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REACH
Roadmap for Petroleum Substances
The REACH Regulation

What is REACH?

REACH is the European Regulation (EC) No 1907/2006, on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

The REACH Regulation was adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the European Union (EU) chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals\(^1\).

How is REACH Evaluation progressing?

Initial registrations for substances manufactured or imported in the EU were made on time to meet three deadlines (2010, 2013 and 2018). As the Registration phase is now complete, the Evaluation phase of REACH gathers momentum. This phase is likely to carry on through the 2020s.

1: Source: ECHA
2: Source: European Commission DG GROW
The submitted registration dossiers may be subjected to compliance checks by the European Chemicals Agency (ECHA).

- Compliance checks are to ensure that the information required is sufficient for the regulators to properly evaluate the substance and its uses. Should regulators identify that there are gaps in the information, registrants are given notice and a deadline to generate the missing information and submit updated dossiers.

- ECHA also evaluates any testing proposals included in the registration dossiers to confirm the proposed studies will effectively generate sufficient data for the assessment of the substance. ECHA will also check that the studies will not result in unnecessary vertebrate animal testing.

Once ECHA have completed compliance checks, local competent authorities (Member States) may select substances for substance evaluation. One of the objectives of evaluation is to identify Substances of Very High Concern (SVHCs).
Substances of Very High Concern (SVHCs)

An objective of REACH is to drive innovation by the industry in order to develop acceptable risk management measures or substitute substances that pose a high risk to human health or to the environment with safer alternatives.

Properties of SVHCs

**Human Health hazard**

- CMR Carcinogenic, Mutagenic or Toxic for Reproduction
- ED Endocrine Disruptive

**Environmental hazard**

- ELoC Equivalent Level of Concern
- PBT Persistent, Bioaccumulative and Toxic
- vPvB very Persistent and very Bioaccumulative

To expedite this objective, the European Commission developed the SVHC Roadmap to 2020. The goal of the roadmap is “to identify all known SVHCs and add these to the Candidate List for authorisation”.

The SVHC Roadmap lists groups of substances to be covered by ECHA’s SVHC implementation plan.
Risk management measures are deemed sufficient.

Confirmed SVHCs may be included in the Candidate List and then in the Authorisation List (Annex XIV), if risk is not deemed to be properly managed. Substances on the Authorisation List cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

Manufacturers, importers or downstream users of a substance on the Authorisation List can apply for authorisation. Authorisations have been granted for a defined period (5, 10 or 12 years) after which a new application will be required. Manufacturers/users are required to use this time to develop safer alternatives which will eventually substitute for the authorised substance.
Restrictions may limit or ban the manufacture, placing on the market or use of a substance. A restriction applies to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports.

A Member State, or ECHA on request of the European Commission, can propose restrictions if they find that the risks need to be addressed on a Union wide basis. ECHA can also propose a restriction on articles containing substances that are in the Authorisation list.

A harmonised classification is agreed at the Community level and is included in Annex VI of the Classification, Labelling and Packaging (CLP) regulation. Any Member State can propose a harmonised classification and labelling.
Using 2013 as the reference year, petroleum substances were registered for REACH with a total of 971 million tonnes manufactured or imported into the EU. This figure rose by just under 6% to 1027 million tonnes in 2018.

**Note:** Widespread uses are professional and consumer uses (and those in articles). Industrial uses are in scope of the SVHC roadmap, but the current view of ECHA is that appropriate risk management measures are correctly applied in industry.
**PetCo Working Group**

In 2016, ECHA formed the Petroleum and Coal Stream Substances Working Group (PetCo WG) with representatives from ECHA, European Commission, Member States and industry stakeholders including Concawe, with a mandate to develop the approach for assessment of petroleum substances for potential SVHC status.

Petroleum and coal substances with SVHC properties are specifically mentioned in the SVHC Roadmap 2020 due to their complexity, variability and the high volumes involved.

The SVHC roadmap agreed highest priority should be given to screening petroleum substances with widespread (professional and consumer) uses for SVHC properties. Petroleum substances which are only used as a fuel or as an intermediate or for industrial uses were assigned a lower priority and it was confirmed that substances which only had fuels uses were outside the scope for authorisation.

In 2017, PetCo WG agreed a new mandate for the prioritisation of substances and coordination of assessment activities. This focuses on the 44 petroleum substances with widespread uses and a total volume of 21.5 million tonnes (2013 basis, see figure in page 11). The categories with the highest volumes of widespread (mainly professional) uses include: bitumens and lubricant base oils.

**Petroleum substances are UVCBs**

The REACH regulation is relatively straightforward for single chemical substances such as Sulfur and some of the mono-constituent petroleum gases. However, most petroleum substances and many other natural products have multiple constituents. Petroleum substances are archetypal UVCBs or substances of Unknown or Variable composition, Complex reaction products or Biological materials.

The biggest challenge in applying REACH to petroleum substances is to account for their UVCB nature. The complexity of UVCB substances means it is impossible to determine the precise chemical composition to the level of each constituent. The variability in detailed composition and the large number of constituents which could reach over a million molecules makes it difficult to represent the composition of petroleum substances at such a detailed level. For many applications of petroleum products, a detailed chemical composition is not necessary, because industry practice is to manufacture and market petroleum substances according to physico-chemical parameters specified in European Standards. Different samples from the same process in a refinery will show some variability in detailed composition, whilst still remaining within the specifications that identify the substance.

**Substance sameness and read-across**

Very few of the 185 petroleum substances registered under REACH have a complete data set generated for the individual substance.

ECHA criticised the petroleum substance dossiers for the lack of detail on chemical composition necessary to prove registrants have registered the same substance and therefore data collected on one sample from one registrant can apply to all registrants of the same substance and also to closely related substances.

In the initial registration process, read-across of data from one substance, where the data was measured or experimentally derived, to related substances was used widely for petroleum substances. Given that many petroleum substances are chemically similar this was considered to be fully justified.

However, in their testing proposal evaluations, ECHA challenged the read-across assumptions made at the time the substances were registered. Additional data is needed to describe the substance sameness in more detail to justify application of the current available hazard data between related petroleum substances.
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.

**Concawe REACH Roadmap**

**FULL TESTING OF 185 PETROLEUM SUBSTANCES**

- Reduce number of petroleum substances for full evaluation
- Reduce average cost per substance
- Agree an acceptable timeline with ECHA & Member States
- Focus testing
  - Overall Concawe testing strategy
- Recover the fair share of costs from all registrants of petroleum substances

**Estimation**

- €600 million
- 1 million
The goal of the Concawe REACH roadmap, as shown in the overview on page 13, is to prioritise petroleum substances for which further work is really needed to inform proper (regulatory) assessment. The roadmap has a holistic approach which allows assessment of all petroleum substances to be more effective in time and cost, and better for animal welfare, while not underestimating potential risks to human health and the environment.

**The Concawe REACH roadmap aims to:**

**Reduce number of petroleum substances for full evaluation**
- rationalising uses of petroleum substances
- prioritising petroleum substances with widespread uses for further assessment

**Reduce average costs per substance**
- data gap analysis, validation of historical data and justifying read-across
- demonstrating similarity within and between petroleum substances
- using experimental design methods to get the most value out of each project to generate data
- refining our environmental assessments with improved models and new experimental data

**Minimise animal testing**
- developing alternative approaches to reduce the number of animal tests that would otherwise be required and allow us to account for the inherent variability in petroleum substances
- in the longer term future, this should lead to a more sustainable approach for toxicological assessment of petroleum substances

**Agree an acceptable timeline with ECHA and Member States**
- depending on number of required animal tests proposed only as a last resort (i.e., in case of a clear data gap when read-across is not possible) and acceptance of a tiered testing approach

**Recover the fair share of costs from all registrants of petroleum substances**
- This is consistent with the requirement in REACH, allowing registrants for the same substance to share information and costs of registration and further work to fill in data gaps in their substance dossiers via “SIEFs” or Substance Information Exchange Fora

**SIEFs (Substance Information Exchange Fora)**

During the registration phase, Concawe had a formal role as the SIEF Formation Facilitator for all registered petroleum substances and is now managing the evaluation phase on behalf of the SIEFs participants. The SIEFs allow for data generated for REACH (by Concawe or one or more of the registrants) to be shared amongst all registrants of the same substance, thus avoiding duplication of effort. The Commission implementing regulation on data sharing ((EU) 2016/9) allows a fair share of the cost incurred in generating data for REACH to be shared amongst co-registrants (post-SIEF). Currently, there are around 4,500 active registrations of petroleum substances.

The Concawe roadmap aims to limit the number of petroleum substances that require a full evaluation to reduce the average cost.
**REACH five-year plan 2019-2023**

Each year Concawe updates the REACH five-year plan, reflecting the progress made as well as formal and informal communications with the regulatory authorities.

In addition, Concawe updates the dossiers at least annually as new information frequently becomes available. Most relevant information is obtained from ongoing work in the Concawe project portfolio.

**Project portfolio**

The Concawe REACH strategy is implemented through individual projects included in the five-year plan. Major scientific projects are developing the information required for full evaluation.

**HUMAN HEALTH**

For the 2010 REACH registration deadline, the Concawe dossiers were completed with all available toxicological information on petroleum substances. Specific endpoint requirements were either fulfilled with actual data on the substance itself, or by application of so called “read-across” to relevant data on related substances. A thorough data gap analysis then identified the need for the generation of new data on the reproductive toxicity endpoint for six Concawe petroleum product categories, where no historical data was available and read-across not applicable.

Reproductive toxicity data is a standard requirement in REACH, comprising of two endpoints namely i) Pre-Natal Development Toxicity (PNNDT) and, ii) fertility (Extended One-Generation Reproductive Toxicity Study (EOGRST)). Permission from ECHA is required before a higher-tier\(^1\) guideline toxicity test in vertebrate animals can be conducted. In 2010 registrations, Concawe submitted testing proposals to conduct two PNNDT and six EOGRTS studies covering the identified data gaps in these six categories.

One representative worst case test sample will be tested as the most relevant representative substance per category.

A multi-year research project was initiated to further underpin the read-across of data coming out of these reprotox tests to the related remaining substances in the tested petroleum categories, in order to prevent additional unnecessary animal testing on these related substances. The current read-across argumentation in the testing proposals was accepted by ECHA only provided that the underlying testing hypothesis, which states that reproductive toxicity is related to the level of 3-7 ring polycyclic aromatic hydrocarbons (PAH) in these petroleum substances, is proven. The research project focuses on a battery of in-vitro assays (i.e., alternative method, such as cellular or tissue based, instead of full animal based assay) to test this reproductive toxicity hypothesis. Although the project is still ongoing at the time of writing this document (early 2019), the already available in-vitro data so far strongly support the above mentioned hypothesis and help prove that further animal testing for this endpoint on these substances is not necessary.

Apart from the current focus on the reproductive toxicity endpoints, more recent re-evaluation of the Concawe dossiers indicated that some further testing will need to be done to address endpoints in categories where the currently available data or read-across argumentation is not sufficiently robust. This is part of the overall REACH strategy for human health, which consists of limited lower- and higher tier animal testing (an informed strategy to testing is applied to prevent unnecessary animal use) as well as the development and application of in-vitro alternative approaches.

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1: Higher tier” refers to the more complex toxicological endpoints (repeated dose / systemic tox, carcinogenicity and reprotox) for which standard OECD guideline testing is needed to fulfill the information requirements. These tests are considered more “delicate” in terms of animal welfare (high number of laboratory animals needed, and often immoral animal exposure conditions), and are generally labour intensive and costly to perform.
At the basis of this strategy is the Cat-App project, which was initiated to address the challenges with read-across of data on UVCBs (current read-across approaches are not applicable to these highly complex substances, as acknowledged by ECHA) in order to eventually minimise the need for testing in vertebrate animals for all hazard endpoints by grouping petroleum substances based on chemical-biological properties, and hence make best use of the already available data within this group.

- This project will improve our understanding of the relationship between chemical composition and biological response of petroleum substances and how this is similar or different between the various petroleum substance groups. The Cat-App framework will allow a scientifically sound justification for read-across approaches of UVCB substances.

- A prerequisite to the overall approach for human health is that the available historical animal test data are accepted by ECHA. Several efforts are underway to provide further evidence of the quality, relevance and applicability of these data. Eventually, the outcome of this, in combination with the rationalisation exercise and the acceptance and application of the Cat-App framework, will define Concawe’s proposed focused tiered testing approach which will only recommend additional testing in vertebrate animals where needed as a last resort while not underestimating potential human health hazards.

- Cat-App is expected to deliver its framework for application under REACH by the end of first quarter 2019, and necessary follow up work for successful implementation is planned.

- Progress can be monitored on the Concawe website: (https://www.concawe.eu/cat-app/)
ENVIROMENT

REACH requires two types of environmental assessments:

- An environmental risk assessment to determine whether the specific uses of a substance can be considered safe for the environment.
- An assessment of whether the substance fulfils the criteria of PBT or vPvB.

Due to the complex nature of petroleum substances, the hydrocarbon block method was developed by Concawe to evaluate the behaviour of these substances when released into the environment. This method divides a petroleum substance into blocks of related constituents on the basis of chemical classes (e.g. n-paraffins, iso-paraffins, naphthenics, and aromatics) and carbon number distribution. The fate and effects of these blocks can then be modelled to assess the environmental risks posed by a substance and its uses. This environmental risk assessment is performed using a tool known as Petrorisk.

In addition to the risk assessment which is conducted using Petrorisk, Concawe has compiled experimental ecotoxicity data for petroleum substances in the registration dossiers which are used for purposes of the REACH information requirements for specific hazard endpoints and for classification and labelling. Concawe has also developed Petrotox, a model which simulates aquatic toxicity testing of petroleum substances based on compositional information using similar principles to Petrorisk. A further technique that has been developed is biomimetic extraction which simulates the uptake of hydrocarbons by organisms and can be used to predict toxicity. Petrotox and biomimetic extraction are powerful screening tools that can be used to support read-across of ecotoxicity data and underpin petroleum substance categories.

Substances meeting the criteria of PBT or vPvB are priority substances under REACH. The PBT/vPvB assessment must consider all relevant constituents and impurities of a substance composition. This poses a significant challenge for UVCBs, which contain a large number of constituents. Concawe’s PBT/vPvB assessment is based on hydrocarbon blocks and utilises a combination of experimental data for individual hydrocarbons and model data for a library of 16,000 representative constituents. This assessment is documented in the Concawe PBT report, which is undergoing its third revision following a review in 2017 by EU Member State Competent Authorities (MSCAs). A new version of the report will be published in 2019.

In addition to updating the PBT report, Concawe is running a number of research projects to generate further experimental data to support the assessment. These include novel approaches to measure the biodegradation of hydrocarbons in water, soils and sediments, investigating the influence of temperature on biodegradation and testing the ecotoxicity of key constituents of interest.

As part of the activities of the PetCo Working Group, Concawe continues to engage collaboratively with ECHA and MSCAs to address concerns about the PBT/vPvB assessment of petroleum substances and to agree an overall approach. As part of this, in 2018 Concawe hosted a seminar on the GCxGC technique, which is used to characterise petroleum substance composition, and a workshop on recent developments in science supportive to the persistence/biodegradation assessment.
Hierarchy of Risks

LICENCE TO OPERATE

LICENCE TO MANUFACTURE / IMPORT

LICENCE TO PLACE ON THE MARKET

INCREASE DATA REQUIREMENTS

INCREASE ADMINISTRATION

INCREASE PRODUCT STEWARDSHIP

Interplay with other legislations (Occupational Exposure Limit (OEL), waste)

Introduction of very strict measures

Authorisation or Restriction

Substances of Very High Concern Candidate List

More data/testing required to pass evaluations

Generate data to fill information gaps

Likelihood of occurrence

Impact

LOW

MEDIUM

HIGH

Keys

1° Risk

2° Risk
Concawe programmes together with FuelsEurope advocacy are in place to mitigate most of the risks, such as central management of the additional data generation and testing maintaining the fuels exemption and work.

However, there remains a significant requirement for maintaining an effective REACH capability within member companies. As an example, refiners need to consider when a change in refining process or in product specifications or contents is sufficient enough to require a registration update.

<table>
<thead>
<tr>
<th>RISKS</th>
<th>MITIGATION</th>
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<tbody>
<tr>
<td><strong>Interplay with other legislation (OEL, waste)</strong></td>
<td>• Active participation by industry with advocacy support</td>
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<tr>
<td>&gt; Authorisation</td>
<td>• Rationalise uses of petroleum substance, so that no CMR petroleum</td>
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<tr>
<td></td>
<td>substances are in widespread use</td>
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<tr>
<td>&gt; Restriction</td>
<td>• Provide alternative safer petroleum substances</td>
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<tr>
<td></td>
<td>• For any petroleum substance classified as PBT, understand consequences,</td>
</tr>
<tr>
<td></td>
<td>“minimise emissions”</td>
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<tr>
<td></td>
<td>• Programme to provide basic PBT and CMR data for petroleum substance</td>
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<tr>
<td></td>
<td>that are data poor</td>
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<tr>
<td></td>
<td>• Verify and modify PETROTOX and PETRORISK models as necessary</td>
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<tr>
<td><strong>Evaluation of dossiers require more data/testing</strong></td>
<td>• Read-across scientific justification</td>
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<td></td>
<td>• Cat-App to underpin grouping and eventually read-across assessments</td>
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<td></td>
<td>with the aim to avoid unnecessary animal testing</td>
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<td></td>
<td>• A battery of in-vitro assays to reduce requirement for additional</td>
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<td></td>
<td>(animal based) reproductive and prenatal development toxicity tests</td>
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<td></td>
<td>• ECHA WGs participation: e.g. work via PetCo, to justify and improve</td>
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<td></td>
<td>read-across</td>
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The European Commission plays an important role in ensuring the implementation of the REACH Regulation. It also adopts measures to update and complete the Regulation. These measures comprise authorisation decisions; new restrictions to deal with unacceptable risks of particular chemicals; laying down test methods; and determining the fees companies pay to the ECHA.

### The Key Players

#### European Commission

The European Commission plays an important role in ensuring the implementation of the REACH Regulation. It also adopts measures to update and complete the Regulation. These measures comprise authorisation decisions; new restrictions to deal with unacceptable risks of particular chemicals; laying down test methods; and determining the fees companies pay to the ECHA.

- Updating and completing REACH legislation, including the periodic REACH Review, the latest one finishing 2017
- Preparing secondary legislation, on REACH and CLP, such as reviewing the annexes and passing specific implementing regulations

#### ECHA

ECHA ensures the effective management of the technical, scientific, and administrative aspects of REACH. ECHA provides information on REACH to companies and the general public. It also develops IT tools and guidance documents to support industry and public authorities in fulfilling their obligations under REACH. A wide range of information is available through the ECHA’s website.

- Compliance checks for registration dossier
- Evaluation for testing proposal, with vertebrate animals
- Implementation/guidance: Preparing Guidance documents. Despite the Regulation being long and complicated, many of the issues are broad and open to interpretation, so these guidance documents, though not legally binding, are seen as steer for correct implementation of many issues, ranging from proper conduct amongst co-registrants in data sharing, to test methods and their application

#### Member States Competent Authorities

National authorities are responsible for enforcing REACH by establishing official controls and penalties for non-compliance. They exchange information and coordinate their enforcement activities through the Forum for Exchange of Information on Enforcement.

- Substance evaluation
- Enforcement: ECHA has no enforcement powers, so these rest with national authorities. REACH and CLP are a national responsibility, therefore each Competent Authority must ensure that there is an official system of controls and lay down legislation specifying penalties for non-compliance with the provisions of REACH. ECHA’s enforcement forum is a way for national authorities to exchange information
- Inspection: National/local authorities carry out inspections of sites, companies and facilities subject to the terms of REACH

1, 2, 3, 6, 7: Source: European Commission
4, 5: Source: ECHA
The Key Committees and Working Group

**Member State Committee**

The Member State Committee (MSC) participates in several REACH processes such as evaluation and authorisation. The MSC is responsible for resolving divergences of opinions among Member States and on proposals for the identification of SVHCs. The Committee provides opinions on ECHA's draft recommendation for the authorisation list (Annex XIV) and draft Community Rolling Action Plan (CoRAP) for the substance evaluation process. If an agreement is not reached within the MSC, the matter is referred to the European Commission for decision-making.

**Committee for Risk Assessment**

The Committee for Risk Assessment (RAC) prepares the opinions of ECHA related to the risks of substances to human health and the environment in the following REACH and CLP processes. The final decisions are taken by the European Commission.

The preparation of scientific dossiers proposing Occupational Exposure Limit (OEL) values for chemicals under the Carcinogens and Mutagens Directive and the Chemical Agents Directive is a new activity for ECHA. This task was transferred from the DG Employment’s Scientific Committee on Occupational Exposure Limits (SCOEL).

**Committee for Socio-Economic Analysis**

The Committee for Socio-economic Analysis (SEAC) prepares the opinions of ECHA related to the socio-economic impact of possible legislative actions on chemicals in the REACH processes. The final decisions are taken by the European Commission. Third party contributions linked to the application will also be assessed.

**REACH Committee**

The Commission is often empowered to implement EU legislation with the assistance of committees composed of representatives from EU countries (this is known as comitology). Member States make up the REACH Committee and have weighted votes according to population.

The REACH Committee was created to give opinions on secondary legislation stemming from CLP and REACH. The committee may also create working groups to examine particular issues. The REACH Committee can make amendments to Commission proposals.

**CARACAL**

This expert group advises the Commission and ECHA on the implementation of REACH and CLP. The group is composed of representatives of national Competent Authorities, representatives of Competent Authorities of the European Economic Area and European Free Trade Association (EEA-EFTA countries), as well as a number of observers from non-EU countries, stakeholders from industry (including Concawe) and trade associations, NGOs, trade unions, and international organisations.

**PetCo**

The Petroleum and Coal Stream Substances (PetCo) Working Group is a platform for Member States Competent Authorities, the European Commission, ECHA and industry stakeholders to discuss and coordinate activities related to those substances.

The working group’s primary activity has been to develop an approach on how to prioritise and address petroleum and coal stream UVVCB substances for further work under the Roadmap for SVHC identification and implementation of REACH risk management measures.
Glossary of REACH terms

Cat-App: New technologies to underpin Category Approaches and read-across under regulatory programmes

CLP: Classification, Labelling and Packaging

CMR: Carcinogenic, mutagenic or toxic for reproduction

CoRAP: Community Rolling Action Plan

DG GROW: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

ECHA: European Chemicals Agency

ED: Endocrine disruptor

EEA-EFTA: European Economic Area and European Free Trade Association

ELoC: Equivalent Level of Concern

EOGRTS: Extended One-Generation Reproductive Toxicity Study

EU: European Union

MSC: Member State Committee

MSCAs: Member States Competent Authorities

NGOs: Non-Governmental Organisations

OECD: Organisation for Economic Co-operation and Development

OGO: Other gas oils

OEL: Occupational Exposure Limit

PACT: Public Activities Coordination Tool

PAH: Polycyclic aromatic hydrocarbons

PBT: Persistent, bioaccumulative and toxic

PetCo: Petroleum and Coal streams Working Group

PNDT: Pre-natal developmental toxicity study

RAC: Committee for Risk Assessment

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

RMOA: Risk management option analysis

SCOEL: Scientific Committee on Occupational Exposure Limits

SEAC: Committee for Socio-Economic Analysis
<table>
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<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>SIEF</td>
<td>Substance Information Exchange Forum</td>
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<tr>
<td>SRGO</td>
<td>Straight-run gas oils</td>
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<tr>
<td>SVHC</td>
<td>Substance of very high concern</td>
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<tr>
<td>UVCB</td>
<td>Substance of unknown or variable composition, complex reaction products or biological materials</td>
</tr>
<tr>
<td>VHGO</td>
<td>Vacuum gas oils, hydrocracked gas oils &amp; distillate fuels</td>
</tr>
<tr>
<td>vPvB</td>
<td>Very persistent and very bioaccumulative</td>
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<tr>
<td>WG</td>
<td>Working Group</td>
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REACH
Roadmap for Petroleum Substances