Brussels, 30 September 2024

Orgalim Position and Recommendations on the Essential Use Concept Communication

Executive summary

Orgalim, representing Europe's technology industries, supports reducing hazardous substances in products to foster a circular economy and a toxic-free environment. Our industries acknowledge the essential use concept's aim to phase out harmful substances swiftly but calls for clearer criteria and principles from the European Commission.

- We emphasise the need to maintain a **risk-based approach** to regulation, where substances posing an unacceptable risk are scientifically evaluated. Also, in certain cases of justified grouping approaches for groups of substances with homogeneous properties and homogeneous risk profiles, a proven risk for the group of substances should be a prerequisite for any restriction. A hazard assessment alone is not considered sufficient.
- The essential use concept should **only have legal effects when incorporated into specific legislation**, as stated in the Commission's Communication.
- Orgalim stresses the importance of **clear legal framework to avoid misunderstandings** affecting investment decisions and we argue that **the definition of "most harmful substances" should be in line with the REACH, CLP Regulations and Stockholm Convention on Persistent Organic Polluters (POPs)** to ensure legal clarity. The list of substances in the Communication is illustrative and open-ended, whereas predictability and clarity are important for industry to ensure that investment in new product development based on a reliable future regulatory landscape. In addition, **clearly defined mechanisms must be established.**
- **A step-by-step approach to the implementation of the essential use concept in legislation is crucial**. Evaluating the essentiality of too many chemicals at once will overwhelm stakeholders, particularly downstream companies, making it difficult for them to acquire sufficient data from their supply chains.
- Many of our companies' products are crucial for the green and digital transitions, health, safety and societal functioning. We recommend **integrating socio-economic impacts within the "critical for society" criterion of the Essential Use Concept (EUC)** to prevent negative implications for European industries and society as a whole.
- We call for a **dynamic interaction between regulators and stakeholders,** ensuring that companies can safely share information and that innovation investments are subject to **flexible deadlines while maintaining technical and economic feasibility assessments**.

We thank you in advance for taking our views into account when introducing the essential use concept principles into specific legislation.

Introduction

Orgalim represents Europe's technology industries, providing innovative technology solutions which are underpinning the twin green and digital transitions and can unlock a greener, healthier, and more prosperous future for the European Union and its citizens. Our industries are fully committed to reducing the content of hazardous substances in their products and supporting a more circular economy. Our position and recommendations on the circular economy can be found here, and our comments on the REACH revision roadmap can be found here.

Moreover, we fully support that individual substances posing an unacceptable risk due to their properties and use profiles should be regulated and phased out at an appropriate pace based on scientific evaluation. Our technology industries, major downstream users of substances and mixtures and article manufacturers are committed to continuously improving the environmental performance and safety of the products they place on the market and to supporting the European Commission's ambitions on the path towards a toxic-free environment.

Orgalim wishes to emphasise that **the current risk-based approach provides a clear legal framework allowing manufacturers to reduce their potential impact on health and the environment**. The essential use concept moves away from this approach and combines a hazard analysis with an assessment of the use / technical function of the substance and the presence / acceptability of alternatives from a societal standpoint. We understand that the implementation of the Essential Use Concept (EUC) will require the collection of a substantial amount of information from stakeholders.

To speed up evaluation processes and to avoid regrettable substitution we understand that in certain cases group approaches for the regulation of chemicals may be required. These should be justified on a case-by-case basis and following a risk based-approach.

In this context, it is particularly important that substances or groups of substances are not banned regardless of any proven risk. To make group approaches transparent and comprehensible, it is necessary to specify which substances are covered by the regulation (e.g. through lists of substances with CAS numbers). Group approaches are also only justified if all substances in a group have homogeneous properties and a homogeneous risk profile. Impact assessments, including socio-economic and technical aspects, are particularly important to anticipate the effects of far-reaching group approaches.

The essential use concept in combination with group approaches has laudable objective; i.e. providing incentives and encouraging companies to be proactive in looking for alternatives. However, as with all new concepts, Orgalim recommends **clarifying some of the criteria, principles and procedures** that were set out in the recent Commission's Communication on the essential use concept. Orgalim also recommends conducting and publishing one or several case-studies to test the possible application of this concept prior to its implementation in different pieces of legislation.

Legal clarity

The Communication states that the essential use concept will only have legal effects when introduced into specific legislation. In that case, careful consideration should be given to its feasibility.

Orgalim highlights that the correct interpretation of a Communication, is merely a recommendation of the Commission within the meaning of Art. 288(4) TFEU. To avoid misunderstandings which could affect investment and reporting decisions, we invite the Commission to **formally reject any suggestions that the Communication can be applied without translating it into a legal framework**.

This request is not a minor detail: Due to the lack of an official definition, the essential use concept included in Appendix C to Annexes I and II of the Delegated Regulation (EU) 2021/2139 was more recently replaced by criteria offering more legal certainty. Delegated Regulation (EU) 2023/2485 also edited Appendix C postponing the re-application of the

essential use concept in the DNSH criteria until further guidance is provided. Due to its non-legislative nature, Orgalim notes that this Communication has no supremacy over the Taxonomy's delegated act.

Orgalim also welcomes the fact that the Commission recognises that **the definition of what is essential may change over time – for example as technology progresses – and therefore proposes regular reviews of essential use permits**. At the same time, Orgalim would like to emphasise the need for planning and investment certainty for our industries, which rely on complex supply chains. Many of those industries manufacture products with long-life spans which require an uninterrupted supply of spare parts throughout their lifetime.

Substances in scope

The essential use concept will apply to the "most harmful substances". Orgalim notes that the list of hazard properties and criteria included in Table 1 of the Communication is open-ended and legally unclear, therefore undermining the clarity and predictability of what the EUC entails, the ultimate goal of the Communication.

In particular, Annex I of the CLP Regulation (footnote 18, page 5) sets self-classification of substances. Also, the Commission Recommendation on safe and sustainable by design (footnote 17, page 5)[1] has a different approach to, and definition of, hazardous substances.

To avoid any misinterpretation and legal uncertainty, Orgalim recommends **limiting the definition of "most harmful substances" to substances meeting the criteria of Article 57 of the REACH Regulation as well as to substances listed in Table III of Annex VI to the CLP Regulation, which provides for a harmonised classification of substances** using the suggested classifications and labelling of substances defined in Table 1 of the Commission´s Communication on the EUC.

This definition should also be included in the future REACH revision and replace the unclear and ambiguous "substances of concern" definition set in the ESPR. As highlighted above, in order to guide ambition, reduce the environmental footprint and boost investments, manufacturers need legal clarity.

Even if the number of substances in scope were to be limited to Article 57 of the REACH or to substances of very high concern (SVHCs) and harmonised classification as proposed above and given the wealth of information to be gathered from stakeholders, it is **essential to adopt a step-by-step approach when implementing this concept in legislation**. **Stakeholders, and in particular downstream users' companies, will not be able to acquire sufficient data from their supply chain if the essentiality of too many substances is evaluated simultaneously**. Nor will a proper and necessarily detailed assessment of the essentiality of a use and the potential societal and economic impacts be feasible for industry, ECHA, Member States and the Commission

We stress the fact that the EUC should not be generally applied to all Most Harmful Substances (MHSs) or SVHC present in a product. It should be limited to those cases where:

(i) The risk, considering potential human exposure to the substance, of a specific application of a substance is proven and,

(ii) There is a need to have additional steps to the risk and socioeconomic assessments.

The expected revisions of REACH, RoHS or any further pieces of chemicals legislation must provide for sufficient consistency, differentiation and clarity, in which cases the EUC should be applied.

Therefore, consideration of SVHCs would be a good starting point. For example, the risk coming from substances which are considered to be MHSs, may be addressed by a broad restriction, with exemptions only for uses that have been

[1] C (2022) 8854 final

demonstrated to be essential. However, this risk management option should only be applied if during the Risk Management Option Analysis (RMOA) phase the regulatory authority has decided that only this option can be effective.

For the time being, it remains unclear to us how the EUC can contribute to speeding up restriction procedures of substances without abandoning the risk-based approach. **We therefore expect, that the EUC will only be applied in specific scenarios and not as a general principle.**

The EUC must not prevent the consideration of legitimate economic needs and demonstrably safe uses, taking into account the entire life cycle. It should not lead to the restriction of applications that have no influence on the regulatory objective. This can only be determined by a risk assessment. The EUC should therefore only be used after the risk assessment and cannot replace it.

As the EUC will be limited to the most harmful chemicals, it is expected that any derogations will be time limited, and will need to be re-evaluated at regular intervals. We advise against reusing the application for renewal approach currently used in conjunction with the 2011/65/EC RoHS Directive and ask for a more streamlined process, which would be less onerous for both industry collating information and governmental agencies handling the applications.

Furthermore, criticality or essential use of a specific substance's function is not information that downstream users' companies typically have readily available. Industry does not prescribe individual components of formulations. Instead, our industries rely on the expertise of material suppliers to determine the optimal combination of substances needed to meet the performance and application requirements of the product during the design process.

The added cost of research, development and testing will also increase the cost of equipment designed for the EU market. In addition, the industry's resources are not sufficient to comply with the burden demands created by the application of essential use requirements.

Criterion 1 - Necessary for health or safety or critical for the functioning of society

Many Orgalim products fit into the non-exhaustive lists of elements describing the criteria "necessary for health or safety" or "critical for the functioning of the society", as they are, for example, critical for the safe operation of products and/or the achievement of the EU's climate ambitions. Driven by our "shaping a future that's good" motto, Orgalim members manufacture products to enable the green and digital transitions.

Our industries carefully select substances and materials to effectively contribute to climate change mitigation. Our products support electrification and a safe and reliable energy system, digital transition (through connectivity, automation and digitization of industry, (including critical infrastructures, chemicals manufacturing and recycling), clean transport (e-mobility, rail, etc.) and help to manage societal risks and impacts from natural crises and disasters (fires, pollutants, etc.).

The indicative list of examples for "necessary for health or safety" and "critical for the functioning of society" gives a useful first indication of in-scope applications of the EUC.

However, we advise careful consideration when interpreting "critical for the functioning of society": For example, a machine used to produce parts of an MRI scanner - where the scanner would be essential but not the production of the machine in itself would not. We are unsure whether the production of components for Industry 4.0 or for various economic sectors and strategic goals of the EU falls under this category, although these components are key to the resilience, economic growth, and global competitiveness of the EU. Furthermore, we are concerned that the EUC could result in the sub-optimisation of environmental achievements; for example, where a certain substance can positively impact the energy efficiency of a product, while also being considered as a harmful substance.

To avoid these unintended consequences, we **recommend integrating socio-economic impacts within the "critical for society" criterion as well as including aspects such as the product's lifespan, the circular economy, and climate impact**: Moving industrial productions outside Europe would not only have negative implications for European

companies and citizens but will also have an adverse effect on the reduction of environmental impacts within the EU. Therefore, the lack of opportunities for successful economic activity may negatively affect the 'functioning of society'.

Ensuring that the 'product categories' being assessed are sufficiently granular will be essential to the correct application of the EUC and its criteria, even if this requires more time and effort.

We very much **agree with the rationale of the evolutionary nature of the essentiality concept**. The chemical composition of products and their application may change over time. Hence, it is important to recognise the potential changes to the essentiality of a use**. However, the current Commission Communication on the EUC does not provide sufficient clarity on how the evolving aspect of essential uses in society can be addressed.** Orgalim stresses the need for planning and investment certainty for our industries, many of which produce products with very long-life spans. In addition, innovations that might become essential in the future, must not be obstructed by the pre-emptive nature of the EUC.

We understand that the EUC is not intended to determine whether a certain substance, product or service is itself essential, but that an assessment of the use and its context is needed (page 7 of the Communication). We therefore recommend **setting up a clear process** for that purpose, **where stakeholders can provide input in the decision-making process and are certain they can share information** (including sensitive information) **in trust,** in order to prevent damaging leaks of such information. This process should be made clear in relevant legislation (for products: REACH and RoHS).

The EUC as communicated only considers specific products used in specific applications. It does not take into account the numerous technologies used to support, develop and manufacture these products. **The upstream supply chain must be included in the consideration of the essentiality of uses.** For industries with low volume use of chemicals, phase-out obligations placed on upstream chemical producers could affect commercial viability for continued supply leading to an increased risk of material obsolescence for industries where no viable substance alternatives are available.

Regarding the proposal to introduce the essential use concept in substitution planning as well as in the REACH restriction/derogation processes, we would like to emphasise the complexity of substitution patterns across different uses and the need for an in-depth analysis, taking into account company and use specific considerations. It is currently unclear whether substitution planning will replace or will be integrated in the existing restriction/authorisation processes and the role of the essentiality assessment in the future REACH revision, but we already note problems in the interactions with suppliers. With this in mind, we recommend that:

1. **The scope of a planned restriction is made clear**, as neither our members as manufacturers nor their suppliers or customers have the instruments or the resources to investigate all uses and potential alternatives.
2. A mechanism is put in place to enable the **consolidation of all value chain actors** (a consultation forum with all stakeholders and value chain actors) and a legal obligation (e.g. concerning imports) establishing the duty to disclose the presence of substances to the relevant actors, while preserving confidential business information (CBI); for example, by opening the REACH SVHC candidate list to the restriction path.
3. The **deadlines for substitution plans** must be set at the outset with sufficient time to conduct thorough assessments, develop alternatives that may not yet exist and implement substitution plans throughout complex supply chains. In cases where external circumstances or the innovation cycle requires even more time than expected for substitution planning, there should be a process for granting appropriate extensions.

Criterion 2 – Acceptability of alternatives

The Communication defines acceptable alternatives as those substances, materials, technologies, processes or products which can provide the functionality and the level of performance that society can accept and which are safer from a societal point of view.

In line with relevant legislation and case law, Europe's technology industries continuously investigate such alternatives, notably by analysing the technical and economic justification for alternative substances or technologies (including quantity and quality) and engaging with suppliers, including requests for alternatives that are not yet available.

Our industries need alternatives to maintain the function (including safety and reliability) and the level of performance (including lifetime) of the original substance or material. In this context, our companies also communicate with customers to clarify possible doubts regarding the proposed alternatives, focusing on the performance of the full formulation rather than the function of a single substance and ensuring that it continues to meet its functional requirements.

We understand from the Commission's Communication on the concept of essential use that acceptable alternatives include any technologies, processes or products providing the function and the level of performance that society can accept, other than a product containing one of the most harmful substances – even if its essentiality has been confirmed. It will be extremely difficult to assess the acceptability of alternatives to a product containing hazardous substances and whose essentiality has been proven.

We emphasise the difficulty of practical implementation in assessing the acceptability of alternatives for society, which could lead to significant time delays due to potential workstream fails. Such assessments will require the development of a **clear methodology and the effective ability to measure societal acceptability** by the body responsible for its evaluation.

Acceptable alternatives must maintain the function (including safety and reliability) and performance level (including durability) of the original substance or material. The possibility of having to accept materials with inferior technical performance would have a negative impact on the competitiveness of European industry and the economic growth of Europe, and is not the right way to proceed. It could put European manufacturers at a significant competitive disadvantage in global markets and reduce the potential for innovation. **The functioning of society includes the principle that the technological status quo can be maintained, and that technical progress is not slowed down compared with the global society. A situation where Europe falls behind other regions in innovation and product development must be avoided. Restricting the use of innovative materials, with a low exposure risk, will negatively impact European businesses and their innovation potential.**

As the products of our industries are either necessary for health or safety, or critical to the functioning of society, and as we reflect on our standards in the light of alternative research and proposals, **we emphasise the importance of considering the societal perspective as a necessary element in meeting the 'acceptability' test of the essentiality concept**.

Orgalim main recommendations

We recommend policy makers to take into consideration the following arguments when applying the essential use concept:

- The **risk-based approach must be maintained**.
- **The EUC must not be linked only to hazards and should only be applied for uses with a proven risk** in a targeted way to ensure the achievement of the Green Deal objectives as well as the innovative capability and competitiveness of European industries.
- A **stable and predictable regulatory framework** is needed to encourage innovation and **clearly defined mechanisms and standards** must be established.
- **Clarification to the legal value of the Communication is important**. Only when the concept is included in revised European chemicals legislation (e.g. during the revisions of REACH or RoHS), will the concept have a legal value (including in references to other legislations, e.g. Taxonomy).

- **Socio-economic impacts must be integrated within the "critical for society" criterion**. The essential use concept should not cause investment and production leaks with negative repercussions for the strategic goals of the European Union (e.g., climate goals, digitalisation, electrification, Industry 4.0, health, defence…), European resilience consequently, for the EU's citizens.
- **The concepts of "critical for the functioning of society" and "acceptable alternative" must be carefully interpreted and precisely defined as to they are included in existing European chemicals legislation, (e.g. under the expected revisions of REACH or RoHS).**
- **When implementing the EUC in chemicals legislation such as REACH, it is important that products and applications are considered at a sufficiently granular level,** to ensure that unintended and disproportionate consequences do not occur as a result.
- **The evolutionary nature of the essentiality must be maintained** as well as the two facets of "health and safety" and "functioning of society". Where new needs arise from society, new aspects should also be considered. Long-term planning and investment certainty are crucial for our industries. Future innovations must not be obstructed and bureaucratic hurdles must not reduce the competitiveness of European industries.
- **A dynamic interaction between regulators and stakeholders should be set up** with the aim of supporting the substitution process. Companies should be invited to safely interact with policymakers (while preserving CBI), regulators should be clear in their planned restrictions, association and communication across value chain actors shall be encouraged, while innovation investments should be considered taking into account flexible deadlines.
- **The definition of "most harmful substances" to Article 57 of the REACH Regulation should be limited and refer to Annex VI of the CLP Regulation laying down a harmonised classification of substances.**
- **The application of the EUC to specific combinations of substances and applications should be limited** where, for example, the Risk Management Option Analysis (RMOA) has concluded that a broad **restriction in combination with the application of the EUC is the most suitable risk management measure**.
- **The upstream supply chain must be included** in the consideration of essential uses, potential alternative substances and potential phase-out deadlines**.**
- **Existing technical and / or economic feasibility assessment processes must be maintained**.

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