Analysis of the BPR and its implementation
An industry reflection

Level playing field

A level playing field refers to fair competition and ensures that all players play by the same set of rules. One of the key objectives of the BPR is to ensure a level playing field.

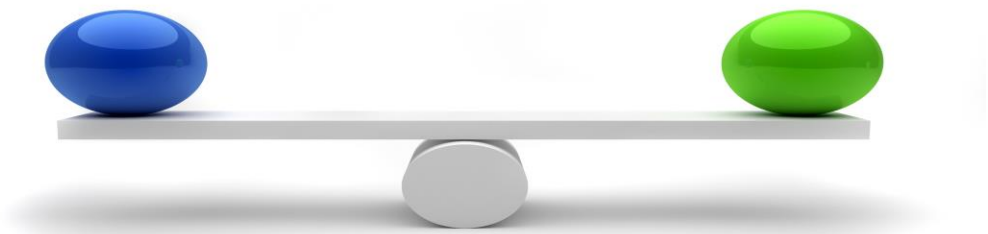
Although the BPR provides the legal framework, market distortion between businesses and geographies often occurs due to complexity, delays, co-existence of the Biocidal Products (BP) Directive rules and the BPR, BPR allowing the Member States to deviate from harmonised decisions and follow national law instead.

Promising opportunity

> *"Recital 58 of the BPR further specifies that a level playing field should be established as quickly as possible on the market of existing active substances (AS) […]"*
>
> CA-May15-Doc.4.13-Final Compliance with and enforcement of Article 95

- The BPR:
  - brought clear timelines for Active Substance (AS) approval and subsequent Biocidal Product (BP) Authorisation
  - created priority lists Active Substance/Product Type (AS/PT) combinations for the Review Programme (RP)
  - put in place processes, such as the Mutual Recognition procedures and Union Authorisation, to ensure harmonisation
  - introduced Article 95, data protection and mandatory data sharing

> *"To achieve this objective, Article 95 provides, in essence, that companies not involved in the review programme (RP) - but benefitting from the submission made – are required to either contribute to the costs borne by the participants in the RP (by negotiating access to the data) or have their own data (or a combination). "*
>
> CA-May15-Doc.4.13-Final Compliance with and enforcement of Article 95



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Unwanted consequence – market distortion

- Diverging interpretation and implementation of guidance and data requirements by Member States (MS) can influence the result of the Risk Assessment, including Risk Management Measures and/or restrictions. This is a consequence of the complexity of the regulation and its implementation
- BPR allows MS, under specific processes, to deviate from harmonised decisions and follow national law instead, which selectively affects applicants based on the geography of their markets
- Delays in the AS approval and BP authorisation create market distortion between businesses and geographies
- The RP priority list unintendedly leads to market distortion and advantage to AS/PT combinations planned towards the end of the RP compared to the same AS/PT combination that was included in a multi AS/PT dossier that fell under 1st or 2nd priority list. The latter will be subject to the BPR rules and restrictions might apply years before the former, where national rules still apply for the BP
- The co-existence of the BPD (Directive 98/8/EC) and BPR rules offer a longer market advantage to applications where the MS' evaluation report has not been submitted before 1 September 2013. The respective AS/PT combination is not subject to restrictions that might be imposed by the BPR to the same AS/PT combination in another dossier where the evaluation report has been submitted after 1 September 2013

"A level playing field is not established for different companies operating in the same PT market, since their products are subject to very different regulatory regimes (BPR versus national systems)"

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

Recommendations:

- Authorities to focus on the finalisation of the RP. This would also reduce complexity and delays in other BPR processes