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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
- ○ 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]	Malta Competition and Consumer Affairs Authority	[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.

The Technical Regulations Division within the Malta Competition and Consumer Affairs Authority (MCCAA) is responsible for the implementation of the BPR in Malta, in line with the Subsidiary Legislation. 430.09 of Chapter 430 of the Laws of Malta entitled Biocidal Products (Implementation of Regulation (EU) No. 528/2012) Regulations (herein referred to as S.L. 430.09)

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	Malta Competition and Consumer Affairs Authority (MCCAA) Technical Regulation Division	www mccaa.org.mt

Advice to applicants/helpdesks on biocidal products	Malta Competition and Consumer Affairs Authority (MCCAA) Technical Regulation Division	www.mccaa.org.mt
Advice to applicants/helpdesks on treated articles	Malta Competition and Consumer Affairs Authority (MCCAA) Technical Regulation Division	www.mccaa.org.mt
Assessment of active substances	Malta Competition and Consumer Affairs Authority (MCCAA) Technical Regulation Division	www.mccaa.org.mt
Assessment and authorisation of biocidal products	Malta Competition and Consumer Affairs Authority (MCCAA) Technical Regulation Division	www.mccaa.org.mt
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)	Malta Competition and Consumer Affairs Authority (MCCAA) Technical Regulation Division	www.mccaa.org.mt

1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	Emergency Unit, Mater Dei Hospital	N/A
Animal poison centre	N/A	N/A
Other	N/A	N/A

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.

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National Legislative measures supporting the transitional period are in line with the provisions of S.L. 430.09, Biocidal Product
s (Implementation of Regulation (EU) No. 528/2012) Regulations.
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2.2. Applicable fees

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

- ( ) Yes
- (●) No

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	220,000
Evaluation of an active substance for Annex I inclusion	110,000
Authorisation of a biocidal product (BP)	37,000
Authorisation of a BP family	48,000
Mutual recognition of an authorisation of a BP	500
Mutual recognition of an authorisation of a BP family	500 + 25 per product family member
Union authorisation of a BP	37,000
Union authorisation of a BP family	50,000
Annual fee	N/A
Other (please specify)	N/A

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

Do you have specific national measures or legislation favouring SMEs?

- ( ) Yes
- (●) No

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

Legislation measure concerning non-compliance and penalties applicable for infringements on the implementation of Reg 528/2012 are in line with the provisions of Article 9 of the Pesticides Control Act, Chapter 430 of the Laws of Malta, and S.L.430.09, Biocidal Products (Implementation of Regulation (EU) No. 528/2012) Regulations

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

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

National Legislative measures supporting treated articles are in line with the provisions of S.L. 430.09, Biocidal Products (Implementation of Regulation (EU) No. 528/2012) Regulations.

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	0	0
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	0	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	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

3.1.1.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

3.1.2. 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	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	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)	4	4	7	11	48	56	71	201
Main group 2 Preservatives (PT6 - PT13)	3	1	2	8	4	14	9	41
Main group 3 Pest control (PT14 - PT20)	5	1	14	16	9	47	46	138
Main group 4 Other biocidal products (PT21 - PT22)	19	6	11	7	45	102	56	246

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 monitoring of biocidal products which have been placed on the market in-line with the provisions of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products as implemented through S.L. 430.09 of the Laws of Malta is carried out via inspections by MCCAA officials duly recognised by the Director General of the Technical Regulations Division. MCCAA officials have a duty to inspect any biocidal product to ascertain that the provisions of the mentioned Act or of any regulations made thereunder have been or are being complied with.

Controls at retailers are performed to check that biocidal products available on the market comply with the requirements of Regulation (EU) 528/2012 and all national legislation transposing it, namely S.L. 430.09. The selection of retailers constitutes 75% randomly selected retailers and 25% targeted retailers. During random these controls, MCCAA officials carried out unannounced controls at retail outlets which may be placing biocidal products on the market. Targeted inspections are carried out as a result of either consumer reports, follow up of random inspections or controls carried out under Regulation (EU) 528/2012, as implemented through S.L. 430.09 of the Laws of Malta.

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

The monitoring of biocidal products which have been placed on the market in-line with the provisions of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products as implemented through S.L. 430.09 of the Laws of Malta is carried out via inspections by MCCAA officials duly recognised by the Director General of the Technical Regulations Division. MCCAA officials have a duty to inspect any biocidal product to ascertain that the provisions of the mentioned Act or of any regulations made thereunder have been or are being complied with.

Controls at retailers are performed to check that biocidal products available on the market comply with the requirements of Regulation (EU) 528/2012 and all national legislation transposing it, namely S.L. 430.09. The selection of retailers constitutes 75% randomly selected retailers and 25% targeted retailers. During random these controls, MCCAA officials carried out unannounced.

controls at retail outlets which may be placing biocidal products on the market. Targeted inspections are carried out as a result of either consumer reports, follow up of random inspections or controls carried out under Regulation (EU) 528/2012, as implemented through S.L. 430.09 of the Laws of Malta.

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	Malta Competition and Consumer Affairs Authority (MCCAA) Regulatory Affairs Directorate	www mccaa.org.mt
Controls on placing on the market of treated articles	Malta Competition and Consumer Affairs Authority (MCCAA) Regulatory Affairs Directorate	www mccaa.org.mt

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	1	1	2	1	0	1	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**

The monitoring of biocidal products which have been placed on the market in-line with the provisions of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products as implemented through S.L. 430.09 of the Laws of Malta is carried out in line with the enforcement strategy outlined in Section 4.1. Annual control figures and non-compliances encountered are identified below.

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	N/A	N/A	N/A	N/A	5	4	10	10	14	12	0	0	0	0
MG 2 Preservatives	N/A	N/A	N/A	N/A	0	0	0	0	0	0	0	0	0	0
MG 3 Pest control	N/A	N/A	N/A	N/A	7	5	4	2	33	28	4	3	8	7
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	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**

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N/A
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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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

- **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))

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Controls on the classification, packaging and labeling of biocidal products are supported via inspections carried out in line wit
h the enforcement strategy outlined in Section 4.1. Annual control figures and non-compliances encountered are identified below.
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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	N/A	N/A	N/A	N/A	5	4	10	10	14	12	0	0	0	0
MG 2 Preservatives	N/A	N/A	N/A	N/A	0	0	0	0	0	0	0	0	0	0
MG 3 Pest control	N/A	N/A	N/A	N/A	7	5	4	2	33	28	4	3	8	7
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	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))

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Safety data sheet and related documentation assessments are carried out at evaluatory stages in line with the notifications and/o
r authorisation procedures for the placement of biocidal products on the market in Malta outlined in S.L.430.09 implementing the
provisions of Regulation (EU) No 528/2012  .  Evaluation of the documentation also considers the provisions of the REACH regulati
ons (EC) No 1907/2006 and compliance with language provisions as outlined in S.L. 427.66 of the Laws of Malta entitled Registrati
on, Evaluation, Authorisation and Restriction of Chemicals (REACH) implementation Regulations.
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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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

- **Controls on advertisement of biocidal products** (article 72 of the BPR and CLP)

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Product related claims are evaluated at the product notification/authorisation are carried out at authorisation/notification stag
es in line with the notifications and/or authorisation procedures for the placement of biocidal products on the market in Malta o
utlined in S.L.430.09 implementing the provisions of Regulation (EU) No 528/2012.
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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 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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

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Active Substance supplier assessments are carried out at authorisation/notification stages in line with the notifications and/or
authorisation procedures for the placement of biocidal products on the market in Malta outlined in S.L.430.09 implementing the pr
ovisions of Regulation (EU) No 528/2012 .
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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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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)

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Active Substance supplier assessments are carried out at authorisation/notification stages in line with the notifications and/or
authorisation procedures for the placement of biocidal products on the market in Malta outlined in S.L.430.09 implementing the pr
ovisions of Regulation (EU) No 528/2012.
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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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

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Active Substance supplier inclusions in the official list assessments are carried out at authorisation/notification stages in lin
e with the notifications and/or authorisation procedures for the placement of biocidal products on the market in Malta outlined i
n S.L.430.09 implementing the provisions of Regulation (EU) No 528/2012 .
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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	N/A	N/A	N/A	.N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

- **Controls on compliance of the biocidal products made available on the market with national legislation** (where relevant)

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As outlined in Section 4.1, the monitoring of biocidal products which have been placed on the market in-line with the provisions of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products as implemented through national legislation S.L. 430.09 of the Laws of Malta is carried out via inspections by MCCAA officials duly recognised by the Director General of the Technical Regulations Division.  MCCAA officials have a duty to inspect any biocidal product to ascertain that the provisions of the mentioned Act or of any regulations made thereunder have been or are being complied with.

Controls at retailers are performed to check that biocidal products available on the market comply with the requirements of Regulation (EU) 528/2012 and all national legislation transposing it, namely S.L. 430.09. The selection of retailers constitutes 75% randomly selected retailers and 25% targeted retailers. During random these controls, MCCAA officials carried out unannounced controls at retail outlets which may be placing biocidal products on the market. Targeted inspections are carried out as a result of either consumer reports, follow up of random inspections or controls carried out under Regulation (EU) 528/2012, as implemented through S.L. 430.09 of the Laws of Malta.

The figures are included within the data provided for in Section 4.4.1.
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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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

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N/A
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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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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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N/A
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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 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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

- **Controls on residue levels of active substances in food and feed (PT3, 4, 5, 18, 19 and 21)**

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N/A
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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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PT 4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PT 18	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PT 19	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PT 21	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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)

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As outlined in Section 4.1, the monitoring of biocidal products including treated articles which have been placed on the market i
n-line with the provisions of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal produ
cts as implemented through national legislation S.L. 430.09 of the Laws of Malta is carried out via inspections by MCCAA official
s duly recognised by the Director General of the Technical Regulations Division.
```

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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

- **Controls on the correct labelling of the treated articles** (article 58 of the BPR)

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As outlined in Section 4.1, the monitoring of biocidal products including treated articles and their labelling, which have been p
laced on the market in-line with the provisions of Regulation (EU) No 528/2012 concerning the making available on the market and
use of biocidal products as implemented through national legislation S.L. 430.09 of the Laws of Malta is carried out via inspecti
ons by MCCAA officials duly recognised by the Director General of the Technical Regulations Division.
```

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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 2 Preservatives	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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)

Malta currently does not have a Poison Center. The Medicines and Poisons Information Service, at Mater Dei Hospital (MDH), is providing a similar service to that offered by a Poison Center. Article 45 of Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures, as amended by Regulation (EU) No 2017/542, promotes the harmonisation of the information collected by the appointed bodies responsible for receiving information from importers and downstream users placing mixtures on the market (Poisoning Centers) in order to formulate preventive and curative measures in the event of emerging health responses. Poisoning incidents related to biocidal products are composite of service provided by the above referred unit. The MCCAA is the appointed body for Malta to support the implementation of the harmonised information system.

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	0	3	0	4	0	2	0	0	0	0	0	1	0	0
MG 2 Preservatives	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MG 3 Pest control	0	2	0	1	0	1	0	0	0	0	0	0	0	0
MG 4 Other biocidal products	0	0	0	0	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	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Number of enquiries on biocidal products	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Number of enquiries on treated articles	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total number of enquiries per year	31	12	34	42	106	219	182

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

.

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

Please specify which kind of information is available in your Member State (e.g. information campaigns, regulatory measures) and include the corresponding links of the relevant websites with information.

	Type of measure	Year	Details
1	Application Form for the notification of a biocide		www.mccaa.org.mt - Application form supporting the notification of biocidal products
2	Guidance on the compilation of safety data sheets CLP Guidance on Labelling and packaging in accordance with Regulation (EC) No 1272/2008 Article 95 listing related information		www.mccaa.org.mt – Guidance material with reference to CLP, REACH, PIC and Biocidal Products Regulations. "Guidance on Labelling and packaging in accordance with Regulation (EC) No 1272/2008" Related links and information to aid the stakeholders outlining suppliers of active substances as outlined in article 95 of the BPR
3	European Commission Biocidal Products portal		www.mccaa.org.mt - Related links and information to aid the stakeholders in better understanding of the BPR regulations 528/2012
4	Database of registered Biocidal Products in Malta		www.mccaa.org.mt – A list containing biocidal products available on the market which hold a notification or authorisation in line with the provisions of Reg (EU) 528/2012 as implemented through S.L 430.09 of the Laws of Malta.

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

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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	N/A	N/A	N/A	N/A	N/A
2	N/A	N/A	N/A	N/A	N/A
3	N/A	N/A	N/A	N/A	N/A
4	N/A	N/A	N/A	N/A	N/A

MG 2 Preservatives

	Product name	Nanomaterial	Brief explanations	Safety measures (Yes/No)	Year
1	N/A	N/A	N/A	N/A	N/A
2	N/A	N/A	N/A	N/A	N/A
3	N/A	N/A	N/A	N/A	N/A
4	N/A	N/A	N/A	N/A	N/A

MG 3 Pest control

	Product name	Nanomaterial	Brief explanations	Safety measures (Yes/No)	Year
1	N/A	N/A	N/A	N/A	N/A
2	N/A	N/A	N/A	N/A	N/A
3	N/A	N/A	N/A	N/A	N/A
4	N/A	N/A	N/A	N/A	N/A

MG 4 Other biocidal products

	Product name	Nanomaterial	Brief explanations	Safety measures (Yes/No)	Year
1	N/A	N/A	N/A	N/A	N/A
2	N/A	N/A	N/A	N/A	N/A
3	N/A	N/A	N/A	N/A	N/A
4	N/A	N/A	N/A	N/A	N/A

9. Any other comment

N/A

Contact

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