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BPR Article 65(3) reporting

1. General information

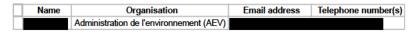
1.1. Member State

For which Memeber State* are you reporting?

("In this survey "Member State" refers to EU Member States, Iceland, Liechtenstein, Norway and Switzerland)

- Austria
- O Belgium
- O Bulgaria
- O Croatia
- O Cyprus
- O Czech Republic
- O Denmark
- Estonia
- Finland
- O France
- O Germany
- O Greece
- O Hungary
- O Iceland
- Ireland
- O taly
- O Latvia
- O Liechtenstein
- Lithuania
- Luxembourg
- O Malta
- O Netherlands
- O Norway
- O Poland
- O Portugal
- O Romania
- O Slovakia
- O Slovenia
- O Spain
- O Sweden
- Switzerland
- O United Kingdom

1.2. Contact details of the person responsible for reporting



1.3. Information on the Competent Authority (CA)

1.3.1. Competent Authorities involved in the implementation of the BPR

How many CAs are responsible for the implementation of the BPR in your Member State? Please do not include enforcement authorities here, as they are specifically covered in section 4.

1

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

	BPR competent authority involved	Website
	1: AEV, Administration under the Ministry for	
Advice to applicants/helpdesks on active substances	Environment, Climat and sustainable	https //environnement public.lu/fr html
	Development	
Advice to applicants/helpdesks on biocidal products	idem	https //environnement public.lu/fr html
Advice to applicants/helpdesks on treated articles	idem	https //environnement public.lu/fr html
Assessment of active substances	idem	https //environnement public.lu/fr html
Assessment and authorisation of biocidal products	idem	https //environnement public.lu/fr html

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	Belgian Poison Center	https //www.centreantipoisons.be
Animal poison centre	1	1
Other	1	1

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
 Yes

O 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.

Loi (modifiée) du 4 Septembre 2015 relative aux produits biocides (Legal text in French only) LINK: http://data.legilux.public.lu/eli/etat/leg/loi/2015/09/04/nl/jo ==> Modified twice (see link). Transitional period: Articles 4 - 6.

2.2. Applicable fees

Do you have specific national measures or legislation regarding fees for BPR procedures?

Yes

O 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

Fee Regulation: Règlement grand-ducal du 4 septembre 2015 déterminant les redevances de traitement en matière de produits biocides - LINK: http://data.legilux.public.lu/eli/etat/leg/rgd/2015/09/04/n2/jo ==> once modified.

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	200 000 € for 1 PT 100.000 € (microorganism) for 1 PT +100.000 € per additional PT
Evaluation of an active substance for Annex I inclusion	10.000 € - 100.000€
Authorisation of a biocidal product (BP)	40.000 € (single BP) 8000€ (single BP already evaluated in the a.s. dossier)
Authorisation of a BP family	80.000 € (BPF)
Mutual recognition of an authorisation of a BP	400 €
Mutual recognition of an authorisation of a BP family	800 €
Union authorisation of a BP	40.000 € (single BP)
Union authorisation of a BP family	80.000 € (BPF)
Annual fee	1
Other (please specify)	For BPs: Additional fees apply in case of more than one a s., more than one user category, more than one PT; in case comparative assessment is required.

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

Do you have specific national measures or legislation favouring SMEs?

Yes
 Yes

O 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

```
Reduction of Fees for SMEs.
Fee Regulation: Règlement grand-ducal du 4 septembre 2015 déterminant les redevances de traitement en matière de produits biocides
- LINK: http://data.legilux.public.lu/eli/etat/leg/rgd/2015/09/04/n2/jo
```

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? (a) Yes

O 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

```
Loi du 4 septembre 2015 relative aux produits biocides - LINK: http://data.legilux.public.lu/eli/etat/leg/loi/2015/09/04/nl/jo ==>
Modified twice (see link).
Please refer to Articles 9- 12 (as modified in 2019)
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2.5. Imported treated articles

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

O 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)	0	0	0	0	0	0	4x (PT19)	4
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	0	0	0	0	0	1	1

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	32	13	0	2	7	5	18	77
Number of products authorised (conditions met for all or some of the uses)	32	13	0	2	7	5	18	77
Number of products not authorised (conditions not met for any of the uses)	0	0	0	0	0	0	0	0

3.1.1.d. Comparative assessments (Article 23)

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications evaluated	1	2	0	4	8	13	10	38
Number of applications evaluated resulting in a granted authorisation without restrictions	1	2	0	4	8	13	10	38
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

3.1.2. 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	1	2	0	0	1	0	4

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	21	16	12	2	2	3	1	57
Number of products authorised (conditions met for all or some of the uses)	21	16	12	2	2	3	1	57
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	6	5	4	0	2	0	0	17
Number of applications evaluated resulting in a granted authorisation without restrictions	6	5	4	0	2	0	0	17
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)	65	112	87	192	294	223	121	1094
Main group 2 Preservatives (PT6 - PT13)	41	13	11	36	43	22	23	189
Main group 3 Pest control (PT14 - PT20)	53	41	34	112	50	102	47	439
Main group 4 Other biocidal products (PT21 - PT22)	0	0	1	0	0	1	0	2

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?

O 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

Enforcement mainly focuses on the making available on the market of biocidal products and treated articles, at the distributor and sales point level. Entities placing biocidal products on the market are in the vast majority of cases not based in Luxembourg. The (industrial) use of biocidal products was only investigated in one project, and on the basis of complaints or alerts.

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	Administration de l'environnement	www emwelt.lu
Controls on placing on the market of treated articles	Administration de l'environnement	www.emwelt.lu

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	4	0	0	1	1	0	0	6

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

1073/630

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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	2019
MG 1 Disinfectants	4	3	0	0	68	62	41	38	118	71	57	31	2	2
MG 2 Preservatives	0	0	2	2	5	3	42	33	3	0	14	14	0	0
MG 3 Pest control	25	25	1	1	52	42	129	85	479	202	31	16	0	0
MG 4 Other biocidal		0	0	0	0	0	0	0	0	0	0	0	0	0
products	0	0	0	0	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

n/a

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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	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))

1073/630

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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	2019
MG 1 Disinfectants	4	3	0	0	68	62	41	38	118	71	57	31	2	2
MG 2 Preservatives	0	0	2	2	5	3	42	33	3	0	14	14	0	0
MG 3 Pest control	25	25	1	1	52	42	129	85	479	202	31	16	0	0
MG 4 Other biocidal	0	0	0	0	0	0	0	0	0	0	0	0	0	0
products	0	0	U C	0	0	0	0	0	U	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))

safety data sheets are always checked authorization process of biocidal products. No specific data available

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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	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)

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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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	2019
MG 1 Disinfectants	0	0	0	0	0	0	0	0	74	57	0	0	0	0
MG 2 Preservatives	0	0	0	0	0	0	0	0	3	1	0	0	0	0
MG 3 Pest control	0	0	0	0	0	0	0	0	71	52	0	0	0	0
MG 4 Other biocidal	0	0	0	0	0	0	0	0	0	0	0	0	0	0
products	0	0	U	0	0	0	U	0	0	0	0	0	0	0

• Controls on the inclusion of active substance suppliers in the official list (article 95(2) of the BPR)

The administrative verification of the article 95 status is part of the transitional period scheme for the placing on the market of biocidal products.

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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	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)

Wether or not the active substance is included in the review program is always checked, as this is a key information to know what c onditions/obligations have to be fulfilled to make the product compliant

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 noncompliances (NC) identified

	Total	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	2019
MG 1 Disinfectants	4	3	0	0	68	62	41	38	118	71	57	31	2	2
MG 2 Preservatives	0	0	2	2	5	3	42	33	3	0	14	14	0	0
MG 3 Pest control	25	25	1	1	52	42	129	85	479	202	31	16	0	0
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	0	0	0	0	0	0

• Controls on the inclusion of active substances suppliers in the official list (article 95(2) of the BPR)

The administrative verification of the article 95 status is part of the transitional period scheme for the placing on the market of biocidal products.

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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	2019
MG 1 Disinfectants	3	3	0	0	65	59	39	36	112	65	48	27	2	2
MG 2 Preservatives	0	0	1	1	4	2	15	12	3	0	8	8	0	0
MG 3 Pest control	23	23	1	1	36	31	72	48	242	138	22	14	0	0
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	0	0	0	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

n/a

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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	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

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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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	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)

1

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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	2019
MG 1 Disinfectants	0	0	0	0	0	0	0	0	0	0	0	0	8	8
MG 2 Preservatives	0	0	0	0	0	0	0	0	0	0	0	0	22	11
MG 3 Pest control	0	0	0	0	0	0	0	0	0	0	0	0	2	2
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	0	0	0	0	0	0

• 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	NC												
	2013	2013	2014	2014	2015	2015	2016	2016	2017	2017	2018	2018	2019	2019
MG 1 Disinfectants	0	0	0	0	0	0	0	0	0	0	0	0	8	8
MG 2 Preservatives	0	0	0	0	0	0	0	0	0	0	0	0	22	11
MG 3 Pest control	0	0	0	0	0	0	0	0	0	0	0	0	2	2
MG 4 Other biocidal	0	0	0	0	0	0	0	0	0	0	0	0	0	0
products	0	0	U	0	0	0	U	0	0	0	0	0	U	0

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	unknown	unknown	unknown	unknown	0	4	0	5	0	7	1	17	0	13
MG 2 Preservatives	unknown	unknown	unknown	unknown	0	0	0	0	0	0	0	0	0	3
MG 3 Pest control	unknown	unknown	unknown	unknown	0	7	0	5	0	5	0	22	0	10
MG 4 Other biocidal products	unknown	unknown	unknown	unknown	0	0	0	0	0	0	0	0	0	0

6. Helpdesk functioning

Please fill in in the following table the information regarding the number of enquiries that Helpdesks receive per year. Note: if your system does not differentiate the queries according to their topic (active substances, biocidal products, treated articles) please indicate the total number of queries per year in the last row

	2013	2014	2015	2016	2017	2018	2019
Number of enquiries on active substances							
Number of enquiries on biocidal products							
Number of enquiries on treated articles							
Total number of enquiries per year							

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

O No

7. Sustainable use measures

In accordance with Article 18 of the BPR, a Commission Report on the sustainable use of biocidal products was submitted to the European Parliament and the Council in 2016, compiling the information provided by Member States. Please find below some questions that are requested in order to follow-up on this report.

7.1. Availability of Best Practices Documents in the Member States

Are Best Practices Documents used or developed for reducing the use of biocidal products to a minimum or for using biocides with less impact on human health and the environment?

○ Yes

No

7.2. Availability of certifications or training schemes for professional users

Are certification procedures or training schemes in place (organised by e.g. eCAs, public authorities, sector organisations) for professional users of biocidal products?

- Yes
- No
- Not anymore

7.3. Information to the public

Have measures been taken to provide the public with appropriate information about benefits and risks associated with biocidal products and ways of minimising their use? (Article 17(5) of the BPR)

O 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

MG1 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	Mite-Killer	Synthetic amorphous silicon dioxide (nano)	PT 18	No - exposure to nanoscale primary particles was not expected during the intended biocidal use	2015 (submitted) 2019 (authorized)
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