

# 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]	The Environment Agency of Iceland	[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.

1

#### 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	The Environment Agency of Iceland	ust is
Advice to applicants/helpdesks on biocidal products	The Environment Agency of Iceland	ust is
Advice to applicants/helpdesks on treated articles	The Environment Agency of Iceland	ust is

Assessment of active substances	The Environment Agency of Iceland	ust.is
Assessment and authorisation of biocidal products	The Environment Agency of Iceland	ust.is
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)	The Environment Agency of Iceland	ust.is

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

	Authority/organisation involved	Website
Poison centre	Poison Information Centre - Icelandic University Hospital	landspitali.is/Eitrunarmidstod
Animal poison centre	N/A	N/A
Other	Administration of Occupational Safety and Health	vinnueftirlit.is

## 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

### 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

The Environment Agency's list of administrative fees No 535/2015. <https://ust.is/library/Skrar/Umhverfisstofnun/Gjaldskrar/Uppf3%a6r%3%b0%20gjaldskr%3%a1%20Umhverfisstofnunar%2021.12.2018.pdf>  
English translation of the part regarding biocides is available:  
<https://ust.is/english/chemicals/fees/>

#### 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	N/A
Evaluation of an active substance for Annex I inclusion	N/A
Authorisation of a biocidal product (BP)	ISK 2.550 000
Authorisation of a BP family	ISK 4.100 000
Mutual recognition of an authorisation of a BP	ISK 330.000
Mutual recognition of an authorisation of a BP family	ISK 475.200
Union authorisation of a BP	N/A
Union authorisation of a BP family	N/A
Annual fee	N/A
Other (please specify)	Simplified authorisation procedure for a biocidal product: ISK 290.400 Simplified authorisation procedure for a biocidal product family: ISK 475.200 Parallel trade permit for a biocidal product: ISK 79.200 Authorisation for a same biocidal product: ISK 79.200 Article 55 derogation: ISK 79.200 Derogation for the purposes of research and development: ISK 79.200 Administrative change: ISK 39 600 Minor change on request: 39.600 Major change on request: ISK 52.800 Fee for renewal of national authorisation and national authorisation subject to mutual recognition is 90% of the original fee.

### 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

The Chemical Act No 61/2013:  
<https://www.althingi.is/lagas/nuna/2013061.html>

Reglugerð um stjórnvaldssektir fyrir brot á efnalögum (Regulation on non-criminal fines for infringements of the Chemical Act No 61/2013):  
<https://www.reglugerd.is/reglugerdir/eftir-raduneytum/umhverfis--og-audlindaraduneyti/nr/21131>

#### 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

### 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	0	0	0	0	0
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	0	0	0	0	0

##### 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	0	0	0	0	0	0	0	0
Number of products authorised (conditions met for all or some of the uses)	0	0	0	0	0	0	0	0
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	0	0	0	0	0	0	0	0
Number of applications evaluated resulting in a granted authorisation without restrictions	0	0	0	0	0	0	0	0
Number of applications evaluated resulting in restrictions (Article 23(3))	0	0	0	0	0	0	0	0
Number of applications evaluated resulting in restrictions (Article 23(3))	0	0	0	0	0	0	0	0

#### 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	0	0	0
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	0	0	0
Number of products authorised (conditions met for all or some of the uses)	0	0	0	0	0	0	0	0
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	0	0	0	0	0	0	0	0
Number of applications evaluated resulting in restrictions (Article 23(3))	0	0	0	0	0	0	0	0
Number of applications evaluated resulting in restrictions (Article 23(3))	0	0	0	0	0	0	0	0

## 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	0	0	0	0
Permits granted	0	0	0	0	0	0	0	0
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	0	0	0	0	0	0	0	0

## 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)	0	0	0	0	0	0	0	0
Main group 2 Preservatives (PT6 - PT13)	0	0	0	0	0	0	0	0
Main group 3 Pest control (PT14 - PT20)	0	0	0	0	0	0	0	0
Main group 4 Other biocidal products (PT21 - PT22)	0	0	0	0	0	0	0	0

## 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

Please describe it and, if it is publicly available, provide the corresponding link. If available in English please include the link to the English version

Every three years the Environment Agency of Iceland publishes a surveillance programme for the upcoming 3 years. BPR enforcement projects are included in this programme.  
<https://ust.is/atvinnulif/efni/efnaeftirlit/eftirlitsaaetlun/>  
 An English version of the surveillance programme is not available.

#### 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

The Environment Agency of Iceland carries out market surveillance. The focus in recent years has been on the making available on the market of biocidal products with a special emphasis on certain product types or active substances.

#### 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 Environment Agency of Iceland	ust.is
Controls on placing on the market of treated articles	The Environment Agency of Iceland	ust.is

##### 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	0	0	2	1	3	1	7	13

#### 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	N/A	N/A	0	0	1	1	0	0	2	2	0	0	1	1
MG 2 Preservatives	N/A	N/A	N/A	12	0	0	0	0	0	0	43	32	0	0
MG 3 Pest control	N/A	N/A	N/A	7	90	58	0	0	1	1	24	14	1	1
MG 4 Other biocidal products	N/A	N/A	0	0	0	0	0	0	0	0	0	0	0	0

- Controls on records kept by authorisation holders, in accordance with article 68 of the BPR

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

Controls on records kept by authorisation holders - Total number of controls per year and non-compliances (NC) identified





MG 4 Other biocidal products															
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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)

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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	23
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	4
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0

## 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	N/A	N/A	36	54	56	47	41

### 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

Because the market is small and companies seeking advice are, as a rule, SMEs, all advice provided can be considered SME specific.

## 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

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	PT 14 products, PT 16 products, PT 18 products	Training scheme for pest control operators	
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

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	Information for consumers on treated articles and active substances.		<a href="https://www.ust.is/graent-samfelag/graenn-lifstill/medhondladar-vorur/">https://www.ust.is/graent-samfelag/graenn-lifstill/medhondladar-vorur/</a> <a href="https://ust.is/graent-samfelag/efnamal/varasom-efni/">https://ust.is/graent-samfelag/efnamal/varasom-efni/</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

## 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					
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**MG 4 Other biocidal products**

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

**9. Any other comment**

This is the first BPR Article 65(3) reporting and it has been quite the challenge to find information from the past 7 years and often the information is not available. The Environment Agency has made changes to improve the filing of information in accordance with this report to be able to deliver a more detailed report for the next 5 years.

**Contact**

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