

Orgalim position on the upcoming revision of the REACH Regulation

Executive summary

Orgalim, representing Europe's technology industries, welcomes the upcoming revision of the REACH Regulation (Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) which has the objective of ensuring that the provisions of the REACH Regulation reflect the ambitions of the Commission on innovation and a high level of protection of health and the environment, as provided for in the Chemicals Strategy for Sustainability.

Our technology industries, major downstream users and article manufacturers, under the REACH Regulation, are fully committed to reducing the content of hazardous substances in their products to support a more circular economy.

Here are our key messages on the public consultation about the targeted revision of the REACH Regulation:

- We would prefer the option 2 "Merging the authorisation and the restriction processes", depending on how the European Commission would merge authorisation and restriction processes.
- REACH should continue to be the main instrument for evaluating and identifying Substances of Very High Concern (SVHCs) with the goal of restricting or authorising them.
- Policymaking and decisions regarding chemicals should be risk-based not hazard-based.
- 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 industry accurately assessing the risk of a substance based on its probability of exposure and the health impact.
- Socio-economic factors should be considered earlier from the industry aspect. It should be evaluated in advance whether the consequences of a restriction or authorisation scenario are proportionate to the anticipated benefits to the environment and to health.
- The extension of the generic approach to risk management would mean, de facto, abandoning the risk-based chemicals assessment already established for good reasons in REACH. This would actually introduce a fundamental paradigm shift towards hazard-based assessment, and the use of the precautionary principle without the evidence to justify such a requirement.

Orgalim position on the proposed policy options 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 thanks the European Commission for the opportunity to comment on the public [consultation](#) about the targeted revision of the REACH Regulation (Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals). The revision of the REACH Regulation was announced by the Chemicals Strategy for Sustainability adopted on 14 October 2020. **Orgalim welcomes the upcoming revision of the REACH Regulation** which has the objective of ensuring that the provisions of the REACH Regulation reflect the ambitions of the Commission on innovation and a high level of protection of health and the environment, as provided for in the Chemicals Strategy for Sustainability.

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Three main options for the revision of authorisation and restriction processes under REACH have been identified by the [European Commission](#):

➤ **Option 1: Keeping the authorisation process, with clarification and simplifications**

This involves modifying elements to address weaknesses identified during its current implementation, but without more fundamental change. This option may include the following elements: strengthening the conformity process for applications for authorisation, clarifying procedures for introducing changes to granted authorisations; transitional provisions for refused authorisations; fixed time limits; clarifying Article 66 notifications for ECHA by downstream users; introduction of "stop the clock" procedures during opinion making and simplified procedures for substances used in small quantities; integration of the concept of "essential uses"; and/or other process changes which aim to improve efficiency of Committee decision making and clarity of definitions and data requirements.

➤ **Option 2: Merging the authorisation and the restriction processes**

Instead of requiring authorisations for the use of certain substances (Annex XIV listing), the concerned substances would be restricted by default. There would be three possible ways to derogate from the default restriction: Derogations would already be included as part of the restriction as proposed and adopted by authorities (as in the existing restriction system); Joint derogations requested by companies (a new element, with the burden of proof on industry); Individual derogations/authorisations requested by companies (similar to existing REACH authorisation system).

➤ **Option 3: Removing the authorisation title from REACH**

This assumes the weaknesses of the REACH authorisation system outweigh its achievements, and that restrictions following the current models of Article 68(1) and 68(2) (if and as appropriate, with certain modifications) alone can better address the risks of the use of substances of very high concern.

Under all the three options, the candidate list would be maintained but used for prioritisation for regulatory action in general and, for this purpose, may be linked with additional obligations for companies (e.g. obligation to provide information on uses, alternatives, emissions or exposure).

- Options 2 and 3 could enable a **level playing field** between EU internal and external supply chains. In option 2, authorisation and restriction are considered together from the start, in terms of time and content. However, there must be a clear process to apply for exemptions afterwards, especially regarding the Essential Use Concept (EUC) and innovation capability. The introduction of option 2 should be accompanied by the introduction of an adapted "candidate list".
- With regard to **legal certainty**, under options 2 and 3, all substances/manufacturers would be treated equally. This is why it would no longer be necessary to check where a product was manufactured, and lack of knowledge about authorisation abroad would no longer be an issue.
- 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 anchored right to apply for exemptions should be introduced.
- It is encouraging to see suggestions in the actual policy debate regarding the creation of a framework for applying the **Essential Use Concept (EUC)**, rather than simply a black and white listing of uses, and that its application will require a case-by-case assessment. However, even with such a framework and case-by-case approach, we have concerns that introducing the EUC could adversely affect regulatory efficiency and negatively impact the safe use of articles and overall sustainability. The clarification of the scope of application is especially important as the Montreal Protocol, which inspired the ongoing policy debate, has a much narrower scope and addressed unacceptable risks (not simply hazard-based). The initial proposal of the Commission in the Chemicals Strategy for Sustainability was to apply the EUC purely on a hazard-basis, i.e. to all 'most harmful chemicals' and to ban their consumer (and professional) uses, except essential ones, regardless of whether they present a risk. The mere presence of a hazardous substance in a process or product should not be associated with the default occurrence of a risk threatening human health or the environment. The EUC has not yet been defined. Neither the need for, nor the impact of, the EUC is clear to us at this time. In particular, it remains unclear how the EUC can help speed up procedures without abandoning the risk-based approach (see below). The EUC can be a building block for socio-economic assessment under the current REACH Regulation. However, the EUC must not prevent the consideration of justified economic needs and demonstrably safe uses taking into account the whole life cycle. In the use of substances for the manufacture of articles, the EUC should only be applied if no safe use limit can be established (a condition for socio-economic evaluation in the current authorisation procedure). In the use phase assessment, the EUC can support the definition of application-specific substance limits in the case of restrictions (concentration in the article or release rates) and the definition of exemptions (analogous to RoHS Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment). In the disposal phase or in the recovery of secondary raw materials from articles, the EUC can support the evaluation of collection and reprocessing concepts (safe disposal) if applicable. The EUC should not lead to the restriction of applications that have no impact on the regulatory objective. This can only be determined through a risk assessment. The EUC should therefore only be used after the risk assessment and cannot replace it.
- Moreover, industry needs to be able to continue producing products using chemicals in a level playing field with non-EU countries. Therefore, a REACH restriction rather than authorisation is the preferred instrument to regulate chemicals. Restriction at least sets equal conditions for the chemical content of EU-manufactured and imported products alike, and therefore also supports a higher quality of material streams. **Therefore, we would prefer option 2, depending on how the Commission would merge authorisation and restriction processes.**
- **REACH is the main instrument to evaluate and identify hazardous substances with the goal of restricting or authorising them.** Based upon the evaluation in REACH, the effects of substances can be regulated in, for example, the RoHS Directive to minimise the effects on the waste from Electrical and Electronic Equipment (EEE). REACH information also influences the choices companies make for the use of chemicals when they develop and manufacture their products (Ecodesign Directive). We recommend that the different legal instruments (REACH RoHS, Ecodesign, etc) are used only for their intended goals. For targeted, and thus efficient, regulation, differentiated but harmonised legal instruments are preferable. Consistent application can therefore also avoid contradictory double regulation.
- **Policymaking and decisions regarding chemicals should be risk-based not hazard-based.** We generally support a risk-based approach instead of moving towards a hazard-based approach (which is the precautionary

principle) because the risk-based approach is based on scientific evidence of how the environment and people are affected. As stressed by the [European Commission](#), the precautionary principle may only be invoked in the event of a potential risk and it can never justify arbitrary decisions.

- The extension of the generic approach to risk management would mean, de facto, abandoning the risk-based chemicals assessment already established for good reasons in REACH. This would actually introduce a fundamental paradigm shift towards hazard-based assessment, and the use of the precautionary principle without the evidence to justify such a requirement.
- The EU and national authorities need to **financially support the industry** in finding alternative chemicals that can substitute 'problematic' chemicals and be involved in the substitution process.
- The criteria to assess the equivalence of alternative substances substituting Substances of Very High Concern (SVHCs) must comprise not only **technical feasibility** and **health impacts** but also **durability, performance, safety levels, quality, costs**, etc.
- It is expected that valid and not regrettable substitution (to avoid that a banned chemical would be 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 the 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.
- As highlighted in our [recommendations on the New Circular Economy Action Plan](#), our **technology industries**, major downstream users and article manufacturers under the REACH Regulation, **are fully committed to reducing the content of hazardous substances in their products to support a more circular economy**. Our industries face numerous challenges in order to know which SVHC are present in their products, as required to fulfil the REACH regulation. They are also engaged in a process of continuously minimising and substituting these substances in their products. **A meaningful exchange of information between all actors in the value chain**, for example electronic equipment focusing on SVHCs, will contribute to a circular economy.
- Even though there is no direct link between the REACH revision and the ECHA SCIP database containing information on substances of concern in articles, as such or in complex objects (products), **we still question the workability and the proportionality of the SCIP database**. We strongly recommend that only the information legally required by REACH Article 33(1) be requested on a mandatory basis. Other information should be requested on an optional basis and contribute to the goals of the Waste Framework Directive Article 9 objectives based on an impact assessment. We also recommend starting with a pilot, with a limited scope, which includes only substances that may generate problems. For more information, see Orgalim [Position Paper](#) about the SCIP database.
- **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 industry accurately assessing the risk of a substance based on its probability of exposure and the health impact.
- It is the responsibility of **all actors** within the industry (from the chemical industry, technology industries and the waste management industry) to minimise the risks and negative impacts of chemical substances on the environment.
- **There is not enough time to create awareness regarding substance restrictions among all the impacted stakeholders and manufacturers because of procedural rules**. Longer consultation periods are needed at every step to provide quality input. Generally, time is always too limited to notify substances, especially when a substance is not yet regulated. Moreover, downstream users are usually focused on products and not on substances themselves. Generally, substances should always first be put on the candidate list before restricting them to allow the industry (especially downstream users) to obtain a clear picture of a chemical's usage and the opportunity to contribute to the consultations in the restriction process.

- 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. There must be proven environmental benefits that exceed the costs to industry.
- **Orgalim believes that effective and resolute enforcement of regulation plays a central role in upholding a well-functioning Internal Market.** While control and enforcement must remain a national competency, Orgalim supports EU-wide actions to support 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 as a possibility.

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of over €2,076 billion, manufacturing one-third of all European exports and providing 11.33 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

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