POLICY PAPER

Making the Biocidal Product Regulation Workable for SMEs: Challenges and Solutions

Key messages

The Regulation's complex requirements make it difficult for SMEs to keep existing products on the market while also investing in biocidal innovation.

Responsible employer practices must include the highest standards of care and caution regarding occupational safety and health requirements, and environmental protection when biocides are used.

The European Commission should apply the lessons learned from REACH to explore further data-sharing opportunities, reduce administrative burdens and increase data efficiency.

A regulatory freeze for newly introduced data requirements should be foreseen. When an authority causes a legally unjustified delay, fees should be reimbursed adequately. Micro and small enterprises should be excluded from fees at all.

Guidance documents should be made more visible, easier to search, and translated into other official EU languages than English.

Background

The Biocidal Product Regulation (BPR) is a highly complex and opaque legislation. The complex requirements of the BPR make it hard for SMEs to keep existing products on the market while also investing in biocidal innovation. SMEunited therefore suggests improving the Regulation through fairer data and cost-sharing, higher regulatory stability, fairer fees, more transparent guidance documents, and closer attention to the consequences of regulatory delays.

Biocidal products are used to control harmful organisms that pose a risk to human or animal health and the environment or cause damage to human activities, by the action of the active substances contained in the biocidal product. Under the BPR, all such products must be

authorised by a competent authority before they can be placed on the market. Authorisation is only granted if the authority's evaluation confirms that the product is safe for people, animals, and the environment and works effectively for its intended purpose.

From the perspective of responsible employer practices, SMEunited emphasizes that the regulation should continue to prioritize the highest standards of care and caution regarding occupational safety and health requirements, and environmental protection when biocides are used.

The BPR has direct effects on those SMEs that are developing and formulating biocidal products. However, it also affects SME customers who use biocidal products for their professional activities. The latter group is much bigger and includes for instance businesses using disinfectants (food, cleaning) or wood preservatives (carpenters, construction), exterminators, formulators of chemical products (cosmetics, cleaning agents, water-based paints) and all kinds of traders of such products.

Data- and cost-sharing

The European Commission should apply the lessons learned from REACH to the BPR to explore further data-sharing opportunities, reduce administrative burdens and increase data efficiency. Data requirements are one of the key drivers of regulatory costs under the BPR. While the REACH Regulation aims to reduce these costs for registering the same substance through specific data and cost-sharing, the BPR does not have such a clear and formal process. However, a fair, transparent, and non-discriminatory data and cost-sharing process is highly beneficial for SMEs. In this context, the Data Sharing Regulation (EU) No 2016/9 has been a notable success in supporting SMEs in the context of REACH.

The BPR's data- and cost-sharing provisions leave too much room for interpretation. Under REACH, a proportional sharing of costs is standard, and every new registrant triggers a reduction of the expenses for the others. However, this is not the case for the BPR. Prices for data access seem independent of the size of companies referring to that data. Hence, costs of several 100.000 Euros are not unusual and have proven to be a critical factor in SMEs' competitiveness and/or survival.

Sometimes a biocidal product authorisation covers different product types (PTs), which, however, are similar. In such cases, only one assessment and lower fees should apply. Another large potential to support SMEs would be a more automatised mutual recognition procedure. That means that the authorisation would start in the Member State where an SME is based. This would make it easier to work with the competent authority due to the same language and geographical vicinity. After this, an SME could approach other relevant competent authorities with a request for mutual recognition, which is much simpler and cheaper to prepare in other languages. Furthermore, reduced fees should be foreseen for SMEs for this procedure.

Regulatory stability and delays

Preparing an authorisation or approval dossier is a considerable workload for SMEs. Financial and organisational planning is crucial for a successful submission. In this respect, changed data requirements during the dossier evaluation process are highly disruptive and slow down the process.

A regulatory freeze for newly introduced data requirements should be foreseen, similar to the recent requirements related to endocrine disruptor (ED) properties. The necessary new data should be requested only after the finalisation of the previous process and within a feasible timeframe.

Too often, authorisation and/or approval dossiers are not processed in the legally foreseen way. Consequently, companies can only enter the market with a delay, causing direct and significant economic damage. Such delays have different reasons, e.g. requests for additional data or an authority's lack of resources. These delays affect not only the producing company seeking BPR registration but also the customer enterprises that rely on these products, especially in cases where no alternative is available on the market.

When an authority causes a delay that is legally unjustified, fees should be reimbursed adequately. The longer the delay, the higher the reimbursement should be. This would help SMEs compensate for some of the economic damage caused by such a delay.

Fees

The EU-level fee structure considers companies' different sizes and foresees relevant reductions for SMEs. This reflects SMEs' particular vulnerability and usually their smaller market share. However, this approach is not followed in almost any national fee scheme. As an alternative to this fee structure, an administratively more effective and economically more supportive solution might be to exclude micro and small enterprises from fees at all. Due to the highly complex legislation, this would be justified and contribute to a better level playing field between competitors of different sizes.

The BPR should enshrine the principle that national fee schemes should be based on a comparable reduction policy similar to the one set out in the Commission Implementing Regulation (EU) No 564/2013.

Guidance documents

The current practice concerning guidance documents is not sufficiently transparent. For an average SME, it is neither possible to follow the relatively intense changes nor easy to keep track of where guidance documents are available and on which topic. Furthermore, guidance documents are generally only available in English, which can be a significant barrier for SMEs.

The pool of guidance documents should be made more visible and easier to search. Changes and ongoing discussion processes should also be tracked more transparently to allow SMEs to quickly understand the status of a specific guidance document. Guidance documents relevant to SMEs should be translated into other official EU languages.

Brussels, 14 April 2025

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