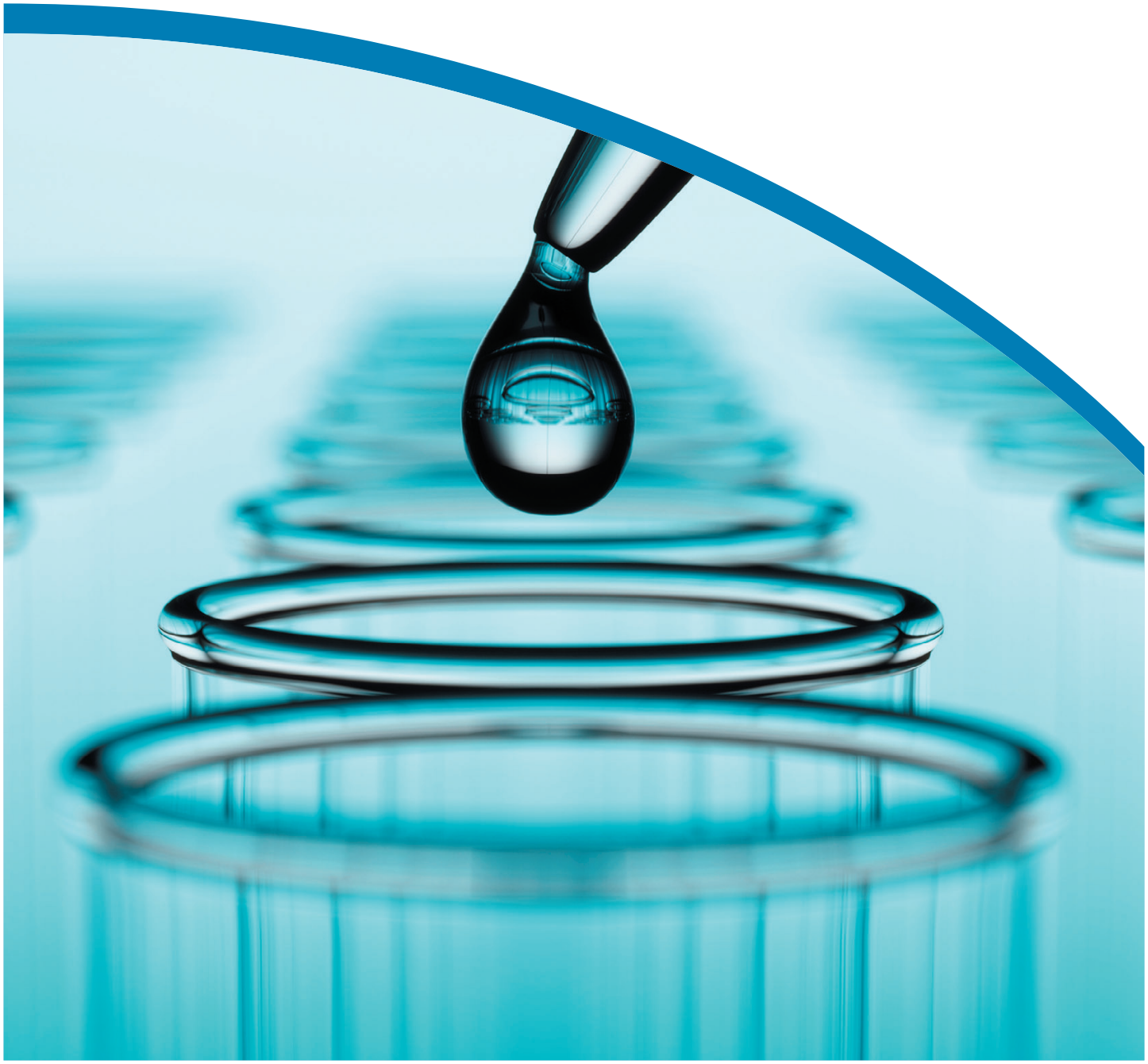
Review

Special REACH Edition

Volume 33 • Number 2
November 2025



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Foreword

Compliance with the requirements of REACH and the classification, labelling and packaging (CLP) regulation is essential for the licence to operate, and to be able to produce and sell petroleum products in Europe. Concawe is managing a portfolio of 140 substances for +/- 4000 registrants and, as such, develops its expertise and energy to keep the dossiers compliant with the evolution of those two regulations. This entire *Review* is focused on Concawe REACH activities, and details some of our latest developments:

- The evaluation of the impact of our substances on the environment is a high focus for the regulator. The first article details the first environmental update that Concawe brought to the REACH dossiers since 2010, applying read-across, predictive models and testing proposals.
- In order to justify read-across between substances and to minimise animal testing, Concawe needs to justify the structural and biological similarities between the substances, the latter being realised for reproductive and developmental toxicity by OECD 422 Tests. The second article describes how these tests led to self-classification of the gas oil substances as Reproductive Toxicity Category 1B (H360FD).
- The third article sets out the developments brought by Concawe to take into account the new requirements of the CLP regulation, which has recently introduced new hazard classes: endocrine disruption (ED); persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB); persistent, mobile and toxic (PMT); and very persistent and very mobile (vPvM).
- The Concawe classification and labelling report is an important document, helping all actors involved in fuels and petroleum products manufacturing and distribution in Europe to comply with the requirements of the CLP legislation. The fourth article presents the key updates presented in the latest two editions of the report.
- Following the evolution of European climate and energy policies, which promote the increased use of low-carbon fuels, Concawe has integrated the scientific study of renewable liquid fuel substances in its scope. The final article in this *Review* presents the scientific challenges and practical implementation of integrating these novel substances into the Concawe REACH portfolio.

Jean-Marc Sohier
Concawe Director

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Cleaning up the data: Concawe's first environmental update to the REACH dossiers since 2010

This article presents a brief overview of the work involved in Concawe's most significant update to the Other Gas Oil REACH registration dossier since 2010. This update will serve as a template for updating the dossiers for the remaining petroleum categories, ahead of the ECHA-mandated 2030 deadline for updating all Concawe REACH dossiers.

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Is it safe? A brief background on chemical regulations

Imagine that you are on a riverside holiday, hoping to catch a fish for dinner. You spot a nearby farm where something is being sprayed on the crops. You glance back at the river—its water looks clear, but some of the fish look ... off. You start to wonder: 'Is it safe to eat the fish? Are there harmful chemicals in the water?'

Figure 1: The value of chemical regulations—would you eat this fish?

Source: AI generated

These are exactly the kinds of questions that chemical risk assessments are designed to answer. A chemical risk assessment combines two key pieces of information: how hazardous a chemical is; and how much of it is actually present in the environment. Toxicology is the science that studies the harmful effects of chemicals. Ecotoxicology, more specifically, focuses on those effects in the environment.

So, in our riverside scenario, you would first identify what chemicals are being used on the farm (chemical identification), find out how much of those chemicals it takes to harm fish (ecotoxicology), and measure or estimate how much of it is in the river (exposure assessment), and then decide whether it is enough to cause concern—or whether it is time to find a seafood restaurant instead.

Many countries have rules that require companies to prove that a chemical is safe before they can promote it or put it on the market. In the European Union, that rulebook is called REACH, which stands for Registration, Evaluation, Authorisation and Restriction of Chemicals.[1] It is overseen by the European Chemicals Agency (ECHA). REACH came into force in 2007.[2] By 2010, companies had to submit information about all chemicals produced in, and imported into, the EU in large volumes—more than 1,000 tonnes per year—and all produced and imported chemicals known to cause cancer (carcinogenic), genetic damage (mutagenic) or reproductive issues (reprotoxic). These submissions are called registration dossiers, and they contain detailed information about each chemical.

For petroleum-based substances, the task of compiling this information was led by Concawe, a scientific organisation representing European oil refiners. Since these companies were all registering similar types of substances, Concawe helped coordinate the effort by forming a Substance Information Exchange Forum (SIEF). This made it possible to share confidential data and build consistent dossiers.

1 'Understanding REACH' (European Chemicals agency website)

2 'REACH' (European Commission website)

A dossier includes several types of information about the substance, depending on how much of it is produced or imported. This includes:

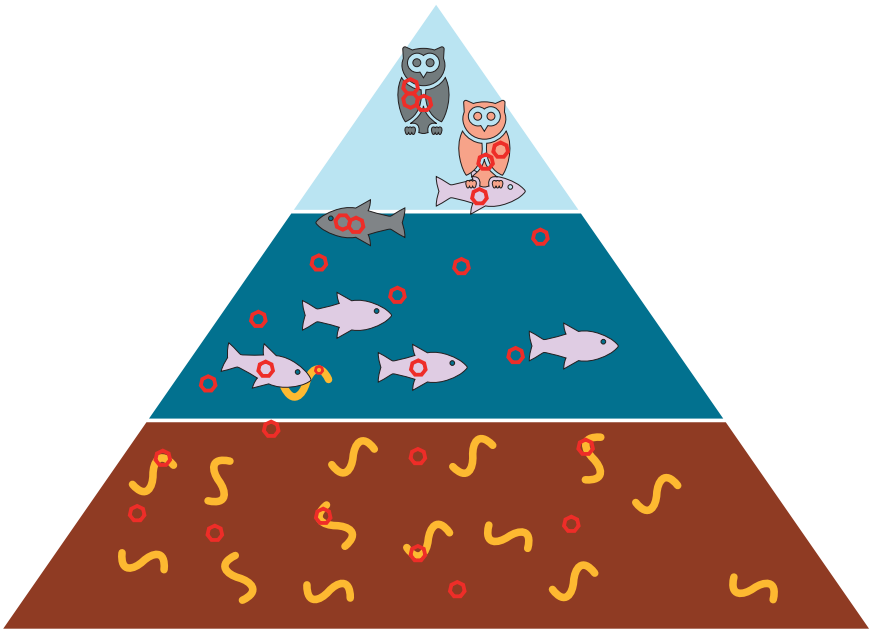
- physical and chemical properties (e.g. is it a solid, liquid or gas; does it dissolve easily in water?)
- human health data (e.g. is it toxic to people?)
- environmental data (e.g. does it break down in nature, or stick around and build up concentrations?)
- descriptions of how it is used and released, to calculate an exposure assessment.

Environmental information is especially important for identifying substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) (Figure 2). These are chemicals that:

- remain in the environment long after they have been released
- build up concentrations in animals and plants over time
- cause harm at low concentrations.

These types of chemicals are the most worrying, because they are more likely to stay in environmental systems after emissions have stopped, and can build up concentrations in organisms upwards through the food chain, with relatively low concentrations leading to toxic or other unpredictable effects. A more thorough explanation of these hazards is given in the article on pages 21–31 of this *Review*.

Figure 2: A PBT/vPvB chemical (red shape), even at low concentrations, can stay in the environment, increase in concentrations in organisms, and be toxic. Would you eat this fish?



Population of the environmental sections of Concawe-supported REACH dossiers since 2007

Between 2007 (entry into force of REACH) and 2010 (the first pre-registration deadline for the highest-volume chemicals), Concawe was responsible for helping to register a large number of petroleum substances. To make the job more manageable, these substances were grouped into categories based on how they were made and what they were used for. For each substance, companies had to provide information on various ecotoxicological data—called Standard Information Requirements (SIRs)—to show that the substances could be used safely. To fulfil a SIR for a REACH dossier, a registrant would either need to provide test data, provide an estimation of the data, typically using a computer model, or have a waiver for that data point because it was not environmentally relevant for the substance or because it was not possible to perform such a test on the chemical. But there was a catch: the SIRs were developed with single, water-soluble chemicals in mind. Petroleum products do not fit well in this paradigm.

Petroleum substances are what's known as UVCBs—chemicals of Unknown or Variable composition, Complex reaction products, or Biological materials. This means that each petroleum substance can contain hundreds to more than millions of different hydrocarbon molecules, with a wide range of carbon chain lengths and types of hydrocarbon molecules. Some of those molecules do not mix well with water (hydrophobic), some evaporate easily (volatile), and others stick to soil or sediment (sorptive).

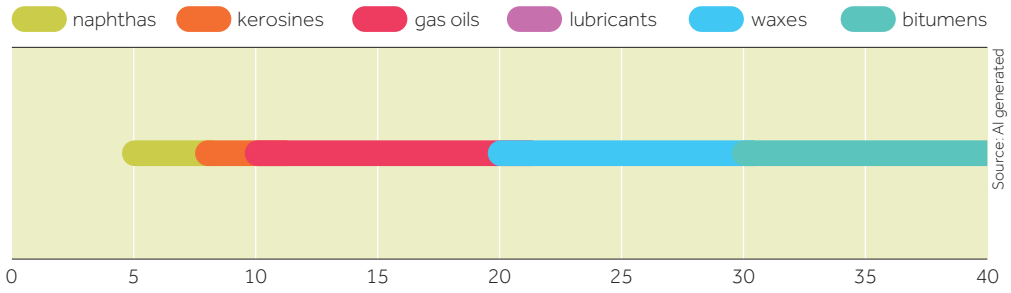
When millions of these molecules are present in one UVCB substance, it becomes very challenging to assess them all together. For evaluating aquatic toxicity, it is not possible to suspend all of the UVCB substances in water (think of oil floating on top of water). It is therefore necessary to utilise an alternative dosing approach, in this case by dosing the water-accommodated fraction (WAF)[1] of the substance, which contains only the water-soluble fraction of the UVCB. Adaptations to the standard test protocols have to be made for the other environmental data as well. When test data were not available, two different approaches—read-across and predictive models—were used to fulfil specific information requirements. These are described in more detail below.

Read-across

Since petroleum substances are, put simply, different fractions of crude oil, the composition of the different substances supported by Concawe overlap and can be treated as a continuum (see Figure 3 on page 7). If one can demonstrate that two substances are similar enough in composition, it is possible to 'read across' ecotoxicological properties from one substance to the other. Concawe made extensive use of read-across in its REACH dossiers, as test data were not available for every substance. This allowed for a more efficient approach to fill in the environmental data needed for regulatory compliance.

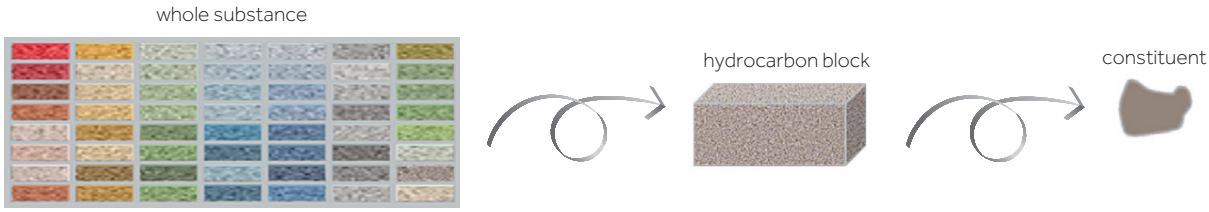
Sometimes, even read-across is not enough—especially when no acceptable test data are available for similar substances. That is where predictive computer models come in. To enable and simplify the assessment of complex petroleum substances, scientists developed the hydrocarbon block approach (see Figure 4 on page 7).[2]

Figure 3: Carbon number ranges and overlap between petroleum substances (up to C40)



Petroleum substances overlap in a continuum of carbon range.

Figure 4: A 'hydrocarbon block' is a hypothetical UVCB fraction that encompasses the constituents that belong to the same chemical class (e.g. isoparaffins) and have an identical carbon number or similar boiling point.



This method simplifies the composition of petroleum substances by grouping potential constituents that are assumed to have similar environmental properties into 'hydrocarbon blocks' (HCBs) based on their molecular size (carbon number or boiling point) and chemical structure, and then selecting one or a few constituents to represent the HCB for further analysis.

The hydrocarbon block approach has been used in the PetroTox model to estimate the aquatic toxicity of petroleum substances.[3] The relative amounts of each HCB in water are based on the compositional data for the petroleum substance and the solubility of each block. PetroTox then uses a concept called the Target Lipid Model (TLM), which assumes that chemicals cause harm when they build up in an organism's fatty tissues beyond a certain concentration limit. The model uses the chemical's octanol-water partition coefficient (Log Kow) to predict how easily it partitions to fat, and compares that to toxicity thresholds. The PetroTox model has been extensively validated using acute and chronic toxicity data for fish, invertebrates and algae for a wide range of petroleum substances. This approach is powerful because it allows scientists to estimate toxicity without having to perform physical tests on every variant of a substance.

PBT assessment

A PBT/vPvB assessment of the registered substance is needed under REACH, and this has been historically one of the more challenging requirements for Concawe substances. PBT/vPvB assessments are performed on a constituent basis, meaning that, in the case of a petroleum substance, a UVCB can be assessed as PBT/vPvB if one of its constituents is persistent (P), bioaccumulative (B) and toxic (T), or very persistent (vP) and very bioaccumulative (vB), assuming that the consitutent is present above a threshold concentration.

Because PBT/vPvB assessments are so complex and important, they are reviewed by a special panel called the PBT Expert Group. This group includes experts from ECHA, EU member state competent authorities, and accredited stakeholders like Concawe. They work together to evaluate difficult cases and provide scientific guidance. Since the Concawe substances are UVCBs, it would be necessary to evaluate millions of constituents that could be in petroleum substances. For a more rational approach, Concawe reverted to the hydrocarbon block approach again: a few representative hydrocarbons were selected from each HCB to perform the PBT assessment. While limited experimental data were available, much of the required biodegradation (persistence) data was generated using predictive models, namely BioHCWin, which was partly developed by Concawe.[4] Bioaccumulation was assessed using limited data and mostly predictive modelling. Toxicity was only addressed for constituents that were P and T, mainly using another predictive model. Concawe's PBT report was evaluated by the PBT Expert Group, with many suggestions being made for improvement.

PetCo

In 2015, the Petroleum and Coal stream Substances (PetCo) Working Group was established at ECHA, with the goal of prioritising PetCo substances for meeting the requirements of the SVHC (Substance of Very High Concern) Roadmap to 2020 (the roadmap prioritises SVHCs). Within PetCo, member state competent authorities, the European Commission, ECHA and industry stakeholders worked together to develop approaches to evaluate the hazards and uses of PetCo substances, as it was recognised early on that these complex substances would be challenging to assess and regulate. In 2022, ECHA announced at PetCo that all PetCo substance dossiers had to be updated by 2030, triggering a more concentrated programme in Concawe.

Present day: updating the environmental sections of Concawe dossiers

While Concawe had already been revising the human health data in its REACH dossiers, real momentum on the environmental sections began in 2021. Discussions with ECHA—particularly through the PetCo group—revealed that more updates were needed to meet current regulatory expectations. Although some minor tweaks had been made over the years, it became clear that a more comprehensive update was necessary. ECHA emphasised the importance of:

- avoiding the use of read-across from unrelated categories
- adding more actual test data where possible
- providing detailed justification documents to support all decisions made in the dossier.

To start this process, Concawe and ECHA agreed to focus initially on a relatively small and manageable category—OGO). The idea was that this update could serve as a template for how to handle the rest of the categories in future updates.

Reviewing and improving the existing data in the dossier

Concawe, with the support of a contractor (wca environment), met with ECHA to review the contents of the OGO dossier and discuss improvements. Some sections required major changes—especially where older information relied on read-across, modelling alone or testing waivers (see summary in Table 1). In cases where no experimental data existed, new testing proposals were submitted by Concawe, and several previously waived data requirements were now fulfilled using model predictions. A few highlights of the updated data requirements include:

- Aquatic toxicity: testing was proposed or conducted where there had previously only been modelling or read-across.
- Soil and sediment toxicity: new testing proposals were submitted where no data existed before.
- Biodegradability: an overhaul of the persistence assessments was undertaken.

All of these updates were aimed at creating a more robust and transparent scientific basis for the dossier—and reducing the risk of failing future ECHA compliance checks.

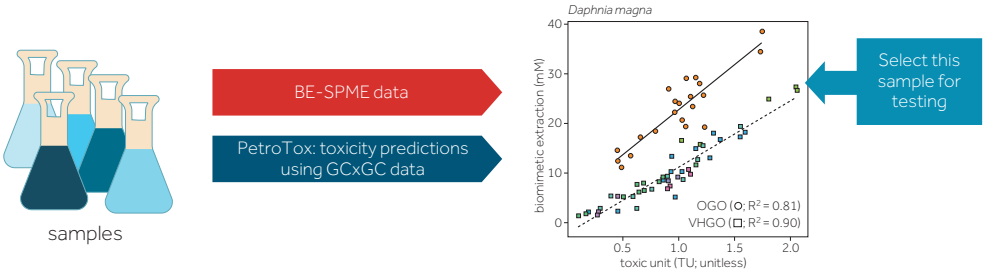
Table 1: Selected environmental data requirements that were significantly changed in the OGO dossier update

Data required	Previous data	Issue	New data
5.2.1 Ready biodegradability	Read-across from another category	Ready biodegradation test not applicable for UVCB	Modelled prediction on constituents
5.2.2 Biodegradation in water: simulation	Modelled prediction		Biodegradation testing proposal on constituent
6.1.1 Short-term toxicity testing fish	Read-across from another category and modelled prediction	No experimental data	Add test data and modelled prediction
6.1.2 Long-term toxicity testing fish	Modelled prediction	No experimental data	Testing proposal
6.1.4 Long-term toxicity testing on aquatic invertebrates	Read-across from another category and modelled prediction	No experimental data	Testing proposal
6.1.5 Toxicity to aquatic algae and cyanobacteria	Read-across from another category	Additional studies available but no detailed analytical data	Conduct testing
6.1.7 Toxicity to microorganisms	Modelled prediction	No experimental data	Conduct testing
6.2 Sediment toxicity	Waiver—testing not needed	No experimental data	Testing proposal
6.3.1 Toxicity to soil macro-organisms except arthropods	Waiver—testing not needed	No experimental data	Testing proposal
6.3.2 Toxicity to terrestrial arthropods	Waiver—testing not needed	No experimental data	Modelled prediction
6.3.3 Toxicity to terrestrial plants	Waiver—testing not needed	No experimental data	Modelled prediction

Choosing the right test sample: finding the worst-case scenario

Once it was decided that testing was needed for an environmental data point, Concawe had to select the appropriate sample to be tested. OGO, like many of the Concawe substance categories, has a large variation in sample compositions and therefore also in expected toxicities. Based on discussions with ECHA, it was decided to select the most conservative (toxic) but still compositionally representative sample for the whole OGO category, which would then only require one test per data point for the category. To identify the most conservative representative sample, available OGO two-dimensional gas chromatography (GCxGC) analytical data were evaluated using two methods: PetroTox predictions and laboratory biomimetic extraction-solid phase microextraction (BE-SPME) (Figure 5). BE-SPME uses silicone fibres that simulate an organism's fat (lipid) content to assess whether the hydrocarbon constituents in the petroleum UVCB will partition to the organism.[5] The more a hydrocarbon partitions into lipid, the more toxic it is expected to be. The composition of the potentially most toxic sample was compared to the compositions of all the other OGO samples to ensure that it was still representative of the category.

Figure 5: Test sample selection using two methods to identify the most potentially toxic sample



New biodegradation conclusions and evaluation approaches

One major shift in the dossier review process resulted from a clarification by ECHA: ready biodegradability (screening) tests are not appropriate for complex UVCBs like OGOs. These screening tests are designed to rapidly identify substances that break down very quickly in the environment (not persistent). But UVCBs contain many constituents of which some may degrade easily, while others may persist. Unless every single constituent can be shown to degrade quickly, the whole substance cannot be considered readily biodegradable. As a result, OGOs are no longer considered readily biodegradable, which affects how the toxicity of the OGOs is being concluded according to the classification, labelling and packaging (CLP) regulation: because there are OGO samples with a modelled chronic aquatic toxicity concentration value below the 0.1 mg/litre threshold, the OGO CLP classification changes from Chronic Aquatic Category 2 (H411) to Chronic Aquatic Category 1 (H410), or from 'toxic' to 'very toxic to aquatic life with long-lasting effects'.

As ready biodegradability data could no longer be used, Concawe had to propose more elaborate simulation biodegradation testing on one or more individual constituents suspected of being persistent. The discussions with ECHA in PetCo and also with the PBT Expert Group took more than a year, during which time Concawe performed an interim update of the PBT report to support the justification and selection of constituents that could be tested. The constituents were selected based on available experimental biodegradation data and data predicted with HC-BioSIM,[6] a new tool developed with the support of Concawe.

The OGO dossier update in numbers

In January 2025, the updated OGO dossier was released to all registrants. This marked the first major update to the environmental sections of Concawe's REACH dossiers—and it sets the stage for how future environmental dossier updates will be handled. Here's what went into it:

- ~ €600,000 in planned testing costs.
- More than 500 pages of supporting documentation, including scientific justifications for every model, read-across decision, and laboratory test.
- Two new aquatic toxicity studies completed and included in the dossier.

Fortunately, many of these materials—especially the justification documents—can be reused or adapted for the dossier updates of other substance categories, helping to reduce future workload and cost.

What's next? A roadmap for the coming years

Over the next five years, Concawe is planning to update all of the remaining dossiers' environmental information requirements, some with testing proposals where necessary. The time frame to accomplish all of the proposed testing will go beyond the 2030 deadline. Some categories, such as lubricant base oils (LBO) and bitumen, are even more complex. These substances are extremely water-insoluble, which makes traditional toxicity testing even more difficult (if not impossible). Concawe will continue to work closely with ECHA to find practical, scientifically valid ways to assess these substances.

In addition, there are new hazard standard information requirements which are being incorporated into REACH and CLP, such as endocrine disruption (ED) and constituents that are persistent, mobile and toxic (PMT), and very persistent and very mobile (vPvM). For more detail on the new hazard classes please see the article on pages 21–31 in this issue of the Concawe *Review*.

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Understanding the reproductive toxicity of gas oil substances: new Repro 1B self-classification and updated risk assessment

As part of Concawe's human health-related testing strategy, a scientific assessment has been undertaken concerning the reproductive and developmental toxicity of gas oil substances. This article summarises the findings of the study, focusing primarily on the OECD Test Guideline 422 results generated, in relation to a range of human health hazard and exposure scenarios. The study highlighted the need for further scientific inquiry and research directions.

Authors
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Introduction

Gas oils represent middle distillate hydrocarbon substances broadly utilised as diesel fuels, heating oils, lubricants, and a variety of other worker and consumer products. Categorised by Concawe as 'Other Gas Oils' (OGO), 'Vacuum Hydrotreated Gas Oils' (VHGO) and 'Straight-Run Gas Oils' (SRGO), these substances vary due to their refining processes and resultant chemical compositions. Gas oils predominantly encompass C10-C25 hydrocarbons, and are substances described as unknown or variable composition, complex reaction products, or biological materials (UVCBs). Given their extensive application across Europe (representing more than 350 million tonnes per year production or import in Europe), regulatory frameworks, notably the EU's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and CLP (classification, labelling and packaging) regulations, mandate comprehensive assessments to ascertain human health and safety, including the potential for reproductive and developmental toxicity. In this regard, this article explores recent advances and further implications, providing insights into the complexity of toxicological evaluation of these substances.

Gas oils and their complexities

Gas oils are, inherently, compositionally highly complex. They are categorised as UVCBs due to their variability arising from disparate crude oil sources and refining processes. Their complex chemical profile comprises thousands of distinct hydrocarbon constituents, including paraffins, olefins, naphthenic ring structures, and aromatic molecules with one to seven rings, all of which can have varying degrees of linear or ring (naphthenic) hydrocarbon groups branching from these structures.

Due to this diversity, advanced analytical techniques are essential for compositional elucidation. Two-dimensional gas chromatography (GCxGC) significantly improves analytical resolution, facilitating detailed hydrocarbon class identification and quantification by number of carbon atoms and molecular structure (paraffins, olefins, naphthenes, aromatics).[1] GCxGC provides what is known as a 'hydrocarbon space map' of a substance, that can be quantitatively used to evaluate individual substances and their categories. Concurrently, polycyclic aromatic compound (PAC)-2 analysis specifically quantifies 3-7 polyaromatic ring content, critical for evaluating toxicity (PAC-2 content has previously been hypothesised to associate with multiple toxicity pathways[2,3,4] and will be the main driver of reproductive and developmental toxicity).

Development of testing strategies and execution of OECD Test Guideline 422

By integrating the data from the analytical profiles of multiple samples of each substance within each Gas Oil category, candidate samples were identified to assess in vivo toxicity. The samples covered the worst case in the category PAC-2 content, complemented with other samples to cover the hydrocarbon space map of the categories as best as possible. These data serve as the initial basis of a confident read-across approach.

The OECD Test Guideline 422 (TG 422)[1] is employed extensively as a combined screening study to assess reproductive toxicity and developmental toxicity parameters, and to assess biological similarity. TG 422 outcomes facilitate establishing biological similarity, and enable biological read-across approaches to complement and verify the aforementioned analytical read-across. These are applied toward meeting higher-tier REACH requirements, such as 90-day repeated dose toxicity (RDT), prenatal developmental toxicity (PNDT) and extended one-generation reproductive toxicity (EOGRT) studies, and to reduce the number of these studies to be conducted. Importantly, the principal of the Concawe read-across hypothesis is that the samples chosen for in vivo analysis are representative of both the substance and category, such that the results from one sample are applicable to the other substances within the category.

As part of Concawe's human health-related testing programme for hydrocarbon substances, selected samples of all substances in the OGO, VHGO and SRGO categories were subject to TG 422 testing, through the oral exposure route by diet in rats. The dietary administration was chosen to achieve systemic exposure, and was supplemented by dermal studies to assess alternate exposure pathways. Within each of these categories, a 'worst-case' sample was identified based on 3 to 7 polyaromatic ring content as determined by the PAC-2 method, and other samples were selected to represent the overall hydrocarbon space map for a given category (see also the Concawe *Review* article on hydrocarbon space mapping[1]).

Results from the OECD TG 422 screening studies

The TG 422 studies have highlighted significant reproductive toxicological concerns for some tested samples. Observed effects include marked increases in post-implantation embryo losses, complete foetal lethality at elevated exposure levels, substantial reductions in litter sizes, and decreased foetal birth weights. Each worst-case sample from each of the three Gas Oil categories resulted in these adverse effects, and a fourth substance, not a worst-case by PAC-2, also had adverse reprotoxicity results (Figure 2). On the other hand, eight tested samples resulted in no adverse reproductive effects, and two samples generated indeterminant or equivocal results.The adverse results had a threshold of effect, i.e. in lower dose exposures of the same samples no reprotoxic effects were observed. These findings demonstrate clear, dose-dependent relationships, strengthening the evidence of reproductive hazards. Critical analysis of maternal toxicity indicators—such as altered body weights and reduced food consumption—provided strong evidence that reproductive outcomes are intrinsically linked to gas oil substances rather than secondary maternal toxicity effects, reinforcing the interpretation and further classification determinations.

[1] Test No. 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test. https://doi.org/10.1787/9789264242715-en

Figure 2: Selected OECD TG 422 testing results for gas oil samples

EC number	265-078-2	265-043-1	270-676-1	270-671-4	265-148-2	269-822-7	265-182-8	272-341-5	265-049-4	265-044-7	265-183-3	270-673-5	265-059-9	272-817-2
CAS number	64741-77-7	64741-43-1	68476-34-6	68476-30-2	64742-46-7	68334-30-5	64742-79-6	68814-87-9	64741-49-7	64741-44-2	64742-80-9	68476-31-3	64741-58-8	68915-96-8
PAH/sample no.	VHGO_S692	SRGO_S686	VHGO_S668	VHGO_S760	OGO_S726	VHGO_S777	OGO_S712	SRGO_S836	VHGO_S721	SRGO_S795	OGO_S809	VHGO_S845	VHGO_S796	SRGO_S715
1-ring	0.04	0.19	0.57	0.59	0.09	0.42	0.58	0.26	0.3	0.05	0.34	0.19	0.07	0.08
2-ring	0.46	0.86	1.94	1.36	1.42	1.74	2.28	4.42	7.2	1.08	4.45	1.01	1.75	1.25
3-ring	0.06	0.13	0.22	0.24	0.29	0.47	0.51	1.85	2.5	3.48	3.36	3.46	4.76	2.99
4-ring	0	0.01	0	0	0	0	0	0	0	0.09	0.25	0.19	0.42	3.24
5-ring	0	0	0	0	0	0	0	0	0	0	0	0	0	0.75
6-ring	0	0	0	0	0	0	0	0	0	0	0	0	0	0
≥ 7-ring	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total 3+ PAH (PAC-2)	0.06	0.14	0.22	0.24	0.29	0.47	0.51	1.85	2.5	3.57	3.61	3.65	5.18	6.98

R positive
equivocal
negative

	Dose	S692	S686	S668	S760	S726	S777	S712	S836	S721	S795	S809	S845	S796	S715	
Mean no. of implantations	0	17.7	17.4	15.4	15.7	12.3	16.7	17.3	17.2	16.8	17	16.1	17.8	16.8	15.6	
	100	15.1	17	15.4	15.4	15.8	16.4	15.7	16.1	15.6	17.1	16.7	15.4	16	16.2	
	300	17.4	18.1	14.3	17	13	16	16	16.5	14.8*	15.9	15.3	15.3	13.9*	15.6	
	750	17	15.1*	14.9	13.9	12.3	15.4	14.4*	13.4*	14.4*	15.5	13.6*	12.9*	13.3*	11.4*	Reduced by > 20–25%
	1,000						15.8	15*				13.3*		13.0*	12.0*	
Mean % post-implantation loss		23.3	16.3	14.1	26.1	23.5	15.1	14.3	12.6	10.9	27.4	23.3	14.9	14.7	12	
		12.5	19.6	11.6	18.4	17	7.1	8.7	12.6	15.9	11.1	26.4	13.4	12.7	15.7	
		25.8	11	8.6	12.8	8.1	9.5	12	11.8	10.3	19.2	33.6	9.3	31.1	16.2	
		23	10.1	16.1	16.7	28	20.1	25.1	13.6	35.3	19.3	50.8	14.6	44.1	43.7*	Observed > 30%
							12.3	15.9				100		45.3	75*	
Mean litter size at PND 0		13.6	14.6	14.7	11.6	9.6	14.2	14.8	14.9	14.9	14.3	12.6	15.2	14.5	13.9	
		13.4	13.7	13.7	12.8	13	15.2	14.4	14	13.1	15.1	12.8	13.4	13.9	13.7	
		14.3	16	13.9	14.8	13.3	14.4	14	14.4	13.3	12.8	10.2	13.8	10.6	13.1	
		14	13.6	12.6	11.7	10.2	12.2	10.7*	11.6	9.3*	12.3	6	11*	9.4*	6.3*	Reduced by > 20–25%
							13.9	12.6				0		9.1*	5.8*	
Mean fetal weight at birth		6.5	6.6	6.4	6.6	6.3	6.5	6.5	7.0	6.7	6.8	6.9	6.6	5.0	6.7	
		6.7	6.9	6.5	6.7	6.5	6.6	6.5	6.7	6.7	6.8	6.8	7.1	6.5*	6.6	
		6.6	6.3	6.6	6.6	6.7	6.3	6.4	6.5	6.3	6.8	6.8	6.6	6.7*	6.3	
		6.4	6.4	6.8	6.5	6.8	6.9	7.0	6.9	6.7	6.5	5.8	6.7	6.8*	6.5	
							6.4	6.4				0		6.2	5.5	Reduced by > 5–10%

Reproductive toxicity category 1B (Repro 1B) self-classification and update of hazard characterisation

After extensive evaluation by Concawe's Health Management Group (HMG), supplemented by independent external expert consultation, gas oils were determined to warrant a Repro 1B (H360FD: 'May damage fertility; May damage the unborn child') self-classification under the EU CLP regulation. This classification indicates definitive animal-based evidence demonstrating potential adverse reproductive impacts on humans. This classification was substantiated by the reproductive toxicity outcomes across multiple TG 422 studies in all Gas Oil categories, and was corroborated by supporting data from a PNDT rat study, aligning with the European Chemicals Agency (ECHA) stance on the data generated. Though the adverse effects were only observed for some tested samples, the new Repro 1B self-classification has been applied to all substances within the categories, given the aforementioned read-across principles and based on the worst-case sample testing outcome, even if the adverse toxicity effects were not observed in other samples tested within the categories.

Category 1 Carcinogen, Mutagen or Reprotoxin (CMR) classification has implications for uses of the gas oil substances. However, importantly, per the EU's CMR Directive 2022/431/EC, the H360 classification specifically has a call-out regarding thresholds: '*For most reprotoxic substances, it is scientifically possible to identify levels below which exposure would not lead to adverse health effects. The exposure minimization requirements laid down in Directive 2004/37/EC should apply only to reprotoxic substances for which it is not possible to identify a safe level of exposure and which are identified as "non-threshold" in the notation column of the Annex III to Directive 2004/37/EC. With regard to all other reprotoxic substances, employers should ensure that the risk related to the exposure of workers is reduced to a minimum.*' As the TG 422 results indicated a threshold of effect, systemic long-term Derived No-Effect Levels (DNELs) could be determined (based on No Observed Adverse-Effect Levels (NOAELs) from TG 422) and indicating a safe level of exposure below which there is no risk to workers' or consumers' health (see Table 1). These DNELs have undergone expert review by the HMG (numbers in bold) and they are generally lower than the previous DNELs (numbers in parentheses) of these categories, and in the case of VHGO, they are much lower.

Table 1: Worker and general population DNELs for Gas Oil categories

	Worker DNELs Long term = 8-hour time weighted average Acute = 15 minutes			**General population DNELs** Long term = 24 hour Acute = event			
	Inhalation systemic long-term (mg/m^3)	**Inhalation systemic acute (mg/m^3)**	**Dermal systemic long-term (mg/kg/day)**	**Inhalation systemic long-term (mg/m^3)**	**Inhalation systemic acute (mg/m^3)**	**Dermal systemic long-term (mg/kg/day)**	**Oral systemic long-term (mg/kg/day)**
OGO	**16.46** (16.40)	5,003	2.91	**3.48** (4.85)	3,002	1.25	**2.50** (1.25)
VHGO	**5.49** (68.34)	4,288	2.91	**1.16** (20.22)	2,573	1.25	**0.83** (1.25)
SRGO	**5.49** (16.40)	1,501	2.91	**1.16** (4.85)	900	1.25	**0.83** (1.25)

Update of exposure scenarios and risk assessment

Safe use is determined by the measured or modelled exposure to a substance being less than the DNEL (i.e. a risk characterisation ratio (RCR) < 1). Previously, gas oil safe use was primarily[2] evaluated and confirmed using the conservative Tier 1 exposure assessment model ECETOC TRA v3.1[5] for both inhalation and dermal exposures. This model is very generalised and makes many conservative assumptions and estimates. However, the decrease in DNELs combined with the revision of TRA to v3.2 to include a more conservative inhalation model (i.e. overestimation of inhalation exposure) indicated exposures higher than the DNEL for almost all uses. Therefore, Concawe has launched an effort to refine exposure assessments to more accurately estimate the inhalation exposure that occurs in gas oil uses.

[2] Importantly, Concawe has conducted some measured data campaigns for gas oils that have been invaluable in the evaluation of their risk (Concawe reports 1/06 and 14/14).

This effort involved the use of Concawe Report no. 1/06, *Human exposure information for EU substance risk assessment of gas oils*.[6] This report contains, in specific detail, a wide variety of industrial and professional jobs and tasks associated with the manufacture, distribution and retail use of gas oils. These fuel-related uses constitute more than 99.9% of the registered tonnage for these substances. These specific and relevant tasks were used to develop exposure scenarios that map to the existing described fuel-related worker uses; these exposure scenarios were then integrated into a higher tier inhalation model, the Advanced REACH Tool (ART) v1.5.[7] Of note, dermal and consumer exposure assessments are still performed using TRA v3.2 as the ART model is currently not fit for purpose for these particular assessments.

Inhalation exposure is driven by a composite of two general airborne entities: aerosols and vapour. Previous research by Concawe has shown that gas oils belong to the group of 'semi-volatile' hydrocarbon substances, i.e. when released to air (for example, as a result of product transfer activity) the resulting stable atmosphere contains vapour and mist (the latter is also called aerosol). The gas oil fraction that can give rise to vapour levels in air consists of the product constituents with individual vapour pressure greater than 10 Pascal (Pa). The complementary fraction, i.e. constituents with individual pure substance vapour pressures below 10 Pa, are assumed to form aerosol (minute droplets) when released to air. The cut-off at 10 Pa between a vapour-generating and aerosol-generating substance is implemented in the ART model and was adopted in the Concawe method for occupational inhalation exposure estimation.

As previously mentioned, GCxGC data were collected as a part of the Concawe Substance Identity Management Group (SIMG) efforts from samples across all substances of each category to develop hydrocarbon space maps. These maps provide median weight percentages in the category for individual hydrocarbon blocks (HCBs) according to carbon number and hydrocarbon chemical class. The vapour pressure of each HCB was estimated by applying boundary layer theory to adjust the estimated air releases.[8] HCBs with vapour pressures ≥ 10 Pa at 25°C constitute the vapour fraction of a substance. This cut-off was based on the definition in the ART user guide. The percent composition of the vapour ART assessment entity was determined by summing the normalised median substance HCBs weight percents (wt%). HCB wt% were converted to mole fractions by dividing by the estimated molecular weights of the HCB. The vapour pressure of the vapour ART assessment entity was determined via Raoult's law where the vapour pressure of a mixture is calculated by summing the products of (mole fraction of a constituent (here HCB)) multiplied by (vapour pressure of that constituent) for all the constituents of that mixture.

It was determined that the median vapour component vapour pressures are 255, 222 and 168 Pa, and mole fractions are 36.6%, 30.2% and 17.5% for VHGO, OGO and SRGO, respectively (thus, VHGO is the worst-case substance for DNEL and volatility).

Importantly, all Gas Oil categories also have many registered non-fuel uses (e.g. lubricants, coatings, oil and gas drilling, and road construction). While these uses constitute < 0.1% of registered tonnage, they represent a wide variety of uses (up to 21 per category) with many contributing scenarios (up to 15) for each use. Creating new unique exposure scenarios to be run in ART was a task too large for Concawe's staff and expertise. As such, these non-fuel uses have been assessed, with some input from registrants and trade associations, with regard to the gas oil composition of the substances used using TRA v3.2.

Risk management measures (RMMs) have been applied to achieve safe use according to HMG's hierarchy of RMMs, prioritising ventilation and time management measures.

Implications for safe use

Using these scientifically-developed exposure scenarios with the measured compositional data-derived vapour pressures, all fuel uses were assessed in ART for inhalation exposure.[3]

Importantly, all fuel-related uses have been determined as safe and supported without the need for additional RMMs beyond those described in the existing job tasks from Concawe Report 1/06.[6] This covers work at refineries, formulation and storage sites, distribution terminals, distribution drivers,[4] and refuelling tasks including full-service service station attendants and mechanics. Notably, to mitigate worker dermal exposure, all tasks now require the use of chemical-resistant gloves with one exception: service station attendants for whom measured data are available—see Concawe Report no. 14/14.[9]

Consumer use of gas oils as fuel (for refuelling automotive diesel engines, garden equipment and recreational vehicles) was also assessed as safe when using the available REACH modelling tools, as well as when using the limited inhalation and dermal exposure measurement data available from previous Concawe projects.

Most non-fuel uses relied on TRA v3.2 modelling and have achieved safe use for almost all uses. However, to achieve safe use, many stringent RMMs have been implemented across almost every exposure scenario. This has involved: reducing the percentage (from 100%, as reflected by industry association and/or registrant input) of gas oil in the use; increasing general room ventilation to minimally 3–5 air changes per hour; implementing local exhaust ventilation; and/or in a few cases (e.g. manual spraying) requiring worker respirators.

[3] Fuel assessments were made at 100% gas oil substance. This may not reflect the real-world product considering additives and renewable component content which varies across EU Member States.

[4] VHGO road tanker (distribution) driving is the highest exposed task (RCR = 0.953). It should be noted that the exposure scenario is based on top loading which was prevalent at the time of Concawe report 1/06. Bottom loading is considered standard practice at present, which significantly reduces inhalation exposure, and as such this RCR value is likely a conservative overestimate.

Regardless of RMM interventions, some non-fuel exposure scenarios cannot achieve safe use. In particular, the use of SRGO and VHGO as a drilling mud in oil and gas field drilling operations is no longer supported and is advised against. Additionally, a few other contributing activities have required reformulations (reduction of the gas oil component), e.g. use in coatings and use in lubricants for professional and consumer contributing activities.

Future directions on exposure modelling

It should be noted that a major component of modelled gas oil exposure comes from the results of TRA v3.2 dermal exposure modelling. This model assumes that the entirety of a substance is instantly absorbed through the skin, which is known not to be the case for gas oils. However, it is the only available assessment model that is readily applied to the uses and substances in the Concawe portfolio. The RCR contribution from this TRA v3.2 modelled dermal exposure is generally 0.471, in other words nearly half the allowable exposure.

The Concawe portfolio would greatly benefit from the development of higher-tier dermal modelling platforms (e.g. the dermal module in ART v1.5). Additionally, measured data for dermal exposure is sparse for gas oil (and almost all Concawe substance) uses. The Concawe portfolio would equally benefit from projects that would support the gathering and/or generation of additional measured dermal exposure data.

Conclusion

Recent advances in the reproductive toxicity assessment of gas oils have impacted the classification and risk management frameworks. Continuous scientific inquiry and adaptive adjustments are imperative for ensuring human health protection, maintaining regulatory compliance, and supporting the sustainable use of gas oil substances. Importantly, this article is associated with human health hazard and exposure scenarios only. Other regulatory implications addressing, for example, labelling, and safe transport, transfer and storage, were also assessed but are beyond the scope of this article.

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New hazard classes: implications and regulatory framework

The introduction of new hazard classes under the classification, labelling and packaging regulation will require industry stakeholders to adapt their existing strategies for the assessment of hydrocarbon substances in order to ensure compliance with the updated regulation. Concawe continues to provide vital support to the registrants in preparing for, and meeting, these challenges in a rapidly evolving regulatory landscape.

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Hazard assessment

Hazard assessment is a critical component of chemical management regulations in Europe and around the globe. It involves identifying and evaluating the intrinsic chemical properties of substances, and focuses on determining whether a chemical can cause adverse effects on the environment and human health. Hazard properties describe what chemical substances may be *capable* of doing, regardless of how or where the chemical is used. Hazard assessments help to identify and understand the innate characteristics of chemical substances, which provides a foundation for managing chemical risks, ensuring safer use and supporting regulatory decisions.

The European Union (EU) has recently updated its regulatory approach to assessing chemical hazards. The Classification, Labelling, and Packaging (CLP) regulation (Regulation (EC) No 1272/2008) has served as the foundation for chemical classification, aligning with the Globally Harmonized System (GHS).[1] In 2023, the EU Commission Delegated Regulation (EU) 2023/707[1] introduced new hazard classes to address gaps in the identification of hazardous chemicals. The regulation seeks to provide better protection for human health and the environment. This amendment to the CLP regulation is a key pillar of the EU Chemicals Strategy for Sustainability (CSS) within the European Green Deal.[2]

The new CLP hazard classes being introduced are:

- ED (endocrine disruption) — Category 1 and 2 in human health (HH)
- ED (endocrine disruption) — Category 1 and 2 in the environment (ENV)
- PBT (persistent, bioaccumulative and toxic) / vPvB (very persistent and very bioaccumulative)
- PMT (persistent, mobile and toxic) / vPvM (very persistent and very mobile).

Concawe plays a significant role in helping the fuel manufacturing and distribution industry to comply with chemical regulations in the EU (i.e. CLP) by conducting hazard assessments of hydrocarbon substances. Concawe follows the European Chemicals Agency's (ECHA's) evolving guidance to ensure scientific consistency in how these substances are assessed within the EU regulatory framework and that compliance is manageable for all registrants.

Hazards 101

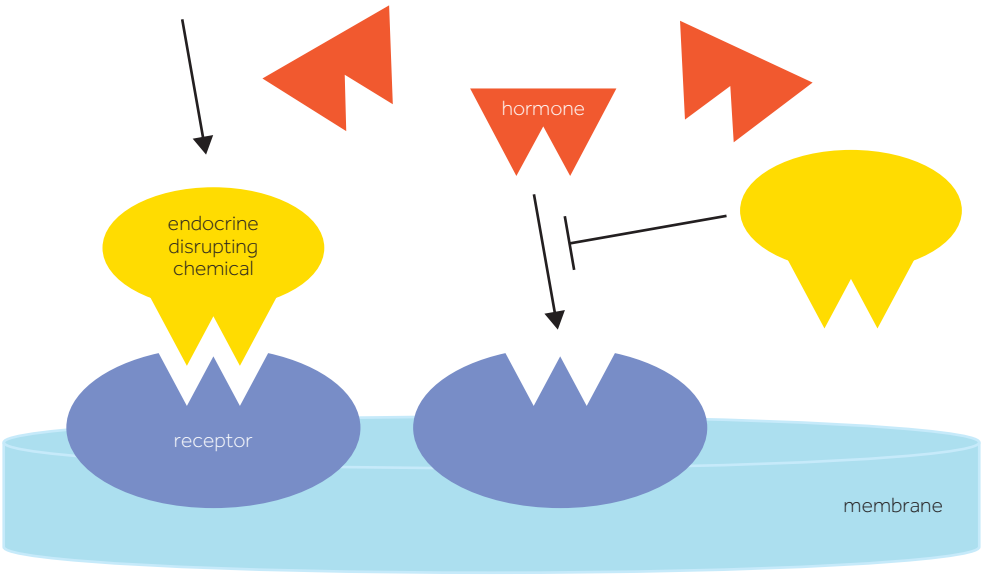
Endocrine disruption (ED)

Endocrine disruptors have the potential to interfere with the natural hormone system of humans and animals, and may thereby cause adverse effects in both humans and wildlife. In all organisms, hormones link the nervous system with bodily functions (e.g. growth, development, reproduction, behaviour). For example, certain chemicals may have structures similar to natural hormones, enabling them to bind to hormone receptors.

1 Globally Harmonized System of Classification and Labelling of Chemicals https://unece.org/about-ghs

As a result, this can block natural hormones from attaching, and potentially disrupt the normal function of the endocrine system (Figure 1). Alterations to hormone receptor function may cause changes in cellular and organ level responses which can cause the body to behave differently. Over time this could lead to adverse effects in organisms. Organism endocrine systems and their function are complex and there can be many different ways in which a substance can disrupt hormone systems. Due to this complexity, endocrine-mediated effects of chemicals can be difficult to demonstrate.

Figure 1: Endocrine-disrupting chemicals can have an impact on the normal function of the endocrine system



Endocrine disrupting chemicals (yellow) may have structures similar to natural hormones (red) enabling them to bind to hormone receptors (purple). As a result, this can block natural hormones from attaching, and potentially disrupt the normal function of the endocrine system.

The CLP regulation differentiates between ED for human health (HH) and the environment (ENV) to account for variations in hormone systems between humans and wildlife, as well as how endocrine-disrupting chemicals may affect them. This distinction aims to implement more effective chemical management strategies (e.g. to account for differences in environmental and human health exposure scenarios) and support consistency in hazard classification. Allocation into one of the two categories within the ED hazard classes is similar to the procedure for carcinogenic and mutagenic substances (see Table 1 on page 23). For ED Category 1, the hazard statements (and codes) are 'May cause endocrine disruption in humans' (HH; EUH380) and 'May cause endocrine disruption in the environment' (ENV; EUH430). For ED Category 2, the hazard statements (and codes) are 'Suspected of causing endocrine disruption in humans' (HH; EUH381) and 'Suspected of causing endocrine disruption in the environment' (ENV; EUH431).

Table 1: New ED CLP hazard classes and their criteria

Category 1 ED — known or presumed ED for HH/ENV	Category 2 ED — suspected ED for HH/ENV
• Based on evidence from human or animal data, or from both human and animal data. • Data shall provide evidence that the substance meets all the following criteria: a) endocrine activity b) an adverse effect in an intact organism or its offspring and future generations c) a biologically plausible link between the endocrine activity and the adverse effect. *However, where there is information that raises doubt about the relevance of the biologically plausible link for humans, classification in Category 2 may be more appropriate.*	• Based on evidence from human or animal data, or from both human and animal data. • All the following criteria are to be fulfilled: a) There is evidence of endocrine activity and an adverse effect in an intact organism or its offspring and future generations. b) The evidence referred to in (a) is not sufficiently convincing to classify the substance in Category 1. c) There is evidence of a biologically plausible link between the endocrine activity and the adverse effect.

Although ED is a newly recognised hazard class under CLP, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation does not yet specify any particular data requirements for this end point. Existing chronic mammalian toxicity and ecotoxicity data requirements in Annex IX and X may offer some insight into endocrine effects. However, there are currently no requirements for data that provide mechanistic information on endocrine activity, which is a key component of the EU's definition of an endocrine disruptor. Consequently, new REACH data requirements for ED, addressing both human health and environmental concerns, are currently in development. Tests that are expected to be considered for fulfilling the REACH ED information requirements are specified by the Organisation for Economic Co-operation and Development (OECD) in *Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption*.[3]

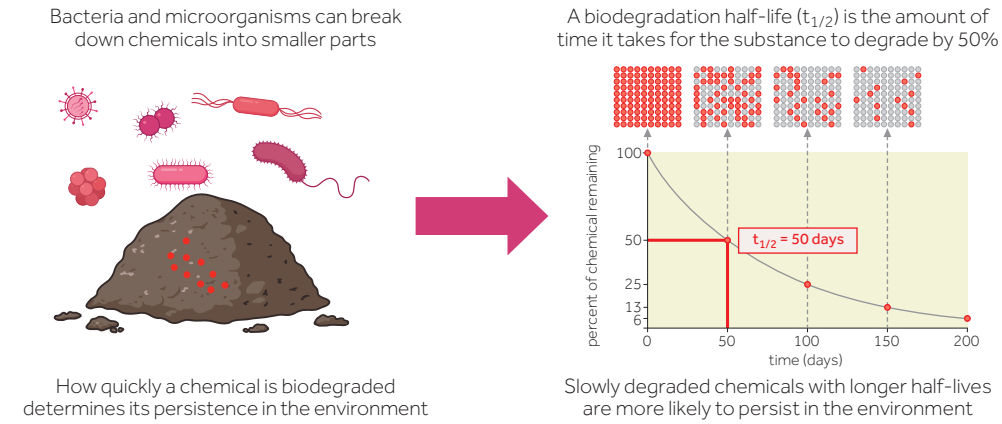
Persistent, bioaccumulative and toxic (PBT) substances

PBT is a classification used in chemical safety regulations to identify substances that pose a hazard to the environment and human health. A substance is considered to be PBT if it does not break down easily and remains in the environment for a long time (i.e. P), it builds up (i.e. accumulates) in organisms over time leading to increased concentrations in food chains (i.e. B), and if the substance has harmful effects on humans or organisms in the environment (i.e. T). A related substance classification is 'very persistent and very bioaccumulative' (vPvB) for substances considered to be even more resistant to degradation and which have higher potential for accumulation in organisms compared to PBT substances.

Persistence (P) refers a chemical's ability to resist biodegradation. Persistent chemicals are slowly degraded and may remain in the environment for long periods of time. How quickly a chemical is biodegraded by bacteria and microorganisms in the environment (e.g. water, soil) determines a chemical's persistence. The biodegradation half-life ($t_{1/2}$) is the time it takes for a substance to degrade to half of its original amount (50%). The $t_{1/2}$ can be measured in the laboratory by adding the chemical to water, sediment or soil and following its disappearance over time (Figure 2). Chemicals that are slowly degraded have longer half-lives and can therefore stay in the environment for long periods of time.

Chemical persistence (P) is determined by measuring the extent to which chemicals are degraded by bacteria or microorganisms present in the environment (e.g. soil). The biodegradation half-life ($t_{1/2}$) describes the time it takes for a chemical to degrade by 50%. Substances with longer half-lives can remain in the environment for longer periods of time.

Figure 2: The biodegradation half-life ($t_{1/2}$) can be measured in the laboratory by following its disappearance over time



How quickly a chemical is biodegraded determines its persistence in the environment

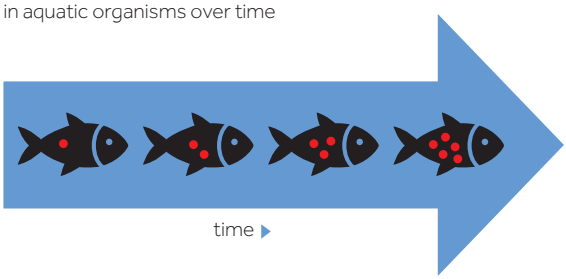
Slowly degraded chemicals with longer half-lives are more likely to persist in the environment

Bioaccumulation (B) occurs when chemical concentrations in organisms exceed those in the surrounding environment. This happens because organisms cannot break down or eliminate these substances as quickly as they absorb them, leading to potentially toxic levels. Two key processes that control bioaccumulation are bioconcentration and biomagnification (Figure 3).

Figure 3: Chemical bioaccumulation can occur through two processes—bioconcentration and biomagnification

a) Bioconcentration

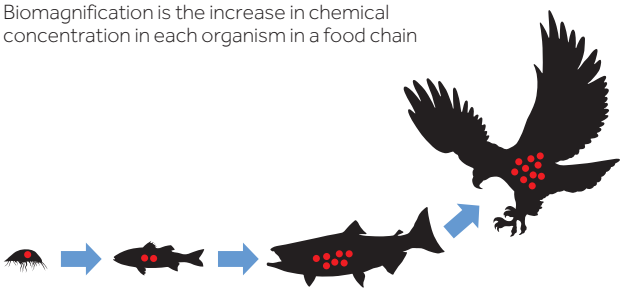
Bioconcentration is the build-up of chemicals in aquatic organisms over time



Process described by the bioconcentration factor (BCF):
BCF = concentration in fish ÷ concentration in water

b) Biomagnification

Biomagnification is the increase in chemical concentration in each organism in a food chain

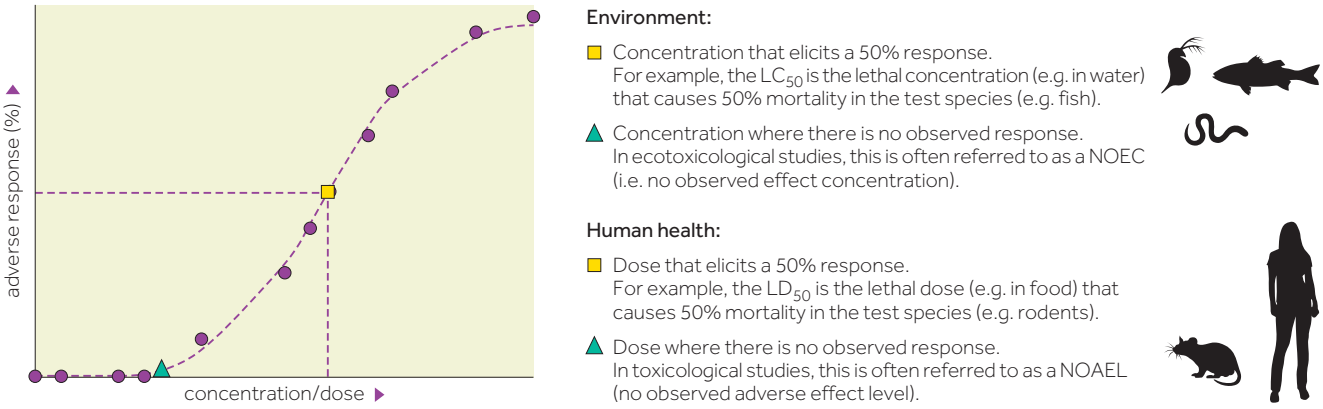


Process described by the biomagnification factor (BMF):
BMF = concentration in predator ÷ concentration in prey

Bioconcentration refers to the build-up of chemicals over time in aquatic organisms (e.g. fish). It is measured by comparing chemical concentrations in fish to those in the surrounding water, known as the bioconcentration factor (BCF, Figure 3). Biomagnification describes how certain chemicals become more concentrated as they move up the food chain. Small aquatic organisms may absorb a pollutant and when fish eat them that chemical accumulates. As larger predators eat those fish, the concentration of the chemical increases even more. Biomagnification is measured by comparing chemical levels in an organism to those in its diet, expressed as the biomagnification factor (BMF, Figure 3)

Toxicity (T) refers to how harmful a substance is to living things. Some chemicals are only harmful at very high concentrations, while others can be toxic in small amounts. Whether a chemical causes harm depends not just on what it is, but also on how much of it a person or animal is exposed to. A dose response curve (Figure 4) is a tool used to understand this relationship between the amount of a substance (i.e. its dose or concentration) and the effect it has (i.e. its adverse response). At low concentrations, there might be no or few effects observed. But as the dose increases, the effect can become stronger. By evaluating these curves, doses causing adverse effects (e.g. LC_{50}, Figure 4) can be identified and safe exposure levels or limits (i.e. NOAEL, Figure 4) can be set to protect the environment and/or human health.

Figure 4: Illustrative figure of a dose-response curve commonly derived in (eco)toxicological studies



Above: the study data (purple circles) are used to derive (eco)toxicological end points (yellow squares, green triangles; see figure for description) which inform Concawe's environmental and human health assessments. These (eco)toxicological end points also inform the assessment of toxicity (T) under CLP (see Table 2 on page 27).

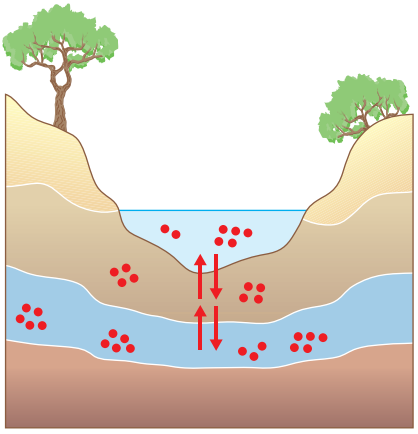
The criteria for the identification of PBT/vPvB properties in chemicals can be found in the REACH regulation and are summarised in Table 2 on page 27. The vPvB CLP criteria is identical to the criteria specified in REACH. For PBT properties, the definitions of persistent (P) and bioaccumulative (B) are also identical. The definition of toxic (T) differs slightly from REACH. Under CLP, a chemical may be T if it is an endocrine disruptor according to hazard classes ED HH or ED ENV.[4] For PBT and vPvB the respective hazard statements (and codes) are 'Accumulates in the environment and living organisms' (EUH440) and 'Strongly accumulates in the environment and living organisms, including humans' (EUH441).

Persistent, mobile and toxic (PMT) substances

PMT is a new classification under CLP used to identify substances that pose risks to water resources. Like persistent and toxic substances considered under the PBT classification, PMT substances also do not degrade easily in the environment (i.e. P) and may be harmful to human health or organisms in the environment (i.e. T). The definitions of P and T applied in PBT assessments also applies to PMT assessments (see Table 2).

The new mobility (M) classification is used to identify substances that move through soil or sediment and can reach water sources, e.g. groundwater. These substances tend to be water soluble and don't sorb (stick) easily to organic carbon in soils or sediment, which means they can travel more freely (i.e. are mobile) in the environment. If substances are both mobile and persistent, they may have a continuous presence in water and may spread more widely in surface waters and groundwater. Mobility is assessed using the organic carbon-water partition coefficient (K_{OC}), which compares how soluble a chemical is in organic carbon relative to how soluble it is in water (see Figure 5).

Figure 5: Mobile (M) chemicals (red) can move through soil or sediment and reach water sources



Mobile chemicals prefer to be in the water column relative to surrounding soil or sediment.

Mobility described by the organic carbon-water partition coefficient (K_{OC}):

$$K_{OC} = \frac{\text{Solubility in organic carbon}}{\text{Solubility in water}}$$

A substance classification related to PMT is 'very persistent and very mobile' (vPvM) for substances considered to be even more resistant to degradation and which have higher potential to spread widely in water systems. The criteria for the identification of PMT/vPvM properties in chemicals can be found in the CLP guidance and are summarised in Table 2. For PMT and vPvM the respective hazard statements (and codes) are 'Can cause long-lasting and diffuse contamination of water resources' (EUH450) and 'Can cause very long-lasting and diffuse contamination of water resources' (EUH451).

Table 2: New PBT/vPvB and PMT/vPvM CLP hazard classes and their criteria

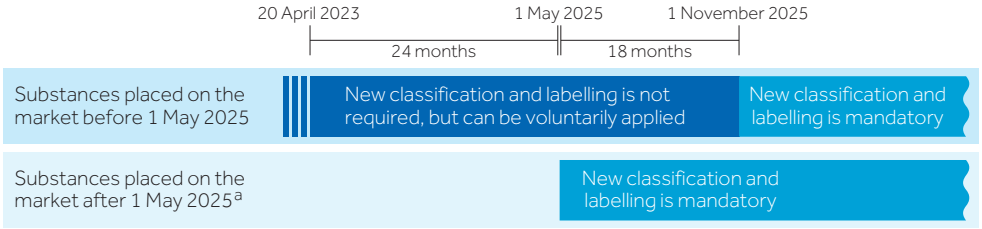
Hazard	Classification	CLP criteria
Persistence	Persistent (P)	Degradation half-life in any of the following compartments is higher than: a) 60 days in marine water b) 40 days in fresh or estuarine water c) 120 days in fresh or estuarine water sediment or in soil d) 180 days in marine sediment
	Very persistent (vP)	Degradation half-life in any of the following compartments is higher than: a) 60 days in marine, fresh or estuarine water b) 180 days in marine, fresh or estuarine water sediment or in soil
Bioaccumulation	Bioaccumulative (B)	Bioconcentration factor (BCF) in aquatic species is higher than 2,000 (i.e. BCF ≥ 2,000)
	Very bioaccumulative (vB)	Bioconcentration factor (BCF) in aquatic species is higher than 5,000 (i.e. BCF ≥ 5,000)
Mobility	Mobile (M)	Organic carbon-water partition coefficient (K_{OC}) is less than 1,000 (i.e. log K_{OC} < 3)
	Very mobile (vM)	Organic carbon-water partition coefficient (K_{OC}) is less than 100 (i.e. log K_{OC} < 2)
Toxicity	Toxic (T)	A substance shall be considered to fulfil the toxicity criterion (T) in any of the following situations: a) The long-term no-observed effect concentration (NOEC) for aquatic organisms is < 0.01 mg/litre. b) The substance meets the criteria for classification as carcinogenic (C; Cat 1A or 1B), germ cell mutagenic (M; Cat 1A or 1B), or toxic for reproduction (R; Cat 1A, 1B, or 2). c) There is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE Cat 1 or 2). d) The substance meets the criteria for classification as endocrine disruptor (Cat 1) for humans or the environment.

Regulatory implementation and timelines

Guidance on the application of the new CLP hazard criteria was issued in November 2024. For chemical substances, which include hydrocarbon substances, the CLP regulation mandates different compliance deadlines depending when substances are placed on the market (i.e. before or after 1 May 2025; Figure 6).

Each of the new hazard classes have already been added in the REACH IT tool, IUCLID. Companies are now able to include information related to the new hazard classes in their classification and labelling notifications, REACH registrations, and dossiers for product and process orientated research and development (PPORD), as well as in their submissions under the Biocidal Products Regulation and poison centre notifications. After the transition period (Figure 6), it will be mandatory for companies to indicate if the substance is classified in any of the new hazard classes.

Figure 6: Regulatory timelines for chemical substances outlining when new CLP hazard criteria are mandated.[5]



[a] This corresponds to substances placed on the market as of 1 May 2025, and to **new quantities** of substances already on the market before 1 May 2025, when the new quantity is placed on the market as of 1 May 2025.

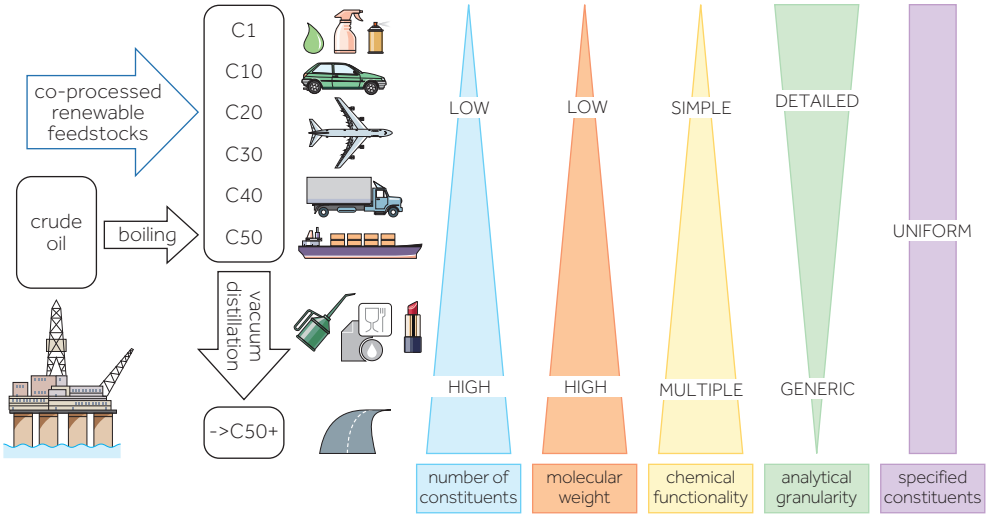
The introduction of these hazard classes will affect chemical manufacturers, importers and downstream users. Companies will need to review their product portfolios to align with the new classification criteria in order to ensure appropriate communication of potential hazards and risks.

How is Concawe preparing for these new hazards?

Concawe follows ECHA's evolving guidance to ensure scientific consistency in how hydrocarbon substances are assessed within the EU regulatory framework and that compliance is manageable for its member companies. Concawe's role is particularly important for providing guidance on how complex substances, including UVCBs (i.e. substances with Unknown or Variable composition, Complex reaction products, or Biological materials) are assessed. UVCBs, such as hydrocarbon substances, do not have fixed chemical formulas.

Hydrocarbon substances are made up of thousands of different hydrocarbon components, which can vary by time and location because they are refined from crude oil. The compositions of hydrocarbon substances produced in refineries are influenced by both the source crude oil, the specific refining processes applied and the operating conditions (Figure 7). Due to this complexity and variability, UVCBs often receive special considerations under European regulations to ensure that their potential hazards are adequately assessed.

Figure 7: The processes and complexity of hydrocarbon UVCBs

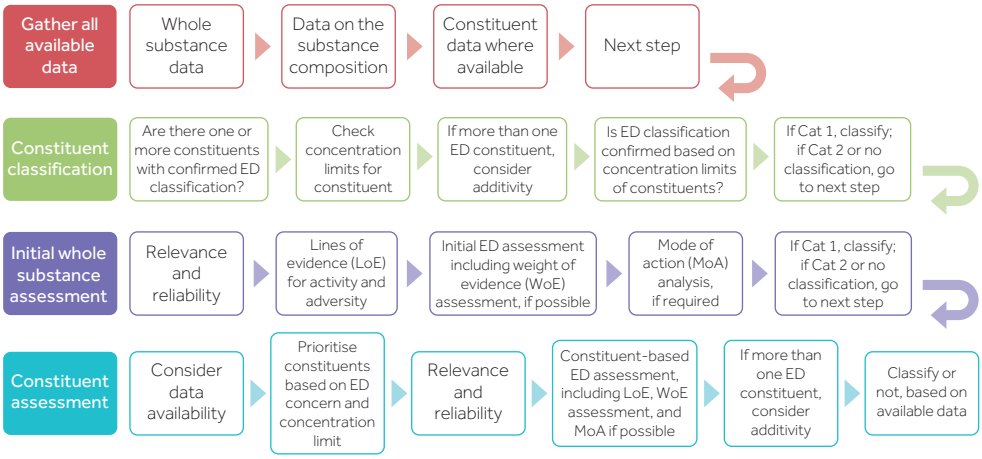


The compositions of hydrocarbon substances produced in refineries are influenced by both the source crude oil and the refining processes applied during fuel manufacturing. This thereby influences the complexity and variability of the hydrocarbon constituents (e.g. their number, molecular weights, chemical functionalities) within these substances which need to be considered in hazard assessments of hydrocarbon substances.

In the case of the new CLP hazard classes, Concawe was heavily involved with the review of the guidance documents for the new CLP hazard classes, where key points were taken up by ECHA during the review and commenting periods. Concawe also plays an important role in helping the fuel manufacturing industry comply with chemical regulations in the EU (i.e. CLP) by conducting hazard assessments of hydrocarbon substances. Last year, Concawe's Environmental Management Group (EMG) completed the update of all the environment sections of the Other Gas Oil (OGO) registration dossier. Details of this update are summarised in the article on pages 4–12 in this issue of the Concawe *Review*. The update included a revision of Concawe's PBT report, as well as EMG's mobility assessment in anticipation of the PMT/vPvM hazard classification.

Members of Concawe's Endocrine Disruption Focus Group (comprising members from both Concawe's Environment and Health Management Groups) have developed a method to assess ED in hydrocarbon substances. Given the UVCB nature of hydrocarbon substances, Concawe's approach for ED assessment is pragmatic, and considers both the available data for the whole hydrocarbon substance itself and for the hydrocarbon constituents that make up each substance (Figure 8). We are currently assessing our substances for ED and working to establish collaborations with other petroleum industry groups to support a more efficient and coordinated assessment process for hydrocarbon substances.

Figure 8: Proposed framework for ED classification of a hydrocarbon substance (hydrocarbon UVCB)[6]



Conclusion

The introduction of new hazard classes under the CLP regulation marks a major development in the EU's approach to chemical hazard assessment, particularly with the inclusion of ED, PBT/vPvB, and PMT/vPvM classifications. These changes are intended to improve the identification and communication of chemical hazards, ultimately supporting the goals of the EU Chemicals Strategy for Sustainability. As regulatory expectations increase, especially for complex substances such as hydrocarbon UVCBs, industry stakeholders must adapt their assessment strategies accordingly.

Continued research and additional regulatory guidance will be essential in ensuring effective implementation and compliance with these new hazard categories. Concawe continues to play a critical role in helping the fuel manufacturing sector to navigate these regulatory developments by developing scientifically sound, pragmatic methodologies for hazard assessment. Through close alignment with ECHA guidance, active participation in regulatory discussions, and ongoing collaborations with multiple stakeholders, Concawe supports its members in preparing for, and meeting, the new regulatory requirements. These efforts will help to ensure that hazard assessments for hydrocarbon substances remain robust, consistent and fit for purpose in a rapidly evolving regulatory landscape.

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Challenges and key updates in the 2024 Concawe classification and labelling report

This article provides a background to the historical development of Concawe's classification and labelling reports since the first edition was published in the 1990s. It outlines some of the challenges faced in undertaking timely and accurate revisions, and provides an overview of the latest edition, published in 2024, which is a landmark update reflecting the increasing complexity of chemical safety regulations and the evolving nature of petroleum and renewable fuel products.

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Historical development of Concawe classification and labelling reports

The first editions of the Concawe classification and labelling (C&L) reports, published in the 1990s, were fundamentally different in scope and regulatory alignment compared to today's comprehensive documents. At that time, the guiding framework was the Dangerous Substances Directive (DSD, 67/548/EEC),[1] which focused on the classification and labelling of hazardous substances through predefined risk and safety phrases. The primary goal of these early reports was to provide industry-wide guidance to promote a harmonised approach to classifying hydrocarbon substances, particularly addressing issues like carcinogenicity, aspiration hazard and flammability—hazards most immediately linked to hydrocarbon substances. These reports were a vital resource in a context where harmonised classifications for hydrocarbon substances were still incomplete, and much of the responsibility for 'self-classification' rested with the manufacturers. Notably, the DSD framework was limited in scope compared to modern classification, labelling and packaging (CLP) regulation, lacking systematic assessments for environmental hazards such as persistent, bioaccumulative and toxic (PBT), and very persistent and very bioaccumulative (vPvB) properties, or modern concerns such as endocrine disruption.

The grouping of hydrocarbon substances in these early reports was based largely on refinery process history, assuming that substances produced under similar processes would share comparable hazard profiles. This grouping allowed for extrapolation of hazard data across categories, a method still applied but much more refined and scientifically grounded today.

The transition to CLP and the United Nations Globally Harmonized System: expanding the scope

With the entry into force of the CLP regulation (Regulation (EC) No 1272/2008)[2] and the repeal of the DSD, Concawe's reports shifted towards a much broader and more complex hazard assessment framework, fully aligned with the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS).[3] Starting in 2010, Concawe's focus expanded to include not only traditional health hazards but also a wider array of environmental and physical hazards, requiring more nuanced methodologies and reliance on comprehensive REACH dossiers.

The 2023 edition: a transition towards new hazard classifications

The 2023 edition of the Concawe C&L report[4] represented a significant update over previous years. It laid the groundwork for addressing the new hazard classes introduced by the EU Commission Delegated Regulation (EU) 2023/707,[5] although full integration was not yet realised. The 2023 report focused on the integration of new EU harmonised classifications for substances of concern, such as cumene, which was reclassified as Carc. 1B under the 18th Adaptation to Technical Progress (ATP), and these are now fully incorporated into this report's recommendations.

This integration ensures that Concawe's C&L recommendations remain fully aligned with the latest legally binding classifications, avoiding discrepancies that could hinder industry compliance.

The 2023 edition incorporated two new renewable UVCB (Unknown or Variable composition, Complex reaction products, or Biological materials) hydrocarbon substances, which reflected the first tangible step towards addressing the growing relevance of renewable fuels.

Furthermore, the 2023 edition reflects a major regulatory advance with the formal inclusion of new hazard classes under Commission Delegated Regulation (EU) 2023/707. These include the classification of substances as endocrine disruptors for both human health (ED HH) and the environment (ED ENV), and as PBT, vPvB, PMT (persistent, mobile and toxic) and vPvM (very persistent and very mobile). The adoption of these new hazard classes signifies a shift in regulatory focus towards emerging environmental and health risks, challenging the industry to re-examine substances that have long been in use but which are now evaluated through new scientific lenses.

This shift will require Concawe to review its entire inventory of hydrocarbon substances to identify those which may fall under these newly defined hazard categories. Given the complex and variable nature of UVCB substances, this required sophisticated weight-of-evidence assessments, the development of new data in addition to the review of existing data, and a review of available chemical, toxicological, ecotoxicological and environmental fate data.

The 2024 edition: a step up in the global content review

The 2024 edition of the Concawe C&L report[6] represents a crucial update in the continuous effort to provide recommendations on hazard classification and labelling for hydrocarbon substances within the European Economic Area (EEA). Reflecting significant scientific and regulatory developments, this new edition addresses the rapidly evolving regulatory landscape, particularly following the entry into force of several ATPs in the CLP regulation and the introduction of new hazard classes under Delegated Regulation (EU) 2023/707.

Despite its essential role for industry compliance, the wide scope and evolving nature of the report pose considerable challenges for its timely and accurate revision. One of the core difficulties lies in the inherent complexity of petroleum-derived UVCB substances. These substances, due to their variable composition, resist straightforward classification and require expert judgment and the use of extensive scientific data, including data from novel testing methods and category-based approaches. As the report aims to encompass more than 27 categories of hydrocarbon substances, each with different chemical profiles and regulatory notes, maintaining consistency and coherence across these substances is an ongoing and technically demanding task.

Challenges and key updates in the 2024 Concawe classification and labelling report

An additional layer of complexity is added by the need to constantly align the recommendations with the ever-evolving CLP regulation, including the 19th, 20th, 21st and 22nd ATPs adopted between 2023 and 2024. These ATPs, along with Delegated Regulation (EU) 2023/707 introducing new hazard classes, will require a thorough review of all substances to ensure that hazard classifications remain compliant and reflect the latest scientific consensus. For instance, the integration of new hazard classes such as endocrine disruptors (for both human health and the environment), as well as substances meeting PBT/vPvB and PMT/vPvM criteria, calls for a re-examination of existing substance dossiers for supporting evidence or testing rationales.

Managing this extensive range of updates requires meticulous internal coordination, especially when it comes to reconciling the various layers of CLP requirements with updated Chemical Safety Reports (CSRs) in registration dossiers.

Ensuring that Appendix 1 (substance listings), Appendix 3 (testing approaches), Appendix 4 (toxicological data reviews) and Appendix 5 (C&L permutations) are fully synchronised represents an important effort. This coordination is further complicated by the need to factor in recent scientific developments, such as the outcome of Extended One-Generation Reproductive Toxicity Studies (EOGRTS) and in vitro testing data addressing mutagenicity and carcinogenicity, which have become essential for proper hazard characterisation.

The wide scope of the report also means that it must provide consistent classification and labelling recommendations for substances produced in refineries, while recognising that some categories, such as lubricating greases or re-refined oils, are intentionally excluded from this report. Striking this balance, between comprehensive guidance and focused scope, while ensuring relevance to both traditional fossil-based and newly developed renewable UVCBs, underscores the technical and strategic challenges faced during its preparation.

The 2024 version of the report introduces a range of important updates compared to the 2023 edition. A key feature of the 2024 update is the inclusion of six new renewable UVCB hydrocarbon substances. This move reflects the growing role of renewable fuels in the energy transition, and Concawe's effort to ensure that these emerging substances are classified and labelled under the same rigorous framework as their fossil-based counterparts. These substances include Co-processed gas oils and naphtha produced from plant, animal or waste plastic origins, such as co-processed gas oil from plant/animal origin (CPGOAV), Co-processed (thermal cracking) gas oil from waste plastics (CPGOPW), Co-processed diesel/gas oil from thermally cracked plastics (CPGOTP), Co-processed (hydrotreated) naphtha from plant/animal origin (CPNAV), and Co-processed naphtha from thermally cracked plastics (CPNTP). Additionally, Co-processed kerosene from animal and vegetable oil/fat (CPKAV) has been included within the kerosenes category, highlighting the expansion of this group to accommodate structurally similar renewable inputs. The creation of five new subchapters (8.24 to 8.28) which exclusively address these substances demonstrates a commitment to addressing the regulatory challenges associated with renewable fuel products.

Another important update is the reorganisation of certain substances within existing categories to better reflect their chemistry. Notably, MK1 diesel, previously treated as a stand-alone substance, has now been integrated into the kerosenes category, aligning its classification with similar materials and simplifying compliance for downstream users. Meanwhile, solvent naphtha, previously part of the naphtha category, has been identified as a stand-alone substance in its own subchapter (8.23), reflecting its distinct chemical profile and specific hazard considerations. These structural changes improve the logical coherence of the report and facilitate easier navigation for users seeking guidance on specific substances.

The report references the ATPs mentioned previously which introduce new harmonised substance classifications and make key changes to existing entries in Annex VI of the CLP regulation. Furthermore, the report acknowledges the updated European Chemicals Agency (ECHA) guidance on CLP criteria (November 2024),[7] which introduces new scientific and methodological considerations, particularly for emerging hazard classes such as endocrine disruption and PMT/vPvM.

Another significant scientific development captured in the 2024 report is the classification of several UVCB hydrocarbon substances for mutagenicity (Muta. 2), based on new data and expert evaluation. Substances such as Unrefined/Acid Treated Oils (UATO), Untreated Distillate Aromatic Extracts (UDAE), Cracked Gas Oils (CRACKEDGO), and Heavy Fuel Oil (HFO) components have been newly classified under this hazard class, reflecting the evolving understanding of their potential genetic effects. This addition reflects the ongoing integration of data from advanced testing approaches, such as modified Ames tests and in vitro assessments, into regulatory frameworks.

Moreover, Appendix 3 and Appendix 4 have been thoroughly reviewed and updated to reflect the latest toxicological testing outcomes, and provide comprehensive discussions on hazard assessment methodologies. Notably, Appendix 4 now includes a general discussion of results generated by EOGRTS according to OECD Test Guideline 443,[1] enhancing the report's alignment with modern reproductive toxicity testing standards and providing a more robust basis for classification decisions.

In conclusion, the 2024 Concawe C&L report is a landmark update that reflects both the increasing complexity of chemical safety regulations and the evolving landscape of petroleum and renewable fuels. The report demonstrates a significant effort to integrate emerging scientific data, regulatory changes and sustainability considerations into a comprehensive framework for hazard classification and labelling. However, the wide scope of substances covered, the inclusion of new hazard classes, and the need to align with the latest ATPs and ECHA guidance make updating this report a substantial technical and organisational responsibility. Its publication ensures that industry stakeholders remain equipped with up-to-date guidance, promoting both regulatory compliance and the protection of human health and the environment in a rapidly evolving regulatory context.

[1] Test No. 443: Extended One-Generation Reproductive Toxicity Study. https://doi.org/10.1787/9789264185371-en

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Expanding the Concawe REACH inventory: integration of renewable fuel substances

Concawe, has responded to the evolving landscape of energy and climate policy by expanding its scope to encompass the scientific study of renewable liquid fuel substances. This article presents an in-depth review of the strategic rationale, scientific challenges and practical implementation of integrating these novel substances into the Concawe REACH portfolio.

Author

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Strategic context: expanding the scope of Concawe

The Board decision taken by the European Fuel Manufacturers Association in July 2022 represents a landmark evolution in Concawe's mandate. As the industry recognises the pressing need for decarbonisation, liquid fuels derived from renewable sources are expected to play a pivotal role in sectors where electrification is less viable. The extension of Concawe's scope to include renewable fuels—such as hydrotreated vegetable oils (HVO), Fischer-Tropsch fuels, waste-derived naphtha and e-fuels—was a logical progression aligned with Europe's 2050 climate neutrality ambition. This strategic expansion allows the sector to consolidate scientific and regulatory efforts under a single expert umbrella, while fostering innovation in compliance mechanisms.

The integration of renewable fuel substances is not only a response to policy directives but a proactive engagement with future regulatory expectations. The fuels landscape is shifting towards life-cycle carbon intensity benchmarks, and regulatory frameworks are beginning to require traceability, sustainability criteria and greenhouse gas reduction calculations that incorporate upstream emissions. In this context, expanding Concawe's role to include renewable substances enables early preparation for substance-level compliance, as well as system-level conformity with emerging legislative instruments such as the Renewable Energy Directive III (RED III) and the Sustainable Finance Disclosure Regulation (SFDR). This foresight strengthens the credibility of Concawe's scientific output and ensures its continued relevance in European policy arenas. Moreover, the consolidation of renewable and fossil fuel data under one framework allows the development of harmonised risk assessment methodologies and supports consistency in hazard communication.

Concawe's evolving role in REACH registration management

Concawe's current role as a facilitator of EU REACH compliance for complex hydrocarbon substances is well established. Managing over 140 substances and more than 4,000 registrations, Concawe supports joint submission dossiers, maintains substance identity profiles (SIPs), and oversees technical consistency with the latest IUCLID[1] requirements. The organisation acts as an interface between industry and the European Chemicals Agency (ECHA), responding to regulatory developments and guiding registrants in dossier updates. The extension to include non-fossil hydrocarbons builds on this foundation, reinforcing the continuity of scientific oversight and enabling efficient integration into ongoing dossier evaluation cycles. Concawe's infrastructure includes dedicated scientific and technical groups, such as the Substance Identity Management Group (SIMG), Environmental Management Group (EMG) and Health Management Group (HMG). These teams collaborate to commission appropriate studies, evaluate data and ensure alignment with ECHA's evolving guidance. The ongoing maintenance of joint dossiers includes validation against technical completeness checks, ensuring that dossier content reflects current data and regulatory requirements. Concawe's active participation in ECHA workshops, technical panels and evaluation processes ensures a bidirectional flow of knowledge and helps shape regulatory expectations in a manner that reflects the practicalities of complex substance management.

[1] https://echa.europa.eu/support/registration/creating-your-registration-dossier/what-is-iuclid-

Within this system, new substance integration is not merely administrative, but is an iterative scientific process. The transition to incorporate renewable substances benefits from this mature regulatory interface, enabling a smoother transition for registrants and a more consistent interpretation by regulators.

Scientific and strategic value of integration

Integration of renewable substances into the Concawe hydrocarbon substance inventory requires scientific assertion of similarity in risk and behaviour under REACH. A key benefit lies in the ability to apply read-across principles. When structural and compositional similarity can be demonstrated, substances may share toxicological and environmental data, reducing the need for new animal testing and aligning with the principles of the REACH Regulation.[1] This contributes to both ethical testing standards and cost efficiency for registrants. Moreover, centralised dossier management reduces duplication and ensures harmonised interpretation of regulatory standards, something that is particularly important for UVCBs where category membership must be substantiated by compositional and biological similarity.[2] Centralising the REACH compliance strategy for both fossil and renewable hydrocarbons improves resource efficiency and scientific cohesion. Integration reduces redundancy by enabling data-sharing across substances with demonstrated similarity, thus fulfilling REACH's aim of minimising animal testing. In addition, Concawe's approach allows registrants of newer fuels to benefit from established datasets and evaluation strategies, including the PetroTox model for aquatic toxicity estimation.[3] For the regulatory community, the value lies in receiving dossiers that are better structured, more transparent in justification, and supported by consistent evidence bases. From a policy perspective, such harmonisation supports the EU's broader goals of promoting circularity, resource efficiency, and safe innovation in the chemicals and energy sectors.

Challenges in the integration of new substances

Despite the strategic imperative, integrating new substances presents several technical and procedural challenges. First, the demonstration of structural similarity requires comprehensive analytical characterisation. An example of this is the use of two-dimensional gas chromatography (GCxGC) enabling hydrocarbon space mapping—a methodology pioneered by Concawe to define compositional boundaries across hydrocarbon classes and carbon number distributions.[2] This analytical technique is resource intensive, requiring five independent samples for each new substance candidate. A second challenge is establishing biological similarity, typically using screening studies such as OECD 422 for human health hazards to compare profiles with category members.[4] Even when such similarity is confirmed, regulatory hurdles remain. Inclusion of a new substance into a category already under ECHA evaluation introduces additional review layers, and necessitates coordination between registrants and Concawe to address financial and data-sharing commitments. Another significant challenge lies in aligning substance identity with ECHA expectations for UVCBs. For many renewable fuels, especially those involving co-processing or pyrolysis of mixed feedstocks, the complexity of composition extends beyond classical hydrocarbon profiles.

Trace elements, minor impurities or oxygenated compounds may complicate the assessment. Furthermore, each registrant's production method may result in slight variations, requiring extensive dialogue to determine whether multiple registrants can adopt a unified approach within a single dossier. Concawe facilitates this harmonisation by coordinating study selection, defining testing strategies and ensuring comparability across datasets. However, limitations in current analytical technology sometimes impede full characterisation. For example, GCxGC cannot reliably separate hydrocarbon substance constituents above a carbon number of around 30, and alternative methods like field ionisation mass spectrometry (FIMS) or high-performance liquid chromatography (HPLC) must be employed. The iterative nature of this process places substantial demands on technical capacity and registrant engagement.

Current integration status and substance examples

As of early 2025, eight new renewable or co-processed substances have been accepted into the Concawe inventory. These range from diesel-type HVO products (EC 951-915-5) to co-processed streams incorporating chemically recycled plastics (e.g. EC 941-803-4). Each substance involved a multi-step evaluation: initial dossier review, comparison against target category justification documents, hydrocarbon space mapping, and—where necessary—OECD 422[2] biological testing. The experiences gained from these integrations highlight both the benefits of centralised dossier management and the importance of early and thorough data generation. For example, the integration of EC 941-379-0, a petroleum kerosene fraction co-processed with plant-based inputs, demonstrated that structural overlap with existing substances can be established even when feedstock origin varies significantly. In contrast, substances originating from chemically recycled plastics required more extensive justification due to the potential presence of unknown or non-hydrocarbon constituents.[5]

The eight new substances serve as a valuable testbed for refining integration protocols. Substances such as EC 940-595-2, a renewable naphtha from animal and vegetable origin will be assessed for its similarity to other naphtha substances in the near future, starting with profiling of each constituent type and concentration using direct hydrocarbon analysis - gas chromatography. In the absence of evidence of structural and biological similarity, the decision to manage the substance as a stand-alone entry rather than forcing category inclusion demonstrates Concawe's commitment to scientific integrity. Each integration case contributes to a growing body of knowledge and helps calibrate the thresholds and benchmarks used in assessing future candidates. This knowledge is also informing guidance materials and framework documents for registrants, improving transparency and predictability of the process.

[2] Test No. 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test. https://doi.org/10.1787/9789264242715-en

Conclusions and outlook

The inclusion of renewable fuel substances into the Concawe REACH inventory underscores the Association's commitment to both regulatory leadership and climate responsibility. By applying rigorous scientific methodologies such as hydrocarbon space mapping and compositional fingerprinting, Concawe is building a framework where substance integration is not only feasible but strategically beneficial. Looking forward, the ability to support increasingly diverse sources of hydrocarbon liquids—ranging from biomass to synthetic and chemically recycled feedstocks—will be central to the evolution of regulatory science in the fuels sector. Concawe's experience and infrastructure place it in a unique position to lead this transition, ensuring that scientific integrity and regulatory compliance remain at the forefront of sustainable fuel development.

Looking ahead, the continuous evolution of Concawe's integration framework will be essential as the number and diversity of candidate substances increase. Future developments may include refinement of hydrocarbon space mapping algorithms, integration of in vitro and NAMs[3] data for hazard assessment, and further collaboration with analytical laboratories to standardise compositional fingerprinting. Furthermore, engagement with ECHA will remain critical to ensure mutual understanding of expectations and acceptable methodologies. There is also scope for harmonising Concawe's inventory with broader EU-level sustainability criteria, including carbon intensity metrics and circular economy indicators. In doing so, Concawe can support not only regulatory compliance but also strategic positioning of its members in the transition to sustainable energy systems. Ultimately, a robust, scientifically sound and transparent integration process will underpin industry confidence and stakeholder trust.

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[3] New approach methodologies—alternatives to animal testing methods in the hazard assessment of industrial chemicals.

Abbreviations and terms

ART	Advanced REACH Tool
ATP	Adaptation to Technical Progress
BCF	BioConcentration Factor
BMF	BioMagnification Factor
CAS	Chemical Abstract Service
C&L	Classification and Labelling
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
CoU	Conditions Of Use
CPGOAV	Co-processed gas oil from plant/animal origin
CPGOPW	Co-processed gas oil from waste plastics
CPGOTP	Co-processed diesel/gas oil from thermally cracked plastics
CPNAV	Co-processed naphtha from plant/animal origin
CPNTP	Co-processed naphtha from thermally cracked plastics
CPKAV	Co-processed kerosene from animal and vegetable oil/fat
CRACKEDGO	Cracked Gas Oil
CSR	Chemical Safety Report
CSS	Chemicals Strategy for Sustainability
DNEL	Derived No-Effect Level
DSD	Dangerous Substances Directive
ECHA	European Chemicals Agency
ED	Endocrine Disruption
ED ENV	Endocrine Disruptors for the Environment
ED HH	Endocrine Disruptors for Human Health
EFMA	European Fuel Manufacturers Association
EMG	Environmental Management Group
ENV	Environment
EOGRT	Extended One-Generation Reproductive Toxicity
EU	European Union
FIMS	Field Ionisation Mass Spectrometry
GCxGC	Two-dimensional Gas Chromatography
GHS	Globally Harmonized System of Classification and Labelling of Chemicals)
GO	Gas Oil
HCB	Hydrocarbon Block
HFO	Heavy Fuel Oil
HH	Human Health
HMG	Health Management Group
HPLC	High-Performance Liquid Chromatography
HVO	Hydrotreated Vegetable Oil
IUCLID	International Uniform ChemicaL Information Database
LBO	Lubricant Base Oil
LC_{50}	The concentration of a substance that is lethal to 50% of a test population
NOAEL	No Observed Adverse-Effect Level
OECD	Organisation for Economic Co-operation and Development
OGO	Other Gas Oil
PAC	Polycyclic Aromatic Compound
PBT	Persistent, Bioaccumulative and Toxic
PetCo	Petroleum and Coal stream substances (working group)
PMT	Persistent, Mobile and Toxic
PNDT	Prenatal Developmental Toxicity
PPORD	Product and Process Orientated Research and Development
PROC	Process Category
RCR	Risk Characterisation Ratio
RDT	Repeated Dose Toxicity
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RED	Renewable Energy Directive
RMM	Risk management measure
SFDR	Sustainable Finance Disclosure Regulation
SIMG	Substance Identity Management Group
SIP	Substance Identity Profile
SIR	Standard Information Requirement
SRGO	Straight-Run Gas Oil
SVHC	Substance of Very High Concern
TG	Test Guideline
TLM	Target Lipid Model
TRA	Targeted Risk Assessment
UATO	Unrefined/Acid Treated Oil

Abbreviations and terms

(continued)

UDAE	Untreated Distillate Aromatic Extract
UVCB	Unknown or Variable composition, Complex reaction product, or Biological material
VHGO	Vacuum Hydrotreated Gas Oil
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile

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