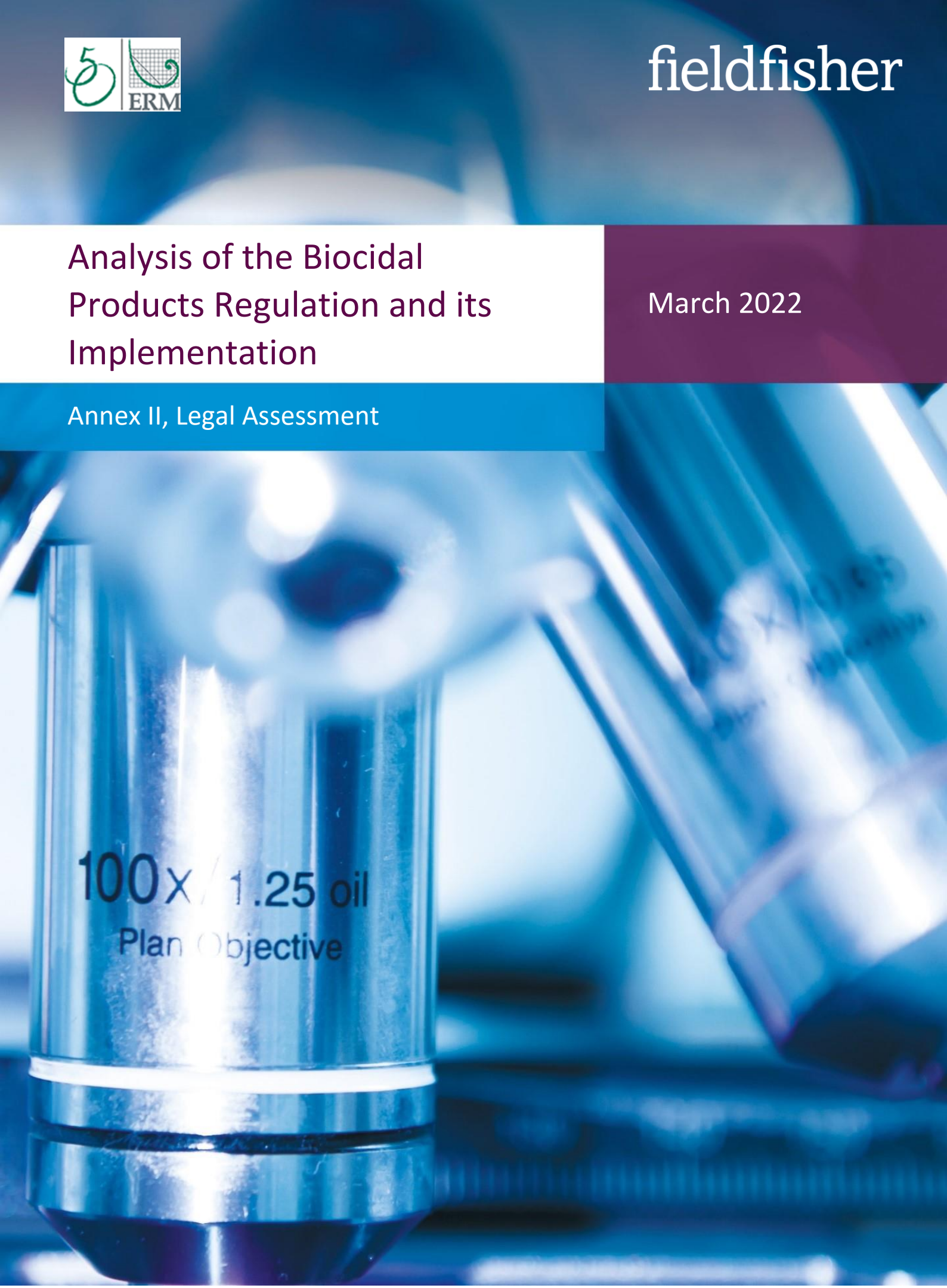
Analysis of the Biocidal Products Regulation and its Implementation

March 2022

Annex II, Legal Assessment



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

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

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

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

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

> *"The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups…".*

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

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

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

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
[2] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

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

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

1.1 Review of new active substances

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

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

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

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

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

1.2 Review of existing ASs

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

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

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

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

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

1.3 AS renewal

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

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

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

1.4 Biocidal product authorisations

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

National Authorisation ("NA")

(Chapter VI, Articles 29 to 31 BPR)

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

Mutual Recognition ("MR")

(Chapter VII, Articles 32 to 40 BPR)

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

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

Union Authorisation ("UA")

(Chapter VIII, Articles 41 to 46 BPR)

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

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

Simplified Authorisation ("SA")

(Chapter V, Articles 25 to 28 BPR)

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

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

Same Biocidal Product Authorisation ("SBP")

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

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

Biocidal Product Family ("BPF")

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

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

2. Legal assessment

Below we assess the BPR at three levels.

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

2.1 General principles of EU law

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

Discretion and manifest error of assessment

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

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

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

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

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

The precautionary principle: when does it apply?

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

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

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

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

The legal authority of guidance

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

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

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

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

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

The principle of legal certainty

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

There are two points here:

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

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

The principle of proportionality

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

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

The right to be heard

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

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

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

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

2.2 Substantive legal issues with the BPR

How to interpret "*biocidal product*"

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

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

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

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

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

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

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

In practice, the interpretation of these functions is inconsistent.

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

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

How to interpret Article 55(1) BPR

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

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

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

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

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

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

c. those containing new actives; and/or

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

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

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

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

Product type (PT) confusion

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

Examples of product types which present such borderline issues are:

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

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

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

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

Borderline products

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

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

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

Mutual recognition

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

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

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

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

Dissemination of commercially sensitive information

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

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

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

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

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

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

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

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

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

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

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

Lack of a level-playing field

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

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

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

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

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

2.3 Procedural legal issues

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

This raises concerns from the perspective of rights of defence.

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

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

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