

# BPR Article 65(3) reporting

## 1. General information

### 1.1. Member State

For which Member State\* are you reporting?

(\*In this survey "Member State" refers to EU Member States, Iceland, Liechtenstein, Norway and Switzerland)

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom

### 1.2. Contact details of the person responsible for reporting

Name	Organisation	Email address	Telephone number(s)
	Ministry of Health		

### 1.3. Information on the Competent Authority (CA)

#### 1.3.1. Competent Authorities involved in the implementation of the BPR

How many CAs are responsible for the implementation of the BPR in your Member State? Please do not include enforcement authorities here, as they are specifically covered in section 4.

Ministry of Health

#### 1.3.2. Details of the Competent Authorities involved in the BPR implementation

	BPR competent authority involved	Website
Advice to applicants/helpdesks on active substances	Ministry of Health	<a href="https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/">https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/</a>
Advice to applicants/helpdesks on biocidal products	Ministry of Health	<a href="https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/">https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/</a>
Advice to applicants/helpdesks on treated articles	Ministry of Health	<a href="https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/">https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/</a>

Assessment of active substances	Ministry of Health	<a href="https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/">https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/</a>
Assessment and authorisation of biocidal products	Ministry of Health	<a href="https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/">https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/</a>
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)	1.National Center of Public Health and Analyses (NCPHA); 2. National Center of Infectious and Parasitic Diseases (NCIPD)	<a href="https://ncpha.government.bg/en/">https://ncpha.government.bg/en/</a> <a href="https://ncipd.org/index.php?option=com_k2&amp;view=item&amp;layout=item&amp;id=190&amp;Itemid=1191&amp;lang=en">https://ncipd.org/index.php?option=com_k2&amp;view=item&amp;layout=item&amp;id=190&amp;Itemid=1191&amp;lang=en</a>

### 1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	The Toxicology Clinic of N. I. Pirogov Multi-Profile Hospital for Active Treatment and Emergency Medicine	<a href="https://pirogov.eu/bg/">https://pirogov.eu/bg/?</a>
Animal poison centre	-	-
Other	-	-

## 2. Relevant national measures and Member State specific measures

### 2.1. Transitional period (Art. 89 BPR)

Do you have specific national measures or legislation for making available on the market of biocidal products during the transitional period?

- Yes  
 No

Please specify below the national regulation(s) and/or requirement(s) during the transitional period or refer to the corresponding link of the relevant website with the requested information. If available in English please include the link to the English version.

Please also indicate whether such regulation(s) and/or requirement(s) changed during the reporting period.

1. Protection Against the Harmful Impact of Chemical Substances and Mixtures Act;
2. ORDINANCE of the form and content of the documents, necessary for the issue of a permit for providing the market of biocide or a group of biocides under art. 18 of the Law for the Protection from the Harmful Impact of the Chemical Substances and Mixtures

<https://www.mh.government.bg/bg/administrativni-uslugi/registri/registar-na-biotsidnite-preparati/>  
<https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/naredba-za-formata-i-sdrzhanie-to-na-dokumentite-neobhodimi-za-iz/>

### 2.2. Applicable fees

Do you have specific national measures or legislation regarding fees for BPR procedures?

- Yes  
 No

Please specify below the national regulation(s) and indicate the corresponding link to the relevant website with the requested information. If available in English please include the link to the English version

1. Protection Against the Harmful Impact of Chemical Substances and Mixtures Act;
2. Excerpt from the Tariff on fees collected by state health control authorities and national centers for public health issues under the Health Act (promulgated in SG, issue No.83 of 16 October 2007, amended SG, issue 39 of 25 May 2010, amended SG, issue 101 of 28 December 2010, amended SG, issue 5 of 14 January 2011, amended SG, issue 16 of 22 February 2011, amended SG, issue 38 of 17 May 2011, amended SG, issue 1 of 3 January 2012, amended and supplemented SG, issue 81 of 23 October 2012, amended and supplemented SG, issue 17 of 23 February 2018 ), applicable to the Republic of Bulgaria for granting of an authorization for making available on the market of biocidal products

<https://www.mh.government.bg/bg/administrativni-uslugi/produkti-sas-znachenie-za-zdraveto/biotsidi/naredba-za-formata-i-sdrzhanie-to-na-dokumentite-neobhodimi-za-iz/>

#### 2.2.1. Fee amounts

Please provide information on the applicable fees for the procedures listed in the table below

	Fee amount
Evaluation of an active substance for approval	22 150 BGN
Evaluation of an active substance for Annex I inclusion	22 150 BGN
Authorisation of a biocidal product (BP)	8 450 BGN
Authorisation of a BP family	13 500 BGN
Mutual recognition of an authorisation of a BP	2 850 BGN
Mutual recognition of an authorisation of a BP family	4 560 BGN



### 3.1.2. Renewal of authorisations

Please indicate in the tables below the figures related to the renewals of authorisations for making available on the market of biocidal products

#### 3.1.2.a. National authorisations

	2013	2014	2015	2016	2017	2018	2019	Total number
Authorisations granted on the basis of Article 19(5)	-	-	-	-	-	-	-	-
Provisional authorisations granted for products containing new active substances (Article 55(2))	-	-	-	-	-	-	-	-

#### 3.1.2.b. Mutual recognitions - concerned MS

	2013	2014	2015	2016	2017	2018	2019	Total number
Derogations (Article 37)	-	-	-	-	-	-	-	-

#### 3.1.2.c. Authorisations of products containing active substances meeting exclusion criteria (Article 5.2)

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications assessed	-	-	-	-	-	-	-	-
Number of products authorised (conditions met for all or some of the uses)	-	-	-	-	-	-	-	-
Number of products not authorised (conditions not met for any of the uses)	-	-	-	-	-	-	-	-

#### 3.1.2.d. Comparative assessments (Article 23)

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications evaluated	-	-	-	-	-	-	-	-
Number of applications evaluated resulting in a granted authorisation without restrictions	-	-	-	-	-	-	-	-
Number of applications evaluated resulting in restrictions (Article 23(3))	-	-	-	-	-	-	-	-
Number of applications evaluated resulting in restrictions (Article 23(3))	-	-	-	-	-	-	-	-

### 3.2. Other BPR procedures for biocidal products

The BPR contains specific procedures that allow the making available of the market of products without an authorisation. Please indicate the related information in the tables below.

#### 3.2.a. Derogations pursuant to Article 55(1)

	2013	2014	2015	2016	2017	2018	2019	Total number
Number of requests received	-	-	-	-	-	-	-	-
Permits granted	-	-	-	-	-	-	-	-
Permits not granted	-	-	-	-	-	-	-	-

#### 3.2.b. Research and development (Article 56)

	2013	2014	2015	2016	2017	2018	2019	Total number
Number of notifications received	-	-	-	-	-	-	-	-
Number of prohibitions	-	-	-	-	-	-	-	-

### 3.3. Number of biocidal products made available on the Member State market authorised under the transitional measures (Article 89)

Please provide the information available, per main group of product-types, on biocidal products made available on the market authorised under transitional measures

	2013	2014	2015	2016	2017	2018	2018	Total number
Main group 1 Disinfectants (PT1 - PT5)	58	89	69	81	73	94	81	545
Main group 2 Preservatives (PT6 - PT13)	12	14	20	43	46	20	21	176
Main group 3 Pest control (PT14 - PT20)	48	26	35	37	27	47	24	244
Main group 4 Other biocidal products (PT21 - PT22)	3	3	3	8	47	3	3	70

## 4. Information on enforcement activities

### 4.1. BPR enforcement strategy

Has an overall strategy been implemented in the Member State for the enforcement of the BPR?

- Yes  
 No

#### 4.2. Control system in the Member States and results of official controls

Please give a brief overview of the way official controls are carried out in your Member State, with special emphasis on the following processes:

- making available on the market of biocidal products;
- use of biocidal products;
- placing on the market of treated articles

In order to be ensured the adherence to the normatively envisaged requirements in the field of the biocides - Regulation (EU) № 528/2012 of the European parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products and the Protection against harmful impact of the chemical substances and preparations Act (PAHICSPA), in Republic of Bulgaria since 2005 was introduced an authorization regime for release of biocides on the market. According to PAHICSPA the biocides are released on the market and they are used when there is an authorization issued by the minister of health, on a proposal of the Expert committee on biocides, established by order from the minister of health. When the biocides contain an active substance/substances, included in the list of approved active substance for specific product type (art. 9, para 2 of Regulation (EU) № 528/2012) there have to be followed the procedures for authorization according to Regulation (EU) № 528/2012. If the active substance/substances of the biocides is/are an existing substance/substances, included in annex № 2 of Regulation (EC) № 1062/2014 and about it there is no decision of the European commission for non-inclusion for the respective product type and it is still not included in the list of the approved active substances for the respective product type, the minister of health has to issue an authorization for release on the market under national procedure.

The regional health inspections make the following surveillance activities on the market:

- control for existence of issued authorizations for release on the market of biocides under PAHICSPA;
- control on the compliance of the classification, labeling and packaging and the field of use of the biocides released on the market with the issued authorizations, as well as the compliance of the provided information in the Information safety sheet with the conditions of the authorization;
- laboratory analysis of active substances of biocides and composition of biocides for the purposes of correspondence with the issued authorizations;
- directed control of the market based on complaints/signals from natural and legal persons, data about arisen incidents from the use of biocides.

Upon planning of the activities of control in sector „biocides“ is taken into account the risk evaluation for the mass and professional consumers of biocides and results from previous inspections/years as well as new information about the risks resulting of their use.

#### 4.3. Enforcement authorities involved in official controls

Please provide the denomination of the enforcement authorities involved in official controls. If applicable, please also provide the links to the relevant websites

	BPR enforcement authority(ies) involved	Website
Controls on placing and making biocidal products available on the market	The regional health inspections	-
Controls on placing on the market of treated articles	The regional health inspections	-

##### 4.3.1. Complaints

Have there been complaints (information about suspected infringements of the BPR rules) received by enforcement authorities in relation to the implementation of the BPR?

	2013	2014	2015	2016	2017	2018	2019	Total number
Number of complaints	38	43	51	62	67	64	52	377

#### 4.4. Controls addressing different parts of the supply chain

The reporting Member State is requested to provide information on the official controls on the implementation of the BPR that have been performed since the entry into force of the Regulation.

Please provide below the information available on the official controls performed with a focus on the following information, where available: number of controls performed, resources used, outcome of controls (in terms of number and type of non-compliances)

##### 4.4.1. Official controls on compliance with BPR rules for making available on the market of biocidal products

- (Total number of) controls on biocidal products made available on the market / (Number of) illegal products made available and points of non-compliance

If detailed figures are available please provide them in the table below

Controls on biocidal products - Total number of controls per year and non-compliances (NC) identified

	Total 2013	NC 2013	Total 2014	NC 2014	Total 2015	NC 2015	Total 2016	NC 2016	Total 2017	NC 2017	Total 2018	NC 2018	Total 2019	NC 2019
MG 1 Disinfectants	-	-	-	-	-	-	6	-	5	1	10	2	14	2









MG 4 Other biocidal products	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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- Controls on the correct labelling of the treated articles (article 58 of the BPR)

If detailed figures are available please provide them in the table below

Controls on the correct labelling of the treated articles - Total number of controls per year and non-compliances (NC) identified

	Total 2013	NC 2013	Total 2014	NC 2014	Total 2015	NC 2015	Total 2016	NC 2016	Total 2017	NC 2017	Total 2018	NC 2018	Total 2019	NC 2019
MG 1 Disinfectants	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MG 2 Preservatives	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MG 3 Pest control	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MG 4 Other biocidal products	-	-	-	-	-	-	-	-	-	-	-	-	-	-

## 5. Poisoning incidents

### 5.1. Poisonings involving biocidal products, severity of the impact

Please provide below an overview of the information reported since the entry into operation of BPR on poisoning incidents involving biocidal products, indicating the active substances and product-types most frequently involved and those involved in incidents resulting in severe health impairments or death (fatal or near fatal incidents)

If detailed figures are available please provide them in the table below

Number of poisoning incidents related to biocidal products per year by poisoning severity

	2013 Fatal/near fatal	2013 Other	2014 Fatal/near fatal	2014 Other	2015 Fatal/near fatal	2015 Other	2016 Fatal/near fatal	2016 Other	2017 Fatal/near fatal	2017 Other	2018 Fatal/near fatal	2018 Other	2019 Fatal/near fatal	2019 Other
MG 1 Disinfectants	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MG 2 Preservatives	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MG 3 Pest control	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MG 4 Other biocidal products	-	-	-	-	-	-	-	-	-	-	-	-	-	-

## 6. Helpdesk functioning

Please fill in the following table the information regarding the number of enquiries that Helpdesks receive per year.

Note: if your system does not differentiate the queries according to their topic (active substances, biocidal products, treated articles) please indicate the total number of queries per year in the last row.

	2013	2014	2015	2016	2017	2018	2019
Number of enquiries on active substances	-	-	-	-	-	-	-
Number of enquiries on biocidal products	-	-	-	-	-	-	-
Number of enquiries on treated articles	-	-	-	-	-	-	-
Total number of enquiries per year	329	340	380	412	526	635	673

### 6.1. Advice to small and medium-sized enterprises (SMEs)

Following Article 81(2) of the BPR, competent authorities have to provide advice to the applicants and in particular to SMEs.

Does your Member State provide specific advice to SMEs?

- Yes  
 No

Please indicate how the advice is customized for the needs of SMEs and refer to the corresponding links of the relevant websites for information

If necessary, we hold meetings, by phone or by e-mail we give additional guidelines / explanations

## 7. Sustainable use measures

In accordance with Article 18 of the BPR, a Commission Report on the sustainable use of biocidal products was submitted to the European Parliament and the Council in 2016, compiling the information provided by Member States. Please find below some questions that are requested in order to follow-up on this report.

### 7.1. Availability of Best Practices Documents in the Member States

Are Best Practices Documents used or developed for reducing the use of biocidal products to a minimum or for using biocides with less impact on human health and the environment?

- Yes  
 No

### 7.2. Availability of certifications or training schemes for professional users

Are certification procedures or training schemes in place (organised by e.g. eCAs, public authorities, sector organisations) for professional users of biocidal products?

- Yes  
 No  
 Not anymore

### 7.3. Information to the public

Have measures been taken to provide the public with appropriate information about benefits and risks associated with biocidal products and ways of minimising their use? (Article 17(5) of the BPR)

- Yes  
 No

Please specify which kind of information is available in your Member State (e.g. information campaigns, regulatory measures) and include the corresponding links of the relevant websites with information.

	Type of measure	Year	Details
1	The information is provided through the website of the Ministry of Health		<a href="http://www.mh.government.bg/bg/">http //www.mh.government.bg/bg/</a>
2			
3			
4			

### 7.4. Measures to address the risk related to the use of biocidal products

Have measures been taken to address the risks related to the use of biocidal products in specific areas such as schools, workplaces, kindergartens or public spaces?

- Yes  
 No

Please specify which kind of information is available in your Member State (e.g. information campaigns, regulatory measures) and refer to the corresponding links of the relevant websites with information.

	Type of measure	Year	Area covered	Details
1	Selection of biocides in schools, workplaces, kindergartens is supported by occupational health services			
2				
3				
4				

## 8. Nanomaterials

Please provide information regarding the use of nanomaterials in biocidal products (Articles 19 and 69 of the BPR), per main group of product-types

### MG 1 Disinfectants

	Product name	Nanomaterial	Brief explanations	Safety measures (Yes/No)	Year
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-

### MG 2 Preservatives

	Product name	Nanomaterial	Brief explanations	Safety measures (Yes/No)	Year
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1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-

**MG 3 Pest control**

	Product name	Nanomaterial	Brief explanations	Safety measures (Yes/No)	Year
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-

**MG 4 Other biocidal products**

	Product name	Nanomaterial	Brief explanations	Safety measures (Yes/No)	Year
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-

**9. Any other comment**

**Contact**

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