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.

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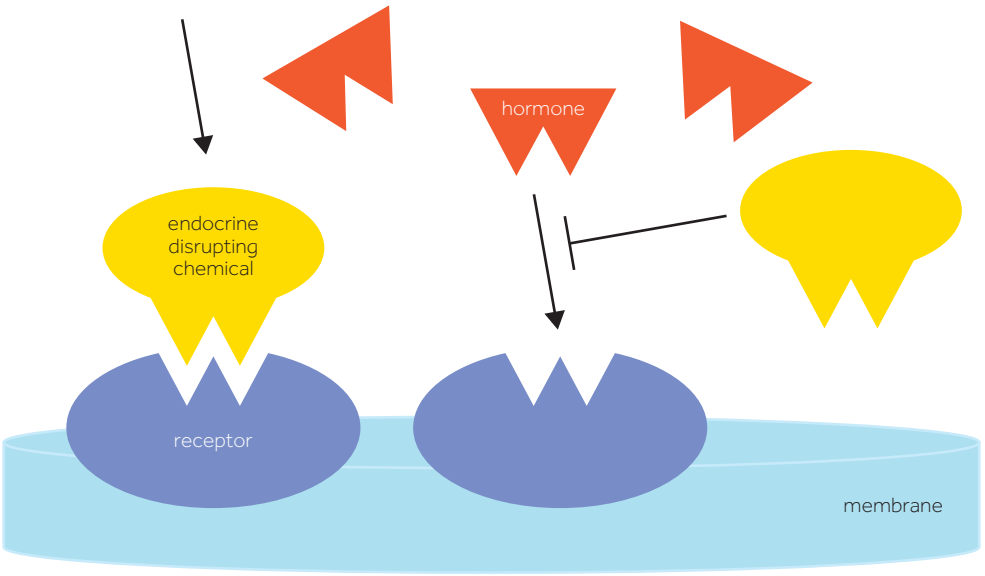
Endocrine disruption (ED)

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]

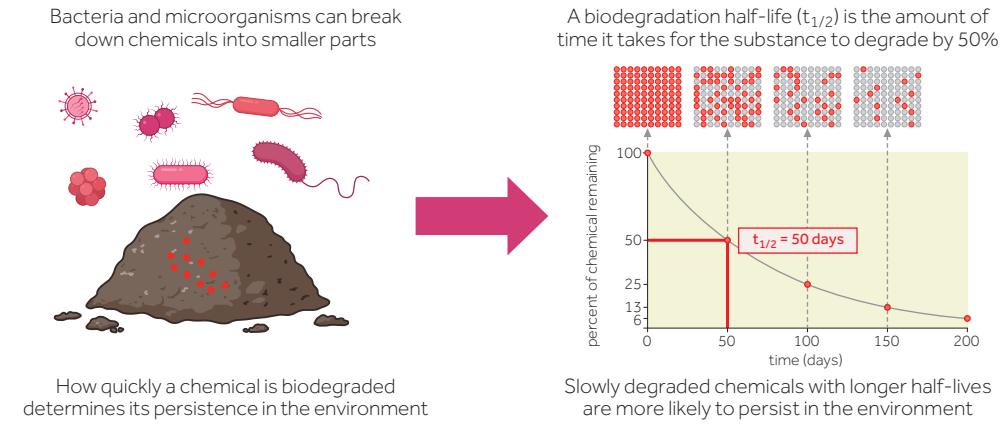
Persistent, bioaccumulative and toxic (PBT) substances

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

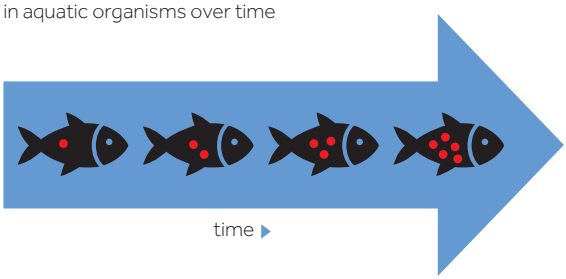
Slowly degraded chemicals with longer half-lives are more likely to persist in the environment

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

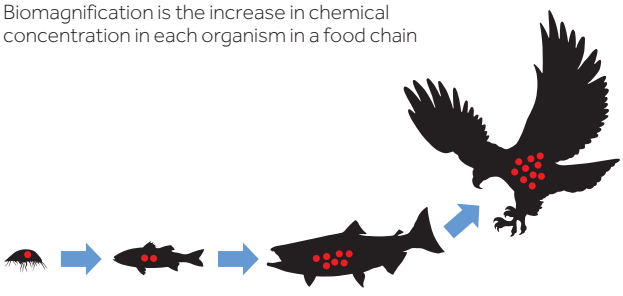
Bioconcentration is the build-up of chemicals in aquatic organisms over time



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

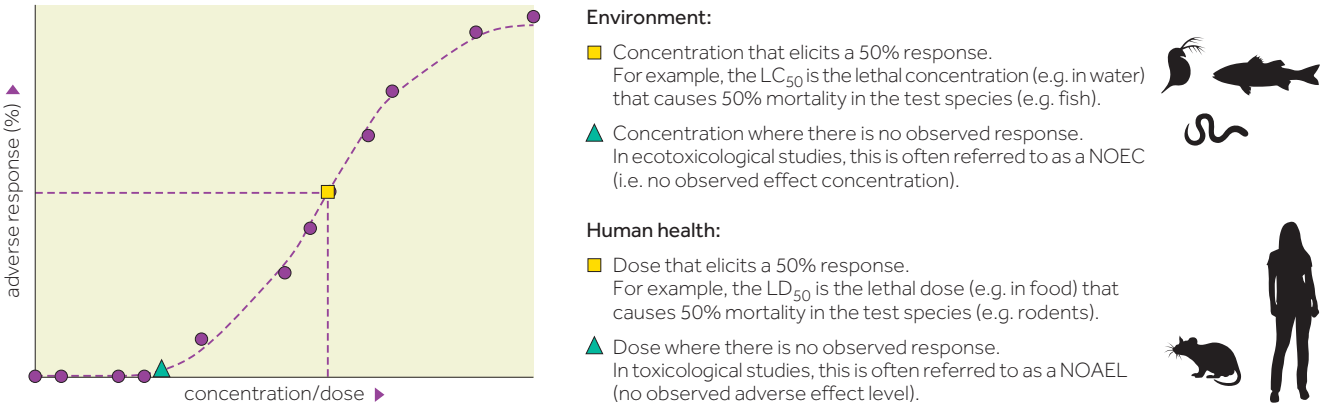


Process described by the biomagnification factor (BMF):
BMF = concentration in predator ÷ concentration in prey

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).

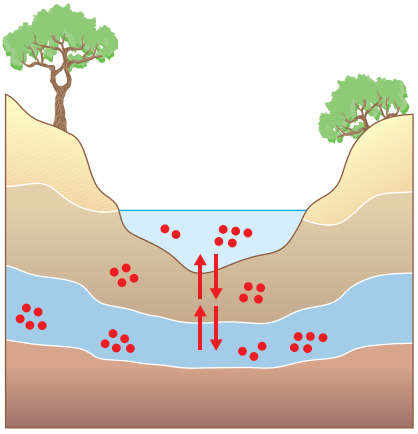
The criteria for the identification of PBT/vPvB properties in chemicals can be found in the REACH regulation and are summarised in Table 2 on page 27. The vPvB CLP criteria is identical to the criteria specified in REACH. For PBT properties, the definitions of persistent (P) and bioaccumulative (B) are 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

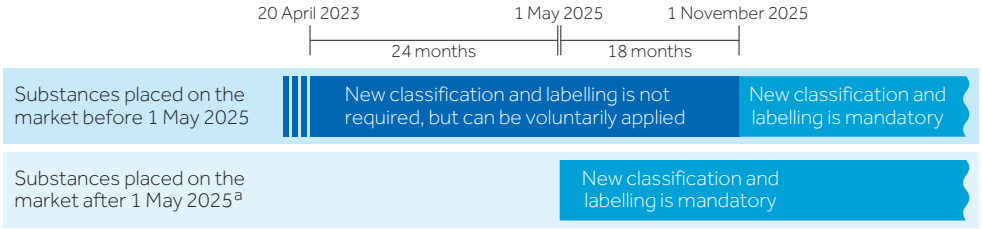
Hazard	Classification	CLP criteria
Persistence	Persistent (P)	Degradation half-life in any of the following compartments is higher than: a) 60 days in marine water b) 40 days in fresh or estuarine water c) 120 days in fresh or estuarine water sediment or in soil d) 180 days in marine sediment
	Very persistent (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.

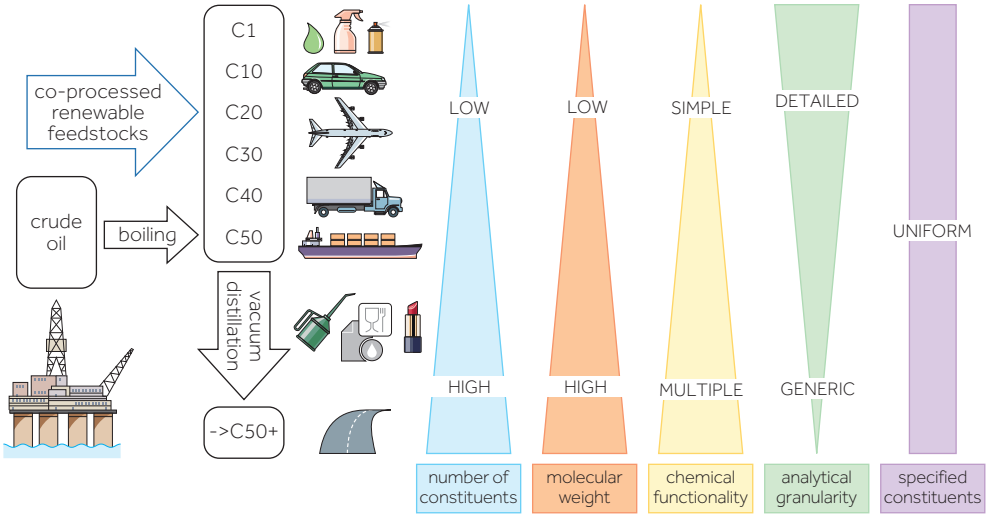
The introduction of these hazard classes will affect chemical manufacturers, importers and downstream users. Companies will need to review their product portfolios to align with the new classification criteria in order to ensure appropriate communication of potential hazards and risks.

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

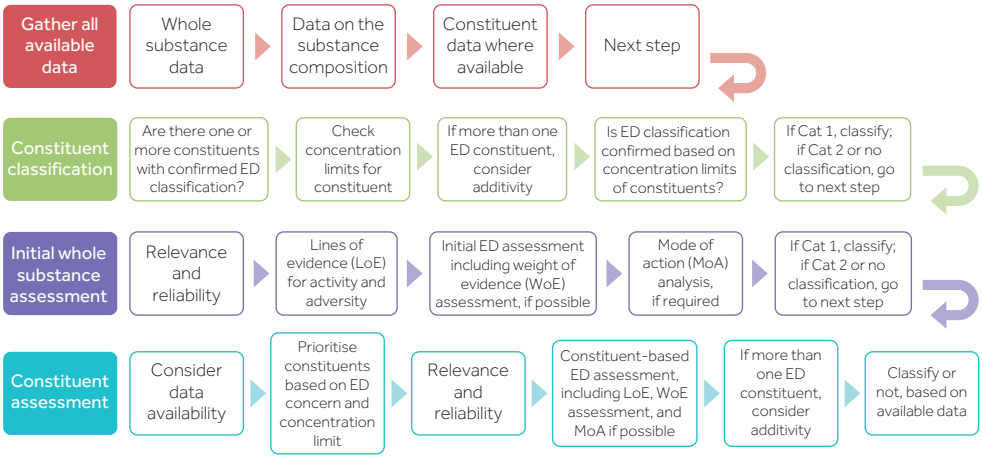


The compositions of hydrocarbon substances produced in refineries are influenced by both the source crude oil and the refining processes applied during fuel manufacturing. This thereby influences the complexity and variability of the hydrocarbon constituents (e.g. their number, molecular weights, chemical 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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