

Analysis of the BPR and its implementation

An industry reflection

Lack of innovation

BPR sets out a highly complex and unpredictable regulatory framework. Based on the current delays and complexity, companies are not able to estimate the regulatory costs, the outcome of the evaluation (when and how) and the time to the market. Unpredictability hinders innovation.



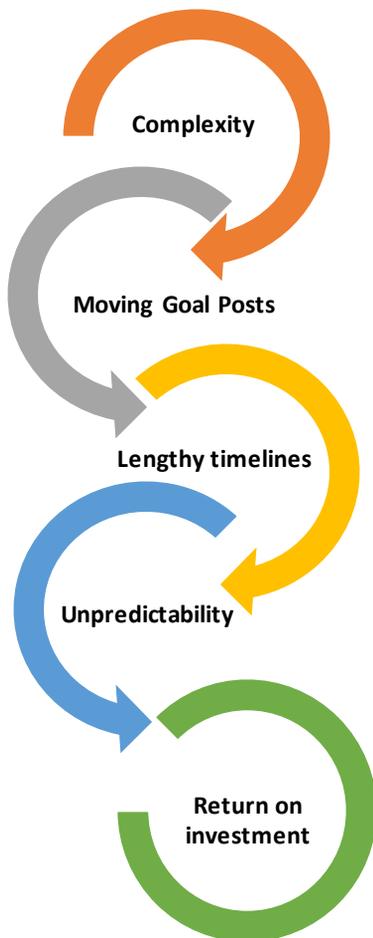
The level of innovation in the biocidal sector is recognised to be very low. The recent report from the Commission acknowledged that innovation around new Active Substances (ASs) has been rather limited, and that only 10 new ASs were evaluated since the entry into application of the BPR. Innovation is mainly limited to reformulating with an existing AS or developing new markets with existing formulations (via new claims).

Long time to Market

- Market opportunities change more rapidly than the time needed to complete the Active Substance approval and Biocidal Product (BP) authorisation processes
- The legal timelines for AS approval and BP authorisation processes are clear, but in practice, the time between submission and decision on a dossier is long and unpredictable
- BP containing new AS are subject to a market freeze¹ until that AS is approved under the BPR

Complexity and unpredictability

- Despite countless guidance documents that have and are being developed, there is still a need for further guidance with gaps and need for further clarification continuously being identified, including scope and borderline clarification
- Moving goal posts makes the outcome of the regulatory process difficult to predict and questions the viability of a new application



Unfavourable environment for innovation

- The hazard-based approach does not properly reflect the real risk of a product and prevents valuable and safe products from being placed on the market
- The BPR is designed to ensure safety by taking the relevant measures when an unacceptable level of risk, is identified. The ambition to achieve “zero risk”, makes the outcome of the Risk Assessment impossible to estimate and does not incentivise innovation
- The timeframe for completing the regulatory process and consequently for accessing the market leads to a limited or late return on investment to cover the high R&D and regulatory costs

“No research in e.g.: new AS is possible due to high research costs in comparison to the potential benefit in the small market segments of biocides.”

Industry survey²

Recommendations:

- Lack of innovation is a consequence of many issues. Implementing all the recommendations in this Fact Sheet series is a good starting point to remove some barriers to innovation
 - ⇒ For instance, reducing the complexity of implementation will lead to less delays and more predictability in terms of timelines and outcome of the evaluation

1 : BPs containing new AS can typically not be placed on the market before both AS approval and product authorisation have been obtained

2 : Industry survey on BPR implementation, 2020-2021