Analysis of the Biocidal Products Regulation and its Implementation

March 2022

Report

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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.

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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]

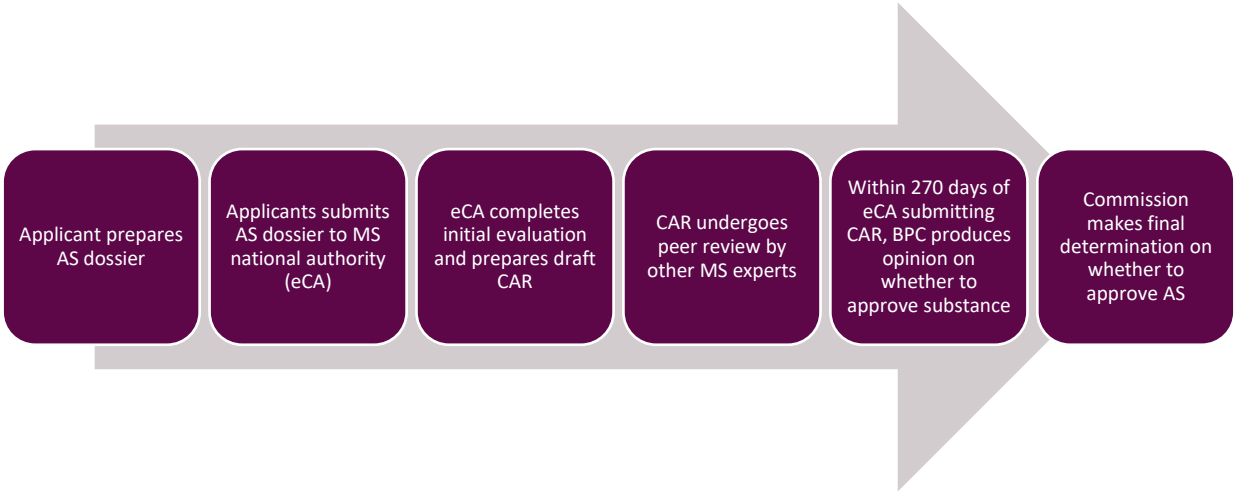
The process of AS approval includes the following steps:

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.

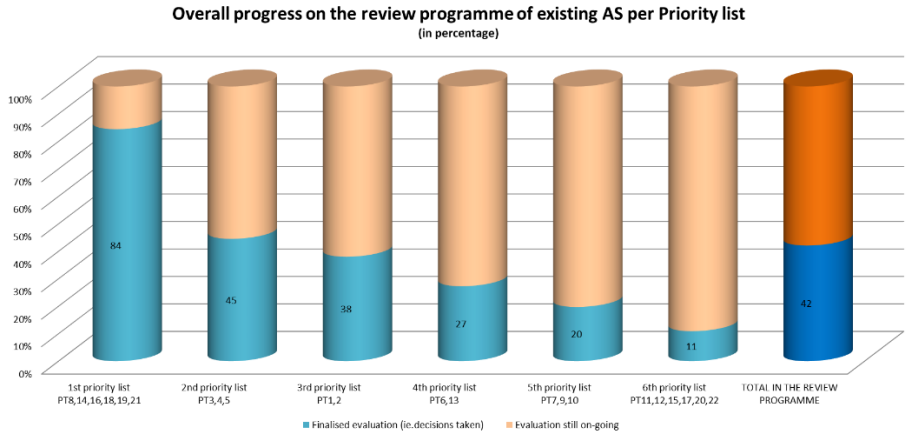
Reflecting on the overall regulatory framework, and the hurdles that it entails for companies, many Survey respondents focused on the competence of eCAs to conduct the relevant assessments. Especially, with respect to the frequent delays in evaluation, they observed that many competent authorities lack 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.

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