

# 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)
	PTCA-DGS		

### 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.

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#### 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	PTCA-DGAV-PT8 PTCA-DGAV-Vet PTCA-DGS	<a href="http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307">http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307</a> <a href="https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAABABLszU0AwArk10aBAAAA%3d%3d#saude-de-a-a-z/biocidas">https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAABABLszU0AwArk10aBAAAA%3d%3d#saude-de-a-a-z/biocidas</a>

Advice to applicants/helpdesks on biocidal products	PTCA-DGAV-PT8 PTCA-DGAV-Vet PTCA-DGS	<a href="http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307">http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307</a> <a href="https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas">https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas</a>
Advice to applicants/helpdesks on treated articles	PTCA-DGAV-PT8 PTCA-DGAV-Vet PTCA-DGS	<a href="http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307">http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307</a> <a href="https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas">https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas</a>
Assessment of active substances	PTCA-DGAV-PT8 PTCA-DGAV-Vet PTCA-DGS	<a href="http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307">http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307</a> <a href="https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas">https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas</a>
Assessment and authorisation of biocidal products	PTCA-DGAV-PT8 PTCA-DGAV-Vet PTCA-DGS	<a href="http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307">http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&amp;cboui=17307</a> <a href="https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas">https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas</a>
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)		

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

	Authority/organisation involved	Website
Poison centre	CIAV - Centro de Informação Antivenenos	<a href="https://www.inem.pt/category/servicos/centro-de-informacao-antivenenos/">https://www.inem.pt/category/servicos/centro-de-informacao-antivenenos/</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.

<http://srvbamid.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=17307&cboui=17307>  
<https://www.dgs.pt/saude-a-a-z.aspx?https://www.dgs.pt/saude-a-a-z.aspx?v=%3d%3dBAAAAB%2bLCAAAAAAABABLszU0AwArk10aBAAAAA%3d%3d#saude-de-a-a-z/biocidas> - 2.1. Período transitório  
Manual de procedimentos internos de avaliação de produtos biocidas (TP8)

### 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

Under revision

#### 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	
Evaluation of an active substance for Annex I inclusion	
Authorisation of a biocidal product (BP)	
Authorisation of a BP family	
Mutual recognition of an authorisation of a BP	
Mutual recognition of an authorisation of a BP family	
Union authorisation of a BP	







MG 3 Pest control															
MG 4 Other biocidal products															

- **Controls on the classification, packaging and labelling of biocidal products** (article 69 of the BPR, and Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP))

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

Controls on classification, packaging and labelling of 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														
MG 2 Preservatives														
MG 3 Pest control														
MG 4 Other biocidal products														

- **Controls on safety data sheets** (article 70 of the BPR, and article 31 of Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH))

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

Controls on safety data sheets - 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														

- **Controls on advertisement of biocidal products** (article 72 of the BPR and CLP)

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

Controls on advertisement of 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														
MG 2 Preservatives														
MG 3 Pest control														
MG 4 Other biocidal products														

- **Controls on the inclusion of active substance suppliers in the official list** (article 95(2) of the BPR)

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

Controls on the inclusion of active substance suppliers in the Article 95 list - 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														

4.4.2. Official controls on biocidal products made available on the market during the transitional period

- **Controls to ensure that the biocidal products on the market contain active substances included in the review programme** (Article 89(2) of the BPR)

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

Controls to ensure that the biocidal products on the market contain active substances included in the review programme - 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														

- **Controls on the inclusion of active substances suppliers in the official list** (article 95(2) of the BPR)

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

Controls on the inclusion of active substance suppliers in the Article 95 list - 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														

- **Controls on compliance of the biocidal products made available on the market with national legislation** (where relevant)

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

Controls on compliance of the biocidal products made available with national legislation - 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														

#### 4.4.3. Official controls on manufacturers

- **Controls regarding the availability of the appropriate documentation in relation to the manufacturing process**, as indicated in article 65 (2) of the BPR

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

Controls regarding the availability of the appropriate documentation related to the manufacturing process - 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														

#### 4.4.4. Official controls on end-users and residues

- **Controls regarding the use of the biocidal products according to the terms and conditions of the authorisation**, as stipulated in article 17(5) of the BPR

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

Controls regarding the use of the biocidal products according to the terms and conditions of the authorisation - 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														

- Controls on residue levels of active substances in food and feed (PT3, 4, 5, 18, 19 and 21)

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

Controls on residue levels of active substances in food and feed - 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
PT 3														
PT 4														
PT 18														
PT 19														
PT 21														

#### 4.4.5. Official controls on treated articles

- Controls concerning the active substance(s) present in the treated articles (articles 58(2) and 94 of the BPR)

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

Controls concerning the active substance(s) present in 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														

- 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)

There is no separate information in biocidal products (active substances or product types) Some information, in general, on rodenticides (anticoagulants), insecticides, piretrines, pesticides or domestic and industrial uses

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							

### 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

Emails, presencial meetings, internet sites

## 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

Please specify which kind of documentation is available in your Member State

	Type of document	Name of document	Product-type(s) covered	Year of document
1	Legislation	Despacho n.º 9022/2017	All	2017
2	Standard	NP EN 16636	All	2015
3				

**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

Please specify which kind of biocidal products or applications are covered by those schemes and include the corresponding links of the relevant websites with information

	Biocidal products or applications covered	Name of the certification or training scheme	Year
1	In progress		
2			
3			

**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

**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			Schools	
2			Workplaces	
3			Kindergartens	
4			Public spaces	

**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
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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