

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) |
|------|----------------------------------------------|---------------|---------------------|
| | Pesticide Registration and Control Divisions | | |

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 - PRCD Pesticide Registration & Control Divisions under Department of Agriculture, Food & the Marine.

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 | PRCD | https://www.pcs.agriculture.gov.ie/biocides/activesubstances/ |
| Advice to applicants/helpdesks on biocidal products | PRCD | https://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/ |
| Advice to applicants/helpdesks on treated articles | PRCD | https://www.pcs.agriculture.gov.ie/biocides/treatedarticles/ |

| | | |
|------------------------------------------------------------------------------------------------------------------------------------------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment of active substances | PRCD | https://www.pcs.agriculture.gov.ie/biocides/activesubstances/approvalofactivesubstances/ |
| Assessment and authorisation of biocidal products | PRCD | https://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/authorisationapplications/ |
| Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation) | PRCD | https://www.pcs.agriculture.gov.ie |

1.3.3. Other bodies involved in the implementation of the BPR

| | Authority/organisation involved | Website |
|----------------------|-------------------------------------|---------------------------------------------------------------|
| Poison centre | National Poisons Information Centre | https://www.poisons.ie/ |
| Animal poison centre | | |
| Other | 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.

S.I. No. 427/2013 - European Union (Biocidal Products) Regulations 2013.

<http://www.irishstatutebook.ie/eli/2013/si/427/made/en/print>

<https://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/nationalnotificationapplications/>

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

S.I. No. 427/2013 - European Union (Biocidal Products) Regulations 2013.

<https://www.pcs.agriculture.gov.ie/media/pesticides/content/biocides/Biocide%20Fees%20Effective%20From%202001-03-2019.pdf>

2.2.1. Fee amounts

Please provide information on the applicable fees for the procedures listed in the table below

| | Fee amount |
|---------------------------------------------------------|------------------------------------------------|
| Evaluation of an active substance for approval | €315,000 |
| Evaluation of an active substance for Annex I inclusion | €55,000 |
| Authorisation of a biocidal product (BP) | €20,000 |
| Authorisation of a BP family | €40,000 |
| Mutual recognition of an authorisation of a BP | €2,500 |
| Mutual recognition of an authorisation of a BP family | €5,000 |
| Union authorisation of a BP | €75,000 |
| Union authorisation of a BP family | €150,000 |
| Annual fee | €225 Professional product €125 Amateur Product |
| Other (please specify) | 2019 revision. |

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

Do you have specific national measures or legislation favouring SMEs?

- Yes
 No

Please specify below the national regulation(s) and refer to the corresponding link of the relevant website with the requested information. If available in English please include the link to the English version

| | | | | | | | | |
|--------------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|---|
| 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 | 1 | 0 | 0 | 42 | 2 | 45 |
| Number of products authorised (conditions met for all or some of the uses) | 0 | 0 | 1 | 0 | 0 | 42 | 2 | 45 |
| 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 | 3 | 0 | 0 | 0 | 0 | 0 | 3 |
| Permits granted | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 3 |
| 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 | 2 | 0 | 0 | 0 | 0 | 0 | 2 |
| 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) | Figures not available for pre 2015. | Figures not available for pre 2015. | 2329 | 2523 | 2359 | 2882 | 3205 | 13298 |
| Main group 2 Preservatives (PT6 - PT13) | Figures not available for pre 2015. | Figures not available for pre 2015. | 352 | 399 | 400 | 490 | 490 | 2131 |
| Main group 3 Pest control (PT14 - PT20) | Figures not available for pre 2015. | Figures not available for pre 2015. | 426 | 393 | 353 | 380 | 374 | 1926 |
| Main group 4 Other biocidal products (PT21 - PT22) | Figures not available for pre 2015. | Figures not available for pre 2015. | 219 | 226 | 215 | 315 | 311 | 1286 |

4. Information on enforcement activities

4.1. BPR enforcement strategy

Has an overall strategy been implemented in the Member State for the enforcement of the BPR?

- Yes
 No

4.2. Control system in the Member States and results of official controls

Please give a brief overview of the way official controls are carried out in your Member State, with special emphasis on the following processes:

- making available on the market of biocidal products;

| | | | | | | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| 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)

After the date of approval of the last active substance contained in a product, no further national registrations will be granted. Following publication of the approval regulation, applicants wishing to continue marketing existing products on the market are requested to demonstrate compliance with the regulation. (i.e. A R4BP3 case number is requested from the applicant to show the product is being supported). If no R4BP3 case number is returned by the company then the National notified product is revoked.

If detailed figures are available please provide them in the table below

Controls to ensure that the biocidal products on the market contain active substances included in the review programme - Total number of controls per year and non-compliances (NC) identified

| | Total 2013 | NC 2013 | Total 2014 | NC 2014 | Total 2015 | NC 2015 | Total 2016 | NC 2016 | Total 2017 | NC 2017 | Total 2018 | NC 2018 | Total 2019 | NC 2019 |
|------------------------------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|
| MG 1 Disinfectants | | | | | | | | | | | | | | |
| MG 2 Preservatives | | | | | | | | | | | | | | |
| MG 3 Pest control | | | | | | | | | | | | | | |
| MG 4 Other biocidal products | | | | | | | | | | | | | | |

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

All products registered under national measures must provide proof of compliance with Article 95(2) (i.e. letter of supply from an Article 95 source or letter of access) before been granted permission to make the biocidal product available on the Irish market. To allow the product remain on the market following approval of the active substance, applicants must provide evidence of access to the dossier.

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)

Routine inspections are carried out each year on wholesalers and retailers in relation to the making available on the market of biocides. Product labels are checked for active substance content and general conformity with our official biocidal product registers.

If detailed figures are available please provide them in the table below

Controls on compliance of the biocidal products made available with national legislation - Total number of controls per year and non-compliances (NC) identified

| | Total 2013 | NC 2013 | Total 2014 | NC 2014 | Total 2015 | NC 2015 | Total 2016 | NC 2016 | Total 2017 | NC 2017 | Total 2018 | NC 2018 | Total 2019 | NC 2019 |
|------------------------------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|
| MG 1 Disinfectants | | | | | | | | | | | | | | |
| MG 2 Preservatives | | | | | | | | | | | | | | |
| MG 3 Pest control | | | | | | | | | | | | | | |
| MG 4 Other biocidal products | | | | | | | | | | | | | | |

4.4.3. Official controls on manufacturers

- **Controls regarding the availability of the appropriate documentation in relation to the manufacturing process**, as indicated in article 65 (2) of the BPR

None to date. Procedures to be developed as part of overall enforcement programme.

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

In 2019 we participated in the Biocides en Force 1 project. 5 paper based and physical inspections conducted on all elements related to treated articles.

If detailed figures are available please provide them in the table below

Controls on the correct labelling of the treated articles - Total number of controls per year and non-compliances (NC) identified

| | Total 2013 | NC 2013 | Total 2014 | NC 2014 | Total 2015 | NC 2015 | Total 2016 | NC 2016 | Total 2017 | NC 2017 | Total 2018 | NC 2018 | Total 2019 | NC 2019 |
|------------------------------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|
| MG 1 Disinfectants | | | | | | | | | | | | | | |
| MG 2 Preservatives | | | | | | | | | | | | | 5 | 3 |
| MG 3 Pest control | | | | | | | | | | | | | | |
| MG 4 Other biocidal products | | | | | | | | | | | | | | |

5. Poisoning incidents

5.1. Poisonings involving biocidal products, severity of the impact

Please provide below an overview of the information reported since the entry into operation of BPR on poisoning incidents involving biocidal products, indicating the active substances and product-types most frequently involved and those involved in incidents resulting in severe health impairments or death (fatal or near fatal incidents)

No data available pre 2017
 2017: 96 incidents reported with no fatalities. 8 incidences reported as minor, 1 as moderate and 2 as severe. Main route of exposure was through ingestion and PT 14 products were the most commonly reported followed by PT18 and PT 19
 2018: 74 incidents reported with no fatalities. 16 incidences reported as minor, 2 as moderate and none as severe. Main route of exposure was through ingestion and PT 14 products were the most commonly reported followed by PT18 and PT 19
 2019: figures not yet available.

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 | 0 | 0 | 0 | | |
| MG 2 Preservatives | | | | | | | | | 0 | 2 | 0 | 0 | | |
| MG 3 Pest control | | | | | | | | | 0 | 94 | 0 | 74 | | |
| MG 4 Other biocidal products | | | | | | | | | 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 | | | | | | | |
| Total number of enquiries per year | 1290 | 1430 | 1000 | 1500 | 1820 | 2010 | 2100 |

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

Most of the Irish companies placing biocides on the Irish market are SMEs. PRCD help by holding Symposiums and publish presentations on our websites to explain processes to SMEs. Latest was 12/03/2020 on legislation and national requirements.
<https://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/prcindustrySYMPOSIUMonbiocidalproducts2020/>

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 | Guidance document | Permanent baiting rules | 14 | 2019 |
| 2 | Guidance document | CRRU Ireland Best Practice requirements | 14 | 2016 |
| 3 | Guidance document | CRRU Rodent Control on farms | 14 | 2016 |

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 |
|---|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | PT 14 Rodenticides | Level 2 award in pest management services (or equivalent) for the use of trained professional use Rodenticides |
| 2 | PT 14 Rodenticides | Lantra Level 3 award in Pest Management services (or equivalent)) for the use of trained professional use Rodenticides https://www.pcs.agriculture.gov.ie/biocides/changestouseofanticoagulantrodenticides/requirementsforregistrationasapestmanagementtrainedp |
| 3 | | |

7.3. Information to the public

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

- Yes
 No

7.4. Measures to address the risk related to the use of biocidal products

Have measures been taken to address the risks related to the use of biocidal products in specific areas such as schools, workplaces, kindergartens or public spaces?

- Yes
 No

8. Nanomaterials

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

MG 1 Disinfectants

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

| | | | | | |
|---|--|--|--|--|--|
| 4 | | | | | |
|---|--|--|--|--|--|

MG 2 Preservatives

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

MG 3 Pest control

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

MG 4 Other biocidal products

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

9. Any other comment

Contact

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