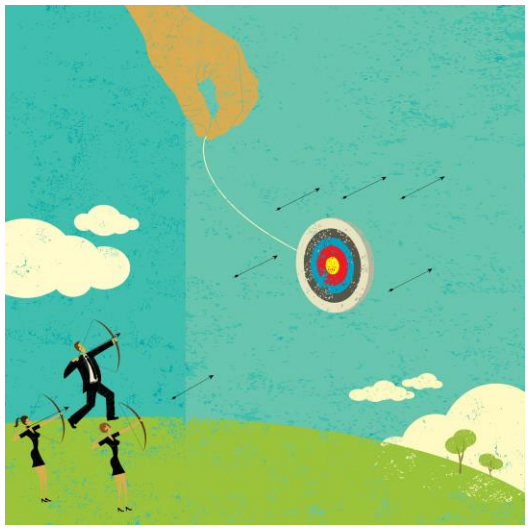
Analysis of the BPR and its implementation
An industry reflection

Moving goal posts

The BPR provides clear data requirements. However, additional guidance is continuously being developed and much of the existing guidance is regularly updated.
The typical application timeline is 6 months for active substances (AS) and 2 years for biocidal products (BP). The applicability of new and/or modified guidance often falls during evaluation and is shifting goalposts.
This was identified as one of the main concerns in the Industry survey[1] as it has an impact on the level playing field, it decreases the predictability, and it contributes to some of the delays.

Triggers

- Guidance gaps or need for further clarification/harmonisation are constantly identified. This is both a factor and a consequence of BPR complexity **(see also fact sheet complexity)**
- Applying new/updated guidance to already submitted applications, in the middle or towards the end of the evaluation
- Delays in AS approval and BP authorisation increase the likelihood that guidance and data requirements change during the evaluation phase



"New guidance should not be applied to on-going applications ("do not evaluate yesterday's work with today's standards")"

Overview report of a series of fact-finding missions on biocides in EU Member States 2017-2018

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Example

Updating of Biocidal Product Families (BPF) concept

- When the BPR entered into force, no guidance was available on the BPF concept
- A first guidance note was developed in 2014
- In July 2019, after 2 years of discussions, a new guidance note was agreed, to be applicable for new submissions less than 3 months later
- A Questions and Answers annex was added in 2020
- Guidance on a harmonised approach to determine the worst-case composition for efficacy of disinfectant BPF was agreed in December 2020

Consequences

Changing the rules during ongoing processes and evaluations of applications (be it AS approval or BP authorisation)

- creates uncertainty and contributes to lack of predictability of the BPR **(see also fact sheet predictability)**
- modifies the viability of BP formulations under review
- requires new data in support of ongoing evaluation which was not envisaged at the outset
- contributes to the delays in the evaluation process **(see also fact sheet delays)**
- hinders or disables innovation **(see also fact sheet innovation)**
- Leads to unforeseen additional costs

Recommendations:

- New requirements should only apply to new applications
- Apply best practices from other relevant regulations (Plant Protection Products Regulation, REACH)

1 : Industry Survey on BPR implementation, 2020-2021