Analysis of the BPR and its implementation
An industry reflection

Fact sheet series: Introduction

Opportunities brought by the BPR

- The Biocidal Products Regulation[1] (BPR) seeks to protect people and the environment. This was seen positively by industry, as it would increase consumer confidence in Biocidal Products (BPs)
- The new processes introduced by the BPR were expected to streamline and harmonise the authorisation of BP and offer new market opportunities

> *"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, whilst ensuring a high level of protection of both human and animal health and the environment."*
>
> Article 1 of the BPR

A.I.S.E./Biocides for Europe BPR Assessment project

- More than 8 years after the entry into force of the BPR, implementation remains a challenge for industry
- A.I.S.E. and Biocides for Europe (Cefic) initiated a thorough assessment of the BPR and its implementation, to identify possible opportunities for improvement
- As part of the project, a survey was conducted amongst the biocides industry actors (entire supply chain) in order to collect experience from companies
- A.I.S.E. and Biocides for Europe would like to thank all these companies for their participation. The completion of this project could not have been possible without their shared experiences

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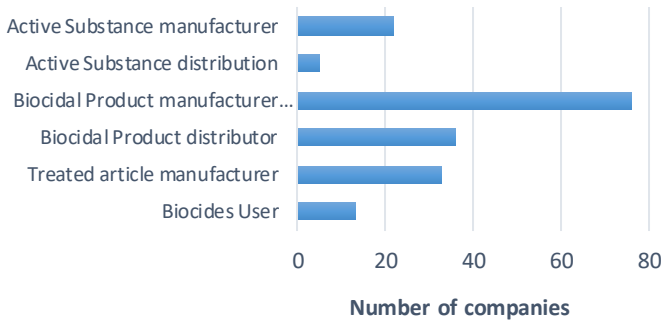
Industry Survey participation

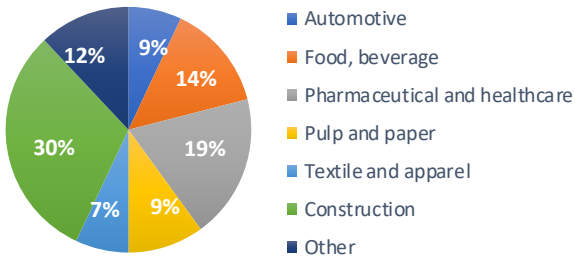
> 100 companies

~ 50 Downstream Users

Supply Chain representation

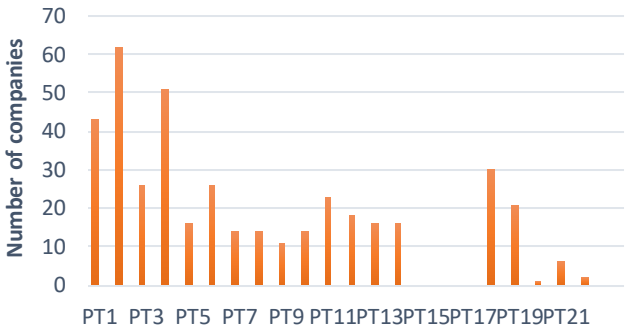


BP users industry sector

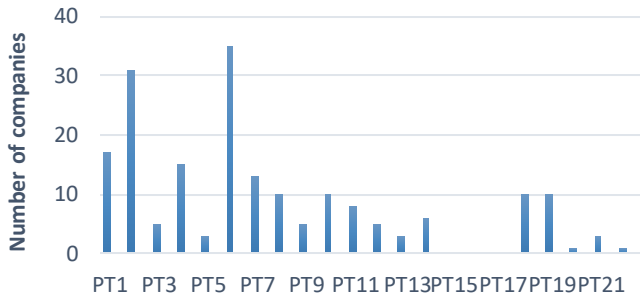


= Covering 22 Product Types (PT)

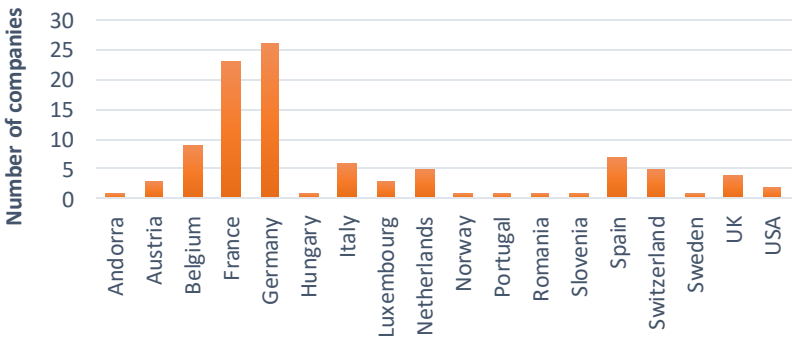
Placed on the market



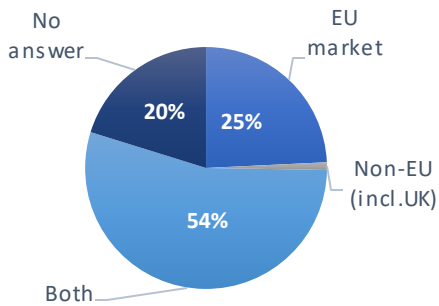
Used in the Supply Chain



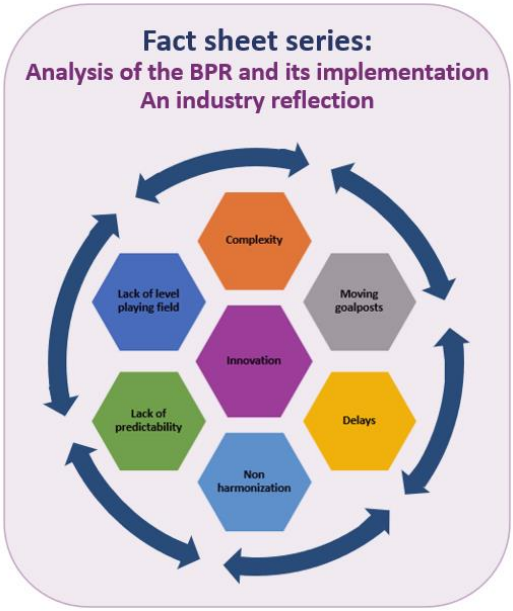
Located in the EU



Worldwide market presence



Factsheet series



- This series of 7 fact sheets highlights the key findings of the A.I.S.E./Biocides for Europe BPR assessment project[2] and related survey[3]
- These messages are supported by references to the Commission report[4] on the implementation of the BPR and the overview report from a series of Fact Finding missions carried out by the Commission in five MS[5]
- These key findings and fact sheets are interlinked and should be read as a whole package to have a comprehensive understanding

About Biocides for Europe and A.I.S.E.

- Biocides for Europe (formerly known as EBPF), is a Sector Group of Cefic
- It is an industry platform, with more than 80 members, where all industry stakeholders involved in the biocides sector – be they active substance manufacturers, formulators, relevant trade associations or national federations– can exchange views and give input in the ongoing debates
- Its members place a wide range of disinfectants, preservatives, insecticides and rodenticides on the market for the benefit of EU citizens
- A.I.S.E. represents the Soaps, Detergents and Maintenance Products industry in Europe
- Its membership includes national associations, value chain partners and represents over 900 companies ranging from small and medium-sized enterprises to large multinationals
- BP manufactured by A.I.S.E. members include a vast range of disinfectants for household and institutional use, as well as insect control products

Reference documents

- [1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
- [2] A.I.S.E./Biocides for Europe BPR assessment report, 2022
- [3] Industry survey on BPR implementation, 2020-2021
- [4] COM(2021)287 final. 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
- [5] Overview report of a series of fact-finding missions on biocides in EU member states 2017-2018

Analysis of the BPR and its implementation
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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

Analysis of the BPR and its implementation
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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.

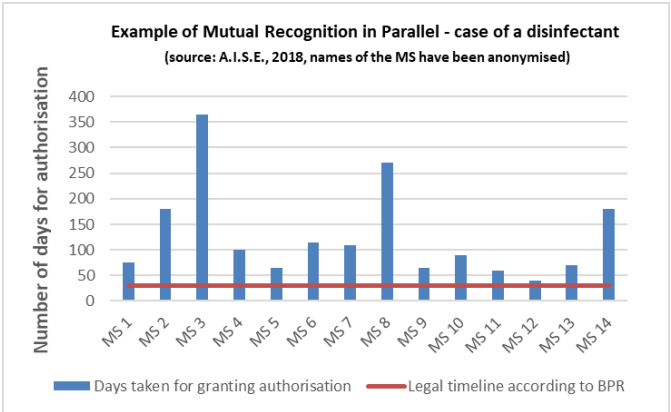
Active substances Review Programme

- 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

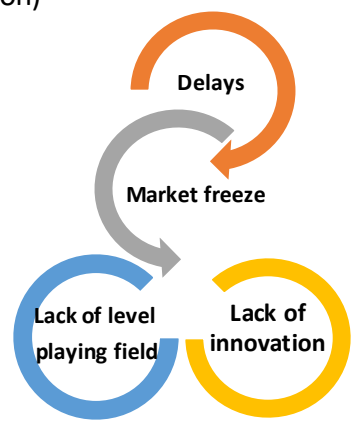
- Lack of resources and/or expertise in some Member States (MS) - which also leads to a concentration of the workload in a very limited number of MS
- Complex technical and policy questions to be addressed during evaluations **(see also fact sheet on complexity)**
- New and additional requirements identified 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

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Lack of innovation

BPR sets out a highly complex and unpredictable regulatory framework. Based on the current delays and complexity, companies are not able to estimate the regulatory costs, the outcome of the evaluation (when and how) and the time to the market. Unpredictability hinders innovation.

The level of innovation in the biocidal sector is recognised to be very low. The recent report from the Commission acknowledged that innovation around new Active Substances (ASs) has been rather limited, and that only 10 new ASs were evaluated since the entry into application of the BPR. Innovation is mainly limited to reformulating with an existing AS or developing new markets with existing formulations (via new claims).

Long time to Market

- Market opportunities change more rapidly than the time needed to complete the Active Substance approval and Biocidal Product (BP) authorisation processes
- The legal timelines for AS approval and BP authorisation processes are clear, but in practice, the time between submission and decision on a dossier is long and unpredictable
- BP containing new AS are subject to a market freeze[1] until that AS is approved under the BPR

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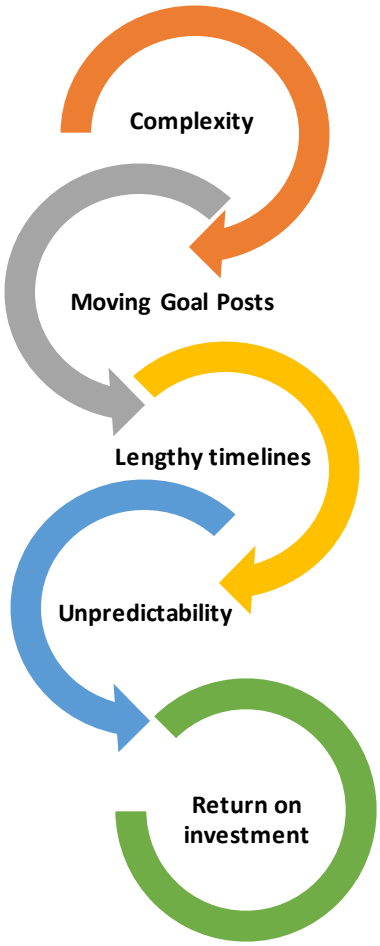
Complexity and unpredictability

- Despite countless guidance documents that have and are being developed, there is still a need for further guidance with gaps and need for further clarification continuously being identified, including scope and borderline clarification
- Moving goal posts makes the outcome of the regulatory process difficult to predict and questions the viability of a new application



Unfavourable environment for innovation

- The hazard-based approach does not properly reflect the real risk of a product and prevents valuable and safe products from being placed on the market
- The BPR is designed to ensure safety by taking the relevant measures when an unacceptable level of risk, is identified. The ambition to achieve "zero risk", makes the outcome of the Risk Assessment impossible to estimate and does not incentivise innovation
- The timeframe for completing the regulatory process and consequently for accessing the market leads to a limited or late return on investment to cover the high R&D and regulatory costs

> *"No research in e.g.: new AS is possible due to high research costs in comparison to the potential benefit in the small market segments of biocides."*
>
> Industry survey[2]

Recommendations:

- Lack of innovation is a consequence of many issues. Implementing all the recommendations in this Fact Sheet series is a good starting point to remove some barriers to innovation
  - ⇨ For instance, reducing the complexity of implementation will lead to less delays and more predictability in terms of timelines and outcome of the evaluation

1 : BPs containing new AS can typically not be placed on the market before both AS approval and product authorisation have been obtained
2 : Industry survey on BPR implementation, 2020-2021

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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.

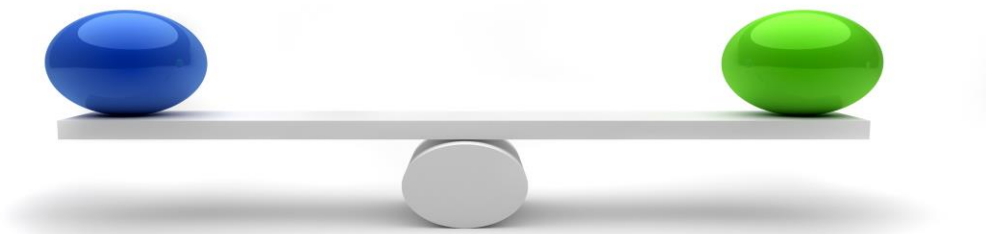
Although the BPR provides the legal framework, market distortion between businesses and geographies often occurs due to complexity, delays, co-existence of the Biocidal Products (BP) Directive rules and the BPR, BPR allowing the Member States to deviate from harmonised decisions and follow national law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

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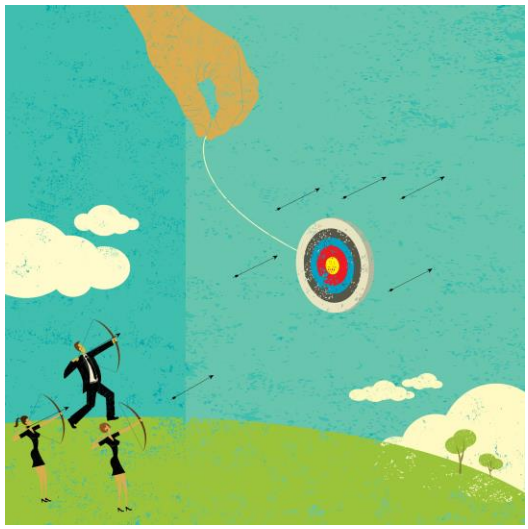
Moving goal posts

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

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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

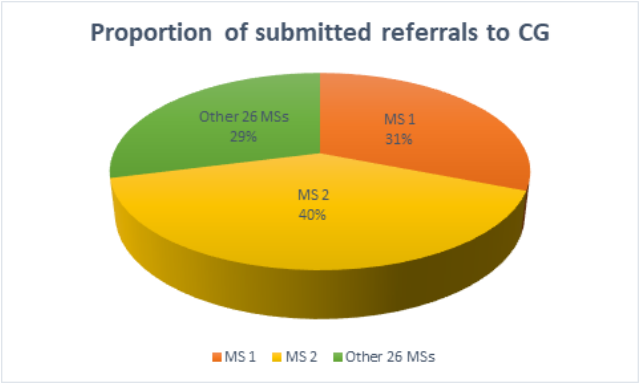

Chart data sources: CA-Dec20-Doc. 4.17. referrals to CG-Art 35 BPR; S-CIRCABC Biocides Coordination Group "record of agreements"

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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 views[1]
- 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

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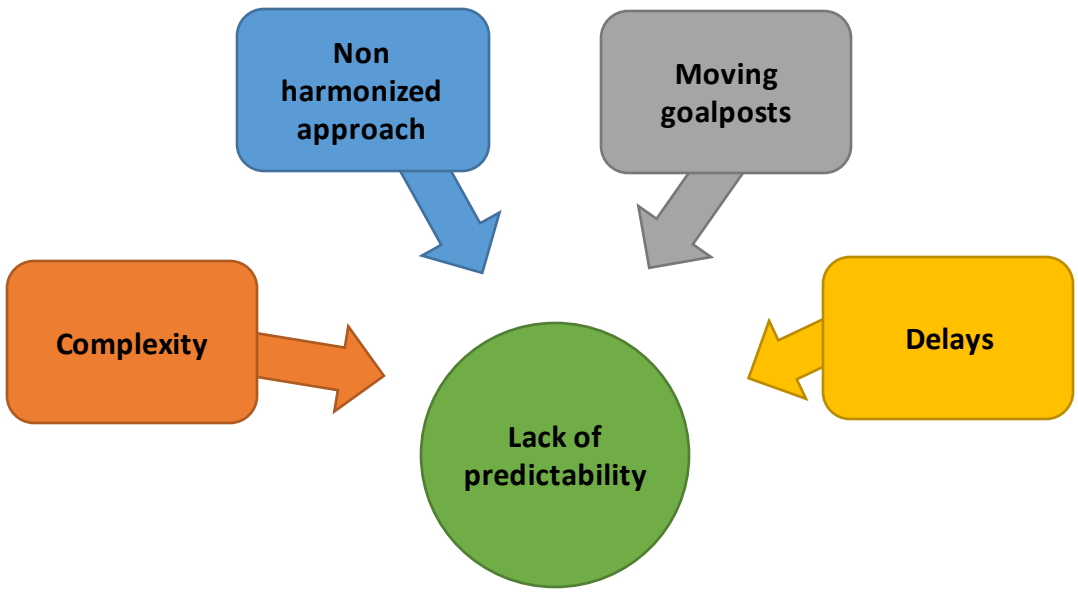
An unpredictable landscape

The lack of predictability created by the implementation of the BPR is one of the major concerns identified in the industry survey.

Lack of predictability in the BPR processes

- Issues related to the accurate identification and borderline status of biocidal products and Product Types
- Uncertainty on how guidance documents will be applied (non-harmonized approach amongst MS)
- Possible retrospective application of a new guidance in the course of an evaluation (leads to further request for information, and difficulties for applicants to anticipate outcome)
- Legal timelines for evaluation and decision exceeded



(See also fact sheets complexity, non-harmonisation, moving goalposts and delays)

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Consequences

- High degree of uncertainty in the outcome of the evaluation process, which challenges the commercial viability of the application and blocks innovation

> *"As the evaluation of product dossiers is longer than expected (more than 3 years) we are facing difficulties to maintain products on the markets and also to be able to deploy the business as expected 3 years after submission of the dossier."*
>
> Industry survey[1]

- Challenge for companies to build business plans and stick to them
  - ⇨ Example: Delays in the active substances (AS) Review Programme makes it difficult for companies to develop a clear strategy to support their products portfolio (e.g., keep a coherent product line, make investments in staff and plants)

> *"As the deadline for approval of AS, (which allows to plan submission of products dossiers, update of products transitional approvals, exit of the market) is delayed month after month, it is impossible to implement a clear strategy within the company (portfolio, investments, ….)"*
>
> Industry survey[1]

Recommendations :

- More predictability on the BPC work programme for active substance approvals: longer term forecast (e.g. 3 years) and higher guarantee of its compliance would help companies better plan their biocidal products' registration and develop clearer business strategy
- Lack of predictability is a result of many different issues. Fixing one issue in isolation will not remove unpredictability - implementing all the recommendations in this Fact Sheet series is a good starting point to address this concern
  - ⇨ For instance, not adding new requirements would decrease complexity, resulting in a lower potential for lack of harmonisation, and lowering the MS resource gap. This would help increase predictability for industry and create better conditions for innovation

1 : Industry Survey on BPR implementation, 2020-2021