	75
15	269	4 347
20	343	366 231
25	402	36 777 419
30	450	4 108 221 447
35	490	493 054 243 760
40	525	62 353 826 654 563

## Petroleum Substances are UVCBs

- **Unknown** or
- **Variable** composition,
- **Complex** reaction products,
- **Biological** materials

- Variability is limited to meet product specification



# Substance identity for petroleum substances – UVCBs

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- Main challenge: balance level of detail in knowledge and of remaining uncertainty in the compositional description of petroleum UVCBs which is acceptable to regulator
- Analytical data are required to
  - Determine substance identity and prove similarity
  - Support for health and environment hazard assessment
- Regulators and industry joining forces for optimal solutions
  - Develop chemical universe for petroleum substances  
but what is acceptable level of uncertainty for regulator?



# Intelligent testing strategies for petroleum substances

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- Fulfilling information requirements for petroleum substance UVCBs by using intelligent testing strategies
- Grouping and read-across for UVCBs is a challenge recognised by scientific community and regulatory authorities
- Objective: Joining forces to find synthesis between ECHA's drive for complete data sets and industry's request for proportionality
  - Avoiding unnecessary tests on vertebrate animals
  - Use all available information to support read-across, including historical data
  - Support grouping and read across assessments with non-animal based biological data, such as Cat-App (<https://www.concawe.eu/cat-app/>)
  - Optimise the time needed to generate new data to fulfil endpoint requirements
- Risk-based approach rather than pure hazard driven data generation





# PBT assessment for petroleum substances

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- No clear and agreed regulatory framework for PBT assessment
  - Only general criteria
  - Standard tests for persistence (P) and bio-accumulation (B) do not work for petroleum UVCBs nor for their constituents (practical issues with volatility, solubility)
  - Regulators' and industry's efforts to jointly develop adapted PBT assessment methods have so far been unsuccessful
- Need for an accepted method for PBT assessment providing legal certainty
- Regulators and industry joining forces for optimal solutions
  - Develop modified methods fit for purpose for P and B assessment for complex petroleum substances
  - Update PBT assessments with (new) modelling and (new) experimental data



# Cocktail effect

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- Addressing the risks of exposure to unintended combinations of chemicals
  - Issue
    - *Not feasible to map out and test all unintended combinations*
    - *No science-based solution for risk assessment available*
  - JRC still carrying out systematic review of the available scientific literature
  - Industry risk assessment is already highly conservative
  - Industry concern: proposed solution of one precautionary “Mixture Assessment Factor” is not proportionate and too generic
- Regulators and industry joining forces for optimal solutions
  - Base regulatory decisions on sound science, adopting a pragmatic and proportionate approach
  - Case-by-case risk-based approach which takes real-life exposure into account early in the process



# Upcoming Commission initiatives

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- Which are the Commission's points of focus for
  - Chemicals Strategy for Sustainability as part of the Zero Pollution Ambition for a Toxic-Free Environment and European Green Deal
  - REACH Review 2022
- How can we contribute early on?



THANK YOU FOR  
YOUR ATTENTION

## Contact

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