

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

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

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Historical development of Concawe classification and labelling reports

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

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

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

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

The 2023 edition: a transition towards new hazard classifications

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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



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