

BPR Article 65(3) reporting

1. General information

1.1. Member State

For which Member State* are you reporting?

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

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

1.2. Contact details of the person responsible for reporting

Name	Organisation	Email address	Telephone number(s)
	Ministry of Health		

1.3. Information on the Competent Authority (CA)

1.3.1. Competent Authorities involved in the implementation of the BPR

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

There are 2 CAs involved in the implementation:
- Ministry of Ecological Transition, responsible for aspects related to the environment
- Ministry of Health, competent for the implementation of BPR, for other than environmental aspects

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 Advice by e-mail: SA-biocidas-ES@mscbs.es	

Advice to applicants/helpdesks on biocidal products	Ministry of Health Advice by e-mail: biocidas-helpdesk@mscbs.es	https://www.mscbs.gob.es/ciudadanos/saludAmbLaboral/prodQuimicos/sustPreparatorias/biocidas/home.htm
Advice to applicants/helpdesks on treated articles	Ministry of Health Advice by e-mail: biocidas-helpdesk@mscbs.es	
Assessment of active substances	Ministry of Health and Ministry of Ecological Transition	
Assessment and authorisation of biocidal products	Ministry of Health and Ministry of Ecological Transition	
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)	Ministry of Health (coordination, national legislation,...)	

1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	National Institute of Toxicology and Forensic Sciences	https://www.mjusticia.gob.es/cs/Satellite/Portal/es/ministerio/organismos-ministerio-justicia/instituto-nacional
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.

In the transitional period, Royal Decree 3349/1983 and Royal Decree 1054/2002 applies. Product types 1, 2, 3, 4, 8, 11 (Against Legionella only), 14 (obsolete), 18 and 19 are registered, but in different Departments.

- PT1, PT2 (use in hospital), PT19 in contact to the human skin: Spanish Agency of Medicines and Medical Devices
- PT3 (use in livestock, but not in contact with the animal skin) and PT18, 19 (use in livestock, but not in contact with the animal skin): Ministry of Agriculture, Fisheries and Food.
- PT 2 (no in Hospitals), 4, 8, 11 (against Legionella), 18 and 19 (other than abovementioned): Ministry of Health: General Directorate of Public Health, Quality and Innovation.

Link to Spanish Agency of Medicines and Medical Devices:
<https://www.aemps.gob.es/cosmeticos-y-cuidado-personal/cosmeticos/biocidas/>

Link to Ministry of Agriculture, Fisheries and Food:
<http://www.mapama.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/higiene-de-la-produccion-primaria-ganadera/registro-de-productos-zoosanitarios/>

Link to the Ministry of Health: General Directorate of Public Health, Quality and Innovation:
<https://www.mscbs.gob.es/ciudadanos/saludAmbLaboral/prodQuimicos/sustPreparatorias/biocidas/home.htm>

The rest of biocidal products of the Ps not mentioned before must be notified to the Ministry of Health, but they are not considered in this report, because they are not registered and not submitted to inspection, except in case of alert.
<https://www.mscbs.gob.es/ciudadanos/saludAmbLaboral/prodQuimicos/sustPreparatorias/biocidas/requisinotifica.htm>

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

Law 53/2002, on fiscal, administrative and social measures. Article 33.
Updated by Law 6/2018, on State's general budgets
<https://www.mscbs.gob.es/ciudadanos/saludAmbLaboral/prodQuimicos/sustPreparatorias/biocidas/tasasBiocidas.htm>
Note: The fees are adapted to the procedures under Directive 98/8. The fees have not been adapted to BPR yet.

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	119 556,12
Evaluation of an active substance for Annex I inclusion	119 556,12
Authorisation of a biocidal product (BP)	2.510,69
Authorisation of a BP family	2.510,69/each meta-SPC
Mutual recognition of an authorisation of a BP	1.195,56
Mutual recognition of an authorisation of a BP family	1.195,56/each meta-SPC
Union authorisation of a BP	2.510,69
Union authorisation of a BP family	2.510,69/each meta-SPC
Annual fee	-
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

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

Royal Decree 1054/2002, regulating the evaluation process for the registration, authorization and marketing of biocides. (articles 30 and 31)
<https://www.boe.es/buscar/act.php?id=BOE-A-2002-19923>
Note: Infringements and penalties are adapted to the procedures under Directive 98/8. They have not been adapted to BPR yet, but it is applicable in any case.

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

There is not specific regulation for treated articles, but Law 14/1986, General for Health, and Law 33/2011, General for Public Health, applies regarding general aspects like "non-compliance of current health regulations", or "non-compliance with the instructions received from the competent authority". This is applicable to treated articles.
<https://www.boe.es/buscar/act.php?id=BOE-A-1986-10499>
<https://www.boe.es/buscar/act.php?id=BOE-A-2011-15623>

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	29	31	5	23	35	54	177

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	6	1	2	9	6	14	38
Number of products authorised (conditions met for all or some of the uses)	0	6	1	2	9	6	14	38
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	1	3	1	0	5
Number of applications evaluated resulting in a granted authorisation without restrictions	0	0	0	1	2	0	0	3
Number of applications evaluated resulting in restrictions (Article 23(3))	0	0	0	0	1	1	0	2
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	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	15	115	7	137

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	289	36	325
Number of products authorised (conditions met for all or some of the uses)	0	0	0	0	0	289	36	325
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	289	36	325
Number of applications evaluated resulting in a granted authorisation without restrictions	0	0	0	0	0	289	36	325
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))								

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	3	3	10	17	12	5	50
Number of prohibitions	0	0	0	2	6	1	0	9

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)	113	365	551	648	547	565	401	3190
Main group 2 Preservatives (PT6 - PT13)	38	7	31	76	31	23	1	207
Main group 3 Pest control (PT14 - PT20)	259	144	222	223	131	123	141	1243
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

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

Surveillance and control of biocides is part of the Public Health activities of the National Health System, according to different rules (Law 14/1986, Law 16/2003 and Law 33/2011). These activities are performed by the competent authorities of 17 autonomous communities and two autonomous cities (ACs).

Each Autonomous community and city has their own strategy to achieve the goals. The coordination of some aspects of these actions is carried out in an Environmental Health WG of the Public Health Commission. They count on a software (e-room) to exchange informal discussions among authorities. The following link shows the webpage where relevant information coming from this WG is available:

<https://www.mscbs.gob.es/ciudadanos/saludAmbLaboral/prodQuimicos/sustPreparatorias/biocidas/submenuCCAA.htm>

The ACs have established its own programs for surveillance and control of the biocides market. In some of these communities the biocide program is integrated within a more generic chemical safety program, where compliance with REACH and CLP is also verified, while in others it is an independent one.

Additionally, the ACs manage the Official Registry of Biocide Establishments and Services (ROESB), which implies the inspection of the establishments registered in it. These establishments are those involved in manufacturing, packing, storing or applying biocides to third parties (Pest control services), of PT 2, 4, 8, 14, 18 y 19. The scope of this inspection varies among ACs.

<https://www.mscbs.gob.es/ciudadanos/saludAmbLaboral/prodQuimicos/sustPreparatorias/biocidas/ROESB.htm>

The framework legislation that creates this registry is national, but the ACs also have the capacity to develop their own regulations, establishing the details of the management of the ROESB. The ACs set out the frequency of the inspections, according with their own criteria regarding the priority or activity risk level.

Inspections can be scheduled, or as a result of complaints or alerts of the Rapid Information Exchange System for Chemicals (SIRIPQ).

The territorial management of surveillance programs within the ACs is the responsibility of each one of them. The territory is divided into Sanitary Districts, and these into Sanitary Areas.

Another related activity is participation in the European Biocide Projects, and training of inspectors.

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

In order to carry out the inspections, ACs count on their own Guidance, Protocols or Instructions, applied to the Official Control

Regarding making available on the market biocidal products, the activities carried out by the enforcement competent authorities include:

- Traceability and verification of compliance with Article 95 of the BPR, which is normally incorporated in the inspection of manufacturers.
- Information systems
- Conditions of the establishments
- Conditions of storage
- Management of hazardous waste
- Review of the classification, labeling and packaging of a selection of biocides
- Review of SDS
- Checking of the LOM (book in which operations of purchase and and sell of biocides classified in certain hazard categories are registered)
- Inspection after alerts (SIRIPQ), upon demand of the population and organizations. Also ICSM is a source of alerts

Regarding the use of biocides

- Control of the compliance of the registration conditions for biocides
- Verification of the training of personnel in Pest Control Services
- Surveillance of the Pest Control Plans (diagnosis, RMM, products used, periods for reentry...), in order to get a rational and safe use of biocides
- Checking of treatment certificates
- One AC declares to check the use of biocides also in other Inspections Programs (e.g. food hygiene, swimming pools or Legionella)

The frequency is different. Information provided by one Autonomous Community (AC) shows the following figures: CM Audits 15% of Pest Control Services, and inspects 70% of marketers, 40% of distributors and 40% of stores annually. Another AC set out four levels for the inspections: basic only check that a biocidal product is registered. Advanced includes inspection of establishment checking all the elements above mentioned

Regarding treated articles.

- Inspection after alerts (SIRIPQ), upon demand of the population and organizations.
- Participation in European Projects BEF-1, BEF-2 and REF-8

One AC also reports advertising control

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	<ul style="list-style-type: none"> • Galicia - Dirección General de Salud Pública de la Consellería de Sanidad (Santiago de Compostela). Jefatura Territorial de Sanidad en A Coruña. Jefatura Territorial de Sanidad en Lugo. Jefatura Territorial de Sanidad en Ourense. Jefatura Territorial de Sanidad en Pontevedra • Asturias • Cantabria - Dirección General de Salud Pública-Gobierno de Cantabria • País Vasco • Navarra • La Rioja - Dirección General de Salud Pública, Consumo y Cuidados. Gobierno de La Rioja. • Aragón • Cataluña • Comunidad Valenciana • Baleares • Murcia - Director General de Salud Pública y Adicciones • Andalucía - Dirección General de Salud Pública y Ordenación Farmacéutica de la Consejería de Salud y Familias. Servicio de Salud de las Delegaciones Territoriales de Salud y Familia. Distritos Sanitarios / Áreas de Gestión Sanitaria. • Cuerpo Superior Facultativo de Instituciones Sanitarias de la Junta de Andalucía. • Ceuta • Melilla • Canarias • Extremadura • Castilla – La Mancha • Castilla y León - Servicio de Sanidad Ambiental. • Dirección General de Salud Pública. Consejería de Sanidad. Junta de Castilla y León • Comunidad de Madrid - Dirección General de Salud Pública. Subdirección General de Higiene, Seguridad Alimentaria y Ambiental. 	Galicia - https://www.sergas.es/Saude-publica Asturias - Cantabria - País Vasco - Navarra - La Rioja - http://www.riojasalud.es/salud-publica-y-consumo Aragón - Cataluña - Comunidad Valenciana - Baleares - Murcia - https://www.murciasalud.es/pagina.php?id=236203&idsec=301 Andalucía - https://juntadeandalucia.es/organismos/saludyfamilias.html Ceuta Melilla Canarias - Extremadura - Castilla – La Mancha - Castilla y León - https://www.saludcastillayleon.es/profesionales/es/sanidadambiental/biocidas Comunidad de Madrid - http://www.comunidad.madrid/servicios/salud/salud-medio-ambiente
Controls on placing on the market of treated articles	Same competent authorities	Same website

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	46	44	48	74	73	55	390

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

As independent authorities, the ACs have not developed a common system to account for inspections and the non-compliance derived from them. This makes the task difficult, and the result shown in the table undervalues the actual data. The table shows the result of 3 ACs, which could recover the figures adapted to the template of this report.

Apart from that, 3 ACs have declared the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2013: 1190 NC 2013: 160
 Total 2014: 858 NC 2014: 68
 Total 2015: 812 NC 2015: 85
 Total 2016: 754 NC 2016: 103
 Total 2017: 624 NC 2017: 90
 Total 2018: 571 NC 2018: 74
 Total 2019: 619 NC 2019: 133

Additionally, other 6 ACs have only provided non-compliance figures, without specifying inspections, or only inspections, without non-compliance data. These data are available if needed.

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	65	23	81	21	57	21	45	3	56	20	114	23	42	9
MG 2 Preservatives	28	6	49	2	27	3	15	0	34	6	45	7	19	3
MG 3 Pest control	51	10	43	11	54	5	32	4	60	10	111	25	89	9
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	1	0	0	0	0	0

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

4 AC declare that they carry out inspections of manufacturers and marketers, checking the information required in article 68 of the BPR, but only 2 of them provide information per year. No detailed data per MG has been provided.

Total 2013: 19 NC 2013: 0
 Total 2014: 73 NC 2014: 2
 Total 2015: 52 NC 2015: 0
 Total 2016: 72 NC 2016: 0
 Total 2017: 52 NC 2017: 0
 Total 2018: 106 NC 2018: 1
 Total 2019: 72 NC 2019: 0

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))

The table below shows the result of 3 ACs, which could recover the figures adapted to the template of this report.
 Apart from that, 4 ACs have reported the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2013: 834	NC 2013: 90
Total 2014: 608	NC 2014: 47
Total 2015: 659	NC 2015: 48
Total 2016: 638	NC 2016: 79
Total 2017: 540	NC 2017: 64
Total 2018: 766	NC 2018: 85
Total 2019: 703	NC 2019: 126

Additionally, other 5 ACs have only provided non-compliance figures, without specifying inspections, or only inspections, without non-compliance data. These data are available if needed.

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	64	12	81	13	56	12	45	2	52	13	114	15	40	9
MG 2 Preservatives	28	3	49	2	27	3	15	0	26	4	42	5	14	1
MG 3 Pest control	50	4	45	6	47	2	33	2	55	4	109	22	81	2
MG 4 Other biocidal products	0	0	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))

The table below shows the result of 3 ACs, which could recover the figures adapted to the template of this report.
 Apart from that, 4 ACs have reported the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2013: 1107	NC 2013: 25
Total 2014: 910	NC 2014: 32
Total 2015: 898	NC 2015: 39
Total 2016: 824	NC 2016: 39
Total 2017: 713	NC 2017: 81
Total 2018: 768	NC 2018: 94
Total 2019: 760	NC 2019: 132

Additionally, other 5 ACs have only provided non-compliance figures, without specifying inspections, or only inspections, without non-compliance data. These data are available if needed.

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	65	9	81	11	56	11	45	1	53	10	114	14	40	9
MG 2 Preservatives	28	3	49	2	27	3	15	0	27	6	43	5	19	1
MG 3 Pest control	48	1	43	3	47	2	32	0	50	1	91	8	67	4
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

The table below shows the result of 3 ACs, which could recover the figures adapted to the template of this report. There is no distinction between biocidal products authorised under European procedures or under national procedures.
 Additionally, other 3 ACs have only provided non-compliance figures, without specifying inspections, or only inspections, without non-compliance data. These data are available if needed.

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	61	7	81	0	56	7	45	0	37	6	111	10	34	3
MG 2 Preservatives	28	1	49	0	27	2	15	0	9	2	36	1	8	0
MG 3 Pest control	37	0	43	1	47	0	30	0	26	0	63	3	25	1
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	40	0	85	0	44	7

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

3 ACs have reported the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2013:	1	NC 2013:	0
Total 2014:	0	NC 2014:	0
Total 2015:	60	NC 2015:	0
Total 2016:	1	NC 2016:	0
Total 2017:	41	NC 2017:	0
Total 2018:	90	NC 2018:	0
Total 2019:	46	NC 2019:	2

These data includes products under procedures of BPR and procedures under national scheme.

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)

The table below shows the result of 1 AC, which could recover the figures adapted to the template of this report.
2 ACs have reported the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2017:	40	NC 2017:	-
Total 2018:	89	NC 2018:	0
Total 2019:	44	NC 2019:	0

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	15	0	3	0	9	0	26	0						
MG 2 Preservatives														
MG 3 Pest control	1	0	1	0	40	0	28	0	61	0	39	0	10	0
MG 4 Other biocidal products														

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

Most of the ACs report that the point 4.4.1 Controls on the inclusion of active substances supplier in the official lists (article 95(2) of the BPR) have included these controls (national procedures)

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)

The table below shows the result of 3 ACs, which could recover the figures adapted to the template of this report. Apart from that, 2 ACs have reported the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2013: 524 NC 2013: 80
 Total 2014: 382 NC 2014: 91
 Total 2015: 480 NC 2015: 80
 Total 2016: 446 NC 2016: 57
 Total 2017: 439 NC 2017: 74
 Total 2018: 633 NC 2018: 105
 Total 2019: 535 NC 2019: 145

Additionally, other 2 ACs have only provided non-compliance figures, without specifying inspections, or only inspections, without non-compliance data. These data are available if needed.

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	64	7	81	11	56	13	45	2	37	10	111	14	136	45
MG 2 Preservatives	28	2	49	2	27	3	15	0	9	2	36	2	8	1
MG 3 Pest control	37	1	43	1	47	1	30	2	27	1	63	5	25	1
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

The table below shows the result of 1 AC, which could recover the figures adapted to the template of this report. Apart from that, 2 ACs have declared the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2013: 0 NC 2013: 0
 Total 2014: 0 NC 2014: 0
 Total 2015: 29 NC 2015: 0
 Total 2016: 47 NC 2016: 5
 Total 2017: 69 NC 2017: 4
 Total 2018: 90 NC 2018: 6
 Total 2019: 76 NC 2019: 10

Additionally, another AC reports to have done 7 inspections, but they are not detailed in MG or years.

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	0	0	0	0	0	0	0	0	0	0	1	1	2	0
MG 2 Preservatives	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MG 3 Pest control	0	0	0	0	0	0	0	0	0	0	1	0	0	0
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	0	0	0	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

The table below shows the result of 3 ACs, which could recover the figures adapted to the template of this report. Apart from that, 3 ACs have reported the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2013: 35 NC 2013: 3
 Total 2014: 101 NC 2014: 7
 Total 2015: 903 NC 2015: 332
 Total 2016: 1272 NC 2016: 364
 Total 2017: 1551 NC 2017: 478
 Total 2018: 1733 NC 2018: 408
 Total 2019: 1504 NC 2019: 397

Additionally, other 1 AC has provided number of inspections (227), without non-compliance data.

GP1: 2013: 15 // 2014: 3 // 2015: 9 // 2016: 20
 GP3: 2013: 1 // 2014: 1 // 2015: 40 // 2016: 28 // 2017: 61 // 2018: 39 // 2019: 10

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	36	4	57	8	54	9	34	1	33	6	100	10	45	10
MG 2 Preservatives	10	1	32	2	26	3	14	0	9	2	33	1	8	0
MG 3 Pest control	28	0	46	0	49	0	33	0	30	0	65	3	27	1
MG 4 Other biocidal products	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

There is not a specific program on residue levels of biocidal active substances in food and feed.
There is a residue levels program in food coordinated by the Spanish Agency of Food Safety and Nutrition, but it is focused in PP residues.

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)

Almost all the controls concerning treated articles have been carried out within the European Project BEF-1.
The table below shows the result of 1 AC, that could recover the figures adapted to the template of this report.
Apart from that, 3 ACs have declared the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2019: 30 NC 2019: 1
Additionally, 1 AC declare to have done inspections to a Paint Company

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													10	2
MG 2 Preservatives													32	11
MG 3 Pest control													8	4
MG 4 Other biocidal products														

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

All the controls concerning labelling of treated articles have been carried out within the European Project BEF-1.
The table below shows the result of 3 AC, that could recover the figures adapted to the template of this report.
Apart from that, 1 AC has reported the total number of controls and non-compliance per year, without distinction among MG, resulting in the following data:

Total 2019: 11 NC 2019: 7

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													10	2
MG 2 Preservatives													68	30
MG 3 Pest control													12	6
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)

The Spanish Poison Center (Spanish-PC) as the Spanish Antitoxic Center receives medical consultations about poisoning and exposures to toxic substances by telephone. The consultations are attended by medical experts in Toxicology who provide toxicological information, for the purpose of prevention, diagnosis and treatment of poisoning, to the person who makes the consultation, be it health personnel or individuals without specific health training.

The doctors who attend the consultations do not have face-to-face contact with the patient at any time, so they cannot directly assess the changes caused, nor confirm the data provided. All intoxication assessment is carried out based on the data provided by telephone by the information requestor.

The classification of the type of product involved in poisoning is established based on the data provided by the information requester (BP, PPP, ...).

The doctor attending the consultation makes an estimate of the severity of the poisoning, according to the following classification:

- Probably asymptomatic intoxication: According to the data provided by the requesting information, either because the product is low toxic and / or the amount to which it has been exposed is small, the appearance of symptoms in the intoxicated person is not expected.
- Probably mild poisoning: When it is estimated, based on the data provided, that certain symptoms may appear as a consequence of exposure to the toxin, although this will be mild and transitory.
- Probably moderate poisoning: When the doctor who receives the consultation, considers that it could manifest symptoms of a moderate nature.
- Probably serious poisoning: When the symptoms that may appear, the life of the intoxicated person can be affected.

There is no category such as "Fatal/Near Fatal", so we can only provide in this field the Poisonings evaluated as "Probably serious", always based on the information sent by the requestor of the information, at the time of making consultation to the Spanish-PC.

Having said that, the Spanish-PC of the National Institute of Toxicology and Forensic Sciences (Ministry of Justice), has provided the data shown in the table and next.

Other consultations attended where biocides are involved but that cannot be considered in the table are the following:

2017 Fatal/Near fatal: 5 Others: 115
2018 Fatal/Near fatal: 6 Others: 132
2019 Fatal/Near fatal: 5 Others: 78

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									64	3645	39	3419	41	3740
MG 2 Preservatives									6	139	0	49	0	45
MG 3 Pest control									44	2717	36	2679	24	2102
MG 4 Other biocidal products									0	0	0	0	0	0

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	1	5	1	13	12	6	16
Total number of enquiries per year	27	180	332	670	930	1035	1251

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

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	Spanish Standard	UNE-EN 171210 -Good practices in Disinfection, Desinsection and Rat Extermination Plans	2, 3, 4, 14, 18, 19	2008
2	European Standard	EN 16636 2015 -Pest Management Services. Requirements and competences	2, 3, 4, 14, 18, 19	2015
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	2, 3, 4, 11, 14, 18, 19	Professional qualification Management for the control of harmful organisms (510 h)	2007
2	2, 3, 4, 14, 18, 19	Professional qualification Pest Control Services (360 h)	2004
3	11	Professional qualification hygienic-sanitary maintenance of facilities susceptible to proliferation of harmful microorganisms and their spread by aerosolization (270 h)	2010

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	Information in the webpage of CCAA		
2			
3			
4			

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

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

	Type of measure	Year	Area covered	Details
1	Information in the webpage of CCAA			
2				
3				
4				

8. Nanomaterials

Please provide information regarding the use of nanomaterials in biocidal products (Articles 19 and 69 of the BPR), per main group of product-types

MG 1 Disinfectants

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

MG 2 Preservatives

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

MG 3 Pest control

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

MG 4 Other biocidal products

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

9. Any other comment

Contact

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