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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
- ○ taly
- ○ 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)
		The Ministry of Economy of the Slovak republic	[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	Dpt. Center for Chemical Substances and Preparations, The Ministry of Economy of the Slovak republic	https //www.mhsr sk/obchod/centrum-pre-chemicke-latky-a-pripravky/biocidy/uvod
Advice to applicants/helpdesks on biocidal products	Dpt. Center for Chemical Substances and Preparations, The Ministry of Economy of the Slovak republic	https //www.mhsr sk/obchod/centrum-pre-chemicke-latky-a-pripravky/biocidy/uvod
Advice to applicants/helpdesks on treated articles	Dpt. Center for Chemical Substances and Preparations, The Ministry of Economy of the Slovak republic	https //www.mhsr sk/obchod/centrum-pre-chemicke-latky-a-pripravky/biocidy/uvod

Assessment of active substances	Dpt. Center for Chemical Substances and Preparations, The Ministry of Economy of the Slovak republic	https://www mhsr.sk/obchod/centrum-pre-chemicke-latky-a-pripravky/biocidy/uvod
Assessment and authorisation of biocidal products	Dpt. Center for Chemical Substances and Preparations, The Ministry of Economy of the Slovak republic	https://www mhsr.sk/obchod/centrum-pre-chemicke-latky-a-pripravky/biocidy/uvod
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	National Toxicological Information Center	http://ntic.sk/ntic_en php
Animal poison centre	State Veterinary and Food Administration of the Slovak Republic, dpt. Animal Health and Welfare Department	https //www.svps.sk/english/
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.

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Art. 20 item 2 Act No. 319/2013 Coll. on competencies of national administrative authorities for the making available on the market
and use of biocidal products and on amendment and supplement of certain Acts (Biocides Act) as amended
( https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/319/20180301# )
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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

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Art. 14 item 1 Act No. 319/2013 Coll. on competencies of national administrative authorities for the making available on the market
and use of bio¬ci¬dal products and on amendment and supplement of certain Acts (Biocides Act) as amended ( https://www.slov-lex.sk/
pravne-predpisy/SK/ZZ/2013/319/20180301# )

Administrative Fees: Item 153a of the Annex of the Act No. 145/1995 Coll. Tariff of Administrative Fees as amanded
( https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/1995/145/20190401 )

Expert Services Fees: Ordinance of the Government of the Slovak Republic No. 340/2013 Coll. laying down the object, required partic
ulars and tariffs applicable to payments and annual fees for the making available on the market and use of biocidal products
( https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/340/20131101 )
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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	• Administrative fee = 2.000 € per application • Validation fee = 35 000 € for 1 PT • Validation fee = 9.000 € for each further PT • Evaluation fee = 170.000 € for 1 PT • Evaluation fee = 50 000 € each further PT • Total fee for 1 PT = 207.000 €
Evaluation of an active substance for Annex I inclusion	
Authorisation of a biocidal product (BP)	• Administrative fee = 750 € per application • Validation fee = 3.000 € for 1 PT • Validation fee = 600 € for each further PT • Evaluation fee = 70 000 € for 1 PT • Evaluation fee = 10.000 € for each further PT • Minimum total fee for 1 BP = 73.750 € • Comparative assessment + 50% of the validation and evaluation fee
Authorisation of a BP family	• Administrative fee = 1.250 € per application • Validation fee = 10 000 € per application • Evaluation fee = 150.000 € per application • Total fee for 1 BPF = 161.250 € • Comparative assessment + 50% of the evaluation fee

Mutual recognition of an authorisation of a BP	Individual BP - Mutual recognition in sequence: • Administrative fee = 500 € per application • Evaluation fee = 6.000 € per application • Total fee for mutual recognition in sequence for 1 BP=6.500 € Individual BP - Mutual recognition in parallel: • Administrative fee= 500 € per application • Evaluation fee: 7.000 € per application • Total fee for mutual recognition in parallel for 1 BP: 7500 €
Mutual recognition of an authorisation of a BP family	BP Family - Mutual recognition in sequence: • Administrative fee= 750 € per application • Evaluation fee= 8 000 € per application • Total fee for mutual recognition in sequence for 1 BPF= 8.750 € BP Family- Mutual recognition in parallel: • Administrative fee = 750 € per application • Evaluation fee: 9.000 € per application • Total fee for mutual recognition in parallel for 1 BPF: 9.750 €
Union authorisation of a BP	Individual BP: • Administrative fee = 1.000 € per application • Validation fee = 3 000 € for 1 PT • Validation fee = 600 € for each further PT • Evaluation fee = 70.000 € for 1 PT • Evaluation fee = 10 000 € for each further PT • Minimum Total fee for 1 BP = 73.750 €
Union authorisation of a BP family	BP Family: • Administrative fee = 1.500 € per application • Validation fee = 10.000 € per application • Evaluation fee = 150 000 € per application • Total fee for 1 BPF = 161.250 €
Annual fee	• BP under transitional measures: 150 € • BP authorised under MR and same biocidal products relating thereto: 300 € • BPF authorised under MR and same biocidal product family relating thereto 450 € • BP under parallel trade: 200 €
Other (please specify)	N/A

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

Do you have specific national measures or legislation favouring SMEs?

- ○ Yes
- ◉ No

2.4. Non-compliance and penalties

Do you have specific national measures or legislation concerning non-compliance and penalties applicable for infringements on the implementation of the BPR?

- ◉ Yes
- ○ No

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

Art. 16 item 1 letter c), d) and e) in accordance with Art. 17 and Art. 18 Act No. 319/2013 Coll. on competencies of national administrative authorities for the making available on the market and use of bio¬ci¬dal products and on amendment and supplement of certain Acts (Biocides Act) as amended
(https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/319/20180301#)

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	0	0	0	0	0
Provisional authorisations granted for products containing new active substances (Article 55(2))			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

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								45
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	1	12	16
Number of applications evaluated resulting in a granted authorisation without restrictions								
Number of applications evaluated resulting in restrictions (Article 23(3))								
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
Provisional authorisations granted for products containing new active substances (Article 55(2))			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

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								39
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						2		2
Number of applications evaluated resulting in a granted authorisation without restrictions								
Number of applications evaluated resulting in restrictions (Article 23(3))								
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
Permits granted			0	0	0	0	0	0
Permits not granted			0	0	0	0	0	0

3.2.b. Research and development (Article 56)

	2013	2014	2015	2016	2017	2018	2019	Total number
Number of notifications received			0	0	0	0	0	0
Number of prohibitions			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)			134	104	216	144	195	793
Main group 2 Preservatives (PT6 - PT13)			55	54	93	67	50	319
Main group 3 Pest control (PT14 - PT20)			38	38	68	50	42	236

Main group 4 Other biocidal products (PT21 - PT22)			0	0	37	13	0	50

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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Every enforcement authority has its specific strategy covering the enforcement activities within the Slovak Republic. The BPR enfor
cement strategies are designed to ensure the achievement and maintaining of the high standards of compliance with BPR Regulation. S
TI BPR enforcement strategy is not publicly available.
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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

AD: Making available on the market of biocidal products and Placing on the market of treated articles:
The Ministry of Economy of the Slovak Republic (MoE) is competent in this area.
The MoE decides on the regulation of the BPR, the national Acts: Biocides Act and proceeds procedurally in accordance with the Administrative Act.

AD: Processes use of biocidal products/treated articles:
the Ministry of Health of the Slovak Republic submits :
- information to the MoE if, during the performance of state health supervision according to a special national Act (§ 54 of Act no. 355/2007 Coll. on the protection, promotion and development of public health and on the amendment of certain laws, as amended) it finds a possible risk from biocidal products and active substances or treated products from the point of view of health protection;.
- to the MoE a summary report on cases of poisoning by biocidal products to the MoE by 31 March each year. (§ 7 of Act no. 319/2013 Coll. on competencies of national administrative authorities for the making available on the market and use of biocidal products and on amendment and supplement of certain Acts as amended (hereinafter only "Biocides Act") (https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/319/20180301#)

the Slovak Trade Inspection (under the MoE):
- when controlling the sale and provision of services to consumers according to a special regulation36) controls compliance with the conditions for making biocidal products and treated products available on the market according to a special Act (art.17 item 1, art. 52, 58, 69 a 72 regulation EÚ no. 528/2012);
- decides on measures to address shortcomings in the availability of biocidal products on the internal market in matters of consumer protection;
- orders the withdrawal of a biocidal product from the market and the disposal of a dangerous biocidal product that does not meet the requirements of a special Act, at the expense of their owner, or the holder, if the owner is not known, and imposes fines.
(§ 8 of Biocides Act) (https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/319/20180301#)

the Slovak Enviromental Inspectorate (under the Ministry of Enviroment of the Slovak Republic):
- provides supervision over the use of a biocidal product which has been authorized by the MoE pursuant to a special Act on the basis of a binding opinion of the Ministry of the Environment;
- imposes corrective measures according to § 15 par. 6 Act. no. 319/2013 Coll. in case of violation of special Act (art. 55 and 56 regulation EU no. 528/2012), if there is a risk of environmental damage, or if it has already occurred, it may order the disposal of the biocidal product and active substances or treated product at the expense of their owner, or the holder if the owner is not known, and imposes fines.
(§ 9 of Biocides Act) (https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/319/20180301#)

the National Labour Inspectorate (under the Ministry of Labour, Social Affairs and Family of the Slovak Republic):
- submits information to the MoE if, during a labor inspection according to a special Act it finds a possible risk from biocidal products and active substances or treated products from the point of view of safety and health protection at work
(§ 10 of Biocides Act) (https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/319/20180301#)

the Veterinary and Food Administration (under the Ministry of Agriculture and Rural Development of the Slovak Republic):
- in case it is found that a biocidal product which has been authorized according to a special Act (regulation EU no. 528/2012) poses a serious immediate or long-term risk to animal health, it shall request in writing the Ministry of Agriculture and Rural Development to take an appropriate temporary measure pursuant to § 6 item 1 letter c) Biocides Act and informs the MoE in writing form of this fact,
- submits information to the MoE if, during an inspection pursuant to a special Act it finds a possible risk from the biocidal product and active substances to animals
- provides supervision over the use of a biocidal product which has been authorized by the MoE pursuant to a special Act (art. 55 regulation EU no. 528/2012) on the basis of a binding opinion of the Ministry of Agriculture and Rural Development
(§ 11 of Biocides Act) (https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/319/20180301#)

Customs authorities
(§ 12 of Biocides Act) (https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2013/319/20180301#)

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 Ministry of Health of the Slovak Republic the Slovak Trade Inspection (under the Ministry of Economy of the Slovak Republic) the Slovak Enviromental Inspectorate (under the Ministry of Enviroment of the Slovak Republic) the National Labour Inspectorate (under the Ministry of Labour, Social Affairs and Family of the Slovak Republic) the Veterinary and Food Administration (under the Ministry of Agriculture and Rural Development of the Slovak Republic) Customs authorities	https://www.health.gov.sk/Index aspx https://www soi.sk/en/SOI.soi https://www.sizp.sk/slovak-environmental-inspectorate/about-us https://www.ip gov.sk/labour-inspection/?ip= https://www svps.sk/english/ https://www.financnasprava.sk/en/businesses/customs-duty
Controls on placing on the market of treated articles	the Ministry of Health of the Slovak Republic the Slovak Trade Inspection (under the Ministry of Economy of the Slovak Republic) the Slovak Enviromental Inspectorate (under the Ministry of Enviroment of the Slovak Republic) the National Labour Inspectorate (under the Ministry of Labour, Social Affairs and Family of the Slovak Republic) the Veterinary and Food Administration (under the Ministry of Agriculture and Rural Development of the Slovak Republic) Customs authorities	https://www.health.gov.sk/Index aspx https://www soi.sk/en/SOI.soi https://www.sizp.sk/slovak-environmental-inspectorate/about-us https://www.ip gov.sk/labour-inspection/?ip= https://www svps.sk/english/ https://www.financnasprava.sk/en/businesses/customs-duty

4.3.1. Complaints

Have there been complaints (information about suspected infringements of the BPR rules) received by enforcement authorities in relation to the implementation of the BPR?

	2013	2014	2015	2016	2017	2018	2019	Total number
Number of complaints			1	4	11	6	2	24

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**

Slovak Trade Inspection:
2015 - 119 controls (controls were carried out at 24 manufacurers and 71 distributors and another 65 controls were carried out in warehouses and retail stores) / 432 species of biocidal products (hereinafter "BP") were inspected / 33 illegal products made available on the market means that 33 species of BP were - (7,64 %);

2016 - 1 control action (was caried out at 10 manufacturers and 35 distributors) and another 28 controls were carried out in wholesale and retail stores) / from 212 species of BP 11 species were placed on the market without being registered in the national BP register (5,19 %) and 4 species of BP by distributors did not submit to Inspectors registration or authorization from the Center for Chemical Substances and Preparations (hereinafter "CCHSP") and/or the decision of the Center for Chemical Substances and Preparations (1,89 %) / 15 illegal products made available on the market (7,08 %);

2017 - 111 controls (75 controls were carried out at 9 manufacurers and 28 distributors and another 36 controls were carried out in warehouses and retail stores) / 289 species of BP were inspected / 7 species of BP were placed on the market without being entered in the national BP register (2,42 %) and 1 species of BP was placed on the market without being entered in the national BP register and/or without an authorization decision from the CCHSP (0,04 %);

2018 - 102 controls (controls were carried out at 8 manufacurers and 25 distributors and another 34 controls were carried out in warehouses and retail stores) / 160 species of BP were inspected / 17 species of BP were placed on the market without being entered in the national BP register (10,63 %);

In 2019 - No controls was carried out for BP. In this year were controls only detergens.

The numbers in the text do not have to match the numbers in the table, because the numbers in the text are only numbers for controls of the STI initiated itself, numbers of ex offo controls.
The numbers in the table are the numbers, including the incentives to carry out the inspection.

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					151	72	88	31	136	31	109	34	30	8
MG 2 Preservatives					82	16	48	3	54	5	31	5	43	2
MG 3 Pest control					113	55	56	9	69	3	38	11	5	1
MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

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

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					80	3	40	4	75	1	35	0	22	0
MG 2 Preservatives					26	0	19	0	29	0	17	0	3	0
MG 3 Pest control					60	1	28	1	54	0	1	0	1	0
MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

- **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 Slovak Trade Inspection

In 2015
From 432 types of the inspected BP, 48 types (11,11 %) were found deficiencies in labeling. The most serious shortcoming was the la ck of information on the label in the state language.
Other shortcomings were:
• missing information on the active substance and its concentration in metric units,
• missing identification data of the marketer,
• missing information on direct or indirect side effects and first aid instructions,
• missing production batch number, date consumption,
• unspecified time required for biocidal effect,
• missing instructions for safe disposal of the biocidal product and its packaging, including a ban on re-use of packaging,
• missing warning "read the enclosed instructions for use before use",
• 1 of the BP (rodent control bait against rats and mice) was packed in a plastic package with a zipper "zip - on". Such packaging is not sufficiently safe and does not meet the requirement for a clearly differentiated packaging from that normally used for food and feed; in addition, the hazardous mixture may leak and endanger or damage human or animal health.

In 2016
From 212 types of the inspected BP, 14 types (6,60 %) were found deficiencies in labeling. The most serious shortcoming was the lac k of information on the label in the state language.
Other shortcomings were:
• missing registration number,
• incorrect registration number,
• missing instructions for safe use and disposal of BP and its packaging, including a ban on re-use of packaging,
• declaration of biocidal effect on the label, the product does not contain active substance,
• biocidal products are were on offer to the consumer after the expiry date.ň
During the inspection controllers did not find any deficiencies in the packaging of the inspected biocidal products.

In 2017
From 289 species of the inspected BP, 22 species were found to be deficient in labeling (7,61 %). The most serious shortcomings wer e the missing information on the label in the state language (not stated at all or not in the codified form of the Slovak language) such as:
- unspecified description of BV effect,
- missing instructions for safe health use and disposal of BP and its packaging, including ban on reuse.
Other deficiencies in the labeling were:
- missing registration number,
- incorrect, non-existent and / or incomplete registration number labeling and
- failure to indicate the active substance.
Another shortcoming was found in violation of § 7 and § 8 of Act no. 250/2007 on consumer protection and on the amendment of the Ac t of the Slovak National Council no. 372/1990 Coll. on offenses as amended. The disinfectant whitening effect has been declared on the label BP, but the dangerous ingredient is not an active substance of BP and thus the entrepreneur has committed deceptive pract ices and unfair commercial practices.
During the inspection, the inspectors did not find any deficiencies in the packaging of the inspected biocidal products.

In 2018
From 160 species of inspected BP, 18 species were found to be deficient in labeling (11,25%). The most serious shortcomings were th e lack of information on the label in the state language, such as warnings, signal words, method of use, instructions for health an d safe use. Another common shortcoming in the labeling was the missing registration number. The indication of the number / batch of the biocidal product and the expiry date under normal storage conditions were also checked. 1 biocidal product was identified in th e consumer offer after the expiry date.

Controls of biocidal product packaging checked:
- the safety of packaging to prevent leakage of a dangerous substance or mixture and to endanger or damage human health or the envi ronment,
- packaging to be clearly different from packaging normally used for food, feed, drinking water and medicines, - the packaging must not be tempting in shape or such as to mislead the consumer or arouse the curiosity of children,
- the packaging of toxic, extremely flammable, highly flammable, harmful and corrosive substances and mixtures must be accompanied by a tactile warning of: Danger to visually impaired and blind people and to toxic and corrosive substances and mixtures in additio n to child-resistant closures.
No deficiencies were found in the packaging of the controlled biocidal products during the controls..

In 2019 - No controls was carried out for BP. In this year were controls only detergens.

The numbers in the text do not have to match the numbers in the table, because the numbers in the text are only numbers for control s of the STI initiated itself, numbers of ex offo controls.
The numbers in the table are the numbers, including the incentives to carry out the inspection.

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					130	16	85	23	93	12	96	25	22	0
MG 2 Preservatives					68	5	47	18	54	6	30	5	27	1
MG 3 Pest control					109	14	41	5	69	4	35	3	5	0
MG 4 Other biocidal products					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 Biocidal Act obliges the entrepreneur to prepare a SDS for each biocidal product that contains chemical substances and mixtures classified as hazardous. The entrepreneur is obliged to provide these SDS to the National Toxicological Information Center and to each customer of the biocidal product (except the consumer) at the latest with the first delivery, so that the recipient can take effective measures to protect life, human health and the environment.

the Slovak Trade Inspection

In 2015
Of the 188 safety data sheets (hereinafter referred to as "SDS") inspected for 15 types of products, entrepreneurs did not have an SDS prepared (7,98 %). These SDS were sent to the National Toxicology Information Center as well as to the recipients of biocidal products only after their elaboration. Deficiencies were found in the content of the SDS in 4 cases (0,09 %), when the classifications of the components of the mixture were not given according to regulation REACH.

In 2016
Of the 152 SDS inspected for 5 types of biocidal products, entrepreneurs did not have an SDS prepared (3.3%) during the inspection. These SDS were sent to the National Toxicology Information Center as well as to the recipients of biocidal products only after their elaboration. No deficiencies were identified from the content page of the SDS.

In 2017
Of the 164 SDS inspected, 5 types of BP (3.05 %) had deficiencies in the SDS for chemicals and mixtures classified as hazardous. These BP did not meet the requirement of the Slovak Chemical Act no. 67/2010 Coll. to send them to customers and the National Toxicological Information Center (NTIC), as well as to provide them in a codified form of the state language. From the content page, no deficiencies were found in the audited SDS. An incorrect final classification was not found during the controls.

In 2018
OF the 96 SDS were checked. For 2 types of BP, entrepreneurs did not submit / had not prepared the SDS during the first control (2,08 %). The obligation to provide it to the National Toxicological Information Center as well as to the recipients of biocidal products in the codified form of the state language was fulfilled in the submitted SDS. From the content point of view, no deficiencies were found in the submitted and controled SDS. From the content page, no deficiencies were found in the controled SDS. The correct classification of the mixture was checked in each case. An incorrect final classification was not found during the controls.

In 2019 - No controls was carried out for BP. In this year were controls only detergens.

The numbers in the text do not have to match the numbers in the table, because the numbers in the text are only numbers for controls of the STI initiated itself, numbers of ex offo controls.
The numbers in the table are the numbers, including the incentives to carry out the inspection.

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					11	7	75	10	131	8	63	13	8	0
MG 2 Preservatives					39	0	31	0	43	0	10	11	26	0
MG 3 Pest control					81	2	46	2	72	0	16	10	5	0
MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

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

the Slovak Trade Inspection

In 2015
From the inspected promotional materials in 32 cases, a missing warning according to the regulation was found.

In 2016
From the inspected promotional materials of biocidal products on the website and on the advertising leaflets, a missing warning according to the Regulation was found in 9 cases. For example, when advertising a biocidal product, the leaflet did not contain a warning in the sense of the regulation: "Use biocides safely. Always read the label and product information before use. "

In 2017
During the controls of advertising and promotional materials of BP in 3 cases (1.04 %) a missing warning according to the BPR regulation was found. During the controls, the inspectors did not find any violations of the conditions of sale of biocidal products classified as dangerous.

In 2018
When advertising a biocidal product, the trader must always state in accordance with Article 72 of the BPR: "Use biocides safely. Always read the label and product information before use. ". These phrases must be clearly distinguishable from other parts of the advertisement and legible. Advertisements for biocidal products shall not present the product in a way that is misleading as to the risks to the human health, animal health or the environment or its efficacy. Promotional and advertising materials must not contain the following information: "low-risk biocidal product", "non-toxic", "harmless", "natural", "environmentally friendly", "animal friendly" or any other similar labeling. In 16 cases (10 %) of the controlled promotional materials of biocidal products on websites and on leaflets, missing warnings under the BPR.

In 2019 - No controls was carried out for BP. In this year were controls only detergens.

The numbers in the text do not have to match the numbers in the table, because the numbers in the text are only numbers for controls of the STI initiated itself, numbers of ex offo controls.
The numbers in the table are the numbers, including the incentives to carry out the inspection.

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					113	60	64	20	102	7	68	13	5	8
MG 2 Preservatives					46	14	32	3	40	0	29	2	7	0
MG 3 Pest control					71	45	26	9	99	0	11	8	5	0
MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

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

the Slovak Trade Inspection
2015 - Out of 119 inspections, it was found that no biocidal products containing active substances which will not be evaluated and which are subject to a marketing ban under the BPR regulation. Only 4 types of products BP from 432 species of BP were identified after the deadline specified by the regulation for their sale, as entrepreneurs did not apply for their authorization (0,09 %).

2016 - By the control action and another 28 controls was found that no biocidal products containing active substances which will not be evaluated and which are subject to a marketing ban under the BPR regulation.

2017 - Entrepreneurs who made BP available on the market in breach of the said legislation were called upon to remedy the shortcomings. The Slovak Trade Inspection enabled the controled persons to take voluntary measures to suspend the sale / distribution of BV and / or to withdraw such a product from sale or from the market until the identified deficiencies were remedied. Only after the voluntary measures were not taken and the deficiencies were remedied, measures to ban sales / supply / distribution were issued. Sanctions under the Slovak law were imposed for repeated violations and administrative proceedings were initiated.

2018 - The Biocidal Act requires the entrepreneur to place only authorized biocidal products on the market. During the inspection, no deficiency was found in relation to the authorization.

2019 - No controls was carried out for BP. In this year were controls only detergens.

The numbers in the text do not have to match the numbers in the table, because the numbers in the text are only numbers for controls of the STI initiated itself, numbers of ex offo controls.
The numbers in the table are the numbers, including the incentives to carry out the inspection.

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					840	0	43	0	81	0	27	110	011	0
MG 2 Preservatives					20	0	12	0	23	0	3	0	2	0
MG 3 Pest control					53	0	21	0	49	0	3	0	2	0

MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

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)

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					115	4	63	0	122	0	64	4	20	0
MG 2 Preservatives					43	0	32	0	45	0	23	0	28	0
MG 3 Pest control					69	1	34	0	70	0	20	0	5	0
MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

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

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					105	0	56	0	108	7	40	0	11	0
MG 2 Preservatives					25	0	20	0	38	0	6	0	6	0
MG 3 Pest control					53	1	24	0	62	0	9	0	5	0
MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

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

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

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

	Total 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					52	7	84	8	133	9	91	21	13	0
MG 2 Preservatives					82	3	46	0	53	10	28	3	26	2
MG 3 Pest control					107	12	41	0	70	0	32	3	5	0
MG 4 Other biocidal products					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

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					1	1	5	N/A	2	N/A	2	N/A	N/A	N/A
MG 2 Preservatives					N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 3 Pest control					N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MG 4 Other biocidal products					N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

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					20	5	38	10	29	5	54	19	3	0
MG 2 Preservatives					31	2	18	0	10	0	10	0	15	0
MG 3 Pest control					45	5	15	1	3	1	18	2	0	0
MG 4 Other biocidal products					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)**

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					0	0	0	0	1	0	2	0	1	0
PT 4					0	0	0	0	1	0	2	0	1	0
PT 18					18	3	0	0	2	1	2	0	0	0
PT 19					1	0	17	3	40	0	4	2	0	0
PT 21					0	0	0	0	0	0	0	0	0	0

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)

```
The Slovak Trade Inspection Authority performed an inspection focused on treated articles only in 2019.

It inspected 69 types of treated articles. No breach was found in this area and no shortcomings were identified.
```

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					0	0	0	0	0	0	0	0	19	0
MG 2 Preservatives					0	0	0	0	0	0	0	0	59	4
MG 3 Pest control					0	0	0	0	0	0	0	0	0	0
MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

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

```
The Slovak Trade Inspection Authority performed an inspection focused on ttreated articles only in 2019.

It inspected 69 types of treated articles and only 2 were found to be in breach - the product was not labeled in accordance with Ar
ticle 58 of the regulation of BPR.
Measures were issued for these 2 types of treated articles to eliminate the identified deficiency.
```

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					0	0	0	0	0	0	0	0	19	0
MG 2 Preservatives					0	0	0	0	0	0	0	0	59	0
MG 3 Pest control					0	0	0	0	0	0	0	0	0	0
MG 4 Other biocidal products					0	0	0	0	0	0	0	0	0	0

5. Poisoning incidents

5.1. Poisonings involving biocidal products, severity of the impact

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

Severity levels:
grade 0 - no signs of intoxication
grade 1 - mild intoxication with mild symptoms
grade 2 - moderate intoxication, more severe or persistent signs of intoxication
grade 3 - severe intoxication
grade 4 - death due to intoxication.

2015
BP poisoning during the period from April 1, 2015 to March 31, 2016.

Severity levels:
level 1: 98 people
level 2: 7
level 3: 0
level 4: 0

Insecticides: 10
organophosphorus: 5
good with name Bochemit (fungicide / insecticide): 5

Rodenticide: 1

Disinfectants: 94
based on chlorine: 63
other: 31

2016
BP poisoning during the period from April 1, 2016 to March 20, 2017.

Severity levels:
level 1: 111 people
level 2: 2
level 3: 0
level 4: 0

Insecticides: 10
organophosphorus: 6
good with name Bochemit (fungicide / insecticide): 4

Rodenticide: 1

Disinfectants: 102
based on chlorine: 59
other: 43

2017
BP poisoning during the period from April 1, 2017 to March 31, 2018.

Severity levels:
level 1: 92 people
level 2: 4
level 3: 1
level 4: 0

Insecticides: 14
organophosphorus: 6
pyrethroids: 2

Fungicide: 3
Rodenticide: 3

Disinfectants: 83
based on chlorine: 57
other: 26

2018
BP poisoning during the period from April 1, 2018 to March 31, 2019.

Severity levels:
level 1: 63 people
level 2: 4
level 3: 0
level 4: 0

Insecticides - pyrethroids: 2

Fungicide: 1
Rodenticide: 1

Disinfectants: 63

based on chlorine: 48
other: 15

2019
BP poisoning during the period from April 1, 2019 to March 31, 2020.

Severity levels:
level 1: 81 people
level 2: 7
level 3: 0
level 4: 0

Insecticides: 23
neonikotíns: 3
organophosphate: 13
pyrethroids: 7

Fungicide: 4
Rodenticide: 4

Disinfectants: 57
based on chlorine: 30
other: 27

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	94	0	102	0	57	0	63	0	57
MG 2 Preservatives														
MG 3 Pest control					0	11	0	11	1	14	0	4	0	31
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							
Number of enquiries on biocidal products							
Number of enquiries on treated articles							
Total number of enquiries per year			>103	>972	>508	814	673

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

HelpDesk via emails
Call center
Conference and lectures (more see part 7.3 of this report)

7. Sustainable use measures

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

7.1. Availability of Best Practices Documents in the Member States

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

- ○ Yes
- ◉ No

7.2. Availability of certifications or training schemes for professional users

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

- ◉ Yes
- ○ No
- ○ Not anymore

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	It depends on the program of a particular educational institution about the interest of people with whom they want to work with chemical and biocidal substances.		every 5 years (§ 16 item 26 Act No. 355/2007 on the protection, promotion and development of public health and on the amendment of certain laws, as amended
2			
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	Lecture / conference	2016	Biocides - general Endocrine disruptors Poison center and it tasks Tests of toxicity
2	Lecture / conference	2017	About Act No. 319/2013 Coll. on competencies of national administrative authorities for the making available on the market and use of biocidal products and on amendment and supplement of certain Acts (Biocides Act) as amended
3	Lecture / conference	2018	Authorisation of active substances Biocides active substances and authorisation of biocidal products
4	Lecture / conference	2019	BP and treated articles BP in situ and nano

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	Lecture / conference	2016	Biocides - general	https //zchfp.sk/?vyber=21#k32
2	Lecture / conference	2017	Biocidal Act - National Act about Biocides	https //zchfp.sk/?vyber=21#k32
3	Lecture / conference	2018	Authorisation of active substances Biocides active substances and authorisation of biocidal products	https //zchfp.sk/?vyber=21#k32
4	Lecture / conference	2019	BP in situ and nano BP and treated articles	https //zchfp.sk/?vyber=21#k32

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8. Nanomaterials

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

MG 1 Disinfectants

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

SANTE-BIOCIDES@ec.europa.eu