

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]	ministry of health	[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.

According to the provisions of Government Decision no. 617/2014 dated July 23rd 2014 on establishment of institutional framework and of measures for enforcement of Regulation (EU) no. 528/2012 of the European Parliament and of the Council of May 22nd 2012 concerning the making available on the market and use of biocidal products:

The Ministry of Health is assigned as competent authority for coordination of national-level measures required for enforcement of the Regulation.

The Ministry of Health, through the National Public Health Institute, the Ministry of Environment through the National Environment Protection Agency and the National Sanitary Veterinary and Food Safety Authority are authorities having roles in implementation of the Regulation, as per their respective competences.

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, through the National Public Health Institute	www.insp.gov.ro
Advice to applicants/helpdesks on biocidal products	Ministry of Health, through the National Public Health Institute	www.insp.gov.ro
Advice to applicants/helpdesks on treated articles	Ministry of Health, through the National Public Health Institute	www.insp.gov.ro
Assessment of active substances	Ministry of Health through the National Public Health Institute Ministry of Environment through the National Environment Protection Agency National Sanitary Veterinary and Food Safety Authority	www.insp.gov.ro www.anpm.ro www.ansvsa.ro
Assessment and authorisation of biocidal products	Ministry of Health through the National Public Health Institute Ministry of Environment through the National Environment Protection Agency National Sanitary Veterinary and Food Safety Authority	www.insp.gov.ro www.anpm.ro www.ansvsa.ro
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)	Ministry of Health Ministry of Environment National Sanitary Veterinary and Food Safety Authority	www.ms.ro www.mmediu.ro www.ansvsa.ro

1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	Ministry of Health through: National Institute of Public Health, Bucharest Emergency Clinical Hospital, Emergency Clinical Hospital Târgu Mures	www.ms.ro www.insp.gov.ro www.urgentafloreasca.ro www.spitalmures.ro
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.

ORDER No. 10/368/11/2010 from 8 January 2010 approving the procedure for the approval of biocidal products that are made available on the market in Romania (consolidated form)
https://insp.gov.ro/sites/Biocide/public_html/Documente/Biocide/OMS_Nr_10_368_11_2010_din_8_ianuarie_2010_EN.pdf
 Amending Normative Acts
 #M1: Order of the Minister of Health, of the Minister of Environment and Climate Change and of the President of the National Sanitary Veterinary and Food Safety Authority no. 433/1042/92/2014
 #M2: Order of the Minister of Health, of the Minister of Environment, Waters and Forests and of the President of the National Sanitary Veterinary and Food Safety Authority no. 910/1657/99/2016
 #M3: Order of the Minister of Health, of the Minister of Environment and of the President of the National Sanitary Veterinary and Food Safety Authority no. 604/880/78/2017

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

Order no. 10/2013 regarding the tariffs charged by the competent authorities for the related activities procedures for placing biocidal products on the market. (consolidated form)

https://insp.gov.ro/sites/Biocide/public_html/Documente/Biocide/Ordinul_10_din_2013_acrtualizat_15_octombrie_2017.pdf

ORDER No. 870/1170/98/2017 dated July 27th 2017 amending the Order of the Minister of Health, of the Minister of Environment and Climate Change and of the President of the National Sanitary Veterinary and Food Safety Authority no. 10/205/19/2013 concerning fees for marketing of biocidal products and for applying for listing of active substances in annex no. I, IA or IB to methodological guidelines for implementation of Government Decision no. 956/2005 on marketing of biocidal products, approved by Order of the Minister of Public Health, of the Minister of Environment and Water management and of the President of the National Sanitary Veterinary and Food Safety Authority no. 1.321/2006/280/90/2007

https://insp.gov.ro/sites/Biocide/public_html/Documente/Biocide/ORDIN_Nr._870_1170_98_2017_din_27_iulie_2017_en.pdf

Emergency Ordinance No 41/2019 establishing some measures to implement the assessment activities necessary for the approval of active substances of biocidal products and for the authorization of biocidal products

https://insp.gov.ro/sites/Biocide/public_html/Documente/Biocide/ordonanta-de-urgenta-nr-41-2019-EN.pdf

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	332.000 euro
Evaluation of an active substance for Annex I inclusion	332.000 euro
Authorisation of a biocidal product (BP)	85 000 euro
Authorisation of a BP family	145.000 euro
Mutual recognition of an authorisation of a BP	Between 12697 – 13756 lei , depending on PT
Mutual recognition of an authorisation of a BP family	-
Union authorisation of a BP	85 000 euro
Union authorisation of a BP family	145.000 euro
Annual fee	-
Other (please specify)	936 lei

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

Do you have specific national measures or legislation favouring SMEs?

- 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

Annex 1 - IV of ORDER No. 870/1170/98/2017 dated July 27th 2017 amending the Order of the Minister of Health, of the Minister of Environment and Climate Change and of the President of the National Sanitary Veterinary and Food Safety Authority no. 10/205/19/2013 concerning fees for marketing of biocidal products and for applying for listing of active substances in annex no. I, IA or IB to methodological guidelines for implementation of Government Decision no. 956/2005 on marketing of biocidal products, approved by Order of the Minister of Public Health, of the Minister of Environment and Water management and of the President of the National Sanitary Veterinary and Food Safety Authority no. 1.321/2006/280/90/2007

https://insp.gov.ro/sites/Biocide/public_html/Documente/Biocide/ORDIN_Nr._870_1170_98_2017_din_27_iulie_2017_en.pdf

Art 1 (5) of Emergency Ordinance No 41/2019 establishing some measures to implement the assessment activities necessary for the approval of active substances of biocidal products and for the authorization of biocidal products https://insp.gov.ro/sites/Biocide/public_html/Documente/Biocide/ordonanta-de-urgenta-nr-41-2019-EN.pdf

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

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	1	0	0	0	1
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)								
Main group 2 Preservatives (PT6 - PT13)								
Main group 3 Pest control (PT14 - PT20)								
Main group 4 Other biocidal products (PT21 - PT22)								

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

GD no. 617/2014 is specified that the Ministry of Health (MH) is assigned as competent authority for coordination of national-level measures required for enforcement of the BPR. Also, in this national regulations mentions the following entities are assigned as authorities responsible for performance of official controls on compliance with BPR's requirements as per provisions of art 65 para. (2) in BPR, as shown below:

- a) Ministry of Health through public health directions;
- b) Ministry of Environment and Climate Change through the National Environmental Guard;
- c) National Sanitary Veterinary and Food Safety Authority through its regional / Bucharest sanitary-veterinary and food safety directions.

Attributions of personnel assigned to perform official controls are approved, as per legal conditions, by Order no. 726/2015. In accordance with this regulations, the assigned representatives (individuals assigned by the public authorities set in GD no. 617/2014) shall perform official controls based on competences on manufacturers, importers, distributors and professional / industrial end users as follows:

- a) Ministry of Health (MH) through public health directorates: PT1, PT2, PT5, PT4 - as per competences set forth in relevant regulations, PT5, PT14, PT18, PT19, PT22.
- b) Ministry of Environment and Climate Change through the National Environmental Guard (NEG): PT6-PT13, PT15, PT16, PT17, PT21;
- c) National Sanitary Veterinary and Food Safety Authority (NSVFSA) through its regional / Bucharest sanitary-veterinary and food safety directions: PT3, PT4 - as per competences set forth in relevant regulations.

The Order no. 726/2015 established that official control means any form of control performed by assigned representatives to provide checks on compliance of biocidal products with relevant legislation. Also, the terms "inspection" represents activity performed within official controls, by assigned representatives, in any type of units in private and public sectors (manufacturers, importers, distributors, professional / industrial end users), consisting in a certified verification of compliance with legal regulations on biocidal products and of consistent application thereof, respectively the official audit of all documents, labels and packaging of biocidal products, of biocidal product records, of applicable standards, of specifications of active substances and ingredients used in manufacture of the biocidal products, of material safety data sheets, of results of internal quality controls and of any other element with relevance for marketing and use of biocidal products, including publicity.

The official control may include investigation of biocidal product, including collection of samples during targeted control action and, in case of suspicions, to assess the respective product in an accredited laboratory to certify that the biocidal product is compliant with legal provisions and requirements set forth in the administrative document for marketing of biocidal products or in the assessment report, as the case may be. If the biocidal product is noncompliant, costs incurred by analysis of biocidal product sample are charged to the manufacturer / importer / distributor, as the case may be.

The assigned representatives have access to all locations, documents and information related to marketed and used biocidal products, based on their respective competences.

The assigned representatives assert violation of the facts specified in GD no. 617/2014 and applies the sanctions established in this national normative act.

The assigned representatives perform official controls based on:

- a) annual official control plans, with predetermined targets;
- b) claims and complaints, when issues claimed require such control;
- c) requests from other authorities.

For the official controls, in addition to the national normative acts, each competent authority uses specific procedures, methodologies and guidelines according to the competencies.

In Romania there is no strategy regarding the control of implementation the BPR, but according to Order no. 726/2015, MH, NEG and NSVFSA prepares annual official control plans and notifies the same to the Ministry of Health until December 15th of each year. MH elaborates, each year, the national market surveillance plan for biocidal products market, as per provisions in Regulation (EC) no. 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

The plan for the following year and the result of the official control activity carried out in the previous year are sent in January by MH for all three authorities to the Ministry of Economy (competent authority for market surveillance in Romania) which sends it to the European Commission.

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	Ministry of Health – competent authority National Environmental Guard National Sanitary Veterinary and Food Safety Authority	a) www.ms.ro b) www.gnm.ro c) www.ansvsa.ro
Controls on placing on the market of treated articles	Ministry of Health – competent authority National Environmental Guard National Sanitary Veterinary and Food Safety Authority	a) www.ms.ro b) www.gnm.ro c) www.ansvsa.ro

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	37	82	33	211	330	167	424	1284

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			0	0	0	0	0	0	0	0	0	0		
MG 2 Preservatives			0	0	0	0	0	0	0	0	0	0		
MG 3 Pest control			10	0	32	0	70	0	72	0	74	0		
MG 4 Other biocidal products			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

	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 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))

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			0	0	0	0	0	0	0	0	0	0	0	0
MG 2 Preservatives			0	0	0	0	0	0	0	0	0	0	0	0
MG 3 Pest control			10	0	32	0	70	14	72	6	74	7	334	59
MG 4 Other biocidal products			0	0	0	0	0	0	0	0	0	0	0	0

- 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))

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														
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)

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)

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			0	0	0	0	0	0	0	0	0	0	0	0
MG 2 Preservatives			0	0	0	0	0	0	0	0	0	0	0	0
MG 3 Pest control			10	0	32	0	70	0	72	0	74	0	87	0
MG 4 Other biocidal products			0	0	0	0	0	0	0	0	0	0	0	0

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	387	0	358	1	318	0	1150	80	1310	77	917	11	450	3
MG 2 Preservatives	13	0	3	0	12	0	2	0	5	0	2	0	0	0
MG 3 Pest control	215	0	178	0	148	0	278	14	303	0	200	3	106	1
MG 4 Other biocidal products	1	0	0	0	0	0	0	0	6	0	5	0	0	0

- 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	387	32	358	20	318	13	1232	42	1463	74	1124	94	630	94
MG 2 Preservatives	13	0	3	0	12	2	151	3	128	4	49	2	38	0
MG 3 Pest control	215	21	178	29	148	24	278	13	303	14	200	13	161	32
MG 4 Other biocidal products	1	1	0	0	0	0	0	0	6	0	5	0	0	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	387	0	358	0	318	0	1150	10	1310	2	917	0	217	4
MG 2 Preservatives	13	0	3	0	12	0	2	0	5	0	2	0	0	0
MG 3 Pest control	215	0	188	0	180	0	348	0	375	0	274	0	76	2
MG 4 Other biocidal products	1	0	0	0	0	0	0	0	6	0	5	0	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														
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	3	115	5	217	1	174	9	188	5	122	0	99	4	163
MG 2 Preservatives	0	0	0	0	0	0	0	0	0	2	0	0	0	33
MG 3 Pest control	6	18	10	168	10	220	10	164	3	76	9	42	0	81
MG 4 Other biocidal products	0	0	1	5	0	2	0	3	2	3	1	3	0	5

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	no data available	no data available	150	1138	1017	417	489

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

Interested persons can access the following link for information: https://insp.gov.ro/sites/Biocide/public_html/html/home.html
The competent authority, together with the professional associations, organizes meetings in which are discussed topics of interest.
At the request of the applicants, representatives of the competent authority have meetings with these to clarify some issues.

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

Please specify which kind of documentation is available in your Member State

	Type of document	Name of document	Product-type(s) covered	Year of document
1	Order of the Ministry of Health	ORDER Nr. 119 of February 4, 2014 for the approval of the Norms of hygiene and public health regarding the living environment of the population	PT2 PT 5, PT 14, PT 18	2014 with subsequent Amendments In 2020, NIPH submitted to the MoH a proposal containing norms amending the Order Nr. 119 for sustainable use of insecticides and raticides
2	Order of the Ministry of Health and the Ministry of National Education	ORDER Nr. 1225/5031 of 24 December 2003 on the approval of the Methodology for the organization and certification of the professional training of the personnel regarding the acquisition of the fundamental notions of hygiene	PT2 PT 5, PT 14, PT 18	2003 In 2020, NIPH submitted to MoH a proposal regarding the training and certification of persons providing services for disinfection, disinsection, rodent control (including fumigation), and drinking water disinfection
3				

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	PT2, PT5, PT14, PT18	GRADUATION CERTIFICATE issued in accordance with the provisions of the Order of the Minister of Health and of the Minister of Education, Research and Youth no. 1225/5031/2003	2003 - present
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

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

Given the busy schedule of experts during the pandemic, some data could not be fully processed.

Contact

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