BPR evaluation - Public consultation

Fields marked with * are mandatory.

Introduction

About you

* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
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- Hungarian
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* I am giving my contribution as
  - Academic/research institution
  - Business association
  - Company/business
  - Consumer organisation
  - EU citizen
  - Environmental organisation
  - Non-EU citizen
  - Non-governmental organisation (NGO)
  - Public authority
  - Trade union
  - Other

* First name

Denisa

* Surname

Klieštíková

* Email (this won't be published)

kliestikova@komora.cz

* 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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- Djibouti
- Libya
- Saint Martin

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- Algeria
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- Andorra
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- Antarctica
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- Ghana
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- Mexico
- Micronesia
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- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- 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

- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- 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
- Greenland
- Grenada
- Guadeloupe
- Guam
- 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
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine

- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

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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					

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					

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

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)					

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

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

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	○	○	○	○

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					

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

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

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

Question 20

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

1500 character(s) maximum

Question 21

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

1500 character(s) maximum

Question 22

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

1500 character(s) maximum

Question 23

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

1500 character(s) maximum

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

Question 25

How would you simplify the product authorisation process?

1500 character(s) maximum

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

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

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

Question 39

At which level of governance should biocidal products be regulated?

- EU level
- National level
- Both EU and national level
- Don't know

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

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

Question 42

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

1500 character(s) maximum

Additional information

You can provide further information.

2500 character(s) maximum

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

Contact

SANTE-BIOCIDES@ec.europa.eu