

Analysis of the BPR and its implementation

An industry reflection

Non-harmonisation

The BPR objective to guarantee harmonisation is not met due to the lack of consistency in its implementation among Member States.

“The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products [...]”

Article 1 of the BPR

BPR and harmonisation

- BPR includes mechanisms and processes to ensure harmonisation such as the Peer review process, the Mutual Recognition (MR) or the Union Authorisation (UA)
- But the BPR also has mechanisms that allow for deviations from harmonisation like disagreements/referrals during the MR
- More than 70% of the referrals to the Coordination Group (CG) have been initiated by 2 MS, which illustrates the lack of balance among MS in the way dossier evaluations are carried out, and in the expertise and resource level

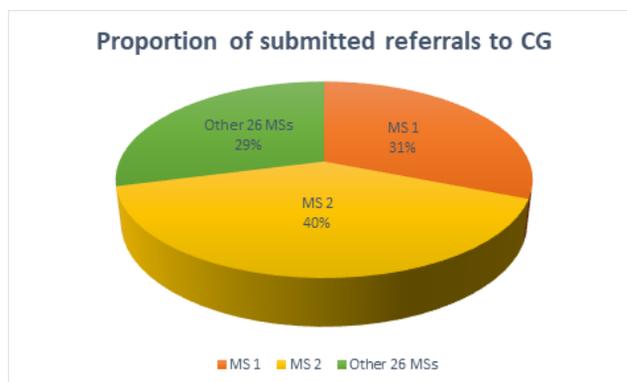


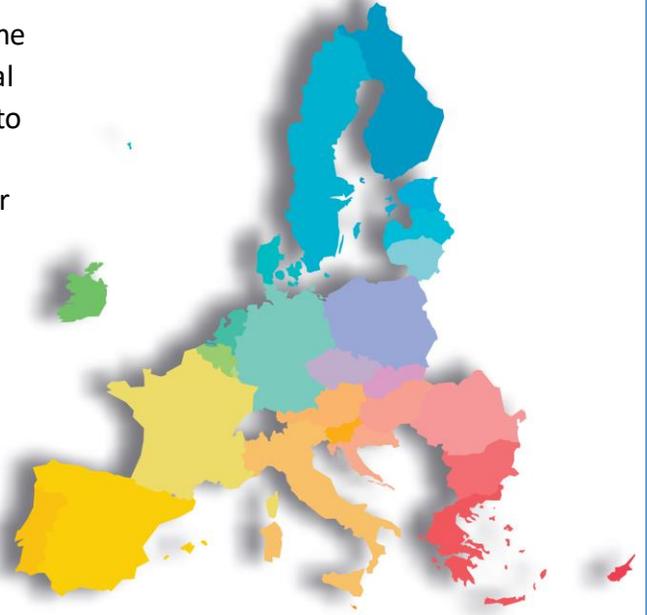
Chart data sources: CA-Dec20-Doc. 4.17. referrals to CG-Art 35 BPR;
S-CIRCABC Biocides Coordination Group "record of agreements"

Transitional measures

- Until the Review Programme (RP) is finalised, the BPR allows for placing on the market of Biocidal Products (BP) according to national rules. Due to the delay in the RP the majority of the BPs still follow national rules which in some cases differ enormously

“a Member State may continue to apply its current system or practice of making available on the market or using a given biocidal product for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product”

Article 89 of the BPR



Different interpretation and implementation

- Different level of resource and expertise lead to differences in assessment outcome
- Different interpretation of the BPR and guidance are adopted by different MS
 - ⇒ Example: Discussions on Treated Articles (TA) for which MSs have different views¹
- The degree of how “binding” a guidance is and its effect on the evaluation process varies among MS
- There are also differences between MS on the amount and nature of the data required, leading to late data requests and delays

Recommendations :

- Increase the expertise in all MS will allow them to rely on each others work
- Analyse the reasons for disagreements/referrals to identify potential lessons learnt to improve harmonisation

1 : 78th Biocides Competent Authorities meeting in 2018