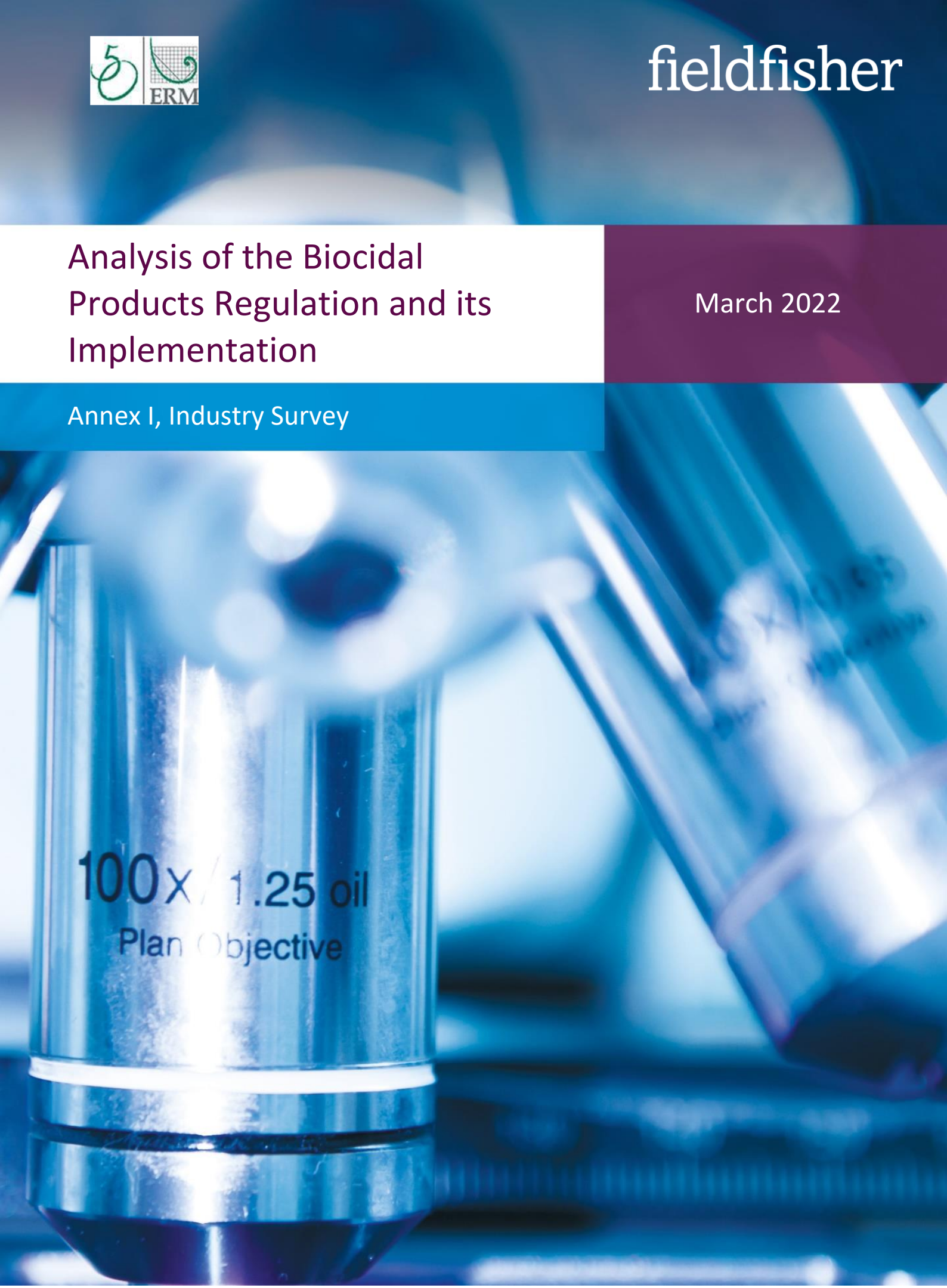
Analysis of the Biocidal Products Regulation and its Implementation

March 2022

Annex I, Industry Survey



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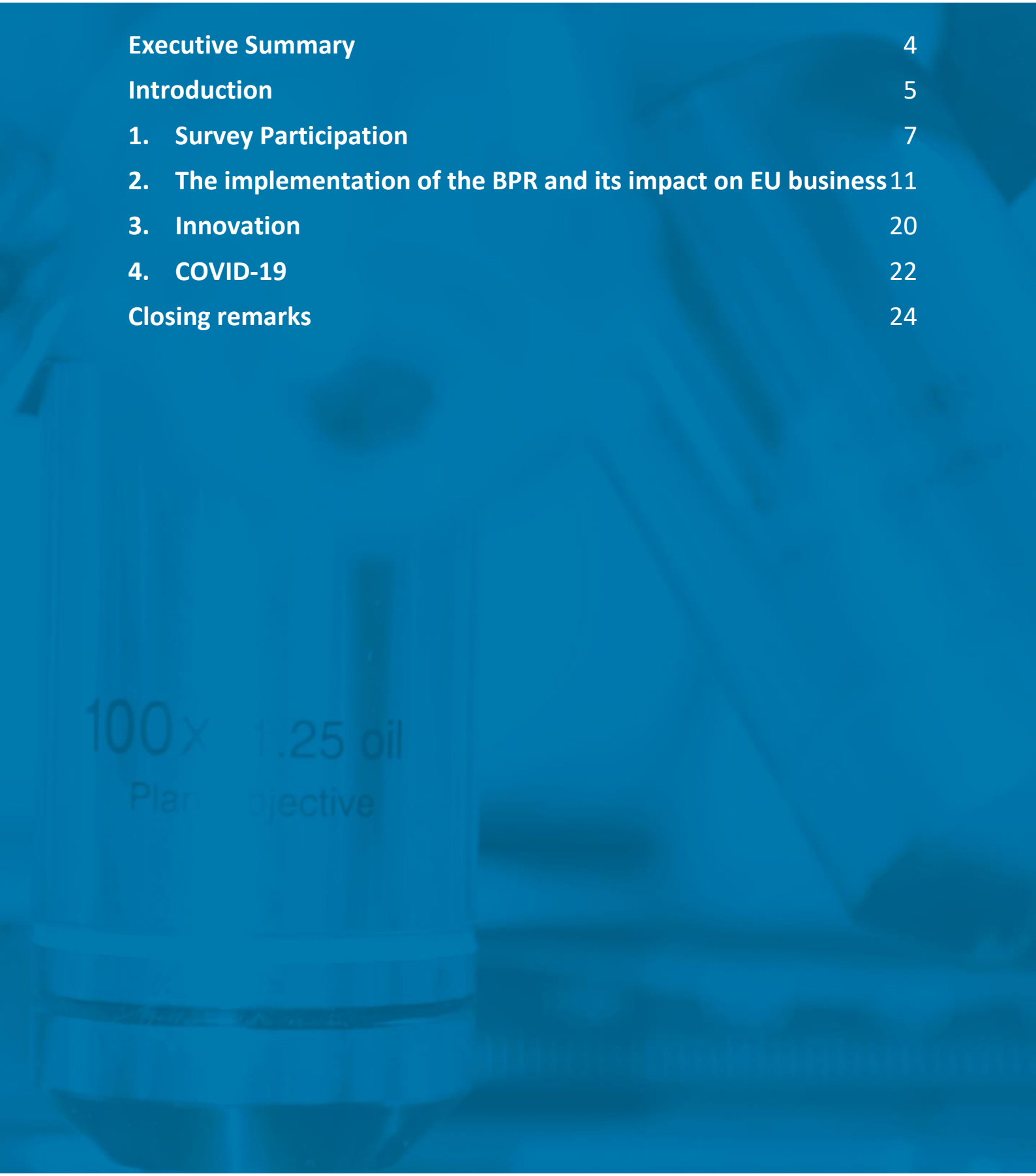

List of acronyms used in this report

AS: Active Substance

BP: Biocidal Product

BPC: Biocidal Product Committee

BPC WG: BPC Working Group

BPR: Biocidal Products Regulation

BPF: Biocidal Product Family

eCA: Evaluating Competent Authority

ECHA: European Chemicals Agency

ED: Endocrine Disruption

EU: European Union

MR: Mutual Recognition

MS: Member State

MSCA: Member State Competent Authority

NA: National Authorisation

No.: Number

PT: Product Type

RAC: Risk Assessment Committee

R&D: Research and Development

SAP: Simplified Authorisation Procedure

SBP: Same Biocidal Product (regulation)

SME: Small and Medium Enterprise

UA: Union Authorisation

Executive Summary

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

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

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

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

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

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

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

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

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

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

Introduction

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

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

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

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

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

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

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

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

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

[5] Product types under the BPR - ECHA

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

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

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

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

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

This report is an overview of the responses.

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

1. Survey Participation

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

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

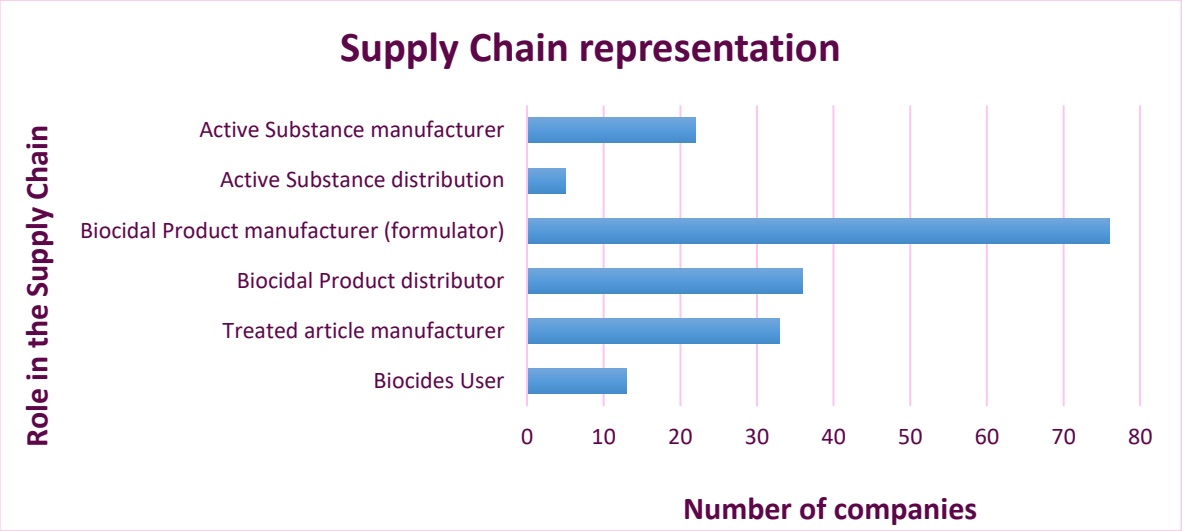

Figure 1.Supply Chain representation

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

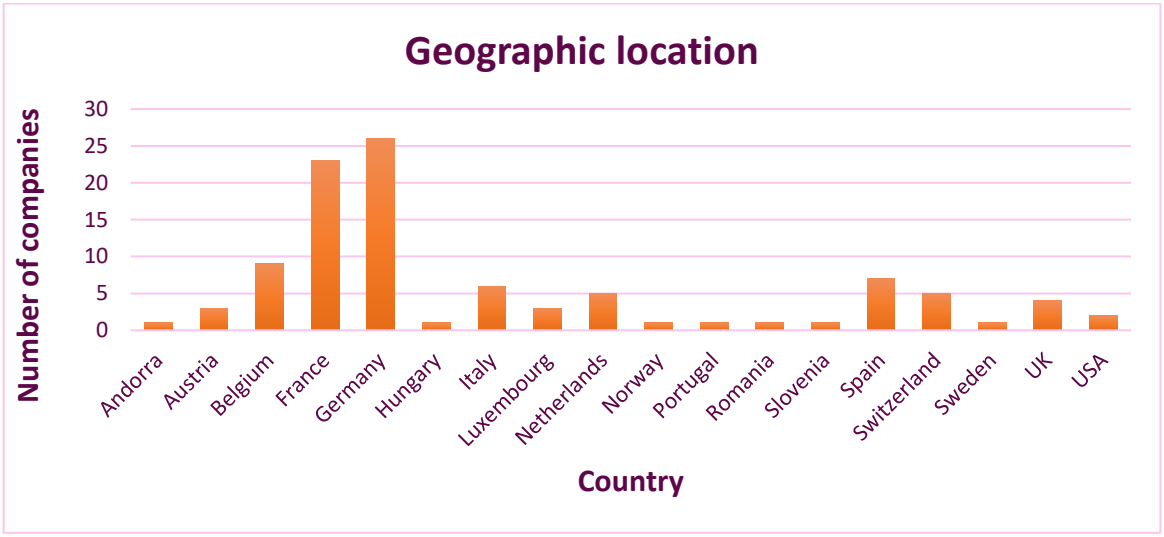

Figure 2. Geographic location

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

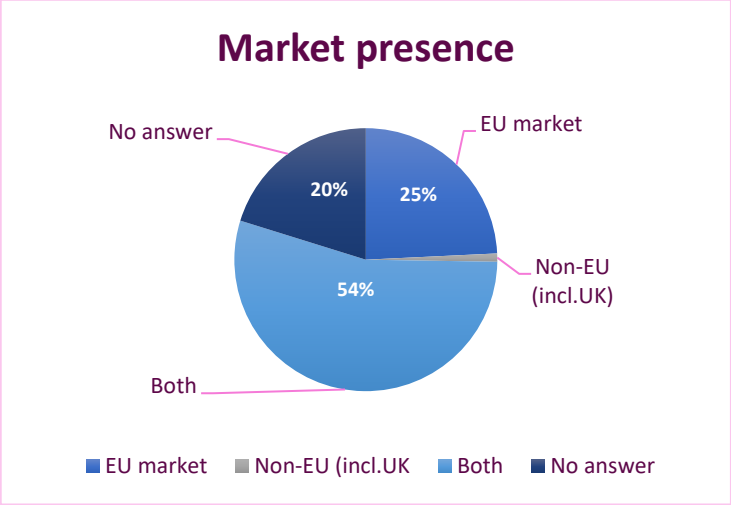

Figure 3. Market presence

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

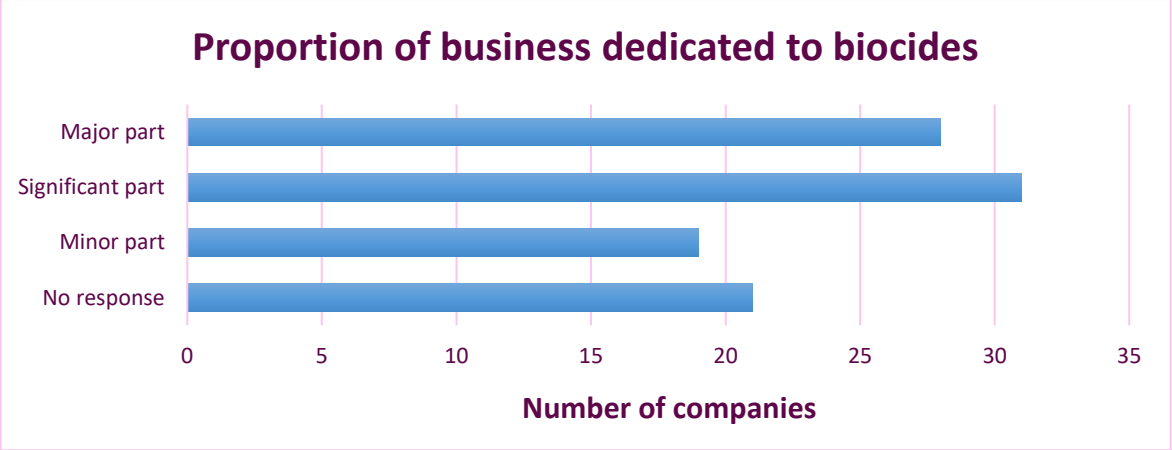

Figure 4. Proportion of business dedicated to biocides

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

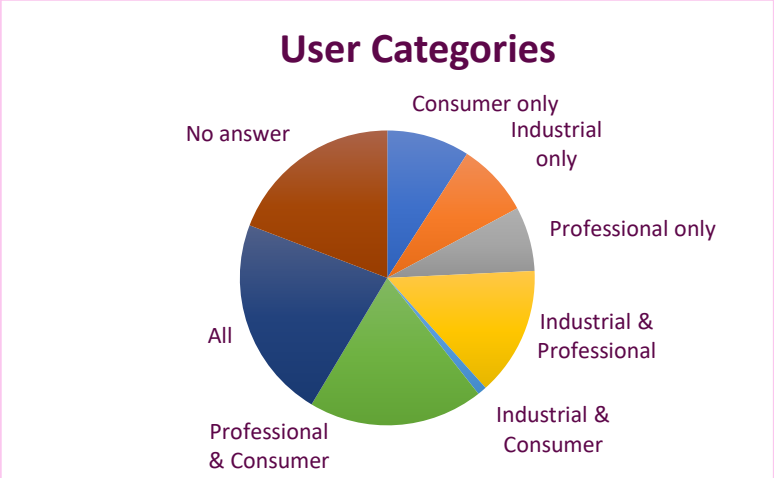

Figure 5. User categories

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

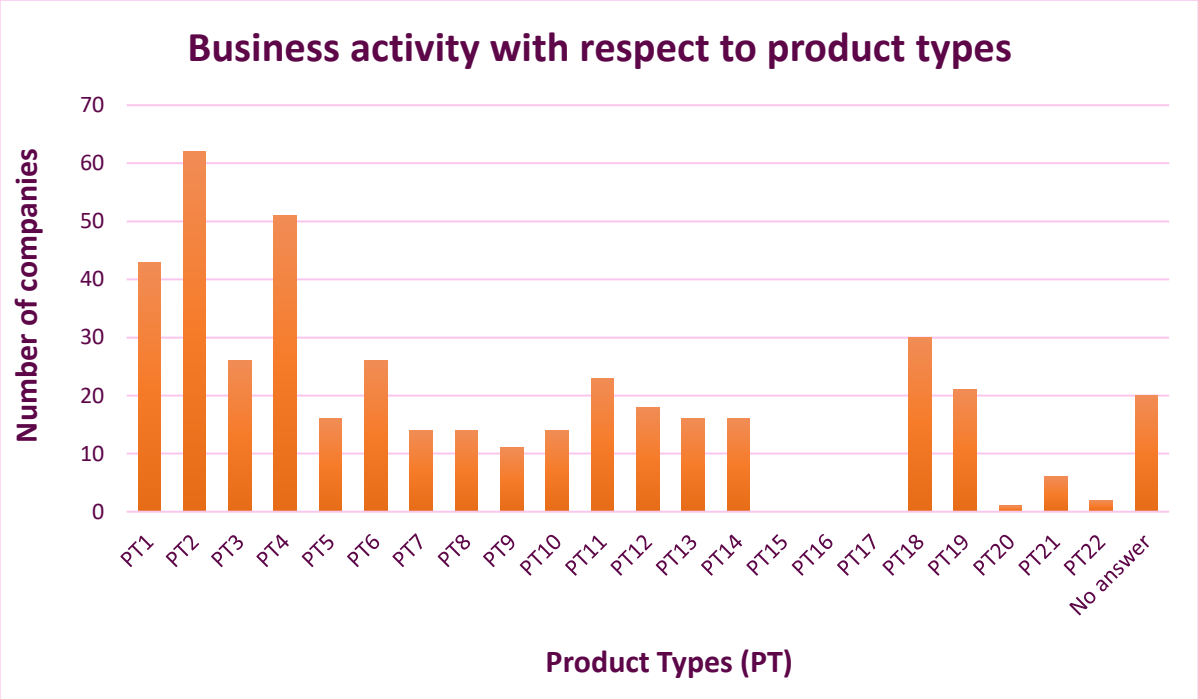

Figure 6. Business activity with respect to PTs

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

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

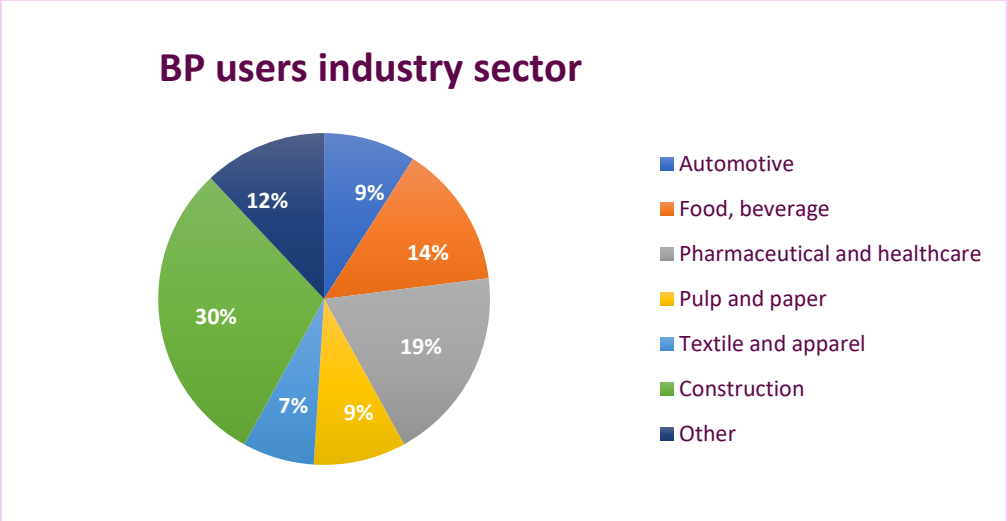

Figure 7. BP users' industry sector

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

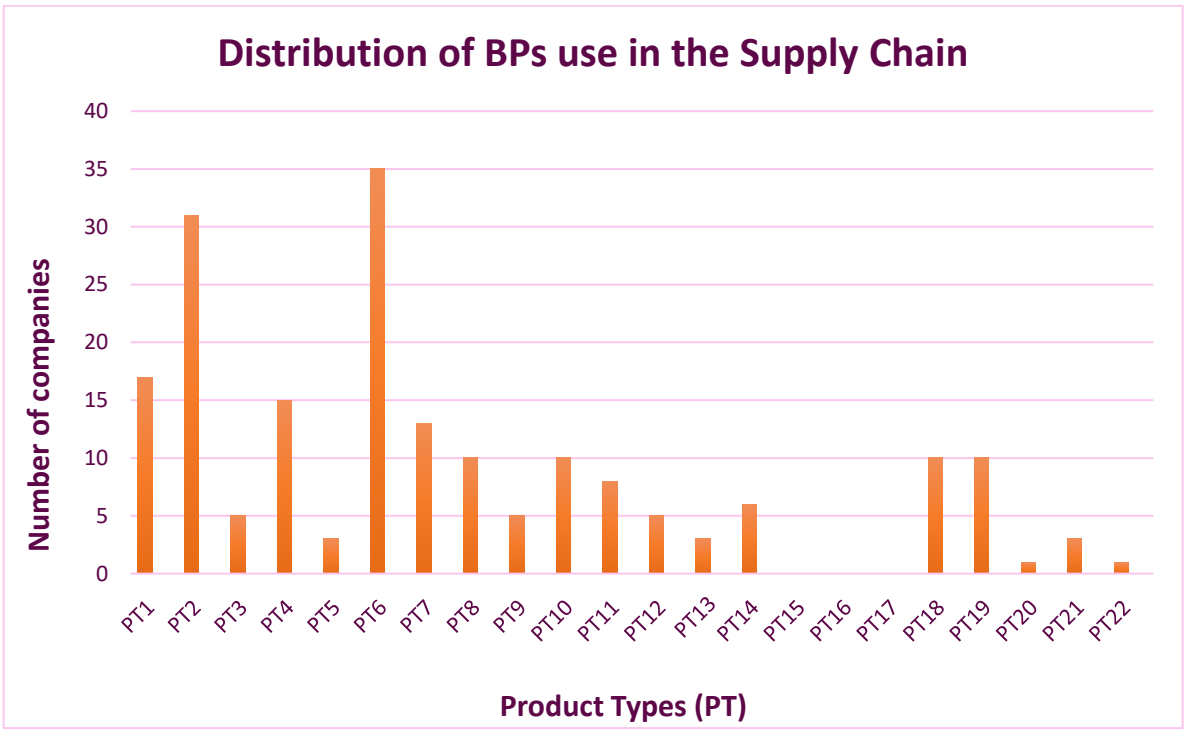

Figure 8. Distribution of BPs use in the Supply Chain

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

2.1. The BPR implementation

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

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

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

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

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

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

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

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

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

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

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

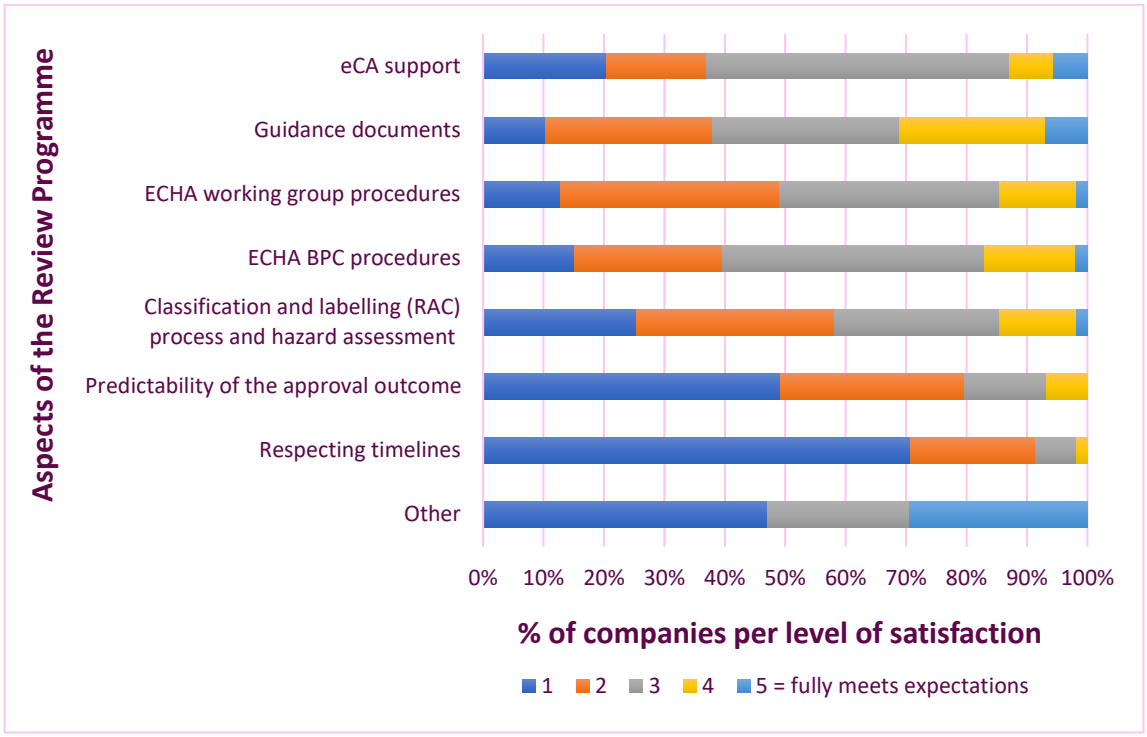

Figure 9. Satisfaction level around various aspects of the AS Review Programme

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

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

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

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

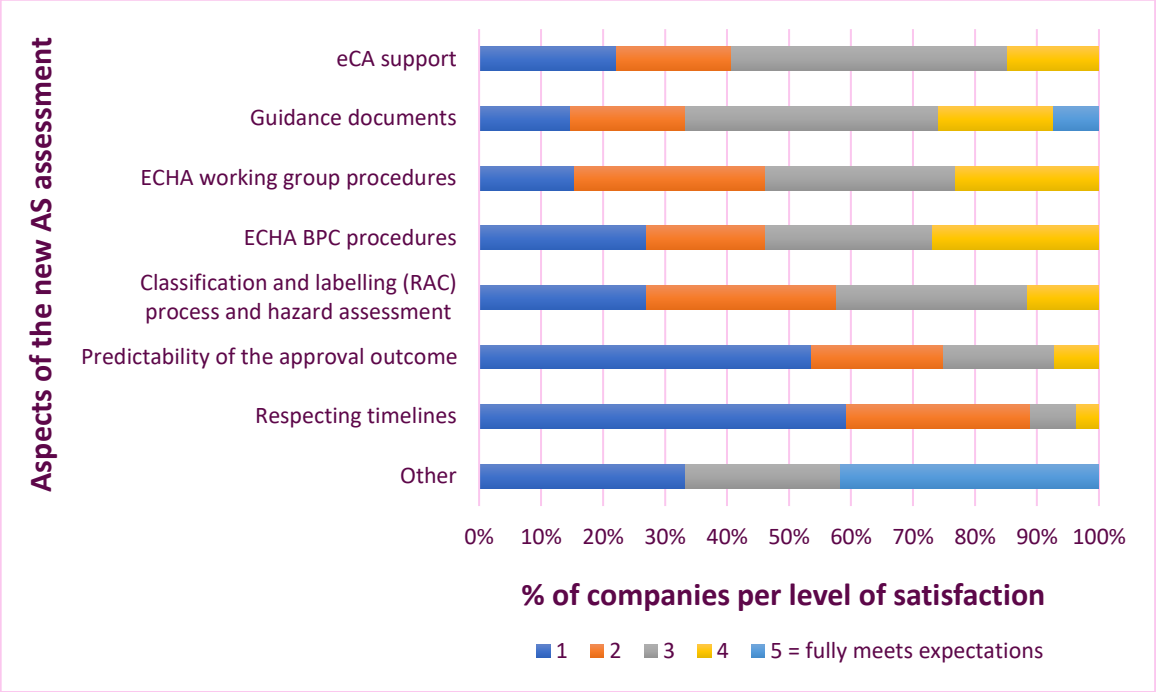

Figure 10. Satisfaction level around various aspects of the New AS assessment process

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

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

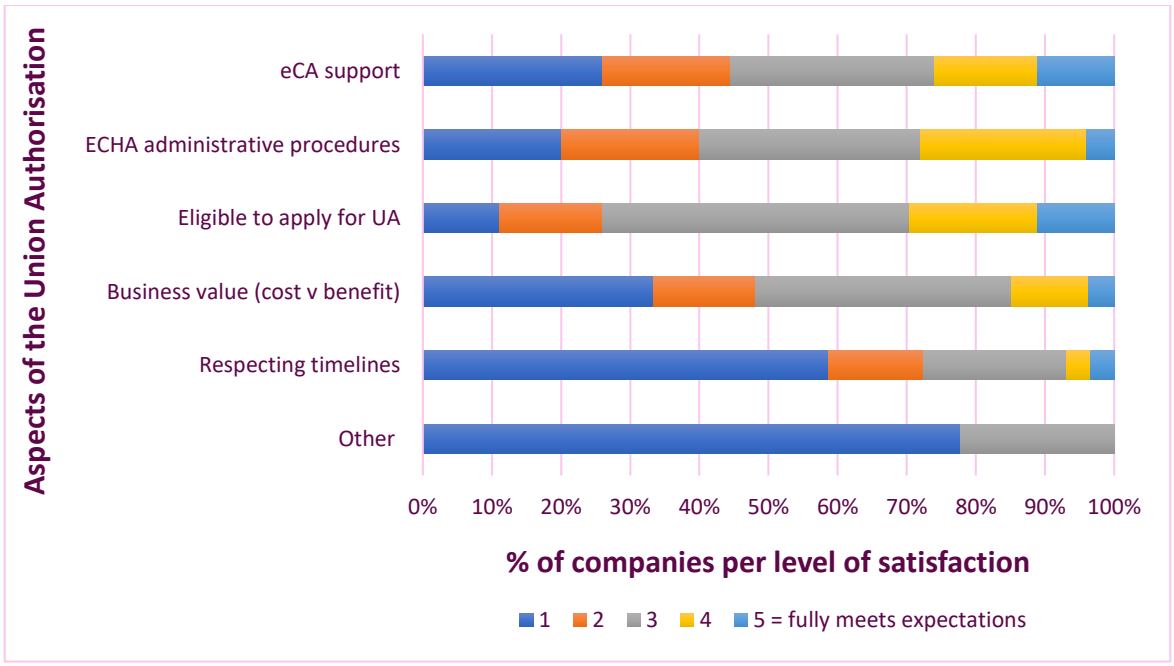

Figure 11. Satisfaction level around various aspects of the Union Authorisation process

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

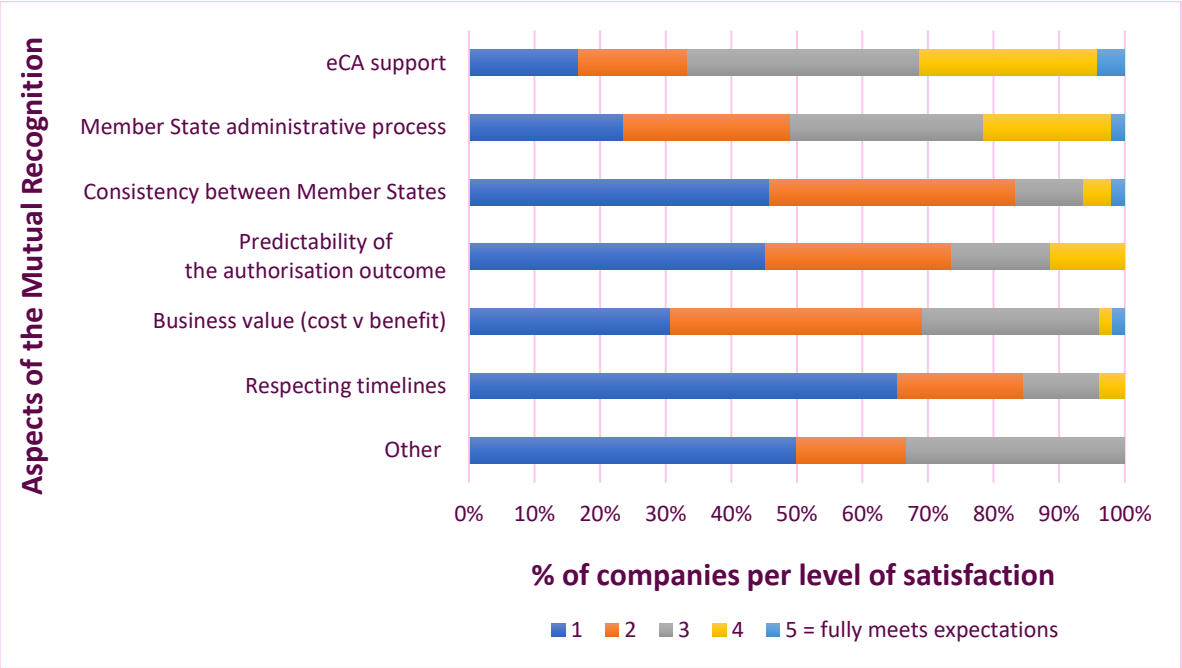

Figure 12. Satisfaction level around various aspects of the Mutual Recognition process

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

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

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

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

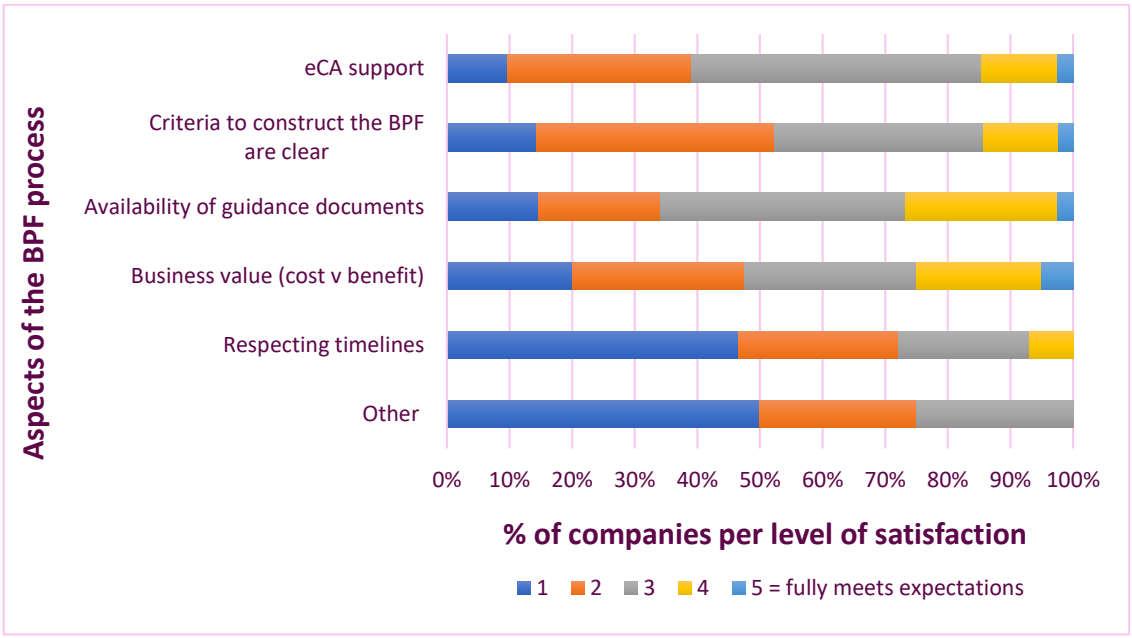

Figure 13. Satisfaction level around various aspects of the BPF process

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

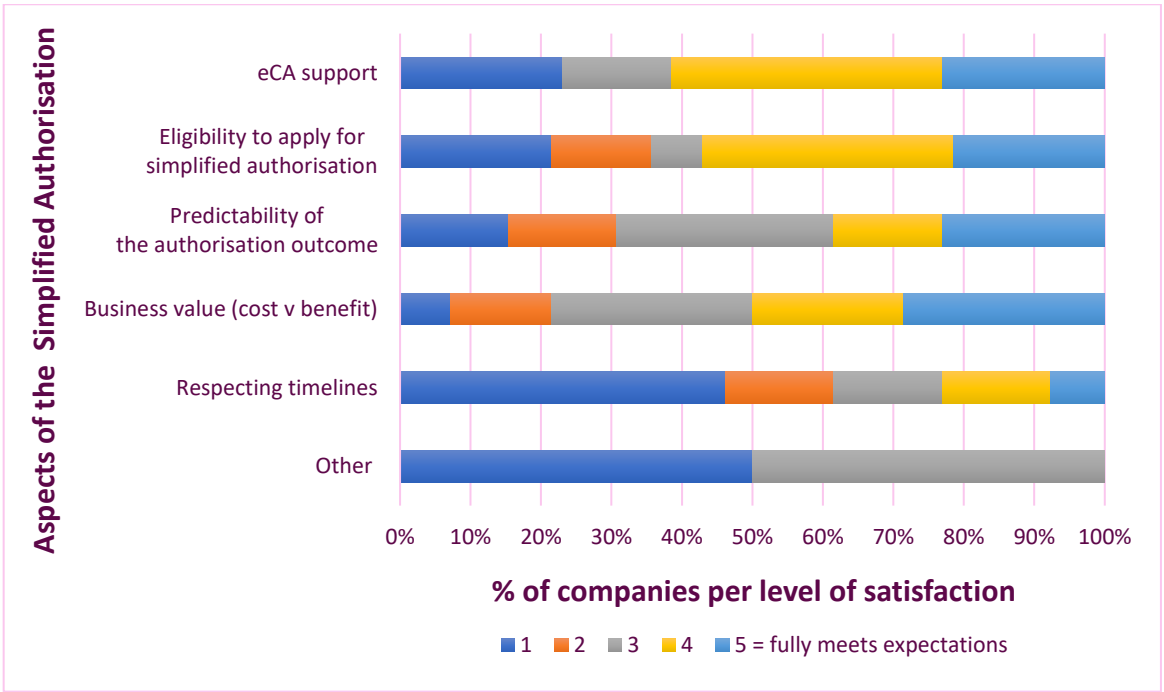

Figure 14. Satisfaction level around various aspects of the Simplified Authorisation Procedure

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

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

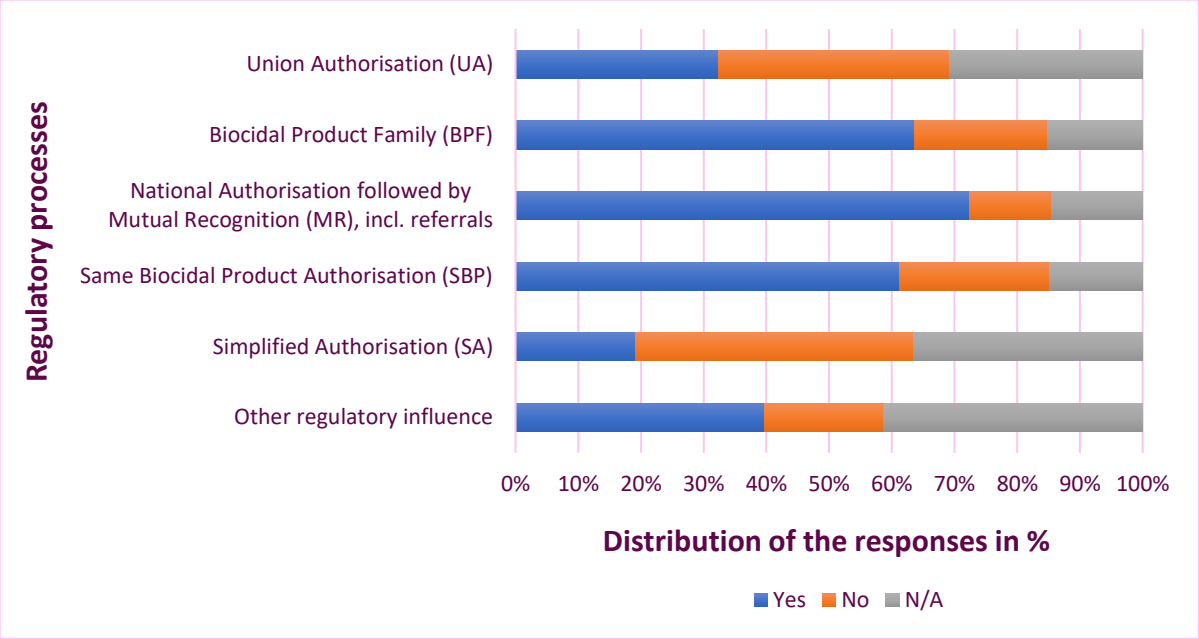

Figure 15. Influence of Regulatory processes on the biocides market/business

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

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

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

Length of processes and delays

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

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

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

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

Unpredictability and complex rules. Changing guidelines/requirements

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

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

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

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

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

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

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

Fees and costs

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

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

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

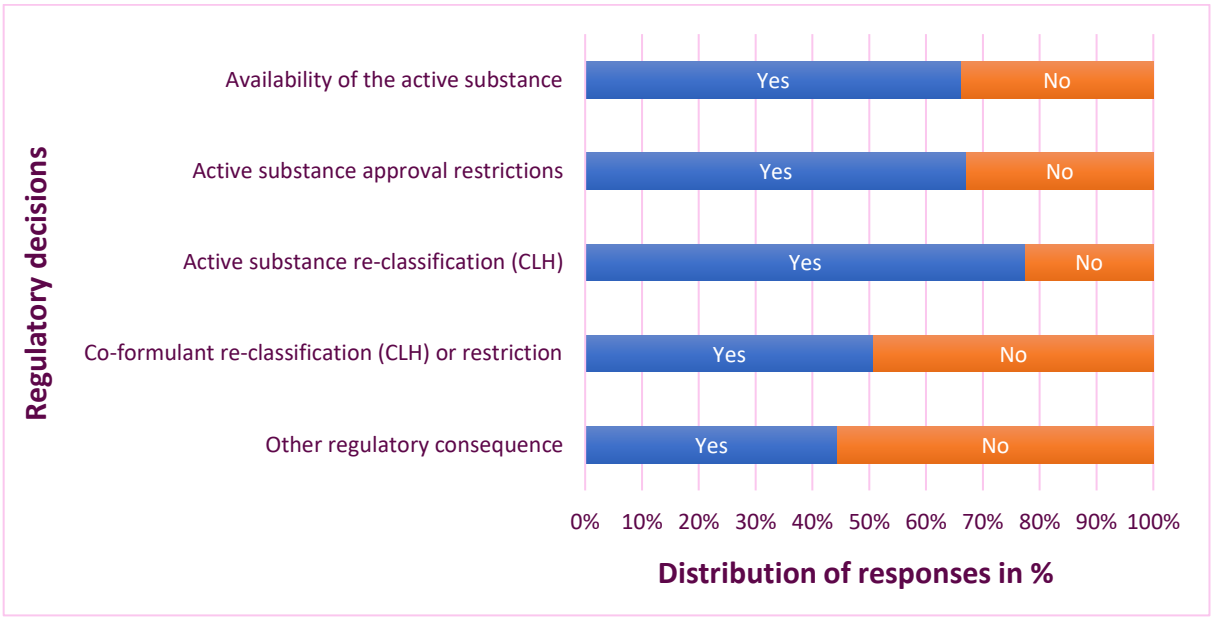

Figure 16. Influence of Regulatory decisions on the biocides business

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

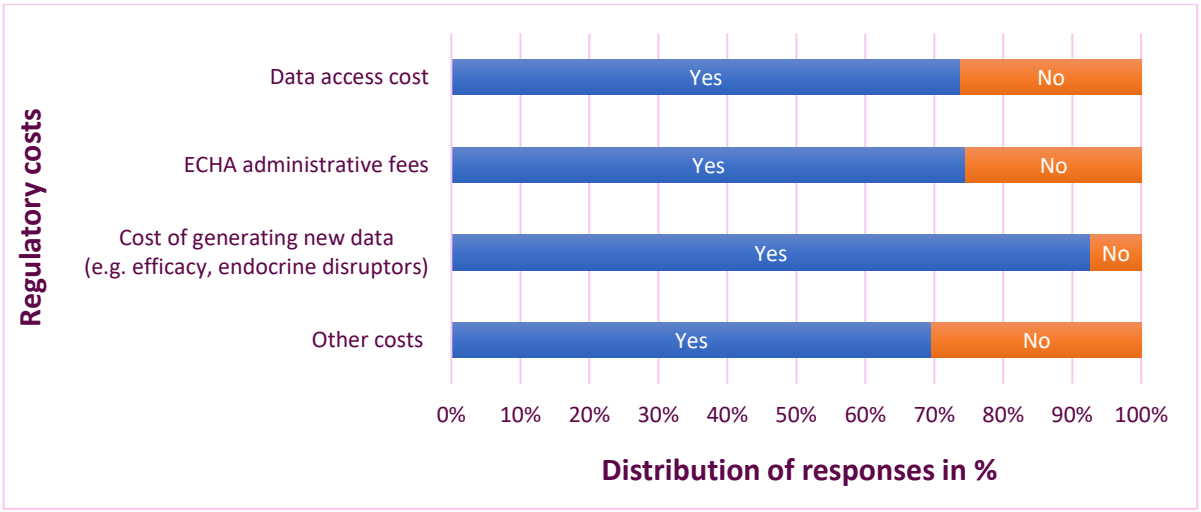

Figure 17. Influence of Regulatory costs on the biocides business

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

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

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

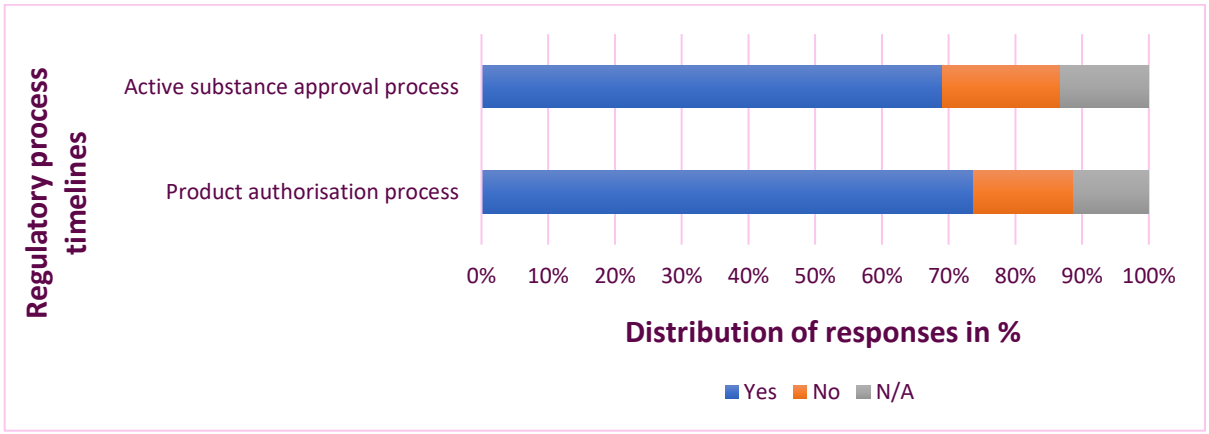

Figure 18. Influence of Regulatory timelines on the biocides business

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

2.3. Looking at the future

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

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

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

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

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

3. Innovation

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

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

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

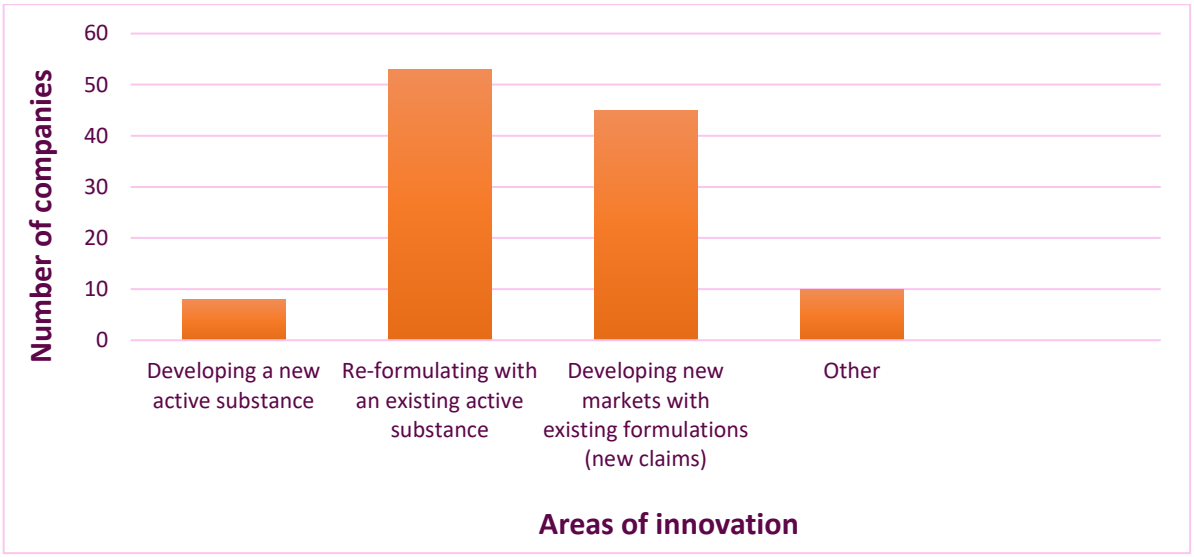

Figure 19. Areas of innovation

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

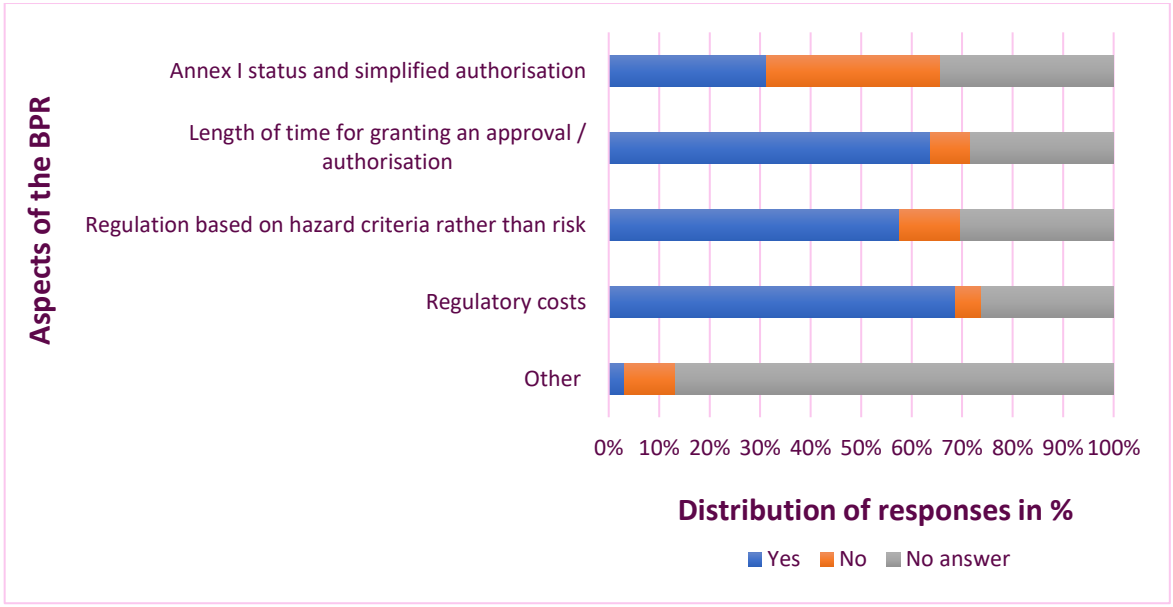

Figure 20. Aspects of the BPR influencing innovation

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

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

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

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

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

4. COVID-19

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

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

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

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

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

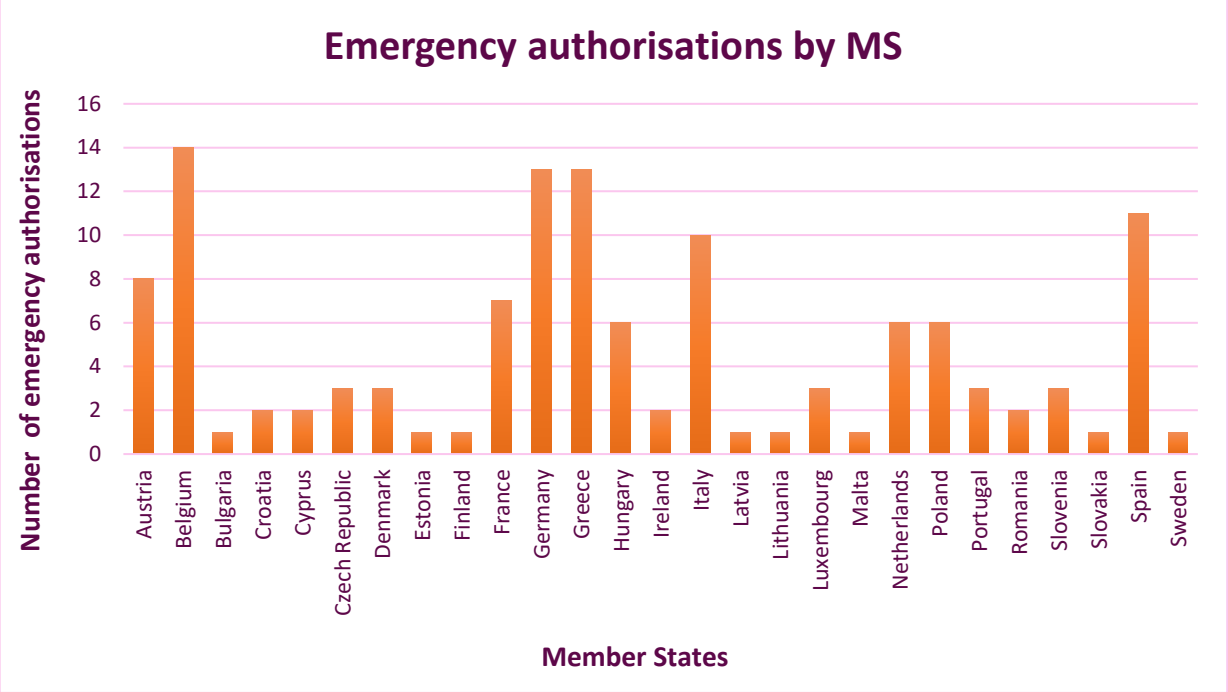

Figure 21. Emergency authorisations by MS

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

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

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

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

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

Closing remarks

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

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