Analysis of the BPR and its implementation
An industry reflection

Delays in the BPR processes

Whilst the BPR text provides clear legal timelines for active substance (AS) approval and biocidal product (BP) authorisation , one of the main issues identified in the Commission's report on the implementation of the BPR[1] and in the Industry survey[2] is the continuous delay in those processes.

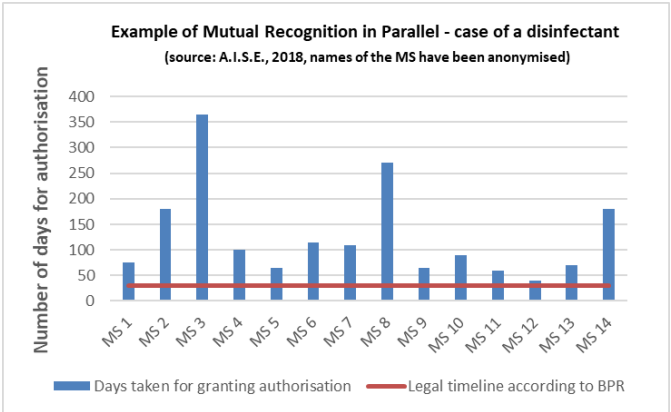
Active substances Review Programme

- The Review Programme (RP) was initially foreseen to be completed in 2010, but it has been extended twice, and now targets to be completed by December 2024
- To date, c.a. 42% of the RP has been achieved[3]

"While 130 assessment reports were submitted overall by MS to ECHA between 2014 and 2018, only 1 report was submitted in 2018 and 7 in 2019."

Commission's report on the implementation of the BPR[1]

Product authorisation



- Union Authorisation: approximately two-thirds are delayed up to one year, approx. 20% between 1-2 years and approx. 10% more than 2 years[1]
- Mutual Recognition: more than 60% of procedures are delayed (about one-third of them for 1-2 years and about half for more than 2 years)[1]

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Reasons for delays

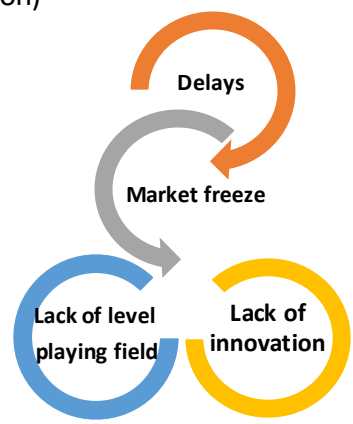
- Lack of resources and/or expertise in some Member States (MS) - which also leads to a concentration of the workload in a very limited number of MS
- Complex technical and policy questions to be addressed during evaluations **(see also fact sheet on complexity)**
- New and additional requirements identified and applied during evaluations **(see also fact sheet moving goal posts)**
- In some cases, poor communication between MS and applicant (e.g. lack of response from the evaluating Competent Authority to a specific enquiry from an applicant in the course of a dossier evaluation)

"The main reason for all delays observed […] is a systemic lack of resources in the Member States."

Commission's report on the implementation of the BPR[1]

Major consequences

- Market freeze[4]
- Companies struggle to define and implement business strategies or invest in research and development (**see also fact sheet innovation**)
- Lack of level playing field **(see also fact sheet level playing field)**



Recommendations:

- Increase level of resources in MS and address the lack of expertise in some MS e.g. via training, increased support from ECHA, to ensure an equal spread of the workload among the 27 MS
- New requirements should only apply to new applications
- Improve communication between evaluating Competent Authorities and applicants

"In order to reduce the delays, without having to significantly increase the resources available, MSs suggested during the fact finding missions minimising the burden of evaluation under the current RP and then conducting a more detailed evaluation, if required, when the approvals of the AS/PT combinations are renewed in future."

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

1 : Report from the Commission to the European Parliament and the Council on the implementation of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, COM(2021) 287 final, 7 June 2021
2 : Industry Survey on BPR implementation, 2020-2021
3 : CA-Dec21-Doc.5.1, 1 Dec. 2021
4 : Example of market freeze due to delays: an 'existing' BP (i.e. on the market under a national regime), for which the authorisation under the BPR is delayed, cannot be reformulated, since it is not possible to use the regulation on changes (Reg (EU) No 354/2013). This could be a serious concern, for instance in case of supply issue of one of the BP ingredients