

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)
	National Public Health Center		

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	National Public Health Center	http //www.antsz hu/
Advice to applicants/helpdesks on biocidal products	National Public Health Center	http //www.antsz hu/
Advice to applicants/helpdesks on treated articles	National Public Health Center	http //www.antsz hu/

Assessment of active substances	National Public Health Center	http://www.antsz.hu/
Assessment and authorisation of biocidal products	National Public Health Center	http://www.antsz.hu/
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)	National Public Health Center	http://www.antsz.hu/

1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	National Public Health Center	http://www.nnk.gov.hu/
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.

Governmental Decree 316/2013. (VIII. 28.) on the specific rules of authorisation and placing on the market of biocidal products / changed during reporting period;/ Joint Decree No. 38/2003 (VII.7) concerning the conditions of manufacture and placing on the market of biocidal products /changed during reporting period/

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

Ministerial Decree No 1/2009 (I. 30.) concerning the administrative procedural and service fees of the National Public Health and Medical Officer Service
http://njt.hu/cgi_bin/njt_doc.cgi?docid=123175.360039

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	45000000 HUF
Evaluation of an active substance for Annex I inclusion	45000000 HUF
Authorisation of a biocidal product (BP)	2500000 HUF
Authorisation of a BP family	5000000 HUF
Mutual recognition of an authorisation of a BP	500000 HUF
Mutual recognition of an authorisation of a BP family	1000000 HUF
Union authorisation of a BP	fee under development
Union authorisation of a BP family	fee under development
Annual fee	not applicable
Other (please specify)	

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?

Derogations (Article 37)	0	0	0	0	0	0	0	0
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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	7	6	13
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	7	6	13
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	1	0	0	0	0	0	1
Number of prohibitions	0	1	0	0	0	0	0	1

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)	165	115	130	131	188	114	126	969
Main group 2 Preservatives (PT6 - PT13)	0	0	0	0	0	0	0	0
Main group 3 Pest control (PT14 - PT20)	69	25	50	27	19	51	35	276
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

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

Official controls are carried out by the chemical safety inspectors of the local Governmental Office. Inspectors are entitled to check and enforce the compliance of biocidal products and treated articles as well. Controls can be triggered by random checks, complaints and annual goals specified by the competent authority for biocides.

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	Government Offices	http://www.kormanyhivatal.hu/hu
Controls on placing on the market of treated articles	Government Offices	http://www.kormanyhivatal.hu/hu

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	no data	no data	no data	no data	no data	10	29	39

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

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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	6471				4416		3793		3290		2024	126	2799	162
MG 2 Preservatives														
MG 3 Pest control														
MG 4 Other biocidal products														

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

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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

	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											913	51	1095	66
MG 2 Preservatives														
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))

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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											1877	119	2296	148
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))

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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											1801	155	2168	110
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)

no relevant data

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)

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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											1272	51	1400	39
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)

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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											1447	14	1647	11
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)**

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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											857	37	947	18
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)**

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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											1143	48	1227	62
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**

No data is available on the PT of the biocidal products thus all controls were provided in the first row of the table (MG 1). If no data is available regarding a certain year then no data is provided in the table.

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											25	1	17	2
MG 2 Preservatives														
MG 3 Pest control														
MG 4 Other biocidal products														

4.4.4. Official controls on end-users and residues

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	2	288	1	313	0	250	0	364	0	442	1	274	1	285
MG 2 Preservatives	0	2	0	0	0	1	0	4	0	0	0	0	0	1
MG 3 Pest control	0	103	0	138	0	103	0	100	0	106	0	80	0	81
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	0	0	0	0	0	0

6. Helpdesk functioning

Please fill in 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			400	100			
Number of enquiries on biocidal products							
Number of enquiries on treated articles							
Total number of enquiries per year	200	350	600	300	300	423	233

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

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	General information on biocides (e.g. risk of household chemicals, list of authorised products, BPR and transitional regulatory background, use of repellents, references to ECHA page etc.) and contact points.	2013 (moved to new homepage in 2019)	https://www.nnk.gov.hu/index.php/kemiai-biztonsagi-es-kompetens-hatosagi-fo/lakossagi-tajekoztatas/mergezesek-megelozese https://www.antsz.hu/biocid/eu_engedelyezes www.oek.hu www.oek.hu/ika
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					

MG 4 Other biocidal products

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

9. Any other comment

Contact

SANTE-BIOCIDES@ec.europa.eu
