LANXESS
Energizing Chemistry

LANXESS Statement on the REACH Revision

We welcome the opportunity by the EU Commission to give input to the planned REACH Revision via a public consultation.

With REACH we already have the most ambitious and comprehensive legislative framework for the assessment and regulation of chemicals in the world. Several in-depth reviews of the REACH Regulation have demonstrated that the REACH processes are working well in achieving a high level of protection of human health and the environment- although in some areas there is room for improvement especially with regard to efficiency.

In contrast to the "targeted revision of the REACH Regulation" as was announced in the Inception Impact Assessment in May 2021, the current consultation indicates that the EU Commission is aiming for a rather extensive revision. A strong tightening of the legal provisions of the REACH Regulation including many undefined terms and concepts such as "essential use", "safe and sustainable-by-design" would, from our point of view, further jeopardize Europe as an important location for the chemical industry and thus hamper the EU's global competitiveness.

Therefore, we argue not only for a targeted but also for a proportionate revision of the REACH Regulation: Instead of further increasing the overall regulatory burden the REACH revision should focus on improving coherence, regulatory predictability and a more harmonized EU-wide enforcement by strengthening the overall efficiency of the REACH processes.
These measures would support the innovative capacity of the EU chemical industry and accelerate the transition to a more circular and green European economy.

Information Requirements:

Since the entry into force of the REACH Regulation in 2007, the information requirements for registration dossiers have continuously been revised and extended (e.g. for nanomaterials and via new guidance documents and submission tools). Although we have put a great deal of resources into REACH implementation right from the start, the European chemical industry is still struggling with the full implementation of the registration requirements of the existing EU REACH regulation as can be seen from the dossier improvement action plan of Cefic and related activities of ECHA which will be ongoing until 2026. Therefore, any further extension of REACH registration requirements needs to be proportionate taking into account the effort and costs required, the potential benefit for human health and the environment as well as animal welfare in case additional vertebrate studies would be required.. From our point of view it is too early for an additional increase of the data requirements.

This is also valid for information on carcinogenicity. While we understand and fully agree that beating cancer is a priority for the EU Commission and the European Parliament, we do not see a need for additional information requirements on carcinogenicity for all substances registered under REACH. In the questionnaire on the REACH revision it is not taken into account that substances registered under REACH are tested for mutagenicity and genotoxicity. This data is relevant also with regard to carcinogenicity because a significant proportion of carcinogens acts via a mutagenic mechanism.

New Approach Methods (NAMs) replacing animal studies:

We fully agree that for the sake of animal welfare animal testing should be a measure of last resort and be gradually replaced by alternative testing methods rather sooner than later. However, NAMs need to be validated and accepted in order to be able to replace animal testing. In this regard it is crucial that the use of NAMs is accepted and harmonized on an international level. There is no benefit of using

NAMs only in the EU (i.e. for REACH purposes) if the test results cannot be used in other chemicals legislations outside the EU (e.g. Korea REACH, Turkey REACH, etc.) because they are not accepted. In this case additional animal studies would have to be conducted. Consequently, no benefit for animal welfare would be gained.

The questions (and the possible answers) regarding NAMs in this public consultation create the impression that there might be a trade-off between the use of NAMs and the protection of human health/the environment or animal welfare, respectively. We are of the opinion that a balance between safety, animal testing and the use of validated alternative testing methods is possible.

Information requirements for 1-10 t substances:

Information requirements for substances that are produced in a rather low quantity must remain proportionate. Significantly increasing the information requirements for substances in this tonnage band would have a large negative impact on SMEs and would present a barrier to innovation for the whole chemical industry and therefore weaken the innovation potential and the competitiveness of the EU.

If concerns regarding potential hazard properties such as carcinogenicity arise, these concerns can be clarified via the established evaluation procedures under REACH such as dossier and substance evaluation.

Endocrine Disruptors:

We do not see a need to extend the standard data requirements for endocrine disruptors in REACH registration dossiers. If there is a reasonable suspicion of endocrine effects, authorities have the possibility to request additional data from the registrants via dossier and substance evaluation.

Any such request must be proportionate and based on a tiered testing approach. This means taking into account:

- Already available information (weight of evidence including toxicological data)
- Assessments that were already performed by authorities
- Use and exposure (e.g. wide dispersive use)
- Internationally accepted and validated test methods
- Animal welfare aspects as well as laboratory capacities

Mixture Assessment Factor:

We do not support a "one-size-fits-all" Mixture Assessment Factor (MAF) as it is discussed by the European Commission and the Member States. A generic MAF or the application of different MAFs for all (groups of) substances is not scientifically justified and neither proportionate nor an appropriate tool to take into account potential combination effects of chemicals. So far, reviews and assessments indicate that combination effects only occur in a limited number of cases in the environment. Moreover, such cases are dominated by a few substances, e.g. pesticides and pharmaceuticals which are designed to have a specific impact on organism (specific mode of action). This differs from most industrial chemicals which have a non-specific mode of action or may have very limited toxicity compared to the former.

Revocation of registration numbers:

LANXESS is highly committed to ensure that the registration dossiers we submitted are fully compliant with the requirements of the REACH Regulation. As a signatory to the Cefic voluntary Action Plan we put considerable efforts into reviewing and improving chemical safety data in our registration dossiers.

We therefore support the “zero tolerance for non-compliance” initiative announced in the Chemicals Strategy for Sustainability. In this regard, we welcome the introduction of a revocation process for registration numbers because no substance or product should enter the EU internal market if it does not comply with EU rules. However, since the revocation of non-compliant registration dossiers is a very powerful tool with considerable consequences for the concerned companies, there need to be clear and comprehensible conditions, legal rights and due process.

Essential Use Concept:

The recent discussions regarding the essential use concept have shown that the application of the concept in practice is very complex and touches upon fundamental questions that go beyond chemicals legislation, such as which uses are considered to be essential and who is going to decide upon the essentiality of a use for society. We therefore echo the call by Cefic for taking into account the following elements when introducing an Essential Use concept in REACH:

- It must facilitate decision-making on whether or not to continue to authorize / derogate a use of a substance subject to a ban or restriction, in line with the Chemicals Strategy for Sustainability.
- It should be strongly linked to scientific assessment and only implemented where an unacceptable risk is identified or where adequate control cannot be guaranteed.
- It has to be transparent, predictable and proportionate to the identified risk.
- It should be done on a case-by-case analysis of individual uses, without excluding entire industry sectors.
- Decisions on Essential Use should be made by a politically accountable and democratically legitimated body that is empowered to take both decisions and responsibility for these decisions.
- Decision-making has to be transparent and should involve representatives from across the stakeholder community, including industry and civil society, to ensure legitimacy of the process.

Reform of Authorization and Restriction

We welcome the plans by the EU Commission to reform the authorization and restriction procedures under REACH. On the one hand, especially the authorization process has turned out to be complex and causing a high legal uncertainty for applicants and other actors in the supply chain. On the other hand, since the submission of the first application for authorization both industry and authorities gained a lot of experience in drafting and assessing applications for authorizations, respectively. Studies by ECHA have shown that the authorization process reaches its aims: a high level of protection of human health and the environment and substitution of Annex XIV substances.

Therefore, we advocate to keep the authorization process in REACH but with clarifications and simplifications in order to make the process more efficient and transparent for all actors involved. This should include a simplified procedure for substances that are used in low quantities and for process chemicals that are only used e.g. in closed and automated industrial settings and for substances which have safe health based thresholds like most SVHC substances that are toxic for reproduction properties. Additionally, clarifications are needed in terms of the assessment standards of RAC and SEAC as well as the REACH Committee in order to improve the transparency of the assessment and decision-making process and to increase legal certainty for applicants.

In contrast, a merger of the authorization and restriction procedure would create a highly complex regulatory system requiring immense resources from both industry and authorities.

Generic Approach to Risk Management

While we agree with the EU Commission that there must not be a risk for consumers from articles that contain SVHC, we are not in support of a generic ban of SVHC as well as other hazardous substances in consumer products. In many cases these substances fulfill a crucial function and are embedded in the matrix of the end product so that there is no release or exposure.

SVHC and other hazardous substances should be restricted if they demonstrably pose an unacceptable risk to human health and/or the environment. Banning (groups) of substances based on their hazardous properties only, i.e. without an assessment of the risks, the availability of alternatives as well as socio-economic impacts would not be proportionate.

Sustainability and hazardous properties are not mutually exclusive. Especially the functionality or reactivity of chemical substances required for certain uses and processes is often inseparably linked to the hazardous property. The generic approach to risk management, if applied as announced in the Chemicals Strategy for Sustainability may hamper the development of innovative and sustainable products in the EU and may therefore threaten the achievement of other Green Deal Goals.