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## ETRMA views on REACH regulation simplification

The European Tyre and Rubber Manufacturers' Association (ETRMA) welcomes the opportunity to provide our views on the REACH regulation simplification. As tyre manufacturers, ETRMA Members are downstream users of chemical substances and mixtures and strive not only to comply with the EU chemical legislations but also to enable safe and sustainable articles on the market.

ETRMA fully supports the objectives of the REACH regulation in safeguarding human health and the environment and believes that a more effective REACH framework must ensure high safety standards while also maintaining the competitiveness and resilience of European manufacturers including for the tyre industry.

### **Enhancing Regulatory Coherence and Simplification**

ETRMA advocates for a coherent and harmonized regulatory framework across the EU. This includes ensuring continuous dialogue between industry and regulatory authorities, improving the authorisation and restriction processes, and avoiding overly simplistic assessments. A clear, predictable, and effective regulatory system would boost competitiveness, avoid fragmentation, and align with broader industrial strategies to secure investments in the EU.

To create a more supportive business environment while upholding safety standards, REACH should be aligned with other legislative frameworks, including the Occupational Safety and Health (OSH) regulations, the Industrial Emissions Directive (IED), the Waste Framework Directive (WFD - Directive 2008/98/EC) and the Water Framework Directive (WFD - Directive 2000/60/EC) among others. This would prevent contradictory requirements and reduce administrative burdens on companies operating across multiple regulatory regimes.

Furthermore, it is essential to ensure that new regulations, such as the Eco-design for Sustainable Product Regulation (ESPR), do not introduce additional risk analysis concepts for chemical substances, which could overlap with or contradict the risk assessments already established under the REACH regulation. Ensuring coherence and avoiding duplication across these regulatory frameworks will foster a more predictable and efficient regulatory environment.

In addition, ETRMA calls for the simplification and harmonization of terminology used for substances. Different communications often use varying definitions such as Substances of Concern, Hazardous Substances, Substances of Very High Concern, and Most Harmful Chemicals. A unified terminology would enhance clarity and consistency across regulatory frameworks, facilitating better understanding and compliance.

## **Introduction of an RMOA framework**

In our view, a more effective REACH framework should implement an improved Risk Management Option Analysis (RMOA) structure that prioritizes high-risk substances to human health and the environment while ensuring regulatory predictability and proportionality.

This framework should evaluate various options for assessing safe uses, analysing viable alternatives, and developing adequate risk management options. An effective RMOA process would optimize the workload for authorities and industry without jeopardizing safety and innovation, while being systematic, transparent, and predictable. It is imperative to include RMOAs before proposing any restrictions to ensure a balanced approach to chemicals management.

The current system often imposes restrictions based on hazard classification alone, without adequately considering actual exposure scenarios and risks. In some cases, this could lead to disproportionate bans, disruptions in raw material supply and limitations on innovation, placing European businesses at a disadvantage in the global market. We believe that the transition towards a risk-based and proportionate approach is essential to secure a strong European industrial base while upholding environmental and health protections.

## **Polymers Registration & Access to Raw Materials**

ETRMA highlights that the proposed extension of polymers registration under REACH presents a major regulatory challenge. While ensuring the safe use of chemicals is a priority, the current approach risks imposing excessive costs and administrative burdens on businesses without a clear scientific justification. The current REACH regulation indirectly addresses polymers by managing their monomers and additives. Introducing new registration requirements for polymers would create unnecessary complexity and a risk of competition with non-EU manufacturers of articles, and in our view would not support a simplified REACH regulation.

Furthermore, increasing the registration requirements for low tonnage substances could disincentive the import of chemicals not sufficiently available on the EU market. This could reduce the availability of raw materials for EU tyre manufacturing, putting the industry at a competitive disadvantage compared to non-EU countries. We believe that any increase in registration requirements for low-tonnage substances should ensure continued access, include agreed-upon transition periods, and carefully consider the impact on the industry.

## **REACH Authorisation Reform Key to Fair Competition and Safety**

The use of substances listed in Annex XIV is only permitted through a granted authorization. However, this requirement does not apply to the use of these substances outside the EU or the import of products that contain them. As a result, the burden falls solely on the EU manufacturers of articles, mixtures, and downstream users.

In our view, this is particularly challenging when no technically viable alternatives are available. EU manufacturers must undergo a complex and time-limited authorization process, placing them at a clear

competitive disadvantage, especially for process chemicals and aids used in the manufacturing of articles but not present in the final product. Meanwhile, non-EU producers of articles can continue using these substances and import articles containing these substances into the EU. This imbalance hinders investment and innovation throughout the EU value chain, leading to the relocation of R&D and production.

The proposal to remove the Authorisation Title should be viewed as a step toward restoring a level playing field for EU manufacturers, without compromising safety. Targeted risk management measures such as Annex XVII restrictions and occupational exposure limits under CAD (98/24/EC) and CMD (2004/37/EC) can ensure equal or even higher levels of protection, while encouraging the use of safer alternatives where available and supporting competitiveness.

### **Essential Use Concept in Authorisations and Restrictions**

ETRMA acknowledges the importance of the Essential Use Concept (EUC) in the broader context of chemicals management, particularly in supporting the transition to safer to human health and environment substances. However, ETRMA expresses concerns regarding the broad application of the EUC within the REACH regulation.

Specifically, we caution against applying the EUC in a way that might lead to subjective decision-making or blanket restrictions on chemicals that are essential for critical applications. Many substances play a crucial role in ensuring the performance, safety, and durability of products including tyres. Their use should not be automatically deemed non-essential without a thorough understanding of actual risks and exposure.

ETRMA calls for a careful, evidence-based approach to the application of the EUC, ensuring that decisions are based on clear, scientific criteria. The concept of "essential use" must be aligned with the specific needs of different industries, including the tyre industry, where certain chemicals are vital for meeting safety and performance standards. Any attempt to apply the EUC should be flexible, allowing for industry-specific exemptions when justified by technical or societal needs.

### **Generic Approach to Risk Management (GRA)**

ETRMA advocates for a risk-based approach to chemical assessment, emphasizing that evaluations should consider both intrinsic properties and actual exposure risks during manufacture and use. A purely hazard-based approach, especially with expanded hazard classifications, creates uncertainty for industries and might put future raw material availability at risk.

This could hinder safe uses, weakening the credibility of chemical legislation. While hazard-based measures may be suitable for certain high-risk substances (such as CMRs), broader regulations should be guided by actual risk to ensure they remain scientifically sound.

**Integration of Mixture Allocation Factor (MAF) in REACH**

ETRMA believes that the integration of MAF into the REACH regulation is unnecessary and could impose excessive regulatory burdens without delivering proportional benefits to chemical safety. The existing REACH framework already ensures rigorous risk assessment and management of substances, making an additional MAF redundant. Introducing a MAF could lead to over-regulation of many mixtures that do not substantially contribute to mixture risk, potentially hindering the European industry innovation and competitiveness.

**Uniform and Continuous Enforcement Essential for a Level Playing Field in the EU**

ETRMA welcomes initiatives aimed at strengthening coherent and uniform enforcement across Member States. Ensuring compliance is essential to guarantee a level playing field and to safeguard fair competition for products placed on the market, both within the EU and between EU-manufactured and non-EU-manufactured articles.

**Digital safety data sheets should be free, open-access, and easy to use**

While electronic formats for sharing safety data are already in use, requiring specific software licenses limits access and undermines effective digitalization. ETRMA supports digital tools to be open-access, free of charge, and user-friendly to ensure broad and efficient implementation across the value chain.