Analysis of the BPR and its implementation
An industry reflection

A complex regulatory framework

Legal

- The complexity of the BPR was apparent at the outset as an amendment[1] was required immediately after adoption to clarify and correct some parts of the original text
- In addition to the BPR, many implementing and delegated regulations were necessary to establish detailed procedures (e.g., same biocidal product regulation[2], regulation on changes[3])
- Coexistence of the BPR and national regimes (until the active substances (AS) Review Programme is completed) adds to the complexity

Guidance

- New guidance was needed from the beginning as BPR introduced new concepts as compared to the Biocidal Product Directive - e.g. in-situ, treated articles (TA), nanomaterials
- Despite countless guidance documents that have and are being developed (Competent Authorities agreed notes, Coordination Group agreements, ECHA guidance/ Opinions/ Recommendations, Technical Agreements for Biocides, etc…), there is still a need for further guidance with gaps and need for further clarification continuously being identified
- Guidance and information is spread across many places: various Commission and ECHA websites and platforms

> *"There is insufficient guidance, or insufficiently clear guidance, for the evaluation of the applications in some specific areas (e.g. test methods for determining the efficacy of biocides for the majority of Product Types)"*
>
> Overview report of a series of fact-finding missions on biocides in EU Member States 2017-2018

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Borderline and scope issues

There are still many areas that lack clarity in terms of scope (despite existing definitions and guidance), such as:

- Borderline with other regulatory frameworks (e.g., cosmetics, medical devices)
- Product Type (PT) definitions
- Distinction between Treated Articles and Biocidal Products (BP)

"The borderline between BP and TA is obviously complicated"

"There is a need for better guidelines and clearer rules in this area"

Market survey on TA, Swedish Chemicals Agency, 2016

Borderline with other EU legislations

- Example: product to disinfect buildings in presence of animals : BP or veterinary medicine?

Borderline Product-Types

- Recurring discussions in Competent Authorities meetings
- Example: discussions on PT11-12[4] borderline cases[5]

Distinction between treated articles and biocidal products

- Guidance exists but the decision on whether the biocidal function is a primary function (BP) or a secondary one (TA) is still subject to MS interpretation
- Example (CA-May18-Doc.6.1.b): flame retardant working cloth with mosquito repellent – out of 10 MS who provided their view:
  - 5 MS consider it is a TA
  - 4 MS consider it is a BP
  - 1 MS considers there is not enough information to decide

Recommendations :

- Creation of a central document capturing previous decisions related to borderline and scope issues (similar to the old Manual of Decisions)
- Creation of an overview of all guidance documents needed to prepare an AS dossier or a BP dossier

1 : Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market

2 : Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

3 : Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

4 : PT11 = Preservatives for liquid-cooling and processing systems, PT12 = slimicides

5 : 88th and 89th Competent Authorities meetings in 2020

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