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Date: 04/03/2026 14:10:06

BPR evaluation - Public consultation

Fields marked with * are mandatory.

Introduction

About you

*Language of my contribution

- ○ Bulgarian
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  - Non-governmental organisation (NGO)
  - (•) Public authority
  - Trade union
  - Other

* First name

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Bescherming persoonlijke levenssfeer

* Scope
  - International
  - Local
  - (•) National
  - Regional

* Level of governance

- ( ) Parliament
- (•) Authority
- ( ) Agency

* Organisation name

255 character(s) maximum

Ministry on Infrastructure and Water Management

* Organisation size

- ( ) Micro (1 to 9 employees)
- ( ) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- (•) Large (250 or more)

Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

* Country of origin

Please add your country of origin, or that of your organisation.

This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.

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- Moldova
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- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria

- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
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- Norway
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- Palestine
- Panama
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- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay

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- Congo
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- Liberia
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- Réunion
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- Russia
- Rwanda
- Saint Barthélemy
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Introduction

Biocidal products (biocides) help to control unwanted organisms that are harmful to human or animal health or to the environment, or that cause damage to materials or human activities. These organisms include pests (insects, rats, mice) and microorganisms (bacteria, viruses, mould).

There are four main groups of biocidal products.

1. Disinfectants: disinfectants for human hygiene (hand disinfectants), general disinfectants (for the home, for food processing areas), drinking water disinfectants.
2. Preservatives: in-can preservatives to prevent the degradation of products / materials by bacteria / fungi in paints, detergents, wood, leather, cutting fluids, cooling tower disinfectants.
3. Pest control products: rodenticides, insecticides, repellents/attractants (mosquito spray).
4. Other biocidal products: anti-fouling paints on boats, embalming and taxidermist fluids.

Biocidal products can pose risks to humans, animals and the environment due to their properties and associated use patterns. Therefore, Regulation (EU) No 528/2012 on biocidal products (Biocidal Products Regulation) governs the making available on the market and use of biocidal products to ensure that they do not result in harmful effects on human or animal health or unacceptable effects on the environment. It maintains the main principles of its predecessor, Directive 98/8/EC, while introducing some additional elements. The Biocidal Products Regulation entered into application on 1 September 2013.

The Biocidal Products Regulation sets the rules for the making available on the market and use of biocidal products and articles treated with such products. It aims to improve the functioning of the internal market for biocidal products while ensuring a high level of protection of human and animal health and the environment.

A Report on the implementation of the Biocidal Products Regulation, adopted by the Commission in June 2021, identified some issues that hinder the proper functioning of the rules. These issues include:

- consistently long delays in both active substance approval and product authorisation processes;
- limited innovation for new biocidal active substances.

The report announced that an evaluation of the Biocidal Products Regulation will take place in 2025. The aim of the evaluation is to assess if the current rules are fit for purpose.

This public consultation will gather evidence from both stakeholders and the public. The findings of the consultation will inform the evaluation process.

More information on the Biocidal Products Regulation can be found on the Commission's website.

• Public consultation

The public consultation gives stakeholders the opportunity to share their views on:

- how to tackle current and future needs;
- whether the rules have contributed to its objectives of improving the functioning of the internal market for biocidal products and ensuring a high level of protection of human health, animal health and the environment;
- the benefits, problems, costs and challenges faced during its implementation.

Respondents are also invited to identify areas for improvement, simplification and cost-savings.

• Instructions

The first section of the questionnaire contains questions about you or the organisation you represent.

The questionnaire is split into a set of general questions for non-experts that require no or little knowledge of the Biocidal Products Regulation, and an additional set of questions targeting experts with good or excellent knowledge of the rules.

Where possible, you should include data and sources of information or practical examples to support your replies.

The questionnaire is available in all EU official languages (and you can reply in any EU official language). You can pause at any time and continue later. You can also download your contribution once you have submitted your answers.

QUESTIONNAIRE NON-EXPERTS

Question 1

Did you know that biocidal products are regulated and authorised in the EU?

- ○ Yes
- ○ No

Question 2

Did you know that biocidal products undergo a thorough risk assessment before being placed on the market?

- Yes
- No

Question 3

Do you believe that biocidal products are necessary to control organisms harmful to human or animal health or to materials and human activities?

- Yes
- No

Question 4

Do you think that it is important to have EU rules in place to ensure the safe use of biocidal products, like disinfectants, preservatives and pest control products?

- Very important
- Important
- Neutral
- Not important
- Don't know

Question 5

Do you feel well informed about the approval decisions on biocidal active substances and authorisations or derogations concerning biocidal products?

- Yes
- No

Question 6

Do you know that there are public information websites, like Information on biocides - ECHA, Overview - European Commission?

- Yes
- No

Question 7

Do you purchase biocidal products like disinfectants or insecticides for home use?

- Yes
- No

Question 8

Do you use biocidal products in your professional life?

- Yes
- No

Question 9

You can give more relevant information here

2500 character(s) maximum

You can upload a concise document, such as evidence to support your responses or a position paper.

Uploaded documents will be published alongside your questionnaire response, serving as supporting material to better understand your position. Although uploading documents is optional, it can provide us with valuable background information.

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

QUESTIONNAIRE EXPERTS

Evaluation criterion: EFFECTIVENESS (to what extent has the Biocidal Products Regulation achieved its intended objectives?)

Question 1

Have the following processes/requirements been effective in ensuring a high level of protection of human health, animal health and the environment?

	Very effective	Effective	Ineffective	Very ineffective	Don't know
Review programme to review the safety and efficacy of all existing biocidal active substances	○	◉	○	○	○
Approval of new active substances	○	◉	○	○	○

Exclusion and substitution criteria and rules for products containing substances meeting these criteria (including comparative assessment)	○	○	◉	○	○
Early review of an active substance approval	○	◉	○	○	○
Inclusion of in-situ products within the scope of the Biocidal Products Regulation	○	◉	○	○	○
Labelling requirements	○	○	◉	○	○
Data requirements for active substance approval	○	◉	○	○	○
Data requirements for product authorisation	○	◉	○	○	○

Briefly explain the reasons for the points you consider the most relevant

1000 character(s) maximum

The BPR's scientific and harmonised approval criteria have contributed to a high level of protection. Hazard based cutoff criteria and substitution provisions are meant to reinforce the precautionary approach. Having said that, substances meeting the exclusion criteria are often approved instead of substituted, albeit a restrictive approval. If the instrument does not bring substitution in most cases whilst being very time and resource demanding, it cannot be regarded as effective. The comparative assessment does not deliver for the same reasons. Furthermore, the Review Program (RP) is seriously delayed due to inefficiencies in the system: see our answer to question 5. The NL pleas for the risk based evaluation aligned with, not exceeding, decisionmakers' needs for informed judgement. See annex for our suggestions to improve the effectiveness of processes.

Question 2

How effective were the following processes/concepts/rules in improving the functioning of the internal market?

	Very effective	Effective	Ineffective	Very ineffective	Don't know
Review programme to review the safety and efficacy of all existing biocidal active substances	○	◉	○	○	○
Approval of new active substances	○	◉	○	○	○
Exclusion and substitution criteria and rules for products containing substances meeting these criteria, including comparative assessment	○	○	◉	○	○
Early review of active substance approval	○	◉	○	○	○

Annex I active substances /Simplified procedure for product authorisation	○	○	◉	○	○
Same biocidal products	○	◉	○	○	○
Biocidal products families	○	◉	○	○	○
Inclusion of in-situ products within the scope of the Biocidal Products Regulation	○	◉	○	○	○
National authorisation of biocidal products /renewals	○	◉	○	○	○
Mutual recognition of national authorisations /renewals	○	◉	○	○	○
Union authorisations/renewals	○	◉	○	○	○
Parallel trade permits	○	◉	○	○	○
Rules for treated articles	○	○	◉	○	○
Labelling requirements	○	○	◉	○	○
Data sharing rules	○	○	○	○	◉
Data protection rules	○	○	○	○	◉
Product-types structure	○	○	◉	○	○

Briefly explain the reasons for your answer for the points you consider the most relevant

1000 character(s) maximum

Exclusion and substitution criteria led to different approaches in Member States Example Creosote.
No incentive to add substance to Annex one.
Borderline discussions between PTs and overlap. For example between PT 7 and PT 8 and PT6 and PT7.

Question 3

Has the Biocidal Products Regulation achieved the following objectives related to the functioning of the internal market for biocidal products?

	Fully	To a large extent	To some extent	To a small extent	Not at all	Don't know
Remove obstacles to free circulation of biocidal products and articles treated with them	○	○	◉	○	○	○

Ensure equal treatment of companies by establishing a level playing field, especially for SMEs and avoid creating monopolies	○	○	◉	○	○	○
Provide legal certainty	○	○	◉	○	○	○
Avoid unnecessary burdens for applicants and authorities	○	○	○	◉	○	○
Ensure effective coordination and harmonisation of actual implementation of rules by Member States (Biocidal Products Committee, Coordination Group, Standing Committee on Biocidal Products, meeting of representatives of Members States competent authorities for the implementation of the Biocidal Products Regulation)	○	○	◉	○	○	○
Ensure compliance with the requirements	○	◉	○	○	○	○
Ensure a certain level playing field between treated articles manufactured in the EU and treated articles that have been imported into the EU	○	○	◉	○	○	○

Question 4

Has the Biocidal Products Regulation achieved its objectives related to ensuring a high level of protection of human and animal health and the environment?

	Fully	To a large extent	To some extent	To a small extent	Not at all	Don't know
Ensure that only safe active substances are used in biocidal products	○	○	◉	○	○	○
Ban or restrict the use of active substances with the worst hazard profile	○	○	○	◉	○	○
Ensure that biocidal products cannot be made available on the market unless authorised	○	○	◉	○	○	○
Encourage use of less hazardous products	○	○	○	◉	○	○
Encourage the development of new active substances on the market	○	○	○	○	◉	○
Ensure availability of biocidal products if needed to combat a serious danger for public health /environment or protect the cultural heritage	○	◉	○	○	○	○

Ensure appropriate enforcement of the rules	○	○	○	◉	○	○
Minimise animal testing	○	○	◉	○	○	○
Encourage sustainable use of biocidal products	○	○	○	○	◉	○
Ensure that only safe articles treated with biocides are placed on the EU market	○	○	○	◉	○	○
Ensure that adequate and necessary information on the risks and precautions for use is conveyed to the user	○	○	◉	○	○	○

Question 5

Has the implementation of the Biocidal Products Regulation been effective?

	Very effective	Effective	Ineffective	Very ineffective	Don't know
Review programme to review the safety and efficacy of all existing biocidal active substances	○	○	○	◉	○
Exclusion and substitution criteria. Rules for products containing substances meeting these criteria, including comparative assessment	○	○	◉	○	○
Analysis of alternatives	○	○	○	◉	○
Simplified authorisation procedure	○	○	○	◉	○
Same biocidal products	○	◉	○	○	○
Biocidal product families	○	○	◉	○	○
National authorisation of biocidal products /renewals	○	◉	○	○	○
Mutual recognition of national authorisations /renewals	○	◉	○	○	○
Parallel trade permits	○	○	○	○	◉
Derogations from the requirements	○	◉	○	○	○
Labelling requirements	○	○	○	○	◉
Data sharing rules	○	◉	○	○	○
Data protection rules	○	◉	○	○	○

Question 6

What factors supported or hindered implementation and how do these factors relate to the EU intervention? You should provide examples and be specific

1500 character(s) maximum

The Review Program is far from completion due to an overburdened system.
Information on safer substitutes should be readily accessible at the outset of the evaluation process for the entire group of substances with a similar application, rather than being gathered ad hoc during dossier assessment.
See annex for suggestions to improve.
The simplified authorisation procedure is predominantly used for products with an extremely mild hazard profile, which limits its ability to address issues in areas where the need for use of (highly regulated) biocidal products is questionable, like cat repellents.
The concept of BPF was in general very ineffective, at least before the BPF guidance was developed (2019). Limited experience is gathered with post BPR guidance applications. Known issues like complexity, extensive SPC, etc. remain but the concept also has its positives like avoidance of duplication of work by allowing concentration ranges.

Question 7

What is the contribution of the exclusion criteria for decision-making on active substances to the following objectives?

	Highly positive	Positive	No effect	Negative	Highly negative	Don't know
Protection of human health	○	◉	○	○	○	○
Protection of animal health	○	○	◉	○	○	○
Protection of the environment	○	○	◉	○	○	○
Reduced animal testing	○	○	○	◉	○	○
Functioning of the internal market	○	○	○	◉	○	○

Question 8

What is the contribution of the substitution criteria for decision-making on active substances to the following objectives?

	Highly positive	Positive	No effect	Negative	Highly negative	Don't know
Protection of human health	○	◉	○	○	○	○
Protection of animal health	○	○	◉	○	○	○

Protection of the environment	○	○	◉	○	○	○
Reduced animal testing	○	○	○	◉	○	○
Functioning of the internal market	○	○	○	◉	○	○

Question 9

How would you qualify the following criteria for the approval of active substances?

	Very lenient	Somewhat lenient	Appropriate	Somewhat strict	Very strict	Don't know
Exclusion criteria	○	○	○	○	◉	○
Substitution criteria	○	○	◉	○	○	○
Criteria for eligibility for Annex I inclusion	○	○	○	○	◉	○
Other approval criteria (i.e. for substances not in Annex I, substances not fulfilling exclusion criteria, substances that are not candidates for substitution)	○	○	○	◉	○	○

Question 10

Are factors other than environmental and human health related, like social and economic factors, sufficiently taken into account in the decision-making for active substances approval?

	Fully	Sufficiently	Insufficiently	Highly insufficiently	Don't know
Social factors	○	○	○	◉	○
Economic factors	○	○	○	◉	○
Other factors (please specify)	○	○	○	◉	○

Briefly explain your reasoning for selecting your responses

1000 character(s) maximum

Social/economic: information on alternatives for art. 5 exclusion substances (and to certain extend also for art. 10 CfSs) peer reviewed by experts with competence in this specific area is lacking.
Other factors: Integrated Pest Management principles, sales and monitoring data (see annex).

There is a need for EU-harmonized methodology to weigh public interests, risks, and alternatives. Also it is recommended to require a substitution plan where it concerns substances of very high concern.

Question 11

A specific objective of the Biocidal Products Regulation is to facilitate substitution of the most hazardous substances with other substances or by alternative methods. Do you think the current rules support the substitution of most/more hazardous biocidal active substances or products?

- ○ Completely
- ○ To a large extent
- ○ To a limited extent
- ◉ Not at all
- ○ Don't know

Question 12

How has the implementation of the Biocidal Products Regulation affected the availability of biocidal products in your country?

- ○ Drop in availability
- ○ Rise in availability
- ○ No change
- ◉ Don't know

Question 13

If you experienced a decline in the availability of certain biocidal products, do you think that the products/methods available can still effectively control harmful organisms?

1000 character(s) maximum

With little or no insight into the volumes of active substances, biocides and treated articles that are on the market, little can be said about the availability of biocidal products to effectively control harmful organisms.

Question 14

How has the implementation of the Biocidal Products Regulation affected the prices of biocidal products in your country?

- ○ Prices fell

- ○ Prices rose
- ○ No change
- ◉ Don't know

Question 15

Have any external factors (technological progress, global challenges, other legislation) influenced the effectiveness of the Biocidal Products Regulation? If yes, how?

1000 character(s) maximum

Depending on their claimed use, chemical substances are regulated under multiple frameworks, often based on some kind of assessments scheme of their intrinsic hazard properties. Applying the principle of “One Substance, One Assessment” (OSOA) would improve coherence and efficiency, and lower administrative and operational burdens, which in turn would lower the threshold for submitting applications. Further development of this concept would also support better consideration of cumulative exposure and environmental emissions.
The effectiveness of the OSOA principle depends on alignment and consistency across regulatory frameworks. At present, the approval criteria under the BPR and others are not fully aligned, for instance the surface water quality standards established under the Water Framework Directive (WFD).
The introduction of ED criteria had a big effect on the effectiveness of the Biocidal Products Regulation. It increased the burden of proof and work load significantly.

Evaluation criterion: EFFICIENCY (Are the costs of the Biocidal Products Regulation justified in view of its benefits?)

Question 16

Are the legal timelines set out in the Biocidal Products Regulation adequate?

	Should be decreased	Are adequate	Should be increased	Don't know
Active substance approval	○	○	◉	○
Active substance renewal	○	○	◉	○
Simplified authorisation procedure	○	○	◉	○
Same biocidal products authorisation	○	○	◉	○
National authorisation of biocidal products /product families	○	○	◉	○
Renewal of national authorisation	○	○	◉	○
Mutual recognition in parallel	○	○	◉	○
Mutual recognition in sequence	○	○	◉	○

Renewal of authorisations granted by mutual recognition	○	○	◉	○
Union authorisation	○	○	◉	○
Renewal of Union authorisations	○	○	◉	○

Briefly explain your reasoning for selecting your responses

1000 character(s) maximum

Given the eCA capacity in EU, timelines should either be increased (preferably not), or procedures should be redesigned so that decision making is more efficient and the intended level of protection is reached as soon as possible, while still delivering robust and well substantiated outcomes. Therefore:
Renewals should not delay the finalization of the RP.
Product renewals should never precede the renewal of the substance as the level of new information to be evaluated will be low.
The assessment framework should be stable.
See annex for more of our suggestions to improve the efficiency of processes.

Question 17

How efficient are the current procedures in relation to the benefits and effects achieved? You should consider the costs incurred by the actors involved (industry, regulatory authorities, consumers).

	Very efficient	Efficient	Inefficient	Very inefficient	Don't know
Review programme	○	○	○	◉	○
Approval of new active substances	○	○	○	◉	○
Active substance renewal	○	○	○	◉	○
Early review of an active substance approval	○	◉	○	○	○
Analysis of alternatives	○	○	○	◉	○
Simplified authorisation procedure	○	○	○	◉	○
Same biocidal products	○	○	○	◉	○
Biocidal products families	○	○	○	◉	○
Inclusion of in-situ products within the scope	◉	○	○	○	○
National authorisation of biocidal products /renewals	○	○	○	◉	○
Mutual recognition of national authorisations /renewals	○	○	○	◉	○

Union authorisations/renewals	○	○	○	◉	○
Parallel trade permits	○	○	○	○	◉
Rules for treated articles	○	○	○	◉	○
Derogations from the requirements	○	◉	○	○	○
Labelling requirements	○	○	○	○	◉
Data sharing rules	○	◉	○	○	○
Data protection rules	○	◉	○	○	○
Transitional provisions, including Article 95 list	○	◉	○	○	○
Data requirements for active substance approval	◉	○	○	○	○
Data requirements for product authorisation	○	◉	○	○	○
Product type structure	○	○	○	◉	○

For those you identified as inefficient, please indicate what actions could reduce regulatory burden or potential alternative policy mechanisms that could improve cost-efficiency.

Give examples and be as precise as possible.

1500 character(s) maximum

The BPR delivers clear benefits. However, the cost–benefit balance is weakened by:
- duplication of assessments across Member States and inconsistent frameworks
- uniform data requirements regardless of hazard profile. Maybe few groups can be deprioritized (like PT19. N. B. for other PTs, no application was ever received)
- slow decision making processes due to dossiers and guidance that are more complex than expected
- iterations in the process due to new relevant information (guidance, data) "emerging" during the evaluation
- resources to be spent on commenting over evaluation, and product renewals that precede the substance renewal (see our answer to Q16).

Maybe it is still fair as all products are equally affected by the ineffectiveness of the system. But this is currently not the case as even within one PT not all actives are evaluated yet under the BPR scheme.
See annex for more of our suggestions to improve the efficiency of processes.

Question 17.a.

Is there potential for rules or reporting simplification and/or burden reduction?

Give examples and be as precise as possible.

1500 character(s) maximum

We advocate for a more implementable BPR that contributes to acceleration of procedures and that promotes innovation and sustainability while maintaining high a high level of protection. Key points include:
- A more targeted, risk-based approach. Pragmatic where possible, strict where needed.
- Faster (more efficient) and focused decision-making. Set priorities.
- Explore reducing the scope of the BPR where other legislation sufficiently protect human health and the environment.
- Only authorize products for the whole Union when there are similar conditions of use.
- Take over the approval of substances of low concern from other regulations (e.g. PPPR and food preservatives regulation)

See annex.

Question 18

What benefits have you experienced as a result of the implementation of the Biocidal Products Regulation?

Give examples and be as precise as possible.

1500 character(s) maximum

Introduction of:
- coordinating role of ECHA and their IT systems
- gain in knowledge on the hazards and risk of substances evaluated
- hazard cut-offs (with derogation possibilities if needed)
- in-situ redefinition
- less free-riding
- new concepts like BPF, UA and SBP
- regulation of treated articles
- SAP principle (despite its criteria should be reconsidered)

See annex.

Question 19

Have the Biocidal Products Regulation’s rules and procedures improved the product authorisation process?

- ○ Fully
- ○ To a large extent
- ◉ To some extent
- ○ To a small extent only
- ○ Not at all
- ○ Don't know

Briefly explain your reasoning for selecting your response

1000 character(s) maximum

From an operational and procedural perspective, the NL observes that the current wording of the BPR prevents an effective and efficient use of assessment capacity, leading to an overburdened implementation system and placing pressure on the intended high level of protection.
See annex for more of our suggestions to improve the efficiency of processes.

Question 20

What are the biggest challenges or bottlenecks you have encountered in the product authorisation process?

1500 character(s) maximum

Complexity, lack of information, high workload, no guidance (no harmonisation), overreliance on risk assessment (request for data to confirm that certain hazardous intrinsic properties are indeed to be excluded) over risk-based management.
See annex for more of our suggestions to improve the efficiency of processes.

Question 21

Do you think that the Biocidal Products Regulation has contributed to the competitiveness of the biocides sector?

1500 character(s) maximum

Competitiveness in the biocides sector is limited.

Question 22

Do you think the Biocidal Products Regulation has contributed to innovation in the biocides sector?

1500 character(s) maximum

In the 2nd half of 2020, the Ministry of IandW, commissioned an exploratory study into the challenges faced by market parties regarding biocidal policy, as well as the potential solutions they envision. The present report, "Exploratory Study: Market Parties and Biocidal Policy" [1], outlines the findings of this study. On innovation the following was concluded:
There is a lack of a business case for innovation, and there is also a perceived absence of (built-in mechanisms for) targeted incentives to stimulate innovation. Government bodies, for example, highlight public interests such as invasive alien species, and the protection of cultural heritage—areas where new/innovative solutions are needed but not being developed (due to too small-scale applications) (see also experiences during the coronavirus pandemic and disinfection).
Potential solutions include the introduction of targeted financial incentives, such as a dedicated fund for small scale applications or a broader public interest fund, alongside streamlined administrative procedures. Additionally, granting controlled experimental leeway could help accelerate innovation and strengthen the underlying business case.
Additionally, there is a need for targeted stimulation of low-risk and acceptable-risk biocides, simplified registration for low-risk substances (e.g., the ‘basic substances list’ under the BPR), and addressing the issue of non-patentable substances.
[1] https://www.tweedekamer.nl/zoeken?qry=2022D30626

Question 23

What are the most important barriers to competitiveness and innovation in this sector?

1500 character(s) maximum

A recent study on the regulatory burden of companies in the chemical production industry [1] concluded the following:

Excessive assessment timelines: The legal maximum assessment timelines for a Competent Authority to assess an application is three years. However, businesses report that, in practice, this often takes several years longer, resulting in substantial additional costs.
High investment threshold: Companies indicate that the costs for the authorisation and registration process at the start of the ten-year period amount to approximately €400,000–€450,000, but can rise to as much as €3 million. In addition to these initial costs, there are annual fees of around €10,000 to maintain registration.

[1] https://open.overheid.nl/documenten/860c91d3-4ee6-4f5f-b8bc-e1e4e60b17de/file

Question 24

What are the most important barriers to creating a level playing field for all economic operators (regardless of size or market position)?

1500 character(s) maximum

The mutual recognition (MR) and Union Authorisation (UA) processes are fully harmonised, However the procedures have some inherent inefficiencies, including:
- general issues that concern all application types: see annex.
- MR in sequence much more complex than MR in parallel in case of new data or disagreement.
- consensus mechanism in case of MR disagreement.
- comments/disagreements driven by scientific interest instead of risk-based approach.
- art 42 similar conditions UA versus art 44(5) national derogations.
- as a side note on the levelness of the playing field, the current fee structure for UA tasks does not facilitate an equitable distribution of contributions across actors. The Member State commenting phase represents a substantial workload, especially when UA and BPF processes coincide. Yet no corresponding fee has been established to compensate for this specific effort.

Question 25

How would you simplify the product authorisation process?

1500 character(s) maximum

We advocate for a more implementable BPR that contributes to acceleration of procedures and that promotes innovation and sustainability while maintaining high a high level of protection. Key points include:
- A more targeted, risk-based approach. Pragmatic where possible, strict where needed.
- Faster (more efficient) and focused decision-making. Set priorities.
See annex for more of our suggestions to simplify processes.

Evaluation criterion: RELEVANCE (Does the Biocidal Products Regulation address current and upcoming challenges?)

Question 26

Is the Biocidal Products Regulation fit for purpose?

- ○ Yes
- ◉ No
- ○ Don't know

Question 27

Is the scope of the Biocidal Products Regulation still relevant?

- ○ Highly relevant
- ◉ Somehow relevant
- ○ Relevant
- ○ Irrelevant
- ○ Don't know

Question 28

Are the following requirements/criteria still relevant in the light of latest technical and scientific developments?

	Still relevant	Need modification	Don't know
Criteria for active substance approval	○	◉	○
Data requirements for active substance approval	◉	○	○
Conditions for authorisation of biocidal products	○	◉	○
Data requirements for authorisation of biocidal product	◉	○	○
Data sharing rules	◉	○	○
Rules for placing on the market of treated articles	○	◉	○

Question 29

To what extent do existing provisions allow enough flexibility to consider new scientific information (for instance, new toxicological information)?

- ◉ Fully
- ○ To a large extent
- ○ To some extent
- ○ To a small extent only
- ○

Don't know

Question 30

Do the rules allow enough flexibility to consider new scientific information, like new toxicological information?

- (●) Fully
- ( ) To a large extent
- ( ) To some extent
- ( ) To a small extent only
- ( ) Don't know

Question 31

How transparent are the processes for approving active substances?

	Fully	To a large extent	To some extent	To a small extent	Not at all	Don't know
Risk assessment by evaluating competent authority	( )	(●)	( )	( )	( )	( )
Peer-review by Biocidal Product Committee	( )	(●)	( )	( )	( )	( )
Risk management by the European Commission	( )	( )	( )	(●)	( )	( )

Question 32

How transparent are the processes for authorising biocidal products?

	Not at all	To a small extent	To some extent	To a large extent	Fully	Don't know
Risk assessment by evaluating competent authority	( )	( )	( )	(●)	( )	( )
Resolving disagreements in mutual recognition procedures in the Coordination Group	( )	(●)	( )	( )	( )	( )
Authorisation decision by Member States or the European Commission	( )	(●)	( )	( )	( )	( )

Question 33

How would you improve transparency?

1500 character(s) maximum

For the sake of transparency, the NL support the recent initiative to delegate the BPC to assess whether art 5 (2) conditions are met. We also welcome recent and future ECHA initiatives to disseminate data to the public from various chemical databases managed by them. For inspectors and end users, it remains difficult to quickly locate the correct and relevant information on authorised biocidal products within the European system.
At Ctgb, we do our utmost best to inform the applicant of the status of his application. However, the level of sharing varies considerably between Member States. Harmonised legal requirements could help move towards a more uniform level of transparency towards applicants.
Public minutes reflects the outcome of discussions in WG/CG-restricted and SCBP. Further transparency on the discussions it selves deems not appropriate.
In some cases the European Commission does not have to follow through with a draft proposal after a decision of the Member States in the SCBP. Transparency can be increased in these cases by setting a deadline for the Commission to put forward a draft proposal and make it obligatory to do so when the Member States made a decision.

Evaluation criterion: COHERENCE (Is the Biocidal Products Regulation consistent internally and with other related EU and international policies and interventions?)

Question 34

Is the Biocidal Products Regulation coherent as a piece of legislation (no contradictions or gaps in its provisions)?

- ○ To a large extent
- ◉ To some extent
- ○ To a small extent
- ○ Not at all
- ○ Don't know

Question 35

Is the Biocidal Products Regulation coherent with the following EU public health and environmental legislation?

	To a great extent	To some extent	To a small extent	Not at all	Don't know
Regulation (EC) No 1907/2006 (REACH Regulation)	◉	○	○	○	○
Regulation (EC) No 1272/2008 (Classification, Labelling and Packaging of Substances and Mixtures Regulation)	○	◉	○	○	○

Regulation (EC) No 1107/2009 (Plant Protection Products Regulation)	○	○	◉	○	○
Regulation (EC) No 1935/2004 (Food Contact Materials Regulation)	○	○	◉	○	○
Regulation (EC) No 1223/2009 (Cosmetics Regulation)	○	○	◉	○	○
Regulation (EC) No 648/2004 (Detergents Regulation)	○	○	◉	○	○
Regulation (EU) 2019/6 (Veterinary Medicines Regulation)	○	○	◉	○	○

Question 36

Is the Biocidal Products Regulation coherent with the following international policies /conventions?

	To a great extent	To some extent	To a small extent	Not at all	Don't know
Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade	○	○	◉	○	○
Stockholm Convention on Persistent Organic Pollutants	○	◉	○	○	○
International Convention on the Control of Harmful Anti-fouling Systems on Ships	○	○	◉	○	○
UN Global Framework on Chemicals	○	○	○	○	◉
OECD legal instruments concerning chemicals	○	○	○	○	◉
UN 2030 Agenda for sustainable development	○	○	○	○	◉

Question 37

Are there any inconsistencies in the Biocidal Products Regulation?

Briefly describe them providing examples.

1000 character(s) maximum

- Though Maximum Residue Limits (MRLs) are mandatory, the BPR contains no mechanism to establish biocide specific MRLs nor a mechanism to amend the default MRL from other frameworks to values realistic for biocidal use. See annex.
- Imported treated articles from outside the EU versus TAs made in EU.
- Producing unauthorized biocides and TAs for export is not prohibited.
- Some products may not be used by certain user groups, but selling these products to these user groups is not prohibited.

Evaluation criterion: EU ADDED VALUE (Does the Biocidal Products Regulation provide benefits that could not be achieved at the national level alone?)

Question 38

Has the Biocidal Products Regulation been beneficial regarding the objectives pursued that could not have been achieved by Member States alone?

- (●) Yes
- ( ) No
- ( ) Don't know

Give examples

2000 character(s) maximum

Benefits: central AS evaluation + level playing field + access in one go to the internal market (to justify the associated investment budget needed to develop data for the dossier) + harmonisation.

Question 39

At which level of governance should biocidal products be regulated?

- (●) EU level
- ( ) National level
- ( ) Both EU and national level
- ( ) Don't know

Briefly explain your answer.

1000 character(s) maximum

Biocidal market access to the internal market is most effectively regulated at EU level, where a harmonised framework can ensure a genuine level playing field, central substance approval, and consistent standards for all operators in support of the free movement of compliant products.
At the same time, the system should retain sufficient flexibility to accommodate legitimate national specificities. Physical and geographical conditions, as well as realistic differences in use patterns, may justify tailored national measures, provided they remain proportionate and compatible with the internal market.
To enhance efficiency and reduce duplication of work, it would be worthwhile to explore in which cases the European Chemicals Agency could assume responsibilities currently held by national competent authorities. A more centralised approach for selected tasks could streamline processes, improve consistency in decision making , and help increase the predictability of the output. See annex.

Question 40

The risk assessment process to approve active substances involves authorities at national and EU level. At which level should this process be handled?

- ( )

National level

- ○ EU level
- ○ Current system (both national and EU level)
- ◉ Both national and EU level, but different than current system
- ○ Don't know

Briefly explain your answer.

1000 character(s) maximum

Co-rapporteurship. More trust building. Review by limited number of peers. See annex for further explanation.

Question 41

The risk assessment process for Union authorisation of products involves authorities at national and EU level. At which level should this process be handled?

- ○ National level
- ◉ EU level
- ○ Current system (both national and EU level)
- ○ Both national and EU level, but different than current system
- ○ Don't know

Briefly explain your answer.

1000 character(s) maximum

ECHA could take over the role of national eCAs, especially concerning central planning and forecasting. Review by limited number of peers. See annex for further explanation.

Question 42

What would be the most likely consequence of not having an EU biocidal products legislation?

1500 character(s) maximum

Lower protection levels, no level playing field, no data protection, more products available albeit with unknown hazards, less knowledge on the effects of biocides, unmet public interests.

Additional information

You can provide further information.

2500 character(s) maximum

Ad. to question 27: The BPR provides rules because, for example, the market can fail to deliver biocides or other solutions in a timely manner to protect public interests. The protection of human, animal, and environmental health, as well as the quality or structural integrity of materials, against harmful organisms, while ensuring a high level of protection of people, animals and the environment, are still public interests of concern.

Ad. to question 35: Regulation (EC) No 1107/2009 and Regulation (EU) 2019/6 in relation to MRLs and monitoring Sales and use.

Ad. to question 36: Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade in relation to the difference in the approach to PPP and biocides in the PIC regulation.

You can upload a concise document, such as additional evidence supporting your answers or a position paper.

Uploaded documents will be published on ‘Have your say’ alongside your answers to the questionnaire.

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

f7aef3b4-d1c5-4885-98a5-e540179d39e7/Annex_1_-_Position_paper_Ctgb_input_BPR_evaluation_20260129.pdf

c908a88e-13d8-4a76-b606-c532c88b0c6e/Annex_2_-_Input_Enforcement_Agencies_BPR_evaluation.pdf

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BPR evaluation - Ctgb position paper from an implementation perspective

SUMMARY

In this position paper the Dutch eCA (Ctgb) sets out its perspective on the review of the Biocidal Products Regulation (EU) No. 528/2012 (hereafter: BPR). While acknowledging the BPR's positive contributions, Ctgb concludes that structural inefficiencies have rendered the current system increasingly overburdened.

To restore the BPR's fitness for purpose, Ctgb proposes three key reforms aimed at maximizing the effective and efficient use of capacity, while maintaining a high level of protection of human and animal health and the environment:

1. **Embedding a fully risk-based assessment system** aligned with decision-makers' needs.
2. **Eliminating procedural inefficiencies** that drain capacity and create systemic delays.
3. **Establishing a dedicated mechanism for biocide-specific maximum residue limits**.

INTRODUCTION

The BPR governs the placing on the market and use of biocidal products in the European Union. It aims to facilitate the free movement of biocides, while ensuring the protection of human and animal health and the environment.

The European Commission is currently evaluating the BPR to assess whether it adequately reflects and meets current needs. This paper sets out Ctgb's position, based on its experience as the Dutch evaluating Competent Authority and its role in the practical implementation of the BPR.

Our assessment is based on the current text and context of the BPR. We note that the Food and Feed Omnibus may also influence the future construction and design of the BPR. As the Plant Protection Products Regulation (PPPR) may also be changed in the future, we emphasize the importance of alignment between the BPR and PPPR frameworks.

ANALYSIS

Ctgb recognises the positive impacts of the BPR. At the same time, experience with its implementation shows that several elements of the current framework do not function as intended. These shortcomings are both procedural and technical in nature and increasingly strain the system. The sections below outline the main issues identified and the solutions Ctgb proposes. These measures are necessary to ensure that competent authorities retain adequate expertise and capacity, and to prevent the system from becoming overburdened again.

Positive developments under the BPR

Several core elements of the BPR continue to add clear value. These include the structured EU-level review of active substances, ECHA's coordination and IT systems, and instruments designed to reduce administrative burdens, such as Union Authorisation, Biocidal Product Families, and Same Biocidal Products.

Arbitration mechanisms for resolving divergent views between Member States have strengthened harmonisation and consistency. Article 95 has improved transparency on hazards while also preventing data free-riding. In addition, hazard-based cut-offs, the simplified procedure for substances of low concern, and criteria for endocrine disruptors support the substitution of hazardous substances. The *in situ* generated substances and treated articles were appropriately added to the scope of the BPR.

Areas where improvement is required

1. Risk-based evaluation aligned with decision-making needs

Several aspects of the current evaluation system lead to delay without improving the level of protection.

Decisions are frequently postponed until dossiers meet evolving or newly introduced requirements, even where available data already allow a meaningful risk assessment. This creates cascading delays and leaves well-known risks unmanaged. A **genuinely risk-based, weight-of-evidence approach**, grounded in expert judgement and using existing data, would allow earlier and more proportionate decisions. New or revised requirements can be clearly identified and assessed at renewal unless emerging information justifies immediate action.

The peer-review process has gradually moved beyond its intended role of addressing substantive differences in conclusions. Scientific debate and discussions on procedural detail often outweigh their added value. **Clear baseline quality standards** would allow peer-review to focus on key issues, applying the same risk-based expert judgement as the evaluation itself. A small, preferably rotating group of peer reviewers would normally be sufficient (instead of all member states by default), comparable to the approach used for medicinal products.

The absence of systematic information on sales and monitoring data limits the ability to distinguish between biocides with meaningful exposure risks from those that are rarely used. Introducing a proportionate, **data-informed prioritisation mechanism** would help focus regulatory capacity where potential health and environment impacts are highest.

In the absence of alternatives, substances marked for substitution are often renewed. These substances ought to be phased out after a reasonable transition period that enables the development and uptake of viable alternatives. To enable this, **information on safer substitutes should be available at the outset of the evaluation**, reviewed by experts with relevant competence, rather than assembled ad hoc during dossier assessment. In case no alternatives already exist, the applicant should be obliged to initiate actions to alter the situation and justify the duration of his derogation (comparable to the REACh **substitution plan**).

2. Robust outcomes with more efficient procedures

Although legal timelines cannot be met currently, the solution does not lie in extending them. Instead, procedures should be redesigned to support faster decision-making while maintaining and well-substantiated outcomes. The main challenges and solutions fall into two categories: procedural design and the organisation of expertise.

2.a Procedural issues

Some categories of biocides are inherently less hazardous than others, such as pheromones. These substances could be handled through alternative, faster **procedures that are proportionate to their hazard and risk**. At the other end of the spectrum, where substances meet both exclusion and derogation criteria and no alternatives exist, the necessary level of technical detail required in ECHA opinions could be defined in advance to streamline assessments.

The current system requires that all substances and products that have already been thoroughly evaluated under EU legislation to be re-assessed on staggered cycles, regardless of their risk profile. Prioritising first evaluations over non-selective re-assessments, combined with a **programmatic renewal approach**, would allow scrutiny and resources to focus on substances that may pose higher risks. Further inefficiency arises because products are renewed independently of the active substances they contain. **Linking product renewals to the renewal of its active substance(s)** would reduce unnecessary work.

Biocidal products that meet the authorisation criteria only by the narrowest margin, and solely through extensive risk mitigation measures, should not be granted authorisation. **Limiting the use of TIERs , as well as on the nature and number of risk-mitigation measures**, would reduce regulatory complexity and enhance overall efficiency. Such constraints would help ensure that authorisation is reserved for products that meet the required standards without relying on disproportionate compensatory measures.

Multiple simultaneous assessments across concerned Member States also contributes to complexity and delay. Allowing only **one application (request) per biocidal product in EU at a time** would reduce parallel processes and diverging situations. Criteria are needed to determine which application type (i.e. renewal, change, mutual recognition, etc.) should be given priority.

Finally, a lack of coordination in timing leads to inefficiencies. **Grouping the evaluation of substances with similar hazard profiles** would streamline assessments and help avoid regrettable substitution.

2.b Expertise-related issues

Depending on their claimed use, chemical substances are regulated under multiple frameworks, often based on some kind of assessments scheme of their intrinsic hazard properties. When these frameworks are not aligned, this results in inconsistent outcomes and duplicated work. Applying the principle of "**One Substance, One Assessment**" (OSOA) would improve coherence and efficiency. Further development of this concept would also support better consideration of cumulative exposure and environmental.

The current expectation is that each competent authority single-handedly performs the full spectrum of tasks and maintains all necessary expertise. A more effective approach would involve **central forecasting and the allocation of applications**, in full or in discrete components, to (co-)rapporteurs based on **available capacity, concentrating specialised expertise in specific biocidal niches within a limited number of Member States, and fair-sharing principles**. Coordination of the components is essential.

New or revised guidance often leads to procedural delays. **Where faster decision-making results in better protection, this should take precedence over postponement to fully accommodate new guidance**, unless emerging information justifies immediate action.

Finally, efficacy is assessed at various points in time, even though **a comprehensive evaluation at the moment of first authorisation should, in principle, be sufficient**. At the substance approval, as well as during future renewals (including product renewals), a lighter review would be adequate, focusing primarily on indications of emerging resistance development and amendments to test protocols.

3. Dedicated procedure for maximum residue limits for biocidal actives substances

The current framework lacks biocide specific maximum residue limits (MRLs). In practice, MRLs set under plant protection or veterinary legislation are used, even though they are not always representative and therefor appropriate for biocidal uses. The BPR provides no mechanism to adjust these MRLs to values realistic for biocidal use, even when mitigating data are available. As a result, certain biocidal products cannot be authorised because the use will lead to exceedance of an irrelevant MRL. **Establishing a dedicated procedure for setting MRLs for biocidal actives substances** would close this gap and provide a workable basis for authorisation.

Together, the reforms proposed in this paper aim to restore the Regulation's fitness for purpose, enabling it to deliver timely, coherent, and effective outcomes while upholding its objectives.

Annex 2 - Input Enforcement Agencies BPR evaluation

Suggestions about enforcement

The Dutch enforcement authorities the Human Environment and Transport Inspectorate (ILT) and the Netherlands Food and Consumer Product Safety Authority (NVWA) set out their perspective on the review of the Biocidal Products Regulation (EU) No. 528/2012 (hereafter: BPR). While acknowledging the BPR's positive contributions, the authorities give some suggestions to improve the enforceability of the BPR in the future.

Current problems

Two major problems hamper enforcement of the BPR (apart from possible capacity issues). One is the rather poor information position of the enforcement authorities, with little or no insight into the volumes of active substances, biocides and treated articles that are on the market. The other problem concerns competence issues with regards to international and internet trade in biocides. As enforcement is a national competence, the inspection is dependent on the cooperation of their international counterparts when it comes to dealing with illegal cross-border (internet) trade.[1]

Consequently, the enforcement authorities operates with too little information and is partly dependent on the goodwill of its international counterparts.

Redefining roles and improving the provision of information

1. More binding and less non-committal cooperation between enforcement authorities in different Member States

To reduce dependence on goodwill of national enforcement authorities (NEA's) and improve enforcement in the field of illegal cross-border (internet) trade, several provisions can be made. They include minimum provisions/agreements for cooperation or follow-up on requests from other Member States (including follow-up on ICSMS); (more or less) mandatory participation of NEAs in EU-wide BPR enforcement projects (and optional participation in pilots); the development of a European enforcement approach to internet trade.

2. Improvement of enforceability of internet trade by Economic Operator at Member State level

Enforceability of internet trade improves by requiring internet traders to have an Economic Operator (EO) physically present in the Member States in which they are not resident and to which they direct their trade. Of course, this also requires clear definitions of and obligations for the EO.

3. Make the entire product chain responsible and liable for (eliminating) the consequences of diffuse pollution or accidents, which are currently borne by the taxpayer

When major environmental problems related to biocides – like Dutch problems with water quality – gradually become apparent, it often shows that many parties are involved: producers, suppliers, various types of users. Usually it is possible to trace which parties are involved, but not which party is responsible. As a consequence, it is ultimately the government – and thus the taxpayer – who pays the bill for dealing with unwanted emissions. It should be possible to say: you are all jointly responsible, so you are all accountable.

4. Digital Product Passport (DPP) for categories of Treated Articles

Treated articles (TA's) are hard to trace. TA labelling obligations (art. 58 BPR) are hard to enforce. An improvement opportunity arises with the introduction of EU digital product passport (DPP) obligations for certain relevant product categories (e.g. textile). It is imperative that BPR requirements

[1] For example: cross-border sales to consumers of products that are only authorised for professional use. It may be expected that there will be less (opportunity for) illegal cross-border (internet) trade once the period of transitional law is over, and even less so when all new authorisations will be Union authorisations. However, illegal cross-border trade will always exist, both within the EU and beyond, because of ignorance or ill will.

are aligned with these DPP obligations. Moreover, it is desirable that certain other product categories that are relevant as TAs under the BPR (e.g. preserved wood) are also brought under DPP obligations.

5. Regulate registration of sales figures and monitoring of effects of biocide use in BPR

NEA's information position improves greatly when biocides sales figures are registered in a harmonised way in all EU MS's (including in those MS's that currently lack such registration systems, like the Netherlands). The obligation for the holders of approvals and authorisations can be integrated in the BPR.
This need is also indicated in consideration 23 of the regulation on statistics on agricultural input and output (EU) 2022/2379.
An example can be taken from plant protection products.
Advantages of registration that are mentioned include an improved identification of societal risks; a realistic picture of how much biocides are used and of how much can end up in the environment.
An additional way to identify risks is to regulate impact-oriented monitoring of the use of biocides (for example, by monitoring the concentrations of active substances at specific hotspots to gain insight into the extent to which the use of biocides poses risks to water quality).

Refining and clarification

6. Clarify definitions in the BPR and align them with national legislation and SPCs:
   - Clarify definition of 'biocides'
   - Align definitions of user types in BPR, national legislation and SPCs
   - Clarify definition of 'use'

Clarify what is to be understood as 'biocides', including borderline cases such as enzymes and biofilms.
Use one and the same definition for user types. Currently and confusingly, wordings include 'general public', 'non-professional user', 'industrial user', 'professional user', 'educated professional user', 'trained professional user' (where also it is generally unclear which education or licence is required).
In the definition of 'use', distinguish between 'having in stock' and 'applying' (e.g. conditions for keeping a biocide safely in stock, can be part of use according to the SPC).

7. Prohibit marketing of biocides for non-authorised uses (and promoting unauthorized biocides)

Currently, the BPR only prohibits *use* of biocides in breach of SPC prescriptions, not the *marketing* in breach of SPC prescriptions. Thus, the latter is not enforceable. The same holds true for promoting unauthorized biocides and promoting unauthorised use as biocide, this too is not prohibited and therefore not enforceable.

8. Make the label part of the dossier; regulate language and trade name on SPC; introduce an enforceability assessment for SPC's of products with Union authorisation

Facilitate the enforcement of correct labelling by making the label part of the dossier on which the authorisation of the biocidal product is based (see also option 24).
Include in art. 69 BPR the obligation to mention the trade name on the label and to have the label in the official language(s) of the MS in which they are placed on the market.
Introduce an enforceability assessment for SPC's of products with Union authorisation, as current SPC's of those products prove to be hard to enforce. Make it also an requirement for distributors for placing on the market only biocides that are in compliance with the authorisation such as a correct labelling. NEA's can enforce on biocides with authorization holders in another MS.

9. Clarify whether unauthorised biocides may or may not be exported

It is not clear why actions taken with a view to exporting a biocidal product are exempt from the definition of 'use'. Does this imply that operations with non-authorised biocides destined for export outside of the EU may take place within the EU?

10. Make ECHA the point of contact for questions about compliance and enforceability, particularly in relation to Union authorizations

National inspectorates need a point of contact for clarification of the exact obligations following from approvals and authorisations. Particularly where Union authorisations are concerned, a point of contact with ECHA is required.