Contribution ID: aa2f50ce-988f-4bc9-bfe6-334e4250a81d
Date: 27/11/2020 13:35 35

BPR Article 65(3) reporting

1. General information

1.1. Member State

For which Memeber 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.

ministry of health

1.3.2. Details of the Competent Autorities involved in the BPR implementation

	BPR competent authority involved	Website
Advice to applicants/helpdesks on active substances	Ministry of Health with ISS and IZSLT	www.salute gov.it
Advice to applicants/helpdesks on biocidal products	Ministry of Health	www.salute gov.it
Advice to applicants/helpdesks on treated articles	Ministry of Health	www.salute gov.it
Assessment of active substances	Ministry of Health with ISS and IZSLT	www.salute gov.it

Assessment and authorisation of biocidal products	Ministry of Health	www salute gov.it
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)		

1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	cav	CVA is a territorial unit, each one has his website
Animal poison centre	none	
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.

D.P.R. 392/98

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

D.M 1 giugno 2016

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	100.000
Evaluation of an active substance for Annex I inclusion	10 000
Authorisation of a biocidal product (BP)	20 000
Authorisation of a BP family	40 000
Mutual recognition of an authorisation of a BP	2.500
Mutual recognition of an authorisation of a BP family	3.500
Union authorisation of a BP	20 000
Union authorisation of a BP family	40 000
Annual fee	none
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

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

D.M 1 giugno 2016

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

2.5. Imported treated articles

Do you have specific national measures or legislation that regulates whether imported treated articles contain only approved active substances?

- ○ Yes
- ◉ No

3. Placing and making available on the market of biocidal products

3.1. Authorisation procedures

3.1.1. Authorisations

Please indicate in the tables below the figures related to the various procedures since the entry into application of the BPR (1st September 2013)

3.1.1.a. National authorisations

	2013	2014	2015	2016	2017	2018	2019	Total number
Authorisations granted on the basis of Article 19(5)	70	70	70	100	80	80	80	About 550
Provisional authorisations granted for products containing new active substances (Article 55(2))	0	0	0	0	0	0	0	0

3.1.1.b. Mutual recognitions - concerned Member State

	2013	2014	2015	2016	2017	2018	2019	Total number
Derogations (Article 37)								0

3.1.1.c. Authorisations of products containing active substances meeting exclusion criteria (Article 5.2)

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications assessed								0
Number of products authorised (conditions met for all or some of the uses)								0
Number of products not authorised (conditions not met for any of the uses)								0

3.1.1.d. Comparative assessments (Article 23)

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications evaluated								
Number of applications evaluated resulting in a granted authorisation without restrictions								
Number of applications evaluated resulting in restrictions (Article 23(3))								
Number of applications evaluated resulting in restrictions (Article 23(3))								

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
Provisional authorisations granted for products containing new active substances (Article 55(2))								0

3.1.2.b. Mutual recognitions - concerned MS

	2013	2014	2015	2016	2017	2018	2019	Total number
Derogations (Article 37)								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
Number of products authorised (conditions met for all or some of the uses)								0
Number of products not authorised (conditions not met for any of the uses)								0

3.1.2.d. Comparative assessments (Article 23)

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications evaluated								
Number of applications evaluated resulting in a granted authorisation without restrictions								
Number of applications evaluated resulting in restrictions (Article 23(3))								
Number of applications evaluated resulting in restrictions (Article 23(3))								

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
Permits granted								0
Permits not granted								0

3.2.b. Research and development (Article 56)

	2013	2014	2015	2016	2017	2018	2019	Total number
Number of notifications received	0	0	2	3	0	1	0	6
Number of prohibitions								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)	50	70	50	60	40	30	10	310
Main group 2 Preservatives (PT6 - PT13)								Non authorisable
Main group 3 Pest control (PT14 - PT20)								Non authorisable
Main group 4 Other biocidal products (PT21 - PT22)								Non authorisable

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

```
We have a strength collaboration with NAS, local policy.
```

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	NAS	Each local NAS have his website
Controls on placing on the market of treated articles	none	

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	50	30	40	50	40	60	40	About 310

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**

```
100/20
```

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	80	15	100	22	120	25	80	14	130	20	100	20	150	26
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**

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														
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))

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 advertisment 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														
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)

```
We control the active ingredient in authorisation step
```

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)

```
We control the active ingredient in authorisation step
```

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)

```
We control the active ingredient in authorisation step
```

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														
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

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														
MG 2 Preservatives														
MG 3 Pest control														
MG 4 Other biocidal products														

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)

```
We have a local control with CAV (poisoning centre)
```

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														
MG 2 Preservatives														
MG 3 Pest control														
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	10	30	20	10	20	10	10
Number of enquiries on biocidal products	80	100	120	100	130	110	130
Number of enquiries on treated articles	20	20	10	30	20	40	40
Total number of enquiries per year	110	150	150	150	170	160	180

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

www.sanita.gov.it

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

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