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Orgalim comments on the REACH revision roadmap

Executive summary

Orgalim, representing Europe's technology industries, welcomes the revision of European Union legislation on registration, evaluation, authorisation and restriction of chemicals (REACH Regulation). Our technology industries, major downstream users and article manufacturers 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 REACH revision inception impact assessment roadmap:

- We call on the ECHA and the European Commission to develop better criteria for determining when authorisation and when restriction is applicable.
- 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.
- We urge to keep the scope of REACH Article 33 limited to Substances of Very High Concern (SVHC) and to not broaden the scope to Substances of Concern (SoC). However, if that were to be the case, we would call for a clear definition of Substances of Concern in order to ensure legal certainty and clear procedure rules.
- REACH should continue to be the main instrument for evaluating and identifying 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.

Orgalim comments on the proposed policy options

Inception impact assessment from the European Commission:

- **Reforming the authorisation process**: Options include clarifications and simplifications of the current provisions, national authorisation for smaller applications, removing the authorisation title from REACH, integrating the REACH authorisation and restriction systems into one and improving the interface with other pieces of legislation (complementing actions under the one-substance one-assessment action under the Chemicals Strategy).
- **Reforming the restriction process**: Options include extending the generic risk approach to restrictions to endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers and substances that affect specific organs; extending the generic risk approach to products marketed for professional use; and operationalising the concept of essential use in restrictions, including the criteria for granting derogations.

- We call on the ECHA and the Commission **to develop better criteria** to determine when authorisation and when restriction is applicable.

- **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, REACH restriction and authorisation should not be merged into a common construct but need to be better harmonised. Authorisation is intended for cases where the socio-economic importance outweighs the risks and no alternative is currently available. This is the reason why there is a sunset date to search for alternatives. Otherwise, authorisation applications would be unduly prolonged. Member States should be encouraged to submit restriction dossiers where a substitution is not readily known. Restrictions should not only be submitted if there is no other means to manage the hazard of an SVHC, but also when some uses are clearly defined and controlled, and other uses are not defined and controlled but can be banned. Article 69 (2) must be applied more strictly for all substances subject to authorisation. This provides that substances in Annex XIV will be reviewed by the Agency after the sunset date to determine whether the risk to humans and the environment from the use of the substance in articles can be adequately controlled. If not, the Agency will prepare a restriction proposal.

- **Double regulation** (POPs, REACH, RoHS, Industrial Emissions Directive (IED), etc.) **should be avoided and resolved. Before deciding on the REACH authorisation route, it should be thoroughly evaluated whether IED/BAT (Best Available Techniques) is a more efficient way of risk reduction and if conflicting requirements arise.** The interplay between REACH and other pieces of EU legislation should improve the implementation of REACH and prevent conflicting requirements, ensuring that the correct risk reduction is implemented. Before authorisation, it should be investigated if other relevant legislation is more efficient for risk reduction and to ensure that conflicting requirements are not implemented. In REACH Article. 58.2 it is stated that uses may be exempted from the authorisation requirement on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment. OSH and Waste legislations are taken into consideration in the review. In addition to human health and waste legislation environmental legislation should also be considered. The main EU instrument regulating pollutant emissions is the Industrial Emissions Directive (2010/75/EU). The IED is already implemented in the Member States. In REACH art. 58.3 it is stated that priority to include a substance in Annex XIV (Authorisation list) should be given to substances with PBT or vPvB properties, as well as wide dispersive use or high volumes. For PBT, vPvB, this means that authorisation is mainly aimed at substances hazardous to the environment. Several of these substances used in the industry are already regulated under the IED. The IED's objective is reducing harmful emissions through integrated prevention and control of pollution of the environment (air, water, land) arising from industrial activities. In particular, a more stringent application of BAT is essential for the achievement of this objective. Both the IED and REACH aim at regulating substances to prevent or, where that is not practicable, to reduce emissions into air, water and land, in order to achieve a high level of protection of the environment taken as a whole. (The IED also includes vibrations, heat and noise). Authorities include BAT in the permits for operating facilities.

- If there is only industrial use of a substance resulting in concentrations of less than 0.1% in the final article, it should be enforced by the regulation to apply **OSH and OEL** values in production on a European-wide level, which is probably equivalent to a restriction.

- **Industry needs enough time** to adapt their products and manufacturing processes, especially when SVHCs are affected by REACH and waste management legislation. Companies need a long-term perspective for substitution, and therefore enough transition time. We suggest aligning the transition times to the procedures in RoHS (48 months for designing out) and also aligning the timing for restriction with the timing for updating the candidate list. The asynchrony between restriction and adding to the candidate substances list leads to an unnecessarily high number of necessary interactions in the supply chain. A less frequent update of the candidate list with then more entries could be seen as a more favoured option.

- 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 SVHCs must comprise not only **technical feasibility** and **health impacts** but also **durability, performance, safety levels, quality, costs,** etc.

- It is more likely that valid and not regrettable alternatives 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 cope with such developments on their own. Here, the Commission must find new ways to enable such 'quantum leap' developments.

Inception impact assessment from the European Commission:

- **Revision of the registration requirements**: Various options for revising the registration requirements for manufacturers and importers will be analysed, including increased information on hazards of concern, documentation of safe use, registration of certain polymers, and information on the environmental footprint.
- **Simplifying communication in the supply chains**: Options for improving safety data sheets (information for downstream companies and workers on chemical risks and protective measures) will be assessed, including in particular harmonised electronic formats.

- 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 1907/2006/EC, **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 Substances of Very High Concern (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 Substances of Very High Concern, will contribute to a circular economy.

- Even though there is no direct link between the REACH revision and the SCIP database, 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) must be requested on a mandatory basis. Other information should be requested on an optional basis and contribute to the goals of the WFD 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.

- **We urge to keep the scope of REACH Articles 33 and or 57/59 limited to Substances of Very High Concern (SVHC) and to not broaden the scope to Substances of Concern (SoC)**. However, if that were to be the case, we would call for a clear definition of Substances of Concern in order to ensure legal certainty and clear procedure rules.

- **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 mostly efficient, regulation, the differentiated but harmonised legal instruments are preferable. Consistent application can therefore also avoid contradictory double regulation.

Inception impact assessment from the European Commission:

- **Revision of the provisions for dossier and substance evaluation**: Various options will be considered for ensuring that registration dossiers are in compliance and that sufficient information for concluding on concerns is available. These include the possibility to revoke registration numbers for non-compliant registrations and to allow authorities to commission tests to obtain hazard information.

- **Policymaking and decisions regarding chemicals should be risk-based not hazard-based.** We 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 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.

- The responsibility of **all actors** within the industry (from the chemical industry, technology industries and the waste management industry) is to minimise the risks and negative impacts of chemical substances on the environment.

- The regulatory management option analysis (RMOA) is voluntary, as it is not part of the processes defined in the EU chemicals legislation. **Therefore, RMOA should be made mandatory** to help authorities clarify whether regulatory action is necessary for a given substance and to identify the most appropriate measures to address a concern.

- **There is not enough time to create awareness for 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.

- **We call for better coordination between the Member States to improve the effectiveness of the public activities coordination tool (PACT).**

- New legislation must always follow the **EU Better Regulation principles** and be based on an **impact assessment** to avoid situations like the recent ECHA SCIP database concerning Substances of Very High Concern in products.

Inception impact assessment from the European Commission:

- **Introduction of a Mixtures Assessment Factor (MAF)**: Options for addressing the risks of exposure to several substances (combination effects) by introducing one of more MAFs in Annex I will be analysed.

Continually raising the level of protection for European consumers is a core value of the members of Orgalim. However, the introduction of a generic Mixture Assessment Factor (MAF) presents several serious concerns for Orgalim members:

- Any speculation regarding the introduction of a MAF must be rooted in a risk-based approach. Failure to do so would potentially introduce a concept with a very high societal cost and only limited benefit.

- A regulatory approach as a MAF should be as targeted as much as possible in order to address the risks of combined exposure. For example, addressing chemicals known to have similar problematic effects; e.g. those affecting specific organs, and to which consumers are expected to be exposed from different sources and via the environment.

- Introducing MAF factors should be based on sound science and factors should be able to be modified in case of new and more robust data.

- In a case where a MAF would be introduced in the REACH regulation the Commission should avoid duplicating existing requirements from other regulations; e.g. exposure to unintentional mixtures of chemicals already exists in the workers' protection legislation.

For these reasons, Orgalim urges the Commission to be cautious with this policy option, and only consider its application in cases where there are no other satisfactory means of controlling risks. In those cases, a MAF should seek to deal with a specific risk management scenario; i.e. based on a case-by-case evaluation.

Inception impact assessment from the European Commission:

- **Revision of provisions for control and enforcement**: Options include establishing minimum requirements for national controls and enforcement, including stricter border controls; and establishing a European Audit Capacity to audit Member States enforcement.

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.

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