EuroBiocides

Executive Summary

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1 Introduction

The EuroBiocides working group was set up on the 6th CLEEN Conference in Bonn in 2005. Since then, the development of tools for making inspections, developing working methods, exchange between participating countries and discussions have been an ongoing process. This also included a workshop with the members of CLEEN at the 7th CLEEN Meeting in Vienna. The active phase of distributing the final Manual and obtaining participant commitments to the project was concluded in the autumn of 2007. The operational phase of the project ran from the beginning of 2007 until autumn of 2008.

Analysis and the compilation of data, including the coordination between the 15 participating countries, began in spring 2009. Finally, the EuroBiocides report was introduced to the CLEEN members on the 11th CLEEN Conference in Sucevita, Romania in September 2010 and published at the CLEEN homepage http://www.cleen-europe.eu in 2011.

The project aims to provide an insight into the extent to which the industrial sector complies with the requirements of Biocidal Product Directive (BPD), Directive 98/8/EC, also including classification and labelling (Directive 67/548/EEC and Directive 1999/45/EC); and into the enforceability of this Directive, taking into account the numerous and complicated borderline cases arising in respect of the Biocides Directive (BPD) and other EU provisions.

2 Number of inspections

15 countries in the CLEEN network participated in the EuroBiocides project. The participating countries were Austria, Belgium, Denmark, Estonia, Finland, France, Germany, Latvia, the Netherlands, Norway, Poland, Romania, Slovenia, Spain and Switzerland.

		Enterprises				
Country	**Number of examined products**	**Producers importers**	**Retailers/ supermarkets**	**Users**	**Wholesale trader**	**Total**
Austria	48	13		1	6	20
Belgium	55	19		1	2	22
Denmark	51	11	8		5	24
Estonia	82	8	2		2	12
Finland	70	16	1		2	19
France	10			10		10
Germany	353	2	102	2	4	110
Latvia	81	11			7	18
Netherlands	50	4	5		1	10
Norway	25	5				5
Poland	80	19	3	21	23	66
Romania	5		3			3
Slovenia	45	3	2	3	7	15
Spain	369	50	14	56	11	131
Switzerland	22	15				15
Sum	**1346**	**176**	**140**	**94**	**70**	**480**

Table 1: Overview of inspections

In total, 1346 products were examined in the project. Germany and Spain handed in more than 53 % of all examined products, but comparing the number of inspected products with the number of inhabitants most products were examined in Estonia, followed by Latvia, Slovenia, Finland and Denmark

Inspections took place in 480 enterprises. A majority, 176 out of 480 (36.7 %) visited enterprises were producers and importers. 140 (29.2 %) inspections took place at retailers/supermarkets and 70 (14.6 %) inspections took place at wholesale traders as shown in table 1.

It is assumed that knowledge about regulations and products is generally higher among professionals and importers compared to retailers/supermarkets and wholesale traders who are at the end of the information and supply chain.

Furthermore, 94 (19.6 %) inspections took place at users. Knowledge about legislation is usually moderate in this category; some are down stream users and use chemicals in the working process.

Problems have been observed within communication and the spreading of information about biocidal products in the whole supply chain, increasing from producers and importers to the end of the supply chain with wholesale traders and retailers/supermarkets.

⇨ Producers and importers have to meet requirements on classification, packaging and labelling and to report information in accordance to Article 20 of the BPD.

⇨ Producers and importers should provide their products with good information material, spread the information and make data available to everyone in charge of these products.

Country	Number of inspected products	Consumers	Professionals	Both	Empty
Austria	48	23	21	4	
Belgium	55	32	18	5	
Denmark	51	10	1	40	
Estonia	82	23	41	18	
Finland	70	14	28	28	
France	10		10		
Germany	353	271	19	63	
Latvia	81	31	35	15	
Netherlands	50	34	11	5	
Norway	25	10	8	7	
Poland	80	22	38	19	1
Romania	5	5			
Slovenia	45	22	22	1	
Spain	369	65	236	68	
Switzerland	22	5	14	3	
Sum	**1346**	**567**	**502**	**276**	**1**

Table 2: Overview of examined products

Consumer products were represented with 567 (42.7 %) examined products for all participating countries, compared to 502 (37.3 %) products mainly for professionals and 276 products (20.5 %) for both consumers and professionals.

Many biocidal products are intended for consumers who generally have less knowledge on both legislation and protection against chemical exposure than professionals.

⇨ Enterprises must provide their products with sufficient information and be aware of all classification and labelling requirements due to the BPD legislation.

⇨ Furthermore, National Authorities shall inform the general public via the internet or by publishing fact sheets, FAQ´s, and other relevant information for specific product types, e.g. insecticides, disinfectants, wood preservatives etc. in formats addressed to consumers.

A majority, 1305 (97 %), of the examined products were preparations. Only 37 were active substances (2.7 %) and 4 were blank (0.3%). The 37 active substances were examined by 7 countries: Spain (16), Estonia (10), Germany (3), the Netherlands (3), Belgium (3), Latvia (1) and Austria (1).

3 Product Types

In total, 18 out of 23 product types included in the BPD were represented.

More than one third of the inspected products belonged to the product types 18 and 19 (insecticides and repellents). Around 20 percent were examined among product type 2 products (disinfectants).

GROUP	Description	Number of examined products (%)	Country examined
MAIN GROUP 1	Disinfectants and general biocidal products (PT1 to PT5)		
PT 1	Human hygiene biocidal products	18 (1.3 %)	9: ES, DE, EE, FI, PL, NL, AT, SI, SUI
PT 2	Private area and public health area disinfectants and other biocidal products.	273 (20.3 %)	13: All except FR and RO
PT 3	Veterinary hygiene biocidal products	31 (2.3 %)	8: ES, DE, EE, FI, PL, NL, AT, SUI
PT 4	Food and feed area disinfectants.	91(6.8 %)	7: ES, EE, FI; PL, SI, AT, SUI
PT 5	Drinking water disinfectants	5 (0.4 %)	2: ES and DE

MAIN GROUP 2	**Preservatives (PT6 to PT13)**		
PT 6	In-can preservatives	28 (2.2 %)	5: ES, PL, FI, DK,SUI
PT 7	Film preservatives	44 (3.3 %)	5: ES, PL, SI, DK, SUI
PT 8	Products used for the preservation of wood, from and including the saw-mill stage or wood products by the control of wood-destroying or wood-disfiguring organisms.	122 (9.1 %)	11: ES, DE, EE, LT, FI, PL, DK, AT, SI, SUI, FR
PT 9	Fibre, leather, rubber and polymerised materials preservatives.	1 (0.1 %)	1: DE
PT 10	Masonry preservatives	14 (1.0 %)	4: DE, PL, FI, DK
PT 11	Preservatives for liquid-cooling and processing systems.	16 (1.1 %)	3: ES, EE, FR
PT 12	Slimicides	2 (0.1 %)	1: ES
PT 13	Metalworking-fluid preservatives	0	
MAIN GROUP 3	**Pest control (PT14 to PT19)**		
PT 14	Rodenticides	127 (8.8 %)	8: ES, DE, EE, FI, PL, BE, NO, SI
PT 15	Avicides	0	
PT 16	Molluscicides	1(0.1 %)	2:DE, DK
PT 17	Pesticides	0	
PT18	Insecticides, acaricides and products to control other arthropods	382 (28.4 %)	All, except FR and RO
PT 19	Repellents and attractants	138 (10.3 %)	11: ES, DE, EE, FI, PL, BE, NL, DK, AT, SI, NO
MAIN GROUP 4			
PT 20	Preservatives for food or feedstocks	2	1:ES
PT 21	Antifouling products	53 (3.9 %)	3: ES, DE, FI
PT 22	Embalming and taxidermist fluids	0	
PT 23	Control of other vertebrates	0	

Table 3: Examined products per product type (PT). The number and the participating countries per product type are listed in the right column. 1 product in the Danish approach were a detergent agent, but is calculated in PT2.

All country approaches were designed/set up according to the recommended selection criteria "high risk", "high volume" and / or "many borderlines".

⇨ The majority of products (84.2 %) were collected among 6 product types: PT2 (disinfectants), PT4 (food and feed area disinfectants), PT8 (wood preservatives), PT14 (rodenticides), PT18 (insecticides) and PT19 (repellents).

⇨ Those product types, which were less documented in this report, were recommended and will be subject to further inspection and enforcement in future common and national projects.

4 Active Substances

4.1 Number of active substances in products

1284 products (95.4 % of all examined products) were examined for the marketability of the active substances (AS) in the products.

In total, 2020 active substances were inspected. More than every fourth product contained more than one active substance. It was possible to find more than one, two, three and four active substances in all examined product types.

AS in product	1	2	3	4	5
Number	751	368	130	33	2
Percent %	58.5	28.7	10.1	2.6	0.2

Table 4: Distribution of the number of active substances in biocidal products

4.2 Active substances not included in Annex II of Regulation 1451/2007/EC

The examination of the active substances showed that 99 (7.7 %) products contained active substances which were not notified in Annex II of the Regulation 1451/2007/EC for the specific product type. The results for the participating CLEEN Members are shown in figure 1 below.

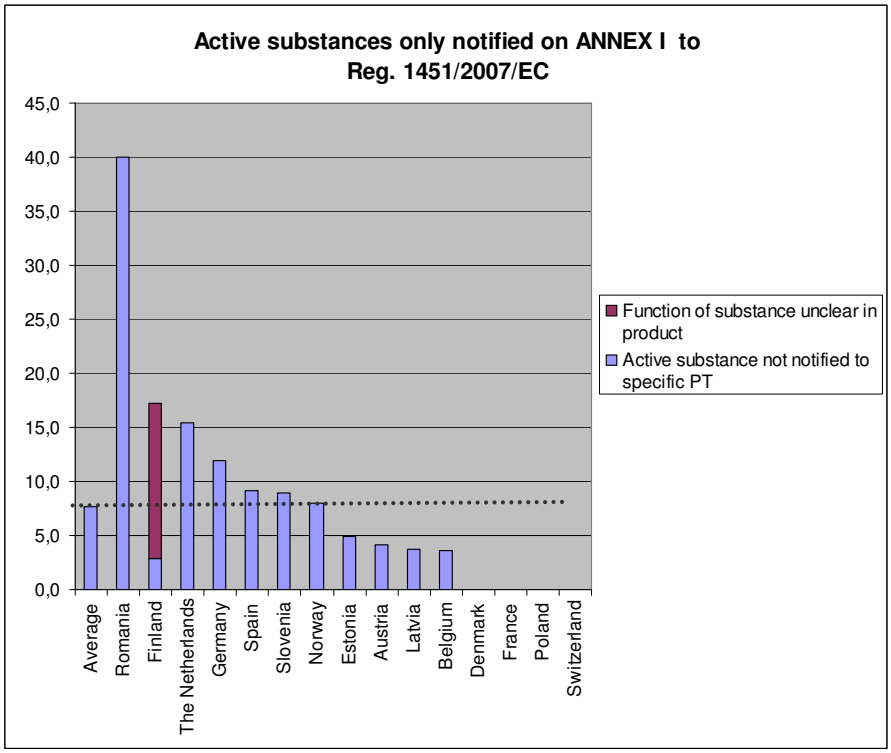

Figure 1: Active substances only notified in Annex I to Reg. EC 1451/2007

PT	2	3	4	5	6	7	10	14	18	19	21	#
Number of forbidden AS	21	1	8	1	1	5	1	13	15	28	5	99
Percent %	8.0	3.2	9.0	20.0	3.8	12.2	10.0	10.2	4.0	23.0	9.8	7.7

Table 5: Distribution of forbidden active substances in the products for the different product types.

A list with the most frequently found names of substances which were not notified in the specific product types (only in ANNEX I), when the inspection phase was running, are shown in table 6 below.

For example problems with marketability occurred for citronella in PT19, because no enterprise handed in a dossier for submission of citronella as an active substance under the review programme.

Substance	Number of products	Not listed on ANNEX II for the specific PT
Citronella	10	18; 19
Benzoic acid, sodium salt	10	14; 18
Chlorpyrifos	5	18; 19
Sodium hydroxide	4	2; 4
Aluminium trisulfate	4	2;
Acetic acid	4	2; 4
Phenothrin	3	2
Juniperus mexicana extract	3	19
Diuron	3	21
Propan 2-ol	3	19; 18

Table 6: Table with the 10 most frequently found illegal active substances (only on ANNEX1). For some of the active substances the phase-out-decision has entered into force later in Commission Decision 2007/565/EC (22-08-2008)

4.3 Active substances with non-inclusion decisions

48 (3.7 %) active substances were illegal because a decision for non-inclusion had come into force for the specific product type. The results for the participating CLEEN Members are shown in figure 2 below.

Characteristic for those countries which found products with non-inclusion active substances was that they were found at retailers (at the end of the supply chain) and that they were mainly intended for consumers and not for professionals.

PT	1	2	4	6	8	10	18	19	#
Number of non included AS	2	2	2	1	4	2	31	4	48
Percent %	**11.8**	**0.7**	**2.2**	**3.8**	**3.3**	**18.2**	**8.2**	**3.3**	**3.7**

Table 7: Distribution of active substances not included in the BPD for the different product types

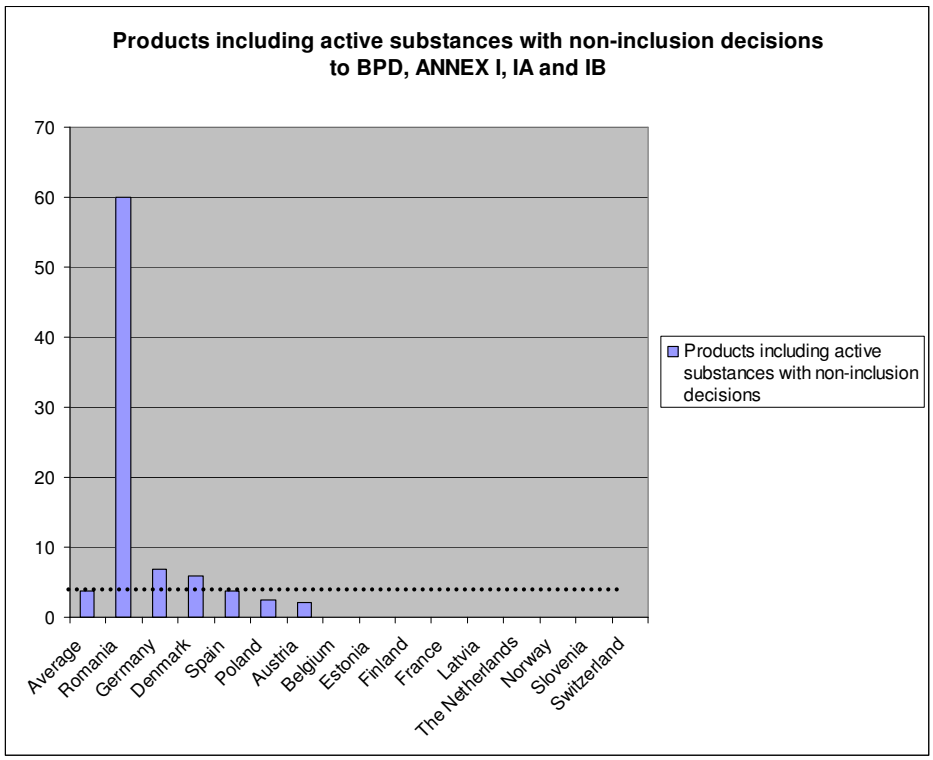

Figure 2: Products including active substances with decision of non-inclusion to BPD, Annex I, IA and IB.

	Examined products	Non-inclusion decision	ANNEX I	Sum #	Percent %
	Figures	Products with active substances forbidden on the market			
Romania	5	3	2	5	100
Germany	319	22	38	60	18.8
The Netherlands	39	0	6	6	15.4
Spain	369	17	34	52	14.1
Slovenia	45	0	4	4	8.9
Norway	25	0	2	2	8.0
Austria	48	1	2	3	6.3
Denmark	34	2	0	2	5.9
Estonia	82	0	4	4	4.9
Latvia	81	1	3	3	3.7
Belgium	55	0	2	2	3.6
Finland	70	0	2/10*	2/10*	2.9/(17.1)
Poland	80	2	0	2	2.5
France	10	0	0	0	0
Switzerland	22	0	0	0	0
Sum / average	**1284**	**48**	**99/109**	**147/157**	**11.4/12.2**

Table 8: Products placed illegally on the market while containing not marketable active substances (listed only in ANNEX I and / or non-inclusion-decision entered into force). * Function was unclear for 10 products with those active substances in the Finnish approach.

The number of biocidal products which included active substances illegally on the marked since 1st September 2006 (not notified in ANNEX II, only in ANNEX I) was too high (in total, 11 to 12 percent).

Additionally, many new non-inclusion decisions have entered into force after the project phase ended in January 2009.

⇨ Further enforcement of the BPD in the intermediate stage is necessary.

⇨ Producers and importers must ensure that information about legality and status of the active substances is spread to all enterprises (users, wholesale traders and supermarkets) in the supply chain as well as to industries and organisations.

4.4 New and not identifiable active substances

"Not found" was filled in to the datasheet for active substances in about 47 products. Evaluation of the list of "not found" substances showed that many of the substances have other functions than a biocidal function.

In total, around 10 active substances of the "not found substances" were by individual assessment identified as "new active substances" not notified to the existing Commission Regulation (EC) 1451/2007.

Questions about new active substances were not a specific part of the project.

⇨ "Not found" and "new active substances" may be subject to examination/ investigation in future projects.

5 Borderline Cases

A total of 130 products (around 9.7 %) with a borderline to either medical devices/pharmacies, plant protection agents, cosmetics, disinfectants and other were reported from 12 participating countries. The highest scores were among the following:

PT	1	2	3	4	5	6	7	8	11	18	19	#
Number of Borderlines	7	60	2	12	1	6	7	7	1	8	21	132
Percent %	38.9	22.0	6.5	13.2	20.0	21.4	15.9	5.7	6.3	2.1	15.2	9.7

Table 9: Number of products with borderlines in examined PTs

Borderlines to	Number	Found in countries	High score
Detergents	69	12	LT 13 in PT2; ES 14 in PT2; and ES 4 in PT4
"Other"	34	8	DK 12 in (PT 6, 7 and 8); TNL 7 in PT19
Cosmetics	13	6	AT 3 in PT19; 3 in DE in PT19 3 in Spain in PT6
Plant protection	7	5	In PT (1); PT8 (1); PT18 (4) and PT19 (1)
Medical devices/pharmacies	7	5	In PT18 (2) and PT19 (4)

Table 10: Number of products with borderlines to detergents, plant protection, medical devices/pharmacies, cosmetics or "others"

Most of the borderline cases were solved according to the information in the "Manual of Decision". But many enterprises were not aware that their products were included in the BPD.

⇨ Further enforcement and information about the scope of the BPD-regulation is necessary. Enterprises must be made aware whether their products are included in the BPD or not (borderlines).

6 Packaging and labelling

Non-compliances in relation to more formal requirements which were easily fulfilled for dangerous substances and preparations / mixtures in accordance to 67/548/EEC and 1999/45/EC were found in large numbers. The following table provides an overview:

Reason	Number (Not OK)	Percent (%)	Found in countries	High score
Missing company name, address etc.	226	17.3	11	35.7% DE, 34.5 % BE, 30 % NL
Labelling indicating "low risk"	66	5.1	8	35 % DE; 10% NL; 9 % DK
Misleading sentences	36	2.8	8	12.0 % NL; 6 % ES
Labelling unclear or indelible	35	2.7	6	18.2 % SUI; 10% FI; 5.1 % ES
Not in national language	27	2.1	7	29 % BE; 6.6 % FI

Table 11: Number of products with labelling problems

Products intended for consumers sold by retailers/supermarkets were more often labelled with forbidden misleading phrases and wrong address information on the package compared to products for e.g. professionals.

⇨ Enterprises must be made aware that also general requirements for dangerous substances and / or preparations / mixtures have to be met.

⇨ Leaflets and labelling must not involve any kind of misleading sentences giving exaggerated impressions about the risk from using biocidal products. (Be aware that biocidal products are designed to destroy organisms).

7 Indication of danger

Most of the biocidal products (1295 out of the total 1346, 96.2 %) were inspected not only in relation to the BPD but also in relation to classification and labelling as it is laid down in 67/548/EEC and 1999/45/EC.

A total of 263 (20.3 %) of those products examined according to danger labelling (including mistakes with symbols and R-sentences) were not in compliance. Furthermore, the indication of danger was characterised as uncertain for additionally 73 (5.6 %) of the examined products. Uncertain means that it was impossible for inspectors during the project phase to clarify whether the classification and labelling of the products were correct or not. Mostly, the reasons were missing or inconsistent information on the label, in the safety data sheet or similar.

Wrong or missing safety information (S-sentences) was found on 274 (21.2 %) products. Indication of safety was mentioned as uncertain for further 7 (0.5 %) of all the examined products.

Wrong classification and labelling of environmental danger was found on 138 (10.7 %) examined products; an additional 9 (0.7 %) products got the status “uncertain” because of missing or inconsistent information.

For some specific product types (PT8, PT14, PT18 and PT19) non-compliances with the environmental danger symbol were higher, because environmentally dangerous substances were used in those preparations more often.

		Danger (not ok)		Safety phrases (not Ok)		Environmental danger (not ok)	
	Examined	**Number**	**%**	**Number**	**%**	**Number**	**%**
Austria	48	17	35.4	13	27.1	27	14.6
Belgium	55	2	3.6	15	27.3	33	30.9
Denmark	42	13	31	8	19.0	3	45.2
Estonia	82	3	3.7	7	8.5	3	2.4
Finland	68	26	38.2	21	30.9	0	2.7
France	10	4	40	1	10	2	0
Germany	353	46	13	76	27.2	17	9.3
Latvia	81	22	27.2	23	28.4	19	3.7
Netherlands	50	1	2	7	14	6	12
Norway	25	20	80	2	8.0	0	52.0
Poland	78	5	6.4	2	2.8	7	2.6
Romania	5	2	40	3	60	13	80
Slovenia	45	1	2.2	0	0	4	0
Spain	330	98	29.7	92	27.9		8.2
Switzerland	22	3	13.6	4	18.2	4	18.2
Sum/average	**1294**	**263**	**20.3**	**274**	**21.2**	**138**	**10.7**

Table 12: Findings within classification and labelling rules for examined products

The majority of the participating countries found products not in compliance with the classification and labelling rules over the accepted limit set to around 4 percent. Many products not in compliance/over the average value were found among those product types which are spread widely in the supply chain (PT2, PT18 and PT19).

⇨ The immense number of products not in compliance with the classification and labelling rules indicates that risk to humans from using biocidal products is relatively high.

⇨ Enterprises are responsible for their products and they have to make an effort to increase the number of products with the right classification and labelling information.

8 Danger symbols

905 (67.2 %) of the examined products had at least one danger symbol. 257 products were not dangerous and had no danger symbols. Furthermore, danger symbols were not necessary on approximately 132 products (but R- and S-sentences were). 57 products were blank/not checked.

Approximately a third of all products had more than one symbol, e.g. both Xn (dangerous for the health) and N (environmental danger) or/and O (oxidising) symbols; or other combinations.

57.5 % of those products with symbols had danger symbols higher than dangerous for health, meaning dangerous for health (Xn), corrosive (C), toxic (T) and very toxic (T+.).

As many as 352 (38.9 %) of the products with symbols, had a dangerous for health symbol and approximately every 4 out of 10 (369 (40.8 %)) of the dangerous products with symbols had a dangerous for the environment symbol as shown in table 13 below:

Symbol name	Symbol	Number	% of products with a symbol out of 905
Very Toxic	T+	9	1.0
Toxic	T	26	2.9
Dangerous for Health	Xn	352	38.9
Corrosive	C	133	14.7
Irritant	Xi	196	21.7
Very Flammable	F+	121	13.4
Flammable	F	66	7.3
Oxidising	O	35	3.9
Explosive	E	0	0
Environmental Danger	N	369	40.8

Table 13: Number of danger symbols on the examined products

The analyses showed that some product types share specific characteristics with a majority of the danger symbols (warnings) in specific classes, e.g. many products in PT18 had both dangerous for health and environmental danger symbols.. Products in PT2 had either dangerous for health, corrosive and irritant symbols or some of those together with the symbol for oxidising.

Many biocidal products are very dangerous (designed to destroy organisms) and are classified accordingly with dangerous for health and environmental danger symbols. Those products can cause risk to humans if not used carefully.

⇨ Enforcement of biocidal products must have priorities and focus according to found infringements and characteristic danger classes for the specific product types.

⇨ It is important to focus on substitution and incitements to produce less dangerous products especially those intended for household consumers.

9 Specific Labelling for Biocides

The 10 questions on labelling (8 specific BPD-requirements) have been examined in 1050 products with legal binding provision in 9 different countries; another 160 products without national authorisation were examined in 11 different countries.

Legally binding provisions for the specific biocidal are only in force for products with an authorisation; but some countries even seem to have a general procedure (legally binding for biocidal products with and without national authorisation), e.g. Germany.

The specific BPD rules were in force for 1050 examined products (more than those reported with national authorisation: in total, national authorisation were filled in for 607 products and no authorisation was filled in for 514 products and 135 were blank).

Products with legal provisions were examined in Belgium, Estonia, Latvia, Germany, Poland, the Netherlands, Slovenia, Spain and Switzerland.

Reason/requirement	Number (not ok)	% Average value (not OK)	High score
Expiry date	321	30.6	50 % NL; 48 % BE; 43.6 % ES;
Safe disposal and reuse of packaging	312	29.7	53 % ES; 26.3 % DE;
Protection of non-target organisms and water	198	18.9	45.5 % SUI; 27.7 % ES
Side effect and direction for first aid	178	17	40.9 % SUI; 32.8 % ES; 24 % BE
Time needed for relevant effect	160	15.2	45.5 % DE; 36 % BE

Table 14: Worst findings for the 8 specific BPD labelling rules - examined products with legal provision.

160 products without national authorisation (no legal provision provided) were also inspected.

Products without legal provisions were examined in Austria, Belgium, Denmark, Estonia; France, Latvia, Poland, the Netherlands, Slovenia, Spain and Romania.

Reason/requirement	Number (not ok)	% Average value (not OK)	High score
Protection of non-target organisms and water	71	44.4	100 % BE; 100 % NL; 75 % ES
Side effects and direction for first aid	71	44.4	100 % BE; 72.3 % NL; 70 % FR
Time needed for relevant effect	60	37.5	100 % BE; 72.2 % NL; 61.5 % DE; 61.1 % NL
Safe disposal and reuse of packaging	58	36.3	100 % BE; 75 % ES; 72.2 % NL
Expiry date	56	35	100 % BE; 72.2 % NL; 61.5 % ES

Table 15: Worst findings for the 8 specific BPD labelling rules among products assumed without legal binding provision.

Norway and Finland did not answer these questions, because legal provisions were not in force, and they are therefore not included in the calculation.

Of cause, the results for the two scenarios (products with and without legally binding provisions) showed that more products with provisions were in compliance with the rules, than those without. For all examined products around 30 percent were not in compliance with at least one of the 8 specific requirements.

⇨ Most of the BPD-requirements seem to be recognised by enterprises, but to improve the attention of the enterprises and to increase compliance with the rules, it is necessary to develop guidelines intended for both enterprises and inspectors.

10 Safety data sheet and composition/information on ingredients

Not all participating countries were in charge of inspecting SDSs. For that reason and because of some uncertainties caused by shortcomings in the SDS part of the questionnaire, the statistical basis differs somewhat. However, the following results were obtained:

- **SDSs available:**
  For 873 (80.2 %) out of approximately 1089 dangerous products SDSs were available. No SDSs were available for 114 (10.5 %) dangerous preparations; further 359 products were not dangerous preparations or not checked).
- **SDSs available only on request:**
  258 SDSs were available only on request (compared to 257 products, which were calculated not dangerous in a prior question), but 237 were not available on request. No answers were given for 840 products. It was not possible to clarify whether the SDSs were available only on request or not necessary.
- **Information on ingredients** was available on 887 SDSs, not available on 54 (further 404 SDSs were not inspected with that focus).
- **Content (SDS**) was checked on 834 products, not checked on 189 and blank on 313

Examination of quality and availability of SDSs were not a main topic in the project.

⇨ Future projects should focus more on the quality and availability of SDSs.
⇨ SDS quality and availability of SDSs for not dangerous products which shall be available on request shall be subject for further inspection of biocidal products.

11 Summary

Examination of 1346 biocidal products in the EuroBiocides project showed that every second product was not in compliance with the BPD rules laid down in 98/8/EC; including also classification and labelling rules (67/548/EEC, 1999/45/EC) due to the statutory provisions laid down in Article 20 of the BPD.

Around 11 to 12 percent of the products contained forbidden active substances.

More than 20 percent of the inspected products were not classified and labelled with the right indication of physical or health danger. In addition, further 11 percent of the products were not classified as environmentally dangerous products. The number of wrongly labelled products increased when risk and safety-sentences (R- and S-sentences) were included.

The number of biocidal products which did not meet at least one of the 8 specific labelling rules for biocidal products was around 30 percent.

Furthermore, 130 products (around 9.7 percent) had a borderline to either medical devices/pharmacies, plant protection agents, cosmetics or disinfectants.

Spain and Germany filled in more than 53.6 % of the examined products; fortunately their results were similar to those of the other participating countries. The main differences in the analysed results depended among others on whether the products ***were registered or not, the intensity of the repetition of the BPD enforcement, the purpose of the products and the enterprises inspected.***

	Examined products	Products not in compliance	Percent of products not in compliance with the BPD legislation
Average	1346	673	50 %
Romania	5	5	100 %
Norway	25	20	80 %
Austria	48	36	75 %
Belgium	55	37	67.3 %
Finland	70	46	65. 7 %
Denmark	51	31	60.8 %
Latvia	81	40	49.4 %
Estonia	82	40	48.8 %
Germany	353	172	48.7 %
Spain	369	174	47.2 %
The Netherlands	50	23	46 %
Poland	80	29	36.3 %
Slovenia	45	14	31.1 %
Switzerland	22	5	22.7 %
France	10	1	10 %

Table 16: Overview and ranging of the number of products not in compliance in the participating countries

Some countries found products not in compliance over the average value as shown in table 16.

The explanation for the high number of infringements in those countries seems to be one or more of the following:

- Many problems with borderline cases were included in their approaches.
- Those approaches focused on infringements; and the number of products “in their hands” was greater than the number (these with mistakes) chosen for examination.
- The national enforcement approach included a majority of products with environmentally dangerous substances for which new rules regarding specific concentration limits for classification entered into force in 2007.
- National rules for authorisation of specific product types, for which the same products were not subject to authorisation in the surrounding countries.

During the project phase different measures where undertaken by inspectors to improve compliance.

Sanction	Number of products	% of products
Removed from market	169	12.6
Product substance prohibited	18	1.3
Sanction – not defined	52	3.9
Advice to enterprise	188	14.0
Further inspection	37	2.7
Information to focal point	100	7.4
Violation	109	8.1
None/blank	673	50

Table 17: Results of enforcement of biocidal products in all participating countries during project phase. In some cases inspection could not be finished during project phase because further inspection was necessary; mainly answered with "further inspection" or "information to focal point". In the cases when no further specific and / or detailed information about enforcement measurements was documented during the project phase they were counted as "violation".

The calculation (table 17) shows that around 14 % of the examined biocidal products were either prohibited or removed from the market during the inspection phase. Danger to health and the environment from using biocidal products were in these cases reduced.

Furthermore, 149 (11.1 %) of the examined products had been legalised (re-labelled, active substances changed to legal etc.); and enforcement of 108 (8 %) products were still in process, when the inspection phase finished in January 2009.

Having in mind that the BPD entered into force more than ten years ago; the results showing that 50 percent of the *examined products were not in compliance with the BPD regulation are far from acceptable and very worrying.*

⇨ Further enforcement of the BPD legislation in the intermediate stage is necessary not only in relation to the BPD rules but also in relation to classification and labelling.

⇨ Enforcement alone can not be responsible for decreasing the number of products not in compliance, but it is an important measure to force companies to pay attention to the legislation, and to reduce biocidal products not in compliance with the BPD rules.

⇨ Enterprises dealing with biocidal products shall continuously be obliged to reduce the risk to humans from using these products, and compelled to give sufficient information to downstream users about any changing of chemical contents in them.

Finally, the propounding EuroBiocides results have clarified the need for selective information to enterprises, consumers and professionals; and accordingly recommendations to the Commission, Competent Authorities and enterprises are elaborated in the final report.