

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)
	Ministry of Health		

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 CA - Ministry of Health

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	Ministry of Health	https://zdravlje.gov.hr/o-ministarstvu/djelokrug-1297/sanitarna-inspekcija/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/1786
Advice to applicants/helpdesks on biocidal products	Ministry of Health	https://zdravlje.gov.hr/o-ministarstvu/djelokrug-1297/sanitarna-inspekcija/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/1786
Advice to applicants/helpdesks on treated articles	Ministry of Health	https://zdravlje.gov.hr/o-ministarstvu/djelokrug-1297/sanitarna-inspekcija/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/1786

Assessment of active substances	Ministry of Health - coordinates expert institutions involved in the assessment - Institute for Medical Research and Occupational Health, Croatian Institute of Public Health, Croatian Agency for Agriculture and Food, Veterinary Faculty, Faculty of Science	https://zdravlje.gov.hr/ominstarstvu/djelokrug-1297/sanitarna-inspekcija/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/1786
Assessment and authorisation of biocidal products	Ministry of Health	https://zdravlje.gov.hr/ominstarstvu/djelokrug-1297/sanitarna-inspekcija/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/1786
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)	Ministry of Health	https://zdravlje.gov.hr/ominstarstvu/djelokrug-1297/sanitarna-inspekcija/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/1786

1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	Institute for Medical Research and Occupational Health	https://www.imi.hr/hr/jedinica/centar-za-kontrolu-otrovanja/
Animal poison centre	-	-
Other	Croatian Institute of Public Health, Croatian Agency for Agriculture and Food, Veterinary Faculty, Faculty of Science	https://www.hzjz.hr https://www.hapih.hr https://www.vef.unizg.hr https://www.pmf.unizg.hr

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.

The list of applicable national legislative acts with links is available at <https://zdravlje.gov.hr/javnozdravstvena-zastita/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/propisi-2536/hrvatski-propisi-2537/2537>
Information about application submission procedure is available at <https://zdravlje.gov.hr/djelokrug-1297/javnozdravstvena-zastita/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/umis-biocidnih-pripravaka-u-registar-1862/1862>

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

Ordinance on fees related to the making available biocidal product on the market - available at https://narodne-novine.nn.hr/clanci/sluzbeni/2014_05_55_1045.html

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	840 000,00 HRK
Evaluation of an active substance for Annex I inclusion	No specific fee
Authorisation of a biocidal product (BP)	75 000,00 HRK
Authorisation of a BP family	150 000,00 HRK
Mutual recognition of an authorisation of a BP	13 000,00 HRK
Mutual recognition of an authorisation of a BP family	23 000,00HRK
Union authorisation of a BP	75 000,00 HRK
Union authorisation of a BP family	150 000,00 HRK
Annual fee	-
Other (please specify)	There are top-up fees for each additional active substance, product type or user category

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

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	70 rodenticides
Number of products authorised (conditions met for all or some of the uses)	0	0	0	0	0	0	0	70 rodenticides
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								
Permits not granted								

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	1	2	0	3
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)	165	135	165	148	157	143	151	1064
Main group 2 Preservatives (PT6 - PT13)	25	14	30	15	51	21	39	195
Main group 3 Pest control (PT14 - PT20)	56	66	71	13	63	37	54	360
Main group 4 Other biocidal products (PT21 - PT22)	40	21	17	36	120	55	19	308

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

The Act on the implementation of the Biocidal Products Regulation - https://narodne-novine.nn.hr/clanci/sluzbeni/2013_04_39_726.html; https://narodne-novine.nn.hr/clanci/sluzbeni/2020_05_62_1235.html

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 according to the annual plan of official controls. Sanitary inspectors perform checks for all PTs. Usually annual plan is created for specific PT (if active substances for specific PT are already evaluated and approved), to check if active substance stated in non-approval decisions are still on the market. The BPRS Forum projects are also taken into account when annual plans are developed.

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	State Inspectorate	https://dirh.gov.hr/o-drzavnom-inspektoratu-9/ustrojstvo-77/8-sektor-za-sanitarni-nadzor-zdravstvene-ekologije/3-proizvodnja-stavljanje-na-trziste-i-uporaba-opasnih-kemikalija-biocidnih-proizvoda-i-tretiranih-proizvoda/228
Controls on placing on the market of treated articles	State Inspectorate	https://dirh.gov.hr/o-drzavnom-inspektoratu-9/ustrojstvo-77/8-sektor-za-sanitarni-nadzor-zdravstvene-ekologije/3-proizvodnja-stavljanje-na-trziste-i-uporaba-opasnih-kemikalija-biocidnih-proizvoda-i-tretiranih-proizvoda/228

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	0	0	0	0	10	10

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

The number of controls cannot be stated since the annual report for checks done by sanitary inspection doesn't contain separate data for biocidal products surveillance. The number of checks have been collected and expressed in total containing information for different areas that sanitary inspectors do control (e.g. food, noise, chemicals, biocides, cosmetics...). Data is available only for 2019

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													236	11
MG 2 Preservatives													59	27
MG 3 Pest control													125	5
MG 4 Other biocidal products													0	0

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

- 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	disinfectants, rodenticides, insecticides	Training for pest controllers http //www.huddd.hr/web/index.php/features-intro-2/obvezna-trajna-edukacija	twice per year
2	biocides classified as dangerous according to the CLP	Chemical safety training https //www.hzt.hr/edukacija/skolovanje-o-kemikalijama.html	every 5 years
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

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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