POSITION PAPER

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Orgalim position and recommendations on the upcoming revision of the REACH Regulation

Executive summary

Orgalim, representing Europe's technology industries, is concerned about the upcoming revision of the REACH Regulation which has the objective of bringing simplification and ensuring faster decision-making. We are greatly concerned that the regulation may not result in the intended simplifications and believe our proposals to be essential to ensure that an adequate balance between sustainability, competitiveness, security and safety can be struck. The cumulative burden of disproportionate and badly designed regulation is holding back Europe's high-tech manufacturing companies in their race to produce the necessary and desired technology solutions required for Europe to reach net zero.

Our technology industries are major downstream users and suppliers of articles under the REACH Regulation. As such, we are fully committed to continue to reduce potential risks associated with the presence of hazardous substances in products and to support a more circular economy. As key actors within the scope of REACH and with strong expertise in use of substances in articles, we believe it is of fundamental importance that the views and perspectives of downstream users and end-users of chemicals are closely and duly considered in the legislative process of the REACH revision, a key deliverable of the Chemicals Industry Package.

To improve and simplify the REACH Regulation framework we believe it is of fundamental importance to:

- **Maintain the risk-based approach**: Regulatory decisions must continue to be based on scientific risk assessments. We oppose an expansion of the Generic Approach to Risk Assessment (GRA) and urge caution regarding the introduction of the Essential Use Concept without a full impact assessment.
- **Pursue the effective simplification of REACH**: transparency, predictability, and scientific rigour must be prioritised in future regulatory action. The grouping of substances should be scientifically justified, and any restrictions must be targeted and proportionate. We call for early information sharing along the supply chain, and recommend that digital tools such as the Digital Product Passport be implemented gradually after proper assessments.
- **Ensure regulatory coherence and alignment with sustainability goals**: A consistent, harmonised approach across EU circular initiatives is essential, including appropriate exemptions for legacy products and spare parts.
- **Enhance competitiveness, enforcement and a level playing field**: New regulatory measures must be preceded by thorough impact assessments following Better Regulation principles. Enforcement across Member States must be strengthened to ensure a level playing field.
- **Support pragmatic substitution planning**: Substitution initiatives must be risk-based, flexible, and supported by adequate funding and research. Unrealistic obligations and overly rigid timelines could disrupt innovation cycles and supply chains, negatively affecting companies, in particular SMEs.

Orgalim position and recommendations for the upcoming revision of the REACH Regulation

Representing Europe's technology industries providing innovative solutions that can unlock a greener and more prosperous future for the European Union and its citizens, **Orgalim is concerned with the upcoming revision of the REACH Regulation** (Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals), as we believe it might not achieve the intended simplifications in the context of reducing regulatory burden and boosting competitiveness as outlined in the European Commission's Political Guidelines, Clean Industrial Deal and the Draghi Report.

Our technology industries, major downstream users and article manufacturers under the REACH Regulation, are fully committed to continuously reducing risks associated with the presence of hazardous substances in their products and supporting a more circular economy. As key actors within the scope of REACH and with strong expertise in substances in articles, we strongly advocate for the active involvement of downstream users and end-users of chemicals in the legislative process of the REACH revision, a key deliverable of the Chemicals Industry Package.

We fully support risk management measures for substances that pose unacceptable risks to human health or the environment, based on sound scientific evidence.
At the same time, certain approaches proposed under the Chemicals Strategy for Sustainability (CSS) may result in conflicting objectives - particularly in balancing circularity, regulatory simplification, industrial competitiveness, and the ambition for a toxic-free environment. Should these approaches be pursued further, a transparent, science-based process involving structured dialogue with industry and a thorough impact assessment is essential to ensure effective implementation.

Enhanced stakeholder participation is critical for making REACH workable and to ensure regulatory certainty, proportionality and targeted measures Many stakeholders often lack the capacity to engage in public consultations due to the onerous technical documents and short timelines. Improving stakeholder participation requires longer consultation periods at every step to ensure qualitative and relevant input.

In our opinion, the REACH regulation functions well in general and sets the highest safety standards worldwide. The concept of scientific risk assessment and the analysis of the most suitable regulatory management option (RMOA) has proved to be effective. It should therefore be maintained and strengthened.

We thank you in advance for your consideration of these recommendations and would welcome the opportunity for a constructive discussion with Orgalim members on how to improve the workability, simplicity and efficiency of the REACH framework further.

1. Mantain the risk-based approach

- **Policy decisions concerning chemicals should continue to be grounded in a risk-based, rather than a purely hazard-based, approach.** We generally support a risk-based approach because it relies on scientific evidence of the actual impacts on human health and the environment.

- **Do not increase the application of the Generic Approach to Risk Assessment (GRA):**
  - **The term "GRA" is misleading, as a predominantly hazard-based legislative approach cannot be regarded as risk-based**. The Commission has committed to introducing the GRA for consumer uses of substances with certain hazards. An extension of its current scope would undermine the core principles of REACH, which is built on risk-based assessment for sound scientific and regulatory reasons.
  - **The frequently cited example of the "existing application of the GRA under REACH Annex XVII, entries 28-30" refers exclusively to CMR substances and mixtures in consumer products**. This is based on a highly conservative approach, given that most of these substances do not have thresholds for effect or exposure, and releases from consumer use cannot be assumed to be negligible. However, this model cannot be transferred to articles, where exposure can be controlled. Substances are often integral to components and products to ensure performance, durability, safety, and sustainability.
  - **If the term "consumer good" is to be used, it must be clearly defined, as it is often unclear, misleading, and used inconsistently – grouping together products that do not share the same characteristics, use patterns, or exposure pathways** from mixtures with direct exposure (e.g. cosmetics), to mixtures with clear handling instructions (e.g. paints, glues), to articles with incidental skin contact (e.g. textiles), and even electronics or household appliances. It is therefore not appropriate to establish general regulatory principles based on such an imprecise and inconsistent concept.
  - **These categories involve very different exposure scenarios**. While distinctions between direct and indirect contact may help in some cases, they often oversimplify complex substance behaviours in real-world applications. Effective regulation already addresses risks from direct contact via REACH and sectoral legislation (e.g. food contact materials).
  - **The revision must acknowledge the diversity of exposure scenarios and avoid blanket assumptions based solely on the presence of hazardous substances**. Substances embedded in stable matrices or sealed components typically do not pose a risk, provided there is no significant release, transfer, or uptake during normal use or end-of-life.
  - **A targeted and proportionate approach should be pursued**. This could include use-specific risk assessments led by manufacturers, reflecting real-world conditions and actual exposure potential.
  - **REACH and CLP include provisions for providing information to professional and industrial users on the safe use of a substance or mixture**. Furthermore, existing workplace safety legislation – such as the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens

Directive (CMD) – provides a robust framework for managing risks from hazardous substances.

- **Refrain from implementing the Essential Use Concept (EUC) in its current form and perform an impact assessment with stakeholder involvement:**
  - As highlighted in our Position and Recommendations on the Essential Use Concept Communication , **the EUC should align with a risk-based approach, ensuring that any restrictions are based on proven risks.** If introduced, implementation must be gradual and proportionate, to avoid overburdening downstream users with excessive data and compliance costs. Socio-economic impacts must be integrated into the "critical for society" criterion to maintain innovation and competitiveness. The EUC should only be applied following a comprehensive risk and risk management assessment – not as a substitute for it. Additionally, defining "most harmful substances" should align with REACH and CLP regulations to ensure predictability for investment and regulatory compliance.
  - **The EUC combines a strictly hazard-based selection of substances with an assessment of the technical function of the substance and the availability and acceptance of alternatives from a societal perspective.** A prior risk assessment of substance applications is omitted, which is not justified in our view.
  - In our opinion, **the evaluation of the 'essentiality' of a substance application requires the collection of information from society.** Additionally, for the majority of substance applications, distinguishing between 'essential' and 'non-essential' is neither simple nor sustainable. This contradicts the necessary reduction of bureaucracy. Compared to the current combination of risk and socio-economic assessment under REACH, it leads to higher reporting and evaluation efforts but does not yield more reliable outcomes.
  - Orgalim views the Commission's current EUC Communication as overly simplistic and impractical to implement. **We therefore urge that, if the concept is incorporated into REACH, it must first be subject to a comprehensive impact assessment.**

2. Effective simplification of REACH

- **Substances should be addressed individually, rather than in groups**. Recent cases, such as the proposed universal PFAS restriction, highlight the challenges of regulating overly broad substance groups and their variety of applications without sufficient supporting data. The complexity of such large-scale restrictions risks creating bottlenecks and undermining legal certainty and predictability.
  - **However, if grouping of substances is justified to prevent regrettable substitutions, it should be based on scientific evidence and on comparable physical, chemical and (eco)toxicological properties, while also considering their specific uses**. In this case, it would be essential to maintain a well-defined scope.

- **The absence of specific CAS or EC numbers makes it difficult to identify these substances in the materials portfolio of industrial users**. A different name may be given to the same substance depending on the suppliers, regions or even regulatory contexts. This complicates identification of these substances in manufacturers' portfolios as they have to search for all possible names for the same substance. In contrast, a CAS or EC number is unique to a given substance, which greatly simplifies its identification and ensures that no such substance is missed.

- **Transparency, certainty and predictability are needed for REACH**. A thorough Risk Management Option Analysis (RMOA) and sufficiently long consultation periods in the preparatory phase of restrictions or RMOAs (at least 12 months instead of 2) before initiation restriction or authorisation procedures by the Commission or ECHA could potentially lead to a more informed and transparent decision-making process, contributing to enhanced engagement of stakeholders and authorities.

- **Scientifically substantiate hazard potential through harmonised classification (CLH)**
  - The prerequisite for including a substance in the authorisation or restriction procedure should be the scientific proof of the "hazard" through harmonised classification in Part 3 of Annex VI of the CLP Regulation (EC) No 1272/2008.
  - Since the consideration of the "hazard" can be omitted or expedited later in the restriction and authorisation procedure within the Risk Assessment Committee (RAC), or during the preparation of Annex XV dossier, the overall regulatory process will only be slightly extended. Conducting the CLH classification before the RMOA can enable a more targeted approach and help avoid unnecessary RMOAs.

- **First information, then regulation**: Where the RMOA leads to a proposal for authorisation and/or restriction, this should be an informed decision-making process allowing contributions from stakeholders. In particular, for substances in articles, it is important that information on the presence of such substances is made available in the supply chain by transmission from each supplier to each industrial and professional recipient (principle of REACH Article 33(1)) – usually through communication based on material declarations.
  - For the authorisation and restriction procedures, the requirements around the candidate list should be revised to improve the flow of information on substances in articles along the supply chain from the initiation of a regulatory process.
  - We therefore propose that substances that are candidates for restriction should first be included in a Candidate List and thus be subject to the information requirements comparable to REACH Article 33. Additional reporting processes or data points should be avoided. Making those substances candidates first will also allow downstream suppliers to have a head start (knowledge of presence in their articles), when restrictions are eventually considered.
  - In addition, as foreseen in other legislation, for example the Restriction of Hazardous Substances Directive (RoHS), for substances in complex articles, adequate transition

periods of at least five years after the publication of a new REACH restriction in the Official Journal are essential to allow for a full conversion of products and supply chains.

- **The Commission should evaluate the potential of, and make optimal use of, digital tools to communicate hazard and safety**. We identify opportunities to simplify the supply chain communication and the improvement of (extended) safety data sheets (SDS) via improved tools for communication following a pragmatic approach for companies, including harmonised electronic formats such as QR codes.

- We recommend to avoid digital tools such as the SCIP database which are overcomplicated and unfit for purpose. In particular, we recommend a staged implementation of the DPP after a detailed impact assessment, including public stakeholder involvement.

- **The use of a SVHC and its health impact on workers and consumers should be re-evaluated before a substance is put on the candidate list,** with actual data provided by the affected industries accurately assessing the risk of a substance based on its probability of exposure and the health impact in different application scenarios.

- **We propose limiting the updating of the Candidate List to once per year**. Updating the Candidate List every six months places an unnecessary burden on industries, their supply chains, and regulatory bodies. Each update requires extensive testing, reporting, and potential reformulation of products.

- Orgalim believes that **reasonable thresholds for restrictions should be established in the legislation**. Limits in the range of trace amounts, contaminations, or below those levels that can be measured with proportionate effort, create legal uncertainty and make enforcement by market surveillance authorities practically impossible.

- A **clear process for applying for exemptions** is currently not provided, or not sufficiently described, in the restriction process. The restriction process should be improved in the course of the REACH revision with regard to the possibility of applying for exemptions. A legally established right to apply for exemptions should be introduced. The PFAS restriction proposal has shown how incomplete initial lists of exemptions can be, if not all stakeholders have been duly identified and consulted in advance.
    - In our view– under a revised restriction/authorisation scheme under REACH – both routes of risk management (company specific derogations as well as broad sectoral exemptions) should be provided for.

- **We are in favour of sufficiently long-term exemptions to avoid uncertainty** and give companies the opportunity to achieve sustainable substitutions and allow for adequate R&D. For complex electronic equipment (IT, medical, aerospace, etc.), it usually takes 5 to 15 years to invest in developing adequate alternatives and develop and implement long-term design, production and

distribution changes. If exemption periods for particular uses are too short, the risk of regrettable substitutes and supply disruptions increases.

3. Ensure regulatory coherence and alignment with sustainability goals

- **We recommend ensuring regulatory coherence across frameworks (e.g. ESPR, PPWR, Green Claims, EU Taxonomy, CSRD) and strengthening REACH as the main instrument to manage the risk associated with the manufacture, supply and use of chemicals.**
    - **Identical regulatory goals and approaches in other frameworks endanger a consistent assessment of substances in products due to inevitable differences and inconsistencies in scope, definitions, and requirements**. The lack of coherence between different regulatory frameworks creates significant challenges for downstream industries and may lead to: (i) increased compliance costs as companies struggle to meet varying standards, (ii) confusion and potential non-compliance due to conflicting requirements (c.f. calculation method on the concentration of restricted substances under REACH, RoHS and battery regulation), (iii) reduced competitiveness in global markets due to complex regulatory burdens, and (iv) barriers to innovation as resources are diverted to managing regulatory complexities
    - **These overlaps and inconsistencies do not increase regulatory strength,** but rather lead to divergencies in the scope and definitions of the different pieces of legislation and thus to non-compliance and legal uncertainty.
    - We therefore also recommend that the **Commission harmonises the definition of substances across all EU legislation** to ensure regulatory clarity, facilitate compliance and prevent double regulation. The lack of coherence between substances within the scope of the EU Taxonomy, the Biocidal Products Regulation (BPR), the Ecodesign for Sustainable Products Regulation (ESPR), the Batteries Regulation, the Corporate Sustainability Reporting Directive (CSRD) and the Construction Product Regulation (CPR) creates inconsistencies in their use and impact. A consistent definition is essential to streamline regulatory requirements and help companies meet their sustainability goals, and the Substances of Very High Concern (SVHC) list is a good starting point.
    - We are **concerned about the Substances of Concern definition under the ESPR and we anticipate significant inconsistencies between REACH and ESPR delegated acts**.
    - **We recommend that the different legal instruments (REACH, RoHS, ESPR, etc.) are used exclusively for their intended goals**

- **Ensure chemical restrictions do not inadvertently undermine circularity objectives by hindering the reuse of products and recycling of materials**. Equipment which becomes waste today was subject to other chemicals legislation when it was placed on the market and contains

so-called 'legacy substances'. REACH should not be an obstacle for circularity.

- European regulations set contradictory objectives between reducing the use of regulated substances (the number of which is increasing rapidly) and deploying the circular economy. For example, to avoid premature obsolescence (waste) and encourage robust markets for used equipment, **regulations should provide appropriate exemptions from chemicals in articles that were previously manufactured or are already in use**.
- Similarly, there should be exemptions for spare parts and components that may contain restricted chemicals but are needed for equipment to be **"repaired as produced"** without costly requalification and recertification. This principle should be implemented in REACH with clear scope without compromising safety or environmental protection.
- Overall **consistency between legislation on chemicals, products and waste is essential to achieving the EU's circular economy and chemical-related objectives**. Increasingly stringent limits for restricted substances on the one hand and the need to increase in the use of recycled materials on the other create a trade-off that we believe needs to be resolved politically.

4. Enhance competitiveness, enforcement and a level playing field

- New legislation must always follow the **EU Better Regulation principles** and be based on an **impact assessment** to ensure that its implementation will be workable, proportionate and will contribute to a circular economy**. We deeply regret the absence of an impact assessment for the REACH revision and call for thorough analysis**. The net benefits for society, taking into account human health and the environment as well as safety, circularity and other societal effects, must be greater than the net costs.

- **Industry needs to be able to continue producing products using chemicals on a level playing field with non-EU countries**. Therefore, we are in favour of a case-by-case analysis, leading to the best risk management option, taking into account the negative effects on health and the environment, the impact on businesses and the practical consideration for market surveillance authorities.

- **Disruptions in supply chains should be avoided and the capacity to produce and use chemicals in Europe should be maintained**. We support the intention from the Commission to improve the quality of registration dossiers. However, proposals such as the revocation of valid registration dossiers every ten years if not updated, or the registration of polymers, may have negative impacts on the entire supply chain – including downstream users.

- **Effective and resolute enforcement of regulation plays a central role in upholding a well-functioning single market.** While control and enforcement must remain a national competency, Orgalim supports EU-wide actions to assist Member States in this effort. EU-based companies are put at a competitive disadvantage when competitors based outside the EU continue with impunity to sell products and articles that do not conform to the same high standards. A coherent framework for enforcement, including minimum requirements for border controls, should be explored. In addition, we are calling for regulatory requirements to be strengthened only when enforcement, controls and tests are proven to be feasible.

- **Market surveillance should be strengthened through balanced and enforceable regulations**, ensuring a level playing field for all market participants, including small and mid-sized enterprises (SMEs).

5. Substitution planning

- **With regard to the Commission's initiative for substitution planning, it should be a risk-based supportive tool rather than an additional bureaucratic burden**, requiring adequate research programmes, financial support, and risk-based prioritisation of substances, such as those on the REACH candidate list and roadmap. The rigid structures proposed — such as mandated action plans, substitution centres, and increased reporting — fail to acknowledge the complexity of supply chains, the need for flexibility in R&D, and the wider societal impacts of substitution. Existing regulatory pressures and company-led initiatives already drive substitution, making additional lists and obligations redundant. Furthermore, the proposal for national substitution centres with enforcement roles raises concerns about governance, resources, and a fragmented EU approach. Finally, realistic timelines for data collection and industry adaptation are crucial to ensure informed and effective substitution efforts.

- The criteria to assess the equivalence of alternative substances substituting substances must comprise not only **technical feasibility** and **health impacts** but also **durability**, **performance**, **levels of safety**, **quality**, **costs**, etc.

- It is expected that valid and not regrettable substitution (to avoid a banned chemical being replaced with another chemical just as harmful or potentially worse) will come from a **totally new technical solution**. In most cases all potential alternative substances to replace one SVHC possess similar technical properties to that SVHC and will therefore also exhibit similar health impacts. Thus, totally new solutions with a 'quantum leap' need to be found and developed, which can only be achieved by massive support and perhaps the concerted actions of all stakeholders in the supply chain. Single companies, and in particular SMEs, are unable to achieve such developments on their own. Here, the Commission must find new ways to enable such 'quantum leap' developments. These challenges need to be taken into consideration when setting deadlines.

- **Sufficient time and flexibility should be afforded during the implementation of new regulations to allow for the development and commercialisation of new solutions**. Substitution planning involves many steps, each of which takes a long time; for example, inventory of current supply chains and products for the presence and function of restricted or banned materials; invent proper substitutes if none currently exist; test and certify new substitutes; incorporate new substitutes in components and finished products; test and certify the new products; and implement the substitution plan across the supply chain. For instance, complex articles such as those manufactured by Orgalim's members can contain thousands of components produced in an extensive global supply chain with numerous tiers of suppliers. Supply chain communications and adjustments are further complicated by components and materials typically travelling across multiple borders, with the presence of many SMEs along the value chain.

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