

ATIEL position on REACH revision

18th of April 2025

The Technical Association of the European Lubricants Industry (ATIEL) represents the combined knowledge and experience of leading European and international engine oil manufacturers and marketers. ATIEL welcomes and supports the European Commission's objectives for the proposal to do a targeted revision of the REACH regulation to further improve the health, safety and environmental information of hazardous chemicals. Based on the information provided by the Commission at the recent CARACAL meeting in April we would like to bring to the attention of the Commission some of the proposed measures that concern us.

The REACH revision presents a crucial opportunity to simplify chemical regulations, removing administrative tasks that add no value and are burdensome for the industry. To enhance competitiveness and foster innovation, it is essential to create a regulatory environment that offers predictability and long-term visibility.

ATIEL calls for a science-based and proportionate approach to chemical regulation under REACH with highlights on several important aspects:

- Questioning the extension of Generic Risk Approaches (GRA) to professional uses and additional hazard categories and advocating for decisions grounded in exposure and risk assessments.
- Finding a blanket application of a Mixture Allocation Factor (MAF) not justified and instead favouring targeted measures that reflect real-world exposure and reduce administrative burdens.
- Proposing proportionate updates to endocrine disruptor information requirements, starting with high-volume substances.
- Highlighting the need for transparent and predictable frameworks for determining essential uses.
- Stressing the importance of improving supply chain communication for all companies.
- Ensuring harmonized enforcement to maintain fair competition across the internal market.

By streamlining processes and focusing on effective, science-based measures, the REACH revision can ensure that the EU chemicals industry remains a global leader while reducing unnecessary administrative burdens.

Lubricants, as mixture formulations, are dependent on thousands of substances registered under REACH for this use upstream. As such, our industry and specific uses are highly vulnerable to changes in Harmonised Classification and Labelling (CLH) of substances and REACH restrictions, which can significantly impact reformulation, effectiveness, and technical tests of lubricants. This impact is felt across the supply chain, and the limited time provided by regulatory processes is often insufficient for adaptation. Ensuring a stable and predictable regulatory framework is vital for the continued innovation and competitiveness of the lubricants industry, which plays a crucial role in global transport, equipment durability, and emissions reduction.

1. Generic approach to risk management

ATIEL considers that widespread use of a hazard-based approach in managing chemicals is not scientifically justified, nor would it comply with the proportionality principle. Hazardous substances should not be restricted or banned when the human exposure and environmental emissions can be controlled, societal benefits outweigh risks, and there are no technically/economically viable alternatives.

In addition, wide scope bans or restrictions of groups of chemically related substances could cluster together substances without sufficient individual scientific data (it is impossible to be both broad and specific). This could be particularly damaging to our sector, which provides solutions that are critical for global transport and European competitiveness, especially in applications with strict performance and safety requirements where substitution options are limited or may not exist.

As such ATIEL suggests that both the 'generic risk management' approach and amendments to entries 28-30 of Annex XVII should be applied in a targeted way, to substances and/or uses where adequate control of risk has not been demonstrated and with prior considerations, such as:

- Adequate scientific scrutiny and socio-economic impact assessment;
- Consultation of expert stakeholders;
- Possible/detected/known/widespread use of the substance;
- Used by vulnerable groups (e.g. children, pregnant women);
- Migration potential of the substance;
- Non-threshold adverse effects.

Extending GRA to additional uses (like professional) would have important consequences on industry without necessarily providing proportional benefits. For professional uses, it is crucial to evaluate exposure and risk comprehensively and base regulatory decisions on these parameters. This ensures that the measures taken are both effective and proportionate, addressing actual risks rather than perceived hazards. For example, if a substance contained in engine oil becomes classified as Reproductive Category 1, it would affect the classification of the entire mixture. This reclassification could lead to stringent regulatory restrictions, making it impossible for garages to change or add oil to cars. As a

result, routine maintenance tasks essential for vehicle operation would be halted, leading to a complete freeze in transportation. This would have far-reaching implications, disrupting not only personal mobility but also the broader logistics and supply chains that rely on road transport. These kinds of unintended consequences need to be thoroughly considered in advance.

ATIEL does not support extending GRA to professional uses and urges the European Commission to continue to consider exposure and risk as critical parameters for decision making. There is a need for science-based evidence decisions and groups of chemically should be managed cautiously to avoid unjustified measures and disproportionate consequences.

2. Combination effects of chemicals and mixture allocation factor (MAF)

A generic MAF is a very simplistic approach to a complex situation and as such ATIEL is not in favour of the introduction of one generic/fixed MAF to be applied to all chemicals. Such a generic MAF would be arbitrary and not based on science, covering largely hypothetical exposures and risks rather than real-life scenarios.

ATIEL believes that considerations of combined exposures should be proportional, targeted, and built on a solid scientific knowledge base as well and should allow for specific evidence-based refinements. Safety factors are already intrinsically added when deriving an acceptable exposure level, such as DNEL or PNEC and these are already conservative.

ATIEL notes, as have others, that industry studies and examples from downstream users, reveal that a generic Mixture Allocation Factor (MAF) would impose significant administrative burdens without effectively addressing combined exposures.

Existing measures seeking to reduce emissions to the environment i.e. the Industrial Emissions Directive, the Urban Wastewater Treatment Directive, or assess real-life combined exposures i.e. Water Framework Directive and Chemicals Agents Directive, offer more targeted and impactful ways to address harmful combined exposures.

Therefore, ATIEL strongly advocates for a more nuanced and scientifically grounded approach to managing combined exposures, rather than the implementation of a generic Mixture Allocation Factor (MAF). This approach should leverage existing targeted measures and evidence-based refinements to effectively address real-life scenarios and reduce administrative burdens.

3. Modifications to the authorisation and restriction processes

ATIEL believes that managing chemicals based on a good understanding of their uses and of potential exposures should continue to be at the core of risk management. Science and data need to remain at the heart of decision-making.

A transparent procedure to ensure that the best and most efficient risk management option can be chosen should be established with an appropriate and transparent consultation process for all interested stakeholders and third parties. Moreover, a more predictable regulatory environment is needed, to allow lubricant formulators to plan and allocate resources effectively, ensuring that chemical management practices are both efficient and compliant. This stability is crucial for fostering innovation and developing viable alternatives without the risk of unintended consequences. Prioritisation criteria for both processes should be carefully reviewed and more possibilities for granting exemptions when exposure is low and risks are adequately controlled should be considered.

Therefore, ATIEL advocates for science-based risk management and transparent decision-making processes, including stakeholder consultations and exemptions when exposure is low and risks are controlled. The existence of viable alternatives is key, and the industry should have time to develop real alternatives without incurring the risk of unfortunate substitution.

4. Update of Annexes (Substance Information Requirements)

The introduction of new hazard classes in the CLP Regulation, especially for endocrine disruptors affecting health and the environment, necessitates an update of Substance Information Requirements (SIR) in REACH to source the data needed for classification purposes and risk assessment. These hazards are relatively new, and there is a general lack of expertise both at the level of authorities and industry on these endpoints. This is coupled with a lack of testing capacities at laboratories and testing protocols that are not all validated and/or inappropriate for difficult substances like UVCBs.

ATIEL believes that targeted updates to the information requirements for endocrine disruptions within Annexes VII, VIII, IX, and X of REACH should be proportionate, especially for lower volume substances. Endocrine disruption-specific testing should start at Annex VIII, where volumes are more significant and can be meaningful for the potential impact on the population and environment, and where *in vivo* adversity studies might exist to allow proper weight of evidence. Otherwise, only flags from mechanistic studies would end up triggering more *in vivo* animal studies, contradicting the roadmap to reduce animal testing.

For substances placed on the market at 1-10 tpa and falling under Annex VII, the quantities are too low to impact the population or environment significantly. There is a risk that additional information requirements will bring much higher costs to low volume registrations, with negative impact where innovative new chemistries are being developed.

As endocrine disruption is a new and very complex endpoint with various ramifications, more clarity on specific elements is needed to avoid confusion and misclassification. This includes differentiating between ED HH Category 1 and 2, experience in choosing the appropriate tests for individual substances depending on the information need and type of substance, interpretation of mechanistic data, mode of action analysis, and adversity observed *in vivo* in a better delimited and guidance-driven weight of evidence.

A more logical approach would be to start assessments in a timely and volume-driven manner by addressing first very high tonnages corresponding to Annex X. This approach is proportional to the risk incurred by high volumes and possible wide dispersive use, and would be a pragmatic approach to allow agencies, member state authorities, and industry to learn and adapt along the way. It would also reduce the pressure on laboratory capacities to implement new studies and perform tests. The investments from industry in generating new data would be better scheduled over time, alleviating the high financial burden. In parallel, the work undertaken to speed up and validate NAMs would build on new and better protocols to assess those specific endpoints.

ATIEL believes that targeted updates to REACH information requirements for endocrine disruptors should be proportionate, starting with higher volume substances to allow for meaningful impact assessments and proper weight of evidence. This approach will enable authorities and industry to adapt gradually, reduce laboratory pressures, and better schedule investments, while advancing the validation of new assessment methods.

5. Essential Uses

ATIEL is concerned that decisions on what will be recognised as an “essential use” will be of a political nature, hugely complex, subjective and likely to vary over time. Whereas EU Industry needs predictability and stability via transparent, science/risk-based decision making and would suggest that essentiality can change following societal needs and/or technical development.

Notably ATIEL would like to point out:

- Importance of lubricants: Lubricants are important to transport and mobility, making them crucial to the EU economy. They help manufacturers meet stricter standards for fuel efficiency, durability, and emissions, supporting both economic and societal goals. Their role spans key sectors like transport, renewable energy, and industry, ensuring smooth operations. As e-mobility grows, lubricants will also be key in driving transport decarbonisation. A general “definition based” approach to essentiality cannot be a viable solution that can ensure sufficient clarity and predictability to industry and consumers.
- Assessment and proportionality: Essentiality should only be evaluated as a last resort when risks can’t be effectively managed. Using vague or overly simplistic criteria to fast-track restrictions on hazardous substances—especially those with societal benefits and manageable risks—should be avoided.

- Transparency and stakeholder involvement: The essential use concept must be applied transparently and consistently, with timely input from all relevant stakeholders.

ATIEL recommends that decisions on essential uses should be transparent, science-based, and adaptable to societal needs and technical developments. Lubricants are critical for the EU economy, transport and mobility sector, and industry. The essential use concept is inherently complex and requires predictability and all stakeholders should be involved in decision-making.

6. Simplifying communication in the supply chains (including in particular harmonised electronic formats)

ATIEL as an Industry organisation actively engages in facilitating dialogue along the supply chain. The traditional horizontal organisation in sector groups and Substance Information Exchange Forums (SIEFs) should be complemented with dialogue in the supply chain to better address the supply chain specific needs and challenges in generating and communicating safe use information.

Communication on how chemicals should be used in a safe manner along the supply chain is key to ensuring safe use. We welcome EU COM initiative to look for ways how to improve communication in the supply chain.

The obligation to transmit information along the supply chain, including the management of extended Safety Data Sheets (SDS), can be a significant challenge. A substantial portion of these businesses also view the associated costs as a considerable burden. These challenges highlight the need for improved communication and support within the supply chain to ensure compliance and safety.

ATIEL emphasizes the importance improved communication and safety assessments along the supply chain. They support the EU Commission's initiative to enhance supply chain communication, addressing the significant challenges faced by companies in managing information and costs.

7. Enforcement

ATIEL appreciates that better cooperation between Enforcement authorities in different Member States is needed in order to establish harmonised interpretations and enforcement practices across EU.

Additionally, enforceability as well as proportionality of regulatory measures need to be ensured before regulatory proposals are adopted. In all cases there is a need to ensure a level-playing field between EU manufacture and EU import of substances, mixtures and articles.

ATIEL emphasizes the need for harmonized enforcement practices, enforceability, and proportionality of regulatory measures to ensure fair competition between EU manufacturers and importers.

ATIEL is hopeful that our comments provided perspective on the challenges faced by the lubricants industry in Europe and our respective customers. Addressing these concerns is crucial to ensure regulatory compliance without hindering industry innovation and competitiveness. Your attention to these matters will help balance safety and sustainability with practical feasibility for businesses within the industry. As ATIEL, we are willing and supportive of a collaborative approach with the Commission on RECAH revision.