AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Improving REACH in 2018 and beyond

Cover paper: framing specific issues within REACH

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2016, directly supports more than 4.5 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium • **T** +32 2 513 68 92
info@amchameu.eu • amchameu.eu • European Transparency Register: 5265780509-97

Introduction

During extensive discussions on the European Commission's REFIT of chemicals policy and the wider REACH 'evaluation', a recurring question was "how REACH can be improved, and which improvements would require changing in the regulation?"

The American Chamber of Commerce to the EU (AmCham EU) approached this question by assesing how REACH should look like after 2020. Although the legal text is clear, improving it and making sure REACH is fit for the 2020 world requires a reflection on how its many processes are applied. Guidance, political will, and commitment from the different actors in the REACH ecosystem can achieve significant progress and improve the application of the regulation.

To ease compliance, improving on the five points below will be key:

1. Clarify timelines for the different REACH processes

While the timing for industry comments is tight and specific, it is fully open-ended for authorities (eg. MSCA response to comments in Substance Evaluation process, or REACH committee final approval of authorisations). These open-ended timelines are damaging for business, as they cannot be aligned with the timeframes used by industry. This is the case for: procurement contracts with suppliers, patent cycles, product development cycles, and product lifetimes.

If these timelines were better aligned, industry could proactively respond to the signals REACH is meant to be sending, such as what substances to substitute as soon as possible.

2. Avoid unequal treatment

Much of the REACH work is carried out by the Member States. This raises the question of whether a substance is being treated equally depending on which Member State and competent authority (MSCA) is doing the work. This is also valid for a Risk Management Option Analysis (RMOA), a substance evaluation and for the restriction process.

Although administrative safeguards are in place, there is often limited political willingness from the European Chemicals Agency (ECHA) or the Commission to challenge a MSCA which may have gone beyond its mandate. This is damaging to the reputation of REACH, as industry cannot plan for unexpected regulatory outcomes. Clarity and guidance on the roles and responsibilities of each actor could greatly improve this perception.

Downstream users, not considered as registrants, may also have difficulties in having their voices heard. Even though they are often requested to provide data for exposure scenarios and other REACH requirements, they have a limited influence if they disagree with the lead registrant on the approach or on the content of the dossier. Moreover, they have limited chances of being heard by the Board of Appeal.

3. Generating additional data should not be an end in itself

Industry bears the burden of proof under REACH, yet improvements can be made in prioritising the critical information which must be shared. Is all missing information critical? Are all information gaps equal?

The proportionality test emerging from recent Board of Appeal decisions around dossier and substance evaluation is a welcome development. It demonstrates that in some cases MSCAs and ECHA have tried to go beyond what was intended by the legal text. ECHA should ensure that requests for additional information follow a predictable path and are based on well-defined principles, such as tiered approach, weight of evidence and read-across. Currently, too many of these concepts are open to interpretation and double standards.

As long as registrants perceive they are being treated unfairly, or that their voice is not heard, REACH's credibility will suffer. As a result, proactive compliance and anticipation based on the spirit of the law will be less effective.

4. Improve Enforcement

REACH is a complex law and compliance is very expensive. Enforcement is essential, otherwise non-compliant actors enjoy a considerable comparative advantage, as opposed to companies who made all the efforts and investments that are required

.

Managing REACH enforcement entails effective decentralisation and mobilisation of many actors at different levels of governance. Enforcing REACH is a longstanding compliance effort, which will not always be the same depending on what REACH process must be enforced. Given this complexity, detailed guidance on how to enforce the different requirements of the regulation (e.g. Registration, Authorisation, Article 33, CLP) should be collaboratively developed. This would ensure a uniform understanding and enforcement practices by the Member States.

This is a problem that is gaining awareness. The REF-4 project report (2018)[1], supported by ECHA, points out that the average non-compliance rate amounted to 18% for 22 REACH restrictions. As the highest non-compliance rates were found among products with no label of origin, the report strongly recommends improving the cooperation between the national enforcement authorities and the customs authorities. This could be done, for instance, by developing unique CN-codes for all substances restricted to facilitate monitoring and enforcement. Common projects and coordination between enforcement and customs authorities are needed.

5. Prevent overlaps between REACH and sector-specific legislation

EU chemicals legislation imposes restrictions and prohibitions on the use of certain substances in products and packaging which directly affect industry. They are contained in multiple sector-specific legislative provisions including the Toys Directive, RoHS, Batteries Directive, Cosmetics Regulation, Packaging and Packaging Waste Directive. These substance restrictions exist alongside and in addition to those contained in Article XVII of REACH. As a result, an unnecessary layer of complexity is created. Industry is compelled by the current EU legal framework to apply several different substance restriction regimes to a single product.

Spreading substance restrictions across multiple pieces of legislation in this way is unsatisfactory for several reasons. In particular:

[1] Forum REF-4 Project Report, Harmonised Enforcement Project on Restrictions (2018).

- It leads to inefficiencies, unnecessary administrative burden, and additional costs for industry;
- It undermines the efficiency and legal certainty of each regulatory risk management measure;
- It leads to inconsistent implementation in Member States.

The decision to restrict a substance should take place after a thorough RMOA has been conducted, and duplication of legislative tools should be avoided at all cost.

The European Commission should continue to produce 'common understanding papers' such as the one on how to avoid overlaps between REACH and RoHS. These guidelines will give clarity to both industry and MSCAs whether sectoral legislation must be given precedence because it better addresses a risk, or when exemptions and scope exclusions must be granted in Annex XVII restrictions to preserve consistency with existing sector-specific legislation. Avoiding multiple restrictions for the same substance will prevent inconsistencies in analytical methods, detections limits, understanding of production processes, which will make compliance and enforcement efforts more effective.

Conclusion

All the topics addressed above are linked to the governance of REACH and how the legal framework does not always match the practice of the law. REACH can be improved and be more effective, should the EU authorities, MSCAs and ECHA focus on the areas of improvements listed above in the run-up to 2020.