

# 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)
[REDACTED]	HELLENIC REPUBLIC MINISTRY OF RURAL DEVELOPMENT AND FOOD DIRECTORATE OF PLANT PRODUCE PROTECTION DEPARTMENT OF BIOCIDES	[REDACTED]	[REDACTED]

### 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.

Three (3)

#### 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	1. Ministry of Rural Development and Food, Department of Biocides 2. Benaki Phytopathological Institute	1) <a href="http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoproostasiamenu/bioktona">http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoproostasiamenu/bioktona</a> 2) <a href="http://www.bpi.gr">www.bpi.gr</a>

Advice to applicants/helpdesks on biocidal products	1. Ministry of Rural Development and Food, Department of Biocides 2. Benaki Phytopathological Institute	1) <a href="http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona">http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona</a>
Advice to applicants/helpdesks on treated articles	1. Ministry of Rural Development and Food, Department of Biocides 2. Benaki Phytopathological Institute	1) <a href="http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona">http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona</a>
Assessment of active substances	Benaki Phytopathological Institute	1) <a href="http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona">http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona</a>
Assessment and authorisation of biocidal products	1. Ministry of Rural Development and Food, Department of Biocides 2. Benaki Phytopathological Institute	1) <a href="http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona">http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona</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	Ministry of Health Children's Hospital "P&A Kyriakou" Athens 11527 Greece	<a href="http://0317.syzefxis.gov.gr/?page_id=75">http://0317.syzefxis.gov.gr/?page_id=75</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.

- Law 721 /1977 ( OJ A' 298) with the amendments
- Joint Ministerial Decision 4829/52048/ 2012 (OJ B'1471) for product types 14 and 18
- Joint Ministerial Decision 132428/2009 (OJ B' 2110) for product types 8,9,10,12,13,15,16,17,19,20,21  
<http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona/5925-nomothesia-bioktona>

### 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

- Joint Ministerial Decision 4616/52519/ 2016 (OJ B' 1367) (for EU Procedures)
- Joint Ministerial Decision 4829/52048/ 2012 (OJ B'1471) for product types 14 and 18 (under transitional period)
- Joint Ministerial Decision 132428/ 2009 (OJ B' 2110) for product types 8,9,10,12,13,15,16,17,19,20,21 (under transitional period)  
<http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona/5925-nomothesia-bioktona>

#### 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	100000 €+50000€/per PT (for chemicals) 50000 €+25000€/PT for additional PTs ( for microorganisms)
Evaluation of an active substance for Annex I inclusion	10000 €
Authorisation of a biocidal product (BP)	20000 €
Authorisation of a BP family	40000€
Mutual recognition of an authorisation of a BP	2500€
Mutual recognition of an authorisation of a BP family	5000€
Union authorisation of a BP	20000€
Union authorisation of a BP family	40000€

Annual fee	0€
Other (please specify)	art.89( 200-3200€)

### 2.3. Measures in favour of small and medium enterprises (SMEs)

Do you have specific national measures or legislation favouring SMEs?

- Yes  
 No

### 2.4. Non-compliance and penalties

Do you have specific national measures or legislation concerning non-compliance and penalties applicable for infringements on the implementation of the BPR?

- Yes  
 No

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

1. Law 721 /1977 ( OJ A' 298) with the amendments  
2. Joint Ministerial Decision 4616/52519/ 2016 (OJ B' 1367)  
<http://www.minagric.gr/index.php/en/farmer-menu-2/plantprotection-menu/plantprotproducts-menu/1409-legplantprod-art>

### 2.5. Imported treated articles

Do you have specific national measures or legislation that regulates whether imported treated articles contain only approved active substances?

- Yes  
 No

Please specify below the national regulation(s) and 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

Joint Ministerial Decision 4616/52519/ 2016 (OJ B' 1367),  
<http://www.minagric.gr/index.php/en/farmer-menu-2/plantprotection-menu/plantprotproducts-menu/1409-legplantprod-art>

## 3. Placing and making available on the market of biocidal products

### 3.1. Authorisation procedures

#### 3.1.1. Authorisations

Please indicate in the tables below the figures related to the various procedures since the entry into application of the BPR (1st September 2013)

##### 3.1.1.a. National authorisations

	2013	2014	2015	2016	2017	2018	2019	Total number
Authorisations granted on the basis of Article 19(5)	0	0	0	5	13	0	7	25
Provisional authorisations granted for products containing new active substances (Article 55(2))	0	0	0	0	0	0	0	0

##### 3.1.1.b. Mutual recognitions - concerned Member State

	2013	2014	2015	2016	2017	2018	2019	Total number
Derogations (Article 37)	0	0	0	5	6	0	0	11

##### 3.1.1.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	7	19	10	12	14	12	34	108
Number of products authorised (conditions met for all or some of the uses)	7	19	10	12	14	12	34	108
Number of products not authorised (conditions not met for any of the uses)	0	0	0	0	0	0	0	0

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

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications evaluated	7	19	10	7	8	12	35	98

Number of applications evaluated resulting in a granted authorisation without restrictions	7	19	10	7	8	12	35	98
Number of applications evaluated resulting in restrictions (Article 23(3))	0	0	0	0	0	0	35	0
Number of applications evaluated resulting in restrictions (Article 23(3))								

### 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)	0	0	0	0	0	95	11	106
Provisional authorisations granted for products containing new active substances (Article 55(2))	0	0	0	0	0	0	0	0

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

	2013	2014	2015	2016	2017	2018	2019	Total number
Derogations (Article 37)	0	0	0	0	0	0	0	0

#### 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	0	0	0	0	0	95	11	106
Number of products authorised (conditions met for all or some of the uses)	0	0	0	0	0	95	11	106
Number of products not authorised (conditions not met for any of the uses)	0	0	0	0	0	0	0	0

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

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications evaluated	0	0	0	0	0	0	0	0
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	0	0	0	0	1	3	3	7
Permits granted	0	0	0	0	0	3	3	7
Permits not granted	0	0	0	0	0	0	0	0

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

	2013	2014	2015	2016	2017	2018	2019	Total number
Number of notifications received	0	0	0	0	0	0	0	0
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)								
Main group 2 Preservatives (PT6 - PT13)	1	1	1	24	2	7	7	43
Main group 3 Pest control (PT14 - PT20)	27	60	45	58	79	48	65	382
Main group 4 Other biocidal products (PT21 - PT22)	5	4	13	24	109	44	1	200

## 4. Information on enforcement activities





- **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
<b>MG 1 Disinfectants</b>														
<b>MG 2 Preservatives</b>														
<b>MG 3 Pest control</b>														
<b>MG 4 Other biocidal products</b>														

#### 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
<b>MG 1 Disinfectants</b>														
<b>MG 2 Preservatives</b>														
<b>MG 3 Pest control</b>														
<b>MG 4 Other biocidal products</b>														

- **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
<b>MG 1 Disinfectants</b>														
<b>MG 2 Preservatives</b>														
<b>MG 3 Pest control</b>														
<b>MG 4 Other biocidal products</b>														

- **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
<b>MG 1 Disinfectants</b>														
<b>MG 2 Preservatives</b>														
<b>MG 3 Pest control</b>														
<b>MG 4 Other biocidal products</b>														

#### 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





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

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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)

The data available does not differentiate between biocides and plant protection products
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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					aprox 100	aprox 100	aprox.100

### 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

## 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

**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

**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

This report is for the product types PT8-10, PT12-21.

The competence for the market control of Biocides ( PT 8,9, 10, 12-21) and treated articles was under the Department of Plant Protection Products and Biocides up to the end of 2017.

In the end of 2017 a new Biocides Department was created which took over the competence of the implementation of Regulation 528/2012

The official controls up to 2020 were carried in ad hoc way and in conjunction with plant protection products market control or when a complain initiate an investigation.

In 2020 the first program dedicated for the market control of biocides (making available on the market) was drafted.(see relevant link)

<http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/bioktona/9991-etisio-progr-elegxon-vioktonon>.

For the use of biocidal products there is annual documentation check regarding the licenced users (pest controllers).

The controls are carried out by the Regional authorities as described below in point 4.3

There are 220 inspectors assigned in Regional level however the control of biocidal products is part of their job.

The overall complexity of the control of biocidal products in our view requires more resources and more training.

## Contact

SANTE-BIOCIDES@ec.europa.eu

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