

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)
	Health Board		

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.

Health Board - Receiving authority, receive applications for authorisations of all biocidal products, registrations, co-ordination of the evaluation process, contact point to Commission, applicants and Competent Authorities of other Member States.

Ministry of Social Affairs - Legal and political issues in relation to Regulation 528/2012.

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	Health Board	www.terviseamet.ee/en
Advice to applicants/helpdesks on biocidal products	Health Board	www.terviseamet.ee/en
Advice to applicants/helpdesks on treated articles	Health Board	www.terviseamet.ee/en
Assessment of active substances	Health Board	www.terviseamet.ee/en
Assessment and authorisation of biocidal products	Health Board	www.terviseamet.ee/en

Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)

Ministry of Social Affairs

www.sm.ee/en

1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	Health Board	www.16662.ee
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.

A biocidal product is permitted to be made available and used in Estonia if it has obtained the relevant authorisation or registration certificate in accordance with Biocidal Products Act (<https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/521012019017/consolid>) or the Biocidal Products Regulation (BPR).

All information for the biocide registration on transitional period is available on Health Board webpage (<https://www.terviseamet.ee/en/chemical-and-product-safety/placing-biocidal-products-on-market>)

A biocidal product is permitted to be made available and used in Estonia if it has obtained the relevant authorisation or registration certificate in accordance with Biocidal Products Act (<https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/521012019017/consolid>) or the Biocidal Products Regulation (BPR).

All information for the biocide registration on transitional period is available on Health Board webpage (<https://www.terviseamet.ee/en/chemical-and-product-safety/placing-biocidal-products-on-market>)

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

All evaluation fees available Biocidal Products Act (Chapter 6): <https://www.riigiteataja.ee/en/eli/ee/525032015014/consolide/current>

All state fees available State Fees Act (Chapter 12; Division 3; Subdivision 5): <https://www.riigiteataja.ee/en/eli/ee/502042015007/consolide/current>

Please note that for some procedures the amount of fee consists of 2 parts: state fee (non refundable) + evaluation fee (refundable, as based on actual expenses).

All evaluation fees available Biocidal Products Act (Chapter 6): <https://www.riigiteataja.ee/en/eli/ee/525032015014/consolide/current>

All state fees available State Fees Act (Chapter 12; Division 3; Subdivision 5): <https://www.riigiteataja.ee/en/eli/ee/502042015007/consolide/current>

Please note that for some procedures the amount of fee consists of 2 parts: state fee (non refundable) + evaluation fee (refundable, as based on actual expenses).

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	1720 € (State Fee) + the initial evaluating charge 133 865 € and the maximum charge 387 945 €
Evaluation of an active substance for Annex I inclusion	1720 € (State Fee) + the initial evaluating charge 133 865 € and the maximum charge 387 945 €
Authorisation of a biocidal product (BP)	1635 € (State Fee) + the initial evaluating charge 28 865 € and the maximum charge 158 170 €
Authorisation of a BP family	1635 € (State Fee) + the initial evaluating charge 55 145 € and the maximum charge 302 190 €
Mutual recognition of an authorisation of a BP	1375 € (State Fee)
Mutual recognition of an authorisation of a BP family	1375 € (State Fee)
Union authorisation of a BP	1635 € (State Fee) + the initial evaluating charge 28 865 € and the maximum charge 158 170 €
Union authorisation of a BP family	1635 € (State Fee) + the initial evaluating charge 55 145 € and the maximum charge 302 190 €

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)	-	-	-	-	-	-	-	Authorisations cannot be sorted by Article 19(5), therefore no information is available
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	12	11	23
Number of products authorised (conditions met for all or some of the uses)	0	0	0	0	0	12	11	23
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)	40	31	52	65	62	61	66	377
Main group 2 Preservatives (PT6 - PT13)	13	3	10	18	15	5	19	83
Main group 3 Pest control (PT14 - PT20)	4	19	23	11	29	9	14	109
Main group 4 Other biocidal products (PT21 - PT22)	7	5	6	13	26	4	0	61

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

There is no common strategy, because controls in different authorities have carried out differently (for example 2 authorities are checking on the basis of complaints (reactional controls), 2 authorities do reactional and scheduled controls.

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

For making available there is needed registration in Estonia (for the biocides containing active substance in the review list). So during the control we check does biocide have registration or authorization. If not, it cannot be on the market and we remove it. For use we check does the used biocide have authorization or registration. The next step is to control, is it used according to the instructions and safety datasheet. If not, we take corrective measures.
For treated articles we check is used biocide allowed to use on this purpose and if yes then we check is everything OK with package and labelling.

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	1) Health Board – over compliance by the manufacturer and importer of biocidal products with the requirements established to making biocidal products and treated articles available and upon wholesale of products, over compliance with the requirements established to biocidal products and the use thereof by professional providers of the pest control service, and in fields regulated by the Public Health Act and the Health Services Organisation Act; 2) Consumer Protection and Technical Regulatory Authority – over adherence to the requirements established to making biocidal products and treated articles available on the retail market; 3) Labour Inspectorate – over adherence to the requirements established to the use of biocidal products in the field regulated by the Occupational Health and Safety Act; 4) Environmental Inspectorate – over adherence to the requirements established to the use of biocidal products from the point of view of environmental hazardousness at the objects of supervision of the field; 5) Veterinary and Food Board – over adherence to the requirements established to the use of biocidal products from the point of view of animal health and the feed and food safety at the objects of supervision of the field; 6) Tax and Customs Board – over the adherence to the requirements established to making biocidal products available upon entering the Community market in accordance with Articles 27–29 of Regulation (EC) No. 765/2008 of the European Parliament and of the Council.	1) www.terviseamet.ee/et 2) www.ttja.ee/en 3) www.ti.ee/est/avaleht 4) www.kki.ee/et 5) www.vet.agri.ee 6) www.emta.ee/et
Controls on placing on the market of treated articles	1) the Health Board – over compliance by the manufacturer and importer of biocidal products with the requirements established to making biocidal products and treated articles available and upon wholesale of products, over compliance with the requirements established to biocidal products and the use thereof by professional providers of the pest control service, and in fields regulated by the Public Health Act and the Health Services Organisation Act; 2) the Consumer Protection and Technical Regulatory Authority – over adherence to the requirements established to making biocidal products and treated articles available on the retail market.	1) www.terviseamet.ee/et 2) www.ttja.ee/en

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	3	20	12	7	12	11	5	70

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

- **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			26	1	9	0	25	12	43	21	50	34	15	4
MG 2 Preservatives			5	0	4	0	9	5	27	8	33	22	5	1
MG 3 Pest control			4	2	18	0	49	4	-	-	9	9	5	2
MG 4 Other biocidal products			2	0	0	0	1	0	-	-	-	-	-	-

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	-	-	7	0	5	0	11	11	14	11	9	9	0	0
MG 2 Preservatives	-	-	5	0	4	0	-	-	-	-	1	1	2	2
MG 3 Pest control	-	-	8	0	-	-	1	1	-	-	-	-	-	-
MG 4 Other biocidal products	-	-	0	0	-	-	-	-	-	-	-	-	-	-

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	15173	1113	14592	996	19685	986	15666	881	13403	873	13169	483	11452	355
MG 2 Preservatives	-	-	-	-	-	-	12	8	-	-	-	-	-	-
MG 3 Pest control	-	-	-	-	22	0	49	0	10	4	5	2	3	0
MG 4 Other biocidal products	15	1	12	0	13	0	17	3	33	3	27	3	26	0

- 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	270	2	279	0	218	0	240	0	222	0	289	2	317	2
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		13		7		10		3		10		7		16
MG 2 Preservatives		-		-		-		-		-		-		-
MG 3 Pest control		32		29		30		18		33		39		40
MG 4 Other biocidal products		-		-		-		-		-		-		-

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							
Number of enquiries on biocidal products							
Number of enquiries on treated articles							
Total number of enquiries per year	-	-	137	116	177	191	283

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

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 8, 10 PT 14-20	professional qualifications of a pest control operator (specialisations Control of domestic pests, Conservation of buildings, fumigation) within the meaning of the Professions Act https://www.kutseregister.ee/kutsed/avalik_kutsetunnistused/	since 2004
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	Notification on the Health Board webpage and in the media	2018	Due to the new classifications of the anticoagulants, the new label elements of the anticoagulants
2	Notification on the Health Board webpage and in the media	2019	Safe use of the mosquito and tick repellents.
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
