POLICY PAPER

Making REACH workable for SMEs: Challenges and Solutions

Key messages

While REACH has improved chemical management and data quality, it poses significant challenges for SMEs in terms of bureaucracy and micromanagement.

Regarding registration, a revision must promote the process orientated research and development (PPORD) notification instrument, reduce discrimination of lower tonnage bands, and further explore data-sharing opportunities.

Regarding authorisation, the swift implementation of a simplified authorization application, better use of data sharing rules in line with confidential business information, and the exemption of certain uses of a substance from authorisation are crucial.

Regarding restrictions, consultations must be more accessible for SMEs, and the legislation must be implementable with a minimum amount of guidance documents. However, when guidance documents are needed, they must be available in all EU languages and provided in time.

Taking stock of REACH

The Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), the EU's key legislation on chemical safety and competitiveness, has improved chemicals management and data quality. However, it presents considerable challenges for SMEs, as it involves an excessive amount of bureaucracy and a high degree of complexity. This paper outlines challenges and proposes possible solutions to strengthen the competitiveness of SMEs in the announced revision of REACH.

Among the positive outcomes of REACH is a significant improvement in the data available on the properties of chemicals and their safe use. Safety data sheets have been greatly improved and now serve as effective tools for professionals to properly manage risks. In addition, there is a general trend toward the professionalisation of chemical management.

Negative aspects include a bureaucratic overload and high levels of micromanagement, which disproportionately drain resources from SMEs compared to larger companies and non-EU

competitors. This raises concerns about the existence of a level playing field between SMEs and larger companies within the Internal Single Market. In addition, enforcement authorities are not adequately equipped to deal with the regulatory framework created by REACH and other chemicals legislation, further distorting the competitive landscape in favour of foreign actors.

We do not believe that a revision of the core text of REACH is strictly necessary to make it more accessible to SMEs. A positive example of effective involvement of SMEs in regulatory processes is the Data Sharing Regulation (EU) No 2016/9. This case illustrates that the interests of large companies and SMEs can often diverge significantly; what benefits one may not benefit the other. It is therefore crucial to engage both sides in a meaningful dialogue.

Registration

A crucial aspect of making the registration process more workable for SMEs and lower tonnage categories is the Product and **Process Oriented Research and Development (PPORD) notification**. In this regard, we see a strong need to promote this instrument more effectively. Despite its limitations, it is a valuable tool that could be better exploited, especially when used with substances in a professional context. We need a more effective strategy than the usual awareness-raising efforts that have taken place to date. We believe this could be built into an inquiry process. When a company initiates an inquiry, it should start with a short PPORD navigator. This tool would allow potential registrants to assess the relevance of a PPORD notification to their specific situation, while increasing their understanding of PPORD and potentially opening up new business opportunities.

However, a more fundamental problem with the registration process is its negative discrimination against low tonnage substances in the range of 1 to 100 tons per year (t/a). This intrinsic feature of the current design of the information requirements makes the expansion of production capacity in this tonnage category less profitable than in others. This situation poses a significant risk to growth and could prevent small companies from scaling up. However, this effect could be mitigated by a hybrid approach combining PPORD notifications with the existing registration system. This model would **spread testing costs over several years** while taking into account market reactions to a substance.

A potential outline for such an approach could be:

- For 1-10 t/a and 10-100 t/a tonnage bands:
  - First 3 years: Half of the data required by Annex VII and all available data
  - Next 3 years: Full Annex VII
- For 10-100 t/a tonnage band:
  - Next 3 years: Half of the data required by Annex VIII and all available data
  - Next 3 years: Full Annex VIII

During each three-year block, the involved enterprise could reassess the substance's profitability and choose to discontinue it if necessary. If they decide to stop, they would not need to submit the next information package. This approach would be reasonable given that

the total quantities of registered substances in the 1 to 100 t/a tonnage bands account for less than 1% of all registered quantities.

Data requirements are one of the key drivers of registration costs. REACH aims to reduce these costs for registering the same substance through specific **data and cost sharing**, which is particularly important for SMEs. In this context, the Data Sharing Regulation (EU) No 2016/9 has been a notable success in supporting SMEs. The lessons learned should be used to further explore data-sharing opportunities to reduce administrative burdens and increase data efficiency. The focus could be on creating clearer data sharing processes between similar substances (e.g. read-across), for other REACH processes (e.g. authorisation) and beyond REACH (e.g. biocidal products).

Authorisation

As shown in Annex XIV, SMEs account for at least half of all applications for authorization. However, the authorization process is a significant challenge for SMEs. While authorization is already a major undertaking for large industry, it can be a matter of survival for an SME. Furthermore, the majority of SME activities, including those involving Annex XIV substances, are typically geographically limited. As a result, the full potential of an EU-wide authorization is significantly reduced. Many small users tend to stay within their own Member State or region. After several years of observation, we have identified several potential areas for improvement, primarily the rapid implementation of a simplified authorisation application for certain instances, such as the following

- Use of a substance in quantities of 100 kg or less**;**
- Use of a substance for spare parts of no longer produced articles**;**
- Use of a substance for maintenance of no longer produced articles**;**
- Use of a substance in a closed environment as a solvent**;**
- Use of a substance with an Occupational Exposure Limit (OEL) in industrial environment.
- Use with a regional limitation.

Such a simplification could include the following, depending on the specific use scenario:

- Lighter requirements for the socio-economic assessment;
- Lighter requirements for the analysis of alternatives;
- Lighter requirements for the chemical safety assessment;
- Lower fees;
- Longer review periods.

Furthermore, we believe that the **data sharing rules**, as known from the registration process, could be a useful element also for the authorisation application process. These rules have proven to be an important element to relieve SMEs from prohibitively high testing costs and to reduce testing intensity in the EU. However, confidentiality plays a very important role in this context, as the application for authorisation contains highly sensitive business information,

such as R&D plans, socio-economic analysis and similar information. Such data requires strict protection measures.

Another potential solution to improve SME compliance with authorization requirements is the **application of Art. 58 (2)**, which allows certain uses of a substance to be exempted from authorisation. However, this article has not been widely used to date. In our view, this represents a missed opportunity to streamline processes and avoid unnecessary regulatory burden. To facilitate wider use of this tool, it is essential to develop a clear and realistic set of criteria.

Restriction

Over time, restrictions have become more extensive and complicated. These restrictions have now reached a level that is **not feasible for SMEs**. The most recent and evident illustration of this is the universal PFAS restriction. The proposal, which entails the prohibition of thousands of substances, has led to significant uncertainty. It became evident that such a comprehensive ban would do significant harm to the Union's economy and society. The collection of proposals for derogations via the public consultation process initiated a substantial bureaucratic exercise, which has further complicated the restriction process. It has shown the importance of preparing a well-balanced and consistent restriction dossier, taking into account the relevant stakeholders upfront.

In general, the collection of potential derogations and other arguments through **public consultation is a process that is inappropriate for SMEs**. The dossiers are voluminous and written in technical English. This is a general problem for ECHA's public consultations, but even more so for the current PFAS restriction due to the complexity of the dossier. Given the complexity of this assessment, the number of potential actors involved and the time needed to collect such data across the supply chain, entrepreneurs are not able to make a full assessment or provide relevant input. We would also like to highlight the results of the EC Essential Use study. The study found that participation is generally low and that SMEs are rarely involved, especially in similar processes such as finding and/or fine-tuning derogations for the Restriction of Hazardous Substances Directive (RoHS).

Complicated restrictions often result in guidance documents that are challenging for non-experts to understand. The microplastics restrictions are a prime example of this. The legal text is complicated, interlinked and technical in nature. However, SMEs often lack the resources to consult legal experts. Our member associations, as service providers to SMEs, face similar difficulties. The **availability of guidance documents in all official languages well in advance is crucial** for such constraints. Time is often of the essence for preparatory work such as labelling and data collection. Having guidance a few months before the deadline is often not enough. If guidance cannot be finalized in time, an alternative could be a timely limited moratorium on enforcement.

Other important aspects

Supply Chain Communication

REACH's communication instruments should ideally function seamlessly throughout the supply chain, with a joint efforts of customers and suppliers to ensure their effectiveness. Regular collection and refinement of data is crucial. **Safety Data Sheets (SDS)** play a key role in this and are well established. However, communicating chemical data up the supply chain remains a more challenging aspect, particularly when a user wants to inform a supplier of a new use that requires a safety assessment..

Awareness of the role of SDSs has increased significantly in recent years, as has their quality. However, the length and technical complexity of the SDS remains a challenge for many users. The sheer volume of information in both the SDS and eSDS can make it challenging to identify the critical elements. Digital transformation offers a significant opportunity to address these challenges. To this end, we must reach consensus on the definition of when a SDS is "made available" electronically. In addition, we propose the introduction of a "basic SDS" (bSDS) to distinguish the current SDS from the electronic version for clarity and organization. This two-page SDS should include key information and hyperlinks to more comprehensive materials. Key information could include an emergency number, emergency procedures, permitted uses, classification and labelling.

We have observed ambiguity regarding the right of downstream users to have their uses identified, which is provided for in Art. 37 (2). This provision needs clearer guidance and, where necessary, enforcement. In this context, it should be noted that Art. 37 (2) gives downstream users the right to have their unknown and/or new uses adequately covered in a registration dossier. Furthermore, if a downstream user decides to cover his new uses on his own and based on Annex XII, it is necessary that this actor also has the possibility to share data with the registrants if necessary.

The **information obligations for substances** in Art. 33 are a significant bureaucratic exercise with limited practical value. The implementation of the SCIP system) has only further amplified these challenges. To ensure the effective functioning of such a system, it is essential to prioritize the systematic development of test methods. Furthermore, substances should not be included in the candidate list until adequate testing methods are available. In addition, the creation of a regulatory approved collection of examples that clearly articulate the "articles within articles" concept would be of great benefit to SMEs as it would facilitate their understanding of what is relevant for assessment. This collection should include all types of articles relevant to the EU. However, given the recent and more focused developments around the Digital Product Passport (DPP) - if not the whole Art. 33 - at least the SCIP system could be abolished.

Risk Management Options Analysis

The **Risk Management Option Analysis (RMOA)** process is an excellent method for determining the most appropriate regulatory tool for a substance. It helps to focus on cases of

concern that should be considered for further regulatory action. These cases may involve individual substances or groups of substances in combination with their uses. This approach allows industry to provide relevant data at an early stage, before a regulatory decision is finalised. This approach allows safe uses to be filtered, streamlining the decision-making process. In addition, other criteria can be seamlessly integrated into this filtering step. The RMOA process improves the management of chemicals, making it more systematic, transparent and predictable. It facilitates a more equitable distribution of responsibilities between regulators and companies and a more efficient allocation of resources. Consequently, there is a clear need for its formalisation and consistent implementation. In addition, it would be beneficial to incorporate regulatory tools from relevant legislation into the RMOA process. The most obvious legislation to integrate is Occupational Safety and Health (OSH).

It is clear that REACH has a key role to play in achieving the objective of OSH legislation, which is to protect the well-being of workers. This can be achieved through improved substance data or more sophisticated risk management strategies. Conversely**, OSH complements REACH** by establishing OELs and enhancing the functionality of SDSs to ensure workers' safety. The potential for overlaps between REACH and OSH is significant and must be avoided, while synergies should be further exploited efficiently. Given the important role of the social partners in the implementation of OSH, it is essential to ensure their continued and full involvement.

The establishment of **Occupational Exposure Limits (OELs**) as an alternative and equivalent Risk Management Option (RMO) to REACH and Classification, Labelling and Packaging (CLP) is crucial for a more proportionate chemicals regulation. We believe that this approach is a valuable alternative to the restriction and authorisation methods currently used. OEL should also be a generally accepted requirement for an exemption under Article 58(2) of REACH, which can make regulatory action more balanced and better targeted to address a problem.

Balancing Financial and Administrative Burdens

Given the rapid regulatory approach of REACH for chemicals, it is essential to ensure the active involvement of affected companies in these processes. Participation in public consultations may be a standard procedure for large industry. For the majority of SMEs, however, the opposite is true. There are several reasons for this disparity: First, the documents consulted are voluminous, technical in nature and often only available in English, making them difficult to understand and navigate. In addition, SMEs often feel that their input is not valuable or taken into account, and SMEs often feel overwhelmed by the sheer volume of public consultations.

The participation of SMEs in public consultations could be improved by **including a short fact sheet** (maximum 2-3 pages) with each consultation dossier. The fact sheet should include (in order of relevance): uses (described in an understandable way, no codes); sectors of use (described in an understandable way, no codes); a (qualitative) assessment of the extent to which uses and sectors are covered and potentially relevant uses and sectors that are missing from the dossier; the proposed RMO; and chemical identifiers. In addition, the fact sheet should be translated into all official languages, be available in an online database with a filter option

for parameters such as use or sector, and include an e-mail notification for specific filter options. Finally, any final regulatory action must highlight where and how input from SMEs and SME organisations has been taken into account.

The EU has a comprehensive regulatory framework for chemical substances. However, identifying all the relevant legislation for a particular substance can be a significant challenge. We greatly appreciate the European Commission and ECHA's implementation of the **European Chemical Legislation Finder (EUCLEF**) project, which aims to streamline this process. This tool is particularly beneficial for SMEs as it significantly reduces the administrative burden and makes compliance easier. Promoting and expanding this initiative should be a priority in the coming years.

We acknowledge ECHA's efforts to improve the suitability of IT tools for SMEs, as exemplified by the chemical data management tool IUCLID Cloud for SMEs. However, one of the main unresolved issues is the **availability of IT tools in languages other than English**. This limitation has a direct impact on the resources of SMEs. Many SME employees lack sufficient English skills to effectively use English-language IT tools. This results in the need for an English-speaking employee to perform simple administrative tasks. This often results in highly skilled employees being assigned to these tasks, reducing their availability for more demanding activities.

REACH imposes a number of requirements, including registration and authorisation, that require the expertise of well-trained professionals in fields as diverse as toxicology, risk assessment, IT, and others. However, many SMEs lack the necessary expertise to meet these requirements. Costly external support is often required as a result. This imbalance in the competitive landscape can potentially lead to the formation of monopolies.

A straightforward solution to level the playing field would be to provide direct financial support to affected companies. One possible solution is the creation of an **SME Compliance Fund**. The allocation of financial resources could be based on the monetisation of negative and/or disproportionate impacts. This funded support could be of a more general nature, such as the provision of test data at significantly reduced prices, or direct support to individual companies based on established criteria, covering the costs of technical consultants and associations that provide practical, individual advice to SMEs. Such a support mechanism would allow SMEs to focus more on their core business rather than being consumed by compliance work. This approach would redirect resources towards production, innovation and training, thereby increasing the EU's competitiveness.

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