

# Analysis of the BPR and its implementation

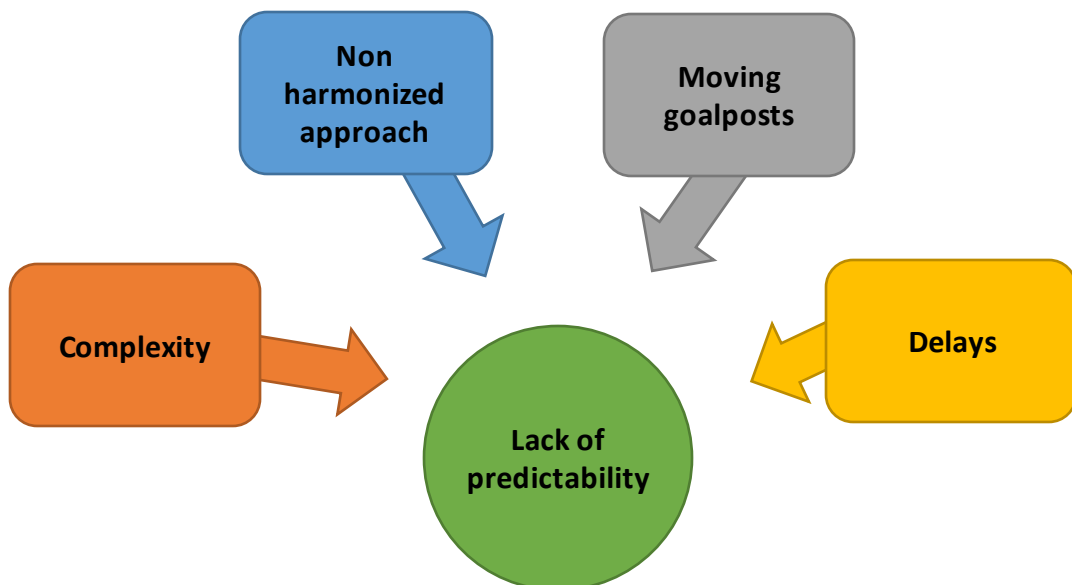
## An industry reflection

### An unpredictable landscape

The lack of predictability created by the implementation of the BPR is one of the major concerns identified in the industry survey.

#### Lack of predictability in the BPR processes

- Issues related to the accurate identification and borderline status of biocidal products and Product Types
- Uncertainty on how guidance documents will be applied (non-harmonized approach amongst MS)
- Possible retrospective application of a new guidance in the course of an evaluation (leads to further request for information, and difficulties for applicants to anticipate outcome)
- Legal timelines for evaluation and decision exceeded



(See also fact sheets complexity, non-harmonisation, moving goalposts and delays)

## Consequences

- High degree of uncertainty in the outcome of the evaluation process, which challenges the commercial viability of the application and blocks innovation

*“As the evaluation of product dossiers is longer than expected (more than 3 years) we are facing difficulties to maintain products on the markets and also to be able to deploy the business as expected 3 years after submission of the dossier.”*

Industry survey<sup>1</sup>



- Challenge for companies to build business plans and stick to them
  - ⇒ Example: Delays in the active substances (AS) Review Programme makes it difficult for companies to develop a clear strategy to support their products portfolio (e.g., keep a coherent product line, make investments in staff and plants)

*“As the deadline for approval of AS, (which allows to plan submission of products dossiers, update of products transitional approvals, exit of the market) is delayed month after month, it is impossible to implement a clear strategy within the company (portfolio, investments, ....)”*

Industry survey<sup>1</sup>

## Recommendations :

- More predictability on the BPC work programme for active substance approvals: longer term forecast (e.g. 3 years) and higher guarantee of its compliance would help companies better plan their biocidal products' registration and develop clearer business strategy
- Lack of predictability is a result of many different issues. Fixing one issue in isolation will not remove unpredictability - implementing all the recommendations in this Fact Sheet series is a good starting point to address this concern
  - ⇒ For instance, not adding new requirements would decrease complexity, resulting in a lower potential for lack of harmonisation, and lowering the MS resource gap. This would help increase predictability for industry and create better conditions for innovation