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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]	Ministry of Infrastructure and Water Management	[redacted]	[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.

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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	Board for the Authorisation of Plant Protection Products and Biocides	www.ctgb.nl
Advice to applicants/helpdesks on biocidal products	Board for the Authorisation of Plant Protection Products and Biocides	www.ctgb.nl

Advice to applicants/helpdesks on treated articles	National Institute for Public Health and the Environment	https://rvs.rivm.nl/helpdesk/helpdesk-risicos-van-stoffen
Assessment of active substances	Board for the Authorisation of Plant Protection Products and Biocides	www.ctgb.nl
Assessment and authorisation of biocidal products	Board for the Authorisation of Plant Protection Products and Biocides	www.ctgb.nl
Other (e.g. authority in charge of setting up the whole organisational framework for the BPR implementation, of adopting national legislation)		

1.3.3. Other bodies involved in the implementation of the BPR

	Authority/organisation involved	Website
Poison centre	Dutch Poison Control Centre Nationaal-Vergiftigingen-Informatie-Centrum-(NVIC)	https://www.umcutrecht.nl/nl/Subsites/Nationaal-Vergiftigingen-Informatie-Centrum-(NVIC) https://www.vergiftigingen.info
Animal poison centre	Dutch Poison Control Centre Nationaal-Vergiftigingen-Informatie-Centrum-(NVIC)	https://www.umcutrecht.nl/nl/Subsites/Nationaal-Vergiftigingen-Informatie-Centrum-(NVIC) https://www.vergiftigingen.info
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.

The national laws are laid down in the 'Wet, besluit en regeling gewasbeschermingsmiddelen en biociden' and 'Regeling Uitzonderin g Bestrijdingsmiddelen'.
During the transitional period, biocidal products can only be made available on the market if they have an authorization given by the Board for the Authorisation of Plant Protection Products and Biocides. Only a few exemptions have been included in national l aw, being 1) in situ generated Ozone, 2) in situ generated active chlorine from NaCl and three other specific biocidal uses as in cluded in the 'Regeling Uitzondering Bestrijdingsmiddelen'

In the Netherlands, there is a regulatory system for many years. Biocidal products are assessed according to our national assessm ent procedures (which are very similar to the BPR procedures). Authorisations according to our national law can only be granted f or products based on active substances that are included in the review programme, as long as the approval date of that active sub stance has not passed yet.

At the moment an active substance has a positive opinion from the BPC, authorisation holders of products based on that active sub stance are informed about the obligation to apply for 're-registration' according to the BPR. At the date of approval, it is chec ked in R4BP whether or not an application for re-registration was received. In case an application was received before the date o f approval, the authorisation holder is allowed to keep the product on the market after the approval date, awaiting the outcome o f the assessment according to the BPR, also when this takes longer than three years due to delay of the assessment procedures. As soon as the BPR procedures are finalised, the BPR-authorisation replaces the authorisation under national law. At that moment, th e authorisation number under the national system (12345N) is replaced by the R4BP asset number (NL-1234567-0000).
If no application for re-registration is received via R4BP before the date of approval, the national authorisation is cancelled w ith a period of grace indicated in article 89.

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

https://english.ctgb.nl/about-ctgb/fees-and-charges
https://english.ctgb.nl/about-ctgb/documents/decrees/2019/01/03/tariffs-decree-2019
https://english.ctgb.nl/about-ctgb/documents/decrees/2018/01/11/tariffs-decree-2018
https://english.ctgb.nl/about-ctgb/documents/decrees/2017/01/05/tariffs-decree-2017
https://english.ctgb.nl/about-ctgb/documents/decrees/2015/12/22/tariffs-decree-2016

Of all authorisation holders in the Netherlands between 90 and 95% is a SME. Therefore special arrangements for SME's will in practice be regular arrangements that apply for all applicants/authorisation holders.

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	Application fee of €15,000 and actual costs incurred with advance payment of €200,000 for average evaluation. Additionally actual costs incurred with advance payment of €75,000 for the activities to complete the application
Evaluation of an active substance for Annex I inclusion	Application fee of €15,000 and actual costs incurred with advance payment of €100,000 for average evaluation. Additionally actual costs incurred with advance payment of €75,000 for the activities to complete the application
Authorisation of a biocidal product (BP)	Actual costs incurred with advance payment of €45,000
Authorisation of a BP family	Actual costs incurred with advance payment of €75,000
Mutual recognition of an authorisation of a BP	€8,024
Mutual recognition of an authorisation of a BP family	€11,560
Union authorisation of a BP	Actual costs incurred with advance payment of €70,000
Union authorisation of a BP family	Actual costs incurred with advance payment of €100,000
Annual fee	€1,220 €1,030 for biocidal product family and €200 per family member
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

The enforcement on infringements of the BPR has been regulated in art 43 of the "Wet Gewasbeschermingsmiddelen en Biociden".

https://wetten.overheid.nl/BWBR0021670/2019-01-01#Hoofdstuk5

In the Netherlands we first give an official warning with a reasonable grace-period for the unauthorized biocidal product on the market or other infringements as incorrect and incomplete labeling.
If this has no effect then we scale up to a penalty (this is regulated in the national law Regeling gewasbeschermingsmiddelen en biociden). In case the unauthorized biocide placed in the market is a consumer product we do not give an official warning, but a penalty is given directly.
Or we give a recovery sanction (this is regulated in the national law de Algemene wet bestuursrecht) under administrative law or even to a penalty under criminal law (this is regulated in the national law Wet Economische Delicten). These sanctions are intended to end or prevent its recurrence in the future violation.

2.5. Imported treated articles

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

- ○ Yes
- ◉ No

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

3.1. Authorisation procedures

3.1.1. Authorisations

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

3.1.1.a. National authorisations

	2013	2014	2015	2016	2017	2018	2019	Total number
Authorisations granted on the basis of Article 19(5)	0	10	2	5	4	6	3	30
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	4	4	3	6	10	18	3	48
Number of products authorised (conditions met for all or some of the uses)								
Number of products not authorised (conditions not met for any of the uses)								

3.1.1.d. Comparative assessments (Article 23)

	2013	2014	2015	2016	2017	2018	2019	Total number
Total number of applications evaluated	3	4	3	6	0	7	1	24
Number of applications evaluated resulting in a granted authorisation without restrictions	3	4	3	6	0	7	1	24
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	50	1	51
Provisional authorisations granted for products containing new active substances (Article 55(2))	na	na	na	na	na	na	na	na

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	52	1	53
Number of products authorised (conditions met for all or some of the uses)								
Number of products not authorised (conditions not met for any of the uses)								

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	52	1	53
Number of applications evaluated resulting in a granted authorisation without restrictions	0	0	0	0	0	52	0	52
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	3	6	5	3	4	5	5	31
Permits granted	3	6	5	3	3	3	3	26
Permits not granted	0	0	0	0	1	2	2	5

3.2.b. Research and development (Article 56)

	2013	2014	2015	2016	2017	2018	2019	Total number
Number of notifications received	0	11	21	19	19	10	16	96
Number of prohibitions	0	0	0	0	2	0	1	3

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)	584	777	822	849	870	915	885	
Main group 2 Preservatives (PT6 - PT13)	280	278	279	285	289	306	312	
Main group 3 Pest control (PT14 - PT20)	180	174	163	148	124	124	137	
Main group 4 Other biocidal products (PT21 - PT22)	43	45	45	46	47	49	47	

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

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ILT
Inspectorate Human Environment and Transport (ILT): Some general information about the enforcement strategy can be found on: http
s://www.ilent.nl/over-ilt/handhaving-en-toezicht/interventie.
A specific ILT enforcement-strategy document for only biocides, will be available after 2021.

NVWA
The Netherlands Food and Consumer Product Safety Authority (NVWA): General enforcement strategy:
https://www.nvwa.nl/over-de-nvwa/hoe-de-nvwa-werkt/toezicht-maatregelen-en-boetes/interventiebeleid/algemeen-interventiebeleid
Specific enforcement strategy for consumer products (including biocides):
https://www.nvwa.nl/over-de-nvwa/documenten/export/veterinair/ks-documenten/interventiebeleid/specifiek-interventiebeleid-product
veiligheid
In 2021 an enforcement strategy for all biocidal products controlled by the NVWA will be published.
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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

ILT
Each year the ILT carries out official controls on one or two PT groups and also controls a number of authorization holders established in the Netherlands. The Inspectorate examines whether the company concerned only makes available authorised biocidal products on the market. The Inspectorate also examines on correct and complete labelling of the biocides and proper advertising of biocidal products, the keeping of proper records according to national law and whether companies comply with article 95 BPR.

Regarding monitoring the users of biocidal products we monitor if the use corresponds with the requirements of the national authorization decision. The ILT also monitors on treated articles for professional use including E-commerce of treated articles.
For more detailed information see the EU report of the Fact Finding Mission of June 2018.

NVWA
The NVWA carries out controls on agricultural production, veterinary and imports, food, feed and catering industry, and consumer product safety. Biocide controls are included as part of the controls where relevant or in specific projects.

The NVWA is responsible for the enforcement of the biocides for consumers. The main focus is on the following PT-groups: PT1, PT 2, PT9, PT18, PT19 and PT21. The activities are divided in projects (risk-based) and in handling of complaints. Part of the projects is sampling of the biocides (or treated articles) and the chemical analysis of the biocidal substances (quality and quantity) and control of labelling. As regards the complaints, most of them are related to unauthorized biocides. In most cases field inspections will take place.

The NVWA carries out risk based controls on all approved, registered and simple cleaning and disinfection places for the cleaning and disinfection of trucks, used for the transport of animals. Due to the outbreak of African Swine Fever (ASF) in Belgium an extra project was launched in 2018 to pay more attention to cleaning and disinfection of trucks. During these controls also samples of the used disinfectants, biocides of product type 3 (PT-3), were checked on their composition and labelling.

The NVWA monitors the use of professional biocides at food business operators that carry out primary production. During regular or project based inspections inspectors can take measures when they observe an infringement of the law on biocides. In 2017 and 2018 targeted inspections were carried out at poultry farms during the fipronil incident; in 2019 inspections were carried out at broiler farms because of an incident with an unauthorized disinfecting bedding powder. So far, NVWA does not carry out specific projects targeted on the use of biocides by food business operators.

Monitoring of biocides during inspections at catering and artisanal production companies takes place by taking chemical samples. If biocides are misused in food production, samples are taken that are tested in the laboratory to determine whether there is residue of the relevant biocide in the food and in what amount.

The NVWA carries out controls in the industrial food/feed production.

In addition to the ILT and the NVWA, there are the following inspectorates in the field of biocides:
• The Inspectorate SZW (for fair, healthy and safe working conditions and socio-economic security for everyone) supervises professional and industrial end users for the benefit of employees' health. See https://www.inspectorateszw.nl/
• The Health and Youth Care Inspectorate (IGJ) oversees the use of biocides in hospitals and health care institutions. See https://english.igj.nl/
• Water authorities oversees water-related applications and / or violations of plant protection products and biocides. See https://www.uvw.nl/
• The State Supervision of Mines (SodM), has general authority for supervision and enforcement at the extraction and transport activities of minerals. See https://www.sodm.nl/

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	The Inspectorate Human Environment and Transport (ILT) The Netherlands Food and Consumer Product Safety Authority (NVWA).	https://www.ilent.nl/ https://www.nvwa nl/
Controls on placing on the market of treated articles	The Inspectorate Human Environment and Transport (ILT) The Netherlands Food and Consumer Product Safety Authority (NVWA).	https://www.ilent.nl/ https://www.nvwa nl/

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	79	121	111	100	115	105	113	744

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**

```
ILT
Over the period from 2013 to 2019 3309 inspections/controls have been registered.
The ILT recalled in total 515 biocidal products without authorisation from the Dutch market in this period.

NVWA
Over the period from 2013 to 2019 NVWA have carried out 739 inspections/controls.
Due to the coronavirus outbreak there was not time enough to gather all data.

Inspections on consumer products focus on making available on the market and advertisement of illegal biocides (and treated artic
les) and correct composition and labelling of authorized biocides and treated articles. The use of biocides in tattoo shops is al
so controlled.
Inspections are carried out as a targeted project, in response of complaints and as part of inspections on other subjects. The gi
ven number of inspections is a total of the targeted biocide project and complaint inspections and the number of other inspection
s were a non-compliance with biocidal law has been observed. Non-compliances are total of measures taken at all inspections and/o
r as a result of non-compliant sample(s) of biocides. Results given below can be specified in some cases.
Inspections in all other fields focus on the use of illegal biocides or the misuse of legal biocides (section 4.4.4). Only few in
spections are intended to control the making available on the market of biocides. Most of the inspections are in response to comp
laints or as part of other inspection visits. Only few projects targeted on use of biocides have been carried out. Measures are m
ostly taken during inspections and for some projects as a result of non-compliant samples.

Number of inspections NVWA- consumer products/ nr. Non-compliances
2013: 81/56; 2014: 141/63; 2015: 126/51; 2016: 53/22; 2017: 151/78; 2018:104/47; 2019: 83/49

Number of inspections NVWA – agriculture / non-compliances
2013: -; 2014: xx/1; 2015: xx/2; 2016: xx/4; 2017: 0; 2018: xx/2; 2019: xx/6;

Explanation NVWA results: when number of inspections is “xx”, it means that inspections are carried out to control on other subje
cts and that during these inspections non-compliant biocides are found. These inspections are not targeted on biocides.
During inspections at wholesalers targeted at plant protection products, in total 15 non-compliant biocides  were found (agricult
ure).
```

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

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

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ILT
No controls by ILT

NVWA
No controls by NVWA
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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														
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))

ILT
Over the period from 2014 to 2015 89 inspections/controls have been registered. Over the period from 2016 to 2019 153 inspections/controls have been registered.

NVWA
In 2017 a project was dedicated to PT01 desinfectants. The labelling of 22 authorized samples was checked: 15 were non-compliant an 6 had minor deviations. Most deviations were observed for missing Hazard and Precautionary measures labelling and wrong user instructions.

Incidently labels of authorized biocides that are sampled as reality checks of inspections of quality systems of companies that sell or produce consumer products are checked, 2013:2 NC; 2014: 3 NC; 2015: 3 NC; 2016: 3 NC; 2017: 5 NC (NC = Non Compliance)

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

Controls on classification, packaging and labelling of biocidal products - Total number of controls per year and non-compliances (NC) identified

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

- **Controls on safety data sheets** (article 70 of the BPR, and article 31 of Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH))

ILT
Over the period from 2014 to 2015 58 inspections/controls have been registered. Over the period from 2016 to 2019 45 inspections/controls have been registered.

NVWA
This is part of inspections dedicated to REACH; inspection data on art 70 of BPR not available.

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

Controls on safety data sheets - Total number of controls per year and non-compliances (NC) identified

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

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

ILT
Over the period from 2015 to 2019 64 inspections/controls have been registered.

NVWA
NVWA did not carry out inspections to check compliance with art 72 of the BPR. NVWA inspects the advertisement of illegal biocides, which is national legislation. These results are part of the results given in the first question of this section (table with results)

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

Controls on advertisment of biocidal products - Total number of controls per year and non-compliances (NC) identified

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

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

```
ILT
We cannot provide accurate numbers, Over the period from 2016 to 2019 9 inspections/controls have been registered. In practice mo
re controls have been carried out on this subject but this has not been registered as such.

NVWA
No inspections have been carried out.
```

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)

```
Is this the same question as 4.4.1 bullet-point 1?

ILT
Over the period from 2013 to 2019 3309 inspections/controls have been registered. Always a check on article 89 (2) BPR.

NVWA
Over the period from 2013 up to and including July 2019 the NVWA have carried out 815 inspections/controls. There is always a che
ck on article 89 (2) of BPR.
```

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)

```
Is this the same question as 4.4.1 bullet-point 6?

ILT
We cannot provide accurate numbers. Over the period from 2016 to 2019 9 inspections/controls have been registered. In practice mo
re controls have been carried out on this subject but this has not been registered as such.

NVWA
No inspections have been carried out.
```

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)

```
ILT
The ILT registration system does not distinguish between BPR-controls and national controls.
So over the period from 2013 to 2019  3309 inspections/controls have been registered.
The ILT recalled in total 505 biocidal products without authorisation from the Dutch market in this period.

NVWA
The NVWA registration system does not distinguish between BPR-controls and national controls
```

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

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ILT
No controls by ILT

NVWA
No controls by NVWA
```

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

Controls regarding the availability of the appropriate documentation related to the manufacturing process - Total number of controls per year and non-compliances (NC) identified

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

4.4.4. Official controls on end-users and residues

- **Controls regarding the use of the biocidal products according to the terms and conditions of the authorisation**, as stipulated in article 17(5) of the BPR

ILT
Over the period from 2014 to 2015 86 inspections/controls have been registered. Over the period from 2016 to 2019 159 inspections/controls have been registered.
Specific on the subject ‘rodenticides PT 14’ the ILT carried out over the period from 2017 to 2019 106 inspections/controls.

NVWA
Inspections focus on the use of illegal biocides or the misuse of legal biocides. Most of the inspections are in response to complaints (possible illegal use) or as part of other inspection visits. Only few projects targeted on use of biocides have been carried out. Measures are mostly taken during inspections and for some projects as a result of non-compliant samples.
Inspections in food- and feed production locations, such as hygiene inspections, (200-600 inspections each year) and agriculture (ca 500 administrative inspections Cross-Compliance each year): biocide control may be part of the inspections.

Targeted projects:
In 2013 471 catering and artisanal production locations were inspected on the use of biocides. 2 inspections were reported as non-compliant.

In 2017 at 31 of 332 cleaning &disinfection places for animal transport samples of disinfecting solutions were taken (PT03). 17 places were non-compliant. 78 samples of disinfecting solutions were analysed: 42 were non-compliant.

In 2018, 991 controls were carried out at 323 cleaning &disinfection places. 371 samples were taken, of which 195 were non-compliant.

In 2014-2019 the hygiene inspections at tattoo/piercingshops, with one of the focuspoints the biocides. The most non-compliances are in the use of biocides - 21% in 2014, 56% in 2015, 46% in 2016, 73% in 2017, 44% in 2018 and 39% in 2019. The increase of non-compliances in 2017 can be declared in the more detailed enforcement.

Inspections at farms (agriculture): In 2017, 56 of 63 inspections were at poultry farms due to the fipronil incident (illegal biocide). 43 of 56 inspections were non-compliant. In 2018, these numbers are 15 and 14, respectively. In 2018, 295 inspections were at flowerbulb growers, of which 10 were non-compliant (misuse of biocides for plant protection purposes); 10 other inspections on the use of biocides, of which 5 were non- compliant. In 2019, 26 inspections were at poultry farms due to an incident with an illegal biocide (bedding powder). All of them were non-compliant. 16 other inspections were found non-compliant on the use of biocides.

Inspections animal transport:
2017: 31/17 means 31 sample locations of which 17 locations are non-compliant; 78/42 means: 78 samples of which 42 are non-compliant.
2018: 371 samples of which 197 are non-compliant (195 wrong dilution; 2 use of illegal biocide).
2019: 2 samples of biocidal products were not compliant (wrong label and used after expiry date).

Water authorities
During the period 2013 to 2019, the water authorities’ inspections focused for biocides specifically on marinas (antifouling) and sports grounds (combating algae on artificial grass pitches). There are no figures available for the inspections of most of the water authorities (there are 21 water authorities in the Netherlands). For the inspections it was checked whether authorized products were used and if the instructions for use were followed.

Inspectorate SZW (for fair, healthy and safe working conditions and socio-economic security for everyone)
ISZW did not conduct any inspections specifically on the biocidal product regulation during the 2013-2019 period.

Health and Youth Care Inspectorate (IGJ)
IGJ has thematic supervision mainly with a focus on infection prevention. The supervision looked at the use of disinfectants, regardless of whether this is a biocide or a medical device (disinfectant with CE making).
Total of inspections / year: 2013:73; 2014:50; 2015:55; 2106:34; 2017:84; 2018:34; 2019:78

State Supervision of Mines (SodM)
SodM did not conduct any inspections specifically on the biocidal product regulation during the 2013-2019 period.

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

Controls regarding the use of the biocidal products according to the terms and conditions of the authorisation - Total number of controls per year and non-compliances (NC) identified

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

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

NVWA carries out controls on residues of biocides in food and feed. In food the main reason of sampling is the control Pt04 desinfectants (e.g, quats) in icecream, cream, and chopped meat products during general inspections. Also baby food is checked. Results on residues are reported yearly to EFSA.

Benzalkonium chloride (BKC) and didecyldimethylammonium chloride (DDAC) are used as biocides for disinfection. Their use can lead to detectable residues in food. Chlorate can occur, as a by-product when using chlorinated biocidal products for disinfection purposes. NVWA monitores these substances in products like baby food, infant formula, vegetables and fish. In 2018 app. 185 samples were tested of which 10 samples were found to be higher than legally allowed.

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)

ILT
Over the period from 2014 to 2015 ILT carried out 69 inspections/controls.
Over the period from 2016 to 2018 ILT carried out 5 inspections/controls.
Over the period from 2019 to 2020 ILT carried out 20 inspections/controls.

NVWA
Within the projects of 2015; information provided on active substances were checked on the label.
In 2016 information of active substances on labels was checked (36 samples) and the active substances were analysed in the laboratory (13 of 36 samples).

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

Controls concerning the active substance(s) present in the treated articles - Total number of controls per year and non-compliances (NC) identified

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

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

ILT
Over the period from 2014 to 2015 ILT carried out 1 inspection/control.
Over the period from 2016 to 2018 ILT carried out 4 inspections/controls.
In 2019 ILT carried out 20 inspections/controls. These inspections were carried out under the flag of the first European enforcement project BEF-1 TA.

NVWA
In 2015 68 treated articles (liquids, glues, paints and sealants) were sampled and checked on correct labelling (no measures)
In 2016 36 treated articles (textiles) were sampled and checked on correct labelling (1 measure, active substance not allowed).
In 2019 NVWA carried out 12 inspections/controls. These inspections were carried out under the flag of the first European enforcement project BEF-1 TA, together with ILT.

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

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

	Total 2013	NC 2013	Total 2014	NC 2014	Total 2015	NC 2015	Total 2016	NC 2016	Total 2017	NC 2017	Total 2018	NC 2018	Total 2019	NC 2019
MG 1 Disinfectants														

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

5. Poisoning incidents

5.1. Poisonings involving biocidal products, severity of the impact

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

The Dutch Poison Control Centre (NVIC) has among other tasks, the legal task to register and report poisoning incidents with chemical substances. The NVIC database contains reported incidents by medical en veterinary professionals.

This concerns reports on acute exposures from the private environment and reports of acute industrial accidents. About 2% of the total number of exposures to people comes from industrial accidents.

Incidents resulting in severe health impairments or death (fatal or near fatal incidents):

In 2018 en in 2019 the NVIC has informed the Ctgb regarding specific severe incidents regarding algae control and burnt oral mucosa of cats and alpha chloralosis and acute neurotoxicological manifestations in dogs.
Regarding algae control (active ingredient - Quaternairy ammonium compounds) Ctgb prescribed additional measures in the summer of 2018 to limit exposure to cats.
Regarding alfachloralose, Ctgb prohibited refill packs of products based on alfachloralose in 2019 for private use.

In 2019, one incident regarding phosphine treated cargo resulted in a severe poisoning incident involving two persons on board of an inland navigation vessel transporting animal fodder. The animal fodder came from a seagoing vessel with phosphide pills in the animal fodder. These pills were not removed; they were not in a sleeve or other measure that would have allowed for easy removal. Phosphine concentrations were initially monitored on board of the seagoing vessel and found below the limit value. However, the pills reactivated after the animal fodder was transferred from the seagoing vessel to the inland navigation vessel. Details on the incident can be found here: https://www.portofamsterdam.com/sites/poa/files/media/pdf-nl/onderzoekscommissie_-_fosfine_incident_met_mvs_fox_definitief.pdf

Incidents reported for disinfectants in the table below are from: General surface disinfectants, fungi control, specific disinfection (swimming pools, water beds, water tanks, water pipelines), algae control and skin disinfection. No distinction has been made between severe and minor incidents.

Incidents reported for pest control in the table below are from: rodenticides, ant control, repellents (insects) and moth control.No distinction has been made between severe and minor incidents.

Specification of incidents reported in 2018 regarding groups (animal, or age group human) for which most incidents were reported.
PT14 Rodenticides; total = 657, animals = 460, < 4 yr = 131
PT18 Ant control; total = 316, animals = 157, < 4 yr = 123
PT01 skin disinfectants; total = 100, < 4 yr = 55
PT19 Repellants (insects); total = 153, < 4 yr = 110
PT02 fungi control; total = 150, 18- 65 yr = 110
PT02 general; total = 197, < 4 yr = 96, 18-65 yr = 62
PT02 algae; total = 100, animals = 46

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		**516**		**565**		**634**		**622**		**606**		**695**		**677**
MG 2 Preservatives														
MG 3 Pest control		**861**		**863**		**880**		**1003**		**985**		**1186**		**1167**
MG 4 Other biocidal products														

6. Helpdesk functioning

Please fill in in the following table the information regarding the number of enquiries that Helpdesks receive per year.

Note: if your system does not differentiate the queries according to their topic (active substances, biocidal products, treated articles) please indicate the total number of queries per year in the last row.

	2013	2014	2015	2016	2017	2018	2019

Number of enquiries on active substances	no separate data, see for BP						
Number of enquiries on biocidal products	769	740	778	992	941	898	768
Number of enquiries on treated articles	-	10	12	13	11	7	7
Total number of enquiries per year	769	750	790	1005	952	905	775

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	Description of IPM for control of rats outside	"BEHEERSING VAN RATTENPOPULATIES OM GEBOUWEN EN VOEDSELOPSLAGPLAATSEN" https //kpmb.nl/KPMB/media/KPMB/Documenten/IPM%20Rattenbeheersing/20160222-KPMB-Handboek-beheersing-rattenpopulaties-buiten-gebouwen-Versie-2-0.pdf	PT14	2016
2	Milieucentraal information on sustainable use of biocides, prevention and non-chemical alternatives for non professional use.	https //www.milieucentraal.nl/in-en-om-het-huis/ongediertebestrijding/		
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	PT14, PT18, PT19 and PT8	Professional competence requirements for pest control the control of fungi in wood and for using fumigation gasses are described in the national law Only professional users with an education, examination and a certificate are allowed to perform these tasks. The use of methylbromide, sulfurylfluoride and phosphine is subject to a notification obligation.	
2	All	Although the KennisNetwerk Biociden (Biocides Knowledge network) is not a training scheme, the network is used to increase and exchange knowledge about biocides, see https //www.kennisnetwerkbiociden.nl/	
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

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	website		Website Milieu Centraal https //www.milieucentraal.nl/over-milieu-centraal/
2	website		Website Waar zit wat in https //waarzitwatin.nl/
3	website		Website Risico's van stoffen https //rvs.rivm.nl/
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	hygiene guidelines for many different sectors			https //www.rivm.nl/hygienerichtlijnen
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	Oropharma Mite-Killer / Luxan Bloedluisspray / U-5 Bloedluisspray / Edialux For- Bug Plus / Cimicidex Spray / Itec Special Mite	Synthetisch amorf siliciumdioxide (nano)	The active substance is a nano material as already recognised in the active substance dossier.	yes	2019 NL-0018553-0000
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

3.1.1. Authorisations
The numbers requested are about applications under the BPR, however art 19(5) and 55(2) are about authorisations. Therefor we gave the numbers for authorisations. The total number of assessments is about the number of decisions (to authorise and to reject).

3.1.1.b. Mutual recognitions - concerned Member State
As far as applications for mutual recognition are concerned, applicants know or are informed by Ctgb which national specific elements are identified in the Netherlands. In order to meet these elements many applicants agree to change their application accordingly.The list of national specific elements is a living document and can be altered in the coming years. See https://english.ctgb.nl/biocidal-products/documents/assessment-framework-biocides/2019/06/01/nl-specific-aspects-em3.2

3.1.1.c. Authorisations of products containing active substances meeting exclusion criteria (Article 5.2)
Condition(s) met / Condition(s) not met
It is not clear which conditions are meant. The conditions of art 5.2 are not applicable for products.

3.1.2.a. National authorisations
Provisional authorisations granted for products containing new active substances (Article 55(2))
It is our understanding that this category does not exist (renewal of a provisional authorisation)

6. Helpdesk functioning
It was not possible to distinguish between Helpdesk questions referring to the BPR and Helpdesk questions referring to national law. In 2018 an estimated half of the questions refereed to the BPR.
As indicted also in the section on fees, 90 - 95% of the authorisation holders in the Netherlands is SME. Therefore special arrangements for SME’s will in practice be regular arrangements that apply for all applicants/authorisation holders.

Contact

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