concawe

ENVIRONMENTAL SCIENCE FOR THE EUROPEAN REFINING INDUSTRY

# review

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Environmental science for the European refining industry

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# Foreword

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Welcome to the latest Concawe *Review*. In this edition there are four articles which may be of interest to you.

The first article describes work done to prepare for the evaluation of petroleum substances under the REACH legislation. As we enter the Evaluation phase of REACH the requirements continue to evolve. In 2016 a working group (PetCo) met, several times, to develop the approach for assessment of petroleum substances. ECHA also issued a major update to their IUCLID software and the Commission issued anticipated letters requiring reprotoxicity testing proposals to be updated to satisfy the new OECD testing protocol (OECD 433). Results from two Concawe research projects for REACH, one to improve the environmental health assessment, the second an analytical programme to improve substance identification, will need to be included in the REACH dossiers. Altogether, this means that we are preparing for significant updates to the common parts of the registration dossiers in the first quarter of 2017.

The second article describes the goals of, and the progress we have made with, the CAT-APP programme, which is designed to improve the scientific understanding of the relationship between chemical composition and biological response. This understanding will inform work to improve the 'read-across' justification, allowing results generated on reference petroleum substances to apply to related substances and ultimately reduce the amount of animal testing that would otherwise be required.

Over the past 50 years the refining industry has made its own significant contribution to the improvement of air quality in Europe. One area of focus for further improvement is the early detection of leaks of volatile organic compounds from refinery plant. Previously, Concawe evaluated the use of optical gas imaging (OGI) as an alternative for leak detection. In the third article in this *Review* we summarise work to assess the capability of a newly developed quantitative OGI methodology to measure the mass emission rate of VOC leaks.

The fourth article in this *Review* is a summary of the industry safety statistics for 2015. Since 1993, Concawe has compiled statistics on work-related personal injuries sustained by employees and contractors working in the downstream oil industry (covering refining, distribution and marketing). For the past seven years we have also collated data on process safety incidents. These data, together with underlying root cause analyses, are discussed in the Concawe Safety Management Group, formed from safety leaders across the industry as part of a coordinated and systematic approach, striving for further safety performance improvements.

Finally, we include an interview with Klaas den Haan who has dedicated the past eight years to Concawe, firstly as Science Executive for Water, Soil and Waste, Oil Pipelines and Safety, but more recently as the Science Executive for REACH delivery. I take this opportunity to once more recognise the extraordinary contribution made by Klaas to the work of Concawe and wish him a long and happy retirement.

# Contents

# A review of REACH registration for petroleum substances in 2016

**Ten years on—addressing the tensions that the REACH regulation has created for the regulatory compliance community.**

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

Ten years after the REACH regulation came into effect, we are much more aware of the tensions that this regulation has created for the regulatory compliance community. This includes many experts within our industry, as well as in the regulatory bodies such as ECHA and the Member States competent authorities for REACH.

REACH is an evolving regulation and although our industry delivered compliant dossiers in 2010, new requirements are emerging which will require updates to the dossiers in order for them to remain compliant.

In 2015, Concawe met with ECHA to share the Concawe strategy and five-year plan for REACH, and to seek ECHA's critique of our plan. Concawe's strategy of supporting registrants of petroleum substances to comply with REACH at the lowest overall cost is consistent with the requirement in REACH to form Substance Information Exchange Fora (SIEFs), allowing registrants for the same substance to share information and costs of further work to fill in data gaps in their substance dossiers.

This article highlights some of the tensions created by these developments, and discusses ways in which they can be addressed.

## Uses of petroleum substances

Following the launch of the Commission's 'Substance of Very High Concern (SVHC) Roadmap', ECHA published the 'SVHC Roadmap to 2020 implementation plan' in 2013. For practical purposes, this article refers to the Commission's SVHC roadmap and the ECHA implementation plan collectively as the 'SVHC Roadmap' except where it is necessary to distinguish them, when they are referred to specifically as either the Commission's SVHC roadmap or the ECHA SVHC plan.

**Table 1 SVHC properties**

| | |
|---|---|
| CMR | Carcinogen, mutagen, toxic for reproduction |
| ED | Endocrine disruptor |
| PBT | Persistent, bioaccumulative and toxic |
| vPvB | Very persistent and very bioaccumulative |

The goal of the SVHC Roadmap is 'by 2020, to identify all known SVHCs and add these to the candidate list for authorisation or restriction'. The SVHC Roadmap foresees the use of screening methods and risk management option analyses (RMOA) to identify the relevant SVHCs, using information from the ECHA registration database, other REACH and CLP databases and further available relevant sources.

The SVHC Roadmap lists, as groups of substances to be covered by the implementation plan, CMRs, EDs, PBTs, vPvBs and sensitisers, which are collectively SVHC properties (see Table 1). Petroleum and coal stream substances with CMR or PBT/vPvB properties are specifically mentioned due to their UVCB (substances of unknown or variable composition, complex reaction products or biological materials) nature and the very high volumes concerned.

The SVHC Roadmap prioritises substances with SVHC properties which are registered for non-intermediate uses within the scope of authorisation. Annex 6 of the ECHA SVHC plan explains that the focus for petroleum substance will be on the non-fuel uses of petroleum/coal stream substances.

Annex 6 demonstrates the need to understand the volumes going into different uses. From the 2013 'volumes and uses survey', Concawe was able to elucidate the breakdown of volumes by major use category. Using 2013 as a reference year, it was noted that 971 million tonnes of petroleum substances were manufactured or imported in the EU. The majority (933 million tonnes) were used as intermediates for processing into chemicals, or used as a fuel. This leaves 38 million tonnes for industrial, professional and consumer uses, which fall under the scope of the SVHC roadmap (Table 2).

A problem with our 2010 dossiers is that related substances were grouped into categories, and the volume for each substance was not broken down by use. Hence, the regulators were unable to distinguish between fuel uses, intermediate uses or non-fuel uses per substance. ECHA made it clear that, without such a breakdown, they would need to assume that the total category volume per substance may be used for non-fuel uses. ECHA have now accepted the summary of volumes provided by Concawe in 2015 for the purposes of the work of the Petroleum and Coal Stream Substances Working Group (PetCo WG), but it will be essential for registrants to clarify the different uses of each substance registered with updated dossiers.

The PetCo WG agreed that petroleum substances that have consumer or professional uses (widespread uses) should be given the highest priority, as these are the chemicals that workers and the general public can be exposed to, and are most likely to find their way into the environment. Industrial uses are also within the scope of the ECHA SVHC plan, although they are currently considered to be of medium priority, assuming that in these uses, adequate worker protection is applied, in compliance with the Occupational Safety and Health Framework Directive (89/391/EEC).

**Table 2 Summary of volumes of petroleum substances by use category**

| Uses outside scope of the SVHC Roadmap | 2013 volume in million tonnes |
|---|---|
| Fuels | 618.0 |
| Intermediates | 315.0 |
| **Uses within scope of the SVHC roadmap** | |
| Industrial | 16.0 |
| Professional | 20.0 |
| Consumer | 1.5 |

Source: Concawe uses survey conducted in September 2015

**Box 1 The PetCo Working Group**

The PetCo (petroleum and coal stream substances) Working Group (WG), comprises representatives from ECHA, the Commission, Member States (currently Denmark, Estonia, Germany, France, The Netherlands and Poland) and industry stakeholders, including Concawe.

The mandate for the PetCo WG is to develop the approach for screening of PetCo substances for potentially relevant SVHCs.

## Chemical composition and substance identity

The ECHA website states that 'unambiguous substance identification is a prerequisite to most of the REACH processes'.

The accepted way of identifying petroleum substances within the industry is by means of a summary of the relevant manufacturing processes and then physical parameters, including but not exclusively, boiling point range and any chemical specifications used to determine the substance. For many uses of petroleum substances a detailed chemical composition is simply not necessary. It is industry practice to market petroleum substances according to physico-chemical parameters specified in European Standards. Furthermore, petroleum substances are archetypal UVCB substances, making it impossible to determine the precise chemical composition to the level of each constituent. Examples of this are given in Table 3 on page 6, which shows that for one class of hydrocarbons only (the alkanes) any petroleum substance with a boiling point higher than 270°C (gas oils and heavier substances) will comprise at least 4,000 constituents. If olefins, naphthenics and aromatics are added, this number would easily exceed 5,000.

Informal feedback from ECHA on the chemical composition provided in the petroleum substances dossiers was that they did not provide sufficient detail on chemical composition for the regulators to be able to evaluate the hazards, or to determine whether the risk management measures in place for our substances were effective. ECHA also made it clear that there was inconsistency between registrants of the same substance, and suggested that some registrants had wrongly identified (a number of) substances.

**Table 3  Petroleum substances are UVCBs**

*The predominant compounds are described by carbon number, boiling point ranges and hydrocarbon types. This table gives the number of isomers for one hydrocarbon class, the alkanes, and shows that the number of chemical compounds increases rapidly with carbon number.*

| | Carbon number | Boiling point (°C) (n-alkanes) | Number of isomers (alkanes only) |
|---|---|---|---|
| | 3 | -42.00 | 1 |
| Gasoline and napthas | 4 | -1.00 | 2 |
| | 5 | 36 | 3 |
| | 6 | 69 | 5 |
| | 7 | 98 | 9 |
| | 8 | 126 | 18 |
| | 10 | 174 | 75 |
| Gas oils | 15 | 269 | 4,347 |
| | 20 | 343 | 366,231 |
| Heavy products | 25 | 402 | 36,777,419 |
| | 30 | 450 | 4,108,221,447 |
| | 35 | 490 | 493,054,243,760 |
| | 40 | 525 | 62,353,826,654,563 |

Thus, later in 2015, Concawe began the first phase of the petroleum substance identity programme. Concawe commissioned an analytical chemistry project in which detailed analyses were conducted on a sample of each of the 197 different petroleum substances registered under REACH.

However, given that petroleum substances are UVCBs, it is important to understand the range of composition for each substance. Therefore, in 2016 Concawe requested that each registrant provide the analytical data given in the registration dossiers for their substances. Concawe has to date received more than 2,800 data sets (representing ~70% of the active petroleum substance registrations) from registrants.

Concawe commissioned a consultant to conduct a statistical analysis of the data set for each registered petroleum substance, and to support Concawe's Substance Identity Group in drafting Substance Identity Profiles (SIPs) for each petroleum substance.

The SIPs should provide sufficient information on chemical composition and composition range, to distinguish one petroleum substance from the next. This will allow Concawe to provide guidance to registrants, who will then be asked to confirm that they have registered with the correct European Community number.

This will address two of the concerns expressed by ECHA, that a number of registrants have incorrectly identified their substance, and that they (ECHA) observe a lack of consistency or even contradictory analytical information between different registrants for the same substance. In turn, this will justify the sharing of data generated on a substance between all registrants of the same substance.

## Grouping of petroleum substances by chemical composition

Over many years, prior to REACH, scientists from industry developed rationales for read-across of data from one substance to related substances, based on chemical similarity, with the goal of minimising unnecessary animal testing. This was accepted on a global basis for different regulatory regimes, and the same approach was used to prepare the petroleum substance dossiers for REACH registration.

However, ECHA challenges this previously acceptable approach. In the draft and final decisions received so far on petroleum substances and reiterated in the 2015 meeting with Concawe, ECHA stated that they only accept the use of read-across from one substance to a different substance when there is clear justification to support it.

The primary goal of the substance identity programme is to understand the differences in chemical compositions, allowing us to distinguish one petroleum substance from another. A second, but equally important goal, is to demonstrate the similarity between different, but related petroleum substances. This second goal is fundamental to the use of read-across from one substance, for which experimental data has been generated, to chemically analogous substances.

## Human health risk assessments.

Prior to REACH, reprotoxicity tests were only required for substances that were suspected to be CMRs, or for chemicals that were designed to be biologically active. REACH was the first chemical regulation in the world to make reprotoxicity data a standard requirement. In the EU, reprotoxicity testing which involves vertebrate species cannot be conducted without permission from ECHA.

By the 2010 deadline, 207 petroleum substance dossiers had been registered for REACH, using a category approach that distinguished 20 different petroleum substance groupings. For six of the category dossiers it was evident that there was insufficient reprotoxicity information available. Therefore, these dossiers contained proposals for two reproductive toxicity studies, one studying prenatal development and another studying development after delivery.

These six testing proposals were for one substance targeted in each category where it was clear that there were information gaps and where read-across was considered to be justifiable to the other substances within the category. The principle was that since the whole substance is tested, the result can be extrapolated to all substances showing a similar composition.

ECHA has challenged our read-across rationale within the six categories, on the basis that the chemical similarity of the substance category members was not sufficiently substantiated. Unless we develop stronger justification for read-across, it is highly likely that the regulators will require additional animal testing for reprotoxicity and prenatal developmental toxicity, even beyond these initial six categories.

During the main registration phase of REACH, the accepted standard test for reprotoxicity was the 'two-generation reprotoxicity test' (OECD 416)[1]. Until 2015, all registrations that included a testing proposal were for the standard two-generation test. The REACH regulation was amended in 2015, when the two-generation reprotoxicity test was replaced by the Extended One-Generation Reproductive Toxicity Study (EOGRTS) (OECD 443). However the Commission suspended decisions on all reprotoxicity testing until consensus on the required technical scope of the EOGRTS was achieved. The Commission sent out letters requiring updated testing proposals in the final quarter of 2016.

A different tension is related to the regulatory requirement for prenatal development toxicity tests (PNDT) to be conducted on two species. Previous practice was to use a single species, typically the rat, for the PNDT work, but in 2015 the requirement for a second species was confirmed by ECHA. This requirement alone would require significant additional testing for petroleum substances, unless an acceptable alternative can be developed.

This is in line with a goal we have in common with ECHA and also with the anti-animal testing lobby, which is to develop alternatives that will minimise the requirement for additional animal testing. In 2016 Concawe initiated a new research programme known as CAT-APP (category approaches and read-across in regulatory programmes). The goal of this research is to improve our understanding of the relationship between chemical composition and biological response to exposure to different petroleum substances. In turn, such information together with the improved chemical composition data will allow us to group petroleum substances for different human health end points, allowing a scientifically-sound justification for read-across between members in the same grouping. The CAT-APP programme is discussed further in a separate article on pages 10–13 of this edition of the Concawe *Review*.

## Environmental risk assessments

The approach developed by Concawe's Ecology Group (EG) for environmental risk assessments has its origin in the early 1990s when Concawe was developing approaches to enable responses to potential prioritisation of petroleum substances under the Existing

[1] More information on OECD testing guidelines can be found at www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788

Substances Regulation[2], the predecessor of the REACH Regulation. Given the complexity of petroleum substances and the fact that the environmental fate and effects properties of their constituents are predictable using Quantitative Structure Activity Relationships (QSARs) that correlate with physical-chemical properties, the EG developed the Hydrocarbon Block (HCB) Method (HCBM)[3]. In principle, such an approach could also be applied to health hazards. However, the range of effects (end points) under consideration is much larger and the data are not as widely available as they are more difficult to generate by block.

The HCBM takes a petroleum substance and divides it into blocks that represents the constituents present on the basis of chemical classes (e.g. paraffins, olefins, naphthenics, aromatics) and carbon number distributions. Originally, these blocks covered ranges of three carbons for each of the then defined 16 chemical classes. Today these blocks are only one carbon number for 16 redefined chemical classes.

For the purpose of an environmental risk assessment the predicted environmental concentrations (PECs) and predicted no-effect concentrations (PNECs) are established for each HCB that is identified in the petroleum substance under assessment. Obtaining the overall perceived environmental risk (ER) is then calculated by adding all the identified HCB-risk ratios or PEC/PNEC-ratios (see equation below).

**Calculating the perceived environmental risk**

$$ER_{ps} = \frac{PEC_{HCB1}}{PNEC_{HCB1}} + \frac{PEC_{HCB2}}{PNEC_{HCB2}} + \frac{PEC_{HCB3}}{PNEC_{HCB3}} + \frac{PEC_{HCB4}}{PNEC_{HCB4}} + \ldots\ldots \frac{PEC_{HCBn}}{PNEC_{HCBn}}$$

This process is automated in the PETRORISK model which is capable of establishing the ER originating from manufacturing the petroleum substance and each identified use at a local, regional and continental scale, taking into account the volumes and perceived release fractions for each of these.

As all petroleum substance constituents are susceptible to distribution over the four environmental compartments, air, water, sediment and soil, as well as being prone to environmental degradation processes, PETRORISK models these environmental fate processes when estimating the PECs for each use and environmental compartment.

The distribution is a function of physical chemical properties including water solubility, vapour pressure and environmental partitioning constants that are either measured or derived by quantitative structure activity relationships (QSARs). However, the environmental degradation rate constants of many constituents are estimated to obtain the environmental half-lives used in the PEC-derivation. To decrease the uncertainty in these bio-degradation fate QSARs, the EG is currently supervising three projects that will look into constituent removal from the environment by biodegradation.

Regarding environmental effects, the required PNECs for simple one- to three-constituent HCBs can easily be established on the basis of ecotoxicological testing. However, many of the HCBs have too many constituents to establish the ecotoxicological data by testing each constituent. In this respect it has to be noted that testing on fish falls under the EU Directive[4] on vertebrate animal testing, which requires Commission consent.

In view of this, and the huge amount of testing that would be required for the derivation of the PNEC for each HCB, the EG has supported academia to develop the Target Lipid Model (TLM) a QSAR effect model that estimates the concentration of any substance that is protective of 95% of the species in a given ecosystem. The EG considers that, given the conservative nature of this model and the large amount of real test data on which it is based, this 95% protection level is equal to a PNEC. The TLM is embedded in the PETROTOX ecotoxicological prediction model which estimates the observed ecotoxicity when a test solution is made by exposing water to a specific amount of the petroleum

[2] Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances (March, 1993).

[3] Concawe report 96/52: *Environmental risk assessment of petroleum substances: the hydrocarbon block method*.

[4] Directive 2010/63 of the European Parliament and of the Council on the protection of animals used for scientific purposes.

substance. In laboratory testing this is known as the water-accommodated fraction (WAF) and is currently the only way of performing ecotoxicological tests on petroleum substances.

In 2013, ECHA issued compliance checks to the lead registrants of 36 petroleum substances which challenged the validity of the TLM and concluded that the petroleum substances registration dossiers lacked valid PNECs. In response, throughout 2014 and 2015, the EG performed additional ecotoxicological testing on aquatic plants and blue-green algae to strengthen the species distribution of the TLM, and contracted a further review of the literature to find additional data for this purpose. The results of this work led to a refinement of the TLM that is now embedded in the PETRORISK 7.04 version of the model.

In 2016, the EG then used the new version of the PETRORISK model to update the environmental risk assessments in the dossiers for the categories covered by the ECHA compliance checks.

Another aspect of the environmental hazard assessment required for REACH is the need to determine whether a substance or constituents are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances. This concept was developed by competent authorities in response to the conclusions of Rachel Carson's book, *Silent Spring*, and led to the creation of a list of 12 persistent organic pollutants (POPs). Today, the authorities are expanding this concept to include PBT and vPvB substances, with the aim of avoiding potential environmental and health issues in the future. As a result, any substance that is considered to be either PBT or vPvB is likely to be added to the SVHC list.

The criteria for determining whether a substance should be classified as PBT or vPvB are stringent and based upon laboratory experimental data and a conservative theoretical interpretation that does not always reflect the environmental reality. Therefore, Concawe is active in the ECHA /industry PBT expert group and the EG is considering further work to develop data that tests the hypothesis that the theoretical approaches are sufficiently protective of the environment.

## Conclusions

Due to the UVCB nature of petroleum substances, the interpretation of the REACH regulation has resulted in the need for scientific dialogue with the regulatory authorities, and within ECHA and the competent authorities in Member States. These regulatory authorities are challenging many of the approaches adopted by our industry. REACH requires actual data to be provided to substantiate each effect, which is challenging for complex substances such as petroleum substances. Where the criticism is valid, Concawe has responded by conducting scientific programmes to provide additional data and improve our understanding. However, where we felt it was merited, Concawe has, and will, continue to challenge the regulatory community. The result is that the information in the petroleum substance dossiers will require significant updates over the next few years, to facilitate the evaluation of petroleum substances and ultimately to assure our customers, and society in general, that we understand the hazards and have effective risk management measures in place to manage the exposure.

# CAT-APP: category approaches and 'read-across' in regulatory programmes

**A new approach to evaluating the toxicological effects of petroleum substances by making use of existing test data aims to reduce, and eventually eliminate, the use of animals for toxicity testing.**

## Toxicity testing in the 21st century

*"It'll soon shake your windows, and rattle your walls, for the times they are a-changin'."* [1]

Windows and walls of conventional regulatory toxicology testing strategies have been shaking and rattling since the publication of *Toxicity Testing in the 21st Century: A Vision and a Strategy*, more commonly referred to as Tox21c, by the US National Research Council in 2007 [1]. This proposed vision has fuelled the discussion and changed the perspective on conservative animal-based toxicology studies, driven by animal welfare considerations and the revolutionary advances made in the field of biotechnology over the past decades. The main aim of Tox21c is to take advantage of these technological breakthroughs and move away from a regulatory testing paradigm that is currently still based on vertebrate animal models, following the '3R' principle in toxicology testing: refinement, reduction and eventual replacement of animal studies for research purposes [2]. Although the publication of the Tox21c vision has contributed to major developments in the field of 'alternatives' (to animal testing) research, practical application—and regulatory acceptance—to replace current testing guidelines is still far away. The question is how to make best use of these available and developing technologies for a more short-term application in regulatory programmes, such as the REACH regulation[2].

## Alternatives for animal testing under REACH

Currently, exposing an animal to chemicals including petroleum substances, following the OECD guidelines for testing of chemicals[3], to evaluate the potential associated toxicological effects is still considered the golden standard to comply with the REACH requirements regarding human health hazard information (i.e. health hazard 'end points', such as carcinogenicity). However, REACH tries to seek a balance between gaining an increased understanding of the potential hazard of a chemical and at the same time avoiding unnecessary animal testing. In other words, testing on an animal should be the last resort, and in order to keep the number of animal tests to a minimum the REACH guidance offers two ways to meet this goal: data sharing (e.g. joint chemical dossier submissions through a consortium of companies registering the same chemical) and alternative methods and approaches.

With regard to alternative methods, the main tool is 'read-across', i.e. using already available test data on a particular hazard end point of a substance to predict the properties of another, similar substance, instead of testing it again for the same end point. This sounds straightforward, and a useful historical toxicological database does indeed exist for petroleum products; hence, conducting an animal study to address an end-point requirement or data gap will, in many cases, be of questionable need. However, there is an additional complexity in applying this approach to petroleum substances: they are a prototypical example of highly complex UVCBs (substances of unknown or variable composition, complex reaction products and biological materials), which present enormous challenges for science-informed regulatory decision making. Although UVCBs are identified on global chemical inventories with unique Chemical Abstract Services (CAS) numbers and names, applying the similarity principle and evaluating their potential toxicity via read-across approaches remains challenging due to the chemical complexity and multiconstituent nature with largely unknown and variable composition. Read-across of petroleum substances within the REACH framework is typically done by grouping the individual substances into product categories with similar manufacturing processes, physical/chemical descriptors (including refining history, boiling point and carbon number ranges) and limited analytical chemical properties (such as hydrocarbon classes). However, category read-across approaches for (petroleum) UVCBs that are based solely on such broad similarity parameters are not considered to be sufficient under REACH.

[1] Written by Bob Dylan, ©1963,1964 by Warner Bros. Inc.; renewed 1991,1992 by Special Rider Music.

[2] Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

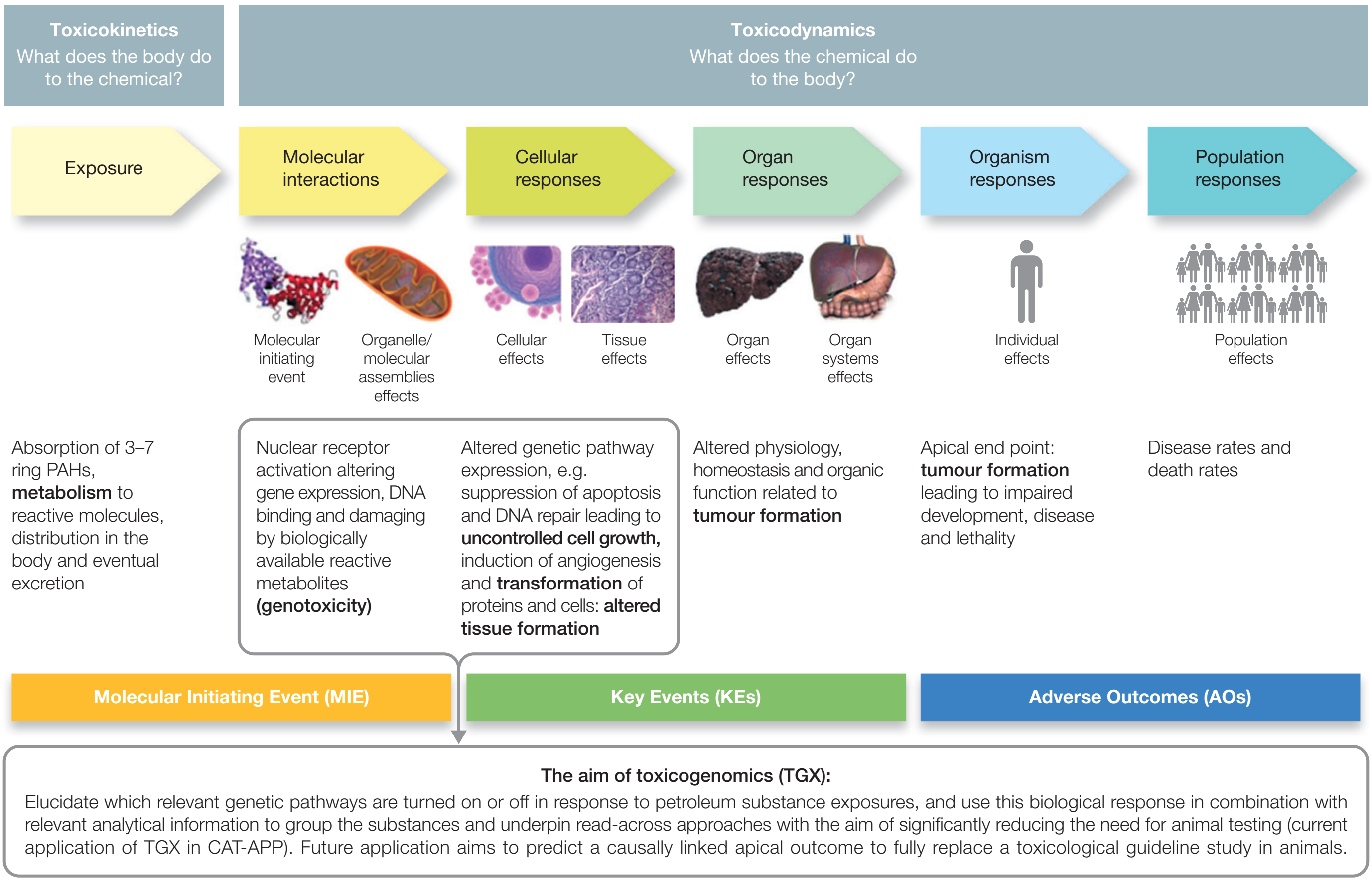
[3] More information on OECD testing guidelines can be found at www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788

Therefore, with respect to animal welfare, and taking into account the high cost and relatively limited predictive power of the current animal guideline tests for determining human health end points, regulators and industry have a common interest in defining a process for (petroleum) UVCBs to ensure that there is no underestimation of hazards, while at the same time minimising or eliminating the use of animals in toxicology testing.

## Mechanistic toxicology

The Tox21c vision aims to move away from studying observable outcomes in response to chemical exposure in whole animals 'in-vivo'[4], such as clinical signs and pathological changes indicative of toxicity at the level of a whole organism (a so-called 'apical end point'), towards predicting these adverse effects based on cellular or molecular events 'in-vitro'.[5] In the latter case, the events that take place during the period from initial exposure through to eventual toxicity can be observed to determine what the body actually does to a chemical (so-called toxicokinetics) and what that chemical does to the body (so-called toxicodynamics). This is illustrated in Figure 1, using carcinogenesis as an example. In mechanistic toxicology, underlying mechanisms leading to certain apical end points, such as tumour formation in the example of carcinogenesis shown here, are elucidated. Once these pathways of

**Figure 1 Illustration of the basic concepts of an Adverse Outcome Pathway in mechanistic toxicology, using carcinogenesis as an example**




[4] In-vivo: Latin for 'within the living', i.e. testing in a whole living animal.

[5] In-vitro: Latin for 'in glass', i.e. testing in components of an organism isolated from their normal biological context (organs, cells, subcellular components, molecules such as DNA, etc.).

toxicity are causally linked to the end point of interest—e.g. molecular markers for the formation of DNA damage linked to tumour formation in carcinogenicity—they can then be used to predict the toxicological end point, i.e. to answer the question, 'does the chemical trigger the pathway(s) leading to carcinogenicity or not'? This pragmatic approach would be used instead of conducting a full mandatory OECD guideline study for the same end point in which rats are exposed to a chemical on a daily basis for a time period of two years to observe tumour formation.

With the new rapidly developing biotechnological tools that have become available in recent decades, mechanistic information can be generated in a cost-effective manner (i) at the cellular level, measuring physiological parameters in toxicity screens (e.g. evaluating cell functionality), as well as (ii) at the molecular level, measuring 'gene expression' changes in so-called 'toxicogenomic' screens (e.g. to observe which genes in which biological pathways are turned on or off—see Figure 1). Note that the word 'screens' is used here, meaning that in both cases short-term rapid assays are developed that are eventually thought to replace costly and time consuming animals studies. However, as indicated above, with the exception of a few prototypical examples that are currently being developed (also under the umbrella of Concawe's Health Management Group (HMG) for petroleum substances), in most cases the predictive power of these screens is not yet sufficient to fully replace a 'golden standard' animal study. The example of DNA damage leading to tumour formation is obviously overly simplified; in real life this, and other, apical events will depend on a highly complex network of numerous interacting pathways. Research efforts are currently ongoing, such as the Adverse Outcome Pathway knowledge base,[6] aiming to elucidate these pathways and especially to link them causally to eventual in-vivo end points. However, it will still take some time for this work to develop an approach that is suitable for practical application in regulatory programmes.

## Chemical-biological read-across and CAT-APP

Considering the breakthrough developments that continue to be made in biotechnology and applied to mechanistic toxicology, as well as appreciating their current shortcomings, Concawe has developed the 'CAT-APP'[7] project—a strategy designed to make best use of the currently available data and screening tools for more realistic, short-term regulatory application. The fundamental principle of CAT-APP is to use the biological pathway information—not to predict toxicity, as described above—but instead to further underpin the similarity principle for grouping petroleum UVCBs. As mentioned on page 10, petroleum categories under REACH are currently based on limited similarity parameters such as boiling point information and other physical/chemical descriptors that define petroleum streams resulting from refining crude oil. The hypothesis is that these broad parameters drive the analytical chemistry of specific petroleum streams which, in turn, drive certain specific types of mammalian toxicity or more general biological responses. For example, certain high boiling point petroleum streams might contain polycyclic aromatic hydrocarbons (PAH) whereas low boiling point streams generally do not, hence these particular petroleum substances have the potential to show PAH-related toxicity. Thus, if it can be shown that specific petroleum substances defined by certain analytical chemical characteristics have similar biological behaviour because of this chemistry, while being distinct from other chemically different petroleum substances, this can provide a much more informed basis for grouping, and for eventually filling data-gaps, by so-called chemical-biological read-across of the toxicological data already available.

In this way the end-point requirement is fulfilled by 'indirect' prediction, supported by similarity in mechanistic biological responses, rather than by directly predicting the toxicological end point based on the mechanistic toxicity pathway.

[6] http://aopkb.org

[7] www.concawe.eu/cat-app-project

Over the course of 2017, a number of human cell lines representing various tissues, as well as functional cell models derived from so-called 'induced pluripotent stem cells', will be exposed to all Concawe registered petroleum substances. Subsequently, in response to these exposures, relevant mechanistic toxicology data will be generated at different levels, using several high-content toxicity screens (HCS), as well as more molecular types of information derived by evaluating gene expression changes using a state-of-the-art toxicogenomics-based approach (see section on mechanistic toxicology and Figure 1). All of these data will be collected and stored along with currently available relevant toxicological, physical/chemical and analytical chemical data in the CAT-APP database. Eventually, an overall integrative analysis of all available data types will define petroleum substance grouping and support chemical-biological read-across in a transparent and visually clear way. It is Concawe's aim that the indirect prediction of toxicological information to be included in Concawe REACH dossiers will significantly reduce the number of animal tests needed.

CAT-APP is expected to deliver its framework for application under REACH by mid-2018. However, initial results will become available and will be published by the end of 2017, among others on the CAT-APP[7] website which will be kept up to date with the latest developments—in addition to already-available background information on this project. A first pilot study presenting the basic principle of CAT-APP has already been published [3], and was acknowledged as one of the most innovative and impactful papers globally by the Society of Toxicology (SOT) in 2016.

## The times are changing

This appreciation by the SOT is an initial indication of the impact that CAT-APP is expected to have on the way we look at the mammalian toxicology of petroleum substances. Over the coming years, the change in the field of toxicology research that started decades ago and received a boost with the publication of the Tox21c vision in 2007 will progress rapidly as a result of the major biotechnological advancements that are still ongoing. Concawe, as a credible and highly appreciated scientific organisation, will follow these developments closely and will continue to be involved. It is therefore inevitable that these developments will be a major factor in driving the research strategy of Concawe's HMG to a significant extent over the coming years. Already, several Tox21c-related projects are ongoing, such as the development of a stem-cell based screening assay for potential mutagenicity/carcinogenicity of petroleum products and mechanistic toxicity work to support our ongoing reprotoxicity studies under REACH, that are expected to be helpful in keeping our heads above the water in a challenging regulatory landscape.

We'll *"better start swimming or we sink like a stone, for the times they are a-changin'."* [8]

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[8] Written by Bob Dylan, ©1963, 1964 by Warner Bros. Inc.; renewed 1991, 1992 by Special Rider Music

# Downstream oil industry safety statistics for 2015

**The 2015 safety statistics report presents data on personal injures and process safety, highlighting trends over the past 22 years of data collection.**

Safety management systems are widely recognised by the oil industry as an essential tool for collecting and analysing safety incident data, and for continuously improving the safety of employees and contractors. To support this effort, Concawe has, since 1993, been compiling statistical safety data for the European downstream oil industry to:

- provide member companies with a benchmark against which to compare their own company's safety performance; and
- demonstrate how responsible approaches to safety management can help to ensure that accidents stay at low levels in spite of the hazards that are intrinsic to refinery and distribution operations.

Most importantly, Concawe's annual safety data report enables companies to evaluate the efficacy of their own management systems, identify any shortcomings, and take corrective actions as quickly as possible.

## What safety data do we evaluate?

Concawe's 22nd report on our industry's safety performance (Concawe Report 12/16) presents statistics on work-related personal injuries sustained by oil industry employees and contractors during 2015. It also highlights trends over the past 22 years of data collection and compares the oil industry's performance to that of other industrial sectors.

The 2015 report compiles safety data submitted by 38 Concawe member companies, representing about 97% of the refining capacity of the EU-28 plus Norway and Switzerland. The statistics are reported primarily in the form of key performance indicators adopted by the majority of oil companies operating in Europe, as well as by other types of manufacturing industries. These indicators are:

- Number of work-related fatalities;
- Fatal Accident Rate (FAR), expressed as the number of fatalities per 100 million hours worked;
- All Injury Frequency (AIF) expressed as the number of injuries per million hours worked;
- Lost Workday Injuries (LWIs) and the Lost Workday Injury Frequency (LWIF) calculated by dividing the number of LWIs by the number of hours worked in millions;
- Lost Work Injury Severity (LWIS), the average number of lost workdays per LWI;
- Road Accident Rate (RAR), the number of road accidents per million km travelled; and
- Process Safety Performance Indicators (PSPIs) that report the number of Process Safety Events (PSEs) expressed as unintended Losses of Primary Containment (LOPCs).

## Process Safety Performance Indicators

Several major industrial incidents, including the Toulouse explosion (2001), the Buncefield fire (2005) and the Texas refinery explosion (2005), have led to increased attention being given to the causation of such events. This has led to several initiatives that focus on the gathering of PSPIs. The lagging indicator for this is the PSEs, mainly Losses of Primary Containment, because these have been proven to be the initiating events for the aforementioned disasters.

PSPI data were collected in 2015 for the seventh consecutive year, following the publication of the latest recommended practice of the American Petroleum Institute. The additional data provide insights into the types and causes of process safety incidents. PSPIs also enable the refining and distribution industry to compare their European process safety performance with similar data from other regions of the world.

Thirty Concawe companies provided PSPI data in 2015. From these responses, a Process Safety Event Rate (PSER) indicator of 1.5 was recorded for all PSEs, which is the lowest result ever. The overall results of the PSPI survey are presented in Table 1 on page 15. Fortunately, none of the reported PSEs resulted in a major incident that the understanding of PSE causation is trying to prevent.

Since the PSI data gathering was started in 2009, there has been a gradual decrease in the PSER, irrespective of the number of reporting Companies, as can be seen in Figure 1 on page 15. This decreasing trend is a good example of the commitment of the Concawe membership to process safety management, and furthermore demonstrates that the systematic gathering of such data enables the membership to actively manage this operational threat.

This article was written by
Dr Klaas den Haan,
Concawe's Science Executive.

## Personal Safety Indicators

Accident frequencies in the European downstream oil industry have been historically quite low; the 2015 data show a 1.0 LWIF for 2015, which is the lowest value ever reported in the sector.

In general, performance indicator results are of greatest interest when these can be analysed for historical trends. The evolution of safety performance over a period of time provides indications on how well safety management efforts are working. Figure 2, for example, shows the changes and improving trends in the three-year rolling averages for the four main performance indicators mentioned above.

The trends in these indicators show a steady performance improvement over the past 22 years, with a slow but constant reduction in LWIF which remained below 2.0 for the seventh consecutive year. Although the data suggest that AIF peaked around 1996–97, this could also result from better data reporting as the AIF indicator was not formally used in all companies in the early years of Concawe's data gathering. Since 1997, the trend in AIF has generally been downwards except for a slight increase in 2010.

Regrettably, seven fatalities in four separate incidents were reported in 2015. Two of these fatalities were due to road accidents, four were due to a single explosion incident and one was caused when a worker was caught by a moving object. The explosion occurred during a shut-down on a manufacturing site. The two road fatalities occurred in the marketing sector.

The seven fatalities in 2015 are among the lowest numbers of annual fatalities experienced since Concawe started to collect safety data (see Figure 3 on page 16). After a steady downward trend during the 1990s, fatalities began to increase again in 2000 with a very high value of 22 fatalities in 2003. This unfavourable trend was reversed in 2004–06 and the fatality numbers have shown little variation since that time. The three-year rolling average for FAR has also stayed at about 2 for the past six years.

The relationships between the AIF, LWIF and FAR are presented in Figure 4 on page 16.

**Table 1 Results of the 2015 PSPI survey**

| | Manufacturing | Marketing | Both sectors |
|---|---|---|---|
| **Companies reporting** | | | |
| Total | 35 | 22 | 21 |
| Process safety reporting | 30 | 17 | 16 |
| Percentage | 86% | 77% | 76% |
| **Hours worked (Mh)** | | | |
| Total | 266.4 | 291.2 | 557.6 |
| Process safety reporting | 249.9 (236.0)[a] | 248.1 | 497.9 (484.0)[a] |
| Percentage | 96% | 85% | 89% |
| **Tier 1 PSE:** PSE | 70 | 25 | 95 |
| **Tier 2 PSE:** PSE | 217 | 82 | 299 |
| **Tier 1 PSER:** PSE/Mh reported | 0.28 | 0.10 | 0.19 |
| **Tier 2 PSER:** PSE/Mh reported | 0.92 | 0.33 | 0.62 |
| **Total PSER:** PSE/Mh reported | 1.15 | 0.43 | 0.79 |

[a] The values in parentheses show the hours reported by companies that provided Tier-2 PSE data.

**Figure 1 PSER data for manufacturing, 2009–2015**

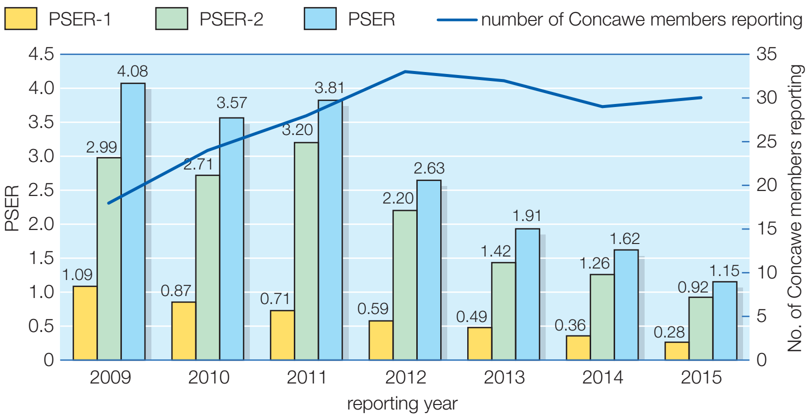



**Figure 2 Three-year rolling average personal incident statistics for the European downstream oil industry**

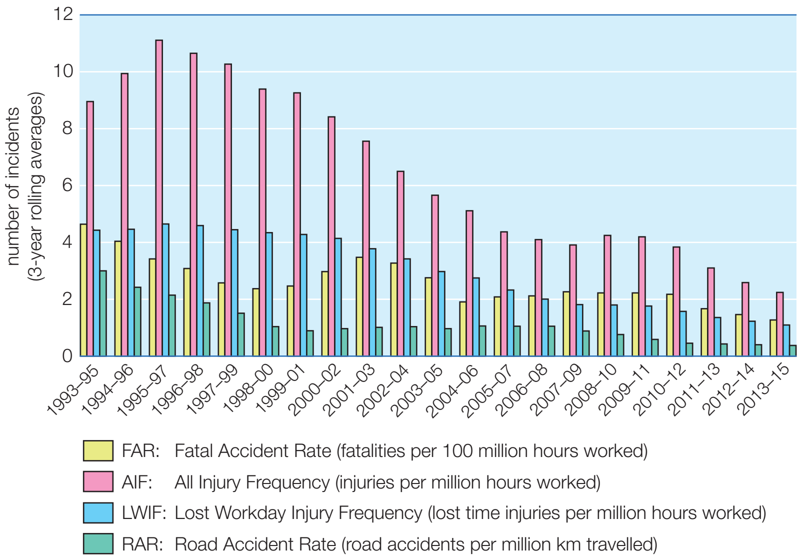


**Figure 3 Numbers of reported fatalities since 1993**

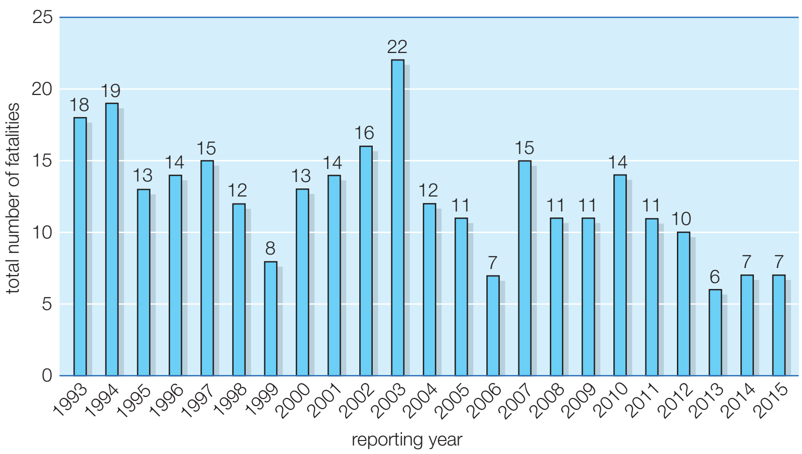



**Figure 4 Relationships between incidents and fatalities for the European downstream oil industry**

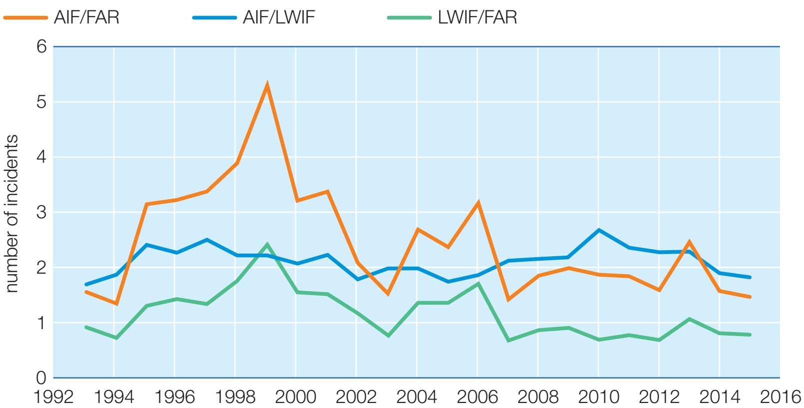
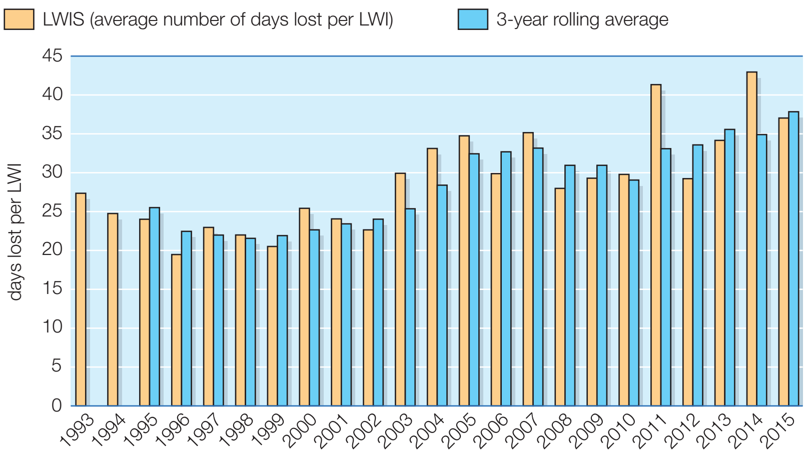



**Figure 5 Lost Workday Injury Severity (LWIS) from 1993–2015 and the three-year rolling average for the European downstream oil industry**




While the number of fatalities per year has an impact on the two curves that are associated with FAR values, the figure shows relatively stable relationships among these indicators over time. Almost half of safety incidents are LWIs and there was approximately one fatality for every 100 LWIs.

Contrary to the positive trends in the LWIF and AIF indicators, the LWIS indicator, expressing the average number of days lost per LWI, increased in 2015. LWIS data and the three-year rolling average are shown in Figure 5. Although the LWIS results declined after peaking in 2010, the three-year rolling average still remains above the all-time LWIS average of 25. Therefore, the severity of the incidents that occur remains a concern.

## Causes of LWIs

In the 2015 survey, Concawe also gathered information on the causes of Lost Work Injuries (LWIs) to see how closely the LWIs could be related to the causes of fatalities. In 2015 the LWIs were categorised in five main categories also used to report the causes of the fatalities. These five categories were selected after ample analysis of the reporting method for this kind of data by other industrial sectors and the current practice within the Concawe membership. The result is a scheme that is very closely related to that of the International Association of Oil & Gas Producers (IOGP), an association comprising many Concawe members and performing scientific advocacy on behalf of their Exploration and Production activities.

A total of 546 LWIs were reported in 2015 of which 537 (98%) were assigned to one of the 5 agreed categories by the reporting member companies. An overview of the LWI incidents and causes are provided in Table 2 on page 17. The trend in LWIs has decreased gradually, from 643 in 2013 to 546 in 2015.

When looking over the longer period since in 2007, the total number of LWIs has decreased by more than 45% from a total of 1029. Taking into account the increased number of Member Companies reporting their safety statistics and the fact that the number of reported working hours has hardly altered, this shows that seri-

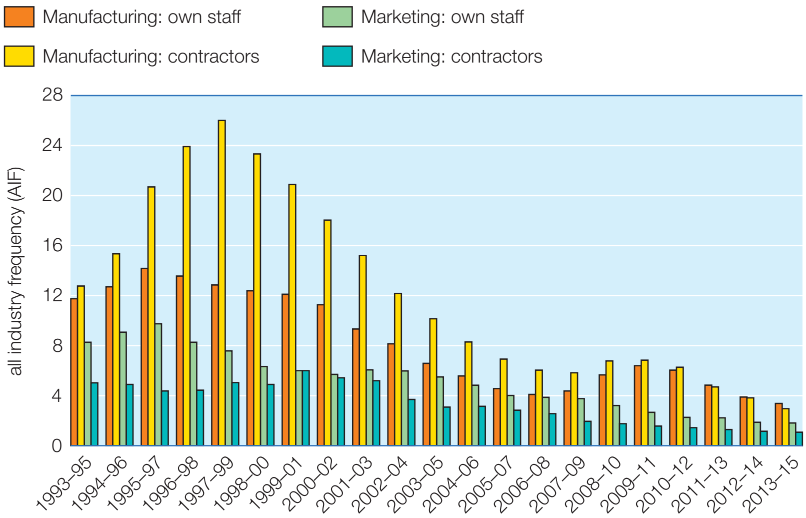
**Table 2 LWIs and their causes**

| 2015 | | | | | | 2014 | 2013 |
|---|---|---|---|---|---|---|---|
| **Cause** | | **Manufacturing** | **Marketing** | **Combined** | **Percentage** | **Percentage** | **Percentage** |
| **Road accident** | Road accidents | 7 | 16 | 23 | 4.2% | 3.9% | 4.4% |
| **Height/falls** | Falls from height | 21 | 26 | 47 | 8.6% | 8.6% | 10.3% |
| | Staff hit by falling objects | 7 | 10 | 17 | 3.1% | 4.6% | 3.6% |
| | Slips and trips (same height) | 79 | 82 | 161 | 29.5% | 27.1% | 32.7% |
| **Burn/electrical** | Explosion or burns | 27 | 6 | 33 | 6.0% | 6.2% | 4.8% |
| | Exposure (electrical) | 4 | 0 | 4 | 0.7% | 0.5% | 0.6% |
| **Confined space** | Confined space | 1 | 0 | 1 | 0.2% | 0.2% | 0.8% |
| **Other causes** | Assault or violent act | 2 | 15 | 17 | 3.1% | 2.8% | 1.7% |
| | Water-related, drowning | 0 | 0 | 0 | 0.0% | 0.0% | 0.2% |
| | Cut, puncture, scrape | 11 | 14 | 25 | 4.6% | 8.6% | 5.0% |
| | Struck by | 28 | 37 | 65 | 11.9% | 10.9% | 9.6% |
| | Exposure, noise, chemical, biological, vibration | 11 | 3 | 14 | 2.6% | 2.5% | 2.6% |
| | Caught in, under or between | 31 | 18 | 49 | 9.0% | 7.7% | 7.3% |
| | Overexertion, strain | 43 | 33 | 76 | 13.9% | 10.0% | 12.4% |
| | Pressure release | 4 | 0 | 4 | 0.7% | 0.9% | 0.9% |
| | Other | 5 | 5 | 10 | 1.8% | 5.6% | 3.1% |
| **Total** | | **281** | **265** | **546** | **100%** | **100%** | **100%** |

ous improvements in personal safety management have been achieved.

In addition, when further analysing the data, it can be concluded that the improvement in the personal safety performance of contractor staff is catching up with that of the sector's own staff, while the LWIF and AIF (Figure 6) performance actually appears to be better for contractor staff. It can be concluded, therefore, that the sector is finding the balance between managing the safety performance of both contractor and own staff. However, further performance improvements for both groups remains a feasible target.

**Figure 6 Historical evolution of All Injury Frequency (AIF), segmented 3-year rolling average**



# Optical gas imaging: from qualitative to quantitative

**New technology capable of quantifying fugitive emissions using infrared imaging may eventually serve as a full replacement for Method 21.**

The detection and repair of fugitive VOC emissions (i.e. emissions from plant components which are designed to be leak-tight, such as pump or compressor seals, valve packing, flange and sample points) is a well-established and regulated practice in sectors such as refining, oil and gas production and chemicals production. The Best Available Techniques (BAT) conclusion number six for the gas and mineral oil refinery sectors recognises two methodologies used for detecting leaks from equipment under leak detection and repair (LDAR) programmes:

- Method 21 (commonly called sniffing)[1] uses a hydrocarbon ionisation detector connected to an aspirated wand to probe for emissions. This methodology was developed by the US EPA and forms the basis of European Standard EN 15446:2008[2].
- Optical gas imaging (OGI) uses an infrared (IR) camera to make images of emissions. A protocol for application of OGI for LDAR was developed recently[3].

The estimation of fugitive emissions is required for reporting purposes. The only established technology to directly quantify fugitive emissions on a leak-by-leak basis is 'bagging', which involves fully or partially enclosing a leak to facilitate sampling in such a way as to determine the emission rate. However, this technique is time-consuming, and is not always practical or possible for every leak detected.

For Method 21, correlation factors for calculating the emission rate as a function of measured concentration have been developed from structured bagging programmes. Results are available for a set of typical plant components across a number of industry sectors. There are many uncertainties associated with Method 21 correlations. Where a large number of leaks are 'sniffed' the average emission rate can be determined from the correlation factors; however, when applied to individual leaks, this approach to estimating the emission rate is less certain.

OGI can be very effective in detecting leaks[4], but does not yet provide the means to take a direct quantitative measurement of each leak rate. This has been a shortcoming of OGI from a regulatory perspective, and has hindered its adoption as a true alternative to Method 21.

A new technology called Quantitative Optical Gas Imaging (QOGI) has been developed to quantify the leak rate by analysing the video image recorded by existing OGI cameras (e.g. FLIR GF300 or GF320[5]). The working principle of QOGI can be briefly described as follows[6]:

- IR images of a leak are analysed for intensity on a pixel-by-pixel basis.
- Each pixel represents a column of hydrocarbon vapour detected between the IR camera and the background. The hydrocarbon vapour absorbs the IR radiation and hence affects pixel intensity.
- Pixel contrast intensity (ΔI) is defined as the difference between pixel intensity in the presence of hydrocarbon and the intensity of the background.
- ΔI is a function of the temperature difference between the background and the plume (ΔT).
- At a given ΔT, the intensity is proportional to the number of hydrocarbon molecules in the vapor column.
- The leak rate is reflected in both pixel intensity and the number of pixels that have a ΔI higher than a certain threshold.

*Providence Photonics' new QOGI tablet—the QL100—can quantify the leak rate by analysing the video image recorded by existing OGI cameras.*

Based on the above principles, the QL100 tablet contains a computer program that takes the raw IR data from an IR camera and analyses it to determine the leak rate. The IR camera must be radiometrically calibrated to establish a temperature scale. The user needs to provide: the ambient temperature; the distance between the camera and the leaking component; and the gas composition. All other variables required for determining the leak rate are programmed into the tablet.

Several controlled experiments, comparing known leak rates of several gases and mixtures to the estimates provided by the QL100, were performed with the prototype version in 2015. The results have been presented at various conferences in the USA, Europe and the Middle-East. Additional experiments were carried out by Providence Photonics in collaboration with Concawe[7] and the US EPA[8].

The test conditions in the Concawe experiment are summarised in Table 1. Overall, the QL100 was able to detect and quantify leaks between 14 and 1100 g/h. For 31 leak scenarios across the conditions listed in Table 1, the estimation error was 6% on average, the minimum being -23% and the maximum 69%.

Further field experiments have been recently undertaken to develop an understanding of data quality indicators that would establish the characteristics and proportion of those leaks detected by OGI that could then be quantified by QOGI to similar or better accuracy than Method 21. Such knowledge would greatly enhance an LDAR programme.

In collaboration with Concawe, the QOGI technique was used to complement an OGI-based LDAR programme in a European refinery. The test included independent bagging with the high-flow sampling technique[4] to obtain a physical measure of the true leak rate. Factors investigated include: sufficiency of temperature difference between the leak and the background; effects of plume obstruction (e.g. in a confined area); movement/changes in the background during measurement; interference due to steam plumes, direct sunlight, etc. The results should be available in 2017.

**Table 1 Test conditions for the Concawe experiment to detect and quantify leaks using Providence Photonics' QL100 product**

| Parameter | Demonstrated range | Remark |
|---|---|---|
| Leaking equipment type | Open end, valve, flange | In pilot test location (not in manufacturing site) |
| Distance to leak | 2–8 m | Different lenses can be used |
| Leak rate | 14–1100 g/h | |
| Leak composition | propane, methane, toluene, propylene and blends thereof | IR response factors developed for many common hydrocarbons |
| Wind speed/direction | 0.3–1.9 m/s | Issues limiting use:<br>• High leaks and no wind (plume cannot be extracted from background).<br>• Small leaks and high wind (plume pixels cannot be captured) |
| Ambient temperature | 15–21°C | |

Based upon the test results to date, QOGI appears promising as a technology to quantify leaks, potentially providing a full replacement for Method 21. Other opportunities exist for this new QOGI technology. It has potential for quantifying other diffuse VOC emissions such as emissions from tank seals, and methane emissions in oil and gas production.

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# Interview with Concawe's Science Executive, Dr Klaas den Haan

**Dr Klaas den Haan talks about his experience as Science Executive at Concawe.**

Klaas den Haan joined Concawe in 2008 and is currently the longest standing Science Executive. He announced that by the end of 2016 he will retire from Shell and thus also terminate his assignment with Concawe. In this interview, Klaas shares with us some of the aspects of his work experience at Concawe.

Q: What did you know about Concawe before joining it in 2008?

A: *In one of my early Shell positions, I was involved with the work on product risk assessments. The Concawe Ecology Group was looking for a Shell Representative.*

*I attended the first meeting as a proxy for somebody else. That was in 1993, still in the Madou building. Back then, Mr Don Short was the Technical Coordinator at Concawe, and Duncan King, well-known to REACH-involved members, was already Chair of the Ecology Group, which he remained until his retirement in 2012.*

*I had been working with Don Short as we were both industry representatives in the technical working group that looked after the existing substances regulation implementation. In those days, the chemical agency was based in Ispra, Italy, close to Lago Maggiore. Don was taking care of petroleum substances and I was there on behalf of the European Centre For Ecotoxicology and Toxicology of Chemicals (ECETOC), looking after the interest of chemical businesses.*

*We were quite successful at the time. The environmental assessments methodology was a joint effort between the authorities and industry. If you now read the technical guidance documents of the REACH Regulation on environmental assessments, there are still parts in there that actually came from the industry and some of the text that I wrote myself.*

*I left this scene in 1998, when I took up another Shell assignment not related to Concawe activities.*

Q: It wasn't until 2008 when you returned to Concawe, this time as the Technical Coordinator. What attracted you in taking on this position?

A: *In 2008, I was approached by several Shell colleagues who informed me about the opportunity of an assignment in Concawe, namely Technical Coordinator (TC) for Water, Soil and Waste. In April I applied, in May got the offer, and I started in September.*

*I was aware of the type of work, I was aware of the role of the TC, I had seen the equivalent in ECETOC. Keeping the working groups together, managing them, that's the challenge, I think.*

*Also, I essentially returned to my environmental science roots and could do more with it than I was doing at that moment in Shell. I saw it as a challenge and also a way of exploring and exploiting my skills and knowledge.*

Q: Did the new role meet your expectations?

A: *It was much better than I expected. Compared with the chemical industry you find that Concawe and the whole Association really unite an entire [refining] sector in Europe. Whereas in the chemical industry it's much more scattered, here you have all the Members working in the same direction as they are challenged by the same issues. If you have a concerted industry position you are much stronger. Concawe is much more open and collaborative with respect to competent authorities, and therefore you have an advantage in opening doors and being listened to.*

*Being a Technical Coordinator at Concawe you are the spider in the web. You have society, industry and regulators and it's the science that is the centre of it. I see a lot of Academics who are purely into the science, focusing primarily on trying to find problems rather than trying to identify the solutions for the problems. And that's one of the attractive sides of working here. You look for the solutions and you promote the solutions yourself. You become part of the pre-political process and sometimes even the post-political implementation phases of legislation. You are almost in the full life cycle of the decision-making process.*

Q: In recent years we have observed a shift in the perception of our industry by the policymakers. Is this something you have experienced?

A: *In general, the industry is faced with an increasingly challenging working environment at the EU level. However, if you see how Concawe was treated by ECHA when it was all starting, and how we are perceived now, we have been able to maintain a very strong reputation.*

Q: This can only be possible if the Association is perceived as a constructive partner by the competent authorities. How can one achieve such status?

A: *You have your own reputation that has developed over time. Furthermore, Concawe has a reputation of delivering. This is the result of almost 55 years of hard work in building the relationships and the reputation. In essence, it even started before Concawe was founded. I am in possession of a paper from 1955, where the issues with respect to environmental quality, soil, water, air were already addressed by one of the founding fathers of Concawe. That discussion went on, and already back then, there was an awareness that to solve these rising concerns we had to work with the authorities, simply because we have a mutual interest. One has to realise that the understanding of the environment, then, was far away from that of today, and industry built a reputation in the '60s that was not so positive. In the late '70s it was realised that emissions and discharges impact the environment dramatically, and since then major improvements have been achieved in reducing these. Today, environmental issues are very different and I sincerely believe that the big environmental issues are no longer determined by the big industrial activities. Therefore, I am disappointed to see that politicians and authorities still focus on industry to resolve these environmental issues, not realising that they are focusing on only less than 5% of the causes.*

*When you see the practice in the refineries and the legislation they have to comply with, for example related to water discharge: refineries reduced their discharge over 99% in the 50 years that Concawe has been in existence. We are at the limit of what technology can deliver. Even some NGOs are recognising that industrial pollution from big industries is an issue of the past. However, the Commission and the Member States still use over 80% of their resources to increase the controls on industrial discharge. As a consequence, the real water quality issues resulting from domestic discharges are hardly addressed. The only Directive dealing with that is from 1992 and this is only completely implemented by a few Member States.*

*The remaining issues are associated with the products and how they are used by professionals and customers. That's were REACH starts to play a role. However, you will not succeed in the delivery when you are only addressing the manufacturers that comply. The Authorities need to focus on the parts of the supply chain that has been out-of-compliance since 1967.*

Q: Before diving into Petroleum Products, your first assignment at Concawe was related to Water, Soil, Waste and Safety. What is the largest piece of the EU regulation you worked on?

A: *I think the Water Framework Directive is the most progressive and largest piece of legislation that we've worked on. And, I think we've been very successful. It's not only the Water Framework Directive, it's also the Waste Directive, the Industrial Emission Directive, Air Quality Directives, and National Emissions Ceiling Directive. All of these associated with manufacturing the substances. REACH should focus on the use and fate of the substances as manufacturing is already covered by other legislation.*

*I feel that several Member States overlook the achievements of the Water Framework and Industrial Emission Directives as they are trying to incorporate industrial emission assessment into REACH. However, that's already regulated by the Industrial Emission Directive through the BREFs [Best Available Techniques Reference Documents]. The Water Group worked on the water part of the BREF. I think this was a big success as the final BREF achieved the regulatory goal and avoided the need for billions of unnecessary investments, not only for air, but also on water and soil issues.*

Q: BREF is recognised as one of the biggest achievements over the past years …

A: *The Water Framework Directive is also a good example that our efforts on understanding the environmental science on several of our substances, or better components in our substances, is pivotal. By having this science available we were able to demonstrate that placing these on the Water Framework Priority List was not warranted. That may sound trivial, but it means these are not on that* *list, which indicates that your emissions controls are already sufficient and no further activities or investment will be required to keep on producing within the EU.*

Q: What other key projects have you worked on?

A: *The Soil Framework Directive. Some Member States still want it, we think it is unnecessary. Concawe demonstrated that the soil legislation driven by Member States was sufficient to solve the problems and that you cannot solve it on an EU-wide basis because of the diversity of the soil types throughout Europe. Swedish soil is not the same as Spanish soil. We don't believe that an EU-wide directive can deliver on good soil and groundwater protection, and have proven that it's not the right thing to do. This means that Member States will continue to use the local legislation already in place or develop this for their country, tailored to their environmental characteristics and needs.*

Q: We focus here on Products, Water, Waste and Soil. However, for years you were also leading Concawe's work on Safety.

A: *Safety is one of the backbones of our industry. We want to be seen as an industry that takes care of its surroundings, its people and customers, and also takes care of their assets. The achievements of the Concawe Safety Group is something I am the most proud of out of anything I've done here in Concawe. Bringing down the number of incidents by almost 60% … seeing the fatality rates go down by 50%. This was achieved by promoting consistent safety performance data gathering, analysing these and then applying a little peer pressure to stimulate change. Gathering data and analysing these allow you to focus on improvement areas, and the results obtained demonstrate the value of this. It is of course still possible to improve and we have to do this because any incident is one too many, and we must also not forget the impact of these on the people involved and their families. Another contributing factor is coordinating the communication between the Members so they can learn from each other, and the SMG network that exists now is, in my opinion, priceless.*

Q: Sharing best practices, exchanging views between Members ...

A: *Safety is the best example. Look in the series of reports and see how the numbers keep going down. The big companies taking smaller companies by the hand. Having the opportunity of communicating with colleagues doing the same role in different companies. We solved many issues without having to consider expensive projects.*

Q: In your current assignment you are focusing on Petroleum Products and REACH in particular.

A: *In REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), I jumped on a full pace riding train. However, I was involved in writing the guidance and understanding the models. Challenging but doable, I thought.*

Q: What in fact is REACH?

A: *REACH in a nutshell is — 'dear industry, please demonstrate that you understand your substances. Please ascertain that the information is there to enable your downstream users to use your substances in a safe way'. And we are doing that. We do the assessments, we write the general safety data sheets (SDS) and then we pass it on to our customers who are responsible for taking these further down the value chain.*

Q: REACH is divided into several stages. Where are we now in the process?

A: *95% of registration work is done, if not more. There will be some additional registration taking place in 2018 for the speciality products. However, I cannot see a lot of work for Concawe, other than maintenance, which in itself is almost as demanding as the first registration round.*

Q: The next stage is the evaluation phase.

A: *The PetCo Working group*[1] *is trying to rationalise the prioritisation of petroleum substances ready for evaluation by Member States. It is a subgroup of*

[1] Working Group created to develop an approach to identify and address petroleum and coal substances and plan the practical implementation of this approach as required by the SVHC Roadmap.

*Member States with ECHA that are looking at the SVHC (substances of very high concern) roadmap. Based on our volumes, our substances are automatically on the list for screening. However, the competent authorities do not want to spend a lot of time on substances that turn out to be safe or free of risk when these are used in the right way, and the SDS have the required information. If there are risks, where is the highest potential for risk? Those are the substances used by consumers and/or professionals.*

Q: What are the challenges ahead for your successor?

A: *Keeping the membership together, delivering the substance identity profiles in a credible and defendable way, otherwise we will lose part of our reputation.*

Q: What would be the future of REACH?

A: *The future of REACH will be, first of all, the rationalisation of the petroleum substances portfolio and to develop it; to have a better understanding of information that may be still missing, and what projects are needed to fill that in a very logical way. We cannot test everything. Especially the health experts have programmes like CAT-APP, which is spot on to really look at the big issues and deal with those.*

Q: Some of our Members do know about CAT-APP but not all. Can you explain in few words the project to our readers?

A: *It's a programme, run by the Health Management Group, in which you want to group substances on the basis of their effects. Rather than do the effects testing on animals, they use cell lines because the science is now sufficiently advanced to allow this. Thereafter, they can group petroleum substances on the basis of the observed effect and, when still required, do a single full-scale animal study on a single member of that group. This means that we don't need to sacrifice as many animals that would otherwise be required if we have to test each petroleum substance for each effect and still obtain a scientifically defendable understanding of the potential hazards of the group of substances.*

Q: Would you recommend your colleagues from your mother company to undertake a similar career path?

A: *I would recommend every HSE advisor to spend at least three years in Concawe.*

*The experience you get here, and also being spider in the web between all the forces that are working, gives you an added value for you and your company. You are exposed to a network that you can use when you get back to your mother company. I hope in the future, and I see that already happening, the Science Executives will enter this organisation in the earlier phases of their careers so that the Member Companies can also profit. The benefit of what they achieve here and the network they build, and also gaining the understanding of the processes at the EU level and at national level, e.g. by getting to know NOIAs (National Oil Industry Associations) is important and should be used when returning.*

Q: On a more private note, what did you enjoy most about your Brussels assignment?

A: *Working here is of course not only the professional life. I am not a person that is not very fond of major cities even though I was born in Rotterdam. I always lived in smaller villages close to the bigger city. You get benefits of the countryside and the large city. We do it now again, going back to The Netherlands. We will be located between Eindhoven and Den Bosch. This allows us to go to museums and theatres in the city while enjoying the benefits of the countryside and the village life on a day-to-day basis.*

Q: Can you lift for us the curtain on your retirement plans?

A: *With respect to the future, I cannot see myself sitting behind the curtains only. The curtain will be open; whether that's activities associated with what I have been doing I will have to see. I still have this feeling that there is an ample opportunity to write one or two books. From the science perspective, I really want to write the book about 'thermodynamics of politically correct visionary aspirations', as many decision makers and politicians should realise that most of their ideas are not feasible according* *to the laws of physics and chemistry. For instance, some of the efforts proposed to fight global warming require an energy investment and therefore $CO_2$ emission that is triple today's emission before it can actually start to deliver keeping emissions stable.*

*Otherwise, free advice can always be given. We are always allowed to do some science voluntary work. Most importantly, I want to be a master of my own clock. Do the things with my wife that we put aside for the past 30 years. Less travel, and spending my air miles wisely. I don't know how many times I have travelled around the world if you add everything up?!*

*I assume that I will cycle a lot, exploring the new surroundings and I will take up my photography, but now seriously. However, we will first go to the Netherlands to a temporary place and start looking to find a permanent place. Furthermore, the first period will be a break to recover and partly reset the brain. These final months have been quite hectic.*

*However, I am also looking forward to following Concawe from a distance, and wish my colleagues lots of success in promoting the refining sector on the basis of sound science, as this remains the easiest manner to advocate your interests and contributions to society.*

# Abbreviations and terms

| | |
|---|---|
| AIF | All Injury Frequency |
| BAT | Best Available Technique |
| BAT REF or BREF | BAT Reference document. Full title: 'Reference Document on Best Available Techniques for ….' (A series of documents produced by the European Integration Pollution Prevention and Control Bureau (EIPPCB) to assist in the selection of BATs for each activity area listed in Annex 1 of Directive 96/61/EC) |
| CAS | Chemical Abstract Services |
| CAT-APP | Concawe project to investigate new technologies to underpin CATegory APProaches and read-across in regulatory programmes |
| CLP | European Council Regulation No. 1272/2008 on Classification, Labelling and Packaging of substances and mixtures. |
| CMR | Carcinogenic, Mutagenic or toxic for Reproduction |
| $CO_2$ | Carbon dioxide |
| ECETOC | European Centre for Ecotoxicology and Toxicology of Chemicals |
| ECHA | European Chemicals Agency |
| ED | Endocrine Disruptor |
| EG | Concawe's Ecology Group |
| EOGRTS | Extended One-Generation Reproductive Toxicity Study |
| ER | Environmental Risk |
| EU | European Union |
| FAR | Fatal Accident Rate |
| HCB | Hydrocarbon Block |
| HCS | High Content (toxicity) Screens |
| HCBM | Hydrocarbon Block Method |
| HMG | Health Management Group |
| HSE | Health, Safety and Environment |
| IR | InfraRed |
| IOGP | International Association of Oil & Gas Producers |
| JRC | Joint Research Centre of the European Commission |
| LDAR | Leak Detection And Repair (programme) |
| LOPC | Loss of Primary Containment |
| LWI | Lost Workday Injury |
| LWIF | Lost Workday Injury Frequency |
| LWIS | Lost Work Injury Severity |
| Mh | Million hours |
| NGO | Non-Governmental Organisation |
| NOIA | National Oil Industry Association |
| OECD | Organisation for Economic Co-operation and Development |
| OGI | Optical Gas Imaging |
| PAH | Polycyclic Aromatic Hydrocarbon |
| PBT | Persistent Bioaccumulative and Toxic |
| PetCo WG | Petroleum and Coal Stream Substances Working Group |
| PEC | Predicted Environmental Concentrations |
| PETRORISK | Spreadsheet-based tool developed by Hydroqual for Concawe designed for conducting environmental risk assessment of petroleum substances |
| PNDT | PreNatal Development Toxicity (test) |
| PNEC | Predicted No-Effect Concentrations |
| POP | Persistent Organic Pollutants |
| PSE | Process Safety Event |
| PSPI | Process Safety Performance Indicator |
| QOGI | Quantitative Optical Gas Imaging |
| QSAR | Quantitative Structure Activity Relationship |
| RAR | Road Accident Rate |
| REACH | Registration, Evaluation, Authorisation and restriction of CHemicals |
| RMOA | Risk Management Option Analyses |
| SIEF | Substance Information Exchange Forum |
| SIP | Substance Identity Profile |
| SDS | Safety Data Sheet |
| SMG | Safety Management Group |
| SOT | Society of Toxicology |
| SVHC | Substances of Very High Concern |
| TLM | Target Lipid Model |
| US EPA | US Environmental Protection Agency |
| UVCB | Substances of Unknown or Variable Composition, complex reaction products or Biological materials |
| VOC | Volatile Organic Compound |
| vPvB | very Persistent and very Bioaccumulative |
| WAF | Water-Accommodated Fraction |

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