Analysis of the Biocidal Products Regulation and its Implementation

March 2022

Report

Report commissioned by A.I.S.E. and Biocides for Europe

Contents

1. Executive summary

More than eight years have passed since the Biocidal Products Regulation ("**BPR**")[1] entered into application. The International Association for Soaps, Detergents and Maintenance Products ("**A.I.S.E.**") and Biocides for Europe decided to gather information on industry's shared experience with BPR implementation. For this purpose, ERM Group, Inc ("**ERM**") carried out an industry survey which received 99 responses, including a high proportion of companies identifying themselves as SMEs. Follow-up interviews were then carried out with 25 companies to gain a more in-depth understanding of the key points raised. The results from this exercise are included in the Annex I Survey.

To supplement the findings of the Survey, Fieldfisher (Belgium) LLP ("**Fieldfisher**") prepared this Assessment Report, which is complemented with a legal assessment and a technical assessment (the latter prepared by ERM). These assessments are included in Annexes II and III respectively.

The Survey, read in conjunction with this Assessment Report and the technical and legal assessments, provide important insights into the BPR's principal achievements, problems in its implementation, and its overall impact on industry but also suggestion for improvement.

The BPR Assessment findings underline that while the BPR has introduced several new concepts that had been welcomed by industry, the implementation of the regulation, with its complexity, remains problematic and raises several concerns to industry.

The BPR has introduced several improvements, but problems remain

New concepts introduced by the BPR, in particular Biocidal Product Families, Same Biocidal Product and Union Authorisations, have provided industry with new ways to bring products market, which could potentially allow them to reduce the costs and administrative burdens associated with obtaining product authorisations, and thus facilitate the placing on the market of the biocidal products. The BPR's increased focus on human and environmental protection is also recognised as a significant achievement because it increases consumer trust in biocidal products placed on the market. At the same time, several issues with the application of the BPR have been identified, which have introduced significant complexity and unpredictability into what is an already complex regime.

Unpredictability is a key hurdle for industry

Unpredictability in how the law, guidance and procedures are applied has been repeatedly emphasised as core hurdle for industry. The BPR is a technical and complex piece of legislation and industry struggles to obtain a well-grounded understanding of the process, submission requirements, timeframes, and evaluation factors prior to entering the evaluation procedure.

Specific issues contributing to unpredictably include:

- Timelines, where provided for in the legislation, are frequently not respected meaning new products pending review can be frozen out of the market for much longer than anticipated;
- A lack of communication from authorities on revised or anticipated timelines;

[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.

- Issues in the accurate identification and borderline status of biocidal products and product types ("**PT**"s);
- A lack of (comprehensive) guidance on certain topics;
- The fact that guidance frequently changes and is then applied retroactively to dossiers which have already been submitted, leading to further requests for information, extended evaluation deadlines and difficulties for industry to anticipate outcomes;
- Different interpretation of guidance by MS
- Differences in resources, expertise and timelines between national authorities;

This lack of predictability stifles innovation, increases costs, and undermines the fairness and transparency of the assessment processes.

The BPR objective to guarantee harmonisation is not fulfilled

Significant progress is needed in order to realise the BPR's objective of harmonising the rules governing the biocides market at European Union ("**EU**") level. There is a wide discrepancy in fees for the same regulatory work, timelines for authorisation differ significantly, interpretation of EU guidance can vary and Member State ("**MS**") national processes and preferences still predominate.

The current regime does not support innovation

The current application of the BPR fails to create the conditions necessary to support innovation. This is mainly due to the difficulties associated with bringing a new product to market. Such obstacles are made worse by the unpredictability in the current regime in terms of timelines and criteria that will be applied to the assessment. The introduction of hazard-based exclusion and substitution criteria and the further focus on hazardous properties instead of assessing the risk also pose challenges to innovation.

The recent COVID-19 pandemic has further brought to light the complexity of the BPR's regulatory regime and highlighted the importance of harmonisation. Biocidal products play a crucial role in stopping the spread of the virus. With a substantially increased demand of disinfectants, industry was required to overcome significant regulatory obstacles. These related to a lack of a timely and harmonised EU-wide response and uncertainties in the application of the emergency authorisation procedure under Article 55 of the BPR.

There are now new challenges for biocides on the horizon, including the need to step up innovation. Examples of innovation in the biocidal sector are currently very limited and mainly focus on formulations of products rather than the development of new molecules. Addressing the shortcomings in the current regime, which hinder innovation, is therefore vital to enable the EU to reach its sustainability objectives.

***

To help address many of the problems in the implementation of the BPR, and in particular the lack of predictability for industry, this report proposes one 'horizontal', catch-all solution and several specific, targeted solutions.

The horizontal solutions consist of a supervisory mechanism to ensure third party review during an ongoing process. This would enable procedural irregularities to be addressed more quickly and ensure greater accountability for those managing the process. Currently, interested parties must wait until the European Commission ("**Commission**") has issued its final decision before they can pursue a remedy (legal) before the EU Courts.

Proposed targeted solutions include:

- Confirmation from the Commission that:
  - the precautionary principle can only be invoked at the point it proposes a risk management measure; and
  - new guidance documents cannot be applied retrospectively once a data dossier has been accepted by an evaluating Competent Authority as being complete.
- A resurrection of a manual of decisions.
- Substantive legislative change to:
  - clarify the application of Article 55 of the BPR;
  - give the Commission the power to make binding rules on treated article claims; and
  - give the Commission the power to compel MS Competent Authorities to adhere to the BPR.

Cost of compliance is not proportionate to the market value

The substantial costs involved in the various BPR processes represent a significant hurdle according to the Survey. Importantly, many of these costs are augmented further due to various reasons, such as delays in the assessment procedure, lack of consistency in the application of rules. The costs are so significant that it has caused companies to reduce their product portfolios and spending on innovation, with SMEs being particularly affected. This finding underlines the need to address problems in the implementation of the BPR in order to make costs more manageable and predictable for the industry.

2. Introduction to the A.I.S.E./Biocides for Europe BPR Assessment project

Since 2013, the BPR has set out the rules governing the placing on the market of biocidal products and treated articles in Europe. It modified the system for the review and evaluation of biocidal products, established by its predecessor, the Biocidal Products Directive ("**BPD**")[2] and introduced several important changes. The scope of products subject to regulation was expanded and several new concepts were introduced, including union authorisation and biocidal product family. The BPR also harmonised processes and established common principles among MSs for the evaluation and authorisation of biocidal products.

More than eight years have passed since the BPR entered into application and as companies active in the biocidal sector have gained experience navigating its new set of rules and procedures, many adjusted their business strategies and operations. This, in turn, has had an impact on the availability of certain biocidal products on the EU market, product innovation and the survival of certain businesses.

With the outbreak of the COVID-19 crisis, biocidal products, including surface disinfectants and hand sanitizers, became vital in the efforts to stop the spread of the virus but supply shortages emerged due to suddenly much higher demand. The regulatory regime's ability to allow new biocidal products to be swiftly brought to market therefore became imperative.

While the covid crisis will be solved, new challenges for biocides industry lie ahead. The Commission set out its future ambitions for the EU's chemicals sector in its EU Chemicals Strategy for Sustainability. One of its key aims is to incentivise industry to find new sustainable solutions for chemicals. The ability of the BPR to adequately support such innovation will therefore be put to the test.

Given the challenges ahead, and in light of the experience gained so far, it is an opportune time to take stock of the performance of the BPR to date. To understand better the implementation of the BPR, its impact on companies operating in the biocidal sector, and identify areas for improvement, A.I.S.E. and Biocides for Europe commissioned this Assessment Report. It follows an invitation to tender dated 24 July 2020 from the two associations and the successful tendering by ERM and Fieldfisher.

The Report's findings are primarily based on companies' experience with the BPR. To gather such experience, ERM, in partnership with A.I.S.E. and Biocides for Europe, created and circulated a questionnaire to over 300 companies active in the EU biocidal sector. The questionnaire focused on the regulatory framework, the effects of the new BPR processes – positive and negative – on the market, as well as the consequent status of the companies' operations and product marketability. ERM carried out targeted follow-up interviews with 25 companies to gain a more in-depth understanding of the key points raised by companies and highlighted in the responses to the questionnaire. The results from this exercise are included in Annex I and referred to throughout this document as the "**Survey**".

Most market players have experienced the transition from the BPD to the BPR and the subsequent change of the relevant procedures required to put a product on the market. Their responses assist in identifying:

- the effectiveness of the new processes;
- the effects that the new processes have on the market and the operations of market players;
- dysfunctional procedures, if any; and
- areas for improvement.

To supplement the findings of the Survey, Fieldfisher prepared this Assessment Report, which is complemented with a legal assessment and a technical assessment (the latter prepared by ERM). These assessments are included in Annexes II and III respectively.

[2] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

Drawing from the Survey, as well as ERM's and Fieldfisher's assessments, this Assessment Report identifies and analyses the BPR's principal achievements and weaknesses, and proposes solutions to improve the legislation, its implementation and its effectiveness.

3. Overview of the BPR

The BPR regulates the placing on the EU market(s) of biocidal products and treated articles. Biocidal products are used to control organisms that can be harmful to human and animal health or cause material damage, such as pests and bacteria. Common examples of biocides include disinfectants, preservatives, and pest control products. To be regulated under the BPR, biocidal products must achieve their effect through the action of active substances ("**AS**") contained in the biocidal product (by any means other than physical or mechanical action).

The BPR aims to facilitate the free movement of biocidal products in the EU, while ensuring a high level of protection for humans and the environment. It introduces a two-tier harmonised approval system by requiring that:

1. All ASs contained in a biocidal product must be approved; and
2. All biocidal products must obtain a product authorisation before they can be placed on the market.

The approval of ASs takes place at Union level, with the subsequent authorisation of the biocidal products at MS level. There is also the possibility to obtain a product authorisation at Union level or to extend national authorisations to other MSs under a mutual recognition procedure.

Certain biocidal products are exempted (temporarily) from the authorisation requirements under the BPR. For example, biocidal products containing ASs included in the review programme off all ASs on the market by 14 May 2000 ("**Review Programme**") can, subject to national law, be made available on the market and used pending the outcome of the Review Programme. Products containing new ASs that are still under assessment may also be made available on the market if a provisional authorisation is granted.

A summary of the main procedures under the BPR is provided below. For an explanation of the regulation of treated articles under the BPR, see section 2.2 of Annex II, the Legal Assessment.

3.1 Active Substance Approval

AS approval is required for all substances used in biocidal products placed on the EU market.

ASs that were not on the market by 14 May 2000 ("**new ASs**") are evaluated under the provisions of the BPR. Such ASs cannot be used in biocidal products or placed on the market until they are approved.

In contrast, ASs that were already on the market by 14 May 2000 ("**existing ASs**") are evaluated and approved through the Review Programme. Existing ASs can still be marketed in MSs, subject to national law and pending a final decision on the AS approval. In total, 727 AS / PT combinations have been included in the Review Programme, but reviews for only around 42% of combinations have been finalised.[3] The deadline for completion of the evaluation of all existing ASs is 31 December 2024, but current indicators show that the 2024 target is at serious risk of not being met.[4]

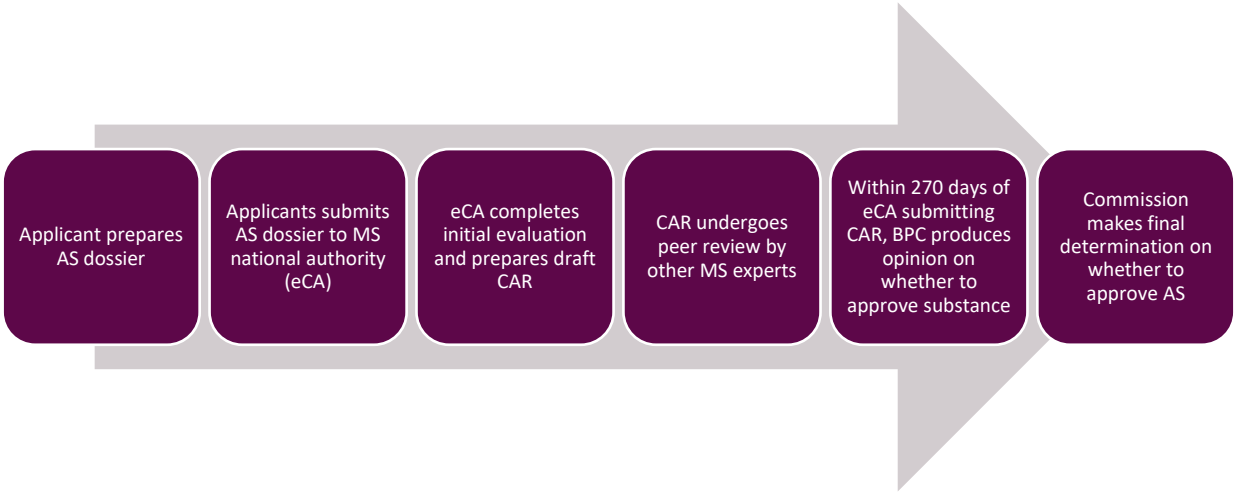
The process of AS approval includes the following steps:

1. The applicant prepares a dossier containing information on the properties of the AS and its safety and efficacy, supported by studies.
2. The dossier is submitted to a MS national authority – the evaluating competent authority ("**eCA**") for initial evaluation of the substance.
3. The eCA prepares a draft report referred to as a Competent Authority Report ("**CAR**").

[3] ECHA, Active Substances Action Plan, 6 February 2020, CA-Dec21-Doc.5.1

[4] ECHA Programming Document(s) 2021 – 2024, 17 December 2020, pg 59.

4. The draft CAR undergoes peer review by other MS experts, and the Biocidal Products Committee ("**BPC**") of the European Chemicals Agency ("**ECHA**") prepares an opinion on whether to approve the AS. This opinion is to be given within 270 days of receipt of the CAR.
5. The BPC's opinion is sent to the Commission, which then makes the final determination on the approval of the AS, in consultation with the Standing Committee on Biocidal Products ("**SCBP**").



With an eye on the protection of health and the environment, the BPR has introduced certain exclusion criteria for ASs such as carcinogens, mutagens, endocrine disruptors ("**ED**"s) and environmentally toxic substances. Relevant exceptions are allowed where there is a lack of alternatives and where the public health and societal benefits, arising from the use of the substance, outweigh any potential detrimental effects.

The exclusion criteria are based on an assessment by the eCA of the classification of hazardous properties of the given AS. Necessarily, that assessment borrows from the assessment criteria in the EU's Classification and Labelling regulation ("**CLP Regulation**")[5]. Whereas exclusion criteria based on carcinogenic, mutagenic, reprotoxic ("**CMR**") properties are consequences leading from harmonised classification under the CLP Regulation, the situation can be different regarding ED or persistent, bioaccumulative and toxic ("**PBT**") and very persistent and very bio-accumulative ("**vPvB**") properties. Indeed, as the CLP Regulation establishes a separate set of procedures for the classification of a substance, it can be the case that there are two assessments being conducted at the same time on the same AS. The same is true for substitution criteria established under Article 10 of the BPR. As of the end of 2019, 3 ASs meeting the exclusion criteria and 4 ASs meeting the substitution criteria have not been approved.[6] In contrast, 21 ASs[7] meeting the exclusion criteria and 20 ASs[8] meeting the substitution criteria have been approved.

For a more detailed overview of AS approval for new and existing ASs included in the Review Programme, see section 1 of Annex II, the Legal Assessment.

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

[6] 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, 7 June 2021, COM/2021/287 final ("**2021 Commission Report**"), pg 5.

[7] This corresponds to 24 AS/PT combinations, of which 7 were approved under the BPR. 10 of these ASs are rodenticides, and the others are mostly preservatives (especially wood preservatives) and insecticides. The majority of these ASs were approved before the entry into application of the BPR. See Staff Working Document accompanying the 2021 Commission Report, 7 June 2021, SWD(2021) 128 final, pg 23.

[8] This corresponds to 37 AS/PT combinations, of which were 26 approved since the entry into application of the BPR. See Staff Working Document accompanying the 2021 Commission Report, 7 June 2021, SWD(2021) 128 final, pg 24.

3.2 Active Substance Renewal

ASs are typically approved for ten years. An application to renew the approval must be made at the latest 550 days before the date on which the approval is due to expire. Shortly after receiving the application, the eCA will determine whether a full evaluation of the application for renewal is necessary. Full evaluation must be completed within a year. If a full evaluation is not considered necessary, the evaluation must be completed in 180 days.

Renewal follows the same eCA and BPC peer review process as applies for AS approval. However, the duration of the BPC peer review depends on the type of evaluation: 270 days in the case of a full evaluation and 90 days if a full evaluation is not required. As in the case of AS approval, the Commission takes a final decision on the renewal of the approval of the AS. AS renewals are typically valid for 15 years.

3.3 Biocidal Product Authorisation

Because of delays in the Review Programme, the majority of the products on the market (several tens of thousands) are still placed on the market under national law. The requirements vary considerably between MSs, with many only requiring a notification to be made. As of the end of 2019, there have nevertheless been around 9,000 products authorised according to the BPR rules following the approval of the AS.[9]

The BPR has introduced multiple authorisation processes to facilitate product authorisation within the EU.

National Authorisation ("NA")

Companies that seek to market their products only in one EU MS can apply for product authorisation in that MS alone. NA assessment under the BPR is conducted by the respective eCAs, which need to evaluate the product and make their decision within 365 days. As of the end of 2019, around 2,600 (28%) products authorised under the BPR were authorised through standalone NAs.[10]

Mutual Recognition ("MR")

Companies that seek to market their products in multiple MSs, can extend their national product authorisation through MR. During a NA application, or upon receipt of product authorisation by a MS, companies can apply for product recognition of the original NA application in other EU MSs. The aim is to speed up the authorisation in other MSs and avoid repetitive evaluations by different MSs of the same product. As of the end of 2019, the majority of products authorised under the BPR (6,400 out of 9,000) were authorised through MR procedures.[11]

Union Authorisation ("UA")

Companies seeking to access the entire EU market can apply for UA, which gives them equal rights of access across EU. The evaluation process for an UA is the same initially as for a NA, including evaluation by an eCA. However, in addition, the eCA submits its evaluation to ECHA for peer review by all other MS The Biocidal Products Committee

[9] 2021 Commission Report, pg 6.

[10] 2021 Commission Report, pg 6.

[11] 2021 Commission Report, pg 6.

submits its opinion to the Commission recommending authorisation or not. As for the AS approval, Commission, in consultation with the SCBP, takes the final decision. 138 applications for UA were submitted by the end of 2019.[12]

Simplified Authorisation Procedure("SAP")

SAP allows the evaluation of certain biocidal products under a simplified procedure (less onerous dossier requirements and faster evaluation). Biocidal products that are deemed not to raise concern to health and the environment are eligible for this authorisation. eCAs should authorise the relevant product within 90 days after accepting an application. As of December 2019, 232 products had been authorised through the simplified procedure.[13]

Same Biocidal Product Authorisation ("SBP")

The BPR allows the authorisation of a product, which is identical to a reference product that has already been authorised. The aim is to simplify and quicken the product authorisation process. 183 applications for SBP were submitted by the end of 2019.[14]

Biocidal Product Family ("BPF")

The BPR allows the grouping of several similar products into a "family" of products, which can be submitted in the same authorisation application (dossier) to an eCA. The aim is to reduce costs and minimise the evaluation. Of the 138 UA applications submitted by the end of 2019, 106 concerned BPFs. The majority of application for SBP authorisations concerned BPFs (105 out of 183 applications).[15]

[12] 2021 Commission Report, pg 6.

[13] 2021 Commission Report, pg 6.

[14] 2021 Commission Report, pg 6.

[15] 2021 Commission Report, pg 6.

4. Project findings

The Survey, the Assessment Report and its technical and legal assessments, cover an extensive array of issues in the application of the BPR, including broader systemic problems and specific niche issues. The following main aspects have been considered:

Key improvements:

- New procedures under the BPR
- R4BP

Regulatory hurdles:

- Hazard-based assessment instead of a risk-based assessment
- Complexity and moving goal posts
- Unpredictability of outcomes in regulatory process
- Level playing field
- Harmonisation
- Costs
- Innovation

4.1 Key improvements

New procedures under the BPR

The most widely recognised achievement of the BPR by the Survey respondents is the introduction of new authorisation processes, such as UA, MR, SBP, SAP, and BPF. These processes, if applied in a harmonised manner, can mitigate the high monetary and time investments required by companies during the various authorisation processes and reduce the hurdles in placing the products on the market.

Respondents recognise that MR allows products to be placed on the market with lower investments – compared to the time and costs involved in individual NAs in multiple MSs – while it can enable SMEs to support the marketing of their products in more MSs without incurring the high costs of a UA. MR is also seen as a means of better facilitating the harmonised evaluation of biocidal products across the EU.

Similarly to MR, the BPF, SBP and SA procedures give companies the chance to access more markets by utilising time and cost-efficient processes. These procedures, in combination with companies' participation in task forces, allow for the reduction of fees and waiting periods relating to authorisation and help facilitate the stated BPR goal of free and harmonised movement of biocidal products in the EU.

The UA offers a "one size fits all" way to access the whole EU market through a single authorisation, but unfortunately its application is limited to certain Product types. Certain Survey respondents also saw it as an opportunity for greater EU harmonisation and as a way to have more transparent process for the evaluation of the biocidal product authorisation dossier. On the other hand, the high fees make the use of UAs less attractive.

While Survey respondents were broadly supportive of these new processes, the possibility for them to increase complexity in many cases remains a concern. For more details on this issue, see commentary on 'Mutual Recognition' in section 2.2 of Annex II, the Legal Assessment.

R4BP

The Survey reported an overall positive opinion regarding the R4BP3 hub, with users indicating an average or above average level of satisfaction.

Respondents reported that the hub has simplified the application submission, standardised relevant documents, and allowed for the easy tracking of the process. Furthermore, it has provided them with supporting tools during the application process. The hub is user-friendly and is mostly useful for larger projects.

Having said that, it must be noted that all respondents stated that the efficiency of the R4BP3 is dependent on the particular eCA and its degree of knowledge and involvement with the system. This has often created issues with the efficiency of the hub and caused delays in the process.

4.2 Regulatory Hurdles

Hazard-based assessment instead of a risk-based assessment

The BPR has increased the focus on health and environmental protection. Survey respondents hope that this focus will lead to the recognition of the benefits that biocidal products have to the society. Authorisation under the BPR is seen as positive reinforcement of company image and driving better relationships with customers.

But at the same time, the BPR has introduced a hazard-based approach. Survey respondents consider the adoption of the hazard-based approach to be a conservative decision, which leads to the reduction of their biocide portfolios and the minimisation of valuable alternatives. Survey respondents that saw a reduction in their biocidal business argued that the existence of a hazard, instead of a risk-based evaluation approach, played a factor in that reduction.

Overall, Survey respondents consider that the adoption of the hazard-based approach further enhances the unpredictability in the evaluation of biocidal products. The unpredictability in obtaining the approval and/or authorisation has been identified as a major hurdle to innovation.

The BPR introduced exclusion and substitution criteria in Article 5 and 10, respectively. Meeting these criteria typically leads to a non-approval decision or very significant restrictions of the use of the substance. The exclusion or substitution of a substance is directly linked to its intrinsic hazard properties rather than to its risk profile.

One of the criteria refers to endocrine disrupting (ED) properties. Survey respondents tended to cite the introduction of ED as a complicating factor requiring investment in new data not only for ASs, but also for non-active substances (the so-called co-formulants) in biocidal products. The outcome of this investment is uncertain not least because the ED Guidance itself requires a very high burden of proof to demonstrate that a substance is not an ED. In attempting to meet the threshold of 'sufficient data' as provided in the Guidance, applicants run the risk of having to conduct a significant amount of animal testing with no or only minor improvement in human health or environmental safety as the outcome.

Complexity and moving goal posts

Guidance

Survey respondents cited a need for guidance or further guidance on multiple topics, including *in situ* biocides, efficacy, Annex I substances, nanomaterials, testing conditions, disinfection claims, confidentiality, risk assessment guidelines and technical equivalence.

Survey respondents also claimed that they have faced classification concerns and borderline issues in the accurate identification of the type of their biocidal products. Companies therefore point to a lack of PT-specific guidance,

which could consider any frequent misclassifications and clarify the PT's scope in order to assist companies in the classification of their products.

Specific examples of problems in the classification of products are discussed in section 2.2 of Annex II, the Legal Assessment, under 'PT Confusion' and 'Borderline Products'.

Constantly updated guidance results in the creation of new requirements which often become applicable upon submission of a dossier but prior to its assessment. It is reported that the preparation of a dossier starts at least 2 years before the submission deadline, but often even earlier. With this in mind, Survey respondents report that guidance comes too late, after dossiers have already been compiled and too often even after submission.

As a result, several eCAs are belatedly requesting further information from companies in light of new guidance. This constant updating of guidance results in longer evaluation periods – since eCAs may or even have to pursue further assessment as a result of a new guidance element. In the same time, this contributes to the general lack of predictability as it leads to higher regulatory costs that initially estimated. Companies reported that such requests by eCAs are made *even after* the evaluation deadline has passed.

Examples of changing guidance include those relating to BPF and efficacy:

BPF

The BPF is intended to provide a simpler way for companies to get similar products to market. Instead of requiring individual authorisations of each product, similar products could be covered by a single "family" authorisation.

The rollout of the BPF concept is very illustrative:

- The BPF concept was first outlined in Article 19 of the BPR, but a guidance note on how to implement the concept was not published until November 2014. This was more than two years after the BPR was published and more than a year after it began to apply.
- Guidance on same BPF applications was then provided in March 2015 and a template SPC (summary of product characteristics) document for BPFs was provided in May 2015.
- After 2 years of discussions among authorities, a new superseding guidance note on BPFs was published in July 2019, which focused on the concept of "similar" products.

In practice, this latest guidance document, which runs to 48 pages, radically overhauls the implementation of the BPF concept. It is being applied by most eCAs, even to dossiers submitted *prior* to its publication. This has resulted in confusion, radical changes to dossiers, further testing being carried out, increased costs and a delayed evaluation by the eCAs.

ECHA Efficacy Guidance

Similarly, the ECHA efficacy guidance for disinfectants has also been pointed out by survey responders as a very illustrative example of development and changing of guidance:

- From entry into force of the BPR on 1 September 2013 to May 2016 – no ECHA guidance existed.
- From May 2016 to Feb 2017 – ECHA published its Transitional Guidance on the Biocidal Products Regulation for Product Types 1 – 5.
- From February 2017 – present, ECHA Efficacy Guidance (Parts B + C) now exists.

The continuous development and modification of existing guidance under the BPR is both the result and the consequence of the complexity of the BPR. The difficulties posed by constantly changing guidance documents are exacerbated by the different interpretation by eCAs. This leads to lack of harmonisation as discussed further below.

Similarly, there are differences in opinion on how binding a guidance document is. This means its effect on the evaluation process accordingly varies among the eCAs. This, in conjunction with the unclear timelines, renders the overall evaluation processes unclear and unpredictable for applicants. See section 2.1 of Annex II, the Legal Assessment, on the legal authority of guidance for more information.

Unpredictability of outcomes in regulatory process

Unpredictability in how the law, guidance and procedures are applied was a key hurdle emphasised in the Survey. Much of the feedback focused on the impossibility for companies to obtain a well-grounded understanding of the process, submission requirements, timeframe and evaluation factors, prior to entering the evaluation procedure. Many respondents claimed that the application of BPR procedures by the eCAs is fundamentally inconsistent with the regulatory provisions. They cited discrepancies in timelines and constant changes in both guidance and the applicable submission requirements, and questioned the fairness and transparency of the assessment processes.

Timelines and Delays

The main issue raised in the Survey with respect to both the AS approval and the product authorisation processes was the departure from the timelines for the assessment process as set by the BPR and Review Programme Regulation.[16]

The overwhelming majority of the Survey respondents reported delays in the evaluation of their dossiers without satisfactory explanations (in their view) given by the eCAs.

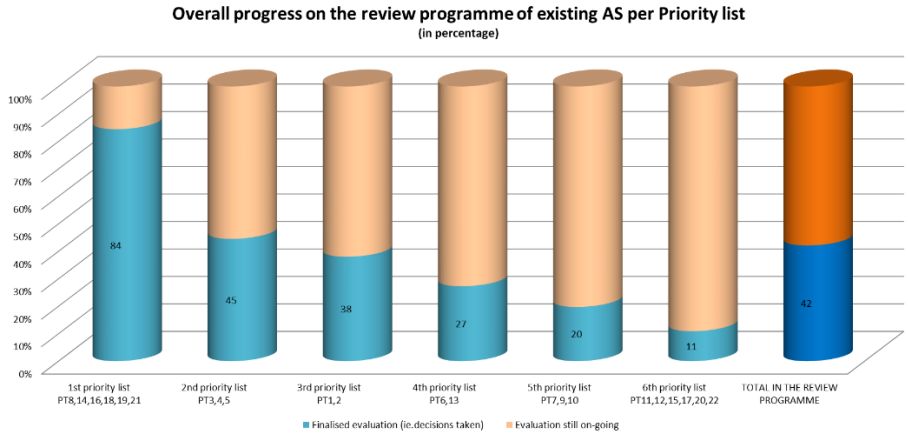
Reflecting on the overall regulatory framework, and the hurdles that it entails for companies, many Survey respondents focused on the competence of eCAs to conduct the relevant assessments. Especially, with respect to the frequent delays in evaluation, they observed that many competent authorities lack sufficient resources to undertake evaluations despite the BPR containing this requirement (Article 81).

Adding to the insufficient resources, a lack of experience and expertise in the assessment of biocidal products has been reported in some cases which makes the evaluation process much lengthier and sometimes more expensive. Such matters are aggravated by the regulatory complexity of the system and the fact that assessments are constantly subject to changing requirements.

The Survey recognises the impact of internal hurdles in the conduct of a full and comprehensive evaluation or justified need for additional information. It is therefore understood that eCAs may present sincere reasons for delays – especially given the BPR's complexity and the focus on safeguarding human health and the environment through in depth evaluations. The Survey respondents are, however, affected by the lack of communication of some eCAs regarding the reasons for delays, or the presentation of new timelines, or even any feedback on the status of the evaluation. Many companies have claimed to have waited between three and five years before they received the product authorisation for marketing they applied for, while the regulatory timeline envisages a validation step of no more than max 120 days and then a max 485-day evaluation step (i.e. 605 days).[17]

These delays are also representative of the inaccurate timeframe presented by the BPR as well as the reasons behind the long delay in completion of the Review Programme which has been on-going since 2014. The Review Programme has categorised the different AS and PT combinations into priority lists; the current progress of the Review Programme shows that 84% of the 1st priority list substances has been evaluated, 45% of the 2nd priority list, 38% of the 3rd priority list, 27% of the 4th priority, and 20% of the 5th priority list[18]. Considering the current status as reported by the Commission, the data provided by our Survey respondents appear accurate.

[16] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.
[17] Articles 29 and 30 of the BPR.
[18] CA-Dec21-Doc.5.1



Classification and Labelling overlapping procedures

With a greater emphasis on the classification of a chemical brought about by the exclusion and substitution criteria of Articles 5 and 10 of the BPR, there is often overlap between conclusions reached on classification as part of the assessment conducted under the BPR with parallel conclusions reached in the separate process, conducted by separate procedure, under the EU's CLP Regulation.

For substances having CMR properties, exclusion and substitution criteria apply where these substances have been classified under the CLP classification as CMR substances (depending on the category).

However, for the other criteria (i.e. ED and PBT and vPvB), the unpredictability brought about by these parallel but separate assessments is most keen where the two conclusions conflict with one another. It also comes about where the BPR has reached a conclusion but the CLP process is yet to conclude. Thus, where the eCA reaches a conclusion that the given AS is an ED substance (or has PBT or vPvB properties), but it is known that that very question is still subject to debate as part of the parallel CLP process, it is not clear how that apparent conflict is to be resolved. There is no mechanism within the BPR which says, for example, that the CLP process is to take priority or that any conclusion reached for Article 5/10 purposes is expressly subject to the CLP process.

This leaves the matter of classification unpredictable and yet it has potentially far-reaching regulatory consequences under the BPR.

Level playing field

Delays in the Review Programme and market distortion

A failure to respect the relevant deadlines and timeframes provided under the Review Programme is one of the central problems identified in the Survey and some examples have been given to illustrate the consequences that delays can have on the market.

Pending the outcome of their evaluation, ASs in the Review Programme may continue to be used in biocidal products that are placed on the market, provided these products fulfil transitional national product requirements. These requirements tend to be less stringent than those applicable under the BPR.

New ASs, in contrast, cannot be marketed until they are assessed and approved. Delays in the Review Programme using up resources within eCAs and ECHA have consequently led to delays also in the review of new ASs. This means new ASs remain frozen out of the market for a much longer period than anticipated. When such ASs are finally allowed to be placed on the market and used in products, companies supporting those ASs find themselves at a clear competitive disadvantage vis-à-vis competitors which have had market access for a longer period using transitional national product notifications/registrations/authorisations.

The competitive disadvantage faced by new ASs is aggravated by the fact that new ASs are subject to higher standards under the BPR, which necessarily entails higher regulatory and data costs. In contrast, the transitional national

product requirements, which existing AS must fulfil in order to access the market, do not generally entail the same level of scrutiny or expenditure.

The consequences of the delay therefore include:

- Creating a distortion in the requirements (e.g., toxicological, ecotoxicological and efficacy) needed for biocidal products, as not all products on the market are subject to the same EU standards; and
- Putting new and innovative products at a competitive disadvantage, through a delay in marketability, compared to existing products.
- Leading to modified or new/additional requirements due to new methodologies and guidance or new hazard criteria (ED was to be implemented later, but also the CA decision to consider one or two of the PBT criteria = P or B or T) which only leads to longer delays (due to need for new/additional studies)

Market Freeze

According to the Survey responses, the frequent delays in the assessment of the relevant dossiers creates a market freeze, which results in market distortion and in a reduction of companies' product portfolios. The latter is mainly the result of the additional costs – not accounted for at the submission stage – and constant changes in the launching date of new products.

Overall, the delays incurred at assessment level in combination with the lack of proper notification and communication between eCAs and applicants creates a difficult regulatory environment in which companies have to operate. The overall outcome is, as Survey respondents say, unpredictable.

In addition, the fact that many eCAs do in fact respect the evaluation deadlines results in, amongst other things, a potential barrier to the smooth functioning of the internal market and the overall fairness of the evaluation procedure vis-à-vis those products for which the evaluation has been delayed. Thus, products evaluated by different MSs will achieve authorisation at a different – arbitrarily determined – timeframe than others. Companies dealing with well-organised eCAs which are willing to communicate and facilitate their understanding of the evaluation timeline can organise their business planning and manage their regulatory (and therefore commercial) expectations. Contrary to that, companies evaluated by eCAs which are unwilling to facilitate applicants' understanding of the evaluation progress, are negatively impacted.

The delay in the evaluation procedures – especially at AS and NA level – also restricts companies' capability to use the BPR's new processes such as MR and SBP. Also, when these processes do become available, and despite recognising the intent of these processes to reduce bureaucracy in the authorisation processes, multiple issues arise in their application. In certain MSs, the MR and SBP processes have lasted up to 3 years, with the result that authorisations have been infrequent. Other companies reported that their BPF dossier has been under evaluation for 5 years. These delays significantly impact companies' operations and undermine the benefits of the new BPR processes. With eCAs requiring an undefined period of time to issue a decision, companies cannot utilise the BPR's MR processes to access and compete in different EU markets. In addition, when MR is conducted in many concerned MSs, the varying evaluation timelines among MSs causes further delays in the authorisation process of the product.

For other companies the delays impeach the possibility to change a co-formulant during the evaluation since the Changes regulation only applies after authorisation. This not only has major financial implications when the co-formulant is no longer supplied on the market, but it also prevents voluntary reformulation towards a product with a more favourable risk profile.

When talking about level playing field, predictably, the complex and increased BPR requirements have particularly affected SMEs, which represent almost 40% of the Survey respondents. The related increase in costs makes it very difficult for SMEs to maintain existing products on the market whilst continuing to finance biocidal innovation. Companies reported decreasing or ceasing their R&D activities as a consequence. This in turn leads to distortion of the market in favour of larger companies.

The demand under the BPR for more comprehensive data dossiers has reduced the number of companies which are able to meet these requirements. Some Survey respondents have decided to limit their operations exclusively to suppliers which already hold substance approvals in order to avoid the long waiting periods and potential non-

approval for ongoing AS approvals. This further limits the companies' choice spectrum, while also affecting the operations of suppliers which are in the process of or do not yet hold such approvals.

The stricter requirements have also forced some respondents to repeat the data collection and submission process, already carried out under the BPD, to fulfil the new criteria, thus incurring additional costs. Others noted that their ASs were not approved and investments into studies and data sharing were consequently lost. Respondents also reported that the new BPR data requirements have obliged them to reformulate their products by lowering AS content or removing some ASs in order to avoid rejection, thereby reducing the products' efficacy and consequent market value.

Harmonisation

Harmonisation of the rules governing the biocides market at EU level is one of the central goals of the BPR (Article 1(1)). However, the experience of the Survey respondents is that significant progress is still needed in this respect.

All Survey respondents reported that the current application of the BPR falls short of this harmonisation goal. There is a lack of harmonisation in the operations of eCAs. Different interpretations of the BPR and its guidance, as well as different data requirements, are being used. eCAs have different levels of resources available to them. This can also lead to differences in assessment times. These differences between MSs suggest that much work remains to be done if the BPR is to meet its objective of effectively harmonising the rules for the marketing of biocidal products. Changes in this regard would also help respond to increased demand for predictability in BPR-related decisions.

The high level of complexity of the BPR and its implementation results in but is also exacerbated by the different interpretations of the BPR by different MSs. Similarly, the degree of how binding the guidance is and its effect on the evaluation process varies among MSs. There also differences between MSs on the amount and nature of the data required, leading to late data requests and delays. These differences render the evaluation processes unclear and unpredictable for applicants and frustrate the BPR's objective of harmonising the rules governing the biocides market at EU level.

Costs

The substantial costs involved in the various BPR processes represent one of the most significant hurdles according to the Survey.

In order to place their products lawfully on the EU market, companies usually incur the following costs:

- Fees to competent authorities and to ECHA arising from AS evaluation;
- Fees to competent authorities and possible to ECHA (UA) arising from biocidal product evaluation;
- Costs associated with access to and development of required data; and
- Time and assistance spent fulfilling all applicable legal and technical requirements, which involves management time and, more often than not, external expert assistance.

Administrative fees

As a result of the BPR's stricter requirements, ECHA and eCAs have increased their administrative fees to reflect the more extensive evaluation that is consequently required of them, further increasing companies' expenses.

ECHA fees are a major source of the extra costs faced by industry. These fees are a new cost factor under the BPR, as they did not exist under the BPD.[19] They can be very significant, for example, 80,000 EUR fee for a UA or 120,000 EUR

[19] The fees are set out in Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to 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.

fee for an AS review (including one PT only). Such fees apply on top of the fees of the eCA, which raises questions about how they are used and whether such significant amounts are justified.

In addition to assessment-specific fees, annual fees of 10,000 EUR and 20,000 EUR are applicable to UAs of a biocidal product and UAs of a BPF respectively. The justifications for charging such high annual fees are not clear.

Other costs

Added complexity in the regime and more stringent data requirements have required companies to increase their expenditure on regulatory consultants, legal costs, the cost of participation in task forces, and internal training and human resources to manage dossier submissions.

Survey respondents generally acknowledge and accept that the increase in data submission and evaluation requirements was prompted by the necessity for greater human, animal and environmental protection. However, they also question whether these requirements and more complex procedures have in practice achieved more accurate evaluations, more appropriate approvals, and an overall benefit to society.

Although not directly imputable to the BPR itself, the extensive and unanticipated length of the Review Programme must be taken into account as a significant factor in the expenses already incurred by its participants.

Impact on business

The overall increase in fees incurred during the approval and authorisation processes has negatively affected business operations, product marketing, market access and investment in biocides innovation. Survey respondents report that they have been obliged to redirect part of their reformulation budget – previously financing R&D, performance tests, authorisation of new formulations etc. – to meet these higher costs. Some comment that there is a subsequent chill-effect on projects, resulting in a lack of business confidence. Others comment that the deficiencies of the BPR demonstrate that it does not understand the actual business needs of the market.

The increased data development and access costs, in combination with all other regulatory costs under the BPR, have impacted the majority of Survey respondents, resulting in a reduction in some companies' product portfolios.

Survey respondents report that they have had to withdraw historical products from the portfolio offering, a decision triggered not for reasons of the environment or human health but for reasons of costs increases under the BPR.

Increased data costs have also caused a shift in companies' product-related decision-making processes, as large regulatory costs are now being considered at an earlier stage. Companies now take fewer risks and are only choosing to develop products with a clear profit potential.

Innovation

The level of innovation in the biocidal sector is recognised to be very low. The recent Commission report acknowledged that innovation with regard to new ASs has been rather limited, and that only 10 new ASs were evaluated since the entry into application of the BPR.[20] Survey respondents identified a range of factors as creating an unfavourable environment for innovation.

The extremely long and unpredictable timelines for obtaining authorisation and approval have been identified as a key disincentive. Delays in the Review Programme, which have a knock on effect on new AS approvals, are cited as a key concern. Furthermore, products containing new AS are subject to a market freeze until the AS is approved, unless provisory authorisation is granted (if the eCA requests and only if the outcome of the evaluation of the AS is thought to lead to an approval). But also launching innovative products in new markets is especially challenging since the net effect of the delays is that new products are being kept off the market for years.

For existing manufacturers, the high regulatory costs associated with the overall process makes the development of new formulations – such as the replacement of a solvent with a "greener" component – very difficult. Such costs

[20] 2021 Commission Report, pg 5.

include the cost of meeting data requirements, as well as regulatory costs associated with obtaining approval and authorisation.

In addition to costs, Survey respondents identified that the BPR process creates too great an uncertainty for investments into innovation. Causes of this lack of predictability include constantly changing guidelines, shifting of the regulatory goalposts and differences in approaches between MSs. The impact is particularly high for SMEs which lack the financial resources to invest in the development of new AS chemistries or innovative products, which might never be brought to market.

Comments from Survey respondents reflect on how the application of hazard based criteria can hinder innovation and note that other regions of the world applying a risk approach have relatively more innovation. As the hazard-based approach does not properly reflect the real risk of a product, use of hazard criteria is causing companies to reformulate products which in practice, in many cases, does not alter the risk profile of the product.

While the new concepts introduced by the BPR, and the increased focus on human and environmental protection were noted by some Survey respondents as positive triggers for innovation, the overall conclusion is that the BPR creates an unfavourable environment for innovation. Companies are, as a result, hesitant to invest in the development of new substances and products.

4.3 Conclusions on fact finding

Taking the project findings together, it is possible to identify a number of trends in the findings, which may be summarised into five key conclusions:

The BPR has introduced several improvements, but problems remain

The report identifies that concepts such as the BPF and UA, SBP and Changes regulation, provide industry with new ways to market, potentially reducing costs and administrative burdens, while the BPR's increased focus on human an environmental protection can help support customers confidence in biocidal products. At the same time, several key failings in the application of the BPR have been identified. Chief among these are the unpredictability of the current regime, moving goal posts and the complexity, the lack of level playing field and harmonisation.

Unpredictability is a key hurdle for industry

Unpredictability in how the law, guidance and procedures are applied has been repeatedly emphasised as a core hurdle for industry. The BPR is a technical and complex piece of legislation and industry struggles to obtain a well-grounded understanding of the process, submission requirements, timeframes, and evaluation factors prior to entering the evaluation procedure. The difficulties are compounded by the fact that timelines are frequently not respected and constant changes appear to be made to both guidance and the applicable submission requirements. This lack of unpredictability stifles innovation and undermines the fairness and transparency of the Review Programme and assessment processes.

Complexity and moving goal posts

The continuous development and modification of existing guidance under the BPR is both the result and the consequence of the complexity of the BPR. The difficulties posed by constantly changing guidance documents are exacerbated by the different interpretation by eCAs.

The BPR objective to guarantee harmonisation is not fulfilled

Significant progress is needed in order to realise the BPR's objective of harmonising the rules governing the biocides market at EU level. There is a wide discrepancy timelines for authorisation, interpretation of EU guidance is different, and MS national processes and preferences still play an important role.

The current regime does not support innovation

The BPR and its implementation fail to create the conditions necessary to support innovation. This is due to the high costs and difficulties associated with bringing a new product to market. Such obstacles are made worse by the unpredictability of the current regime in terms of timelines and criteria that will be applied to assessment. The shift towards hazard-based criteria also poses challenges to innovation.

Cost of compliance is not proportionate to the market value

The substantial costs involved in the various BPR processes represent one of the most significant hurdles according to the Survey. As a result of the BPR's stricter requirements, ECHA and eCAs have increased their administrative fees to reflect the more extensive evaluation. The increased data submission and evaluation requirements under the BPR have also considerably increased costs for businesses. As the amount of these costs is not proportionate to the value of certain products, companies have made the decision to reduce their product portfolios, as well as their investment in biocides innovation. SMEs are particularly impacted by these cost increases.

5. Lessons learned and the road ahead

In this section 5, the implementation of the BPR is addressed from a different angle. It aims to identify lessons that can be drawn from the transition from the BPD to the BPR, the COVID-19 Crisis and also the application of the Plant Protection Products Regulation ("**PPPR**")[21]. It also briefly discusses a new challenge on the horizon posed by the Chemicals Strategy for Sustainability. The discussion in section 5 provides further context to the report and prepares the proposed solutions for improvement discussed in section 6.

5.1 From BPD to the BPR

The BPR entered into application on 1 September 2013 and it replaced and repealed the BPD. The objective of the new regulation was, and still is, to improve the functioning of the internal EU market for biocidal products, whilst aiming to provide a high level of protection for humans, animals and the environment.

The aims of both pieces of legislation are set out in various recitals to the BPD and BPR, respectively. Some of these aims are common to both the BPD and BPR, e.g. a desire to minimise tests on animals, the mutual recognition of authorisations between MS and separate processes for product that pose a low risk. However, the BPR takes the regulation of biocides to a different level with the introduction of significant changes to the rules on AS approval and biocidal product authorisation, for example:

- Introducing exclusion criteria for AS based solely on hazard classification.
- Introducing Union wide authorisation, for certain categories of biocidal products.
- Expanding the rules concerning the placing on the market of treated articles.
- Introducing a new simplified authorisation procedures (Article 25 and Annex I).
- Creating a list of authorised AS suppliers ("**Article 95 List**").

Although the BPR made changes to the regulation of biocidal products, the basic principle of first ensuring the AS safety for humans and the environment at EU level, followed by MS authorisation of products containing that AS, remained the same as under the BPD.

As indicated above, the BPR introduced new concepts for the regulation of biocides that were intended to facilitate easier access to the market. However, the complexity of the BPR was apparent at the outset as amendment (Regulation (EU) No 334/2014) was immediately required to correct and clarify many parts of the original text, as outlined in the first 30 recitals. A notable example was the change to the 'transitional measures concerning treated articles' (Article 94) that was needed to remove the 'market freeze' created by the original text:

> *"As Article 94(1) of Regulation (EU) No 528/2012 applies only to treated articles already placed on the market, an unintended ban on most new treated articles was introduced from 1 September 2013 until the approval of the last active substance contained in those treated articles. The scope of Article 94(1) should therefore be extended to include new treated articles. That Article should also provide for a phasing-out period for treated articles for which no application for the approval of the active substance for the relevant product-type is submitted by 1 September 2016. To avoid potentially serious adverse effects on economic*

[21] Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

operators and whilst fully respecting the principle of legal certainty, provision should be made for those modifications to apply from 1 September 2013".

As envisaged in the BPR, implementing and delegated Regulations were necessary to establish detailed procedures, further underlining the complexity of the regulation. These included, for example:

- Regulation (EU) No 354/2013 on changes of biocidal product authorisations;
- Regulation (EU) No 414/2013 specifying a procedure for authorisation of same biocidal products;
- Regulation (EU) No 564/2013 on the fees and charges payable to ECHA;
- Regulation (EU) No 88/2014 specifying a procedure for the amendment of Annex I;
- Regulation (EU) No 492/2014 supplementing the rules for the renewal of authorisations of biocidal products subject to mutual recognition;
- Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products; and
- Regulation (EU) 2017/2100 setting out scientific criteria for the determination of endocrine-disrupting properties

The scope of the BPR with respect to other legislation is outlined in Article 2, but the absence of clear definitions across different regulations has resulted in the need for Commission guidance on scope, most often for products that border the PPPR and cosmetic products[22] legislation. For example, the borderline between cosmetic and biocidal products required a 28-page guidance document in July 2013[23] advising MS Competent Authorities ("**MSCA**"s) on this demarcation (see also section 2.2 of Annex II, Legal Assessment, on 'Borderline Products').

It is worth stating that Commission guidance of this type is only issued in the interest of consistency and "*Member States are not legally obliged to follow the approach set out …, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law*". Consequently, MSCAs have the obligation to determine the correct scope of a biocidal product, subject to review by the courts, on a case-by-case basis, meaning that consistency is subject to individual MS opinion.

This reliance on case-by-case decision-making distracts from the intention of the BPR to improve the functioning of the internal EU market by harmonising the rules for biocidal products. In many of the responses received from companies in the Survey, it is this return to individual MS decision making that is a major source of complexity and uncertainty in the process of authorising products.

In Article 3 of the BPR, a number of BPD definitions relating to market activity were changed, namely:

- **'Making available on the market'** - *"any supply of a biocidal product or treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge".*
- **'Placing on the market'** - *"the **first** making available on the market of a biocidal product or treated article".*
- **'Use'** - *"all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the Union".*
- **'Treated Article'** - *"any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products".*

With respect to 'making available on the market', according to Article 95 of the BPR, from 1 September 2015, biocidal products may no longer to be made available on the market unless either the manufacturer or the importer of the AS (substance supplier), or the manufacturer or the person making available on the market the product (product supplier) is included on the Article 95 list.

This new requirement, aimed at creating a level playing field in the biocides market in the EU resulted in significant new guidance, new administrative processes via ECHA and questions concerning the variable degree of enforcement

[22] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.
[23] CA-Jul13-Doc.5.1.h, available on CIRCABC.

conducted by MSs.[24] Indeed, there was considerable uncertainty how to enact the requirements of Article 95, both within industry and with regulators. The history of the CA note for discussion from May 2015[25] concerning 'Compliance with and enforcement of Article 95' is worth noting in this regard as an earlier draft version included a discussion on in-situ and precursors, whereas the final version decided to avoid this discussion altogether and leave it for a separate CA note.

Linked to Article 95 is the introduction of mandatory sharing of vertebrate and other relevant data between the data owners and applicants. Here again further guidance was required to explain the intentions of the legislation and give industry information concerning their rights and obligations.

One of the most significant areas of change brought about by the BPR is the expanded focus on treated articles. In the BPR itself, the intentions regarding treated articles are stated simply: "*To protect human health, animal health and the environment, and to avoid discrimination between treated articles originating in the Union and treated articles imported from third countries, all treated articles placed on the internal market should contain only approved active substances*" [26] and to "*enable consumers to make informed choices, to facilitate enforcement and to provide an overview of their use, treated articles should be appropriately labelled*".[27] However, as seen in other areas of the BPR, the practical consequences arising from these intentions raise multiple questions, not least on how treated articles are defined, when is it required to regulate, who is responsible for compliance, and how should the performance (efficacy) and safety of treated articles be judged and mitigated if concerns are identified.

Correctly defining a treated article has proved to be especially difficult and open to case-by-case interpretation by MSs. This was highlighted by the Swedish Chemicals Agency in their market report from 2016[28] which concluded that:

> "*the differences in their* [MSCAs] *responses emphasize that the definition of treated articles in the biocidal products regulation is subject to interpretation. There is a wide range of opinions whether the biocidal function of a product is primary or not. Furthermore, countries are not consistent about whether liquids and mixtures with a biocidal function are regarded as biocidal products or treated articles. In conclusion, there is a need for better guidelines and clearer rules in this area*".

Some Guidance on treated articles comes in the form of a number of Commission guidance documents, in particular the note from 2013[29] answering frequently asked questions on treated articles. Whether this guidance provides clear rules in this area is itself a question that will receive many different opinions.

The change from BPD to BPR set ambitious aims to improve the functioning of the internal EU market for biocidal products and to increase protection for humans, animals and the environment. Has the BPR succeeded in these aims? It has certainly succeeded in increasing the regulation of biocides, but in doing so it has created a regulatory framework so complex that it may well impede the function of the internal EU market through inconsistency and delay and over-ambitious protection levels. These factors will discourage innovation due to the excessive cost of compliance the BPR creates, the unpredictability and complexity of the processes.

5.2 COVID-19

The COVID-19 pandemic constitutes the most acute example of a failure in the BPR's harmonisation system. Notwithstanding certain initiatives on the part of both the Commission and ECHA at various points in the crisis, it is clear that the BPR was ill-prepared to deal with such highly demanding health emergencies.

Although the majority of Survey respondents reported that most MSs were cooperative and quick to provide emergency permits during the COVID-19 crisis, the authorisation and assessment occurred at a national level without the facilitation of an EU-wide emergency authorisation regime. Common input on the COVID-19 emergency

[24] CA-Nov16-Doc.7.4 – Final, available on CIRCABC.
[25] CA-May15-Doc.4.13-Final, available on CIRCABC.
[26] Recital 52 of the BPR.
[27] Recital 53 of the BPR.
[28] Market survey on articles treated with biocides. Swedish Chemicals Agency. 2016. Article number: 511 221.
[29] CA-Sept13-Doc.5.1.e., Revision 1, December 2014, available on CIRCABC.

authorisation process was the lack of an automatic EU registration for products that were already registered in a certain number of MSs.

If ECHA had centralised the list of local MS authorisations, products qualifying for an emergency authorisation could have been given– and considering the unique urgency involved, should have been given – access to all MS markets by MSCAs acting through R4BP3 without the additional bureaucracy, time constraints and burden on the emergency authorisation system.

Similar problems arise when eCAs interpret the available advice in a manner inconsistent with the interpretation of the Commission or ECHA. The implementation at a national level of differing, stricter or more lenient requirements than those established by and implemented at EU level results in evaluation discrepancies, and potentially additional costs for companies who need to provide additional information to achieve authorisation from an eCA with different requirements.

The rules within the BPR on emergency authorisations – Article 55(1) – are themselves relatively poorly drafted and open to interpretation as noted above.

Companies which charitably turned to manufacturing hand gels according to the World Health Organisation's formulae discovered that they could not legally give their products away for free to charities, schools, the local community, hospitals (etc.) without risking an infringement of the BPR and enforcement measures against them.

Hand gels are effective because of their content of ethanol. Production and supply of ethanol to the EU market (as well as to the global market) became of some concern not just for the manufacture of products to combat COVID-19 but also for other, unrelated products.[30]

There was no coordinated, EU-wide approach to ensuring the supply of this critical AS and the fact that ethanol is not yet approved under the BPR prevented any harmonisation at product level.

While most companies had good intentions when manufacturing and placing products on the EU market to combat COVID-19, there were also a small minority of companies marketing unsafe products in the EU.[31]

In order to address the shortcomings in the BPR, core parts of industry (Biocides for Europe, A.I.S.E., and FECC (the European Association of Chemical Distributors)) coordinated their activities in an attempt to centralise a common understanding of how the emergency authorisation procedure under Article 55(1) BPR functions together with all decisions taken at MS level. The initiative ensured guidance was available to industry on Article 55(1), increased transparency of the different national practices, and provided a comprehensive one-stop-shop for "live" information on national requirements, which was lacking.[32]

5.3 PPPR

The BPR and PPPR both aim to improve the function of their respective markets in the EU, while ensuring a high level of protection for humans, ('non-target') animals and the environment. A comparison of these regulations can show if there are lessons from the PPPR arena that may be applicable to the BPR.

A substance can be approved under the PPPR only if at least one use of the substances in plant protection products ("**PPPs**") is proven safe for people's health, including residues in food, for animal health and has no unacceptable effects on the environment. In this regard, the BPR and PPPR are aligned, both having the principle of establishing one safe representative use for Union level approval of an AS.

The initial approval of PPPs and BPR ASs is valid for a limited period and the approval of an AS is reviewed periodically. Under both schemes, applications are submitted to an eCA who performs the necessary scientific evaluation for the first and subsequent approvals.

[30] See "*Increase in Industrial-Grade Ethanol Prices: The COVID-19 Impact*", Aranca, 3 November 2020l; and "*COVID-19 risk of synthetic ethyl alcohol shortage for the production of food packaging*", FTA Europe, 18 March 2020.
[31] "*OLAF investigation keeps dangerous hand sanitiser off the shelves*", OLAF, 15 December 2020.
[32] See the "*Practical Guide on Covid-19 Fast-Tracking Supply of Disinfectants*" and its Annexes on the Biocides for Europe, A.I.S.E., and FECC websites.

For both the BPR and PPPR, the approval of ASs takes place at EU level and the subsequent authorisation of products takes place at MS level. Mechanisms such as MR, comparative assessment and provisions to reduce animal testing are part of both regulations.

Independent Expert Review

In the framework of the PPPR, the European Food Safety Authority ("**EFSA**") performs an independent scientific review of the ASs; the Rapporteur Member State ("**RMS**") prepares a draft assessment report ("**DAR**"), which is then peer-reviewed, but ultimately EFSA experts perform their own assessment of the DAR. This is in stark contrast to the BPR where MSs perform this task under the stewardship of ECHA (i.e. Working Group and BPC Chairpersons). Discussions at Working Group level, while being chaired by an ECHA employee, are driven by the eCA, with substantive contributions from approximately 5-7 MSs according to experience. The result is that the proposals of the eCA are in the main carried through to BPC level, which is composed of MS representatives and the BPC Chair. The Chair can direct the discussions but ultimately its hands are tied and the decision comes down to a MS vote, which inevitably rubber-stamps the decisions of the Working Groups.

The difference: independent EFSA experts are involved in the PPPR AS process but independent ECHA experts are not involved in the BPR AS process.

IT Systems

The Commission has developed the PPP Application Management System ("**PPPAMS**") to enable industry users to create applications and submit these to EU MSs for evaluation. EU MSs then manage these applications within the system, concluding with the authorisation opinion. PPPAMS is not yet operational, but the anticipation is an avoidance of duplication of work, easier monitoring of applications, and an easier and faster process. A clear parallel under BPR is the R4BP3 system managed by ECHA. As both systems appear to operate to the same basic principles and objectives, sharing of experience gained could inform both PPPR and BPR regimes regarding best practice.

Both PPPAMS and R4BP3 function to manage workflow but they leave open the possibility for MSs to operate other 'manual' systems. This overlaying of EU and MS systems is one of the causes of the complexity experienced by companies responding to the Survey. Closer adherence to agreed collective EU tools is necessary for the regulatory process to operate efficiently.

REFIT

In December 2012, the Commission announced the launch of the Regulatory Fitness and Performance Programme ("**REFIT**"). Its aim was to have in place a simple, clear and predictable framework for business, workers and citizens so that the policy objectives of EU legislation are achieved and the benefits are enjoyed at the lowest cost and with a minimum of regulatory burden.

Among the tools used under REFIT are fitness checks, comprehensive policy evaluations designed to ascertain whether the regulatory framework for a policy sector is fit for purpose.

Starting in November 2016, the Commission has conducted a REFIT evaluation of the EU PPP legislation.[33] The Commission adopted the PPP REFIT report on 20 May 2020. Comments with respect to the BPR are included in the Staff Working Document[34] accompanying the report and the main conclusions resulting from this analysis are the following:

[33] Report from the Commission to the European Parliament and the Council Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, 20 May 2020, COM/2020/208.
[34] Commission Staff Working Document accompanying the document Report from the Commission to the European Parliament and the Council Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides', 20 May 2020, SWD(2020) 87.

- PPP REFIT considered time-limited approvals as proportionate tools to reach the objective of protecting human and animal health and the environment. The use of these tools under the BPR may be similarly proportionate, although the BPR has introduced complexity due to the length of the review programme and delays in the authorisation of products under the BPR and the various national schemes under transitional arrangements (Article 89).
- PPP REFIT concluded that approval criteria/exclusion criteria have a "signalling effect" and do not seem to have a negative impact on the number of available products under PPP. The same "signalling effect" is relevant to the BPR but as biocides historically have less data available (not having the legacy of regulation compared to PPP) the requirement to conclude on exclusion criteria negatively affects biocides due to the cost to develop data on a chemical sector containing a high proportion of SMEs.
- The publication of the list of candidates for substitution again has a "signalling effect", which might reduce the use of ASs identified as candidates for substitution. However, as comparative assessments have not led to any substitutions, PPP REFIT questioned whether the additional costs (time and resources) are justified for PPP. The conclusion is also valid for the BPR although in some cases the reason not to substitute a particular substance is a lack of alternatives owing to the gradual erosion of actives available particularly for certain PTs (e.g. wet state preservatives, PT6).
- PPP REFIT considered the timeline for the renewal process for PPP ASs should be proportionate to the associated workload and necessary resources. The PPP conclusion is valid for the BPR and in practice, the biocide review processes experience delay. For ASs subject to shortened approval periods (e.g. PT14), the product authorisation process risks overlapping with the renewal process with the consequence of additional cost to authorisation holders having to respond to frequently changing requirements.
- PPP REFIT identified outdated information, poor quality and incomplete data provided in MR dossiers, as well as national requirements, as reasons negatively affecting proper implementation of the MR process. The MR process for biocides is not working for similar reasons: in particular, MSs applying their own national criteria too often and interpreting guidance according to national preferences.
- Under the BPR, an applicant may apply for UA as an alternative to applying for a NA and MR. There is no such provision in the PPPR; instead, an EU zonal system is available. PPP REFIT concluded the zonal system was not working in a sufficiently effective way. The experience of UA under BPR would appear to be the same according to the Survey.
- PPP REFIT stated that 'simplified' procedures were allowing a steady increase in the number of substances accepted in the categories of basic substances and low-risk substances. The possibility exists under the BPR to develop these types of substances more widely, but regulatory processes are overly complex and incentives for industry too small to drive a significant increase in biocides of this type.
- PPP REFIT noted that MSs generally do not consider alternative methods to animal testing. The conclusion is valid for the PPPR and the BPR and is the result of the underlying conservatism that exists in the review process, exacerbated by the need to establish hazard criteria as a requirement for approval. A risk based approval process would allow regulators to take a proportionate approach to data generation allowing a greater possibility to use alternative methods to animal tests.
- The data-sharing mechanism works effectively according to PPP REFIT and supports a reduction in animal testing. The conclusion is valid for the BPR however, as stated previously there is generally a greater need to develop data for BPR purposes, increased by the need to establish hazard criteria. This increased need for animal data may offsets reductions achieved by data sharing.
- The Commission has published scientific criteria to identify substances with endocrine disrupting properties. The biocidal products criteria apply from 7 June 2018; the PPP criteria apply from 10 November 2018. There is not yet sufficient experience to evaluate these criteria and the associated ED-guidance. However, an expansion of the scope is already occurring with the focus turning to non-active substances under BPR. ED investigations appear to be taking the form of academic research projects questioning the requirement for proportionality in EU legislation.
- The authors of this report are not aware of a similar REFIT exercise undertaken for the BPR; however, judging from the feedback received to the Survey it is necessary to help remedy problems with implementing the BPR.

5.4 Chemicals Strategy for Sustainability

On 14 October 2020, the Commission adopted its Chemicals Strategy for Sustainability ("**CSS**")[35]. In brief, it aims to:

- better protect citizens and the environment; and
- boost innovation for safe and sustainable chemicals.

The strategy forms part of the EU's wider ambitions under the European Green Deal, the EU's growth strategy to make the EU a sustainable, climate neutral and circular economy by 2050. Moving towards a zero-pollution and toxic-free environment are among its key commitments.

At the outset, it should be acknowledged that biocidal products are important tools to protect human health, animal health and the environment. Their indispensable role in securing human health protection was affirmed during the recent COVID-19 crisis, when surface disinfectants, hand sanitisers and other biocidal products became vital to stop the spread of the virus. Biocidal products can also contribute to sustainability objectives in other ways. For example, by prolonging the lifetime of a diverse range of products and materials, protecting against food spoilage, and facilitating less resource-intensive alternatives to single-use products (e.g. sanitary and drinking water applications). In the case of several biocidal applications, non-chemical alternatives may not always be effective, practical or even available.

It is therefore important that the social, environmental and economic impact of biocidal products are considered in the round and that the EU's strategy to promote sustainability ensures that sufficient biocidal products remain available to achieve these objectives.

Increasing human and environmental protection

As discussed in section 4.2, under 'Hazard-based assessment instead of a risk-based assessment', the BPR has already considerably increased the focus on health and environmental protection by increasing the safety and data requirements for biocides and by requiring the elimination of certain hazardous ASs.

Among its objectives, the CSS aims to phase out the most harmful chemicals for non-essential uses, especially consumer uses, and minimise and substitute as far as possible substances of concern. Such objectives appear to be already met through the exclusion and substitution criteria for ASs, and the comparative assessment for biocidal products containing AS candidates for substitution. It therefore appears that the BPR, if implemented correctly, is already fit for purpose in terms of meeting the CSS's safety objectives as they apply to biocides.

In support of this position, the Commission previously published a report on the sustainable use of biocides[36] which recognised that the BPR provides very powerful mechanisms to phase out the use of substances of high and very high concern. A study contained in the report also concluded, with regard to additional measures, that the risks posed by biocidal products to health and the environment were already appropriately addressed under the current mechanisms.

Given the protection objectives of the CSS appear to be already met under the BPR, it would seem unnecessary to prioritise imposing further safety requirements on biocidal products, as part of this strategy.

Boosting innovation for safe and sustainable chemicals

A cornerstone of the CCS is its acknowledgment that innovation in the chemicals sectors needs to be stepped up, as it is vital to finding new solutions and securing the transition of our economy and society towards sustainability. The

[35] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability, Towards a Toxic-Free Environment, 14 October 2020, COM (2020) 667.
[36] Report from the Commission to the European Parliament and the Council on the sustainable use of biocides pursuant to Article 18 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, 17 March 2016, COM (2016) 151.

CSS notes, in the context of the wider chemical regulatory regime, that even front runners still encounter major economic and technical barriers, and a more coherent, predictable and stronger regulatory framework is needed to drive innovation.

A key finding of this Assessment Report is that the way in which the regulatory regime applies to biocides, under the BPR, is posing significant obstacles for innovation. Challenges include the extremely long and unpredictable timelines for obtaining authorisation and approval, lack of transparency, lack of consistency in the application of rules, and the regulatory burden and costs associated with bringing new products to market.

Examples of innovation in the biocidal sector are currently very limited. If this trend is maintained, the biocides industry will undoubtedly struggle to deliver the level of innovation demanded of it under the CSS. Addressing the shortcomings in the current regime, which hinder innovation, should therefore be considered an important objective for the purposes of reaching the EU's sustainability objectives.

Such measures are also necessary to maintain the viability and competitiveness of the EU's biocidal industries and therefore contribute to another one of the CSS's objectives; strengthening the EU's open strategic autonomy.

The CSS's objective of ensuring greater simplification of the chemicals framework and of making the assessment processes simpler and more transparent appears to be an opportunity to address many of the failings in the current implementation of the BPR. However, it should be ensured that any proposed improvements actually reduce the level of complexity and unpredictability in the current regime, instead of causing further disruption.

6. Proposed solutions

6.1 Take-aways from the Assessment

Based on Fieldfisher's legal assessment, ERM's technical assessment, the Survey respondents' input and the lessons that can be learned from elsewhere, it seems quite clear that while the BPR has made some improvements, there is a combination of industry dissatisfaction with the overall functioning of the BPR and objective failures at a technical/legal level.

The position can be summarised as followed:

1. The BPR has introduced several improvements, but problems remain.
2. Unpredictability is a key hurdle for industry.
3. The BPR's objective to ensure harmonisation is not fulfilled.
4. The current regime does not support innovation.
5. Cost of compliance is not proportionate to the market value.

No regulation will satisfy everyone at every level and not all issues of interpretation or application of the BPR have a neat remedy to them. For example, the fact that industry may be hesitant to innovate in developing new ASs or biocidal products or other technologies might well in part be an undesirable outcome of the adoption of the BPR. However, the project findings also suggest that industry is further disincentivised to innovate by reason of the way of the BPR is currently implemented, and consequently there may be scope for improvement.

Below we list what we understand to be the key, relevant points of concern. For each we provide our brief assessment as to their importance and also the extent to which we believe they could be subject to remedy. The importance of a concern is measured only against the Survey results and ERM's/Fieldfisher's actual experience and the potential for remedy is considered in the context of what is realistically viable, as opposed to desirable but probably unachievable.

In our view, there is one common and recurring theme which underpins all the concerns: **unpredictability**.

That is a concerning finding given that the choice of moving from the BPD to the BPR – from a Directive to a Regulation – was, in part, designed to ensure greater harmonisation in the interpretation and application of the law. That simply has not been achieved. There are too many instances where industry is left with a lack of clarity. Whether that is a matter for business whose interest is indeed in seeing an improvement in the "*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*" (Recital 1 of the BPR) or in the rule of law which requires, *inter alia*, legal certainty, resolving as much of that unpredictability ought not to be a contentious ambition.

The unpredictability comes as a result of several factors:

- Delays:
  - Through no fault of industry, they may find their products off the market simply because the eCA is under-resourced/staffed/budgeted.
  - New guidance may intervene during a review and new regulatory goalposts may be set accordingly requiring further incurring of costs and additional time for assessment.
- Shifting regulatory goalposts:
  - As noted, new guidance can seriously affect the evaluations conducted by the eCAs/ECHA. The fact that the guidance is applied to dossiers that have already been submitted is one issue. A second issue is that its actual interpretation and application can vary across MSs.
- The shift in aim of the assessment:

  - With the introduction of exclusion and substitution criteria, the focus of the assessment of safety has shifted from risk to hazard. It invites the precautionary principle to be invoked at inappropriate times. For a more detailed overview of this issue, see section 2.1of Annex II, the Legal Assessment.
- Costs:
  - They will be higher or lower depending on the changing data requirements.

Looking at each factor's feasibility to change:

- The question of delay cuts both ways. If one is in the Review Programme, delay keeps you on the market while if one is a new AS, delay keeps you out. Normally when a regulatory deadline is set, it is the law and therefore should be respected. The lack of legal power to challenge (on which, see below at Section 6.2) tends to mean that there is no realistic way of enforcing a deadline. That said, it would seem obvious to state that ensuring clarity on deadlines so that both businesses and the regulator can manage their affairs is to the benefit of every party involved.
- The fact that scientific knowledge is in perpetual progress inevitably means that guidance documents are updated and that is to be expected, indeed welcomed. That said, it is the lack of harmonious interpretation and their retrospective application or implementation at various stages of the evaluation, which causes uncertainty and unfairness.
- The focus on hazard over risk is an undeniable legislative intention. It is difficult to see how one can shift the focus back without a sea-change in the EU. However, it can be argued that the identification of a hazard property for a given substance should not lead to its exclusion and substitution if the risk assessment does not identify any unacceptable risk. Nevertheless, this cannot be achieved only by changes to the implementation of the BPR, but rather by the amendment of the legal text.
- On costs, the question here is somewhat out of the hands of industry. Requesting the EU to impose a consistent, harmonious costs structure may be opposed by MSs for a variety of reasons. However, industry supports a fee system proportional to the resources and time invested in the evaluation of a dossier.

6.2 Potential solutions

We propose one 'horizontal', catch-all solution and several specific, targeted solutions.

Horizontal solution

Whether or not any specifically targeted solutions for improvement are adopted, there is, in our view, a clear 'justice'/rights of defence deficit, due to the limited possibilities to obtain recourse in the event certain matters have not gone correctly. See section 2.3 of Annex II, the Legal Assessment, for further information.

For instance, the options for an applicant to obtain recourse are limited where:

- a regulatory deadline is missed and it is to the detriment of the participant in the Review Programme;
- new guideline is applied retrospectively to data submitted 5 years previously according to old guidance;
- an eCA is delaying for no reason and that delay means exclusion from the market for longer than had been anticipated; or
- an eCA or the BPC mistakenly invoked the precautionary principle to conclude that the AS has a certain hazardous property.

There is no formal procedure in any of these cases, enabling an interested party, such as a participant in the Review Programme, to force a third party to review such matters.

Legally, in the case of AS approval and UA it is only the final Commission decision approving or rejecting the application that can be challenged as a matter of law before the courts. And those courts are at the EU level, in Luxembourg, and the likelihood of prevailing is limited unless, for example, a clear and manifest error of assessment has been committed. Our experience is that the EU Courts tend to favour the discretion of the relevant authorities over the alleged grievances of the industry affected.

Short of a direct legal challenge against the Commission decision, three other options are potentially available:

- An action for failure to act where it can be shown that the Commission, for example, failed to do something which would have concluded with a decision being sent to the applicant. These are rare actions and hardly ever successful.
- A complaint to the European Ombudsman on the grounds that there has been maladministration. Such complaints have, in our experience, also not been successful.
- Calling upon the Commission – in its role of "*guardian of the Treaties*" – to step in and correct any mistakes. It rarely does so not least because there is no sanction if it does not.

There is the possibility to pursue legal remedies in national law in the case of national biocidal product applications.

However, before deciding to instruct lawyers, which can sometimes be viewed as an aggressive move, applicants should have the possibility to have oversight of MS and ECHA decisions. They do not have this possibility. The BPR operates under a structure where there is no oversight at any point by any third party of what the eCA does or what, for example, the BPC does – except by the EU Courts in Luxembourg when it is in all probability too late in any event, or by national Courts for national biocidal product applications.

In order to redress this, the BPR could either be revised or the Commission could adopt guidance (which is binding on it) in order to bring in some sort of supervision mechanism. The BPR could borrow from examples elsewhere:

- Under the REACH Regulation,[37] when ECHA imposes a study generation requirement on a (group of) company/ies, those companies can challenge that decision before the Board of Appeal of ECHA. That Board is an independent Board which will reconsider substantively the merits of that study requirement. Importantly, a legal challenge before the Board has suspensive effect meaning that, while the companies can still place their substance on the market, they will not have to generate the study until the Board finalises its decision. There is also an appeal possible of Board of Appeal decisions to the General Court of the EU in Luxembourg, as per Article 94(1) of REACH.
- Under the PPPR, if EFSA confirms that certain information is about to be disclosed to the public, the company concerned can argue for non-disclosure. If EFSA insists on disclosure, there is an administrative appeal process which involves someone further up the hierarchy within EFSA reviewing the decision to disclose the information. Naturally that has suspensive effect and it will generate a final decision which itself is challengeable before the EU courts (albeit, if a challenge is initiated, that will not have suspensive effect and the information will be released in the meantime unless suspension is exceptionally granted).
- Also under the PPPR, a co-RMS is appointed fulfilling a limited role but nevertheless one where it provides input on the assessment conducted by the RMS. There is no equivalent of a "co-eCA" under the BPR.

We recognise that creating a separate BPR Board of Appeal or extending the competence of the current Board of Appeal to deal with matters beyond data sharing issues under Articles 62/63 of the BPR is a relatively substantive solution. It implies an increase in the budget of the Board, perhaps an increase in personnel and sitting Board members and an assumed competence to be able to handle this increased scope of work. That competence can, however, be assumed given the positive quality thus far of the decisions issued by the Board in the context of the REACH Regulation.

A novel approach would be to ensure that at each substantive stage of the overall regulatory process, the participant/applicant has a statutory right to request a time-limited review by a third party, preferably by someone higher in the hierarchy. For example, if the eCA has delayed matters unreasonably or applied a guidance document against its terms, the chair of the BPC Committee could be requested to intervene and judge whether the matter is

[37] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

of sufficient seriousness as to prevent the assessment from proceeding to the next stage. Similarly, if the matter for concern arises during a Working Group or BPC meeting, the relevant official of the Commission should be formally invited to confirm his/her satisfaction that the rules have been fully respected.

Such a staged set of (potentially mandatory) administrative reviews need not take time – a matter of a month each, for example. But whatever delay is created would be compensated by the right to see issues which arise from the application of the BPR being addressed early in the process and at a time that they can be corrected.

Whether such a horizontal solution can only be effected by way of an amendment to the BPR – involving the Council of Ministers and European Parliament – is not clear. But even if that is the case, there would be nothing preventing the Commission from binding itself with a new guidance document on how it is going to assure the right of comment of participants/applicants throughout the review process and in that guidance confirm when it is that the participant/applicant can demand a 'hearing' and the grounds for doing so. It would then only be the Commission's final decision that would be subject to formal, substantive review by the EU's Courts.

Targeted solutions

A general catch-all guidance document

There are certain aspects of the way in which the BPR is run that must be addressed directly. Again, many of these can be resolved by the adoption of binding guidance. For example, such guidance could capture the following:

- Confirmation that the Commission's Communication on the Precautionary Principle applies through the review process and that, accordingly, the principle can only be invoked by the Commission at the point it proposes a risk management measure.
- Confirmation that new guidance documents cannot be applied retrospectively once a data dossier has been accepted by an eCA as being complete.

A resurrection of a manual of decisions

There are so many grey areas between the various PTs and between the BPR and other EU rules and regulations that there is a clear desire and need to centralise – with the aim of harmonising – decisions taken by MSs and at the EU level on the regulatory definition of a substance. For further information, see section 2.2 of Annex II, the Legal Assessment, under 'PT Confusion' and 'Borderline Products'.

While Article 3(3) of the BPR provides the mechanism for formal decisions to be taken which are binding on the company concerned and which provide some authoritative guidance for others, a central repository of decisions from across the relevant MS authorities is absent. That absence is accompanied, however, by a series of guidance documents on borderline issues which adds further confusion as they vary from MS to MS. There is no legal clarity meaning that there is also no business clarity.

Conducting an exercise where definitive guidance is given in a centralised document, capturing previous decisions and concretising the lowest-common denominator approach between all 27 MSs, would assist. That document could be a living document, amendable whenever relevant.

Substantive legislative change

Other aspects of the BPR would require substantive amendment by legislative change. They include:

- Revising Article 55 so that it clarifies all the definitional issues indicated in section 2.2 of Annex II, Legal Assessment (see 'How to interpret Article 55(1) BPR'), and ensures that a comprehensive, harmonised approach can be applied. The fact that the MSs which saw most applications for derogations during the COVID-19 crisis were the ones that provided the greatest clarity on how they were applying Article 55(1) is an indication of why greater clarity is desirable and would be successful.
- Giving the Commission the power to make binding rules on treated article claims. The main treated article guidance document dates from 2013, and despite its main aim of establishing a harmonised way of analysing

claims, inconsistencies across MSs remain. Something should be done to ensure a harmonised approach. Legislative amendment of the BPR should be required to allow the Commission the possibility to adopt an implementing or delegated Regulation laying down common criteria for the analysis of biocidal claims. Inspiration can be taken from the Cosmetics Claims Regulation.[38]

- Giving the Commission the power to compel MSCAs to adhere to the BPR. This right of action could be initiated by the Commission itself, another MS, or a party directly and individually concerned. Inspiration can be taken from the administrative review procedure in the Food Contact Materials Regulation.[39]

[38] Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.
[39] Article 14 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

7. Conclusions

While the BPR has made some improvements, notably in terms of providing new ways to bring products to market and increasing the level of health and environmental protection, there is a combination of industry dissatisfaction with the overall functioning of the BPR and objective failures at a technical/legal level.

Chief among the problems in the current functioning of the BPR is the lack of predictability for applicants regarding timelines and what data requirements and assessment criteria apply. This results in increased costs and also undermines the fairness and transparency of the BPR's processes. Part of this unpredictability arises out of the differences in approach which persist among MSs. While the BPR aims to harmonise the evaluation of biocidal products at the union level, much work remains to be done in order to achieve this objective.

Related to unpredictability is the high level of costs associated with compliance under the BPR. These costs relate to administrative fees, the cost of running or obtaining access to studies and also the management, legal and technical costs associated with BPR applications. Importantly, objective failures at a technical/legal, including changing guidance and delays in review can increase those costs considerably.

The lack of predictability for applicants, lack of level playing field and increased cost burdens, which are a result of the way the BPR is currently implemented, deter companies from investing in product innovation, including more sustainable alternatives. This makes achieving the EU's CSS objective of transitioning the chemical's industry towards sustainability more difficult.

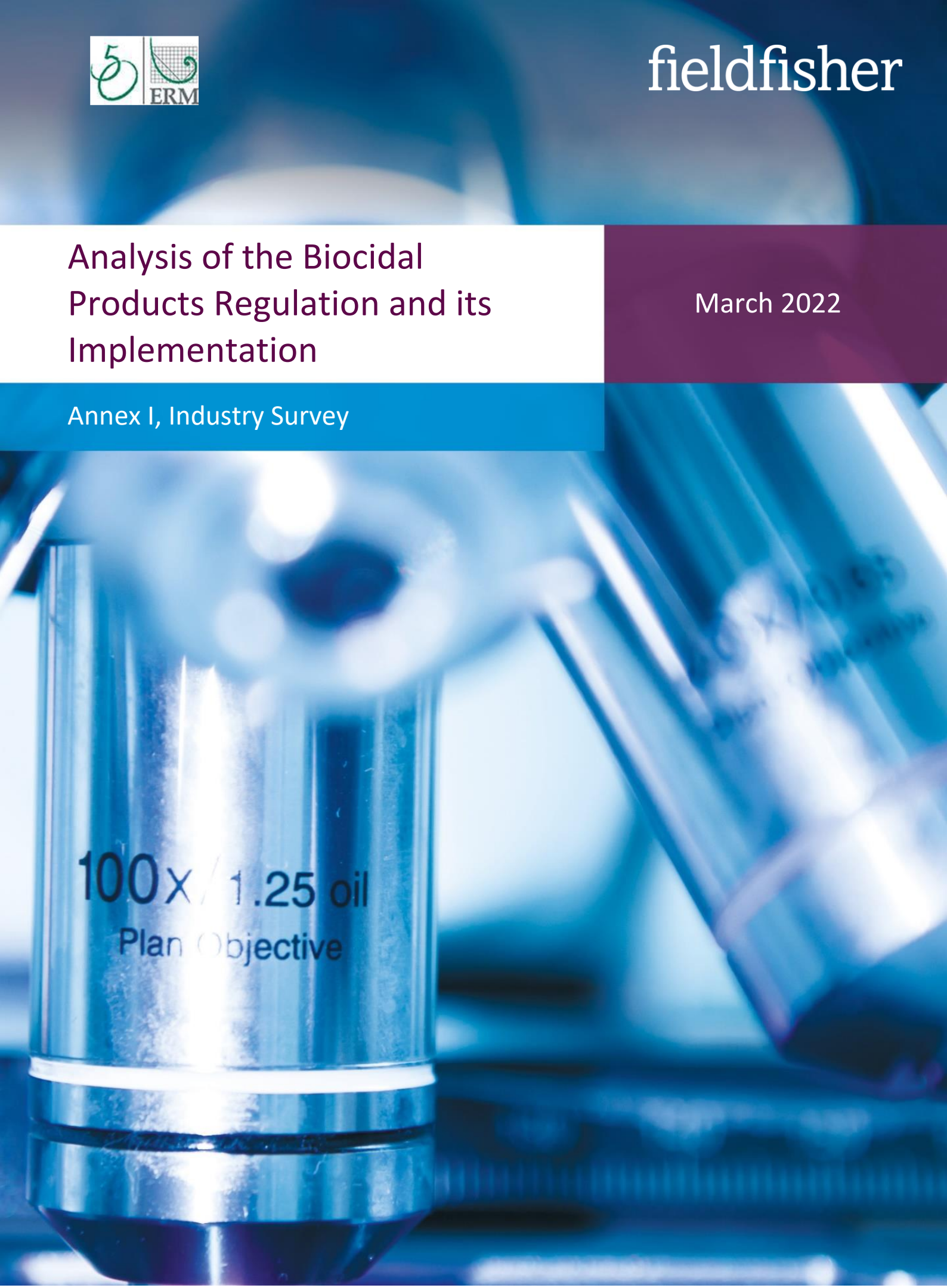
There are however possible solutions to the challenges associated with the current implementation of the BPR. One horizontal solution is to introduce a formal supervisory mechanism. Other possible solutions are more targeted in their approach, including further guidance and legal revisions to the BPR.

* * * *

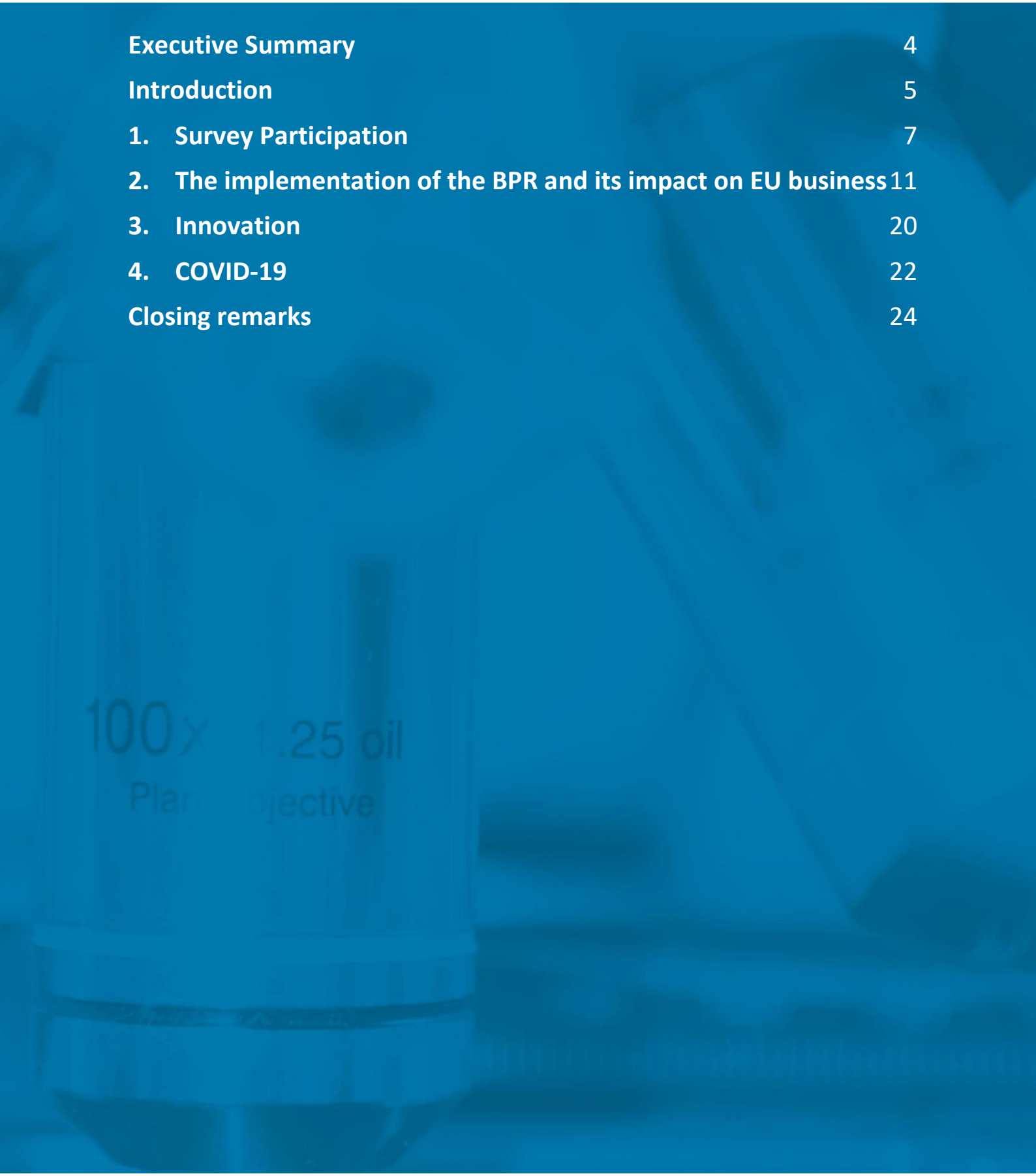
Analysis of the Biocidal Products Regulation and its Implementation

March 2022

Annex I, Industry Survey



Contents



List of acronyms used in this report

AS: Active Substance

BP: Biocidal Product

BPC: Biocidal Product Committee

BPC WG: BPC Working Group

BPR: Biocidal Products Regulation

BPF: Biocidal Product Family

eCA: Evaluating Competent Authority

ECHA: European Chemicals Agency

ED: Endocrine Disruption

EU: European Union

MR: Mutual Recognition

MS: Member State

MSCA: Member State Competent Authority

NA: National Authorisation

No.: Number

PT: Product Type

RAC: Risk Assessment Committee

R&D: Research and Development

SAP: Simplified Authorisation Procedure

SBP: Same Biocidal Product (regulation)

SME: Small and Medium Enterprise

UA: Union Authorisation

Executive Summary

A.I.S.E.[1] and Biocides for Europe[2] conducted a Survey with industry to get an insight into the impact of the Biocidal Products Regulation (BPR) on the business environment for biocides and the perspective on the future operation of the Regulation. The timing coincided with the preparation by the European Commission of the first report on the implementation of the BPR, that has been published in June 2021 and has been submitted to the European Parliament and Council.

The findings presented in this report come from *ca* 100 companies that responded to the Survey, about half of which were **Small and Medium Enterprise**s. Companies responding to the Survey were active in a wide variety of biocide business areas, including disinfection, preservation and pest control, with companies having multiple roles in the supply chain and operations in multiple markets. The Survey represents a significant cross section of the biocides business.

The impact of the BPR on the biocide business is a complex mix of technical, commercial and regulatory challenges. When commenting on the BPR, companies highlight **the complexity of the legislation and its accompanying guidance**. Companies consider that maintaining BPR compliance is not proportionate to the market value of biocides, with resource and **high cost of compliance** focused on running and finalising the regulatory processes (approval of active substances and/or authorisation of biocidal products) of existing portfolios rather than investing in innovation. **The commercial impact of maintaining compliance falls disproportionately on SMEs** as these businesses indicate a lack of in-house regulatory expertise and insufficient resources to fund the high cost of generating the data required by the BPR.

A common theme from the Survey is the **lack of predictability created by the implementation of the BPR**, with industry expectations of the process of active substance approval and product authorisation not met. The main concerns are **the delays to evaluate applications**, coupled with changes to guidance and data requirements (e.g., Biocidal Product Family concept: 2014 guidance significantly changed after 5 years) applicable not only to new dossiers, but also to those already under evaluation, some of them submitted more than 20 years ago like some Active Substance dossiers. These factors all create a **high degree of uncertainty in the regulatory outcome that** challenge the commercial viability of the application **but more importantly removes incentives for innovation**.

A lack of harmonisation and a properly functioning internal market for biocides in the European Union is another common concern of the Survey respondents. Pre-existing Member State specific requirements remain valid for product authorization also after the approval of the Active Substance/Product Type combination under the BPR when the process should follow a harmonized procedure. This causes a high number of delays in the Mutual Recognition process.

The complexity of the regulation and its implementation results in diverging interpretation and implementation of guidance and data requirements by Member State. Moreover, under specific processes, BPR allows MS to deviate from harmonised decisions and follow national law instead. These issues **create market distortion between businesses and geographies** and again introduce uncertainty in the regulatory process removing incentives to invest in biocides.

The ongoing COVID-19 crisis magnifies the key themes highlighted by companies in the Survey. BPR did not allow for a harmonised European Union action and the overly complex regulatory processes hampered an effective supply of disinfectants in the beginning of the pandemic. The consequence was a delayed response to society needs and knock-on effects to other sectors, but also unnecessarily but significantly increased the workload for both Member State and industry.

To address the challenges created by the implementation of the BPR, companies indicated a desire for more clarity, consistent implementation, enforcement of timelines and a reduction of complexity.

[1] International Association for Soaps, Detergents and Maintenance Products: https://www.aise.eu/

[2] Biocides For Europe: https://www.biocidesforeurope.org/

Introduction

Eight years have passed since the entering into force of Regulation 528/2012[3], the Biocidal Product Regulation, referred throughout this document as the BPR. The BPR introduced several changes to the existing Directive 98/8/EC (The Biocidal Products Directive, BPD) and brought up new concepts, processes, timelines, and players.

BPR was received with interest by industry. It was expected to simplify and streamline the processes, to ensure a level playing field through the Article 95 list and a high level of harmonisation for biocidal product (BP) authorisation via the mutual recognition or Union authorisation processes. Several of the new concepts brought in by the BPR (comparing to the BPD) were thought to facilitate the processes and offer new market opportunities to companies in particular Small and Medium Enterprises (SMEs). Among those, the most important, identified also in previous industry surveys, were the Same Biocidal Product (SBP), the Biocidal Product family (BPF) and the possibility to apply for changes of a BP Authorisation.

With the growing experience on the BPR implementation, during the last 2-3 years, Industry associations received feedback from members with growing concern around the implementation of the BPR. Many flagged significant delays not only those well known for the Review Programme (RP), but in the majority of the BPR processes (Product Authorisation (PA) both for Mutual Recognition (MR) and Union Authorisation (UA), renewals, changes of PA). The lack of resources of Member States (MSs) Competent Authorities (MSCAs) and the increasing complexity of the implementation of the BPR with many ramifications and countless guidance documents both policy and scientific significantly contribute to the delays. Many member companies highlighted that continuous changes of guidance, the lack of harmonisation due to specific national law or programmes, but also due to the delays in the RP and the transitional measures for the BPs significantly reduce the predictability for companies.

In general, concerns during the last few years were highest around the barriers to innovation such as the high investment in the regulatory compliance, the complexity of the regulation and delays, the lack of harmonisation and predictability, all leading to long or unknown time to placing on the market of a new BP.

A.I.S.E. and Biocides for Europe ran an industry Survey between November and December 2020 to assess whether the opportunities brought in by the BPR were fulfilled, to pinpoint any challenges, and suggest areas for improvement based on the industry's experience.

A.I.S.E. represents the European manufacturers of cleaning, hygiene, and disinfectant products. Its membership totals 29 national associations, covering about 900 companies ranging from small and medium sized enterprises to large multinationals. BPs manufactured by A.I.S.E. members include a vast range of disinfectants for household and institutional use, as well as insect control products.

Biocides for Europe (formerly known as EBPF), a Sector Group of Cefic[4], is an industry platform that brings together more 63 member companies, both active substance (AS) manufacturers and BP formulators, 9 trade associations and 11 national federations. Its members, SMEs and multinationals, place on the market a wide range of disinfectants, preservatives, pest control products and antifouling products. The portfolio of its members covers the 4 main groups of BPs and almost all the 22 product types[5] defined in the BPR and serve industrial, professional and consumer users.

[3] REGULATION (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products

[4] The European Chemical Industry Council https://cefic.org/

[5] Product types under the BPR - ECHA

The Survey was shared with all the members of A.I.S.E. and Biocides for Europe, respectively, including companies and national federations (and their members), but also associated members of Biocides for Europe (FECC[6], Croplife Europe[7], CEPE[8], BACS[9], TEGEWA[10] and EuroChlor[11]).

Recognising that BPs play a very important role in various industries, the Survey has also been shared with the 8 industry associations listed below, users of BPs with an invitation to forward the Survey to their Membership.

- CEPA - Confederation of European Pest Management Associations
- EDANA - European Trade Association for the Nonwovens and Related Industries
- EFCC - European Federation for Construction Chemicals
- EFCI - European Cleaning and Facility Services Industry
- EOSCA – European Oilfield Speciality Chemicals Association
- EWPM - European Wood Preservative Manufacturers Group
- FEICA - Association of the European Adhesive & Sealant Industry
- FDE - Food and Drink Europe

All Survey responses were treated as strictly confidential. Consequently, the data and comments presented in this report are in aggregated form only and as such are not identifiable to any individual person or company.

Follow up interviews were held with a subset of 25 companies that responded to the Survey. The companies selected included large and small businesses, different industry types and different roles in the biocide supply chain. Interviews were held during December 2020 and January 2021.

This report is an overview of the responses.

[6] The voice of Chemical Distribution in Europe: https://www.fecc.org/
[7] European Association of Crop protection industry: https://croplifeeurope.eu/
[8] The voice of paint, printing ink and artist's colour in Europe: https://www.cepe.org /
[9] British Association For Chemical Specialities: https://bacsnet.org/
[10] Association of Manufacturers of Process and Performance Chemicals: https://www.tegewa.de/en/
[11] https://www.eurochlor.org/

1. Survey Participation

The findings are based on the input received from *ca* 100 companies of which a 40% identified themselves as SME. These companies represent the entire biocides industry from ASs and BPs manufacturers to distributors, treated articles (TA) manufacturers and BP users.

Many companies identified themselves as having **multiple roles in the supply chain** (Figure 1), with 'BP manufacturer' the most common, followed by 'BP distributor' and 'TA manufacturer'. A relatively small number of companies identify themselves as only 'AS manufacturer' or 'AS distributor'.

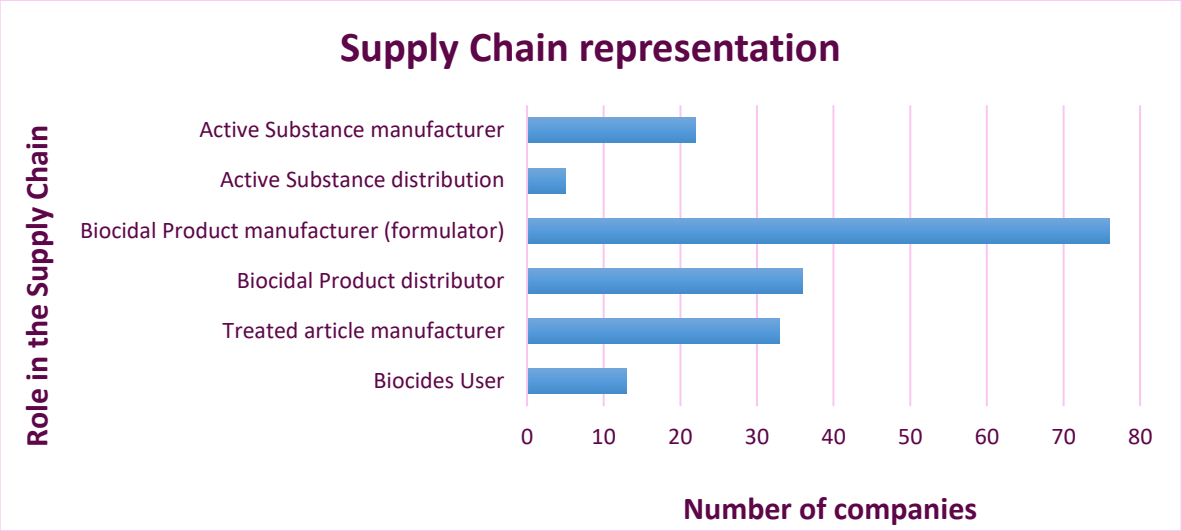


Figure 1.Supply Chain representation

The companies responding were both national and international companies operating in the biocides industry located (head quartered) **in most areas of the EU,** with a high proportion located in France and Germany (Figure 2).

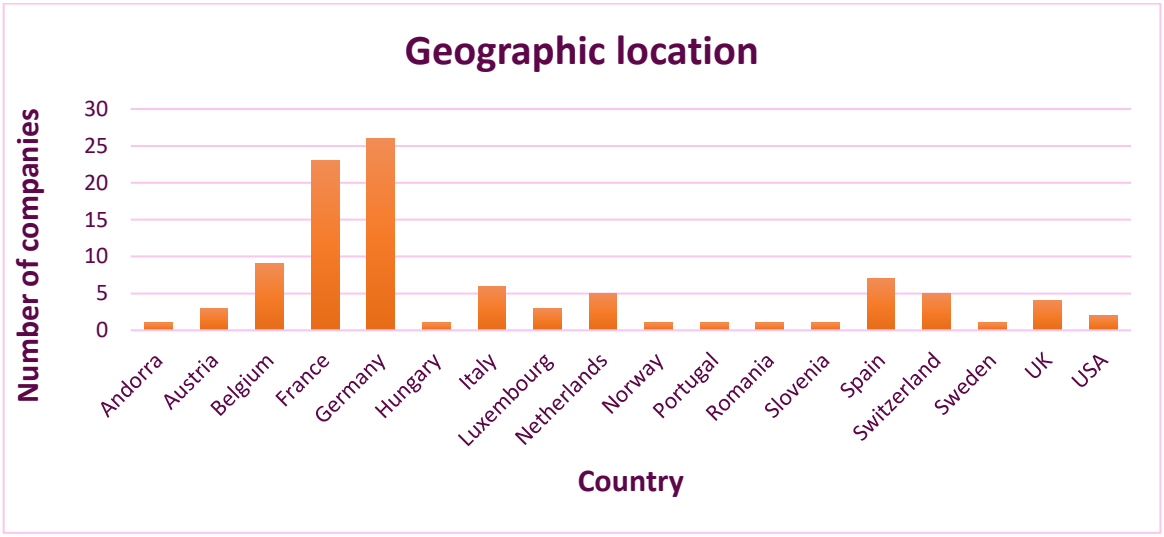


Figure 2. Geographic location

The majority of companies responding identified themselves as **active in both EU and global markets** (*ca* 70%), with a smaller proportion (*ca* 30%) only active within the EU (excluding the UK).

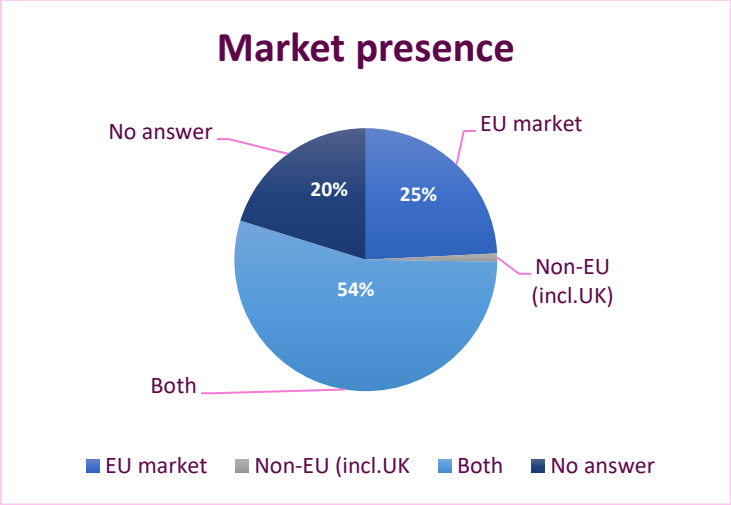


Figure 3. Market presence

And the majority of companies responding indicated biocides to be the 'major part', or the 'significant part', of their overall business (Figure 4).

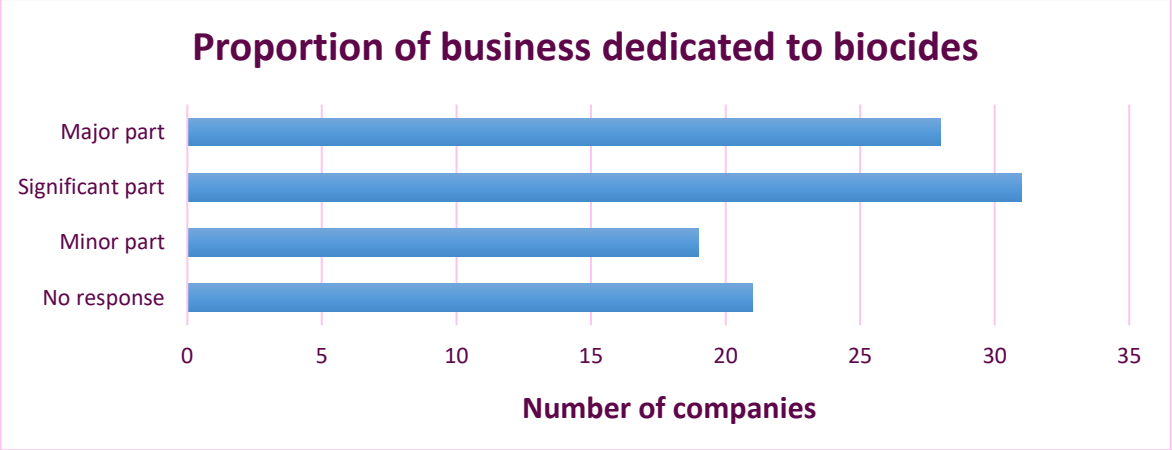


Figure 4. Proportion of business dedicated to biocides

Most companies identify themselves as **active in multiple markets** (Figure 5), with 'industrial/professional', 'professional/consumer' and 'consumer/professional/industrial' the most common. The results clearly illustrate the diverse nature of the biocide market and its role in many different areas of business.

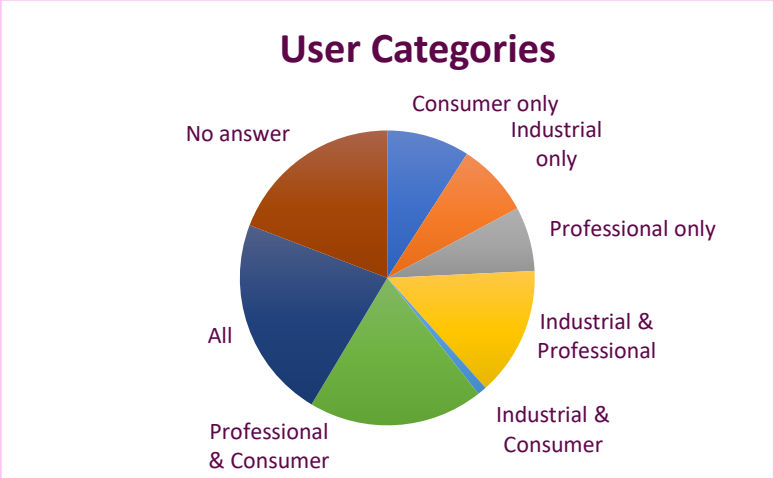


Figure 5. User categories

Information on the distribution of business activity with respect to PTs (Figure 6) shows the **most common activity is disinfection, in particular PT2 and PT4**. Business activity in PT1 is also high, enhanced due to the ongoing COVID-19 crisis which was a point emphasised in follow up interviews. PT6 and PT11 are the most significant areas of business for preservative biocides, whilst pest control concentrates mostly on rodenticides PT14, insecticides PT18 and insect repellents PT19.

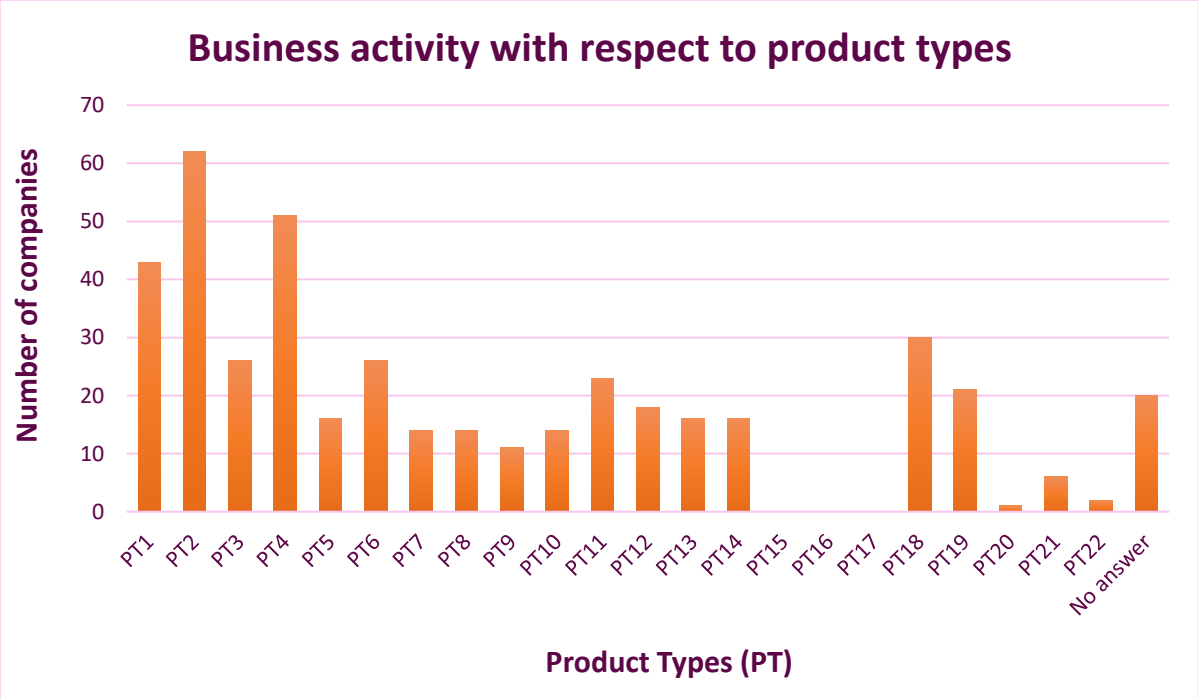


Figure 6. Business activity with respect to PTs

The eight **industry sectors** engaged in the survey (CEPA, EDANA, EFCC, EFCI, EOSCA, EWPM, FEICA, FDE) involve the use of TAs or are users of BPs and represent a wide variety of downstream user sectors.

Companies responding are active in all the sectors suggested (automotive, food/beverage, pharma/healthcare, pulp/paper, textiles, and construction), with pest-control identified as an additional use under 'other' (Figure 7).

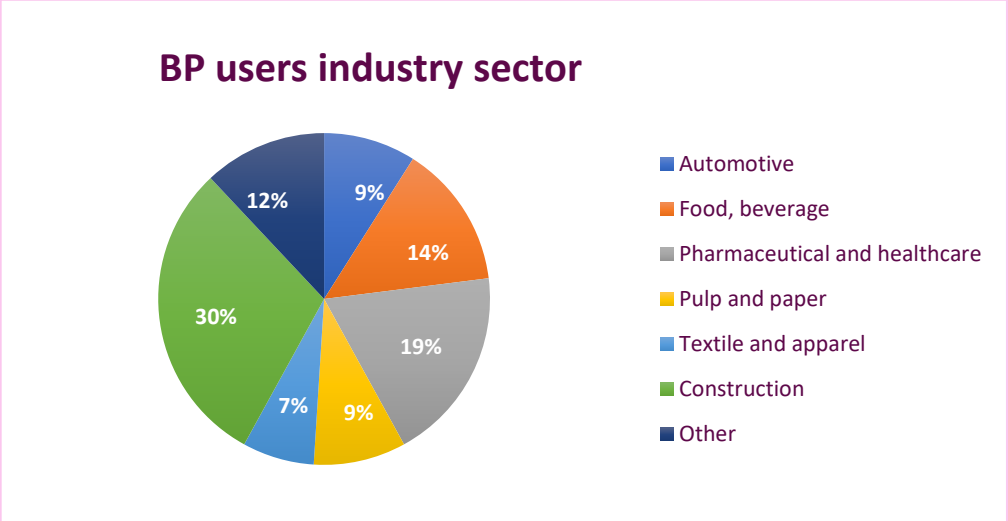


Figure 7. BP users' industry sector

Information on the distribution of the respondents' business activity, with respect to PTs (Figure 8), showed that the **most common activity was disinfection**, in particular PT2. PT6 was the most significant areas of business for preservative biocides, whilst pest control focused mostly on insecticides and insect repellents.

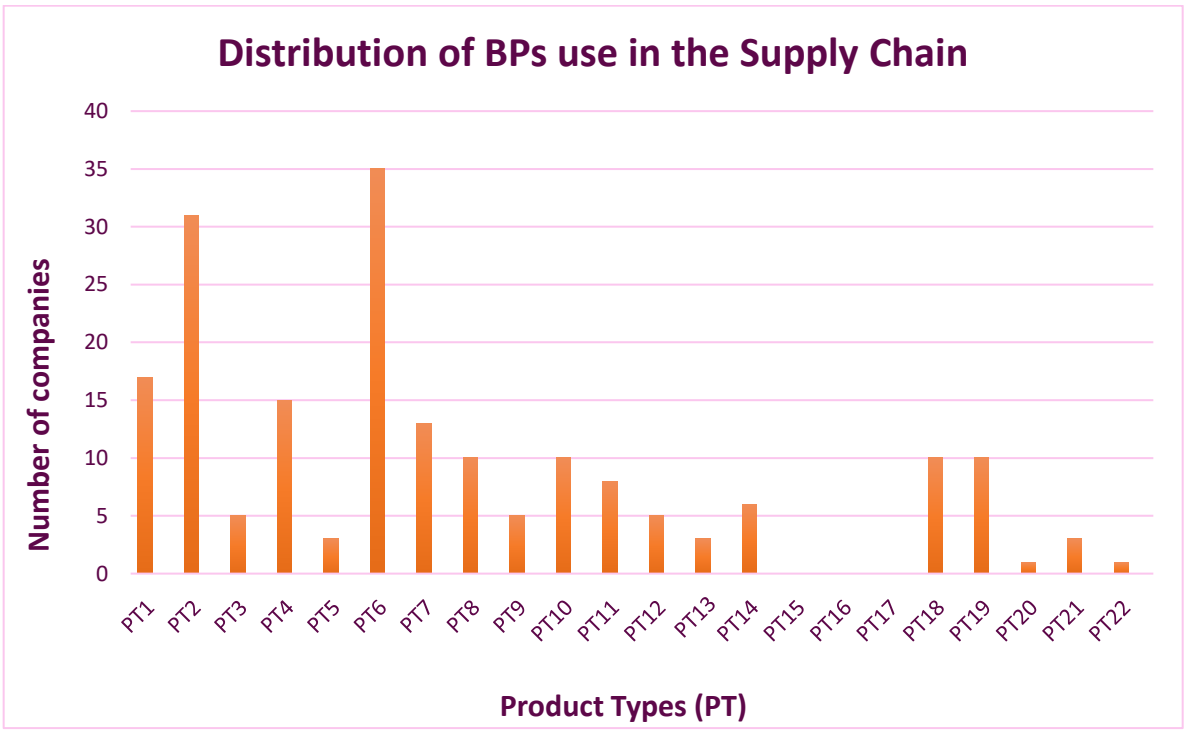


Figure 8. Distribution of BPs use in the Supply Chain

2. The implementation of the BPR and its impact on EU business

2.1. The BPR implementation

BPR was received with high expectations by all stakeholders. Main expectations from industry were that BPR would create a level playing field by simplifying and streamlining processes (e.g. Article 95 list, Review Programme deadlines for all AS per PT, etc) leading to a high level of harmonisation of BP authorisations.

The Survey explored industry's view on the implementation of the Regulation. The following is a summary of the main topics identified from the responses.

The aim of the BPR is to have **safe BPs** on EU market - *ensuring a high level of protection of both human and animal health and the environment* – but this should recognise a proper balance of hazard and risk in assessments for AS approval and BP authorisation. Instead, the introduction of hazard-based decisions at the AS approval level, brings a disproportionate level of regulation. This stops the process and prevents a proper Risk Assessment of the BP, based on exposure under realistic conditions of use, which would allow for appropriate Risk Mitigation Measures at the BP authorisation level, where needed.

The BPR provides the legal framework to **create a level playing field** – *the free movement of products within the Union*. It provided **clear timelines** for AS approval and subsequent BP authorisation and put in place processes, such as the mutual recognition procedures, to ensure **harmonisation**.

But the implementation of the BPR came before guidance/legal clarity was available and the timelines set were too ambitious considering the lack of resource/experience within Member State Competent Authorities (MSCAs). The timelines for authorisation differ significantly, interpretation of EU guidance is different, and MS national processes are still applicable until the Review Programme and authorisation of BPs are completed.

In 8 years, the implementation of the BPR became **extremely complex.** This causes significant **delay** in delivering decisions for ASs and BPs and makes the outcome completely **unpredictable** but also deviates from the main aims of the legal text, **harmonisation** and **level playing field.** The result is the **distortion of the market**. Furthermore, due to the complex implementation, the **cost of compliance** affects SMEs disproportionately.

Such **non-harmonised biocide market** has visible consequences and, in the absence of support for the biocides industry within the EU, companies look for alternatives outside the EU.

In order to deepen these responses, the Survey invited companies to rate their level of satisfaction with different aspects of the implementation for the following regulatory processes:

- AS review programme.
- New AS assessment process.
- Union authorisation (UA).
- Mutual recognition (MR).
- Biocidal Product Families (BPF).
- Simplified authorisation procedure (SAP).

The level of satisfaction was rated against companies' expectations on a scale of 1 to 5 where five represented fully meeting expectations.

Figure 9 shows the range of opinions received on the **AS review programme**.

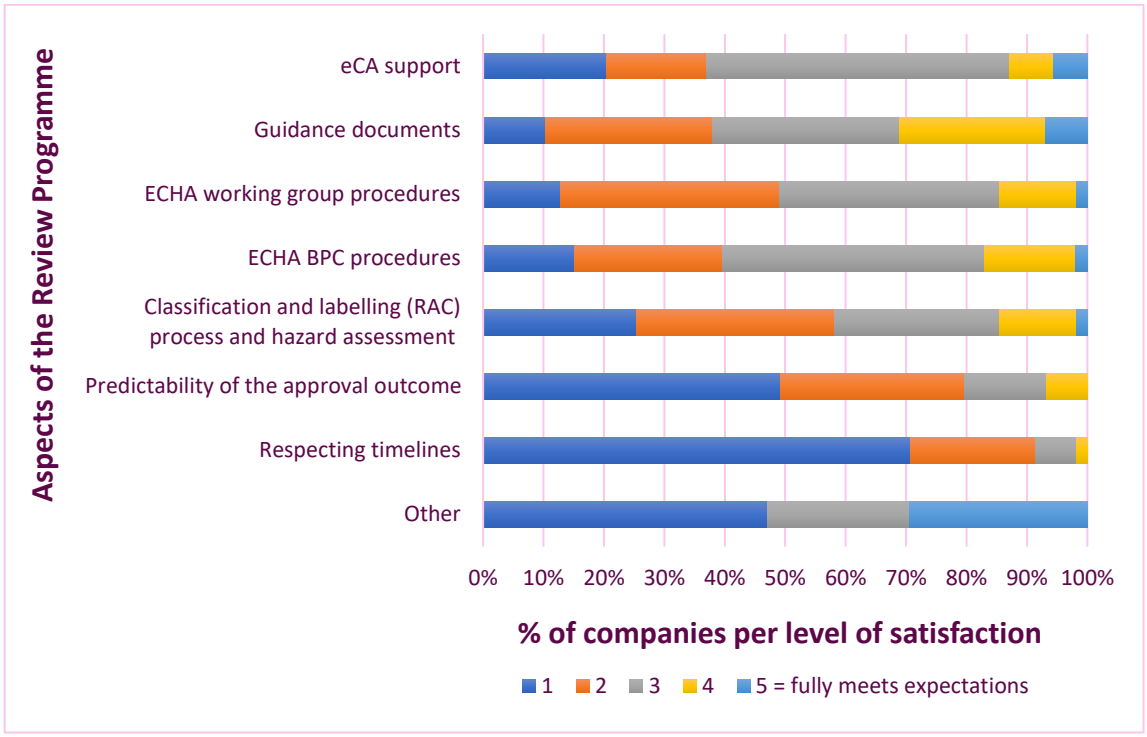


Figure 9. Satisfaction level around various aspects of the AS Review Programme

Support provided by the evaluating CA (eCA) received a mostly neutral opinion. As positive feedback companies indicated many eCAs were helpful, but in some cases, communication was slow or offering limited help. Companies appreciated pre-submission meetings with MSCAs and greater access to this resource was requested. Companies use the pre-submission meeting with the eCA as a way to ensure dossiers contain the correct information before submission. The satisfaction level regarding guidance documents was equally spread. Company comments cited issues with guidance coming too late in the process and sometimes with limited or very late access to applicants during guidance development. However, the highest concern around guidance for the respondents is the inconsistent application among MSs, particularly for MR authorisation.

The level of satisfaction with ECHA Working Group, BPC and RAC procedures was generally low. Various issues were cited as reasons for low ratings, including lack of coordination between WGs, a small number of MSCAs leading continuous development of guidance and steering policy during evaluation and a lack of transparency during commenting.

Predictability of the approval outcome and respecting **timelines** were the areas where companies had the most concerns. **Changing guidance** during an ongoing process was the main reason for the lack of predictability.

The opinion of companies supporting **new ASs** was broadly similar to that expressed for the review programme as it is shown in Figure 10. Predictability of the approval outcome and respecting timelines were again the areas of highest concern for companies, especially since delays are blocking the access to the market.

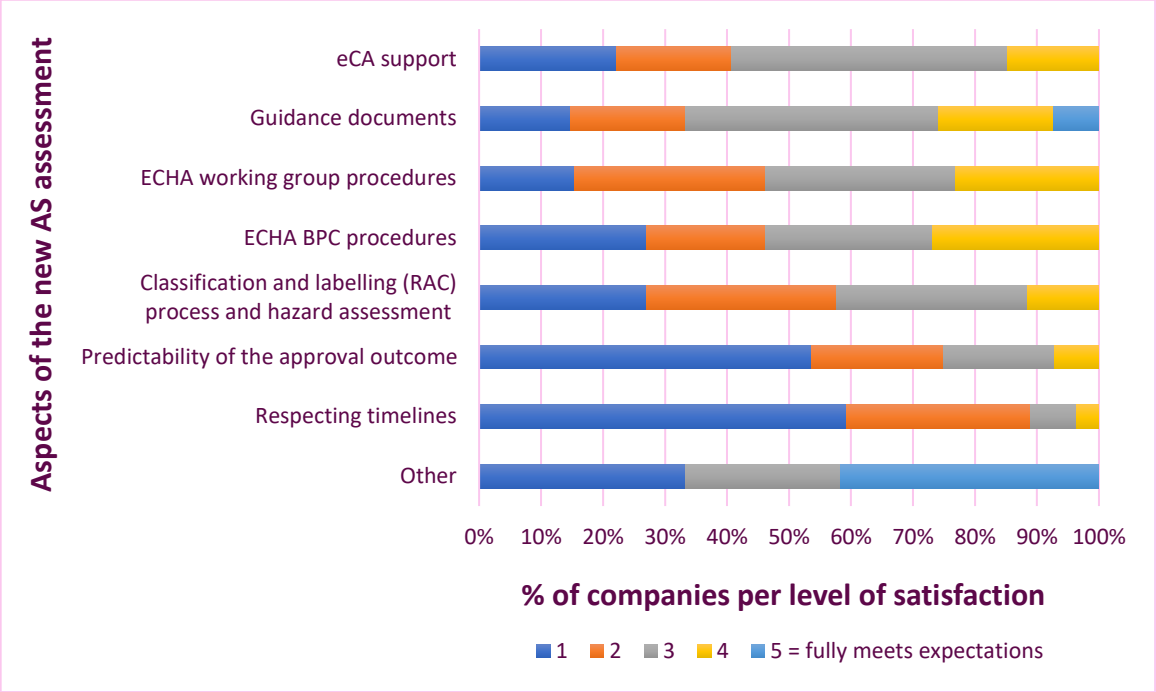


Figure 10. Satisfaction level around various aspects of the New AS assessment process

Regarding UA, as illustrated in Figure 11, the opinion of the level of support available from eCAs and ECHA, and eligibility for UA was overall neutral with some companies indicating expectations not met, whilst others appeared to be satisfied. Difficulties encountered were typically the result of **poor communication or inconsistent application of guidance**.

Overall, the business value of UA did not meet company expectations, influenced mainly by the **disproportionate amount of time** necessary for approval, the lack of flexibility in the procedure (e.g., inability to make minor formulations changes) and overall, the high cost involved.

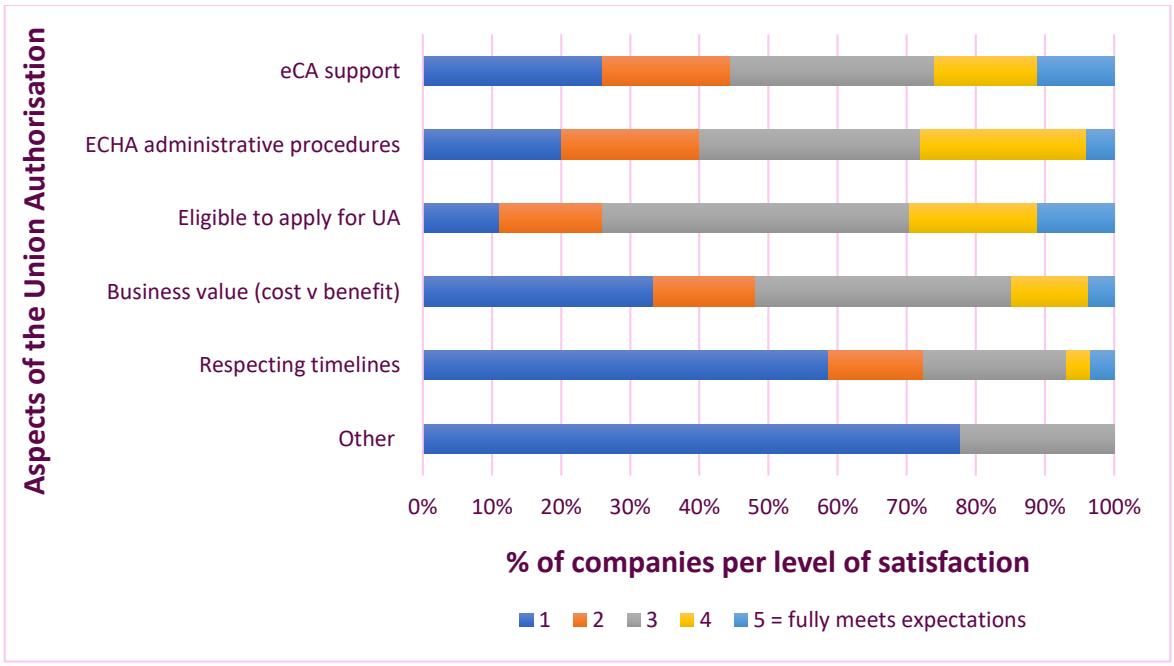


Figure 11. Satisfaction level around various aspects of the Union Authorisation process

Expectations regarding eCA support for MR, reported in Figure 12, were generally met, although experiences varied between different MS. Administrative processes were thought to be too complex, although again there was variation between MS. Consistency, predictability and business value for MR did not meet expectations with companies rating these aspects less than 3 out of 5 in the majority of responses. **Inconsistency** was a concern especially the different interpretation and application of guidance between different MS. **Respecting timelines** was again a significant area of concern.

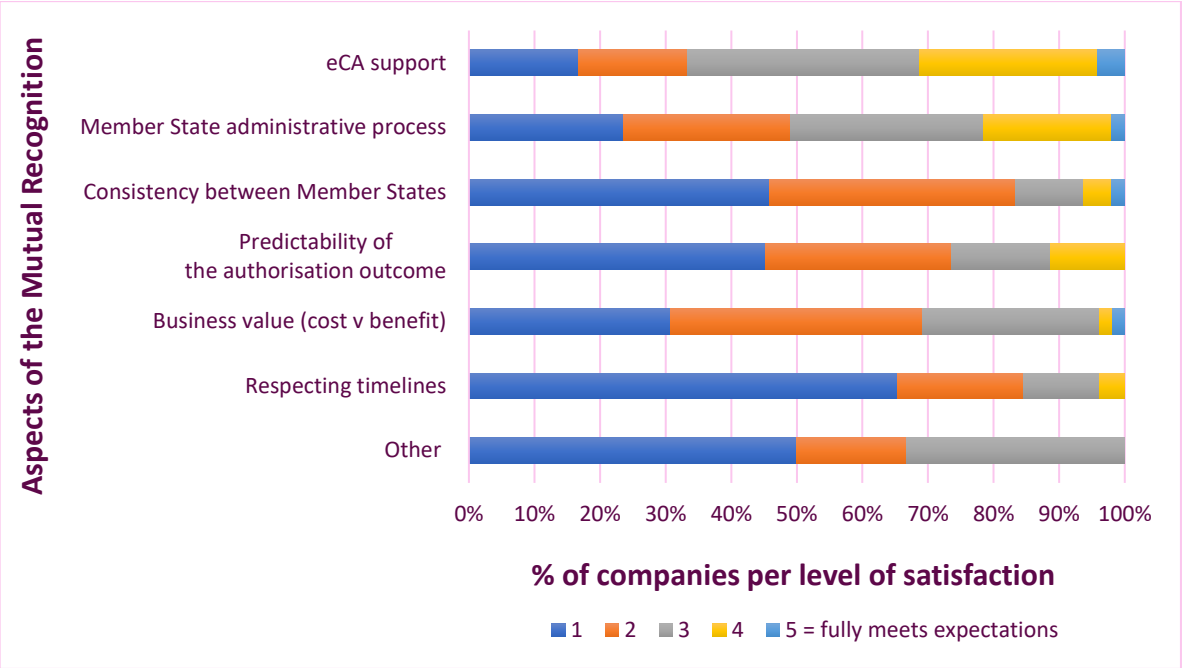


Figure 12. Satisfaction level around various aspects of the Mutual Recognition process

Company expectations regarding eCA support for the BPF process, as shown in Figure 13, are generally met. But the level of support and **communication** with MS is variable according to the feedback received.

Opinions on the criteria to construct the BPF were rather negative. The criteria to construct the BPF are too complex according to companies. Identifying worst-case scenarios for efficacy, stability and risk assessment is challenging and MS applying new criteria to ongoing assessments is a significant concern as this fundamentally changes the expectations of the BP authorisation application.

Expectations regarding availability of BPF guidance were mixed with the particular concern of guidance arriving after dossier submission.

The expectation with respect to the business value of BPF was generally more negative. **Cost and respecting timelines** were concerns, with a high proportion of companies stating that timelines did not meet expectations.

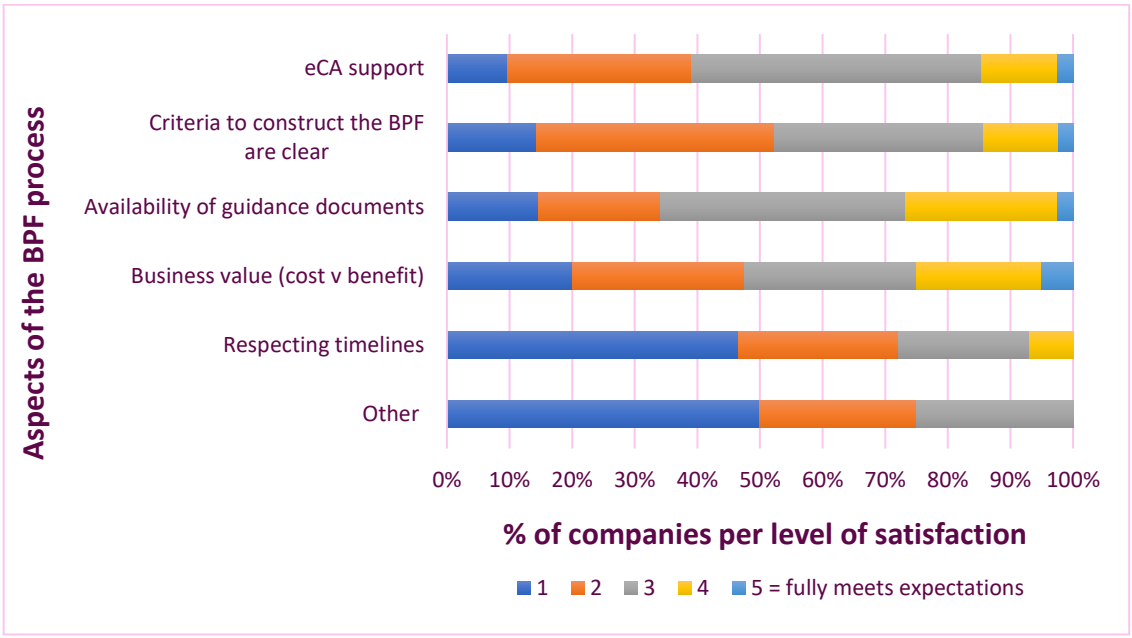


Figure 13. Satisfaction level around various aspects of the BPF process

Figure 14 shows the opinions received on the Simplified Authorisation process. In general, eCA support, eligibility for authorisation and predictability of outcome were meeting expectations and the concept of SA was providing business value. As seen with other regulatory processes, the issue of **respecting timelines did not meet companies' expectations.**

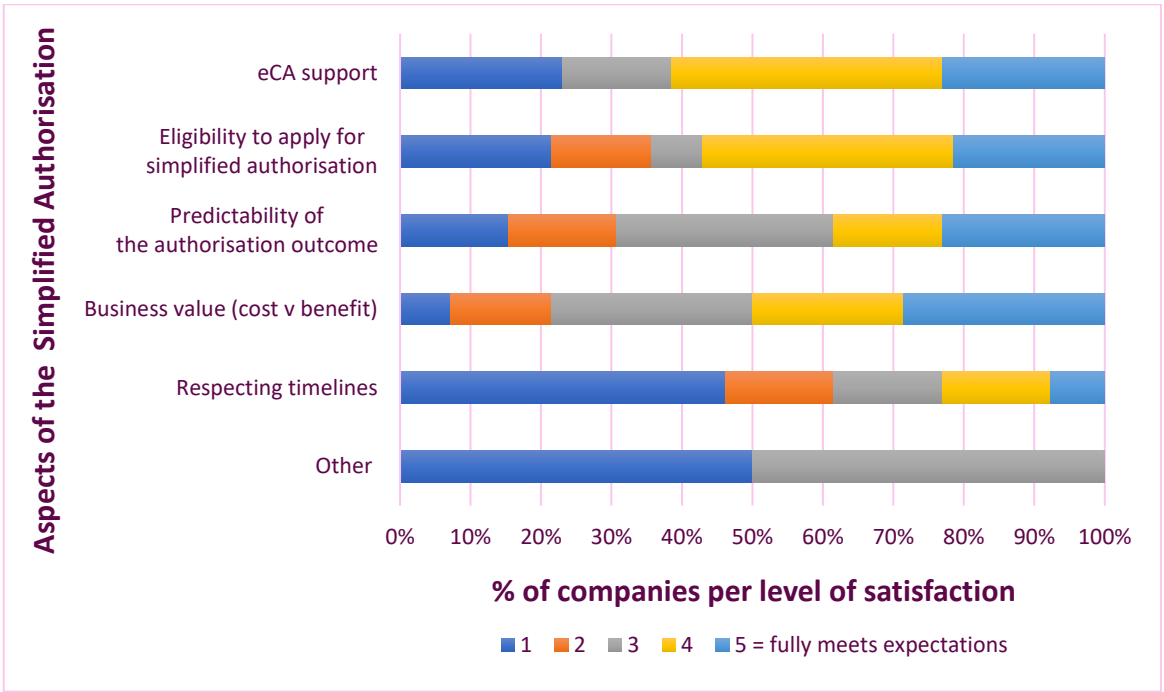


Figure 14. Satisfaction level around various aspects of the Simplified Authorisation Procedure

2.2. The impact of the BPR implementation on the biocides business

The Survey also explored how the challenges faced in the different regulatory processes have impacted the BPs businesses and market. Figure 15 represents how new regulatory processes introduced by the BPR had influenced the changes in the size of companies' biocide business.

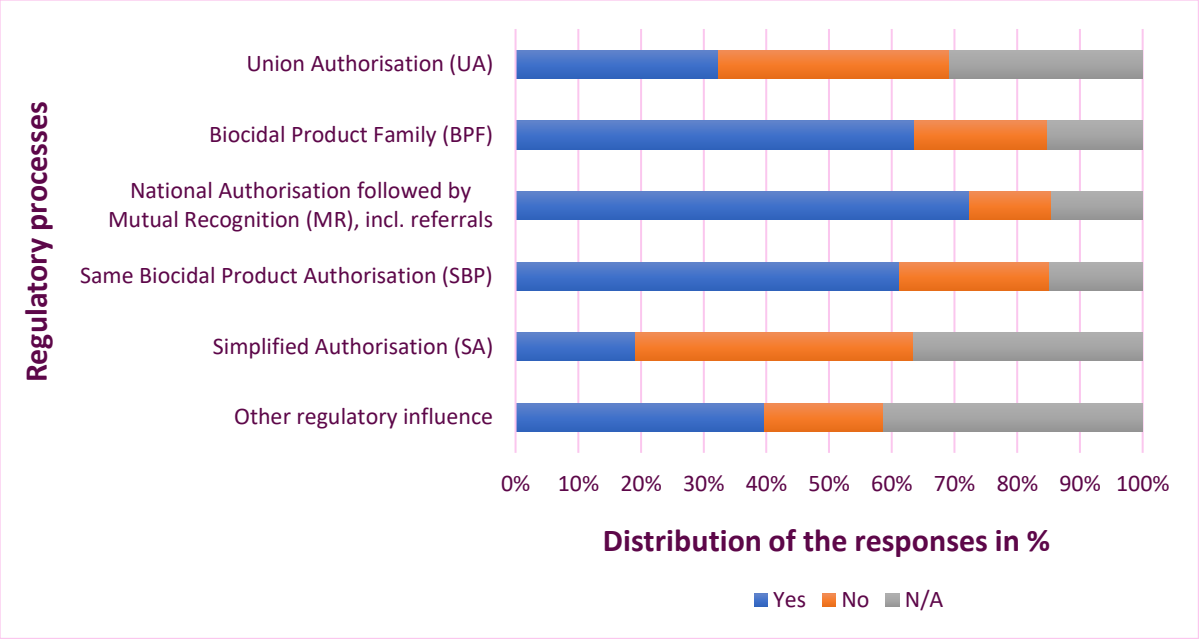


Figure 15. Influence of Regulatory processes on the biocides market/business

Overall, for those companies responding to the Survey, BPF, BP authorisation via MR and SBP were the regulatory processes significantly influencing the size of the biocide business. The effect of UA was broadly neutral, whilst SAP had little effect on the changes seen in biocide business activity.

Companies indicating a positive influence on their business did cite the intended benefits of BPF, MR, SBP and UA, namely ease of application, harmonisation and the potential for cost reduction.

However, far more companies cited problems with the implementation of these regulatory processes, notably the following key issues came up multiple times during feedback, as the common reasons:

Length of processes and delays

Length of time to achieve AS approval and/or BP authorisation is a **disincentive to innovate** as market opportunities change more rapidly than the time needed to complete the process. For new ASs and BPs, the lack of market access over this time means no revenue generation to fund the high level of cost before authorisation.

Delays to the approval of ASs makes it difficult to implement a clear strategy to support BPs (e.g., keep a coherent portfolio; make investments in staff and plant). The long evaluation time for BP dossiers, with delays varying between a few months and a few years above the legal timeline of 3 years, places a freeze on the development of improved BPs (e.g., reducing AS content, substituting with 'greener' chemistry alternatives).

Factors increasing the length of MR authorisation process often result from disagreements between reference and concerned MS on risk assessment and data. Involvement of the Coordination Group (CG) should facilitate the process and minimise/reduce delays, but in many cases additional delays occur as other MS (not concerned) join the discussion and ask for modifications as a result of the discussions.

The fact that sometimes authorities do not have adequate and/or sufficient resources has a clear and obvious effect on the processes.

Unpredictability and complex rules. Changing guidelines/requirements

The length of the processes for AS approval and BP authorisation increases the likelihood that guidance and data requirements change during the evaluation phase. A proper balance needs to be ensured when developing guidance between must have and nice to have guidance and also the applicability time needs to be carefully considered.

On the one hand, without proper guidance, industry and authorities do not know what standard to achieve, which results in bespoke decisions and a lack of harmonisation between different AS/BP evaluations.

On the other hand, changes to guidance during BP evaluation creates uncertainty (e.g., TA claims, claims for enveloped viruses for PT2) and changes the viability of BP formulations under review (e.g., requiring new data to support the evaluation that was not envisaged at the outset).

Companies also noted that the framework of the guidance can be too rigid, for example, efficacy guidance does not always reflect the diversity of uses and claims that are necessary in practice. This situation can lead to a divergence of the BP or use from the PT it was belonging. This has serious consequences, and not only results in extra cost, as each PT requires new fees and extra resources to prepare and evaluate applications, but also may jeopardise the placing on the market of the BP if the reallocated PT has not been supported in the AS approval

In addition, efficacy claims are becoming more restrictive, but the requirements dealing with the norms (testing) do not always correspond to the use - e.g., medical norms are requested for laundry disinfection for the general public. (

Companies frequently commented on the complexity of the BPR and the unpredictability of the approval and authorisation processes for ASs and BPs, respectively. In particular, the development of policy and guidance during evaluations create a high degree of uncertainty on the outcome and it was strongly emphasised that evaluations should progress using rules existing at the outset. Companies recommended that updates should only apply to new applications or applied at renewal for ongoing applications. Guidance applied to already submitted dossiers that have passed their evaluation deadlines represents extra costs and delays that the applicant did not estimate and has no control over.

Together with the changes in guidance and applicability of new guidance to dossiers under evaluation, respecting timelines and the lack of consistency among MSs were issues emphasised by companies when referring to the predictability of the outcome

Fees and costs

Costs include consultancy fees, internal resources, fees for testing, Authority/evaluation fees, fees for letters of access, as well as the cost to make the BP, which is affected by raw material (AS) costs. However, the biggest concerns shared by the respondents of the Survey were related to the high evaluation fees and the obligation to be paid upfront in most MS, without any indication on the timelines of the evaluation and the outcome.

The Survey also explored how the different regulatory opinions have impacted the BPs businesses and market. Figure 16 represents the industry view.

A high proportion of companies responding to the Survey indicated that availability of ASs, restriction or re-classification of ASs had influenced the change in their biocide business and the majority of these companies indicate the influence was detrimental to their business. Negative effects dominated the responses received from companies. In the feedback received, removal (e.g., non-approval decision) of ASs had the predictable outcome of removing BPs from the market and many responses indicate reformulation as a significant negative effect due to cost and regulatory uncertainty.

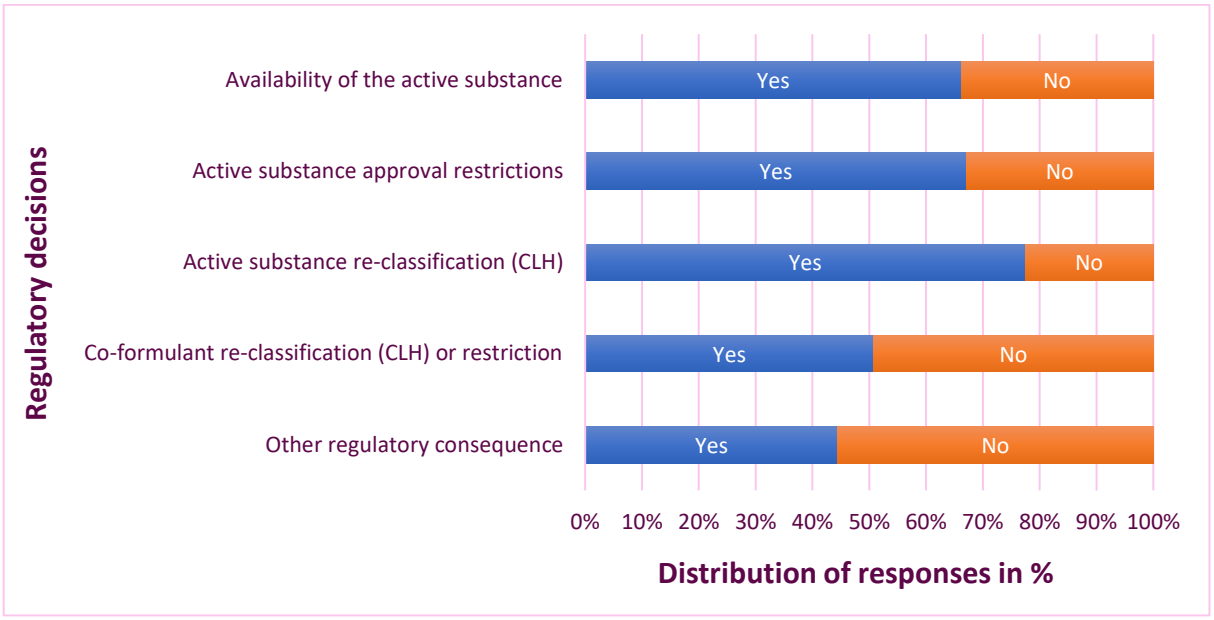


Figure 16. Influence of Regulatory decisions on the biocides business

Figures 17 and 18 illustrate how regulatory costs and length of regulatory processes respectively have influenced the biocide business of the companies.

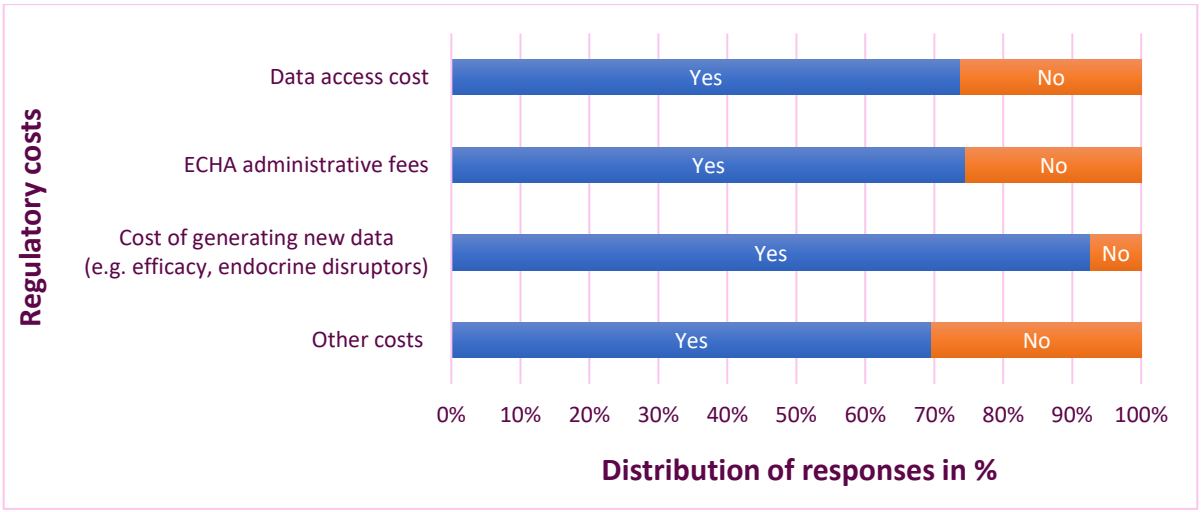


Figure 17. Influence of Regulatory costs on the biocides business

Predictably, the regulatory costs are influencing changes in the biocide business, according to >70% of companies that have indicated an increase in costs due to evaluation fees, data generation, consultancy and legal advice, administration, BP reformulation, staff recruitment, retention, and training.

The increased regulatory costs force companies into reducing their biocide portfolios but more importantly it decreases the fond allocated **to research and development**.

A specific point noted by companies was the wide range of fees charged by MSs for AS and BP evaluation. **The difference in MS fees** was a significant driver of companies' choice of markets.

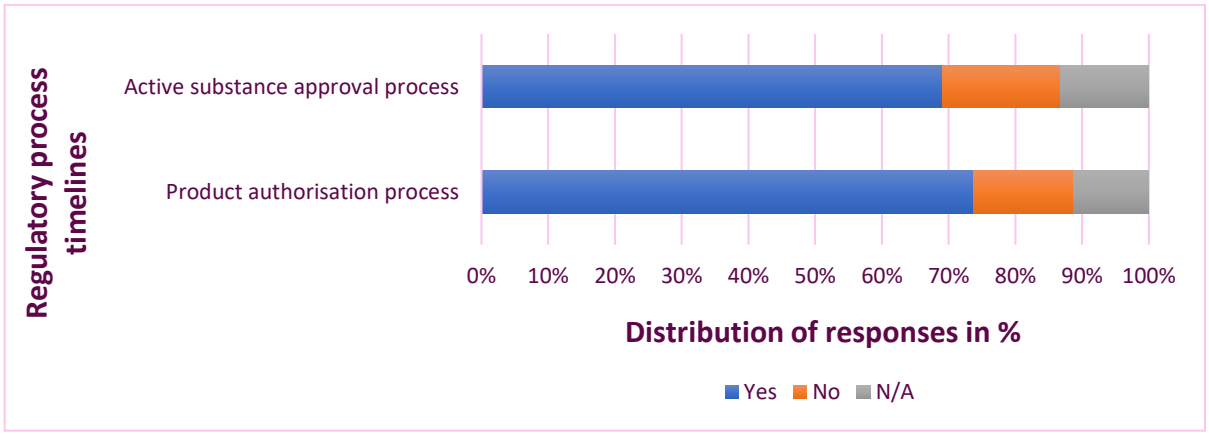


Figure 18. Influence of Regulatory timelines on the biocides business

Companies considered the time taken to approve ASs and authorise BPs had a significant influence on their business, with over ca 70% citing this as a reason for the change of the biocides market. Specifically, the **long evaluation process** created a barrier to developing new markets because it restricted the ability to plan, respond quickly to new market opportunities and adapt formulations in response to other market changes. **Delays in the evaluation process resulted in significant uncertainty,** with changes in guidance cited by companies during feedback as a particular problem.

2.3. Looking at the future

When the Survey invited companies to predict the likely future of their biocides business, most companies refrained from providing a forecast and pointed to the **impossibility of future predictions due to the complexity of procedures.**

From the responses, some companies experienced an increase in their disinfectants' business due to high demand during the Covid-19 pandemic. The development of new markets via the MR process and the loss of competition due to high cost and complexity of the BPR were other general reasons for an increase in business.

Decreases were attributed to the domination of the market by larger companies, many having responsibility (control) for AS approval and data access. The high cost of BPR procedures and the cost of maintaining existing BPs on the market (e.g., data, fees) creates a barrier to market access resulting in fewer BPs. The decreasing availability of ASs has a direct impact on BP availability, whilst indirectly the negative image of biocides due to an association with pesticides or concerns regarding Endocrine Disruption also has a downward pressure on BP availability.

The Survey also explored the opportunities that BPR provides to improve its implementation. Companies were invited to comment on changes they would propose.

In general, the **suggested changes** to the BPR processes indicate a desire for **clarity** with respect to what is required of applicants and authorities as well as **consistency** in implementation, **enforcement** of requirements and respecting the legal **timelines**. There was also a strong call to return to a **risk-based evaluation** scheme rather than hazard-based assessment and to **reduce complexity** of the processes and changes of data requirements during the evaluation.

3. Innovation

The Survey dedicated a specific section to innovation. The aim of this section was to quantify the impact of the BPR and its implementation on innovation.

Companies were asked to indicate the number of new BPs/formulations per PT that they had introduced in the EU market since the entry into force of the BPR. The five PTs with the highest number of new entries of BPs / formulations are PT2, PT4, PT1, PT18 and PT3. Most of the new BPs / formulations introduced per PT were in the less than 5 BPs per company range.

According to the responses, a very low number of companies are developing a new AS, as shown in Figure 19. The vast majority of companies are either re-formulating with an existing AS or developing new markets with existing formulations via new claims.

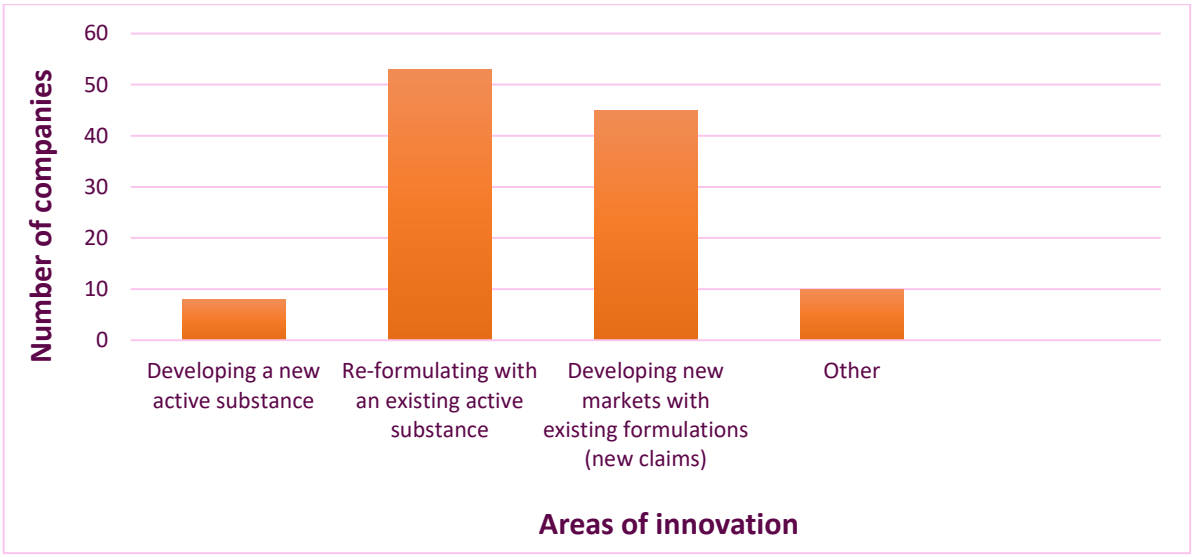


Figure 19. Areas of innovation

Figure 20 shows the influence of various aspect of the BPR on innovation.

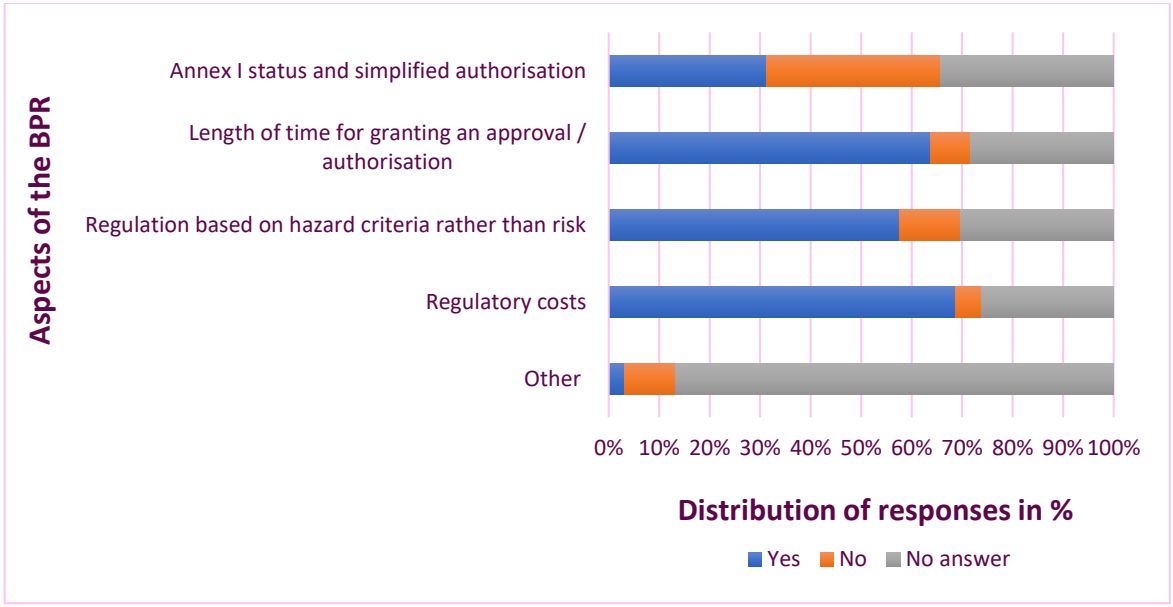


Figure 20. Aspects of the BPR influencing innovation

In general, the comments point towards high costs due to the lengthy timelines, changes in guidance, long and unpredictable timelines being a hindrance to innovation. **Regulatory costs** are having the greatest impact on innovation in the biocide business and are causing a freeze in R&D. The costs of BPR processes and the unpredictability of the outcomes create a high uncertainty for investment in innovation.

A similar number of respondents considered Annex I status and SAP influenced innovation or not. Companies explained that while, on the one hand, the list of AS ingredients in Annex I is far too limited at present, on the other hand Annex I ASs typically do not offer the level of efficacy of another ASs. However, the fast process for SAP has been recognised as a reason for customers to choose BPs containing AS listed on Annex I of the BPR. The speed of the SAP grants a presence on the market with lower risk.

The **length of time** for granting an approval / authorisation was cited as a significant disincentive for innovation in the majority of Survey responses.

For the majority of respondents, innovation is negatively affected by regulation that is based on **hazard criteria** rather than risk. Comments state that other regions of the world have relatively more innovation due to the use of a risk approach.

Importantly, the hazard-based approach does not properly reflect the real risk of a BP. The use of hazard criteria is causing companies to reformulate BPs, which in practice does not minimise the overall risk profile of the BP in many cases.

4. COVID-19

The Survey also dedicated a section to COVID-19 as the most recent example of the challenges in implementing BPR for the parties involved.

The aim of this section was to learn about the impact of the crisis on the biocides business, how the implementation of the BPR helped to ensure the availability of disinfectants on the market and the lessons learnt from the experience.

A significant number of Survey respondents experienced an increase in the market for their BPs due to the COVID-19 pandemic. The specific markets noting an increase were PT2, PT1 and PT4 being those associated with disinfection.

About a third of the Survey respondents were not involved in the disinfectants business before COVID-19 and these were evenly split when asked if remaining in the disinfectants business was an option once the crisis was over.

The use of emergency authorisations in Member States was a common method of entering the market, using either Art. 55.1 BPR (in case of approved AS), national measures (in case of not yet approved AS) or both. Figure 21 documents the MS in which the Survey respondents applied for emergency permits.

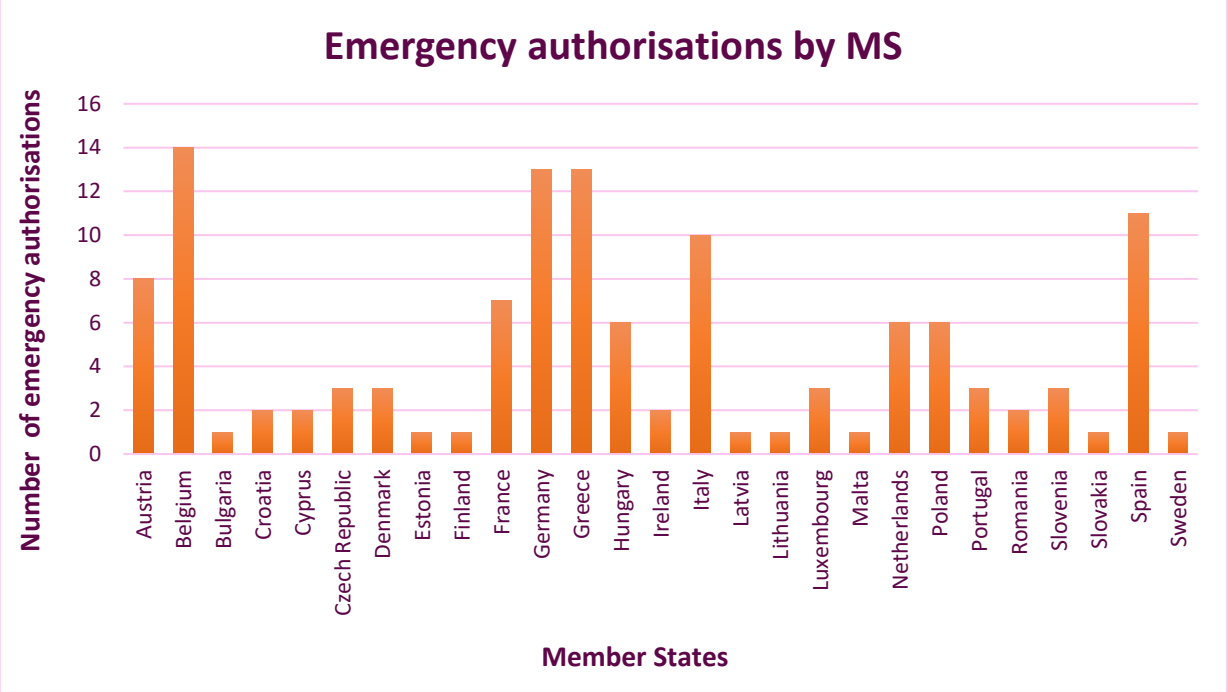


Figure 21. Emergency authorisations by MS

In general, the MSs with the highest number of applications are also the MSs that the Survey respondents identified as having the best emergency permit practice, which were commonly: **predictability, clarity, pragmatism and speed**. A number of MS were mentioned specifically, namely:

- Belgium - open to discussion, rapid but still with checks on efficacy, predictable
- Germany – pragmatic, clear guidance and rapid
- Spain – predictable process
- Luxembourg - rapid
- Netherlands - rapid but still with checks on efficacy

The regulatory elements that hindered the process were Article 95, labelling, length of process, legal entity, complexity and lack of harmonization.

The Survey also invited companies down in the supply chain (TAs' manufacturers and BPs users) to say if the COVID-19 crisis had impacted their business significantly.

Overall, the impact of COVID-19 was mainly a delay and shortage in supply chains and higher prices, affecting about 50% the companies that responded. The need for biocides was affected both positively and negatively, with companies seeing an obvious increase in disinfectant use but also a reduction in business activity due to a general downturn in economic activity.

Closing remarks

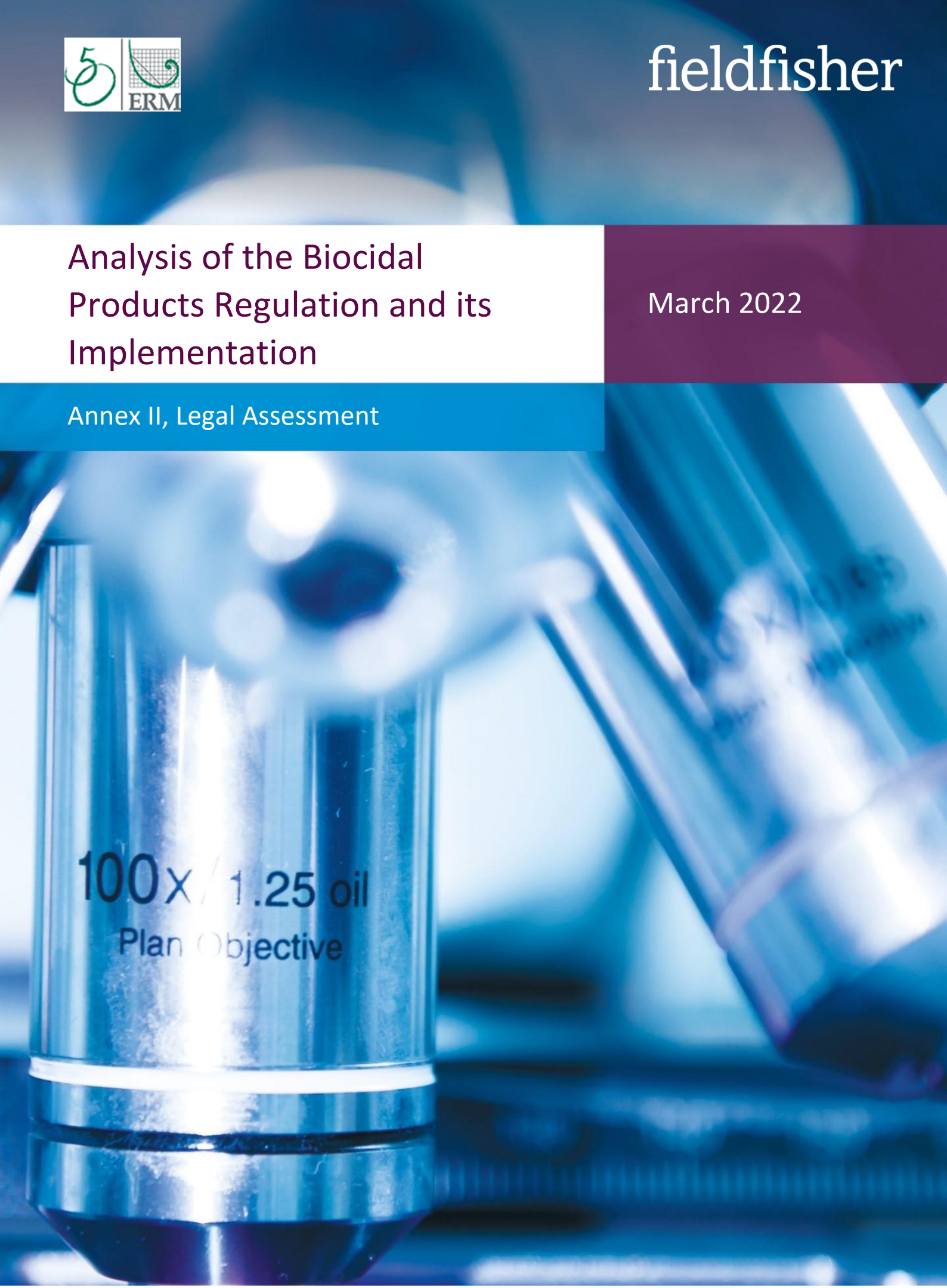
The Survey is part of a broader project run by A.I.S.E. and Biocides for Europe on the assessment of the BPR and its implementation. This report simply provides a factual overview of the questions addressed to industry and the contributions received to the Survey.

The analysis of the responses to the Survey will be an integral part of the final report of the BPR Assessment project.

Analysis of the Biocidal Products Regulation and its Implementation

March 2022

Annex II, Legal Assessment



Contents

1. The Biocidal Product Legislative framework: Overview of its aims and its processes

The Biocidal Products Regulation ("**BPR**")[1] came into effect on 1 September 2013 and replaced the Biocidal Products Directive ("**BPD**").[2] The BPR regulates the placing on the EU market(s) of biocidal products and treated articles, and limitations attached to their use. Biocides are used to control organisms that can, directly or indirectly, be harmful to human and animal health or cause material damage. Examples of biocides include disinfectants, preservatives, pest control products and others that act against harmful organisms. Only biocidal products which achieve their effect through the action of active substances ("**AS**") contained in the biocidal product (rather than through physical means) are regulated by the BPR.

Recital 3 provides the legislator's overall intention of the BPR with regard to biocidal products in the European Union ("**EU**"):

> *"The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups, such as pregnant women and children. This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment. With a view to removing, as far as possible, obstacles to trade in biocidal products, rules should be laid down for the approval of active substances and the making available on the market and use of biocidal products, including rules on the mutual recognition of authorisations and on parallel trade"*

That intention is captured in Article 1(1) of the BPR:

> *"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. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups…".*

The overall legislative intention seeks, therefore, to strike a balance between, on the one hand, the free movement of biocidal products within the EU with, on the other hand, a high level of human health and environmental protection. More focus is placed on the latter concern by reference to vulnerable groups and – in overarching fashion – the precautionary principle.

In order to strike that balance, the BPR sees the introduction of innovative concepts and mechanisms focused on facilitating freedom of movement within the EU (amongst them, union authorisations, biocidal product families and mutual recognition processes). To ensure fairness between competitors, the BPR also imposes data sharing obligations in certain circumstances which reduces free-riding concerns. The BPR also sees the introduction of various measures designed to increase the level of human and environmental protection such as the Article 5 (exclusion), and Article 10 (substitution) criteria for certain active substances.

The BPR also aims to achieve a greater level of harmonisation throughout the EU, as confirmed in Article 1(1) of the BPR. The choice of housing the innovations and intended improvements in a Regulation as opposed to a Directive

[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] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

was in particular designed to ensure that the law would be interpreted and applied more uniformly than was the case under the BPD.

The BPR aims to achieve the above aims through a complex set of rules and procedures which build on the work done under the BPD. An overview of the principal review procedures is provided below.

1.1 Review of new active substances

AS approval is required for all substances used in biocidal products marketed in the EU market. ASs which were not on the market by 14 May 2000 ("**new ASs**") are evaluated under the provisions of the BPR. Such ASs cannot be used in biocidal products or placed on the market until they receive approval.

The process of obtaining approval for a new active substance begins with the applicant preparing an AS dossier and submitting this to an evaluating competent authority ("**eCA**") for evaluation. The eCA then prepares a draft report referred to as a Competent Authority Report ("**CAR**"). The report is then submitted to the European Chemicals Agency ("**ECHA**") for peer review by other Member State ("**MS**") experts.

Prior to submission of the CAR to ECHA, the participant is allowed a 30-day commenting period on the draft CAR and the conclusions of the evaluation. Under Article 10(3), if the AS is a candidate for substitution, a public consultation is launched, allowing commenting by interested parties on ECHA's opinion on the approval or renewal of the AS.

ECHA's Biocidal Products Committee ("**BPC**") then prepares an opinion on the AS within 270 days of receiving the draft CAR. This opinion is sent to the European Commission ("**Commission**") which then makes the final determination, in consultation with the Standing Committee on Biocidal Products ("**SCBP**"), on the approval of the AS. The final act is adopted by the Commission through a comitology procedure under Article 82(3) of the BPR.

Under Article 5 of the BPR, with an eye on the protection of health and the environment, the BPR has introduced certain exclusion requirements for hazardous ASs such as carcinogens, mutagens, endocrine disruptors and reprotoxic and environmentally toxic substances. Relevant exceptions are allowed where there is a lack of alternatives and where the public health and societal benefits, arising from the use of the substance, outweigh their potential detrimental effects.

1.2 Review of existing ASs

Existing ASs refer to ASs which were already on the market by 14 May 2000 and were being reviewed under the BPD but whose review has not yet been finalised. The approval of these existing ASs is performed through the AS Review Programme ("**Review Programme**"). It aims to complete the evaluation of all existing ASs by 31 December 2024. The way that the review is conducted is regulated by Article 89 of the BPR and implementing regulations.

Under Chapter 2 of the current Review Programme Regulation[3], AS approval applications are evaluated by a designated eCA in accordance with Articles 4 and 5 of the BPR. The eCA produces an assessment report with its conclusions and, under Article 6(4), the eCA shares its draft assessment report with the participant company, allowing it 30 days for the submission of written comments on the report and the evaluation conclusions. The finalised report is then submitted to ECHA.

Following submission of the final assessment report, it is sent to the ECHA's BPC for its opinion. Under Article 8(2) when the AS is a candidate for substitution, a public consultation is launched before the submission of ECHA's final opinion to the Commission. The Commission then prepares a draft decision without undue delay.

Pending the finalisation of the review of these ASs, they can be placed on the market on their own or in biocidal products according of the national rules applicable in each MS (Article 89 of the BPR).

[3] Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012.

1.3 AS renewal

An application to renew the approval must be made at the latest 550 days before the date on which the approval is due to expire (usually 10 years minus 550 days). The renewal dossier should include any studies that were assessed for the first approval, as well as any new studies and information. ECHA carries out initial checks on the application and it is then forwarded to the eCA for evaluation.

The eCA will determine whether a full evaluation of the application for renewal is necessary. Full evaluation has to be completed within a year and provides eCAs with the opportunity to request additional data from the applicant. If a full evaluation is not considered necessary, the evaluation must be completed in 180 days.

Evaluation follows the same peer review and BPC opinion as applies for AS approval. However, the duration of the peer review depends on the type of evaluation; 270 days in the case of a full evaluation and 90 days if a full evaluation is not required. As in the case of AS approval, the Commission takes a final decision on the renewal of the approval of the AS. AS renewals are typically valid for 15 years.

1.4 Biocidal product authorisations

Once an AS is approved, the rules relating to the authorisation of a biocidal product containing it are various. The BPR has introduced multiple authorisation processes to facilitate product authorisation within the EU.

National Authorisation ("NA")

(Chapter VI, Articles 29 to 31 BPR)

Companies that seek to market their products in only one MS can apply for product authorisation in that MS alone. NA assessment under the BPR is conducted by the respective eCAs, which evaluate the product and make their decision within 365 days post-validation.

Mutual Recognition ("MR")

(Chapter VII, Articles 32 to 40 BPR)

Companies that seek to market their products in multiple MSs can extend their national product authorisation through MR.

During a NA application, or upon receipt of a NA from a MS, companies can apply for product recognition of the original NA application in other EU MSs. The aim is to speed up the authorisation in other MSs and avoid repetitive evaluations by different MSs of the same product.

Union Authorisation ("UA")

(Chapter VIII, Articles 41 to 46 BPR)

Companies seeking to access all EU markets can apply for an UA which gives them equal rights of access to all EU MS markets.

The evaluation process for an UA is the same initially as for an NA, including evaluation by an authorised eCA. However, in addition the eCA submits its evaluation to ECHA, which then reviews the evaluation and submits its opinion to the Commission recommending authorisation or not. Again the Commission, in consultation with the SCBP, takes the final decision.

Simplified Authorisation ("SA")

(Chapter V, Articles 25 to 28 BPR)

SA allows the evaluation of certain biocidal products under a simplified procedure (less onerous dossier requirements and faster evaluation).

Biocidal products that are deemed less harmful to health and the environment, but no less effective are eligible for this authorisation. eCAs should authorise the relevant product within 90 days post-validation.

Same Biocidal Product Authorisation ("SBP")

(Chapter IV, Article 17(7) BPR and Commission Implementing Regulation (EU) No 414/2013, as amended)

The BPR allows the authorisation of a product, which is identical to a separate product that has already been authorised. Again, the aim is to simplify and quicken the product authorisation process.

Biocidal Product Family ("BPF")

(Chapter IV, Article 17(3), Article 17(6), Article 19(6) and Article 22 BPR)

Finally, the BPR allows the grouping of several similar products together into a "family" of products, which can be submitted in the same authorisation application to an eCA. The aim is to reduce costs and minimise the evaluation time as there should be less data requirements for the products together than if they were separated into individual product authorisation applications.

2. Legal assessment

Below we assess the BPR at three levels.

We discuss (at section 2.1) the general principles of EU law that, in particular, overshadow/underpin the BPR and its application, (at section 2.2) some non-exhaustive examples of where we have seen substantive legal issues, and at (2.3) the procedural deficits.

2.1 General principles of EU law

In the application of the various provisions of the BPR and its implementing regulations, the authorities involved – principally the eCAs, ECHA and the Commission – are bound by certain general principles of EU law. The main principals are highlighted below.

Discretion and manifest error of assessment

The European Courts accord the EU authorities (which includes all actors in the BPR process) a broad discretion in how they carry out their assessments to determine whether risk management measures are to be adopted. That discretion has, however, its restrictions. The EU Courts have noted (Case T 115/15, *Deza, a.s v ECHA*, paragraphs 163-164):

> *"… in accordance with settled case-law, where the authorities of the European Union have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt, review by the European Union judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the European Union judicature cannot substitute its assessment of scientific and technical facts for that of the authorities of the European Union on which alone the FEU Treaty has placed that task […]. Nevertheless, the broad discretion of the authorities of the European Union, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts. However, even though such judicial review is of limited scope, it requires that the European Union authorities which have adopted the act in question* ***must be able to show before the European Union judicature that in adopting the act they actually exercised their discretion, which presupposes that they took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate****"* (bold highlighting added).

This restriction on discretion has the following effect: for as long as a relevant party has submitted information (data, studies, reports) to the relevant authorities and it can be shown that it is relevant for the authorities involved to review that information, but where they do not, this could amount to a manifest error of assessment justifying the annulment in law of the legal act concerned (C-691/15 P, *Commission v Bilbaína de Alquitranes and Others*, paragraph 55).

This restriction is important given the data-intensive nature of the procedures established by the BPR. There are occasions where reports and studies are generated (sometimes at great cost) for consideration by the authorities concerned but without a substantive review subsequently taking place. This can arise due to changing guidance and varying scientific study requests (leading to constantly moving goalposts). At times, moreover, the data have to be submitted to bodies which are established to consider risk management options as opposed to others which are more suited to reviewing detailed technical and scientific issues. The tendency for reviews to be delayed can also tempt applicants to produce more data for input to the process, which in turn applies pressure on the authorities to receive those data.

Though the finding of a manifest error is rare, the lack of respect for the core procedural deadlines and the proliferation of guidance documents opens the door to the argument that the authorities fail to review all relevant factors carefully enough.

The precautionary principle: when does it apply?

Recital 3 of the BPR states that the BPR *"should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment."* Article 1(1) of the BPR reflects that by confirming that *"the provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups".*

While the principle is front and centre of the BPR, from a legal point of view, it is not relevant at all points of application of the BPR's provisions. The EU Courts have been consistently clear that application of the precautionary principle assumes that "*there is uncertainty as to the existence or extent of risks to human health" and that "protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures*" (Case C 616/17, *Blaise and Others*, paragraph 43). One core condition that must exist prior to invoking the precautionary principle is that a risk assessment is carried out and concluded. Such an assessment has several steps, the first being to identify and characterise the hazard, then to assess exposure to the hazard and finally to characterise the risk. It is, however, only at the end of those steps that decision-makers on risk management measures can invoke the precautionary principle to impose a restriction and if they do so, they must do so proportionately.

The principle can therefore only be invoked at the stage of the consideration of risk management measures, for example, in application when the Commission adopts an Implementing Regulation or Decision. The principle cannot be invoked earlier during the risk assessment stage by ECHA.

However, it is seen from time to time that the eCAs, for example, refer to the precautionary principle in order to reach conclusions that are unrelated to the question of which risk management measure is appropriate. In other words, the reference is often made prematurely during the process of risk assessment. The temptation to do so arises in particular where the science is not definitive on a given endpoint. However conclusions adopted at this stage, although cautious, cannot be justified by reference to a *precautionary* approach. If that occurs, that would constitute grounds to challenge.

The legal authority of guidance

EU law has created a hierarchy of sources of law. At the top are international agreements, decisions of the EU Courts and the EU Treaties and, at the bottom, are recommendations, opinions, guidelines, etc. from the Commission and its agencies.

This last tier on guidelines, etc., does not generally have the binding force of law. There are however two occasions in which guidelines can be argued to be legally binding:

a. First, where the underlying legal act on which they are based says so. That is the case, for example, with Article 10 of the BPR which provides that "*the Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter, in particular Article 5(2) and Article 10(1).*" That express legal basis provides legal force to any guidance notes eventually adopted.

b. Second, where the Commission (for example) does "*lay down for themselves guidelines for the exercise of their discretionary powers*", it must do so without "*departing from the Treaties*" and in the knowledge that the EU Courts will judge "*whether the disputed measure is consistent with the guidelines that the institutions have laid down for themselves*" (Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, paragraph 119.)

On the contrary, where applying guidance documents too strictly would lead to infringement of BPR provisions or general principles of EU law (such as right to be heard), the rule provided in the guidance should be set aside and the BPR provision or general principle of EU law should prevail.

The principle of legal certainty

The principle of legal certainty requires, "*particularly, that rules of law be clear, precise and foreseeable in their effects, in particular where they may have adverse effects on individuals and undertakings and that, as regards the principle of the protection of legitimate expectations, the Court of Justice held that a person may not plead a breach of that principle unless the administration has given him precise assurances*" (Case C 419/17 P *Deza a.s. v ECHA,* paragraph 69).

There are two points here:

a. First, if the given law and/or guidance is unclear, any acts subsequently adopted are vulnerable to challenge (and the same applies to the act itself if it is unclear). During a procedure under the BPR, there may be definitional issues such that the clear application of the law cannot be guaranteed. This assumes importance in particular in enforcement proceedings where, for example, a MS authority claims that a company has placed a biocidal product on the market without a product authorisation but that company claims that its product does not fall within the definition of a biocidal product. It may be argued that the definition of biocidal product lacks legal certainty.

b. Second, if a member of the Commission or eCA or other EU body involved in a review process or otherwise providing an indication of how events may unfold does so, in particular, in writing, then whatever expectation that that assurance legitimately raises can be relied upon against that body. If it is not respected, then again the subsequently adopted act is vulnerable to challenge. This has particular application where assurances are given on the ability to submit more data to resolve outstanding scientific doubts notwithstanding that actual data submission deadlines have passed.

The principle of proportionality

Article 5(4) of the Treaty on European Union: "*the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties*". All EU acts must (a) be suitable to achieve the desired end, (b) be necessary to achieve the desired end and (c) not impose an excessive burden in relation to the objective sought to be achieved (Case C-15/10, *Etimine SA v Secretary of State for Work and Pensions*, ECLI:EU:C:2011:504, paragraph 124).

When considering if an AS can be approved, conditions are often attached. Some are more onerous than others. The Commission must be seen to balance its view of which one is more appropriate than the other by reference to the overall objective sought and the burden that it imposes on industry. The same should be true for product authorisation (whether national or Union authorisation).

The right to be heard

The right to be heard is enshrined in Article 41(2)(a) of the Charter of Fundamental Rights of the EU (the **"Charter"**),[4] according to which the right to good administration includes "*the right of every person to be heard, before any individual measure which would affect him or her adversely is taken*". Article 41(2) of the Charter is of general application and it has broad scope, being applicable in all procedures liable to culminate in a measure adversely affecting a person. According to the settled case law of the EU Courts, the right to be heard (i) guarantees every person the opportunity to effectively make his views known during a procedure and before the adoption of a decision; and (ii) requires the authorities to pay due attention to the observations submitted by the person concerned

[4] Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407.

by a measure, examining carefully and impartially all the relevant aspects of the individual case and giving a detailed statement of reasons for their decision (Case C-277/11, *M.M.*, paragraphs 84-87).

Were the Commission and/or eCA and/or ECHA (i) not to afford interested stakeholders, such as participants in the Review Programme or applicants for Union Authorisation, relevant opportunities to make their views effectively known and (ii) not to take into account their submissions/ comments (or without providing valid justification), that failure could constitute an infringement of their right to be heard, as well as, potentially, the specific provisions within the BPR that permit comments to be submitted at various stages.

2.2 Substantive legal issues with the BPR

How to interpret "*biocidal product*"

The definition of a biocidal product is well-established under Article 3(1)(a) of the BPR. While it is relatively detailed, it can and does give rise to questions as to what exactly it covers.

For example, some greater clarity had to be given by the EU Court in case C-592/18 *Darie BV v Staatssecretaris van Infrastructuur en Milieu* concerning products containing probiotics that act preventively against a harmful organism. The Court clarified that:

- the probiotic effect of a product does not prevent it from being considered a biocide under the BPR provided that this effect does not result merely from physical or mechanical action;
- the purposes of biocides listed by the BPR includes preventive action, and that such products are "*generally used in contexts free of harmful organisms*";
- the destruction of harmful organisms themselves is not required by the definition of "*active substance*" under the BPR;
- preventive action on the potential habitat of such organisms by removing their "*food environment*" is sufficient; and
- the period within which a product takes effect is irrelevant to whether it is a 'biocidal product' or not. In other words, products having a delayed action over time can still be biocides.

How to interpret whether a "treated article" has a primary biocidal function?

Unlike under the BPD, the BPR includes treated articles within its scope at Article 58 with respect to the rules for placing articles on the market, but also more generally.

The definition of a treated article is stated clearly in the BPR. It means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products. The terms substance, mixture and article take their definition from the REACH Regulation[5] and include solid objects and liquid materials.

However, it is the interpretation of the "*function*" of the article that creates confusion. If the article is deemed to have a secondary biocidal function, then it is regulated solely as a treated article. However, if the article is deemed to have a primary biocidal function, then it is regulated as a biocidal product.

In practice, the interpretation of these functions is inconsistent.

[5] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Authorities judge on a case-by-case basis, taking into account factors such as intended use and claims, the function of the article and consideration of the concentration, mode of action and efficacy of the active substance(s). To enable industry to comply with its regulatory obligations the guidance applicable to treated articles in this respect should be unambiguous and applied consistently.

How to interpret Article 55(1) BPR

Derogations from the lengthy process of biocidal product authorisations can be granted under certain, restricted circumstances. Article 55(1) of the BPR provides that, "*by way of derogation from Articles 17 and 19, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means*".

In light of the COVID-19 pandemic, recourse to Article 55 assumed urgent importance. However, Article 55 failed in practice to offer the MS authorities and Commission the regulatory tools necessary to ensure adequate emergency protection. The legal issues impeding the reaction were:

(i) the fact that Article 55 itself is not sufficiently clear;

(ii) the lack of provision allowing for a harmonising emergency authorisation across all MSs; and

(iii) the practice of *de facto* extending the initial MS derogation by waiting for one day after the initial derogation has expired and then re-granting the same derogation for an apparently new application is legally dubious.

Under Article 55(1), MSs, initially at least, are permitted to act independently and unilaterally waive the requirements of a BPR authorisation. However, the provision does not directly address whether technical equivalence or the usual requirement to ensure supply from an Article 95-listed company are required. Clarity that such requirements were not waived only came late. Also, Article 55(1) does not make clear exactly which type of substance can be included in the biocidal products it covers. It is not clear, for example if it applies to the following cases:

c. those containing new actives; and/or

d. those containing actives subject to a non-approval decision; and/or

e. those containing actives in non-notified PTs; etc.

An FAQ from ECHA later clarified that, where all the active substances in a biocidal product are "*new*" substances, i.e. substances that are not approved and not included in the Review Programme, Article 55(1) can be used. It is still however unclear whether ECHA considers that Article 55(1) covers biocidal products containing ASs that are approved or in the Review Programme but for a different PT.

On the lack of harmonisation, the last paragraph of Article 55(1) allows for individual MSs to extend the duration of the emergency authorisation beyond 180 days by means of an implementing act taken at EU level. However, there was no means by which one implementing measure could be applied to several or all MSs together. This lack of harmonisation seriously impeded the rollout of the emergency procedure and led to some questionable practices by some MSs. For example, to bypass the use of implementing acts, many companies applied for a new authorisation under Article 55(1) just one day after their initial derogation expired. This meant that for that one day gap, products covered under the derogation could not have been made available on the market or used, without breaching the BPR. The inconsistent MS practice on this issue and lack of guidance from authorities has led to legal uncertainty and confusion in the market.

Product type (PT) confusion

There is a lack of PT-specific guidance which could provide clarity on how to avoid misclassifications by companies of their products.

Examples of product types which present such borderline issues are:

a. PTs 2 and 4: these PTs are frequently differently interpreted; they can both address the disinfection of equipment and similar or broader uses such as surface disinfection, but ultimately their use areas are different – coming to this conclusion is however not easy. In addition to the broad scope of PT 2, a lack of guidance makes it difficult for companies to know what to produce in terms of the required data for approval – especially with regards to efficacy tests.

b. PTs relevant to the treatment of water: there is insufficient guidance to separate PTs 2, 4, 5, 11 and 12. All PTs address water-related uses, but lack accuracy in their descriptions and the distinction between themselves. MSs also do not appear to apply a common approach to making the necessary distinction.

c. PT 9: PT9 covers the use of biocidal products for the purposes of preserving the textile with which they are treated, and prevent the settlement of micro-organisms. The definition presents a very broad scope and even covers products which would not normally be considered to fall under its scope. For instance, filters and membranes that are treated with polymeric material while in storage will fall under the scope of PT 9, and not under PT 6 preservatives for products during storage.

Other products which create frequent confusion and require additional guidance are PTs 6, 9,and 11; PTs 11 and 12; and PTs 18 and 19.

Borderline products

The COVID-19 pandemic has thrown into sharp relief the regulatory grey areas that exist between the BPR and other EU regulations including, in particular, the Cosmetics Regulation[6], Medical Devices Regulation[7] and Medicinal Products Regulation[8].

Depending on the claims made on the relevant advertising material, packaging, the product's website (amongst other sources), a product marketed in the EU may be considered a biocidal product or a medicinal product or a medical device or a cosmetic or, even, in some cases, a combination of several product categories. Each category brings with it distinct regulatory consequences. For example, pre-marketing approvals are in place for certain biocidal products, while lighter touch regulatory obligations apply to cosmetic products. As noted, much depends on the claims made. For example, if the product in any way gives the impression that it is designed or presented as treating or preventing a disease, it will fall within the Medicinal Products Regulation. That will also most likely be the case if a claim is made against a specifically named pathogen or disease, such as "*Effective against COVID-19*". If, on the other hand, claims are made only that the product is good for cleaning hands, it is likely to be a cosmetic product. Adding claims to the effect that it assists with disinfection or hygiene pushes the categorisation more towards biocidal products, in particular if it is accompanied by a claim along the lines of "*Kills viruses*".

The various regulations do not provide sufficient clarity, however, on when exactly a given product is caught by a given regulation. Instead, businesses must rely on guidance documents issued both by the Commission and by relevant competent authorities in MSs. Neither of these provide absolute clarity and they are sometimes inconsistent with one another.

Mutual recognition

Authorisation according to the MR procedures should be granted under the same terms and conditions as the (initial) MS authority to which the application has been made for authorisation. However, in certain cases, the other MSs concerned may propose to refuse to grant the authorisation or to adjust its terms and conditions.

[6] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.
[7] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
[8] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

In other words, while the law provides for a superficially attractive and neat solution, the reality is that there is some distrust between certain MS authorities. While disagreement is envisaged by the BPR, which requires MSs to send a detailed explanation of the reasons for their opposition to the reference MS on the grounds that the application does not meet the conditions laid down in Article 19 BPR, the MSs must thereafter use best endeavours to resolve their differences through a coordination group. When an agreement is not reached within 60 days, the reference MS informs the Commission which then takes a final decision by means of an implementing act. Again, this adds delay and a layer of regulatory doubt that the applicant will have hoped to have avoided.

The same issue is also relevant for UA where a MS makes a request for a derogation under Article 44(5) of the BPR in order to exclude the application of the authorisation in its territory or to apply it only under specific conditions.

Dissemination of commercially sensitive information

The BPR contains far-reaching dissemination provisions, both at active substance and product level, and reflected in the following provisions:

a. Article 67(3)(a) – ECHA will publish the degree of purity and identity of impurities of the AS if essential for classification and labelling.

b. Article 67(2)(b) – ECHA will publish the summary product characteristics ("**SPC**") of the biocidal product. According to Article 22(2), the SPC shall contain a list of what can be viewed as very sensitive details on the product, including:

   i. qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products;

   ii. manufacturers of the biocidal product (names and addresses including location of manufacturing sites); and

   iii. manufacturers of the active substances (names and addresses including location of manufacturing sites).

Article 66(3) of the BPR outlines that access to sensitive information (name and address of biocidal product manufacturer and AS manufacturer, content of AS in the BP, etc) shall not be refused after a biocidal product authorisation is granted. This is presumably to cover access to documents ("**ATD**") requests under the ATD Regulation[9].

The explicit referencing of the details of the AS and biocidal product that would normally be published, and which would normally be given further to an access to documents request, creates a presumption that they will be made publically available. This makes it more difficult for the relevant authorisation holder and its commercial partners to protect commercially sensitive data and prevent its disclosure. In reality, much commercially sensitive information is published, both at the AS and biocidal product level.

Further, the information to be published as part of the summary of the biocidal product characteristics is vague, especially the information relating to qualitative and quantitative composition. Article 22(2)(e) of the BPR refers to "*qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products*." It is unclear how this criteria of "*essential knowledge*" is to be applied and who decides this.

It is also not clear why the right to confidentiality of the applicants is limited to this extent. If the purpose was to facilitate review by NGOs and academia, these provisions appear to have gone much too far. A more balanced alternative would have been to rely on the access route under the ATD Regulation, as this would give the data owner and ATD applicant an equal and fair opportunity to input into the decision.

[9] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

Lack of a level-playing field

Article 95(2) aimed to correct the situation of "*free riders*" under the BPR by obliging all companies that do not support an AS, either as a new or existing AS, to submit a dossier to ECHA to be on the Article 95 list. Such companies could also submit a third party dossier to a MS Competent Authority ("**MSCA**") in the context of a product application, and the MSCA could verify that the AS dossier is complete and update ECHA. However, in practice a level-playing field is not attained.

Many Article 95(1) applications only contain a Letter of Access ("**LOA**") to the data already submitted by the relevant company supporting the existing or new AS. Data developed thereafter is frequently not included in the LOA (mainly because data sharing on future unknown and unquantified data is virtually impossible to do). The result is that the Article 95 applicant remains on the list without paying for access to this new data, at least until AS renewal.

In Fieldfisher's experience, the validation by ECHA of Article 95(1) applications is frequently different from and less onerous than that performed by the eCA for the relevant AS. Again the result is that the Article 95(1) applicant remains on the list without having paid for relevant data.

The validation by MSCAs of third party dossiers is also frequently different and less onerous than that performed by the eCA, with the same results.

For active substance approval, ECHA disseminates information on the AS dossier, as outlined above. However, in contrast nothing is published for Article 95(1) applications or third party dossiers.

2.3 Procedural legal issues

If one takes, as an example, the procedural rules under the Review Programme as established by the current Review Programme Regulation, the applicant in the review of an existing AS is given the legal right to submit comments at a stage of the review. Under Article 6(4), it is stated that "*prior to submitting its conclusions to the Agency, the evaluating competent authority shall give the participant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation Regulation*." There is no express right to submit comments thereafter even during ECHA's review of the eCA's assessment report.

This raises concerns from the perspective of rights of defence.

If, for example, the participant considers that a manifest error has been committed, that a legitimate expectation has been frustrated, or that a technical guidance note has been unlawfully applied retrospectively or prospectively, its ability to register those concerns/legal complaints in a formal context is limited. Between the conclusion of the eCA's role in issuing the assessment report and the adoption of the final decision by the Commission, there is no formal avenue to register the complaints. The only solution is deeply unsatisfactory: a judicial review challenge of the lawfulness of the decision ultimately adopted and published before the General Court in Luxembourg under Article 263 TFEU. Such a challenge does not lead to the automatic suspension of the decision, save in extremely exceptional circumstances (we are aware of two successful suspension claims in analogous regulation – the Plant Protection Product Regulation[10] – over the last 20 years).

There is therefore no practical appellate body or other administrative review body available to a participant should it have concerns over the review. The above issue is also replicated in the case of a Union authorisation application and review.

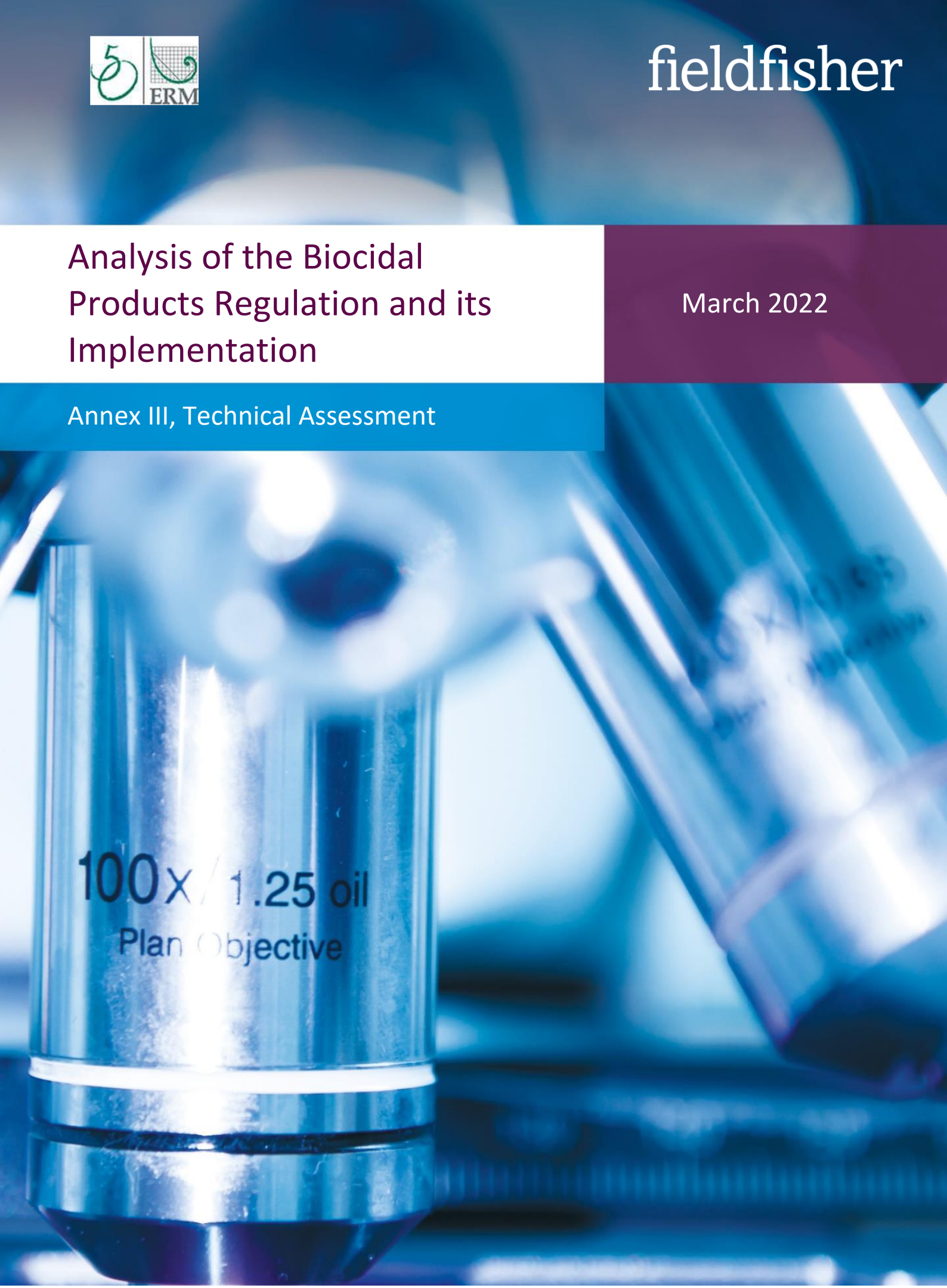
* * * *

[10] Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

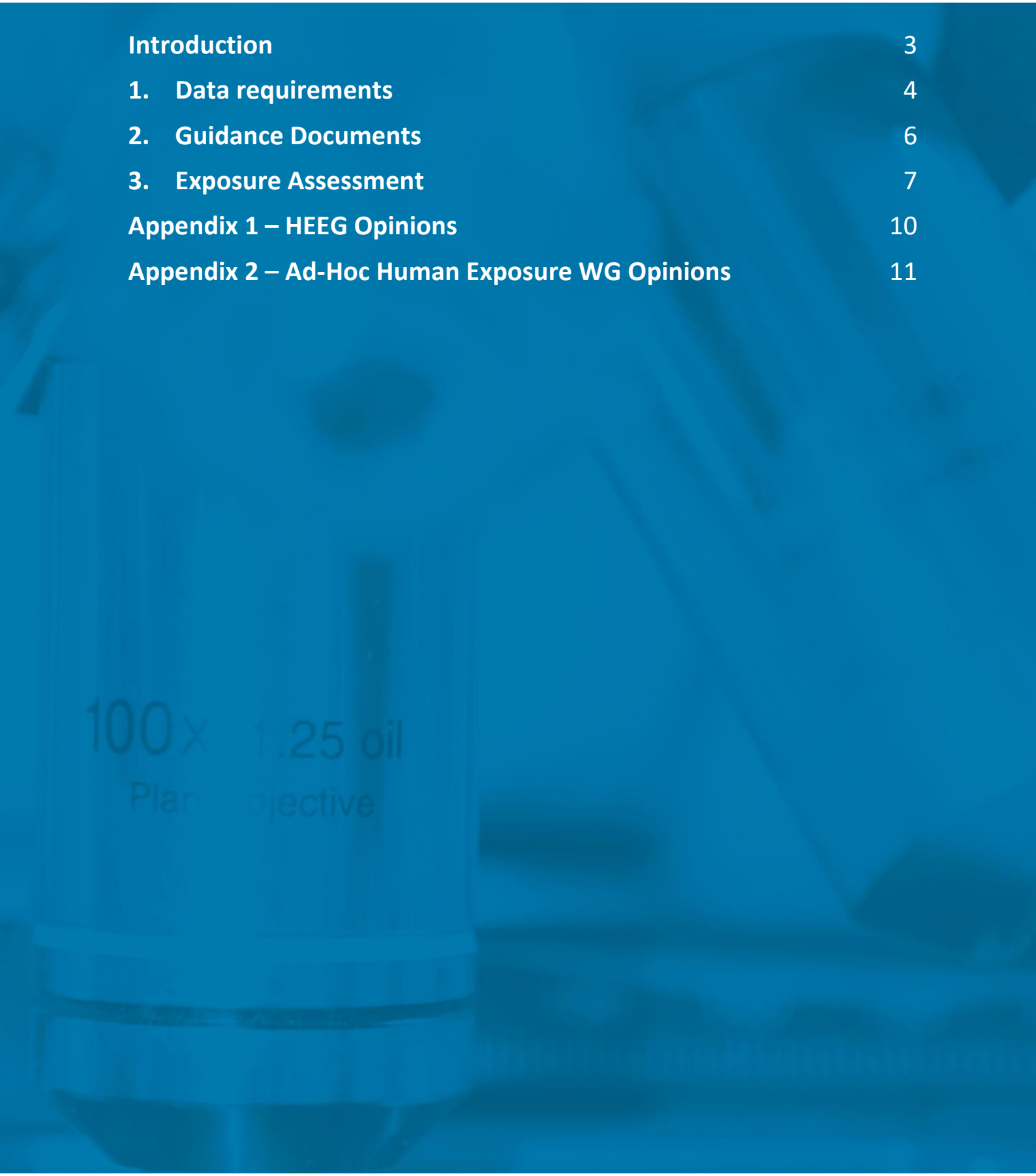
Analysis of the Biocidal Products Regulation and its Implementation

March 2022

Annex III, Technical Assessment



Contents



Introduction

The Biocidal Products Regulation (BPR) came into effect on 1 September 2013, establishing a new framework regulating the placing on the EU market of biocidal products and treated-articles. Biocides are used to control organisms that can, directly or indirectly, be harmful to human and animal health or cause material damage and include, for example, disinfectant, preservative and pest control products that act against these harmful organisms.

The BPR is a highly complex piece of chemical legislation that brings into its scope a huge variety of biocidal products and their uses, and the multitude of chemistries that these products contain. The technical evaluation required by the BPR to establish safe use of biocidal products must accommodate active substances with widely differing hazard profiles and products with a wide diversity of exposure potential for humans and the environment. At the same time, the technical evaluation must maintain a consistent, transparent and non-discriminatory treatment of each application. This represents a significant challenge.

A further challenge is reconciling the objective of the BPR to "e*nsure a high level of protection of both human and animal health and the environment*"; within a technical evaluation that balances the societal need for biocides against the intrinsic hazard they may pose, in a proportionate manner.

This Technical Assessment considers changes to the data requirements applicable under the BPR, the scope of the guidance available to applicants and evaluators and the methodology used to estimate exposure when evaluating the approval of active substances and authorisation of product under the Regulation.

1. Data requirements

The information required to support the approval of an active substance is listed in Annex II of the BPR, with the corresponding data requirements for biocidal products listed in Annex III. In general, the requirements are clear and in most cases are based on OECD type studies or similar recognised testing protocols that are familiar to Industry and Authority technical experts.

A 'complete' dossier is required to support applications for active substance approval and product authorisation (both under BPR and formally under the BPD), which is a dossier containing sufficient information (study data or other relevant sources) for the evaluating Authority to conduct its review.

As envisaged in the BPR, the need for study data can be adapted (waived) as outlined in Annex IV i.e. not submitting data on the grounds that i) testing does not appear scientifically necessary, ii) testing is not technically possible or iii) not required based on exposure considerations. However, the suitability of data waiving is often subjective and divergence of opinion is a source of uncertainty. Nevertheless, if applied in a pragmatic manner, data waiving is important to reduce reliance on test data particularly for non-critical data points and should be the first option considered where the BPR requires animal tests.

The Annex II and Annex III information requirements have recently been revised[1]. Notable changes include; tiered testing for properties such as irritation, neurotoxicity and genotoxicity that favour *in vitro* tests over *in vivo* tests, changing requirements for genotoxicity (replacing the UDS assay with an appropriate in vivo somatic cell genotoxicity assay) and accepting the extended one-generation reproductive toxicity study (EOGRTS) as a suitable test for long term reproductive effects. These changes are welcome, in particular the move to reduce the reliance on certain vertebrate animal tests and changes taking account of scientific advances since the BPR was written.

The changes to data requirements shown above followed discussion between the various biocide Stakeholders as envisaged in Article 85 of the BPR, which allows provisions of the Regulation to be adapted to scientific and technical progress, through delegated acts. The changes to Annex II and Annex III apply from 15 April 2022 but may be applied by Applicants from 15 April 2021, by way of derogation. The Regulation amending the BPR and implementing these changes is clear that applications for approval of actives and applications for authorisation of product submitted before 15 April 2022 shall be evaluated based on information requirements applicable on the day of submission of such applications. This is welcome as it avoids retrospective application of these changes, which is a problem that has caused uncertainty and delay in the function of the BPR on many occasions according to companies responding to the Survey.

Having clear data requirements is important to the smooth operation of the BPR, but equally important is the understanding of how the data will be interpreted. This type of information is made available through less 'legal' routes in guidance and opinions developed in an ongoing manner, for example in Working Groups. This 'learning by doing' approach has resulted in significant uncertainty especially where guidance and opinions are only available many years after the submission of dossier and often come from individual substance evaluations that as a result lack transparency.

Endocrine Disruptors

A key data requirement introduced by the BPR is the need to establish endocrine disruption (ED) criteria for active substances, but it was not until September 2017 – 4 years after the introduction of the BPR - that these criteria were finally clarified[2], with accompanying ECHA/EFSA guidance only available the following year in June 2018. The topic of ED is highly complex, with the main guidance document running to 135 pages. An ED Expert Group was established in February 2014, coordinated and hosted by ECHA to give advice to EU Member State competent authorities (under REACH and BPR) and ECHA.

[1] COMMISSION DELEGATED REGULATION (EU) 2021/525 of 19 October 2020 amending Annexes II and III to 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

[2] COMMISSION DELEGATED REGULATION (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

The focus of attention on ED requires new studies that were not envisaged when review programme dossiers were submitted and are not part of the Annex II or Annex III data set. These tests are of a type not usually required in regulatory submissions (e.g. E-modality: uterotrophic bioassay (OECD 440), A-modality: Hershberger bioassay (OECD 441), S-modality: H295R steroidogenesis assay (OECD 456))[3]. Other non-standard studies required for ED assessment have only recently been included in the OECD suite of tests (e.g. XETA assay (OECD 248))[4]. These studies require further animal testing and test facilities capable of conducting the work with sufficient resource and expertise to interpret the results in a Regulatory context can be limited.

The impact of this additional data requirement on the review of active substances is significant to the point of delaying completion of the review beyond the stated end date of 31 December 2024. Of greater concern is the narrow focus on determining hazard criteria even to the point of investigating substances that are essential to endocrine function (e.g. iodine).

The need for additional testing should also consider the likelihood of exposure (risk) in a more balanced approach and there is a clear need to establish thresholds to trigger when effects need to be investigated. This is especially relevant in the case of impurities in active substances, where the presence of an impurity identified as an ED means the active substance itself is considered to have ED properties, unless demonstrated otherwise[5].

The investigation of ED effects is not restricted to active substances but has been further extended, with the need to consider the ED potential of non-active substance used as product co-formulants, with implications extending into other legislation (REACH). This retrospective change to the BPR data requirements has the potential to introduce further delay, cost and new testing requests into the review of biocidal products.

Other significant examples of retrospective changes to data requirements include nanomaterials, treated article efficacy, efficacy of co-formulants and disinfection by-products.

Nanomaterials

In the case of nanomaterials, the change required the reappraisal of active substance identity for substances already supported with dossiers submitted under the BPD and the provision of new data by Applicants to confirm substances did not meet new criteria defining nanomaterials.

Substances identified as nanomaterial attract special attention under the BPR and products require labelling to alert users to the (hazardous) presence of a nano material irrespective of the risk of exposure. An interesting example here is silicon dioxide used as an insecticide (PT18).

Synthetic amorphous silicon dioxide is a biocide active substance identified as a nanomaterial based on primary particle size and specific surface area by volume according to the Commission recommendation on the definition of nanomaterial (2011/696/EU). Available data showed that primary particles are aggregated (> 100 nm) and under conditions of normal use, it was considered that these aggregates are the smallest stable particles. In this context, liberation of primary particles and exposure to nano-objects was not expected and the hazard and risk of nano-particles of silicon dioxide was not evaluated (not required).

This highlights the potential for contradictory information to be communicated to users and the need for risk assessment to be at the forefront of regulatory decisions. Hazard should only be communicated to the user where it exists, otherwise the communication is misleading.

Efficacy

Efficacy requirements for treated articles have undergone fundamental changes under the BPR, with the ongoing development of guidance running parallel to review programme evaluations. These changes were influenced by Member State initiatives, for example the funding of a Working Paper on the Efficacy Assessment of Treated Articles[6] by the Nordic Council that informed a large part of the treated article update to the Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C) in February 2017.

[3] E, A and S refer to the so called EATS endocrine modalities (estrogenic, androgenic, thyroid and steroidogenic)
[4] Xenopus Eleutheroembryonic Thyroid Assay
[5] CA-March21-Doc.5.1- ED properties impurities.docx
[6] Efficacy Assessment of Treated Articles - A guidance http://dx.doi.org/10.6027/NA2014-904, NA2014:904, ISSN 2311-0562.

The changes require detailed information on the efficacy of articles in addition to demonstrations of the benefit of treating such articles, new information that moves the assessment of efficacy beyond a simple proof of innate efficacy that was the need previously for active substance approval. In addition, the claims made for treated articles have become the focus, with efficacy data needing to support exactly the claim made even for active substance approval where such data is not required[7].

A co-formulant being a potential active substance in a disinfectant product has also developed as an important topic since the introduction of the BPR, requiring a justification of its function in the formulation and how this influences the efficacy of the product. In cases where justification is not conclusive tests are required to demonstrate the 'non-activity' of the co-formulant.

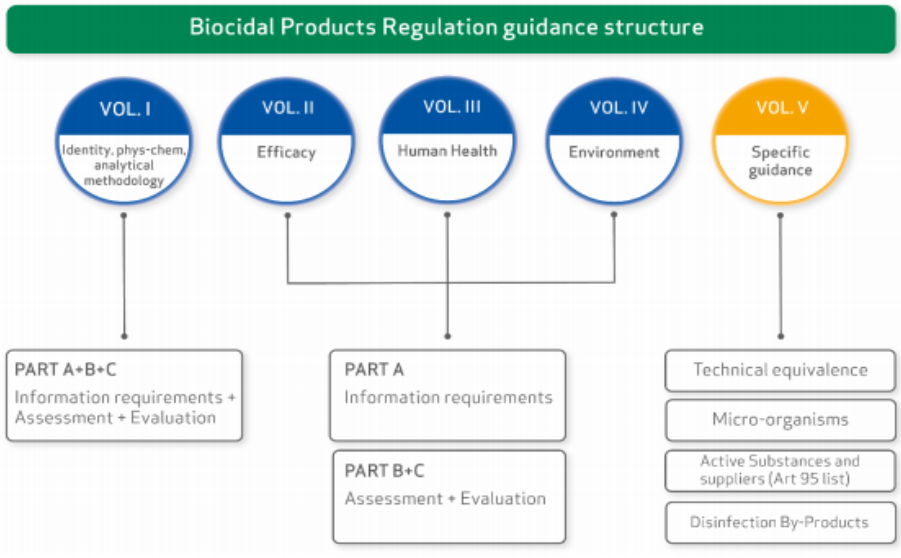
Disinfection By-Products

Disinfection by-products is another topic influenced by Member State initiatives, in this case by the Netherlands who have worked on harmonising an EU approach since 2011. The Competent Authorities (CAs) and the Technical Meetings (TM) decided that a risk assessment of DBPs should be conducted as part of the authorisation of the halogenated biocidal products. The TM agreed that a harmonised approach to such a risk assessment should be found for all halogenated disinfectants for Annex I inclusion (of the then BPD) and now active substance approval for the BPR, instead of postponing it to the national authorisation stage. Such a requirement changes the direction of active substances under review further delaying the process and places the responsibility for data generation disproportionately on a smaller number of companies (review programme participants).

2. Guidance Documents

Due to the wide scope of the BPR and the wide variation of efficacy, exposure and risks of biocidal products, the general rules provided in the BPR and its Annexes are specified in guidance in order to promote efficient and harmonised implementation of the regulation. The aim of the Guidance is to provide detailed and practical direction on which study data and other information should be submitted, when applying for active substance approval and product authorisation. Guidance is available to both Applicants and MSCA Evaluators.

The BPR sets out the broad criteria necessary for the approval of active substances and biocidal products containing those substances. The technical requirements needed to fulfil these criteria are detailed in formal guidance documents and other technical advice (such as the Technical Agreements for Biocide - TAB) which is published by ECHA. Guidance on Information Requirements are provided in Part A of the guidance and the Assessment and Evaluation of information in Part B +C guidance. The complete ECHA guidance series (to date) in support of the BPR is shown below:



[7] CA-Sept15-Doc.6.4 - Note to BPC EWP

The BPR guidance was developed based on the Technical Notes for Guidance (TNsG) that existed under the BPD. Much of the guidance remains unchanged, although it has been reformatted into a slightly more readable format in the current ECHA documents.

The main differences are:

- The term information requirement is used instead of data requirement. The new term reflects the fact that applicants do not in all cases need to supply data originating from studies, information from other sources being acceptable.
- Harmonisation with Guidance from other legal frameworks, for example REACH (Regulation (EC) No 1907/2006) is referred to for definitions and data waiving criteria.
- Core data requirements have been modified and certain long-term animal studies are only required when necessary.
- The BPR also allows for the adaptation of information requirements based on exposure as well as the use of techniques such as read-across, (Q)SAR and calculation methods.
- It is possible to provide a reduced data package on a case-by-case basis when applying for product authorisation, taking into account the nature of the product and the expected level of exposure.

The above descriptions point towards a degree of flexibility in providing information to support applications. However, in the case of active substance approval this should be seen in the context of BPR Article 6(2), which states that "*sufficient data shall be provided in order to make it possible to determine whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1), if required by the evaluating competent authority under Article 8(2)*".

To establish exclusion criteria under Article 5(1) information concerning carcinogenicity (C), mutagenicity (M) and reproductive toxicity (R), in addition to information on endocrine disrupting (ED) potential and environmental persistence (P), bioaccumulation (B) and toxicity (T) are required. The need to conclude CMR properties and the level of classification under CLP creates a very high threshold to waive the data needed for these endpoints. This represents a fundamental change introduced by the BPR where an absence of data can no longer be accommodated by using additional safety factors in a risk assessment to account for uncertainty.

The clear consequence of not providing information to conclude Article 5(1) exclusion criteria is non-approval. An example here is the insecticide empenthrin, which was not approved for PT18 based on the absence of a 2-year carcinogenicity study[8]. The waiver submitted in place of study data was rejected, in part, because (Q)SAR was seen as not convincing for the lack of alerts for carcinogenicity.

The outcome for empenthrin underlines that study data are key to establishing substance endpoints. The difficulty comes in balancing the aims of the BPR to reduce animal testing and the use of the precautionary principle that underpins the regulation (Recital 3... "*This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment")*.

3. Exposure Assessment

An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in Article 19(1)(b) – the so called, one safe use principle. The criteria in Article 19(1)(b) stipulate (briefly) that products should be (i) sufficiently effective; (ii) have no unacceptable effects on the health of humans or animals and iii) have no unacceptable effects on the environment, including any impact on non-target organisms.

[8] Biocidal Products Committee (BPC) Opinion on the application for approval of the active substance: Empenthrin Product type: 18 - ECHA/BPC/182/2017. Adopted 13 December 2017.

Exposure assessment of the use of biocides provides significant information to determine what is considered acceptable and provides what is perhaps the largest area of uncertainty and controversy within the BPR. Biocides have a wide use pattern with many different uses, users and possibilities for exposure for humans and the environment.

Human Heath

Human health exposure assessments are guided by the opinions of Human Exposure Expert Group (HEEG – see Appendix 1) and the Ad hoc Working Group on Human Exposure (see Appendix 2) both of which prepare recommendations on issues concerning human exposure for which a harmonised approach is desirable. The accompanying ECHA guidance document - Biocides Human Health Exposure Methodology (365 pages) - is also available.

The information provided by these sources must be read together as multiple options exist when trying to model exposure scenarios and selecting which option is likely to be acceptable to evaluating Authorities is often unclear.

The opinions available from HEEG and the Ad hoc Working Group are complex, providing in many cases detailed technical background to the issues in question. Summary documents such as 'Recommendation No. 6 of the BPC Ad hoc Working Group'[9] have the highest value giving a more user-friendly overview of the available models and example scenarios for each PT where the model is applicable. Transferring these models into simple downloadable Excel calculators, would simplify the preparation and evaluation of dossiers and facilitate a more harmonised approach to risk assessment. Currently, these calculators are only available for a limited number of scenarios (an example case being the RISKOFDERM model).

In general, exposure models consider what are described as 'realistic worst-case scenarios', but in many cases, the calculated exposures actually represent extreme scenarios. This occurs because (each time) the worst-case value for individual components of the model is used.[10]

The outcome of risk assessments determine whether active substances may or may not be approved, or products authorised, but such decisions must consider the likelihood that the modelled exposure scenarios will occur in reality (e.g. PT6 - a child touching wet painted surfaces on a daily basis).

If models identify risk, the use of appropriate labelling should be an adequate measure to limit exposure and still permit approval of active substances and authorisation biocidal products (e.g. specifying professional only use in the event that risk is identified for infants).

Use instructions are an accepted feature of products in general and it should be a default assumption that users comply with these instructions. Regulatory decisions should not be based solely of risk identified for isolated or extremely rare scenarios (e.g. PT21 - toddlers exposed to wet paint by climbing on a boat in the garden) that could reasonably be avoided by appropriate use instructions.

Environment

Environmental exposure assessments are guided by emission scenario documents (ESDs) which are used to estimate the initial release of substances from biocidal products (or treated materials) to the environment. ESDs are available for each Product Type and consist of written guidance that include calculation methods to model exposure. Many of these documents are old, pre-dating the BPR, but recently a number of accompanying Excel spreadsheet tools have been added[11] by ECHA that help, if not necessarily simplify, the task of modelling exposure.

[9] Recommendation No. 6 of the BPC Ad hoc Working Group' on Human Exposure Methods and models to assess exposure to biocidal products in different product types'

[10] For example, the HEEG Opinion 'An approach to identification of worst-case human exposure scenario for PT6' (Section 3.1) - here exposure is determined by: the a.s. concentration in the product; the amount of the a.s. deposited on the surface; the likelihood of contact between consumer and the surface; the intensity, frequency and duration of such contact and for volatile substances, the ventilation rate. Worst case values are given for each component of the model which cummulatively results in highly unrealistic scenarios.

[11] Available for all PTs except PT3, PT11. PT12, PT16, PT17 and PT20 at the time of writing.

Assessment reports often cite precedent set by earlier substance evaluations and some of the decisions taken are captured in the Technical Agreements for Biocides (TAB), which is divided into separate documents addressing Chemistry, Efficacy, Toxicology and Environmental issues, as well as 'Cross-Cutting' issues. Whilst this is helpful, it follows the 'learning by doing' approach that has caused significant uncertainty for ongoing evaluation.

Environmental exposure assessment involves the estimation of release based on assumptions of how products are used and a common observation from those responding to the Survey is that exposure assessments are too conservative and the 'precautionary principle' is applied in a manner that simply selects the worst-case each time a choice of values is needed. As models require multiple inputs these worst-case choices are compounded, with the risk of taking the assessment beyond anything that might be considered proportional and realistic.

Appendix 1 – HEEG Opinions

HEEG opinion 1 - Mixing loading model 7 alternatives, Annex v2.2.1 – Calculator for RISKOFDERM Dermal Model

HEEG opinion 2 - Potential & Actual Hand Exposure

HEEG opinion 3 - Use of ConsExpo for the Exposure Assessment for Professional Users

HEEG opinion 4 - Amendment of TNsG on Human exposure to biocidal products Antifouling painting model

HEEG opinion 5- Human exposure assessment to biocidal products used in metalworking fluids (PT13) This HEEG opinion has been replaced by Recommendation 7 of the Ad hoc Working Group on Human Exposure Recommendation 7 – Professional exposure PT13

HEEG opinion 6 - Harmonising the use of new and old versions of the TNsG on human exposure and of BEAT

HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4

HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8)

HEEG opinion 9 - Default protection factors for protective clothing and gloves

HEEG opinion 10 - Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants)

HEEG opinion 11 - Exposure model Primary exposure scenario - washing out of a brush which has been used to apply a paint, Annex - General exposure calculator for washing out of brushes

HEEG opinion 12 - Harmonised approach for the assessment of rodenticides (anticoagulants)

HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocide active substance

HEEG opinion 14 - An approach to identification of worst-case human exposure scenario for PT6

HEEG opinion 15 has been replaced by HEAdhoc Recommendation 17

HEEG opinion 16 - Biocidal products: model for dipping of hands/forearms in a diluted solution

HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping

Appendix 2 – Ad-Hoc Human Exposure WG Opinions

Recommendation 1 - Hand disinfection PT1 [PDF]

Recommendation 2 - Mopping and wiping time PT2 [PDF]

Recommendation 3 - Spraying models low pressure downward uses PT18 [PDF]

Annex - Studies with spraying applications PT18 [XLS]

Recommendation 4 - Cleaning spray equipment PT21 [PDF]

Recommendation 5 - Toddler scenario PT21 [PDF]

Recommendation 6 - Methods and models – version 4 [PDF]

Annex - PT18 professional exposure [XLSX]

Recommendation 7 - Professional exposure PT13 [PDF]

Recommendation 8 - Consumers protection factor from clothing[PDF]

Recommendation 9 - Professional hand disinfection in hospitals [PDF]

Annex - Inhalation exposure calculation ConsExpo [XLS]

Recommendation 10 – Paints non-professional application by brushing and rolling[PDF]

Recommendation 11 - Proposal for harmonisation PT19 assessment - version 2.1[PDF]

Recommendation 12 - Default values for indoor Transfer Coefficient[PDF]

Recommendation 13 - Teat Disinfection Products for Veterinary Hygiene (PT3)[PDF]

Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products[PDF]

Recommendation 15 - Harmonisation of PT2 small surface disinfection exposure scenarios[PDF]

Recommendation 16 - Applicability of ConsExpo for water based disinfectants [PDF]

Annex - Modelling approaches used for calculations [XLS] (The numerical solution of the differential equations requires Visual Basic. Opening the attached document might display a warning message about the included macros.)

Recommendation 17 - Occupational exposure during application and removal of antifouling paints