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Take EU biocides legislation to the next level

Recommendations for streamlining environmental risk assessments and for reducing environmental impacts

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Wörlitzer Platz 1
06844 Dessau-Roßlau
Tel: +49 340-2103-0
Fax: +49 340-2103-2285
buergerservice@uba.de
Internet: www.umweltbundesamt.de

/umweltbundesamt.de
/umweltbundesamt

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Take EU biocides legislation to the next level

Recommendations for streamlining environmental risk assessments and for reducing environmental impacts

by

Maren Ahting, Corinna Burkart, Daniel Frein, Anja Kehrer-Berger, Sabrina Kraus, Nancy Ludwig, Christiane Meier, Katja Michaelis, Eleonora Petersohn, Caroline Riedhammer, Jana Schmidt, Susanne Schmidt, Ricardo Schöps, Maura Schwander, Torsten Schwanemann, Sascha Setzer, Christoph Stang, Christiane Stark, Stefanie Wieck

On behalf of the German Environment Agency

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Executive Summary

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR) came into force in 2013, resulting in more than a decade of experiences with environmental risk assessment under this legislation. Our suggestions for improvement can be divided into two categories: "streamlining environmental risk assessments" and "reducing biocide emissions to the environment". The proposals of these two categories need to be considered as complementing each other. To be able to simplify environmental risk assessments, accompanying measures are necessary to achieve the high level of protection as requested in Article 1 of the BPR.

Experiences have shown that the processes for environmental risk assessments **need to be simplified to allow for faster decisions**. Also, since BPR has been adopted, the "One Substance One Assessment" (OSOA) approach in the "Chemicals Strategy for Sustainability" has been newly developed to account for the increasing complexity in chemicals assessments. To streamline environmental risk assessments, the following proposals are made:

- **Definition of disinfection by-products and consequences**: Disinfection by-products need to be differentiated from "residues" and "reaction products".
- **Resolve inconsistencies in definitions on risk management**: "Risk mitigation measures" and "risk management" need to be clearly defined.
- **Skip assessment of representative product during active substance approval**: Evaluation of representative products should be omitted.
- **Adapt identification of candidates for substitution**: Only those substances should be identified for which an actual cause for concern exists on basis of their intrinsic properties.
- **Decision on applicability of aggregated exposure assessment**: The European Commission has to take a decision regarding the legal consequences of unacceptable environmental risks arising from aggregated exposure assessments.
- **Establish publicly available data collection on making available on the market of biocidal products**: Data on quantities of active substances in products that are placed on the market should be collected annually and published as transparent as possible.
- **Include plants as potential target organisms in PT 9**: To allow the environmental assessment of products for root penetration inhibition incorporated in materials under the BPR, plants should be listed as target organisms in product type (PT) 9.
- **Remove attractants from the BPR**: Attractants currently being assessed under the BPR do not give cause for concern and should therefore be removed from its scope.
- **Review of groundwater/bank filtrate assessment**: A focus on substances that are relevant for groundwater and drinking water and clearly formulated requirements will make the authorisation procedure more efficient without lowering the level of protection.

While first environmental benefits of the BPR can be observed, research shows that some biocidal active substances still enter the environment in significant amounts and will continue to do so, based on their intended uses. To reach the goals of the EU's Zero Pollution Ambition, it is inevitable **to reduce emissions to the minimum possible.** Following proposals are made in this regard:

- **Environmental endocrine disrupting properties as exclusion criterion**: Endocrine disrupting properties of active substances reaching the environment need to lead to the same regulatory consequences as endocrine disruptors for human health.
- **Sustainable management of harmful organisms**: Proper use of biocidal products should be linked to the ten general principles for a Sustainable Management of Harmful Organisms.
- **Restrict sales to authorised users**: If a biocidal product is authorised for other user groups than the general public, the biocidal product shall only be supplied to the members of these user groups.
- **Training of professional users**: Potential user groups of biocidal products should be defined and basic training requirements for trained professional users should be specified.
- **Large-scale outdoor practices and uses**: Large-scale outdoor practices or uses of biocidal products should be linked to overarching management measures.
- **Enhance simplified authorisation**: Authorisations according to Article 25 need to consider potential hazards to the aquatic environment.
- **Harmonize requirements for treated articles**: Imported treated articles should only be treated with biocidal products that are authorised in the EU or that comply with the same standards as set out in the BPR.
- **Improved labelling of treated articles and better information for their users**: The person responsible for the placing on the market of a treated article shall be responsible for the labelling of the treated article as well as for providing all relevant information on the biocidal treatment of the treated article to the consumer.
- **Advertisement for products authorised under Article 25**: Stakeholders need to be able to communicate the difference of biocidal products authorised under the simplified authorisation procedure compared to other biocidal products to the public.
- **Better communication on the label and in advertisements**: On labels and in advertisements, the product type should be stated instead of the general term "biocides".
- **Provide advice at the point of sale**: Based on decisions during product authorisations, self-service of biocidal products should be prohibited for these products and advice to consumers should be provided.

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a.s.	Active substance(s)
BPR	Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation)
CA	Competent Authority
CfS	Candidate for substitution
CLP regulation	Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures
DBP	Disinfection by-product
ECHA	European Chemicals Agency
ED	Endocrine disruptors
EU	European Union
IPM	Integrated Pest Management
OSOA	One Substance One Assessment
PBT	Persistent, bioaccumulative and toxic
PEC	Predicted environmental concentrations
PNEC	Predicted no-effect concentration
PMT	Persistent, mobile and toxic
PPPR	Regulation 1107/2009 concerning the placing of plant protection products on the market
PT	Product type
REACH	Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCS	Scientific Committee on Consumer Safety
SuMaHO	Sustainable Management of Harmful Organisms
R4BP	Register for Biocidal Products
vPvB	Very persistent, very bioaccumulative
vPvM	Very persistent, very mobile
WHO	World Health Organisation

1 Need for action

After *Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products* (BPR) came into force in 2013, many experiences with environmental risk assessment under this legislation have been gained.

ON THE PLUS SIDE

Although the review program of existing biocidal active substances being on the market before 14 May 2000 has not been concluded yet, emissions of active substances to the environment are decreasing due to the EU-wide regulation of biocidal active substances, which can be shown for some cases. One example is the former disinfecting substance Triclosan, which also has been used in cosmetic products. In a recent publication, a statistically significant decrease of triclosan was shown for samples from German surface water bodies for the time period of 2008 to 2021.[1] These findings are consistent with the non-authorisation under BPR in 2014 and 2016 due to its properties and a stop of production in 2018 due to low market demand for non-biocidal uses.

ROOM FOR IMPROVEMENT

Despite positive developments with and through the BPR in the EU, there is still potential and need for improvement in order to maximise the benefits of the authorisation procedures. This need is based on two shortcomings: (1) deficiencies in efficiency of the regulation and (2) ongoing pollution of the environment with some biocidal active substances.

(1) The review program for substances being on the EU market before 14 May 2000 is still not concluded, although it was originally scheduled to be completed after a 10 years period. Delays in the process required prolongations of the deadline and ultimately lead to the recent decision to extend the deadline to the year 2030. Though, not only the approval processes of biocidal active substances are heavily delayed. Product authorisation processes often also exceed the intended timescales for their evaluation for different reasons. Based on the "Better regulation" principles of the EU, existing regulation needs to be reviewed whether they are fit for purpose and contribute to their goals. Experiences have shown that **the processes for environmental risk assessments under BPR could be simplified to allow for faster decisions.**

    This is supported by the results of the EU Commission's "*Fitness check of the most relevant chemicals legislation (excluding REACH)*"[2], hereafter referred to as "Fitness check". Also, since the BPR has been adopted, the "One Substance One Assessment" (OSOA) approach in the "Chemicals Strategy for Sustainability" has been developed to account for the increasing complexity in chemicals assessments. Its ideas need to be taken into account as well.

(2) Potentially harmful biocidal active substances which were approved under BPR, are still detectable in the environment, in amounts leading to concern. As an example, two approved azole fungicides were frequently detected in German surface water samples[3]: Propiconazol

[1] Dierkes et al. (2025): Retrospective trend analysis of biocides in suspended particulate matter of major German rivers. In: Environmental Science Europe 37. https://doi.org/10.1186/s12302-025-01053-5

[2] European Commission (2019): Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses. https://commission.europa.eu/publications/fitness-check-most-relevant-chemical-legislation-excluding-reach_en (23.05.2025)

[3] Kopp et al. (2025): Einträge von Bioziden in Gewässer über Mischwasserentlastungen und Regenwassereinleitungen und die Auswirkungen auf die Gewässerqualität am Beispiel der Stadt Karlsruhe. UBA-Texte 09/2025. https://www.umweltbundesamt.de/publikationen/eintraege-von-bioziden-in-gewaesser-ueber (23.05.2025)

and Tebuconazol. Azole fungicides are used in plant protection products or biocidal products. Besides Propiconazole being known as endocrine disrupting compound, azole fungicides raise concern as their occurrence can be correlated to a more frequent abundance of azol-resistant, human pathogen *Aspergillus* species.[4] To reduce their emissions, provisions during product authorisations are not enough. Training of professional users or advice for the general public at the point of sale could support a more sustainable use.

This is only one example, highlighting the need to strengthen environmental risk assessment and to put more focus on the use-phase of biocidal products. The latter is of high relevance as many uses which will also be prospectively indispensable, lead to unavoidable emissions to the environment. To reach the goals of EU's Zero Pollution Ambition, it is inevitable **to reduce these emissions to the minimum possible.**

The proposals of the two categories need to be considered as complementing each other. To be able to reduce administrative burden of approval and authorisation procedures, accompanying measures targeting the use-phase need to be implemented to achieve high level of environmental protection.

[4] European Food Safety Agency et al. (2025): Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp. In: EFSA Journal 23. Issue 1. https://doi.org/10.2903/j.efsa.2025.9200

2 Structure of the document

Based on experiences made during environmental risk assessments, research projects, and new approaches in EU chemicals assessments, the authors compiled recommendations to make BPR fit for the future. The recommendations relate to certain existing articles or chapters of the BPR. Thus, they are presented in the order of their appearance in the BPR. Based on the expected benefit, the recommendations were assigned to either **streamline the assessment** or to **reduce biocides emissions to the environment**. The proposals contained in this document can be attributed to these two categories, which are discussed in more detail below. The corresponding icons allow easy classification. Each recommendation is divided into the subsections (a) "Background", (b) "Proposal for a solution" and (c) "Resulting benefit".

(1) Streamline assessments

Streamlining of processes will not only enhance efficiency but also foster a responsive and transparent system meeting the needs of all stakeholders involved. This can be achieved by using different levers:
(a) **efficiency** can be increased by skipping steps without added value for environmental protection to save resources,
(b) **coherence** can be improved by better coordinating regulations and processes to prevent dual structures,
(c) **governance and transparency** can be optimised to avoid vagueness in the legal text leading to misunderstandings and disputes.
Based on these levers, different targets for streamlining of the assessments are identified.

- Definition of disinfection by-products and consequences
- Resolve inconsistencies in definitions on risk management
- Skip assessment of representative product during active substance approval
- Adapt identification of candidates for substitution
- Decision on applicability of aggregated exposure assessment
- Establish publicly available data on making available on the market of biocidal products
- Include plants as potential target organisms in PT9
- Remove attractants from the BPR
- Review of groundwater/bank filtrate assessment

(2) Reduce biocide emissions to the environment

Reduction of biocide emissions to the environment can be achieved by **enhancing the provisions regarding biocidal active substances or products** under the BPR or by further measures **targeting the use phase** of the products. As biocidal active substances are designed to affect organisms and emissions to the environment can often not be completely prevented, these further measures are an important element missing at the moment. Better knowledge of the harmful organisms, how to prevent them and how to choose the most sustainable management options are key elements.

- Environmental endocrine disrupting properties as exclusion criterion
- Sustainable management of harmful organisms
- Restrict sales to authorised users
- Training of professional users
- Large-scale outdoor practices and uses
- Enhance simplified authorisation
- Harmonise requirements for treated articles
- Improved labelling of treated articles and better information for their users
- Advertisement for products authorised under Article 25
- Better communication on the label and in advertisement
- Provide advice at the point of sale

3 Chapter I of BPR: Scope and definitions

3.1 Definition of disinfection by-products and consequences

a. Background

The BPR requires in its Article 19 (1) b) iv. an environmental risk assessment of residues of biocidal products. According to Article 3 (1) h), residues include reaction products of the active substances. Although not explicitly mentioned in the legal text, current understanding is that this includes also so-called disinfection by-products (DBPs). DBPs result from reactions of active substances with the organic and inorganic matrix present when they are applied and further reactions of DBPs with each other.

It is well known, that the formation of DBPs is a highly complex process with numerous influencing factors such as presence of organic and inorganic matter, temperature, pH, contact time or applied concentration of the active substance, whose influence as well as their possible interactions, have not yet been fully investigated and understood. This results in unpredictable DBP mixtures for each specific case. Additionally, the composition may be subject to further changes over time, e.g. due to reactions of the already formed DBPs among each other. A large number of DBPs can be formed, i.e. in scientific literature more than 600 substances are reported.[5] Nonetheless, only a few of those known DBPs have already been studied with regard to effects on environmental biota as well as their environmental fate and behaviour. In addition to these uncertainties and open questions on the known substances, a whole range of unknown compounds can be formed. This complexity makes it impossible to define standard conditions for ecotoxicological testing or chemical analysis.[6]

For these reasons, a classic environmental risk assessment of DBPs according to the provisions of the BPR is not feasible in our point of view. On technical level, discussions on this topic have already required much resources without finding a solution. This situation is aggravated by the fact that literature data also indicate a risk for mixture toxicity and cumulative effects. Under these circumstances, an assessment for only a few marker DBPs, as currently foreseen by the BPR Guidance on disinfection by-products[7], may lead to a sense of "false security": If this risk assessment indicates acceptable risks for environment, one cannot be sure that the main "risk drivers" are covered based on the data currently available for DBPs in general. Rather, due to the precautionary principle, it must be assumed that in the case of DBP-forming active substances, an unacceptable risk for the environment cannot be completely excluded. Hence, preventive measures are always necessary if DBP formation is likely for a certain use of biocidal product that is needed. Building on those aspects, a pragmatic approach is needed to deal with DBPs under the BPR, which will prevent additional loops with assessments and requests for further testing or analysis that cannot change the outcome of the assessment regarding environmental risks.

[5] Richardson (2011): Disinfection By-Products: Formation and Occurrence in Drinking Water. In: Encyclopedia of Environmental Health. Pages 110-136. https://doi.org/10.1016/B978-0-444-52272-6.00276-2

[6] Hüben et al. (2023): Consideration of disinfection by-products in the environmental risk assessment of biocidal products. UBA-Texte 119/2023. https://www.umweltbundesamt.de/publikationen/consideration-of-disinfection-products-in-the (23.05.2025)

[7] European Chemicals Agency (2017): Guidance on the BPR: Guidance on Disinfection By-Products. ECHA-17-G-01-EN. https://echa.europa.eu/documents/10162/2324906/bpr_guidance_vol_v_dbp_new_en.pdf/c7d11d09-8ae5-317f-0eeb-ec8b2aa938b3?t=1499425521377 (23.05.2025)

b. Proposal for a solution

DPBs are currently not explicitly mentioned in the legal text, but it must be assumed that they are covered by the definition given for „*residues"* in Article 3 (1) h) BPR as well as by the term „*reaction products*" mentioned in Annex VI to the BPR, which require a consideration in environmental risk assessment. However, as described above, this is not possible for DBPs. Hence, exemptions must be introduced for the definition of DBPs in the BPR as well as for their management during the authorisation process.

Options for exemptions are either i) creating a separate definition for DBPs under Article 3 (1) BPR or ii) to establish an explicit exception for DBPs under Article 3 (1) h) of the legal text based on the definition of DBPs given in the *In-situ* Recommendations[8], e.g.: *„Disinfection by-products (DBP) are not impurities and cannot be considered as reaction products. Components formed during the intended use of the active substance are not regarded as reaction products"*.

As a consequence of this change, Member States will have to i) agree on the formation potential of DBPs during active substance approval and ii) develop and agree on precautionary measures to be applied for the corresponding products to prevent the formation of DBPs as far as possible.

c. Resulting benefit

The proposed solution will ensure a harmonized approach for the precautionary management of DBPs in the EU. It will also help to simplify the assessment for all involved stakeholders thereby saving valuable resources. It increases the protection of the environment as the formation of DBPs and their releases into environment will be reduced to a minimum by the application of precautionary measures during product authorisations.

3.2 Resolve inconsistencies in definitions on risk management

a. Background

Biocidal products are used to kill, to destroy or to deter living organisms. Considering the potential risks associated with the use of biocides, one major principle laid down in the BPR is that only biocidal products whose use results in acceptable risks to the environment shall be authorised. As basis for the decision-making process for the environmental risk assessment, Annex VI sections 65 and 66 focus on the PEC/PNEC principle. Concerning products for which an unacceptable environmental risk has been identified, section 66 in Annex VI BPR states that "the evaluating body shall judge, on the basis of the size of that ratio and on other relevant factors, whether […] appropriate risk reduction measures are necessary, or whether the biocidal product cannot comply with criterion (iv) under point (b) of Article 19 (1)."

Although the establishment of appropriate "risk reduction measures" is already a regulatory precondition for authorisation of several biocidal products, the BPR remains unclear what exactly constitutes a "risk reduction measure". Additionally, the BPR uses varying formulations in this context like "risk management measure" (e.g. recital reasons paragraph 64) and "risk mitigation measure" (Article 19 (5)) with unknown differentiation.

[8] European Chemicals Agency (2025): In situ generated active substances and their products - Information requirements and risk assessment for approval and authorisation. ECHA-25-H-03-EN. https://echa.europa.eu/documents/10162/17234/situ_as_precursors_wg_recommendation_en.pdf/0c6aee50-5c29-bccc-3836-bb033a015144 (23.05.2025)

This gap in the BPR and related guiding documents is leading to an increasing uncertainty among responsible authorities. It is often the subject of discussion according to which criteria the authorisation of biocidal products has to be restricted or rejected. As a consequence, biocidal products may be authorised based on divergent standards and their regulation may neither be appropriate nor sufficient.

b. Proposal for a solution

In the short-term, clarifications should be included in Article 3 (1) BPR to determine the meaning of the terms in the framework of the authorisation of biocidal products and how they relate to each other. In the medium-term, guiding principles for a harmonised understanding of suitable risk mitigation measures and appropriate risk management will be necessary.

We propose to use the terms "risk mitigation measure" and "risk management" throughout the BPR in the following definitions.

Risk mitigation measures *are applied in cases where unacceptable risks are determined during product authorisation. They could be defined as measures which reduce emissions of biocides to the environment and minimise the identified risk for a specific use to an acceptable level.*

Examples for risk mitigation measures are (i) measures that reduce emission of the product (e.g. reduction of use frequencies, use only at restricted treated areas, top coatings, specific application techniques) or (ii) measures that reduce the exposure of the environment (e.g. drift reduction nozzles, ground coverage, cleaning requirements, bait protection station) with the product. The responsible authorities need to conclude and agree whether the risks of the relevant use can be reduced to an acceptable level with these measures and whether the requirements of criterion (iv) under point (b) of Article 19 (1) are met for authorisation.

Risk management *concerns the overall reduction of the possibility of harm by biocidal products. It is not necessarily related to reaching an acceptable level of risk as defined by Article 19 (1) BPR as precondition for authorisation.*

On the one hand, risk management might become necessary in cases where authorisations according to Article 19 (1) cannot be granted due to unacceptable risks and authorisation according to Article 19 (5) is considered. On the other hand, it is an important lever to protect humans, animals and the environment (see Annex VI point 18 d) BPR) by applying measures reducing the likelihood of misuse especially for consumer products (e.g. appropriate packaging sizes and providing dosing aids).

Other examples for risk management may include (i) measures to restrict the use (e.g. only professional or trained users, application areas) or (ii) measures for a proper use (e.g. supporting a sustainable management of harmful organisms, mandatory information and awareness-raising requirements).

c. Resulting benefit

Clear definitions and guidance for risk mitigation and risk management are an important component to adequately regulate risks arising from the use of biocidal products. Appropriate guidelines therefore reduce the need for coordination and thus increase the efficiency of the regulatory process, while also creating uniform authorisation conditions across Member States.

Excursus: Principles for the evaluation of "appropriateness" of risk mitigation measures

For many biocidal products with unacceptable environmental risks, the establishment of "appropriate risk reduction measures" is a regulatory precondition for authorisation (see Annex VI section 66 BPR). However, besides a lacking definition for the term "risk mitigation/reduction measure" (see above), the BPR also remains unclear in what "appropriate" means.

Guiding principles need to be established helping to decide on the "appropriateness" of potentially relevant measures. Especially with focus on non-professional users, clarification is needed which instructions (risk reduction/mitigation measures and use instructions) are feasible, covering aspects like comprehensibility, practicability and motivation[9]. For this reason, there is a need to collect more empirical data on the user perspective. This would allow to extrapolate from a comparatively limited, but scientifically collected set of individual observations to generalised EU guiding principles to decide on feasible risk mitigation measures. These principles should also address the impact of feasible measures on relevant parameters of the emissions scenarios. In the long term, guiding principles should be added to Annex VI in section "Effects on the environment" or a Guiding Document should be developed. However, in order to decide on the "appropriateness", also the relevance of regulatory issues covered by terms like compliance, implementation and enforceability needs to be clarified.

[9] Bearth et al. (2024): Consumer Survey on Biocidal Products and Environmental Risks. UBA-Texte 148/2024. https://www.umweltbundesamt.de/publikationen/consumer-survey-on-biocidal-products-environmental (23.05.2025)

4 Chapter II of BPR: Approval of active substances

4.1 Skip assessment of representative product during active substance approval

a. Background

The active substance procedure under the BPR is progressing very poorly, so that the review procedure for the so called "existing active substances" has already had to be extended twice. This means that many biocidal products containing existing active substances are still available on the market and will continue to be, even though they haven't been fully evaluated yet. As a result, there could be potential risks for humans and the environment and there is yet no proof of their efficacy. The main reason for this delayed process is the complex approval procedure foreseen by the BPR. One important aspect that complicates active substance approval processes is the fact that not only an assessment of the active substance itself is required for the approval of the active substance in the first step, but also an assessment of the potential risks of a possible use of the active substance in a representative product (see Articles 4 and 6 BPR). Experiences gained so far indicate that the choice of the representative product by the applicant can have a fundamental influence on the authorisation of active substances. Hence, in the current assessment practise, a lot of resources are invested in the evaluation of these products that might never enter the market, delaying the process accordingly. Following active substance approval, evaluations of the real products that will enter the market are again necessary during product authorisation. As a final consequence, many problems must be discussed again in this step. Therefore, in our point of view, a paradigm shift in the assessment scheme is necessary to accelerate the assessment of biocides at European level.

b. Proposal for a solution

The proposal is to adapt the requirements of active substance approval in Article 4 and 6 to skip the assessment of the representative product.

Following this proposal, an applicant for an active substance would need to submit a PT-specific core data set (i.e. on environmental fate and behaviour, effects on environmental non-target organisms, classification and labelling), which can be customised to the product-specific use pattern of the respective active substance. One example for these product-specific use patterns is if the active substance is potentially only to be used for indoor products with no releases into the environment, then no soil degradation study or similar may need to be submitted. Based on this PT-specific core data set, the approval decision for the respective active substance will be limited to the uses as potential product range for product authorisation.

The hazard assessment will help identifying active substances that have problematic intrinsic properties for the environment such as being persistent, bioaccumulative and toxic (PBT) or endocrine disruptors. If no derogations according to Article 5 (2) BPR apply, these problematic active substances would not be authorised. Amongst other derogations, Article 5 (2) a) BPR contains the possibility for applicants to demonstrate that the risk from exposure to the active substance in a biocidal product, under realistic worst-case conditions of use, is negligible. While this derogation explicitly refers to the exposure towards the active substance during the use of a biocidal product, a representative product is not necessary to prove the fulfillment of the

criterion of negligible exposure. Experiences show that this is discussed rather qualitatively than by using exposure calculations for the representative product.

Products containing approved active substances would undergo full environmental risk assessments during product authorisation, including exposure assessments. The evaluation of the products containing the respective active substance at product authorisation will be based on the data submitted during the active substance procedure, supplemented with specific exposure-related data for the respective product uses. New studies would only be accepted during product authorisation, if they are strictly product-specific and are required for the refinement of the risk assessment.

c. Resulting benefit

With these changes the labour-intensive and time-consuming evaluation of representative products during active substance approval would no longer be necessary and resources could be used to complete the review program and accelerate product authorisations.

Furthermore, the revised assessment strategy will lead to an equal treatment of all applicants, as it will not be the selection of the product evaluated as part of the active substance approval that influences the final conclusion of approval process, but only the intrinsic properties of the active substance.

4.2 Environmental endocrine disrupting properties as exclusion criterion

a. Background

Currently, only the identification of substances as endocrine disruptors (ED) for human health leads to the fulfilment of the exclusion criteria under Article 5 (1) d) BPR and the resulting regulatory consequences. In contrast, the identification of a substance as an ED for organisms in the environment only leads to tagging as a candidate for substitution according to Article 10 (1) e) BPR and the refusal of authorisation of respective products for uses by the general public. This discrepancy leads to a weaker position for the environment compared to human health. Instead of a hazard-based approach, only a statement on the acceptability of the risk is currently required, taking into account the ED properties. However, this generally leads to the conclusion that no conclusive statement is possible, as no safe limits (i.e. PNECs) for environmental organisms can currently be derived for ED. This approach not only contradicts the scientific understanding that EDs should in principle be assessed in a hazard-based approach, it also complicates the decision-making process and unnecessarily ties up capacities. Another important aspect is, that also the regulatory consequences differ for environmental EDs identified under BPR and *Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market* (PPPR). According to the latter, active substances, safeners, synergists, and basic substances with environmental ED properties may not be approved.

For reasons of consistency, we also see the need to adapt article 5 (2) (a) according to the provisions of the PPPR by focussing on exposure rather than risk and thus reduce the scope for interpretation to a minimum.

b. Proposal for a solution

In order to achieve a high level of protection for the environment, a revision of Article 5 BPR is required. The following proposal of the revised Article 5 (1) d) and Article 5 (2) a) considers the above-mentioned shortcomings regarding EDs in the environment[10] under BPR and PPPR:

Article 5 (1) d):

„active substances which, on the basis of the criteria specified ~~pursuant~~ in Regulation 2017/2100 ~~to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and third subparagraphs of paragraph 3,~~ are considered as having endocrine-disrupting properties that may cause adverse effects in humans or the environment ~~or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties~~;

Article 5 (2) a):

„the ~~risk to~~ exposure of humans, animals or the environment ~~from exposure~~ to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment“

c. Resulting benefit

This change would provide the clear message that also endocrine disruptors for environmental biota should be excluded, leading to the non-approval/non-authorisation of endocrine disruptors in general, unless they are absolutely necessary or are used in closed systems. Thus, their emissions to the environment will be prevented.

[10] Additions are underlined, deletions are ~~crossed out.~~

5 Chapter III of BPR: Renewal and review of approval of an active substance

5.1 Adapt identification of candidates for substitution

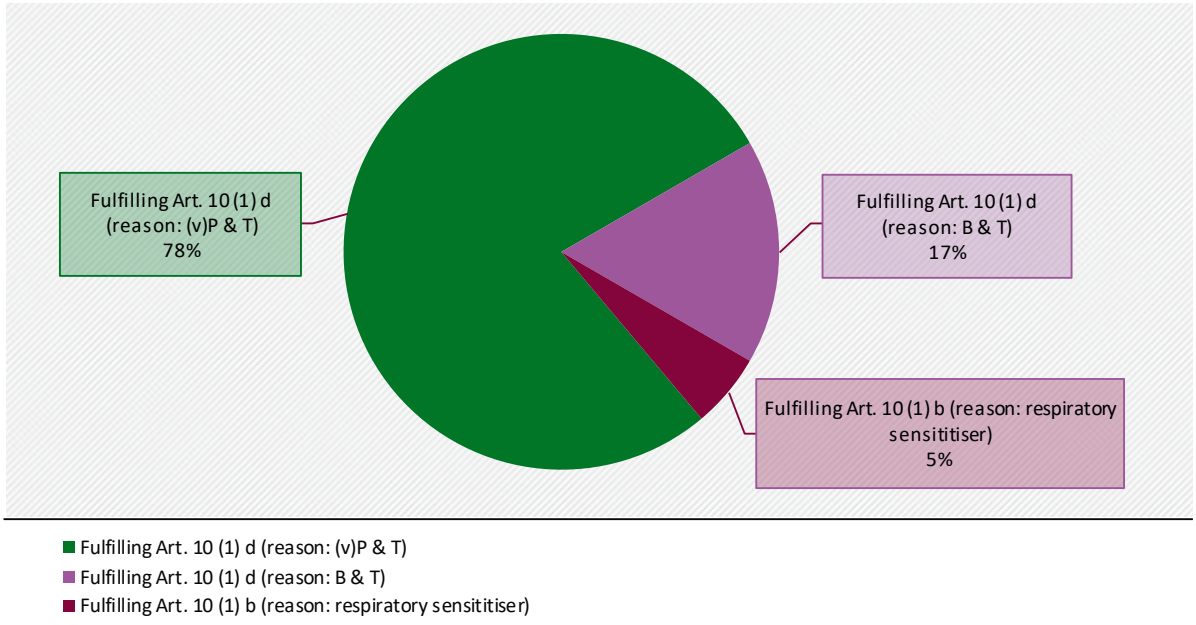
a. Background

The BPR prescribes a comparative assessment at product authorisation level if the product contains an active substance that was identified as a candidate for substitution (CfS) as part of the active substance evaluation process. Until now, 37 substances, representing 26% of all approved biocidal active substances are classified as CfS. While 19 of these substances have been classified as CfS according to Article 10 (1) a) because they fulfil the exclusion criteria, the remaining 18 substances fulfil other criteria laid down in Article 10 (1) b)-f).

The so-called substitution principle and the comparative assessment were first introduced in the plant protection area with *Regulation 1107/2009 concerning the placing of plant protection products on the market* (PPPR). To our knowledge, not a single product has been substituted - neither under BPR nor under PPPR. Against this background, a study to support the REFIT evaluation of EU legislation on plant protection products and pesticide residues concluded that the comparative assessment is one of the areas that has a negative impact on the effectiveness of the PPPR, as it leads to an increased workload for the competent authorities without any substantial benefit.[11] From our perspective, this conclusion also applies to the BPR and calls for appropriate adaptations. We consider the comparative assessment a valuable mechanism that should be further developed to increase environmental protection. The most effective way forward involves improving the guidance by elaborating on procedures, highlighting case studies, and offering concrete recommendations to ensure consistent and effective use (see box below).

Another important aspect that needs to be discussed is Article 10 (1) BPR laying down the criteria for determining substances to be substituted. Revision is particularly needed for paragraph d), classifying substances that meet two out of three PBT (persistent, bioaccumulative, toxic) criteria as CfS. As biocides are intended to harm or even kill organisms, they must exhibit a certain toxicity by definition. In addition, a certain stability and therefore persistence of active substances is a necessary and desirable property for specific product types (e.g. in wood and material protection) and applications. Hence, a large number of biocidal active substances will fulfil the "two out of three" criterion in Article 10 (1) d) "*by design*" so that they can achieve the desired impact at all. This is reflected in the fact that all but one substance classified as CfS according to Article 10 (1) b)-f) are CfS because of this Article 10 (1) d). The majority of CfS have gained this status by being classified as (very) persistent and toxic (see Figure 1).

[11] European Commission (2018): Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005). https://data.europa.eu/doi/10.2875/88433 (23.05.2025)



Comparable results were obtained for active substances in plant protection products (Altenburger et al., 2017, Report No. (UBA-FB) 002256/ENG))

Source: Document CG-62-2024-16 AP 16.2

Figure 1 Justifications for substances being CfS under Article 10 (1) b)-f) [n=18]

If one takes a closer look at the criteria for bioaccumulation and persistence, the latter are comparatively conservative and the triggers are quite easily exceeded. This is also underpinned by the fact that almost 40% of the already authorised active substances in biocides are persistent or even very persistent, but only 6% fulfil either the B or vB criterion. It is known that both properties are related to each other in the sense that persistence promotes bioaccumulation. This is one of the reasons why these two criteria were originally established as a double (vPvB) or triple (PBT) to identify substances of very high concern. Regulatory consequences for the mere fulfilment of the persistence criteria, also in connection with toxicity, was not what the inventors had in mind. Hence, in our point of view the substitution criterion in Article 10 (1) d) BPR does not appear to be suitable for significantly improving environmental protection. If a large number of active substances is classified as CfS, the intended distinguishing character of the substitution principle is lost. As a consequence, the process only increases the workload for all stakeholders without a significant impact for the protection of the environment.

The same holds true for the declaration of PMT/vPvM (persistent, mobile, toxic) substances as CfS as it has been proposed by the Competent Authorities (CA) for Biocidal Products in their CA-meeting. It has to be assumed that substances meeting the (v)P and T criterion, but not the B criterion, will often also meet the PMT/vPvM criteria due to the defined threshold for M. For this reason, establishing PMT/vPvM as additional criterion for CfS would not bring any benefit, but only increase the workload.

b. Proposal for a solution

With regard to the identification of candidates for substitution, we propose an adjustment of Article 10 (1) BPR. In this context, it should be reviewed whether the criterion “two out of three of the PBT criteria” in Article 10 (1) d) should be omitted. The same applies to PMT/vPvM as substitution criteria.

c. Resulting benefit

In terms of environmental protection, the identification of problematic substances and comparative assessment of the corresponding biocidal products are fundamentally useful instruments. However, the substitution criteria established with the BPR and the procedure for comparative assessment have not yet proven their worth. A revision considering the above-mentioned approach would increase the efficiency of the process.

Furthermore, the high number of substitution candidates due to the fulfillment of P/vP and T, especially for certain chemical groups, has led to high pressure on the persistence assessment in the past. This can be seen, for example, in the different interpretation of the P/vP criteria between plant protection and REACH (e.g. P/vP trigger at 12°C vs. 20°C), but also in numerous recurring discussions about persistence in the context of active substance evaluations. The deletion of this substitution criterion for biocidal active substances could ultimately promote the achievement of the OSOA goal.

Excursus: Improve Guidance on comparative assessment

Problem: The basic idea of the concept of comparative assessment is to be supported in principle. However, there is room for improvement, as in most cases, comparative assessment already stops after the first screening step, in which the chemical diversity is checked. For this screening, the Guidance on Comparative Assessment[12] considers three "active substance/mode of action"-combinations to be an appropriate chemical diversity in order to avoid the development of resistance. But as the proportion of CfS is high in most main groups, alternatives are rare.

Proposal: Based on our experiences, we believe that there are certainly options to significantly improve the applicability of the concept of comparative assessment by revising the existing guidance. In our opinion it would be promising to also include the comparison of application methods instead of only comparing active substances. Different application methods of products for the same use result in different environmental exposure and thus different risks (e.g. outdoor ant control: bait stations have lower risks than openly pouring the product; fly control indoors: a window sticker has lower risks than spraying of the product). Thus, it would be possible to compare products containing even the same active substance if they have a different application method. With this approach, comparative assessments would not necessarily stop at the screening step.

In addition, the performance of the comparative assessment is currently hampered by different data sets for biocidal products due to different application methods; different refinement stages of the exposure assessment and missing detailed and readily available data on application methods of already authorised products. These points should also be addressed in a revision of the Guidance.

[12] European Commission (2015): Technical Guidance Note on comparative assessment of biocidal products. CA-May15-Doc.4.3.a–Final

6 Chapter IV of BPR: General principles concerning the authorisation of biocidal products

6.1 Sustainable management of harmful organisms

a. Background

BPR currently states in its Article 17 (5) that a proper use of biocidal products is "the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken". Adhering to these principles it is crucial to minimise potential risks for the environment. However, users are left alone with how the practical elaboration of this could look like, as there is currently no further information in BPR of what proper use means.

This is different from the legislation on plant protection products (PPPR), *i.e. Regulation 1107/2009 concerning the placing of plant protection products on the market*. The proper use of plant protection products according to its Article 55 is explained in more detail through the "General principles of integrated pest management" in Annex III of *Directive 2009/128/EC* on *establishing a framework for Community action to achieve the sustainable use of pesticides*.

For biocidal products, instructions for use and risk mitigation measures defined during product authorisation can only partly bridge this gap as they need to be product- and risk-related and cannot take the holistic perspective needed for a proper use of biocidal products. While there are some Best Practice Codes by different stakeholders available in Member States, there are no overarching principles to guide these Codes and to harmonise their approaches.

b. Proposal for a solution

The OECD Working Party on Biocides translated the basic idea of the concept of Integrated Pest Management (IPM) for plant protection products to a concept for biocides. The focus was shifted from managing plant pests to the sustainable management of harmful organisms posing a potential threat for humans, animals or materials. The resulting "10 general principles for a Sustainable Management of Harmful Organisms (SuMaHO)" (see textbox below) should be included in a new Annex to the BPR and referenced in the definition of "proper use" in Article 17 (5).

Based on these principles, it would be desirable to successively further develop Best Practice Guidance documents for the sustainable management of specific harmful organisms, especially to support professional users of biocidal products.

c. Resulting benefit

Establishing general principles would simplify the elaboration or further development of Best Practice Codes and harmonise the understanding of "proper use" in the responsible authorities in the Member States. Providing this support to professional users would help them conducting control measures of harmful organisms in line with the legislation. Also, providing support on how to manage harmful organisms sustainably would reduce potential emissions of biocidal active substances to the environment without compromising on protection against these organisms.

10 general principles for a Sustainable Management of Harmful Organisms (SuMaHO)[13]

These general principles of sustainable management of harmful organisms are valid for those organisms posing a potential threat for humans, animals or materials. They pick up the idea of the concept of IPM for plant protection products and translate it to biocides[14]. It is a holistic approach that includes a prioritization and combination of available effective measures to minimize harm for humans and the environment.

1. **Take preventive measures**: Beneficial conditions allowing intrusion, settlement, development or reproduction of harmful organisms should be adapted to prevent this, if possible.
2. **Support antagonists**: Especially for rodents and insects, natural antagonists should be supported. If control measures are deemed necessary, unintentional side effects on antagonists need to be considered during choice of measures.
3. **Analyse the situation**: Presence of harmful organisms should be monitored and their potential of doing harm should be identified as required to conduct targeted management measures. The same holds true for all circumstances influencing the infestation or the contamination with germs and its management.
4. **Know the options**: Current state of knowledge in science and technology on the biology and management of the harmful organism needs to be determined. This includes preventive, non-biocidal, and biocidal measures, respectively, for its effective management and the related hazards and risks.
5. **Define the goal**: The goal of management measures needs to be defined to select appropriate measures. It should reflect what is realistic and expedient under the circumstances on site. Legal requirements as well as potential consequences of implementing or waiving any management measures need to be incorporated in the decision.
6. **Decide on necessity**: Based on the knowledge on the targeted harmful organism and the defined goal a decision needs to be taken whether management options are necessary on site at the given time.
7. **Choose the approach**: Priority should be given to those effective measures with the lowest negative impact on humans and the environment, especially non-biocidal options. If biocidal products need to be used, efficacious options posing the lowest risks for humans and the environment should be chosen. Their use needs to be combined with preventive and non-biocidal measures to reduce their use to the minimum necessary. Potential side effects need to be reduced further by using suitable procedures and techniques. With regard to harmful vertebrates, measures should be as humane as possible. The appropriate timing of the measures has to be defined based on the biology of the harmful organism and the relevant circumstances.
8. **Fight resistance**: If resistance to the biocidal product has already been reported, the active substance is known to act at a single biochemical target site and/or repeated use of the biocidal products is necessary, resistance management strategies need to be applied to maintain efficacy of the products and to avoid cross-resistance. This can include the use of biocidal products with different modes of action or use of non-chemical alternatives, application of the biocidal product at an effective dose, and/or avoidance of release and accumulation in the environment.
9. **Verify and document success**: To ensure a successful operation, achievement of the previously defined goal needs to be checked after measures have been implemented. If the goal has not been reached, the chosen approach and measures need to be adjusted. Achieving or failing to achieve the defined goal as well as measures taken and adjusted need to be documented.
10. **Maintain monitoring**: Continuous monitoring of harmful organism should be implemented to early detect critical reinfestation or germ contamination levels and proceed with appropriate management options. Preventive measures should be re-evaluated and adapted if necessary.

[13] OECD (2023): 10 general principles for a Sustainable Management of Harmful Organisms (SuMaHO). ENV/CBC/MONO(2023)23. https://one.oecd.org/document/ENV/CBC/MONO(2023)23/en/pdf (23.05.2025)

[14] The approach is applicable to management concepts of harmful organisms on site, it is not transferable to preventive treatment of articles with biocides. For disinfectants, IPM measures until now have only been compiled for a very limited range of applications (OECD Series on Biocides No. 12: OECD Survey on integrated pest management (IPM) in the field of private area and public health area disinfectants; ENV/JM/MONO(2016)70). For this reason, the discussion for the applicability of the principles to disinfectants should be postponed to a later point in time when more knowledge on their use is available.

6.2 Decision on applicability of aggregated exposure assessment

a. Background

In environmental risk assessment, emissions from one (specific) use are calculated and the resulting ratios of "predicted environmental concentrations "(PEC) and "predicted no-effect concentration" (PNEC) indicate whether unacceptable environmental risks are to be expected. However, many biocidal active substances are used in several biocidal products and possibly in different PTs. Adding up the emissions of a single substance from all uses and products is called aggregated exposure. This approach aims to quantify the total emissions of individual biocidal active substances and to estimate potential risks to the environment resulting from their emissions. The term "aggregated exposure" is not specifically mentioned in the BPR. Instead, in Article 19 (2) BPR it is stated that "the evaluation […] shall take into account the following factors: […] (d) cumulative effects, (e) synergistic effects." These terms were defined subsequently in a CA-document (CA-Sept12-Doc.5.1.a) and for "cumulative effects" it was written, that "*No definitive and universally applicable definition can be given as the use and significance of this term differ between e.g. human health and environmental risk assessments, different regulatory frameworks, and different research areas. The term "cumulative" is used in the context of both, exposure and effect, for both, single and multiple chemicals and routes. Therefore, we propose that the terms "aggregated exposure" and "mixture toxicity" respectively shall be used for the purpose of this guidance.*" Within this CA-document, it was clarified that a guidance is needed for assessing both aggregated exposure and mixture toxicity.

A guidance for mixture toxicity assessment was published in 2017 and has since then become regulatorily established. Similarly, a guidance for aggregated exposure assessment was completed in 2020 and agreed by the relevant technical bodies. However, this guidance has yet not been published and is, therefore, not mandatorily applied in environmental risk assessment. This is mainly because the legal consequences of an unacceptable environmental risk due to aggregated exposure are still unclear and a decision by the European Commission in this regard is pending.

In the meantime, further experience has been gained in biocide environmental exposure assessment over the last decade. These experiences suggest that a reliable and reasonable aggregated environmental exposure assessment for biocidal products is not feasible in reality. The use of biocidal products is highly diverse and differs, among other factors, in terms of application patterns, application techniques, user groups or location and time of application. This great diversity makes it almost impossible to estimate the decisive inputs of biocidal active substances into the relevant environmental compartments (water, sediment, soil, groundwater, air) at a specific point in time and location in a way that is both reliable and reasonable.

Furthermore, it must also be noted that currently the exposure assessment of individual biocidal products has to generally reflect the realistic worst-case exposure scenario. Aggregating various worst-case assessments would consequently lead to an overly conservative aggregated assessment. To counteract this, various refinement steps would have to be performed for each product included in an aggregated assessment. This would inevitably increase the assessment effort significantly for both applicants and authorities.

b. Proposal for a solution

Valid legal definitions of the terms "cumulative effects" and "synergistic effects" in Article 19 (2) are required, as the BPR is currently unclear in this regard. In this context, the European Commission should clarify that the assessment of aggregated exposures does not fall under the term "cumulative effects" and is, therefore, not required in the environmental risk assessment.

c. Benefit

The regulatory situation regarding aggregated exposure assessment has been unclear for years, causing uncertainty for all involved parties. Clarification would therefore be very important. Since no decision-relevant aggregated exposure assessment has been conducted to date, omitting aggregated exposure assessment does not represent a decrease of the current level of environmental protection. However, it would certainly further simplify the BPR and prevent it from becoming more complex.

6.3 Restrict sales to authorised users

a. Background

During their authorisation, the use of biocidal products can be restricted to specific user groups, for example to ensure compliance with complex risk mitigation measures for the prevention of environmental damage. However, the sale of products to user groups that are not covered by the authorisation is not regulated under BPR. Thereby, restricting the availability of these products is a prerequisite to ensure that the products are only commercially available to the persons allowed to use them. This is essential to ensure fulfilment of risk mitigation measures as conditions for authorisations.

b. Proposal for a solution

A new provision should be included in chapter IV of the BPR that if a biocidal product is authorised for other user groups than the general public, the biocidal product shall only be supplied to members of the respective user group (see also section 6.4 Training of professional users).

c. Resulting benefit

Restricting the product availability to authorised user groups supports the implementation of risk mitigation measures and the plausibility of legislation as only suitable user groups would have access to the respective products. Thereby, it supports optimal "return of investment" since it makes sure that the protective goals pursued by the authorisation procedure are actually achieved.

6.4 Training of professional users

a. Background

To manage harmful organisms sustainably, users of biocidal products need to take consecutive reasonable decisions on site. This is especially true for professional users of biocidal products, who are confronted frequently with decisions and apply biocides on a regular basis as part of their job. Trained professional users are allowed to use biocidal products that have been restricted for others for reasons of e.g. environmental safety. Without adequate training, implementation of risk mitigation measures and thus fulfilment of the conditions for authorisation of biocidal products cannot be expected. Complex application methods using e.g. application devices might also require specific knowledge and competence. Hence, training and further education of professional users of biocidal products is a key element to achieve sustainable use of biocides as a prerequisite for a high level of environmental protection and to avoid unnecessary use or even misapplication.

At the moment, there are no requirements regarding the necessary qualification of professionals in the BPR. The report of the Commission according to Article 65 (4) BPR states that by 2019, "certification or training schemes for professional users are present in 20 Member States and under development in two others".[15] Those schemes are varying in focus and concept.[16]

b. Proposal for a solution

To prevent further diverging national legislation, we propose the following:

As a first step, it is necessary to adapt Article 3 (1) BPR clarifying that user categories of authorised products are "general public", "professional user" or "trained professional user".

As a second step, a new article on basic training requirements should be added in chapter IV in the BPR, referencing the user category "trained professional user" in Article 3 (1). Competent authorities in the Member States shall appoint a body to provide initial and follow up training to professional users on established subjects. Already existing training schemes which fulfil the basic requirements should be recognized as appropriate trainings, even if they might require higher standards. Training certificates or central electronic registers of trained professionals (see also section 6.3 Restrict sales to authorised users) should be provided.

As it would be complex to implement training schemes for too many users in parallel, we propose to focus on one PT in the beginning and to potentially widen the scope after an evaluation. From an environmental perspective, rodenticides (PT 14) would be a good choice as these are products being used in the open environment and in the vicinity of humans while being only authorised under Article 5 (2) of the BPR.

c. Resulting benefit

What we want to achieve is that trained professional users of biocidal products have received adequate training to manage harmful organisms in the most sustainable way, including

[15] European Commission (2021): Commission Staff Working Document accompanying the report from the Commission to the European Parliament and the Council according to Article 65(4) of the BPR. SWD(2021) 128 final. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD%3A2021%3A128%3AFIN (23.05.2025)

[16] Wieck et al (2024): Shaping a proper use of biocides - Learning from national examples to enhance environmental protection during the use-phase of biocides. https://www.umweltbundesamt.de/publikationen/shaping-a-proper-use-of-biocides (23.05.2025)

preventive measures, alternatives and application of biocidal products (see section 6.1 Sustainable management of harmful organisms). This could reduce potential emissions of biocidal active substances to the environment. Harmonised definitions of the user groups would also reduce discussions during authorisations of biocidal products.

6.5 Large-scale outdoor practices and uses

Specific large-scale outdoor practices or uses of biocidal products lead to high emissions of biocidal active substances to the environment, simply due to their purpose. Examples of these uses are control of mosquitos or oak processionary moths or application of algaecides on roofs, facades or paths. To keep environmental risk assessment as efficient as possible, we propose to take overarching measures to achieve a high level of protection for the environment as demanded in Article 1 of the BPR.

Drift to non-target areas

a. 1. Background

When biocidal products are applied outdoors via spraying, parts are always drifted to non-target areas.[17] If equipment with a high drift potential is used, biocidal active substances unnecessarily enter non-target areas with detrimental effects for the environment. This might be different to equipment in industrial or service sectors where the Report of the Commission according to Article 18 BPR concluded that a lot of equipment is already designed to minimize exposure and avoid overdosing.[18] Drift could be reduced by up to 75% by choosing appropriate equipment (e.g. low-drift nozzles)[19], which are already state of the art in plant protection. However, requirements for machinery used for the application of biocides with regard to environmental protection are not defined at EU level.

b. 1. Proposal for a solution

Spraying equipment for large-scale outdoor application of biocidal products should be obliged to fulfil requirements related to the protection of the environment. These could be comparable to

(i) the *Directive 2006/42/EC on machinery* – Annex I point 2.4. Special emphasis should be placed on the requirement of machinery being designed and constructed to ensure that the biocidal product is deposited on target areas to prevent drift to the environment (point 2.4.5.2)
or
(ii) the guidance "Equipment for vector control - Specification guidelines"[20] of the World Health Organisation (WHO). Special emphasis should be placed on the required droplet spectrum as specified under its point 4.10.

[17] Langkamp-Wedde et al. (2020): Reduction of drift in spray application/ nebulization of biocides - Derivation of risk reduction measures and device requirements. UBA-Texte 55/2020. https://www.umweltbundesamt.de/publikationen/reduction-of-drift-in-spray-application (23.05.2025)

[18] European Commission (2016): Report on the sustainable use of biocides pursuant to Article 18 of Regulation (EU) No 528/2012. COM(2016) 151 final. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016DC0151 (23.05.2025)

[19] Langkamp-Wedde et al. (2023): Possibilities to reduce drift by 75 percent in biocidal applications of insecticides with cannon sprayers. In Environmental Sciences Europe 35. https://doi.org/10.1186/s12302-023-00729-0

[20] World Health Organisation (2018): Equipment for vector control - Specification guidelines. WHO/CDS/NTD/VEM/2018.08. https://www.who.int/publications/i/item/9789241513821 (23.05.2025)

Adjusting application rates

a. 2. Background

Users of spraying equipment should be able to set an appropriate application rate to ensure that biocidal products are applied properly. If too high volumes are applied, run-off to environmental compartments occurs.[21] However, there are no legal provisions demanding that machinery for the application of biocides allows the adjustment of applications rates.

b. 2. Proposal for a solution

Spraying equipment for the application of biocidal products should be obliged to be fitted with means to adjust the application rate easily, accurately and reliably. A regulation could

(i) be comparable with *Directive 2006/42/EC on machinery* and its Annex I point 2.4.5.1 on application rate
or
(ii) refer to the specifications of the WHO guidance "Equipment for vector control - Specification guidelines"[22], where requirements on flow rate control are specified for various devices.

Protection of especially sensitive areas

a. 3. Background

Areas that are vital for the protection of nature and biodiversity are under high pressure due to a variety of external stressors. In nature restauration efforts, chemical pollution is assumed to be one of the major obstacles in succeeding.[23] These areas are specifically sensitive to biocidal input as biocidal active substances are designed to affect organisms. In some cases, target organisms might even belong to the same group as the protected species in these areas (e.g. insects, vertebrates). Therefore, pollution by biocidal products through large-scale outdoor applications is in conflict with legislative protection goals for such areas. For this reason, specific measures to protect certain areas should be established.

b. 3. Proposal for a solution

For sensitive ecosystems, large-scale outdoor applications or uses are of special concern. This is especially relevant for algaecides (PT 2), rodenticides (PT 14), insecticides (PT 18), anti-fouling products (PT 21) as well as for products for the protection of materials that are applied via spraying (PT 7, 8, 9, 10) or treated articles containing material preservatives that might enter protected water bodies. Furthermore, some of these product types comprise explicitly target organism groups that might be protected in these areas.

Uses of these products should be limited as far as possible in the Member States. If spraying of biocidal products is deemed necessary, measures to minimize emissions to the environment

[21] Langkamp-Wedde et al. (2025): Reduction of environmental impact of biocides - Practical study of drift of biocide application equipment and development of drift mitigation measures. UBA-Texte 11/2025. https://www.umweltbundesamt.de/publikationen/reduction-of-environmental-impact-of-biocides (23.05.2025)

[22] World Health Organisation (2018): Equipment for vector control - Specification guidelines. WHO/CDS/NTD/VEM/2018.08. https://www.who.int/publications/i/item/9789241513821 (23.05.2025)

[23] Brettschneider et al. (2023): Much effort, little success: causes for the low ecological efficacy of restoration measures in German surface waters. In: Environmental Sciences Europe 35. https://doi.org/10.1186/s12302-023-00736-1

should be considered, such as use of low-drift equipment (see above). To better differentiate between conventional and more progressive machinery, standards should be defined for drift-reducing equipment, comparable to standards for the application of plant protection products. Based on these standards, lists of machinery appropriate for the spray application in sensitive areas could be established.

Application on sealed surfaces

a. 4. Background

If biocidal products are applied outdoors on sealed horizontal surfaces, run-off of the active substances into the surrounding environment after application or precipitation occurs. On the one hand, this is especially relevant for emissions of algicidal active substances to soils after removal of green growth from sealed paths. For example, Benzalkonium Chloride, an active substance used for this purpose, has shown to affect the microbial community in soil and, therefore, has the potential to lead to antimicrobial resistance in soils[24]. This contradicts the goal of the EU Soil Strategy for 2030 to reduce soil pollution at the source. On the other hand, emissions of algicidal active substances to stormwater and receiving surface waters occur during and after cleaning of facades and roofs. For example, concentrations of benzalkonium chloride in runoff water are still in a range that would affect insects up to 13 months after roof treatment.[25] As these emissions cannot be mitigated with risk mitigation measures during product authorisation, further measures are necessary.

b. 4. Proposal for a solution

Use of biocidal products on sealed surfaces should be prohibited if there is a high risk of run-off into the environment or sewage systems. Exemptions could be made for biocidal products eligible for simplified authorisation procedure, if available. This would supplement the regulations already implemented in the area of plant protection products for the general protection of nature and groundwater in Article 11 of *Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides*. It would also be in line with the policy recommendations of a research project from the Danish Environmental Protection Agency.[26]

c. Resulting benefits for b.1 to b.4

If products are intended to be used in the open environment, environmental risk management can always be expected to be necessary. All four measures discussed above aim at optimising this large-scale outdoor use of biocidal products. Such general approaches are more efficient compared to risk mitigation measures being implemented one-by-one in product authorisations. For this reason, their implementation can save resources during product authorisations. The measures would reduce potential emissions of biocidal active substances to the environment. Furthermore, they would increase harmonisation between the application of biocidal and plant protection products.

[24] Zeng et al. (2022): Short-Term Benzalkonium Chloride (C12) Exposure Induced the Occurrence of Wide- Spectrum Antibiotic Resistance in Agricultural Soils. In: Environmental Science & Technology 56 (21). https://doi.org/10.1021/acs.est.2c04730

[25] Gromaire et al. (2015): Benzalkonium runoff from roofs treated with biocide products – *In situ* pilot-scale study. In: Water Research 81. https://doi.org/10.1016/j.watres.2015.05.060

[26] Danish Environmental Protection Agency (2024): Emissions of Quaternary Alkylammonium Compounds (QUAT-Fate). Pesticide Research 222. https://www2.mst.dk/Udgiv/publications/2024/04/978-87-7038-613-5.pdf (23.05.2025)

7 Chapter V of BPR: Simplified authorisation procedure

7.1 Enhance simplified authorisation

a. Background

For biocidal products containing only active substances that give no rise to concern and that are listed in Annex I, the BPR foresees a simplified authorisation process. It aims at promoting biocidal products of low concern (e.g. for the environment). In order to be eligible for a simplified authorisation, a biocidal product must fulfil the criteria as given in Article 25 BPR, e.g. excluding substances of concern or nanomaterials and proof of sufficient effectiveness.

However, a hazard assessment for the aquatic environment for the product as a whole according to *Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures* (CLP regulation) is lacking. For the classification of the biocidal product according to the CLP regulation, the so-called summation method (see Annex I Part 4 chapter 4.1.3.5.5 CLP regulation) is applicable. This method takes account of the fact that biocidal products are usually mixtures that may contain several hazardous substances at rather low concentrations. Especially for products eligible for a simplified authorisation it should be ensured that products as a whole are not classified as hazardous to the aquatic environment.

b. Proposal for a solution

We propose to add the following criterion to Article 25 BPR: “The biocidal product is not classified as hazardous to the aquatic environment (H400, H410, H411)”.

c. Resulting benefit

The proposed addition to Article 25 BPR would ensure that products authorised under the simplified procedure do indeed give no rise to concern for the aquatic environment.

8 Chapter XIII of BPR: Treated articles

8.1 Harmonise requirements for treated articles

a. Background

If treated articles are produced in the EU (case a) and then placed on the European market, biocidal products have to be applied that are authorised according to the BPR. Furthermore, restrictions for the production of treated articles and the labelling requirements for treated articles from the authorisation of the biocidal product and/or the active substance approval have to be followed.

In contrast, if treated articles are produced in third countries and imported into the EU (case b), it is not obligatory to use a biocidal product which is authorised in the EU. According to recital 52 and Article 58 (2) BPR, the only requirement is that the active substances contained in the treated article must be approved in accordance with the BPR.

This procedure leads to unequal handling of treated articles that are manufactured in the EU (case a) and treated articles that are imported into the EU (case b), resulting in potentially higher or unacceptable exposure of the environment with chemicals and a discrimination of manufacturers within the EU.

The uncertain level of safety for the environment from treated articles manufactured in third countries arises from the following reasons:

- Treated articles that are imported into the EU may contain higher concentrations of active substances: No environmental risk assessment and no assessment of the mixture toxicity is conducted for the biocidal product which is used for the production of the treated article, meaning that active substances may be contained in significantly higher concentrations than it would be the case for treated articles manufactured in the EU.
- Treated articles that are imported into the EU may contain substances of concern in unknown concentrations: Co-formulants in the biocidal product are not assessed and can be contained in the treated article at concerning levels.
- Treated articles can be imported into the EU that would be prohibited to be manufactured in the EU for a use in the EU: To produce a treated article for the EU in the EU, only authorised biocidal products which are restricted to certain uses and treatment methods are allowed. Treated articles from third countries can be manufactured by using biocidal products that would not pass the authorisation procedure in the EU. An example is wood for use class 4b (in direct contact with water) that is impregnated outside the EU and then used in the EU. Most, if not all, wood preservatives assessed so far fail the environmental risk assessment for this use class. It would also be possible to import treated wood for use class 5 (in contact with marine water), depending on the interpretation of Article 58 (2) BPR and whether this is explicitly excluded in the active substance approval.

- Treated articles that are imported into the EU may have less restrictive labelling with regard to their use than treated articles produced in the EU: Biocidal products that are used in third countries to treat the articles might have different or no labelling requirements.

b. Proposal for a solution

In order to ensure the high level of environmental protection in the EU, it should be verified if Article 58 BPR can be extended regarding the obligation that imported treated articles must only be treated with biocidal products that are authorised in the EU or that are authorised in a third country in an authorisation procedure comparable to the BPR.

Until this is implemented, it is of high importance to consider potential restrictions for treated articles and labelling requirements for treated articles during active substance approval. Currently, this is the only process step where restrictions for imported treated articles can be set. However, some labelling requirements can only be set as a result of the environmental risk assessment in the product authorisation and cannot be addressed at the substance approval stage. For this reason, the obligation for manufacturers outside of the EU to use biocidal products authorised under BPR or in an authorisation procedure comparable to the BPR must be the ultimate goal.

c. Resulting benefit

If it can be ensured that the imported treated articles fulfil the same requirements as treated articles produced in the EU, a higher level of environmental protection can be assumed. Furthermore, this would lead to equal treatment between producers of treated articles in EU and third countries, resulting in fairer competition.

8.2 Improved labelling of treated articles and better information for their users

a. Background

The obligation to provide information about treated articles is currently split between two legal entities: According to Article 58 (3) and (4) BPR, the person responsible for the placing on the market of a treated article is responsible that the labelling requirements are fulfilled. According to Article 58 (5), the supplier of a treated article shall provide consumers after request, within 45 days, free of charge, with "information on the biocidal treatment" of the treated article. However, no precise details are given as to what information is covered. This makes it complicated for the user of a treated article to request and receive appropriate information about the biocidal treatment. Beyond that, a particular situation arises in the case where EU citizens obtain treated articles directly from outside the EU for instance via online trade, as those customers would become the responsible persons to fulfil the requirements of Article 58.

b. Proposal for a solution

It is proposed that the person responsible for the placing on the market of a treated article shall be responsible for the labelling of the treated article according to Article 58 (3) or (4) as well as, beside the supplier, for providing information on the biocidal treatment of the treated article to the consumer according to Article 58 (5). In order to improve enforceability, contact information of the person responsible for the placing on the market of a treated article shall be given on each label of a treated article. A supplier needs to be established in the EU for online-trades from

outside the EU. Moreover, Article 58 (5) should describe explicitly which information on the biocidal treatment have to be provided to the consumer.

Revised Article 58 (3) second sentence[27]:

> *3. The label referred to in the first subparagraph shall provide the following information:*
>
> *(f) The address and further contact information of the person responsible for the placing on the market of the treated article and a statement that further information on the biocidal treatment of the treated article can be requested free of charge from this person.*

Revised Article 58 (5):

> *5. Notwithstanding the labelling requirements set out in paragraph 3, the supplier and the person responsible for the placing on the market of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article including all information that are required on the label according to Article 58 (3) or Article 58 (4).*

To account for particularities of online trade, it is proposed to establish the need of responsible persons within the EU in Article 58 to avoid situations in which consumers become responsible according to Article 58 (following Article 4 number 11 of the CLP-regulation, valid from 1/7/2026). We suggest the following wording:

> *"A treated article shall not be placed on the market unless a supplier established in the Union, which shall be identified on the label, in the course of an industrial or professional activity fulfils the requirements set out in this Regulation with regard to the treated article in question."*

In the future, digital product passes could be a valuable instrument to increase transparency along the value chain. They could provide information on the batch number and manufacturing date of the treated article and the contact information of the manufacturer (if not identical with the person responsible for the placing on the market).

c. Resulting benefit

This measure will increase the traceability of treated articles, especially if they are produced outside of the European Union. Users of treated articles would have a direct contact address to ask for information about the treated article and it is clear which information the user can expect. Better information on the biocidal treatment of treated articles will improve use and service life of treated articles and could contribute to reduce emissions of biocidal active substances to the environment.

[27] Additions are underlined.

9 Chapter XV/Section 2 of BPR: Information about biocidal products

9.1 Advertisement for products authorised under Article 25

a. Background

Biocidal products containing active substances that do not give rise to concern according to Article 28 BPR are eligible for a simplified authorisation procedure according to Article 25 if they fulfil all of its preconditions. The lack of concern is what separates them from other biocidal products. If the application of a biocidal product is necessary, the use of those products is preferable from an environmental point of view. However, the current phrasing of Articles 69(2) and 72(3) BPR prevents stakeholders from being able to communicate this difference to the public.

b. Proposal for a solution

Article 69(2) and Article 72(3) BPR should include an exemption or a specific regulation for biocidal products authorised under Article 25. This could be the permission to use a specific phrasing such as "[enter name of product type] of low concern" on the label and in advertisements. Also, consideration under ecolabel-schemes should be possible.

c. Resulting benefit

Potential users of biocidal products would be enabled to make better informed choices during the purchase as they would be able to differentiate between the two categories of authorisation. If biocidal products authorised under Article 25 are preferred compared to other biocidal products for this reason, active substances with better environmental risk profiles are used, leading to less potential environmental risks.

9.2 Better communication on the label and in advertisement

a. Background

Risk perception has a high influence on the adherence to use instructions and risk mitigation measures of the general public.[28] As the term "biocide" is artificial and often not correctly understood by the general public, the products are often classified in categories that might not lead to appropriate risk perception. 24% of the respondents in a publication in 2024[29] and 33% of the respondents in a publication from 2017[30] associated "biocides" to categories such as "Organic product or quality" or "Medicine or health".

Article 69 BPR currently defines the content of the labels of biocidal products. However, it does not require authorisation holders to state the name of the PT of the respective product. In advertisements, Article 72 BPR requires the use of the sentences "Use biocides safely. Always

[28] Bearth et al. (2024): Protection motivation when using biocidal products – A survey study in Germany. In: Environmental Science and Pollution Research 31. https://doi.org/10.1007/s11356-024-34639-2

[29] Bearth et al. (2024): Consumer Survey on Biocidal Products and Environmental Risks. UBA-Texte 148/2024. https://www.umweltbundesamt.de/publikationen/consumer-survey-on-biocidal-products-environmental (23.05.2025)

[30] Wieck et al. (2018): Consumers' perceptions of biocidal products in households. In: International Journal of Hygiene and Environmental Health 221. Issue 2. https://doi.org/10.1016/j.ijheh.2017.11.005

read the label and product information before use.". The word "biocide" could be replaced by a clear reference to the product type being advertised.

b. Proposal for a solution

In Article 69 (2), a statement of the product type should be required for the label. This statement should not be numerical but should be based on the name of the PT in Annex V or, where reasonable, a more specific indication based on the name in Annex V (e.g. "algaecide").

In Article 72 (1), the required sentences should always refer to the name of the PT as defined in Annex V or, where reasonable, a more specific indication based on the name in Annex V (e.g. "algaecide") and should not use the word "biocides".

c. Resulting benefit

If both articles would require a more specific description of the product on the label and in advertisement, the general public might become more aware of potential environmental risks associated with the products and thus adhere to risk mitigation measures. Ultimately, this contributes to a better protection of the environment from biocidal active substances.

9.3 Provide advice at the point of sale

a. Background

When a member of the public is confronted with the decision on how to deal with a harmful organism, complex choices have to be made. Identifying the harmful organism correctly is one of the steps, choosing appropriate management measures another. Regarding potential measures, the member of the public has to decide what preventive, non-biocidal and biocidal measures should be selected. All these choices are decisive for proper use of biocidal products according to Article 17 (5) BPR. If biocidal products finally are chosen, risk mitigation measures might apply to protect the health of the users or the environment. Adherence of the general public to these measures strongly depends on their risk perception, so raising awareness of potential risks of the products is important.[31] Informing the public is already a task of the Member States according to the before-mentioned Article 17 (5). However, even though Germany is maintaining a specific website (www.biozid.info) informing about biocidal products, their proper use, potential risks and alternatives, relevant knowledge of the German general public seems to be quite low[32,33].

Therefore, it seems to be important to provide the relevant information more actively along the supply chain to the general public, especially for products with properties raising concern. The need for appropriate information along the supply chain was also emphasized by the report to the European Commission's "*Fitness check*"[34]. The point of sale is an important opportunity to communicate on these topics. However, there is no mechanism in the BPR ensuring that the

[31] Bearth et al. (2024): Protection motivation when using biocidal products – A survey study in Germany. In: Environmental Science and Pollution Research 31. https://doi.org/10.1007/s11356-024-34639-2

[32] Bearth et al. (2024): Consumer Survey on Biocidal Products and Environmental Risks. UBA-Texte 148/2024. https://www.umweltbundesamt.de/publikationen/consumer-survey-on-biocidal-products-environmental (23.05.2025)

[33] Wieck et al. (2018): Consumers' perceptions of biocidal products in households. In: International Journal of Hygiene and Environmental Health 221. Issue 2. https://doi.org/10.1016/j.ijheh.2017.11.005

[34] European Commission (2019): Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses. https://commission.europa.eu/publications/fitness-check-most-relevant-chemical-legislation-excluding-reach_en (23.05.2025)

general public is informed at the point of sale. The report of the Commission according to Article 18 BPR only proposed to regulate sales via products authorisations[35]. In practice, this is not feasible as only the authorisation holder can be obliged within the scope of the authorisation. As part of the authorisation, he can be obliged to include the required indications in the instructions for use for the product, which are then also binding for the user. However, it is not possible to regulate the actual sales situation of the products to the user within the scope of the authorisation from our point of view. For this reason, a regulation of sales requires overarching legal background to create the necessary framework. Some Member States have therefore already implemented national regulations on sale for specific biocidal products.[36]

b. Proposal for a solution

We propose to add a new provision on sale to general public to chapter XV, section 2 in the BPR:

Based on the outcome of the hazard and risk assessment, specific products should not be supplied in self-service and may only be dispensed with the necessary advice. From an environmental point of view, it is expected that this would especially be relevant for products that are openly used outdoors and which require complex risk mitigation measures. A respective labelling requirement needs to be established, in order to enable distributors to easily identify the concerned products.

c. Resulting benefit

Such a provision would enable Competent Authorities to decide during product authorisation if refusal of self-service and need of advice are deemed necessary for the respective product. It would enable members of the public to make better informed decisions. This would reduce potential emissions of biocidal active substances to the environment in general, reduce misuse and increase adherence to risk mitigation measures, specifically for biocidal products which give rise to concern.

9.4 Establish publicly available data on making available on the market of biocidal products

a. Background

The European market for biocidal products currently is a black box, when it comes to quantities of active substances in products placed on the market. These values would be important for well-founded prioritisation of active substances for environmental monitoring and better attribution of contamination to potential sources. Also, these data would be valuable for monitoring the success of environmental protection by BPR, for example trends towards the use of active substances listed in Annex I, BPR or the implementation of environmental risk mitigation measures. Concerning the tonnage-based exposure assessment in the context of environmental risk assessment, these data would also be of relevance.

[35] European Commission (2016): Report on the sustainable use of biocides pursuant to Article 18 of Regulation (EU) No 528/2012. COM(2016) 151 final. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016DC0151 (23.05.2025)

[36] Wieck et al (2024): Shaping a proper use of biocides - Learning from national examples to enhance environmental protection during the use-phase of biocides. https://www.umweltbundesamt.de/publikationen/shaping-a-proper-use-of-biocides (23.05.2025)

This lack of data has also already been criticised in the Fitness Check[37]. Regarding the data generation of quantities placed on the market, there is currently no provision in the BPR. However, Member States are starting to collect their own national data based on different methodologies leading to no comparability of data between the countries.[38] This is a missed chance of comparing different risk management approaches in the Member States and puts unnecessary bureaucratic burden on companies that are required to adapt their data reporting to national requirements.

b. Proposal for a solution

We propose to add a new article with the following content:

Following a harmonized procedure, Member States should collect the quantities of active substances in products that are placed on the market annually by the marketing authorisation holders. The European Commission should publish these as transparently as possible.

The report of the European Commission according to Article 18 BPR concluded that "in the future, the Register for Biocidal Products (R4BP) hosted by the European Chemicals Agency (ECHA) might offer a tool to collect such data.". This would be in line with Article 76 (1) g) BPR, already requesting ECHA to establish and maintain database(s) with information on active substances and biocidal products. The solution should be in line with the new One Substance One Assessment data platform that is currently discussed on EU level.

Existing data collection schemes in Member States could be used as models. To ensure comparability of data, we recommend to start the data collection after the completion of the review program.

c. Resulting benefit

From our point of view, harmonised data collection makes it easier for companies to report their data. It also leads to better comparability regarding risk management approaches for biocides in all Member States. Together with environmental monitoring data, it is an important prerequisite to identify the most efficient approaches of risk management. Additionally, collection of data will help to have a better basis for estimating emissions to the environment during exposure assessment and to verify the assessment work. Last but not least these data will help with the interpretation of monitoring data in order to identify the sources and, if necessary, make regulatory adjustments.

[37] European Commission (2019): Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses. https://commission.europa.eu/publications/fitness-check-most-relevant-chemical-legislation-excluding-reach_en (23.05.2025)

[38] Wieck et al (2024): Shaping a proper use of biocides - Learning from national examples to enhance environmental protection during the use-phase of biocides. https://www.umweltbundesamt.de/publikationen/shaping-a-proper-use-of-biocides (23.05.2025)

10 Annexes of the BPR

10.1 Include plants as potential target organisms in PT9

a. Background

Herbicides are mainly covered by the *Regulation 1107/2009 concerning the placing of plant protection products on the market* (PPPR). Some herbicides are anyhow used in material preservation such as root protection agents in roof membranes. This use is completely different compared to typical plant protection scenarios but is similar to other PT 9 uses regarding the protection of roof membranes. An important emission pathway to the environment is rainwater, when active substances leach from the materials during precipitation. These emissions in urban areas can exceed limit values for surface waters.[39] To the best of our knowledge, these herbicide uses are currently not evaluated appropriately under the PPPR. Necessary measures to protect the environment are therefore not addressed. Furthermore, PPPR does not foresee any provisions on treated materials even though this is of high relevance for roofing membranes treated with root protection agents.

b. Proposal for a solution

The description of PT 9 (Fibre, leather, rubber and polymerised materials preservatives) in Annex V should list plants as additional target organisms. With this addition, related products for root penetration inhibition incorporated in materials could be assessed under the BPR.

c. Resulting benefit

Coherence would be improved if herbicides used for the protection of materials would be assessed under the BPR. Emissions into the environment from materials protected with root penetration inhibitors could be realistically modelled and regulated. Existing scenarios for the assessment of emissions in urban areas can be easily utilised. This would result in better environmental protection due to appropriate risk assessment. As a potential consequence, alternative materials that do not require chemical root penetration inhibition might be promoted.

10.2 Remove attractants from the BPR

a. Background

Attractants are substances that are used to attract harmful organisms. They are classified as PT 19 according to Annex V of the BPR. Attractants falling under Annex V BPR are either (a) pheromones or (b) food or feed. Attractants do not meet the literal definition of a biocidal product as they can neither kill nor render harmless pests. Attractants merely attract pests, which are then rendered harmless or killed either by a biocidal active substance (e.g. PT 14, PT 18) or physical effects (snap trap, sticky trap). In this sense, it may be argued that attracting products that are assigned to PT 19 and thus contain only attractant active substances do not meet the definition of biocidal products according to the BPR.

Attractants currently being assessed under the BPR do not give cause for concern from an environmental perspective. This applies in particular to all food and feed substances which are mostly listed in Annex I of BPR and do not, by definition, give rise to any concern. Against this

[39] Wicke et al. (2022): Emissions from Building Materials – A Threat to the Environment? In: Water 14(3). https://doi.org/10.3390/w14030303

background, the regulatory effort, both for applicants and authorities, seems disproportionate to the potentially negative consequences that would result from an unregulated use of products containing only these substances.

b. Proposal for a solution

Attractants should therefore be excluded from the BRP. This may be achieved by removing "attracting" as a relevant mode of action to control harmful organism from the definition of PT 19 in Annex V of the BPR.

c. Resulting benefit

Removing attractant active substances from the BPR would reduce the workload for industry and authorities without significantly reducing the level of protection.

10.3 Review of groundwater/bank filtrate assessment

The BPR stipulates in Article 19(1)(b)(iv) that a biocidal product should have no unacceptable effects itself, or as a result of its residues, on groundwater and drinking water. According to Annex VI, point 68, the requirement is not met if the use of the biocidal product results, under the proposed conditions of use, in foreseeable concentrations of the active substance or a substance of concern, or of relevant metabolites, breakdown or reaction products (summarised here as transformation products) in groundwater that exceeds the lower of the following concentrations:

- the maximum permissible concentration laid down by *Directive 98/83/EC on the quality of water intended for human consumption* (replaced by *Directive (EU) 2020/2184 on the quality of water intended for human consumption*), or
- the maximum concentration as laid down following the procedure for approving the active substance under this regulation, on the basis of appropriate data, in particular toxicological data (abbreviated here as Tox-Threshold),

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

In the context of the evaluation and authorisation of biocidal products, four points have arisen during the implementation of these requirements, of which an amendment or clarification should be discussed.

Evaluation effort

a. 1. Background

Depending on the product and the number of active substances, transformation products and substances of concern, groundwater assessment can be relatively complex and labour-intensive. Limit values might be exceeded for some substances due to unrealistic assumptions for various reasons. These reasons could be for example a lack of higher tier degradation simulation studies especially in case of readily-biodegradable active substances or a lack of valid physico-chemical data for a reliable modelling of the expected concentration in groundwater, occurring

particularly in the case of substances of concern. Risks that are derived based on these assessments do not reflect actual risks and might lead to unnecessary difficulties and delays in active substance approvals or product authorisations.

b. 1. Proposal for a solution

To streamline the groundwater assessment within the scope of BPR, it is proposed that a quantitative groundwater assessment should be limited to those substances that are classified as relevant. The assessment of relevance should be based on substance intrinsic properties and consider the specific circumstances of the use and authorisation of biocidal products, without contradicting the general principles of groundwater protection.

In the case of active substances, the Annex I listing can already be understood as an assessment of relevance and it should be possible to exclude these substances per se from the groundwater assessment (see also point 2). A list of further active substances for which no groundwater assessment is deemed necessary should be compiled and agreed on a case-by-case basis. Examples may be lactic acid, propan-1-ol or propan-2-ol and inorganic rapidly reacting substances like ozone, active chlorine, chlorine dioxide or hydrogen peroxide.

The current legal text of the BPR already links the assessment of transformation products for the groundwater to their relevance (see Annex VI, point 68). In accordance with *Directive (EU) 2020/2184 on the quality of water intended for human consumption* a *"pesticide metabolite shall be deemed relevant for water intended for human consumption if there is reason to consider that it has intrinsic properties comparable to those of the parent substance in terms of its pesticide target activity or that either the parent substance or its transformation products generate a health risk for consumers"*. It would be conceivable to carry out this relevance assessment on the basis of the SANCO guidelines[40] applicable for plant protection products - with biocide-specific adjustments where needed. However, the relevance assessment for all transformation products regarding groundwater should be based on substance intrinsic properties and, therefore, be done already as part of the substance approval. This would reduce the workload at product level and ensures harmonized decisions.

Since a relationship to the parent substance cannot be established for substances of concern, an alternative concept could be to define intrinsic substance properties that trigger groundwater relevance for a specific substance of concern.

Consequently, guidance for an assessment of relevance for groundwater for transformation products and substances of concern shall be developed.

No groundwater assessment for Annex I substances

a. 2. Background

No groundwater assessment is carried out for products that solely contain Annex I substances, if the products meet the requirements for simplified authorisations according to Article 25 BPR. However, for products that contain "normal" biocidal active substances and, additionally, an

[40] European Commission (2021): Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Regulation (EC) No 1107/2009. Sanco/221/2000 – rev.11. https://food.ec.europa.eu/system/files/2021-10/pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr-rev11.pdf (23.05.2025)

Annex I substance, an assessment for the Annex I substance would have to be carried out under current regulations, as it is by definition also classified as an active substance. In regulatory practice, however, this is waived with reference to the Annex I listing.

b. 2. Proposal for a solution

Annex I substances should generally be excluded from the groundwater assessment.

Limit value for substances of concern

a. 3. Background

The entry of substances of concern into groundwater is assessed in accordance with the applicable guidelines. However, the limit value for biocides of *Directive (EU) 2020/2184 on the quality of water intended for human consumption* do not generally apply to these substances.

b. 3. Proposal for a solution

To close this regulatory gap, we propose that the same rules for setting limit values considered relevant for active substances and transformation products should be applied to substances of concern.

Applicable regulation for groundwater limit value

a. 4. Background

Annex VI point 68 addresses groundwater, but defines the relevant limit value solely via *Directive (EU) 2020/2184 on the quality of water intended for human consumption*, even if the *Directive 2006/118/EC on the protection of groundwater against pollution and deterioration* is available as well.

b. 4. Proposal for a solution

It needs to be legally evaluated if a reference to *Directive 2006/118/EC on the protection of groundwater against pollution and deterioration* is reasonable in the context of the assessment of groundwater under the BPR.

c. Resulting benefit for b.1. to b.4.

The assessment of emissions to groundwater is a recurring issue that is repeatedly discussed between member states. A focus on substances that are relevant for groundwater and drinking water and clearly formulated requirements in the legal text of the BPR and guidance documents will reduce the workload in product authorisation and make the authorisation procedure more sound without lowering the level of protection.

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