

CEPE's recommendations and proposals to CARACAL

INTRODUCTION

CEPE is the European Council of the Paint, Printing Ink and Artist's Colours Industry. Our industry directly employs 100.000 people and is a key supplier to many industrial, professional and consumer downstream users.

Regulatory burden is a major concern for our sector, with a high impact on competitiveness, innovation and investment decisions. The European paint and printing ink industry is particularly affected by complex and rapidly evolving regulations.

The core objective of the second term of Ms. Von der Leyen is to make the EU more competitive. To achieve this, the European Commission has committed to, amongst others, simplification and reduction of administrative burdens by 25%, and by 35% for SMEs. Unfortunately, this commitment has been completely ignored with regard to chemical legislation, as the meeting of CARACAL on April 3rd proved.

- Regulatory simplification means revising legislation to minimize complexity and administrative burden to enable a more competitive and innovative industry.

REACH is the most advanced regulation in the world for the protection of human health and the environment. Whilst it has contributed significantly to achieving these objectives in Europe, it is also restricting the competitiveness of the EU Industry in a global market.

REACH is directly influenced by the harmonised classifications coming from CLP. With the CLP amendments, we see that more and more challenges in the form of regulatory triggers that will be very difficult to deal with. Therefore, a risk-based approach should be maintained at the core of REACH.

Simplification could be brought with a clear and realistic Roadmap, as proposed jointly by DUCC, bringing legal certainty and business predictability as well as allowing the involvement of all stakeholders at an early stage. This would be key to speeding up the decision-making in the regulation of chemicals while maintaining EU industrial competitiveness.

Keeping in mind the need to reduce administrative burden and ensuring the competitiveness of the EU industry, the concepts currently being developed that focus on hazard need to be considered with caution.

REACH should be the only regulation on chemical safety when not covered by more specific legislation such as on food, food contact, medical devices or plant protection, and there should not be duplication in other legislation (e.g. consideration of substances of concern in ESPR, Toy and FCM with different definitions). Hazard endpoints should be common to all these chemical regulations, but risk assessment should be specific to the application and should consider the routes of exposure.

This document presents CEPE's views with respect to the CARACAL presentation of the EU Commission.

OVERALL KEY REQUIREMENTS FOR REVISION

CEPE believes that the revision should be targeted and use a risk-based approach focussing on simplification and increased predictability to reduce unnecessary burdens and recognise the importance of coatings in improving EU competitiveness and sustainability.

REACH is a landmark piece of legislation that has propelled the EU to the forefront of the efforts for a more sustainable future. A revision should be used to further boost the competitiveness of the EU industry rather than harming the EU competitiveness agenda.

1. REGISTRATION/EVALUATION

The current system is proportional (tonnage-based requirements) and ensures a level playing field with the principle of “no data no market”. The evaluation process takes the necessary steps to ensure that the dossiers are complete and of good quality. The proposal to limit the validity of the registrations to 10 years should not add to the administrative burden and costs.

Polymers

Notification or even registration of polymers in the REACH regulation will create additional complexity and inefficiencies. For example, CEPE members might be unnecessarily targeted for certain niche applications that entail modifying existing polymers to market needs. This would bring about new obligations for CEPE members with questionable added value, adding once again to the administrative burden, because they would need to notify/register a large number of imported polymers. Instead, an assessment should define a target group of polymers to avoid unnecessary burden to industry.

MAF

A MAF should not be applied across the board given that sufficient safety factors are already embedded in the way substances are risk-assessed today and because it is not founded on commonly agreed science. CEPE has amply demonstrated in previous documents how a MAF would be devastating for this industry sector. It would add administrative burdens to manufacturers, for example the need to develop a high number of Downstream User risk assessments and chemical safety reports, potentially triggering new animal testing, and could lead to the disappearance of a large number of paint and coating products.

Substance Evaluation

With the number of substances potentially under scrutiny on the rise, the existing roadmap could be extended to establish priority substances and their use combinations. Member states should not be allowed to deviate from this list. Such a roadmap would provide regulatory predictability and allow companies to focus their time and resources appropriately.

2. RISK MANAGEMENT - authorisation and restriction

What matters most (substance/use combination/exposure) should prevail when it comes to risk management options.

A better understanding upfront of the use, exposure and alternatives of certain substances would allow for a well-founded decision as to which regulatory route, if any, should be used.

New classifications under the CLP could lead to certain substances being listed as substances of very high concern (SVHC) for which there are no alternatives. Even where alternatives are available,

substitution takes several years and customer qualification in certain industries such as automotive and aerospace can take up to 10 years.

Additionally, CEPE is convinced that a mechanism such as the essential use concept will make this choice neither easier nor faster and will be a confusing factor in the choice of the most appropriate regulatory instrument. It might lead to huge requests for derogations if based on overly narrow criteria, leading to even greater overload for regulatory authorities. As an example, consider how to differentiate between a decorative paint versus a paint for corrosion protection, or how to consider mental or psychological well-being for which artist's colours are essential.

The Authorisation process

So far, the authorisation route has not significantly impacted our industry – with the exception of aerospace – because when a substance becomes a SVHC, we make every effort to substitute it.

The SVHC nomination sometimes happens very fast as it is purely hazard-based and thereby can take downstream users by surprise. One recent example is the proposal to classify talc as a carcinogen. Many more substances could be listed in a short timescale due to the new CLP hazard classes and the new CLP grouping approach, making it difficult for DUs to follow and take actions early.

The SVHC listing follows a less-formalised process than the harmonised classification under the CLP and it is sometimes used to force the phaseout of substance because it has a recognised blacklisting effect. If the process of SVHC identification is kept, then the substances on the Candidate List need to undergo a Regulatory Management Options Analysis with use and exposure information being provided.

The prioritisation for entry into Annex XIV could be improved by changing the criteria to better reflect what matters most, instead of a simple scoring exercise without any real impact.

If a better decision-making process right at the start of any initiative is available, the authorisation process could only be chosen for well-justified use cases (and not for all uses of a SVHC). The burden for both ECHA and industry is then substantially reduced.

In other words, authorisation should only be used as a last recourse and only if a detailed assessment has concluded that none of the other regulatory routes have been able to cover the concerns and that there are no unacceptable adverse impacts on the EU industry.

The Restriction process Art 68(1)

The restriction process has in principle been well designed, as authorities can use it to address specific identified risk and propose risk mitigation measures. However, we have observed that the following could be improved:

- Lack of prioritisation and coordination of all the activities of authorities. We are seeing an increased level of activities affecting our industry and are facing difficulty in following them all and taking the necessary steps to substitute/reformulate where necessary, thereby focusing resources in forced reformulation and not pure innovation. Substitution can take many years.
- The restriction process is problematic for DUs because public consultations offer limited time to provide relevant information on use, exposure and alternatives and help authorities to identify where derogations are needed. Also, authorities do not have the relevant expertise to judge the quality and relevance of the information received.
- Persistency alone is being increasingly used as a proxy for risk in determining the need for restriction of substances, stressing the increased use of the precautionary principle. Substances without a hazard should not be restricted.
- Broad and unspecific restrictions are increasingly used to address a wide range of substances and uses, sometimes without proper substance identification, which creates uncertainty for implementation and enforcement (e.g. microplastics, PFAS, grouping approach).

- The current restriction process does not provide a formalised way to make a robust analysis of alternatives in order to make the proper regulatory decision.
- Restrictions should always be clear (no divergences in interpretation) and enforceable.

The GRA (Generic Risk Management) Art 68(2)

As long as the GRA is a blanket ban and does not include any formal process to take into account socio-economic impacts, risk or alternative considerations, unexpected and disproportional impacts cannot be ruled out. Therefore, we strongly insist not to amend Art 68(2) with the expansion of other hazard classes and beyond consumer use.

Key Points to be considered for efficient risk management

1. Identify the substance/uses combinations that matter most. This requires a call for more granular information on use (in which sector/application is the substance used) and exposure (industrial, professional, consumer and indoor/outdoor exposure if relevant) prior to any regulatory measure being taken.
2. Establish a clear and yearly roadmap targeting the substances/uses combinations that matter most at a pace that both industry and authorities can reasonably manage and to which Member States must abide.
3. Identify the best regulatory route that should be used for each substance/use combination, whether within REACH or outside REACH (OSH, IED...) and avoid double regulations.
4. When the phaseout of substances is triggered by hazard-based mechanisms, for those uses that matter most, a robust analysis of alternatives system is initiated early in the process. This would ensure a “safe space”, allowing competitors to work together while ensuring the respect of confidential information. The understanding of the (non)-availability of alternatives will also help guide the decision-maker as to the best regulatory route to choose.

3. ENFORCEMENT

Overall, CEPE supports the ideas to strengthen enforcement. Enforceability should be taken into account, especially under restriction.

Different rules within and outside the EU together with ineffective enforcement, especially at the borders, results in an uneven playing field. EU companies strive to place compliant products on the market, whereas non-compliant imported products may easily reach the EU market because of the lack of enforcement.

4. SIMPLIFICATION AND TRANSPARENCY

Some provisions of REACH already result in high burden to CEPE members, which negatively affects their competitiveness outside EU27. These should be considered for simplification as for any new measure.

- Registration costs (e.g. LOAs) can be a significant entry barrier for companies, especially SMEs
- Reporting requirements under restrictions (e.g. microplastics)
- When (re)importing substances/mixtures from outside the EU, the substance volume tracking provision in REACH determines a high administrative burden on CEPE members, which already operate in a very complex supply chain, having to track thousands of substances in thousands of products through hundreds of suppliers.
- The high administrative costs negatively reflect on product prices when competing in extra EU markets with manufacturers who do not have to sustain such costs.

Simplification should not only mean quicker regulation but also allow for impact assessments and appropriate transition periods for any measure.

The content for **Extended Safety Data Sheets** should be evaluated – they are too complex and not user-friendly, as information is hard to find. For example, uses that are determined to be safe in the Chemical Safety Report, listing the “Identified Uses” in section 1 of the SDS, and including references to such sector documents should be sufficient. Harmonised digital formats focusing on information that really matters could help.

CONCLUSION

REACH is a landmark piece of legislation that has propelled the EU to the forefront of the efforts for a more sustainable future. However, a revision should be used to further boost the competitiveness of the EU industry rather than harming the EU competitiveness agenda. DUCC has provided more detailed steps for a prioritisation roadmap which should provide the needed predictability in enhancing REACH.

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