

# EuroBiocides

## Final report



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## Introduction

The Chemicals Legislation European Enforcement Network (CLEEN) is a voluntary network of chemical inspectorates in the European Union, Norway and Switzerland which aims to coordinate the enforcement of EU chemical legislation by developing common strategies and tools for the inspectors in the member countries. It is basically a forum for information exchange and it performs enforcement projects as proposed by its members.

The EuroBiocides working group was set up on the 6th CLEEN Conference in Bonn in 2005. Since then, developing working methods and tools for making inspections has been an ongoing process. This also includes a workshop with the members of CLEEN at the 7th CLEEN Meeting in Vienna in 2006. The active phase of distributing the final Manual and obtaining participant commitments to the project was concluded by the end of 2007. The operational phase of the project ran from spring 2007 until autumn 2008. Analysis and the compilation of data, including the coordination between the 15 participating countries, began in spring 2009. Finally, the report was introduced to the CLEEN members on the 11<sup>th</sup> 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 Biocidal Product Directive (BPD), also including classification and labelling (Directive 67/548/EEC and Directive 1999/45/EEC); and into the enforceability of this Directive, taking into account the numerous and complicated borderline cases arising in respect of the Biocidal Product Directive (BPD) and other EU provisions.

Glossary and definitions are placed in APPENDIX 1 to this report.

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## 1 Summary

The exchange of information and experience among the Member States to avoid differences in the way the Directive 98/8/EC is enforced in the different EU Member States and EES (European Economic Space) and thus to avoid inconsistent competitiveness of the relevant enterprises was obtained through examination of 1346 biocidal products according to:

- Problems and borderline cases in enforcing the Directive;
- Packaging, classification and labelling,
- The marketability of active substances;
- SDSs and chemical contents in the products;
- Providing support and disseminating information to the enterprises;

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

An EuroBiocides manual was developed from 2005 to 2007, the manual included specific tools, working methods for selection and collection of products, product and enterprise questionnaires and corresponding excel database (with the same questions), in which the data was calculated and analysed.

More than 450 inspectors have been trained in examination of the specific BPD rules and participated in the enforcement of the biocidal products. Names of country responsible and inspectors are listed in APPENDIX 9 and 10.

### Results of enforcement

***50 percent of the 1346 biocidal products examined in the 15 European countries were not in compliance with the BPD legislation.***

Around 12 percent of the products contained forbidden active substances. More than 20 percent of the inspected products were not classified and labelled with the correct indication for physical or health danger. In addition, 11 percent of the products were not correct classified as environmentally dangerous. The number of wrongly labelled products increased when risk and safety-sentences (R- and S-sentences) were counted in. 30 percent of the products did not meet at least one of the 8 specific labelling rules for biocidal products.

Furthermore, 130 products (around 9.7 percent) had a borderline to either medical devices/pharmacies, plant protection agents, cosmetics or disinfectants. The majority of enterprises selling those products were not aware that these products were included to the BPD legislation.

23 product types are included in the BPD, and 18 of those were examined in this project.

In particular 6 product types, PT2, PT4, PT8, PT14, PT18 and PT19, represented the recommended selection criteria: “many borderlines”, “high volume“ and “high risk”, and were well documented in the project, both in number of products (1133 products, 84.2 %) and in number of countries who examined those products.

The number of products not in compliance was highest in PT2, PT18 and PT19. These products are widely spread in the supply chain and many are intended for consumers or both consumers and professionals. And accordingly, the number of forbidden active substances was highest in PT18 and PT19 for which the deadline for submission of data was among the first (“high risk”) in the review programme.

480 enterprises were inspected; a majority, 176 (36.7 %) out of 480 visited enterprises were producers and importers; 140 (29.2 %) were retailers / supermarkets, 94 (19.6 %) were users, and 70 (14.6 %) were wholesale traders.

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

During the project phase different measures were undertaken by inspectors to improve compliance as shown in table 1-1

The main differences in the analysed results for each country approach depend among others on whether the products were registered or not, whether national authorisation was in force or not and of the intensive repetition of BPD enforcement, the purpose of the products, the enterprises and the product types inspected.

Enforcement results and actions taken against products not in compliance are reported collectively for all participating countries in chapter 5.1, p. 49 and separately on a national level for each participating country in chapter 5.2.

<b>Sanction</b>	<b>Number of products</b>	<b>Percentage</b>
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 – ((no specifications)*	109	8.1
None/blank	673	50

**Table 1-1: Results from the enforcement of biocidal products in all participating countries during the project phase. In some cases inspections could not be completed during the project phase because further clarification was necessary; “further inspection” or “information to focal point” were mainly reported in these cases. 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”.**

Because of follow-up actions undertaken by inspectors and because of slightly different time schedules in the participating countries, the final results were not always available at the end of the project phase, January 2009. Reasonably the question about results could not be fully compared, but the following results have been calculated:

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

## **Conclusion**

The EuroBiocides project has ensured that enforcement was carried out successfully, harmonized and that the results was comparable between the participating countries.

The process of developing the manual, the examination of the BPD legislation for each product and the coordination between 15 countries was immense. Consequently, with respect to the workload future common enforcement projects will focus on and be limited to specific product types.

The results showed that half of the examined products were not in compliance with the regulation, which, of course, is not acceptable. Having in mind that the BPD entered into force more than ten years ago, the results are worrying and indicate the necessity of further inspections, not only in relation to the BPD legislation in the intermediate stage but also in relation to classification and labelling.

Unfortunately many of those biocidal products not in compliance were classified with both dangerous to health and the environment and many were intended for consumers, which have little or no knowledge about the BPD-legislation.

As a result of this observation, enterprises dealing with biocidal products shall be forced to reduce the risk to humans from using these products, and give sufficient information to downstream users about any change in the chemical contents of the products.

Furthermore, the propounding EuroBiocides results have clarified the need for selective information to enterprises, customers and professionals and accordingly, recommendations to the Commission, Competent Authorities and Enterprises are elaborated in the end of this report.

This final report will be introduced and forwarded to the Competent Authorities in 2011.

## **2 Background and Goals**

### **2.1 Legislation**

Directive 98/8/EC (BPD) of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market entered into force on 14 May 1998. The Member States had to implement the Directive not later than 24 months after its entry into force.

The BPD concerns the authorisation for placing on the market of biocidal products within the Member States. Article 1(2) of Directive 98/8/EC applies to biocidal products as defined in Article 2(1)(a) but excludes products that are defined or within the scope of the 18 other Directives.

According to Article 1(2) of Directive 98/8/EC the Directives and Regulations listed in APPENDIX 2 of this report are exempted from the scope of the BPD.

Further, Article 1(3) of the Directive applies without prejudice to relevant Community provisions or measures taken in accordance with five other Directives, which are explicitly listed.

### **2.2 Definitions**

Article 2 of Directive 98/8/EC provides definitions on concepts; this includes biocidal products, low-risk biocidal products, basic substance, and active substance, substance of concern, harmful organism, and residues, placing on the market, authorisation, frame-formulation, registration and letter of access.

Pursuant to the Directive 98/8/EC the definitions for biocidal products, active substances and basic substances apply as written below. These definitions are the key to solving whether or not a product is included in the scope of the Biocidal Product Directive.

### **a) Biocidal products**

Article 2 of the BPD defines biocidal products as "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means".

### **c) Basic substances**

A basic substance is defined as "a substance which is listed in Annex IB, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluents, which itself is not a substance of concern and which is not directly marketed for this biocidal use".

Substances which could potentially be listed in Annex IB are carbon dioxide or nitrogen.

**d)** Furthermore, an active substance is defined as "a substance or micro-organism including viruses or a fungus having general or specific action on or against harmful organisms".

An exhaustive list of the 23 product types with an indicative set of descriptions within each type is provided in ANNEX V to the Directive. ANNEX V is repeated and placed in APPENDIX 3 of this report.

## **2.3 Review of notified existing substances**

According to the BPD, active substances in biocidal products, placed on the EU market prior to 14 May 2000 (all notified active substances)<sup>1</sup>; will be reviewed in a Community programme that has to be carried out within 14 years. If, after the review, they are accepted for use in biocidal products in specific product types, they will be included in ANNEX I, IA or IB to the BPD.

### **Identification of existing substances**

The first phase of the review programme was established by Commission Regulation (EC) No. 1896/2000 of 7 September 2000, which lays down the procedures for identification and notification of existing active substances. Only substances, which were notified acceptably, are reviewed in the programme.

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<sup>1</sup> Postponed until 14 Mai 2014: Commission Regulation (EU) No 298/2010 of 9 April 2010 amending Regulation (EC) No 1451/2007 as regards the extension of the duration of derogations allowing the placing of biocidal products on the market <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:090:0004:0005:EN:PDF>

The second phase of the review programme was established by Commission Regulation No. 2032/2003 of 4 November 2003 (last amended by Commission Regulation No. 1849/2006 of 14 December 2006)<sup>2</sup>, which lays down the procedures and details for the rest of the review programme. Identified active substances, notified active substances, prioritisation of the product types to be reviewed, designated Rapporteur Member States, and time tables are listed in the Annexes to the second Regulation.

Biocidal substances which are neither identified nor notified into ANNEX I can not be placed on the market according to Commission Regulation 1451/2007, Article 4(1).

An exhaustive list of existing active substances to be examined under the review programme is set out in ANNEX II of 1451/2007/EC. The list specific to each existing active substance includes the product types in respect of which the substance would be examined under the review programme. A designated Member State was chosen to implement each substance.

First, active substances used in product type 8, wood preservatives, or product type 14, rodenticides, will be assessed.

Deadline for dossier submission under the review programme	Product type	Comment
28 March 2004	8,14	Combinations of an active substance and a product type for which no dossiers have been submitted are withdrawn from the review programme.
30 April 2006	16,18,19, 21	
31 July 2007	1, 2, 3, 4, 5, 6, 13	
31 October 2008	7,9,10,11,12,15,17,20,22,23 <sup>3</sup>	

**Table 2.3-1: Deadline for dossier submission under the review programme**

### **Not notified and new active substances**

From the date of entry into force of Commission Regulation No 1451/2007/EC, any active substances not listed in ANNEX I shall be deemed not to have been placed on the market for biocidal purposes before 14 May 2000 (Article 4(3) of 1451/2007/EC).

<sup>2</sup> Commission Regulation No 1451/2007, 4 Dec 2007 repeals Commission Regulation (EC) No 2032/2003, available at <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2007:325:SOM:EN:HTML>

<sup>3</sup> Product type 10, 11, 20 and 22 will be included in these projects.

As any substances not listed in the Regulation (EC) No 1451/2007, are prohibited and must be authorised or registered as a new substance, and the necessary dossier for submission and authorisation are to be laid down according to the rules and procedures set out in Articles 3 and 5 of Directive 98/8/EC. The assessment and decision on the inclusion of the substances into ANNEX I of the Directive must be made at community level, and placing on the market is assumed to be in compliance with the BPD (no “intermediate stage”).

### **Non-inclusion and phasing-out**

Commission Regulation (EC) No 1451/2007 Article 4(1) stipulates that biocidal products containing active substances listed in ANNEX II for which no notification to a specific product type has been accepted of the second Review Regulation may not be placed on the market.

In accordance with Article 4(2) of Regulation 1451/2007/EC, biocidal products containing active substances for which a decision was taken not to include for certain and all of their notified product types in ANNEX I, IA or IB to the Biocidal Product Directive within the Review programme, shall be withdrawn from the market within 12 months after the decision to withdraw has come into force, unless otherwise stated in the non-inclusion decision. A list of non-inclusion decisions (with phasing-out phase) is available at [http://ec.europa.eu/environment/biocides/pdf/list\\_dates\\_product\\_phasing\\_out.pdf](http://ec.europa.eu/environment/biocides/pdf/list_dates_product_phasing_out.pdf).

Decision concerning non-inclusion in ANNEX I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market of certain substances to be examined under the 10-year work programme as referred to in Article 16(2) concerning substances and products types for which no company or Member State indicated an interest in taking over the role of participant for. These decisions shall apply from the day following its publication in official Journal of the European Union.

All decisions of non-inclusion in ANNEX I, IA or IB to Directive 98/8/EC are available: [http://ec.europa.eu/environment/biocides/non\\_inclusions.htm](http://ec.europa.eu/environment/biocides/non_inclusions.htm).

## **2.4 Hazardous substance information on biocidal products**

### **General**

Biocidal products and active substances, which have not yet been authorised, must be classified and labelled by the marketing enterprise according to the information available and to Article 20 (despite Article 20(3) b, d, e, and k) of Directive 98/8/EC.

## **General rule for the classification and labelling of biocidal products**

Since 30 July 2004 biocidal products and active substances must be classified, labelled and packed according to the regulations of Directive 1999/45/EEC due to the statutory provisions in Directive 98/8/EC Article 20.

## **Safety Data Sheet (SDS) for biocidal products**

Under Directive 91/155/EEC, as amended by Directive 2001/58/EEC (Safety Data Sheet Directive) Safety Data Sheets must be available for biocidal products from 30 July 2004<sup>4</sup>.

Thus according to Directive 1999/45/EEC a Safety Data Sheet must be available if the biocidal product is a dangerous preparation, and in case of professional use. For biocidal products not classified as dangerous but containing dangerous substances a Safety Data Sheet must be available on request<sup>5</sup>. This should be mentioned on the packaging of the product<sup>6</sup>.

## **Additional labelling and duties to supply information of biocidal products according to Directive 98/8/EC** (if Article 20 (3) is in national force, e.g. products with legal authorisation)

Active substances and products containing new active substances must be classified and labelled according to all items of Article 20 of the Biocidal Product Directive.

Under Article 20(3) of Directive 98/8/EC, it is, in addition to the mentioned requirements, necessary to acquire specific information on products with legal authorisation (products outside the "intermediate stage"). This information is also necessary for biocidal products, which are not dangerous preparations under Directive 1999/45/EC. Labels shall not be misleading or give an exaggerated impression of the product and, in any case, not mention the indications "low-risk biocidal product", "non-toxic", "harmless" or similar indications. In addition, the label must show clearly and indelibly items a) to m), which are listed below.

It is necessary to distinguish where and at which time the information needs to be provided:

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<sup>4</sup> replaced by REACH-regulation Article 31(6) (EC) No 1907/2006

<sup>5</sup> REACH-regulation Article 31(1) and (3) (EC) No 1907/2006 and

<sup>6</sup> Annex V character C of Directive 1999/45/EEC

The following information is always necessary on the label of a biocidal product with a national authorisation:

- a) the identity of every active substance and its concentration in metric units;
- b) the authorisation number allocated by the competent authority (**after authorisation**);
- c) the type of preparation (e.g. liquid concentrates, granules, powders, solids, etc.)
- d) the uses for which the biocidal product is authorised (e.g. wood preservation, disinfection, surface biocide, anti-fouling, etc.) (**after authorisation**);
- (e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation; (**after authorisation**)
- (f) particulars of likely direct or indirect adverse side effects and any directions for first aid;
- g) if accompanied by a leaflet, the sentence 'Read attached instructions before use';
- (i) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;
- (j) the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated,[...] and if applicable (**after authorisation**) the categories of users to which the biocidal product is restricted;
- k) information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water;
- m) for microbiological biocidal products, labelling requirements according to Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work.

Member States shall require that items 3(a), (b), (d) and where applicable (g) and (k) always be carried on the label of the product.

Member States shall permit items 3(c), (e), (f), (h), (i), (j) and (l) to be carried elsewhere on the packaging or on an accompanying leaflet integral to the packaging. These items of information shall be regarded as label information for the purposes of Directive 98/8/EC.

Biocidal products and active substances, which have not yet been authorised, must be classified and labelled by the marketing enterprise according to the information available and according to national legislation.

## **Advertisement for biocidal products**

It is necessary to distinguish advertising from classification and labelling.

According to Article 22(1) of Directive 98/8/EC every advertisement for a biocidal product is accompanied by the sentence “Use biocides safely: Always read the label and product information before use”.

Member States shall prescribe that advertisers may replace the word ‘Biocides` in the prescribed sentences with an accurate description of the product-type being advertised, for example wood preservatives, disinfectants, surface biocides, anti-fouling products, etc

According to Article 22(2) advertisements for biocidal products do not refer to the product in a manner which is misleading in respect of the risks from the product to human or the environment. Under no circumstances may the advertising of biocidal products mention “low-risk biocidal products”, “non-toxic” or “harmless” or any similar indications.

Important deadlines for relevant enforcement according to BPD can be seen in APPENDIX 4.

## **2.5 Scope**

### **Borderline cases**

In the preparation prior to the identifications and notifications, Member States and the industrial sector submitted a number of questions on various issues, in particular, questions about borderline cases between the BPD and other Directives, and between the 23 product types covered by the BPD.

Questions about the scope of the BPD and the answers are collected and published by the European Commission in a Manual of Decisions on the Commission website<sup>7</sup>, and further information about scope issues can be viewed under “scope documents” and “rules of provisions”, and under “guidance documents”.

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<sup>7</sup> Manual of decision:  
<http://ec.europa.eu/environment/biocides/manual.htm>

### **Borderline cases between the BPD and other Directives**

First, if the products in APPENDIX 5 to this report are covered by any of the Directives mentioned in Article 1(2) of the BPD these are exempted from the purposes of the 98/8/EC Directive.

As a consequence of Article 1(2) of BPD, the definition of “biocidal products” includes the necessary individual scopes of the related areas of regulations on medicinal products, medical devices, commodities, feeding stuffs and plant protection products (PPPs).

Scope of borderline cases and the criteria (which are not legally binding) in relation to medicinal products, medical devices, foodstuffs and commodities, feeding stuffs, plant protection products and detergents on

<http://ec.europa.eu/comm/environment/biocides/borderline.htm> can be used in the event of doubt. Furthermore, the scope of the borderline cases is summarised in an overview in APPENDIX 5 to this report.

### **Borderline cases between product types and solutions within the definition of biocidal products**

Another important borderline case to be discussed under the scope of the implementation of Directive 98/8/EC concerning the placing on the market of biocidal products, which shall be handled in the Manual of Decision, includes solutions as to whether a product is biocidal or not, and when they are extended to one or more of the 23 product types. The phrasing of biocidal product in the definitions under Article 2 of the BPD is very important:

**(A) ”Active substances“:** Substances with a general or specific effect on harmful organisms: Whether a product contains any active substances included in one of the product types and whether the product has a specific or harmful effect on any harmful organism.

**(B) ”put up in the form in which they are supplied to the user...“**

A distinction between production and downstream users as to find out whether the active substance in the final product is a raw material or used in the final product with and without biocidal functions.

**(C) “... intended to ...”**

The intended use of the product is the relevant criterion for the decision whether or not a product is a biocidal product. Decisive for the determination of a biocidal product is its predominating earmarking claim according to objective criteria, as documented and judged

objectively by an average informed user. Objective criteria could be e.g. the public offer of a reward or the presentation of a product. If it is offered e.g. as a product with „antibacterial“, „disinfectant“, „sanitise“, „fumigate“, „fungicidal“ or „biocidal“ properties the product is a biocidal product, if it is not exempted by Article 1 (2) of Directive 98/8/EC (as e.g. cosmetics).

**Furthermore a so called “dual use” is also possible:** If a product has a non-biocidal main function and a biocidal secondary function and a claim for the biocidal secondary function is made, then it is possible that the product has to fulfil either both regulations or only one. An example could be a cosmetic product which also has some biocidal effects. Here it depends on the rules laid down in the Cosmetic Product Directive (CPD). If the product has properties that are allowed by the CPD it is covered by the CPD and subsequently excluded from the BPD. If the product is not covered by the CPD it shall be considered a biocidal product. For example: A mosquito repellent which also has skincare effects is covered by the BPD.

“Under the BPD a biocidal product is defined as such and therefore it is not necessary to put a claim on the label. However, it is reasonable to expect that an intended biocidal effect would be reflected in a relevant claim. In absence of such a claim, on the label or elsewhere, some other relevant indication or user instruction in which the product is presented beyond its formulation, e.g. presentation of the product, user instruction would be needed to justify a conclusion that it was “intended” to be biocidal. In case of doubt it may be helpful to refer to the “judgement of an average informed user” or to check the claim of similar products placed on the market.

**(D) “by chemical or biological means and“**

Products with physical effects (e.g. plane flaps) are not biocidal products.

ANNEX V of the Directive 98/8/EC includes a list of 23 product types. Many active substances have been notified as being used in more than one product type (ANNEX II to Commission Regulation (EC) 1451/2007). Specific questions about whether certain products and substances are biocidal products, or whether the function of a product with several potentially active substances and a product with a notified and a non-notified substance, are biocidal have already been discussed and described in the Manual of Decisions.

### 3 Objectives and goals

The objectives of the EuroBiocides project were

- to carry out harmonised European enforcement of the Directive 98/8/EC;
- to find out which industries and enterprises are dealing with biocidal products and substances;
- to produce better and clear information for the industries and retailers who are in charge of placing biocidal products and substances on the market;
- to elaborate recommendations to the Commission, the national authorities and the industries;
- to advise industries and to examine the degree of knowledge on the legislation.

The main goals were:

- to exchange information and experience among the Member States to avoid differences in the way the Directive 98/8/EC is enforced in the different Member States and thus to avoid different competitiveness of the relevant enterprises;
- to reduce risks to human health and the environment from using biocidal products, which are not in compliance with the legislation;
- to prepare enforcement strategies for each country suitable for the national situation;
- to map out similar market conditions on a joint and national level.

In order to support the EuroBiocides' objectives and goals the inspectors were facing the following challenges as to the enforcement:

- examination of classification and labelling to ensure safe use
- active substances and products which have not been identified or where no notification has been accepted (non-inclusion), and substances, which have not been notified in a specific product type according to ANNEX II of the consolidated Review Regulation and are removed from the EU market from 1 September 2006;
- non-included substances which were to be removed from the EU market in compliance with non-inclusion decisions and phasing-out of substances after 1 September 2006;
- paying attention to problems that might occur, if the inspectors have to deal with a high number of unclear borderline cases.

In order to ensure effectiveness, enforcement of the legislation must be comparable within the Member States of the European Union and the European Economic Area and thus inspections and enforcement should be carried out as part of this project.

## **4 Project description**

As the EuroBiocides project comprises training as well as inspections, the preparation of inspectors was carried out in three phases, which according to the project manual were as follows:

- 4.1. Preparation phase
- 4.2. Inspection phase
- 4.3. Reporting phase

### **4.1 Preparation phase**

The preparation phase was carried out on CLEEN-meetings with a German proposal for the project in Bonn in 2005, followed up by group work in Vienna, Austria in 2006, and finally adopted in Krakow, Poland, May 2007. In this phase the participating countries, the working group and the schedule of the project was decided on.

#### **4.1.1 Participating countries, working group and preparation of checklist**

The working group included Denmark, Germany, Spain, the Netherlands and Switzerland. Since 2007, the project management has been carried out by Denmark who acted as focal point for all administrative tasks including completion and coordination of the manual, drafting the time schedule and handing over the manual, as well as distribution of other general information to the participating countries.

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

The project was organised by using the EuroBiocides manual, including the necessary tools for preparation of inspectors and training in the relevant legislation, as well as a step by step checklist and working method (APPENDIX 6). The checklist was prepared by the WG and complied with the legislation and the topics of the project in general.

#### **4.1.2 Preparation of the participating countries**

Preparation of the participating countries included implementation of the proposed strategies. The national authorities selected enterprises for the purpose of carrying out inspections and examining their products.

Each country had to:

- train the national inspectors in order to become familiar with the technical guidelines, the working methods, tools and the results form.
- inform involved authorities and trade organisations about the project;
- finalise the completion of procedure documentation;
- prepare their inspection, i.e., company visits
- provide information about the project to trade associations and enterprises;
- draw up a working plan taking into account the Manual and the inspection tools: "Questionnaire Enterprises" and "Questionnaire Product".

#### **4.2 Inspection phase**

During this phase the inspections were carried out:

##### **4.2.1 Selection of products and product groups:**

At the 7<sup>th</sup> CLEEN meeting a proposal was put forward that every participating country should inspect at least 10 enterprises and 5 different products/active substances. Furthermore, the suggested working method in APPENDIX 6, to select products by the criteria: "many borderlines", "high volume" and "high risk", has been followed by most of the participating countries.

It was proposed to make inspections of product types 1, 2, 5, 8, 18, 19 and 21 under the scope of the preliminary Manual in 2006, but because of the change of time schedule and deadlines, product types 3, 4, 6, 7, 13, 14 and 16 were recommended as well. It was even accepted that some countries inspect product types 10, 11 and 20.

Dossier submission under the review programme for each product type is shown in table 2.3.-1.

Prolongation of the review programme from 2012 to 2014 meant that only active substances in PT14 and PT18 with a deadline 28 March 2004, and PT16, PT17, PT19 and PT21 with a deadline 30 April 2006 could easily be among the non-inclusion decisions, but only few for PT1, PT2, PT3, PT4, PT5, PT6 and PT13 with a deadline 31 July 2007, when the inspection phase was nearly finished.

PT7, PT9, PT10, PT11, PT12, PT15, PT17, PT20, PT22 and PT23 had a deadline 31 October 2008 and no decisions were taken for those product types when the project finished. Non-inclusion decisions among those product types with a later deadline were found, e.g. in PT2, PT4 and PT10, because some active substances were phased out from 1 September 2006 or because no company or Member State have showed an interest in the substance.

The 23 product types covered by the legislation are placed in APPENDIX 3.

#### **4.2.2. Inspection working method**

Inspection tools “Questionnaire Enterprises” and “Questionnaire Products” are placed in APPENDICES 7 and 8 of this report.

##### **APPENDIX 7: “Questionnaire Enterprises” (one form per inspection).**

This questionnaire mainly includes questions which answer the objective of the project. The form is very convenient in order to have an ambitious dialogue with all enterprises.

The entire “Questionnaire Enterprises” form, APPENDIX 7, was voluntary to hand in.

##### **APPENDIX 8: “Questionnaire Products”**

This questionnaire about the collected products was submitted in order to meet the goals of the project, and it mainly constitutes a checklist of subjects which should be controlled.

The questionnaire includes:

- examining problems and borderline cases in enforcing the Directive;
- examining labelling, classification and packaging;
- examining SDSs and advertisement;
- examining the marketability of the biocidal products;
- providing support and disseminating information to the enterprises;

The questionnaire checklist includes 35 questions for which between 1 and 7 different answers are possible.

An Excel format “Excel Questionnaire and result form” (corresponding to APPENDIX 8 of the EuroBiocides Project Inspection Manual) was developed to deal with all the data. The format included 7 excel sheets, of which 6 sheets corresponded to the “Questionnaire Products” in APPENDIX 8; the 7<sup>th</sup> sheet was the “Inspection Result form” where the results of the enforcement were filled in.

A drop boxes with the possible answers were given in the Excel sheets and the possible answers chosen in accordance with the results for the examined product.

All questions in the “Questionnaire Products” in APPENDIX 8 had to be transferred to the “Excel Questionnaire” and result form” before it was handed in to the working group.

**APPENDIX 9:** Names of countries and contact persons.

The 15 national co-ordinators can be found in APPENDIX 9.

**APPENDIX 10: Focal points, national co-ordinators and list of participating inspectors**

More than 450 inspectors participated in the project and were skilled in the enforcement of biocidal products. A list with names of focal points, national co-ordinators and names of the participating inspectors can be found in APPENDIX 10.

### **4.3 Reporting phase**

All results concerning the inspection of the companies, specific problems, product data and enforcement results were submitted by the Member States after the inspection phase ended January 2009.

All participating countries submitted their results into the Excel Results Form which was prepared for the EuroBiocides project. APPENDIX 7 was not obligatory and only 1 country (Latvia) handed in that enterprise information, however, many countries added comments to this subject in their specific country overview presentation.

An introduction to the final report was prepared by the WG in spring 2010, and was presented to the CLEEN group by the participating countries at the 11<sup>th</sup> CLEEN conference in Sucevita, Romania, 7-8 September 2010.

#### **4.3.1 Evaluation of the “questionnaire product” form and the data filled in**

The parameters for considering the selected companies as well as the products are well defined, and the working group found most of the information in the reports from the participating countries acceptable in order to keep the results comparable and sufficient.

However, some minor mistakes, such as blank, no answer and non comparable data, were observed in 6 specific areas of the Excel result form in APPENDIX 8:

1. 69 percent of the answers for national fee (question 1.4) were “blank”. Furthermore, the question about national authorisation was not clear enough, because national authorisation was mistaken for national registration in many approaches. And several of the participating countries have later been asked to clarify this specific question.
2. Question 2.12 and 2.13 about “Indication of danger” had the following options: “OK”, “not OK”, “not applicable”, “uncertain” and “blank”. The answers were somewhat confusing as “blank” in some approaches referred to “not applicable” with the interpretation “not dangerous product” and in other approaches “blank” was used if the product had not been checked. The mistakes have been clarified case by case and “blank” was changed to “not applicable” and decreased from 165 products to 95 in this process.
3. 10 questions (question 2.16 to 2.25) represented the 8 specific BPD-requirements for labelling. Legally binding provisions 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. An additional question whether the requirements were legally binding or not, would have fulfilled the analysis and consolidated the final result of products not in-compliance with these requirements.

Furthermore a question about the penetration of the products on the market (national or international brand) would also have supported the interpretation of the results and would in general have improved the interchange between the participating countries

4. Safety Data Sheets must be available, if the biocidal product is a dangerous preparation (question 3.1a) intended for professional use, according to Directives 1999/45/ EEC as statuted in Article 21 of Directive 1998/8/EC.

Or safety Data Sheets must be available on request, if the biocidal product is not classified as dangerous (question 3.1b). Question 3.1b may have been unclear, or should have been separated into two questions: one for dangerous products and one for not dangerous products; in addition, the possibility to answer “not checked” would have been appropriate.

Examination of SDSs (question 3.1c to 3.1d) was difficult to work out, mainly because not all countries are in charge of checking the SDSs (question 3.1 d) and other countries only checked the content of chemical substances available in the SDS.

5. Questions 4.1 to 4.4 about advertisement were not answered on a regular basis for all participating countries and were treated as voluntary/not analysed in this report. However, non-compliance with regards to misleading sentences and labelling impression could be analysed within the questions regarding packaging (question 2.1 to 2.10).
6. The answers for the final questions (“prohibited”, “further enforcement necessary” etc) depended on if the enforcement process was finished when the results were handed in or not. The results were not comparable, and in some cases the answers were blank. (Explanations or enforcement status and strategies can be found under each country and some countries, Spain and Germany, also added overview comments).

Furthermore, to improve the handling of the results in the Excel results form, all the sheets should have been better connected: **question 1.2** (Product type) under “Sheet Section 1” should be repeated as a first column under **question 3.2**, “Please indicate active substances and concentration; as well as EINECS or CAS number (if available)” under “Sheet Section\_3\_3.1 – 3.2” . The same was the case in tasks for National Authorisation, **question 1.3**, which should have been repeated in “section\_2\_2.16-2.25” with the Specific BPD requirement for classification.

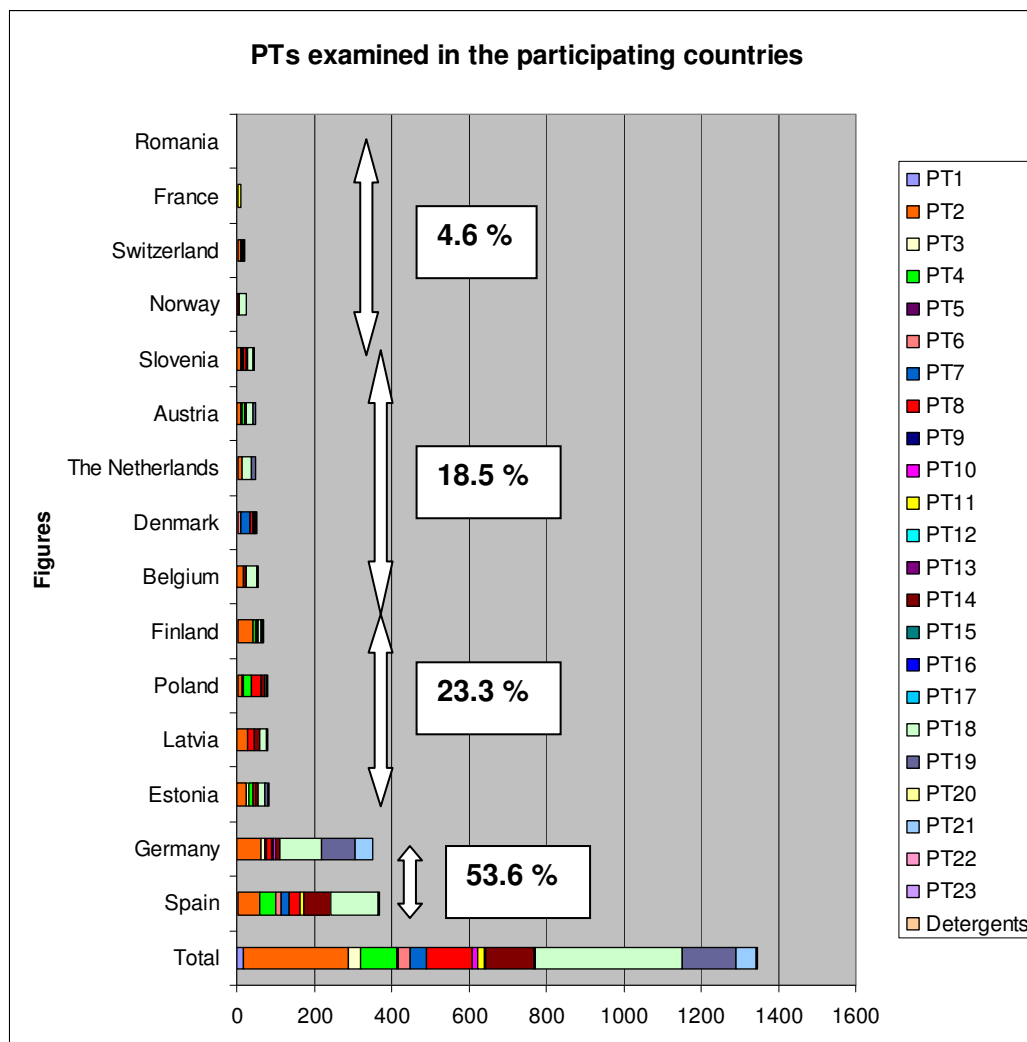
As a result of all the evaluation work, a list with definitions of specific terms in the database and the glossary which was used is prepared in APPENDIX 1 in order to avoid those mistakes in future joint projects.

As all countries have handed in sufficient data to the Excel result form, all countries have been included in the presentation of the results without reservation to numbers of examined products, specific themes or extractions. Those parameters can be obtained and studied in the following presentations of the countries.

## 5 Enforcement and results

### 5.1 All countries (summary and averages)

In total, **1346 products** were examined. The total number of examined products in each product type and the number and names of countries who have dealt with the specific product types are shown in the figure below.



**Figure 5.1-1: Overview of collected products in each country (more details under national chapters and in table 5.1.2)**

According to the Figure above the projects can be grouped into four types based on the number of examined products handed in.

Spain and Germany examined more than 350 products each, which totals 53.6 % of all examined products.

Estonia, Latvia, Poland and Finland, examined between 70 and 82, a total of 313 products, 23.3 %.

Countries with more specific approaches Belgium, Denmark, the Netherlands, Slovenia and Austria examined between 48 and 55 products, a total of 249 products, 18.5 %.

Norway, Switzerland, France and Romania reported a total of 62 products, 4.6 %

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

In total, about 70 (5.2 %) products had similar names, (but not necessarily the same content).

In fact, products with the same name were very different with regards to classification, labelling and ingredients. The reasons were:

- The products were “old products” which were no longer manufactured but still offered by retailers. Sometimes classification and labelling of these older products were not OK.
- Packaging was changed by the manufacturer but the product name stayed the same.
- Products with the same name contained different active substances. Sometimes manufactures substituted active substances when they have the status of “phase-out” with other active substances, but the product was placed on the market with the same name.
- Sometimes products with the same name were manufactured or imported by different companies.

The project was conducted in a very efficient way: Only few products seemed to be inspected twice but the products may have been different because of the above mentioned reasons: 14 products (around 4 %) in the German project seemed to be repeated (similar name on product/checked more than once). 3 products (less than 1 %) in the Spanish approach seemed to be repeated, those products were inspected in five different regions in Spain.

2 products in the Polish project (around 2 %) had similar names. 1 product with a similar/repeated name was found in the German and Austrian project; 1 product with a

similar/repeated name was found in the Latvian and Estonian project, 1 product with a similar/repeated name was found in the Estonian and German project, 1 in Latvia and Poland and 1 in Latvia and Germany.

Comparing the number of inspected products with the number of inhabitants most products were examined in Estonia, followed by Latvia, Slovenia, Finland and Denmark. This can be seen in the table below.

Country	Number of inspected products	<u>Number of inhabitants (M)</u> <sup>8</sup>	Inspected products per 1 M inhabitants
Estonia	82	1.3	63.1
Latvia	81	2.3	35.2
Slovenia	45	2	22.5
Finland	70	5.4	13.0
Denmark	51	5.5	9.3
Spain	369	46.1	8.0
Belgium	55	10.6	5.2
Norway	25	4.9	5.1
Austria	48	8.3	4.6
Germany	353	82.3	4.3
Netherlands	50	16.6	3.0
Switzerland	22/200*	7.8	2.8/28.2*
Poland	80	38.1	2.1
Romania	5	21.5	0.2
France	10/450*	64.3	0.2/7.0*
<b>Total</b>	<b>1346</b>	<b>317</b>	<b>3.6</b>

**Table 5.1-1: Inspected biocidal products in relation to inhabitants of participating countries**

**\*Number of products not handed in to the project, but mentioned as part of the national approaches/strategies in France and Switzerland**

### Product types

18 out of 23 product types included in BPD were reported in the final project.

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<sup>8</sup> <http://www.auswaertiges-amt.de>, downloaded 29.07.2010.

PT	#	1	2	3	4	5	6	7	8	9	10	11	12	14	16	18	19	20	21
Austria	48	1	10	4	6				4							16	7		
Belgium	55		16											10		25	4		
Denmark	51		6				7	22	7		5					2	2		
Estonia	82	1	24	5	11				8			1		5		17	8	2	
Finland	70	3	37	3	6		2		3		1					8	3		4
France	10								4			6							
Germany	353	1	61	11		3			16	1	7			10	1	109	87		46
Latvia	81		27						19					13		18	4		
The Netherlands	50	2	11	2												23	12		
Norway	25		1											7		16	1		
Poland	80	5	10	4	18		1	1	22		1			10		4	4		
Romania	5															5			
Slovenia	45	1	6		7			2	7					4		15	3		
Spain	369	2	56	1	41	2	14	18	30			9	2	68		122	3		1
Switzerland	22	2	8	1	2		4	1	2							2			
Sum #	<b>1346</b>	18	273	31	91	5	28	44	122	1	14	16	2	127	1	382	138	2	51

**Table 5.1-2: Number of biocidal products examined and the distribution on PTs in each participating country. 1 borderline product in the Danish approach claimed to be a detergent were examined in the project. This product was included to PT2 in table 5.1-2 and 5.1-3 below**

**Between 91 and 382 products were examined in PT2, PT4, PT8, PT14, PT18 and PT19 (in total 84.2 %).**

Product types: PT2 (disinfectants), PT4 (food and feed area disinfectants), PT8 (wood preservatives), PT14 (rodenticides), PT18 (insecticides), PT19 (repellents) included more than 91 products each, and counted 84.2 % of all examined products.

- Disinfectants, PT2 included 272 products (20.2 %); insecticides, PT18 included 382 products (28.4%), in total 48.6 % of all examined products. Both PT2 and PT18 were examined in 13 countries.
- Repellents, PT19 included 138 (10.3 %); wood preservatives, PT8, included 122 (9.1 %) products; rodenticides, PT14, included 127 (9.4 %); and food and feed area disinfectants, PT4, included 91 products (6.8 %), in total 35.6 % of all examined products. PT8 and PT19 were inspected in 11 countries and PT4 and PT14 in 7 and 8 countries respectively.

<b>MAIN GROUP 1</b>	<b>Disinfectants and general biocidal products (PT1 to PT5)</b>	<b>Number of products (percent %)</b>	<b>Country examined</b>
Product type 1	Human hygiene biocidal products	18 (1.3%)	9: Spain, Germany, Estonia, Finland, Poland, The Netherlands, Austria, Slovenia, Switzerland
Product type 2	Private area and public health area disinfectants and other biocidal products.	273 (20.3 %)	13: All except France and Romania
Product type 3	Veterinary hygiene biocidal products	31 (2.3%)	8: Spain, Germany, Estonia, Finland, Poland, The Netherlands, Austria, Switzerland
Product type 4	Food and feed area disinfectants.	91(6.8 %)	7: Spain, Estonia, Finland, Poland, Slovenia, Austria, Switzerland
Product type 5	Drinking water disinfectants	5 (0.4%)	2: Spain and Germany
<b>MAIN GROUP 2</b>	<b>Preservatives (PT6 to PT13)</b>		
Product type 6	In-can preservatives	28 (2.2 %)	5: Spain, Poland, Finland, Denmark and Switzerland
Product type 7	Film preservatives	44 (3.3%)	5: Spain, Poland, Slovenia, Denmark and Switzerland
Product type 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: Spain, Germany, Estonia, Latvia, Finland, Poland, Denmark, Austria, Slovenia, Switzerland and France
Product type 9	Fibre, leather, rubber and polymerised materials preservatives.	1 (0.1%)	1: Germany
Product type 10	Masonry preservatives	14 (1.0%)	4: Germany, Poland, Finland and Denmark
Product type 11	Preservatives for liquid-cooling and processing systems.	16 (1.1%)	3: Spain, Estonia and France
Product type 12	Slimicides	2 (0.1%)	1: Spain
Product type 13	Metalworking-fluid preservatives	0	

<b>MAIN GROUP 3</b>	<b>Pest control (PT14 to PT19)</b>	<b>Number of products (percent %)</b>	<b>Country examined</b>
Product type 14	Rodenticides	127 (9.4 %)	8: Spain, Germany, Estonia, Latvia, Poland, Belgium, Norway, Slovenia
Product type 15	Avicides	0	
Product type 16	Molluscicides	1(0.1%)	2:Germany
Product type 17	Pesticides	0	
Product type 18	Insecticides, acaricides and products to control other arthropods	382 (28.4%)	All, except France and Romania
Product type 19	Repellents and attractants	138 (10.3%)	11: Spain, Germany, Estonia, Finland, Poland, Belgium, the Netherlands, Denmark, Austria, Slovenia and Norway
<b>MAIN GROUP 4</b>	<b>Other biocidal products (PT20 to PT23)</b>		
Product type 20	Preservatives for food or feedstock	2 (0.1%)	1: Estonia
Product type 21	Antifouling products	51 (3.9 %)	3: Spain, Germany and Finland
Product type 22	Embalming and taxidermist fluids	0	
Product type 23	Control of other vertebrates	0	

**Table 5.1-2: Examined products in PTs included to the BPD. In the right column, examined products per country.**

**Between 14 and 51 products were examined in PT1, PT3, PT6, PT7, PT10, PT11 and PT21 (in total 15.0 %)**

- Human hygiene biocidal products, PT1 (1.3 %); veterinary hygiene biocidal products, PT3 (2.3 %); in-can preservatives, PT6 (2.2 %); film preservatives PT7, (3.3 %); masonry preservatives PT10, (1.0 %); preservatives for liquid-cooling and processing systems, PT11 (1.2 %) and antifouling, PT21 (3.9 %), 15.0 % of all products were examined in those product types.
- PT1 (1.3 %) were examined in 9 countries and PT3 (2.3 %) in 8 countries, but PT6 (2.2 %), PT7 (2.2%), PT10 (1.0%), PT11 (1.1%) and PT21 (3.9 %) were examined in 3 or 5 different countries.

### Up to 5 products examined in PT5, PT9, PT12, PT16 and PT20 (below 1 %)

- Up to 5 products were examined in PT5, food and feed area disinfectants, (0.4%); fibre, leather, rubber and polymerised materials preservatives, PT9 (0.1%); slimicides, PT12 (0.1%); and molluscicides, PT16 (0.2 %) and PT20 Preservatives for food or feedstock were examined in 1 and 2 countries.

### No products examined in PT13, PT15, PT17, PT22 and PT23

- No products were examined in metalworking-fluid preservatives (PT13), avicides (PT15) pesticides (PT17) preservatives for food or feedstock (PT20) embalming and taxidermist fluids (PT22) and control of other vertebrates (PT23).

The division into types of enterprises and purpose of the products for all participating countries was as in the figures below:

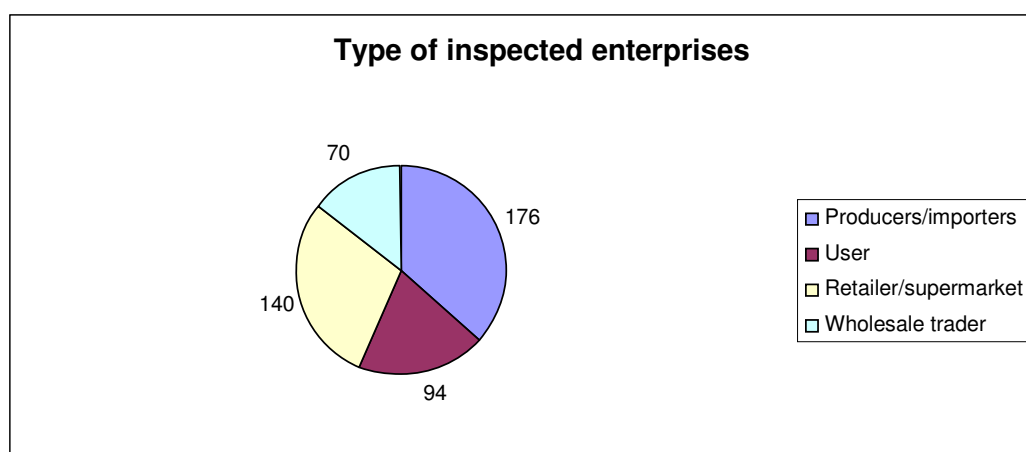


Figure 5.1-2: Overview of type of enterprises inspected in all participating countries.

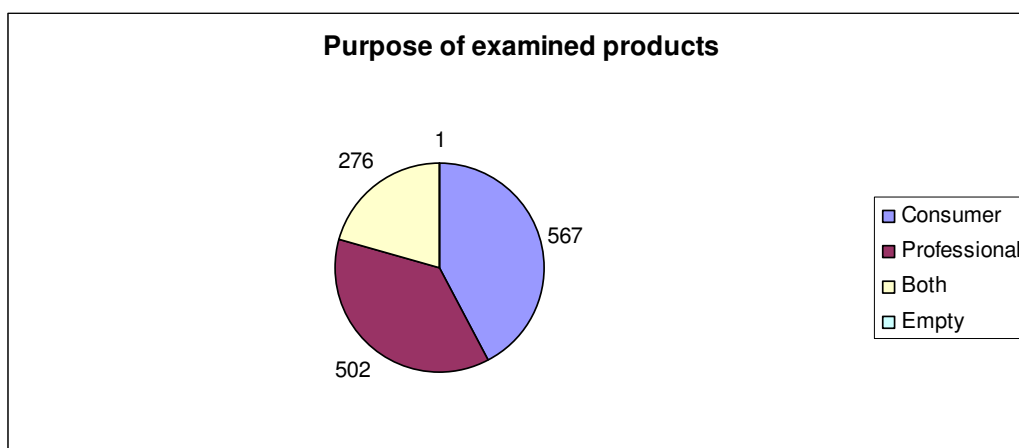
Inspections took place in 480 enterprises.

- A majority, 176 out of 480 (36.7 %) visited enterprises were producers and importers. 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 supply chain. The majority were inspected in Spain (50), Belgium (19), Poland (19), Finland (16) and Switzerland (15)
- 140 (29.2 %) inspections took place at retailers/supermarkets. Here the expected infringement is usually higher compared to products from professionals, depending on the information in the supply chain from producers to retailers. The majority were

inspected in Germany, 102 retailers/supermarkets, in Spain 14, in Denmark 8 and the Netherlands 5.

Information about health and safety does not always reach the retailers/supermarkets.: It is a fact that manufacturers or importers do not always provide SDSs or other relevant information through the supply chain.

- 94 (19.6 %) inspections took place at users, e.g. 56 in Spain, 21 in Poland and 10 in France. Knowledge about legislation is usually moderate in this category; some are down stream users and use chemicals in the working process.
- 70 (14.6 %) inspections took place at wholesale traders; their knowledge about biocidal legislation is largely based on information from producers/importers; and the expectation about knowledge and infringement is close to being the same as for retailers and supermarkets. The majority were inspected in Poland (23), Spain (11), Latvia (7) and Slovenia (7).



**Figure 5.1-3: Overview of examined products in all participating countries**

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

The impression is that professionals generally have greater knowledge on both legislation and protection against chemical exposure than consumers.

## Labelling and packaging

Packaging was examined on 1307 (97.1 %) out of all 1346 products.

According to questions 2.1 to 2.8 in the "Questionnaire product" form and Article 20 in the BPD, the following results were found:

1. General comments on packaging were filled in for 9 products (0.7 %), 1 in Denmark and 8 in Spain. Another 3 (0.2 %) products in PT19 were packed like mints (sweets for children) in the Belgian approach.
2. Labelling was unclear and not indelible on 35 (2.7 %) products in 6 different countries, the majority with 4 (18.2 %) in Switzerland; 7 in Finland (10 %) and 19 (5.1 %) in Spain.
3. Misleading sentences were found on 36 (2.8 %) products in 8 different countries, a majority in Spain with 22 (6 %) followed by the Netherlands with 6 (12 %)
4. Labelling indicating low risk was found in 66 (5.1 %) products in 8 different countries, a majority in Germany, 35 (10 %); the Netherlands 5 (10 %) and Denmark 4 (9 %)
5. 2 (0.1%) products, 1 in Germany and 1 in Slovenia did not have a regular trade name on the product
6. Chemical names were missing on 19 (1.5 %) products in 4 different countries, 5 (50 %) in France; 9 (12.9 %) in Finland; 4 (5.1 %) products in Estonia and 1 (2.2 %) in Slovenia.
7. All national languages were not present on 27 (2.1 %) products in 7 different countries, as many as 16 (29 %) products in Belgium (3 national languages), 4 (6.6 %) in Finland (2 national languages) and 2 in Denmark (4 %).
8. Company name, address, telephone number etc. were missing on 226 (17.3 %) products in 11 different countries; a majority, 126 (35.7 %) in Germany; 16 (34.5 %) in Belgium; 15 (30 %) in the Netherlands; 1 (20 %) in Romania; 42 (11.4 %) in Spain; 5 (13.2 %) in Austria 4 (9.1 %) in Denmark; 5 (8.2 %) in Finland; 5 (6.6 %) in Latvia etc.

Additionally, the questionnaire checklist questioned whether the products were dangerous or not, and whether there were chemical names of the component on the preparations

9. 257 (19.1 %) products were not dangerous products. Only few products have not been examined according to dangerous properties, and no information/blank about danger was filled in for 57 products. Altogether, 1294 products were examined

according to danger labelling (including not applicable/not dangerous), 51 products were blank/no information/not checked, and with this calculation another 6 products were identified dangerous.

10. 63 preparations out of approximately 1031 dangerous preparations (6.1 %) had no chemical names on the product; Latvia reported 34 products missing chemical names, Estonia reported 4 products, Finland reported 9 products, Slovenia reported 1 product and France reported 5 products.

The results for the specific participating countries are placed in chapter 5.2.1 to 5.2.15.

### **Danger symbols**

905 (67.2 %) of the examined products had at least one danger symbol. 257 (19.1 %) 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.

<b>Symbol</b>	<b>Figures</b>	<b>% of products with a symbol out of 905</b>
T+	9	1.0
T	26	2.9
Xn	352	38.9
C	133	14.7
Xi	196	21.7
F+	121	13.4
F	66	7.3
O	35	3.9
E	0	0
N	369	40.8

**Table 5.1-4: Calculation of danger symbols of examined products**

The symbols were mentioned as “not OK” for approximately 179 (13.3 %) products, for which the labelling with symbols were missing or the symbols on the products were wrong.

57.5 % of the examined products, shown in table 5.1-4, with a symbol had danger symbols higher than dangerous for health, meaning dangerous for health (Xn), corrosive (C), toxic (T) and very toxic (T+).

More than a third of all products with symbol, 352 (38.9 %), had dangerous for health symbols and 369 (40.8 %) of the examined products had dangerous for the environment symbols.

Some product types share specific characteristics with a majority of the danger symbols (warnings) in specific classes, e.g. products in PT2 included all danger symbols, but a majority of the products were classified as irritant: Specific characteristics have been pointed out in the following.

#### **Very toxic (T+) and toxic (T) substances**

9 of the examined products were very toxic and 26 were toxic

Very toxic substances were found in 6 different product types: PT2 (1), PT4 (1), PT8 (2), PT12 (1), PT14 (1) and PT18 (2), mainly among the well represented product types.

Toxic substances were found in 9 out of the 17 examined product types: PT2 (3), PT4 (2), PT6 (1), PT7 (3), PT8 (3), PT9 (1), PT12 (1), PT14 (1) and PT18 (11)

#### **Harmful (Xn); (PT14 and PT8)**

Products with dangerous for health were found in many different product types, but over the average value (38.9 %) in PT14 and PT8 but they were also well represented in PT2 and PT18. Examples can be studied in the Spanish, German, Latvian, The Netherlands and Belgian approach.

#### **Corrosive (C); (PT4)**

14.7 % of the examined products were corrosive, the majority were found in PT4, examples are shown in the Spanish, Estonian, Polish, Finnish, Slovenian and Austrian approach.

#### **Irritant (Xi); (PT2)**

Irritant products were found in almost every examined product type, but were highly represented and over average value (21.7 %) for PT2 products.

#### **Very flammable (F+); (PT18)**

Most of the very flammable products were found in PT18 and PT19, but over the average value, 13.4 %, in PT18.

#### **Flammable (F); (PT2 and PT19)**

Flammable products were found in PT2, PT8, PT18 and PT19, but over the average value 7.3 % in PT2 and PT19.

#### **Oxidising (O); (PT2 and PT4)**

Oxidative products were mainly found in PT2 and PT4, and over the average value 3.9 % in both product types.

### **Dangerous for the environment (N); (PT8, PT14, PT18 and PT19)**

Products with environmental danger symbols were found in most of the examined product types, but over the average value 40.8 % in PT 8, PT14, PT18 and PT19.

### **Risk and Safety sentences (Results – indication of danger)**

The number of examined products according to their classification was 1295 (96.2 %) out of a total of 1346 products filled in. The examined products included “not dangerous” as the procedure was that “not dangerous” products were examined in order to find out if they were dangerous or not, but some countries answered “not applicable” instead of “OK”, the last would have indicated that the product had been examined.

Germany, Poland, Finland, Austria, Norway, Switzerland and Romania filled in “uncertain” for some products, mainly because the examination had not finished or because data were missing.

### **Indication of danger (Non-compliance around 20 %)**

A total of 263 (20.3 %) of those products examined according to danger labelling (including mistakes with symbols and R-sentences) were not OK. 4 countries: the Netherlands (2.0 %), Slovenia (2.2 %), Belgium (3.6 %) and Estonia (3.7 %) showed results for this parameter at an acceptable level, set to around 4 % of non-compliances.

Indication of danger was uncertain for 73 (5.6 %) of all the examined products.

### **Indication of safety (Non-compliances around 21 percent)**

For safety (S-sentences) the number of products which were not in compliance/not OK were calculated to 274 (21.2 %). Only Poland (2.5 %) and Slovenia (0 %) came up with a result under an acceptable limit, in this case set to around 4 %. All other countries found mistakes with indication of safety in more than 4 % of the examined products.

Indication of safety was mentioned uncertain for 8 (0.6 %) of all the examined products.

### **Indication of environmental danger (Non-compliances around 11 percent)**

Calculations showed that Environmental danger labelling was not in compliance in 138 (10.7 %) of the examined products, uncertain was mentioned for 9 (0.6 %) of the examined products.

5 countries: Estonia (3.7 %), Latvia (3.7 %), Finland (2.9 %), Poland (0 %), Slovenia (0 %) and France (0 %) showed results for this parameter at an acceptable level, set to around 4 % of non-compliances.

For some specific product types (PT8, PT14, PT18 and PT19) non-compliances with the environmental danger symbol were remarkable higher, because those product types include higher percentages of products with environmentally dangerous substances.

The results for the specific participating countries are placed in chapter 5.2.1 to 5.2.15.

### **Safety Data Sheets (SDS)**

As indicated in section 4.3.1: **Evaluation of the “questionnaire product” form and the data filled in**, sources of error and shortcomings in the questions about SDSs in the questionnaire products form were a problem, and shall be an object for further investigation of the BPD.

However, the following data were obtained and compiled from the data filled in:

- **SDSs availability:**

For 873 (80.2 %) out of approximately 1089 dangerous products SDS were available. No SDSs were available for 114 (10.5 %) of the examined preparations; further 359 products were not dangerous preparations or not checked).

- **SDSs available only on request:**

258 were available only on request (compared to 257 products, which were not dangerous), 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 SDS, not available on 54 (further 404 SDS were not inspected with that focus)

- **Content (SDS)** was checked on 834 products, not checked on 189 and blank on 313

- **Active substances examined:** Active substances were examined in 1284 (95.4 %) products in accordance with the information in the SDSs or other sources with information about contents of chemicals in the products.

## Borderlines

The following results were found for borderlines for which all (1346) products were examined:

MAIN GROUP	I: Disinfectants					II: Preservatives				III: Pest Control	
	PT	1	2	3	4	5	6	7	8	11	18
Borderlines	7	60	2	12	1	6	7	7	1	8	21
Percent % out of examined PTs	38.9	22.0	6.5	13.2	20.0	21.4	15.9	5.7	6.3	2.1	15.2

**Table 5.1-5: Borderlines found in examined PTs**

- 132 (around 9.7 %) of the 1346 examined products were borderlines.
- Borderlines were found in 11 different products types:
  - Remarkably many borderlines (over the average value out of the examined products in the PTs) were found in PT2 (22 %), PT4 (13.2 %), PT7 (15.9 %) and PT19 (15.2 %). Borderlines in PT2 respective PT19 were found in 10 and 8 countries, PT4 in 3 countries, P6 in 2 countries and PT7 in 1 country (Denmark).
  - 5 respectively 4 countries found borderlines in PT8 (7) and PT18 (8), but in percent values in PT8 (5.7 %) and PT18 (2.1 %) under the found average value.
  - The percentage of borderlines in PT1 (38.9 %) and PT5 (20 %) was high too, but the number of examined products in those product types was low, and the result was therefore less documented.
- A majority of 69 (5.1 %) out of all examined products had a borderline to detergent, mainly in PT2, but also products in PT4 and PT8.
- 34 (2.5 %) products had a borderline to others, the majority in PT8, PT7 and PT6.
- 13 (1 %) products with borderlines to cosmetics were found in PT1 (4), PT6 (3) and PT19 (6).
- 7 (0.5 %) products had a borderline to plant protection agents found in 4 different product types, PT2, PT8, PT18 and PT19, the majority in PT18.
- Borderlines to medical devices were found in 6 (0.5 %) products; in PT18 (2) and in PT19 (4).
- The number of borderlines was different for each country approach, but remarkably high (over the average value) in many of those countries which examined PT2, e.g.

Latvia (13), Estonia (9) and Spain (17) and for products in PT6, PT7 and PT8, e.g. in Denmark and Spain. For products in PT18, e.g. the Netherlands (3) and Slovenia (2) and PT19, e.g. the Netherlands (9) and Austria (3) (see under the specific country approach) reported borderline cases.

- Countries which examined products from either professionals/importers, retailers or wholesale traders for which the majority were intended for consumers or both, e.g. borderlines in Denmark (33.3 %), the Netherlands (30.0 %), Finland (21.4 %) and Latvia (21.0 %) generally found more (over the average value) borderlines.

### **Specific BPD-rules for labelling**

8 specific BPD-requirements (always necessary on the label of a biocidal product with a national authorisation) were examined.

The answers filled in for products which already had a national authorisation were approximately 697 (51.8 %), (this question was also affected by mistakes, because some answered yes in the meaning national registration, not authorisation, but the mistakes have later been clarified). The answers for no authorisation were 514 (38.2 %) and blank 135 (10 %).

Norway and Finland did not fill in data (blank) for these questions, and were not included in the calculation.

The question as to whether a procedure was in force (legal binding) for those products examined or not was not included in the questionnaire. And whether the products without authorisation were included to a legally binding procedure for the specific requirements or not, has not been proved on a regular basis for all examined products.

The calculation of products not in compliance with the 8 specific BPD-requirements was analysed in three scenarios 1: for all examined products, 2: products with legally binding provisions and 3: products without national authorisation for which no legal provision was provided, as reported in the following:

The average value was calculated for the 10 questions covering the 8 specific BPD requirements in each of the 3 scenarios and for the countries which have examined the BPD-rules. The average calculation does not give information about the number of products not in compliance; it is a simple estimate which is useful for comparison of the results found in each country.

**1: Results of the 8 BPD-requirements for all examined products.**

The 10 questions for labelling (8 specific BPD-requirements) have been examined in 13 countries involving 1210 products, for which the average of the 10 questions was calculated to 18.4 %. A majority of the findings were found in question h) and last part i), indicating that around 30 % of the products were not in compliance with a least 1 of the 8 specific requirements.

The results for the 10 questions varied between 8.1 % (lowest for the first question about identity of every active substance) and among the highest, 30.6 % (for the question about safe disposal and reuse of packaging) and 31.2 % (question about expiry date) for all examined products. 4 questions: f), h), last part i) and l) were identified (grey in the table) as being among those less known to the enterprises dealing with biocidal products.

<b>Examined BPD-requirements:</b>	<b>Figures for 1210 examined products</b>	<b>Percent (%) Not OK</b>
First part a) Identity of every active substance	98	8.1
Last part a) Concentration in metric units	137	11.4
c) Indication of the type of preparation	177	14.6
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	249	20.6
g) If accompanied by a leaflet: Sentence „read instructions before use“	158	13.1
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	370	30.6
First part i) Formulation batch number or designation	173	14.3
Last part i) Expiry date relevant to normal conditions of storage	377	31.2
j) Period of time needed for the biocidal effect, if relevant	220	18.2
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	269	22.2
<b>Average value for the following 10 questions (8 requirements):</b>		<b>18.4</b>

**Table 5.1-6: 8 Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always necessary on the label of a biocidal product with a national authorisation). The average calculation is a simple mathematical estimate useful for comparison between participating countries and products with and without legally binding provisions.**

## **2: Results of the 8 BPD-requirements for the products with authorisation/legally binding provisions**

Belgium, Estonia, Latvia, the Netherlands, Poland, Slovenia, Spain and Switzerland, had a majority of products with national authorisation for which provisions of the legally binding procedure were provided. In addition, Germany informed that they have a legally binding procedure for the specific BPD-requirements. With this calculation, approximately 1050 of all examined products were provided with a legally binding provision for the specific requirement, the average value for the 10 questions was calculated to 12.1 % (compared to 18.4 % for all examined products). Again a majority of the findings were found in question h) and last part i), indicating that around 30 % of the examined products were not in compliance with a least 1 of the 8 requirements, similar to the results found for all products.

In general, the results were 1 to 7 % better than for the calculation of all products, questions h), j), last part i) and l) were still among those with the highest percentage of products not in compliance with the specific BPD-rules.

## **3: Results of the 8 BPD-requirements for the products without national authorisation (no legal provision assumed)**

The countries which had products both with and without national authorisation in their approaches were divided and calculated separately, e.g. Belgium, Estonia, Latvia, Spain, Slovenia and the Netherlands.

In addition, Austria, Denmark, Romania and France reported products without national authorisation for which no legally binding provisions were provided; the average value for the 10 questions was calculated to 38.1 %.

Of course, the results showed that more products without national authorisation were not in compliance compared to those with and without authorisation (all), compiled in table 5.1-6.

The Worst “statistical calculation” (46.3 %) were in question f) about direct or indirect adverse side effects and any directions for first aid followed (44.4 %) by question l) about any specific danger to the environment, particularly concerning protection of non-target organisms and avoidance of contamination of water,

The average results were remarkably good for those products bearing in mind that no legally binding provisions were provided for those products. More detailed analyses of each country approach are placed in sections 5.2.1 to 5.2.15.

Evidently, further inspections focusing on these BPD rules are necessary.

Most of the BPD-requirements seem to be considered by the companies, but in order to increase the attention of the companies and to increase compliance with the BPD requirements, the development of guidelines may be useful for both enterprises and inspectors.

Country	Products with legal provision		Provision unknown	
	Examined products	Average (%)	Examined products	Average (%)
<b>Slovenia</b>	44	5.9	1	10
<b>Estonia</b>	78	6.7	4	30
<b>Poland</b>	79	7.3		
<b>Latvia</b>	71	11.8	10	35
<b>The Netherlands</b>	32	12.2	18	56.7
<b>Belgium</b>	50	15.4	5	72
<b>Germany</b>	353	19.9		
<b>Spain</b>	321	19.3	13	36.2
<b>Switzerland</b>	22	22.3		
<b>Austria</b>			48	20.8
<b>Denmark</b>			46	28
<b>France</b>			10	50
<b>Romania</b>			5	42.2
<b>Sum/average of the 10 specific BPD questions</b>	<b>1050</b>	<b>12.1</b>	<b>160</b>	<b>38.1</b>

**Table 5.1-7: Overview of the average calculation for the 10 questions (8 specific BPD requirements) in the participating countries, distributed in products with a legally binding procedure and products without authorisation for which no knowledge about legally binding procedure was available. The average calculation is a simple mathematical estimate useful for comparison between participating countries and products with and without legally binding provisions.**

### Products with active substances only on Annex I (Not notified to specific PT)

Active substances which were not notified to a specific product type in ANNEX II of REG (EC) 1451/2007, but identified as an existing active substance in ANNEX I, have been forbidden since 1 September 2006, provided that the function of the substance in the product was biocidal.

Function of the active substances in the product was sometimes difficult to assess in these cases as substances were filled into the questionnaire with notes like: “function of the substance in the product unclear”, “only in ANNEX I, but concentration of substance in the product not biocidal”. For all examined active substances, uncertainties about function were mentioned in approximately 15 cases.

These active substances (only in ANNEX I) were found in 11 different product types, indicated in table 5.1-8 below:

PT	2	3	4	5	6	7	10	14	18	19	21	#
<b>Austria</b>	1									1		2
<b>Belgium</b>										2		2
<b>Denmark</b>												0
<b>Estonia</b>	2		2									4
<b>Finland</b>	2/5*	0/3*	0/2*									2/10
<b>France</b>												0
<b>Germany</b>	9	1		1			1	2	1	19	4	38
<b>Latvia</b>									3			3
<b>The Netherlands</b>	1								2	3		6
<b>Norway</b>								1	1			2
<b>Poland</b>												0
<b>Romania</b>									2			2
<b>Slovenia</b>								1	2	1		4
<b>Spain</b>	6		6		1	5		9	4	2	1	34
<b>Switzerland</b>												0
<b>Sum #</b>	<b>21/5*</b>	<b>1/3*</b>	<b>8/2*</b>	<b>1</b>	<b>1</b>	<b>5</b>	<b>1</b>	<b>13</b>	<b>15</b>	<b>28</b>	<b>5</b>	<b>99/109</b>
<b>Examined products</b>	263	31	89	5	26	41	10	127	379	122	51	1284
<b>Percentage</b>	<b>8.0</b>	<b>3.2</b>	<b>9.0</b>	<b>20.0</b>	<b>3.8</b>	<b>12.2</b>	<b>10.0</b>	<b>10.2</b>	<b>4.0</b>	<b>23.0</b>	<b>9.8</b>	<b>7.7/8.5</b>

**Table 5.1-8: Products with ANNEX I active substances (not notified to specific PT in ANNEX II) in the participating countries. In the table above “not found” and non-inclusion-decisions are not taken into account (Figure of non-inclusion-decisions and “not found are counted below). \* (Function unclear)**

1284 (95.4 %) of all the products filled in were examined according to marketability of the active substances. The calculation showed that between 99 (7.7 %) and 109 (8.5 %) products contained active substances only in ANNEX I to regulation 1451/2007 when the inspection phase was running and the data was filled in.

Among the well documented product types, 78 out of 103 products with illegal active substances were found: in PT2 ( 9.9 %), in PT4 (11.2 %), in PT14 ( 10.2 %) and in PT19 (23 %), but in PT18 “only” 4 %.

Country	Examined products	Product with active substances (only notified in ANNEX I)	Biocidal function of active substance (only notified in ANNEX I) unclear	Product with active substances only in ANNEX I (percent % of examined products)
Romania	5	2		40
Finland	70	2	10	2.9/17.1
The Netherlands	39	6		15.4
Germany	319	38		11.9
Spain	369	34		9.2
Slovenia	45	4		8.9
Norway	25	2		8.0
Estonia	82	4		4.9
Austria	48	2		4.2
Latvia	81	3		3.8
Belgium	55	2		3.6
Denmark	34	0		0
France	10	0		0
Poland	80	0		0
Switzerland	22	0		0
<b>Sum/average</b>	<b>1284</b>	<b>99</b>	<b>10</b>	<b>7.7/8.5</b>

**Table 5.1-9: Figures of active substances (only notified in ANNEX I), ranged in accordance with the numbers of finding in the participating countries. Function was unclear for 10 products with those active substances in the Finnish approach.**

20 (5.9 %) out of the 2020 active substances examined (in total) were only notified in ANNEX I.

After finalization of the inspection phase in 2008, approximately 15 of these active substances found in PT18, PT19 and PT21, but only notified in ANNEX I, were phased out on a specific date, (mainly because no company or Member State indicated an interest in taking over the role of participant for the substances) published and listed on the non-inclusion list for the

specific product type, and for that reason left out of the inclusion list: ANNEX I, IA and IB to the BPD.

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 below.

CAS no / EINECS no	Active substances, Not notified on ANNEX II	PT	Non-inclusion decision
1310-73-2 / 215-185-5	Sodium hydroxide	2 and 4	
10043-01-3 / 233-135-0	Aluminium trisulfate	2	
64-19-7 / 200-580-7	Acetic acid	2 and 4	
120-51-4 / 204-402-9	Benzyl benzoate	14 and 18	<a href="#">Commission Decision 2007/565/EC (22-08-2008)</a>
2921-88-2 / 220-864-4	Chlorpyrifos	18	<a href="#">Commission Decision 2007/565/EC (22-08-2008)</a>
121-75-5 / 204-497-7	Malathion	18	<a href="#">Commission Decision 2007/565/EC (22-08-2008)</a>
8000-29-1 / 289-753-6 and 106-22-9 / 203-375-0	Oils, Citronella	19	
91722-61-1 / 294-461-7	Juniperus mexicana extract	19	<a href="#">Commission Decision 2007/565/EC (22-08-2008)</a>
330-54-1 / 206-354-4	Diuron	21	<a href="#">Commission Decision 2007/565/EC (22-08-2008)</a>
67-63-0/ 200-661-7	Propan 2-ol	18 and 19	<a href="#">Commission Decision 2008/809/EC</a>

**Table 5.1-10: Table with the 10 most frequently found illegal active substances (only on ANNEX I). For some of the active substances, the phase-out-decision has entered into force later.**

### Non-inclusion decisions

In addition to the above mentioned biocidal products, further 48 (3.7 %) of the inspected biocidal products contained active substances notified in the review programme (ANNEX II of REG (EC) 1451/2007) for which a non-inclusion decision entered into force during the project phase. Such products placed illegal on the market were found in 7 countries, as shown in table 5.1-11 next page:

For all (2020) examined active substances, the number was 51 (2.8 %) active substances for which a non-inclusion decision to a specific product type had been taken.

Non-inclusion decisions were found in 7 different product types. The product types for which many products have been examined (> 91 products), among others PT8 (4), PT19 (4) and PT18 (31) included many findings.

In total, 8 countries examined 17 products in PT1. 2 of those, Germany and Spain, which examined respectively 1 and 2 products discovered products with active substances for which a non-inclusion decision had been taken.

The Danish approach included Decanoic acid (CAS nr. 334-48-5) in PT10 products, which has been on the non-inclusion list since 1 September 2006, because no company or Member state showed interest in defending the specific active substance and substitutes were found.

PT	1	2	4	6	8	10	18	19	#
<b>Austria</b>								1	1
<b>Belgium</b>									0
<b>Denmark</b>						2			2
<b>Estonia</b>									0
<b>Finland</b>									0
<b>France</b>									0
<b>Germany</b>	1						19	2	22
<b>Latvia</b>							1		1
<b>The Netherlands</b>									0
<b>Norway</b>									0
<b>Poland</b>			1		1				2
<b>Romania</b>							3		3
<b>Slovenia</b>									0
<b>Spain</b>	1	2	1	1	3		8	1	17
<b>Switzerland</b>									0
<b>Sum #</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>4</b>	<b>2</b>	<b>31</b>	<b>4</b>	<b>48</b>
<b>Examined products</b>	17	267	89	26	121	11	378	122	1284
<b>Percent</b>	<b>11.8</b>	<b>0.7</b>	<b>2.2</b>	<b>3.8</b>	<b>3.3</b>	<b>18.2</b>	<b>8.2</b>	<b>3.3</b>	<b>3.7</b>

**Table 5.1-11: Products with active substances for which a non-inclusion decision had come into force in the participating approaches.**

3 of the examined products contained butyl-3-iodo-2-propinyl ester carbamic acid (CAS no 55406-53-6) which according to [Commission Decision 2007/565/EC](#) was to be phased out for products in PT18 from 22-08-2008, but several non-inclusion decisions for some of the

frequently found substances have continuously entered into force since the inspection phase ended, e.g. non-inclusion decisions were on the non-inclusion list for Boric Acid for PT1, PT2, PT3, PT6, PT13 and PT18.

The following table 5.1-12 shows the calculation of products with active substances not notified in ANNEX II since 1. September 2006 and others which were listed on the non-inclusion decision list since 22-08-2008:

	<b>Examined products</b>	<b>Products illegal on the market (non-inclusion decision)</b>	<b>Products illegal on the market (only on ANNEX I)</b>	<b>Products illegal on the market</b>	<b>Percent (%)</b>
<b>Sum #</b>	<b>1284</b>	<b>48</b>	<b>99/109</b>	<b>147/157</b>	<b>11.4/12.2</b>
<b>Romania</b>	5	3	2	5	100
<b>Germany</b>	319	22	38	60	20.1
<b>The Netherlands</b>	39	0	6	6	15.4
<b>Spain</b>	369	17	34	52	16.3
<b>Slovenia</b>	45	0	4	4	8.9
<b>Norway</b>	25	0	2	2	8.0
<b>Austria</b>	48	1	2	3	6.3
<b>Denmark</b>	34	2	0	2	5.9
<b>Latvia</b>	80	1	3	4	5.0
<b>Estonia</b>	82	0	4	4	4.9
<b>Belgium</b>	55	0	2	2	3.6
<b>Finland</b>	70	0	2	2	2.9
<b>Poland</b>	80	2	0	2	2.5
<b>France</b>	10	0	0	0	0
<b>Switzerland</b>	22	0	0	0	0

**Table 5.1-12: 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 (few ( 2 or 3) products included both active substances not notified in a specific product type in ANNEX II and in the non-inclusion list).**

The enforcement of active substances for those products illegally on the market since 1 September 2006 (not notified in ANNEX II, only in ANNEX I) and decisions for non-compliances, discovered high percentages (around 11 to 12 %) of forbidden active substances and therefore there is a need for further enforcement of the BPD in the intermediate stage. In addition, the review programme was in its early stages when the project started, and the results may not be sufficient to illustrate the current situation as several new decisions have come into force

### Frequently found active substances

13 different substances were the most frequently found substances among the inspected biocidal products. These substances were found in at least 10 to more than 30 of all examined products. 3 of them were classified as toxic; 6 of them were classified as dangerous for the environment:

In relation to all the substances for which at least one non-inclusion-decision was taken, only few of them were found in the examined products. Not all of these substances were legal on the market in all product types, this was the case when a substance was notified in different product types and the decision was taken only in one or part of these product types; it is useful for further inspection projects to know how broadly the substances are spread on the market:

Active substance	CAS no	EU classification
Piperonylbutoxid	51-03-6	no legally binding classification
Permethrin	52645-53-1	Xn, N
Didecyl dimethyl ammonia Chloride	7173-51-5	C, Xn
Chlorpyrifos	2921-88-2	T, N
Sodium hypochlorite	7681-52-9	C, N
Quaternary ammonia compound, benzyl-C12-18-alkyldimethyl-, chloride	68391-01-5	no legally binding classification
Quaternary ammonia compounds, benzyl-C12-16-alkyldimethyl-, chloride	68424-85-1	no legally binding classification
Butyl-3-iodo-2-propinyl ester carbamic acid	55406-53-6	no legally binding classification
Cypermethrin	67375-30-8	T, Xn, Xi, N
Propiconazol	60207-90-1	Xn, N
Quaternary ammonia compound, C12-14-alkyl[(ethylphenyl)methyl]dimethyl-, chloride	85409-23-0	no legally binding classification
Boric acid	10043-35-3	T
N,N',N''-trichloroisocyanuric acid	87-90-1	Xn, Xi, O, N

**Table 5.1-13: Overview of the most frequently found substances in the inspected biocidal products for which a non-inclusion decision has entered into force before the start of EuroBiocides**

### Not found substances

47 (3.7 %) products contained substances which could not be found in the regulation to the BPD (EC) 1451/2007. Evaluation of the list of not found substances showed that many of the substances have other functions than being biocidal. Only 10 of those “not found substances” were by individual assessment identified as “new active substances” and could have biocidal functions even not proved according to the specific products in all cases.

These new active substances were found in Spain, 2 products in PT7, in Germany, 1 product in PT19, and 2 or 3 product in the Netherlands, in PT2, PT18 and PT19, 4 products in Slovenia 2 in both PT14 and PT18.

For all (2020) examined active substances, 47 (2.3 %) substances could not be found in regulation EC 1451/2007.

### **Infringement and sanctions**

Every second product examined in the project was not in compliance with the legislation.

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

<b>Sanction</b>	<b>Number of products</b>	<b>Percentage of products</b>
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 (no specifications)*	109	8.1
None/blank	673	50

**Table 5.1-14: 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 clarification was necessary, mainly answered further inspection or “information to focal point”.**

Many of the products including ANNEX I (not notified in a specific PT) active substances (7 to 8 %) and non-inclusion substances (3.7 %) – approximately 11 to 12 % were either among those removed from the market (12.6 %), prohibited (1.3 %) or met with not specified sanctions (calculated to less than 3.9 %).

Some products which had serious mistakes with classification and labelling (e.g. no label, missing symbols etc.) and products which did not have a legal national authorisation were also represented among those products which were removed from the market.

Around 400 of the products which had problems with classification, labelling and packaging received either sanctions like administrative orders or issued enforcement notice on; or advice to enterprises or information to focal point (importers/producers/other responsible). Information to focal point was given by inspectors for different reasons; mainly because

communication about the product was an undergoing process between the responsible and the administrative authority. 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”.

Because of follow-up actions undertaken by inspectors and because of slightly different time schedules in the participating countries, the final results were not always available at the end of the project phase.

Reasonably the question about results could not be fully compared and blank or undefined “none” was filled in for approximately 800 (59.4 % ) products. The following results have been calculated:

- Out of those 169 products in table 5.1-14, another 13 products, which were already prohibited, were during further inspections/follow-ups with the enterprises removed from the market. In total (169 +13 = 182) (13.5%) products were removed from the market;
- About 149 (11.1 %) of the examined products had been legalised (re-labelled, active substances changed to legal etc.), and
- Further inspection were necessary for 108 (8 %) products when the project finished in January 2009.

The results of examined biocidal products not in compliance in the participating countries are shown in the following figure:

<b>Country</b>	<b>Examined products</b>	<b>Products not in compliance</b>	<b>Percent of products not in compliance with the BPD legislation</b>
<b>Average</b>	1346	673	50 %
<b>Romania</b>	5	5	100.0 %
<b>Norway</b>	25	20	80.0 %
<b>Austria</b>	48	36	75.0 %
<b>Belgium</b>	55	37	67.3 %
<b>Finland</b>	70	46	65.7 %
<b>Denmark</b>	51	31	60.8 %
<b>Latvia</b>	81	40	49.4 %
<b>Estonia</b>	82	40	48.8 %
<b>Germany</b>	353	172	48.7 %
<b>Spain</b>	369	174	47.2 %
<b>The Netherlands</b>	50	23	46.0 %
<b>Poland</b>	80	29	36.3 %
<b>Slovenia</b>	45	14	31.1 %
<b>Switzerland</b>	22	5	22.7 %
<b>France</b>	10	1	10.0 %

**Table 5.1-15: Overview and ranging of the number of products not in compliance in the participating countries**

Details for each country are presented and pointed out in the following chapters with tables and result overviews for all participating countries concerning classification and labelling, biocidal control and enforcement strategies.

## 5.2 Participating countries

### 5.2.1 Austria

Austria handed in **48 products** from the inspections in 7 regions: Carinthia, Salzburg, Styria, Tirol, Upper Austria, Vienna and Vorarlberg.

Biocidal products were examined in 7 product types with a majority in PT18: 16 insecticides; PT2: 10 disinfectants; PT19: 7 repellents and PT4: 6 food and feed disinfectants

Product type	Figures
PT1	1
PT2	10
PT3	4
PT4	6
PT8	4
PT18	16
PT19	7

**Table 5.2.1-1: Number of biocidal products in relation to product types inspected in Austria**

Carinthia: PT8

Salzburg: PT18 and PT19

Styria: PT18 and PT19

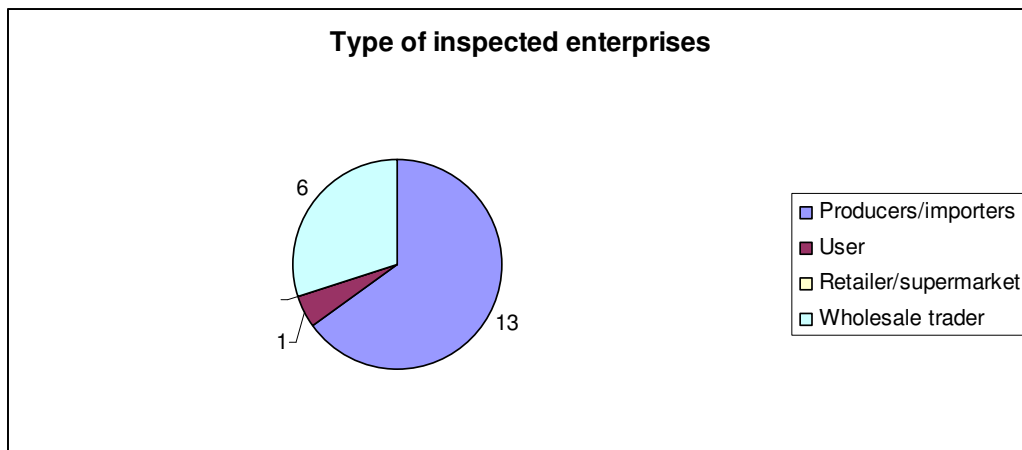
Tirol: PT19 and PT2

Upper Austria: PT2, PT3 and PT18

Vorarlberg: PT2 and PT18

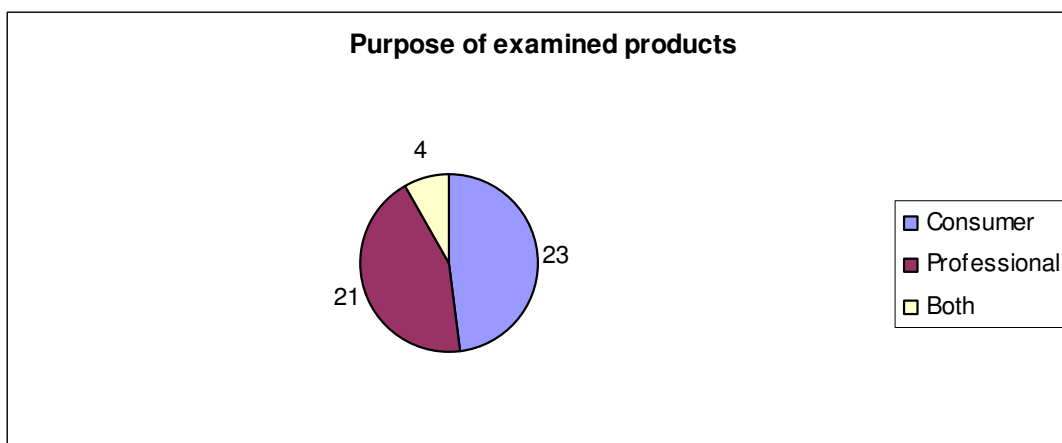
Vienna: PT1, PT2, PT3 and PT4.

The division into types of enterprises and purpose of the products was as shown in the figures below:



**Figure 5.2.1-1: Number of products in types of enterprises inspected in Austrian project.**

More than 20 enterprises were inspected. 1 to 4 products were collected from each enterprise, around 13 of the inspections took place at producers/importers (66.5 %). 6 at wholesale traders (30 %) and 1 at users (5 %).



**Figure 5.2.1-2: Overview of the purpose of examined products in the Austrian project.**

23 of the collected products were intended for professionals (47.9 %). 21 products were intended for consumers (43.8 %) and 4 for both (8.3 %).

None of the examined products are subject to national authorisation due to the fact that in Austria a national authorisation regime does not exist.

### **Labelling and packaging**

1. Labelling and packaging were examined on 38 products out of 48; packaging was in compliance for those products examined
2. 1 product in PT3 had a misleading sentence
3. Insecurity with regard to low risk phrases were mentioned for 2 products in PT19 which claimed: “Free of preservatives”

4. 3 products in PT19 with R43 were labelled “also for people with sensitive skin”
5. National language and trade name were OK on all examined products
6. 5 products did not have complete address, but had an old company name or address
7. All products had chemical names on the product
8. 4 products were not dangerous products

### SDS and chemical composition

- In general all SDSs were available
- Salzburg examined 3 out of 6, Vorarlberg 6 out of 6, Tirol 4 out of 8, Upper Austria 0 out of 5, Vienna 8 out of 9, Carinthia 4 out of 4, Styria did not give information about examined SDSs – in total, 25 examined SDSs out of 48 possible.

### Classification

Austria	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	Not applicable (not dangerous)
PT											
1	1					1					
2	10			1	1	6	1	2	1		
3	4				3						
4	6				1	4					
8	4			1						1	2
18	16			6		2	2	8	2	14	1
19	7			1				1			1
#	48			9	5	13	3	11	3	15	4

**Table 5.2.1-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized.**

- None of the examined products included T+ or T substances
- 9 of the examined products were classified with Xn, a majority 6 (37.5 %) in PT18 out of 16 examined, 1 in PT2, PT8 and PT19.
- 13 products were classified as corrosive, 1 in PT2, 3 in PT3 and 1 in PT4.
- 13 products were classified as irritant, 1 in PT1, 6 in PT2, 4 in PT4 and 2 in PT18.
- 3 products, 1 in PT2 and 2 in PT18 were classified as very flammable.

- 11 products, 2 in PT2, 8 in PT18 and 1 in PT19 were classified as flammable
- None of the examined products were classified as oxidising
- In total 15 products, a majority 14 (87.5 %) out of 16 examined in PT18 and 1 in PT8 were classified with environmental danger.

#### **Indication of danger (classification)**

- Mistakes with indication of danger (other than dangerous for the environment) were found in 17 out of 48 examined products, 35.4.1 %. ( 1 in PT1, 2 in PT2, 1 in PT4, 10 in PT18 and 3 in PT19)
- Uncertainty about indication for danger was mentioned for 1 product in PT2 (lack of data)
- Mistakes with indication of safety-phrases were mentioned in 13 out of 48 products, 27.1 %, (4 in PT2, 2 in PT4, 5 in PT18 and 2 in PT19.)
- Uncertainty about safety-phrases was mentioned for 1 product in PT2 (lack of data)
- Mistakes with indication of environmental danger were not OK for 7 out of 48 products (14.6 %), 2 products in PT2, 2 in PT4 and 3 in PT18.
- Uncertainty about indication of environmental danger was mentioned for 1 product in PT19 (lack of data)

#### **Biocidal investigation**

##### **Borderlines:**

- 7 borderlines out of 48 examined products (14.6 %) were detected within PT2 and PT19 in Austria
- 4 products in PT2 had borderlines to detergents – although the examined products were within the scope of BPD (horizontal legislation)
- 3 product in PT19 had a borderline to cosmetics (the use on skin was mentioned)

### Specific BPD-rules for labelling:

National authorisation was not in force for the examined products. Legally binding procedures were assumed not in force for the products examined in table 5.2.1-3. The average calculation is a simple estimate useful for comparison between the participating countries. Worst “statistical calculation” (35.5 %) were found in question l concerning labelling for non-target organisms and avoidance of contamination of water.

<b>Examined BPD- requirements:</b>	<b>Figures for products without authorisation</b>	<b>Percent (%) (Not OK)</b>
	<b>No legal provision</b>	
First part a) Identity of every active substance	5	10.4
Last part a) Concentration in metric units	6	12.5
f) Indication of the type of preparation	15	31.3
g) Particulars of likely direct or indirect adverse side effects and any directions for first aid	13	27.1
g) If accompanied by a leaflet: Sentence „read instructions before use“	6	12.5
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	5	10.4
First part i) Formulation batch number or designation	14	29.2
Last part i) Expiry date relevant to normal conditions of storage	10	20.8
j) Period of time needed for the biocidal effect, if relevant	9	18.0
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	17	35.4
<b>Average for the following 10 questions ( 10 requirements):</b>		<b>20.8</b>

**Table 5.2.1-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple estimate useful for comparison between the participating countries.**

### **Active substances:**

- 1 product in PT19 contained citronella oil, cedar wood oil, essential oil of eugenia caryophyllus, peppermint oil and lemongrass oil; all of these 5 active substances are listed in ANNEX I of the Review Regulation (EC) No 1451/2007 (but not in the specific product type in ANNEX II). 1 disinfectant in PT2 contained certain active substances (alkyldimethyl ammonium), which were not notified to the specific product type in ANNEX II (only in ANNEX I).
- Non-inclusion decision has been taken for active substance bone oil in PT19 (CAS 8001-85-2 / EINECS 232-294-3).

48 products containing at least 1 active substance were examined (95 active substances), 21 products contained 1 active substance, 14 contained 2 active substances (most in PT4), 8 products (1 in PT2, 1 in PT8 and 2 in PT18) contained 3 active substances, 4 products (3 in PT18 and 1 in PT19) contained 4 active substances, 1 product in PT19 contained 5 active substances.

### **Enforcement**

2 products were prohibited and 4 removed from the market because of mistakes with legality of active substances. Sanctions were given in 4 cases because of incompleteness with first aid measures, misleading sentences etc. Furthermore, advice was given to enterprises in 23 cases, because of mistakes with classification and labelling. For 3 products the result column was not filled in, but violation was detected in 3 products in PT19 (infringement with classification and labelling):

Non-compliances were found in 36 (75 %) of all examined products and those products were not in compliance with the BPD legislation in the Austrian approach.

When the project period finished in January 2009, 11 products out of the 36 not in-compliance were legalised. Besides that 1 of those products already given sanction were finally prohibited.

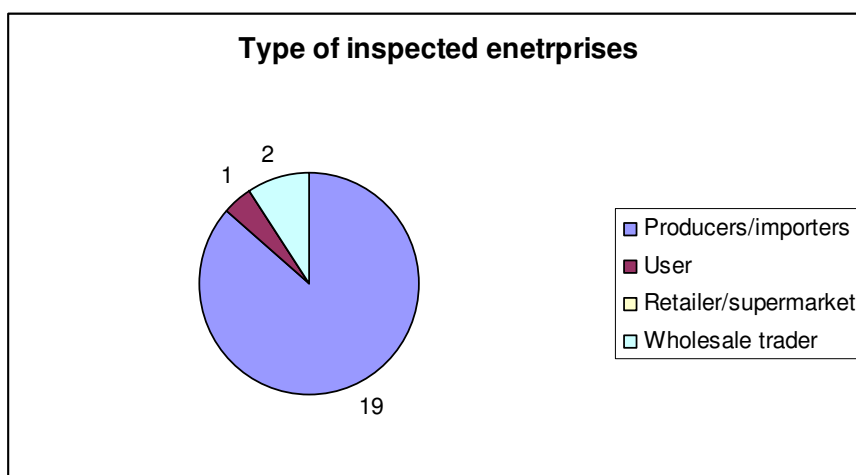
## 5.2.2 Belgium

Belgium handed in **55 products**. The biocidal products were examined in 4 product types, mainly represented with 25 insecticides in PT18, 16 disinfectants in PT2 and 10 rodenticides in PT14.

Product type	Figures
PT2	16
PT14	10
PT18	25
PT19	4

**Table 5.2.2-1: Number of biocidal products in relation to product types inspected in Belgium**

22 companies were inspected. The division in types of enterprises and purpose of the products was as shown in the figures below:

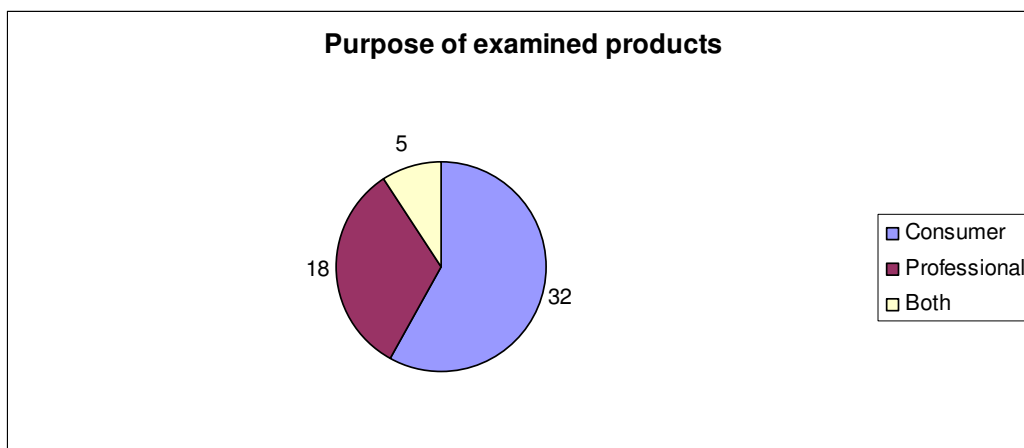


**Figure 5.2.2-1: Overview of type of enterprises inspected in the Belgian project.**

The majority of the inspected enterprises, 19, were producers/importers (86.4 %), 1 (4.5 %) was a user and 2 (9.1 %) were wholesale traders.

32 of the examined products were intended for consumers (58.2 %), 18 for professionals (32.7 %) and 5 for both (9.1 %) as shown in figure 5.2.2-2.

National authorisation/registration is mandatory for all biocidal products in Belgium, and all biocides are subject to a fee. 5 products without national authorisation were detected: 4 biocides in PT19 (with active substances like naphthalene and paradichlorobenzene) and 1 preparation in PT2.



**Figure 5.2.2-2: Overview of the purpose of examined products in the Belgian project.**

### Labelling and packaging

1. 4 products in PT19 were packaged like mints (sweets for children). The same products were subject to authorisation.
2. All labelling was clear and indelible.
3. 2 products had misleading packaging, 1 product was transparent (difficult to read the R- and S-phrases) and 1 looked like a flower.
4. "Bio", "irritant" and other low-risk messages were present on 4 products.
5. 16 products, from 6 different importers were not in all 3 official national languages.
6. Trade name was generally present.
7. Company name, address and telephone number were not complete on 19 products.
8. 15 of the verified products were not classified as dangerous (no dangerous substances above the threshold).
9. Chemical names were on all products, if applicable.

### SDS and chemical composition

- All SDSs were available, but 12 safety data sheets were not examined in detail
- Non-conformities were detected in 15 SDSs.

### Classification

- 1 toxic substance was found in PT18
- 14 of the examined products were classified as harmful to health, Xn, (13 (81.3 %) out of 16 of the examined products in PT2).
- 3 products were classified as corrosive, 2 in PT2 and 1 in PT18.
- 3 products were classified as irritant, 1 in PT2 and 2 in PT18.

- 4 products in PT14 were classified as very flammable.
- 13 out of 16 examined products in PT2 were classified with oxidising (81.3 %).
- 25 products were classified as dangerous to the environment, the majority in PT18 (13 out of 25 examined, 52 %) and in PT2 (9 out of 16 examined, 56.3 %).
- The 10 examined rodenticides in PT14 were not classified as dangerous, neither were the 5 insecticides in PT18.

Belgium PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	Not applicable
2	16			13	2	1			13	9	
14	10										10
18	25		1	1	1	2	4			13	5
19	4			4						3	
#	55		1	18	3	3	4		13	25	15

**Table 5.2.2-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized.**

#### Indication of Danger

- Mistakes with labelling for indication of danger (other than dangerous to the environment) on 2 products, 1 in PT2 and 1 in PT19. (2 out of 55 examined products, 3.6 %)
- Mistakes with labelling for indication of safety-phrases in 15 out of 55 products (27.3 %), 5 in PT2, 9 in PT18 and 1 in PT19.
- Mistakes with labelling for indication of environmental danger were not OK on 17 out of 55 products (31 %): 10 products (55.6 %) out of 25 examined in PT18, 6 (60 %) out of 10 examined in PT14 and 1 (25 %) out of 4 examined in PT19.

#### Biocidal investigation

##### Borderlines:

- 1 product in PT18 was a borderline case to a medical device (a Scalibor dog collar).

##### Specific BPD-rules for labelling:

National authorisation was in force for 50 out of 55 examined products. 5 products did by mistakes not have authorisation and were banned. Products with and without legally binding procedures were shown in table 5.2.2-3. Most of the products not in compliance were found in

question last part i) about expiry date for those products with authorisation, indicating that around 48 % (grey in table 5.2.2-3) of the products were not in compliance with at least one of the 8 specific BPD-rules.

Examined BPD-requirements:	Estimates of figures for 50 products with authorisation	Percent (%)	Figures for 5 examined products without national authorisation	Percent (%)
		Not Ok		Not OK
		Legal provision	No legal provision	
First part a) Identity of every active substance	0	0	0	0
Last part a) Concentration in metric units	1	2	2	40
c) Indication of the type of preparation	0	0	4	80
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	12	24	5	100
g) If accompanied by a leaflet: Sentence „read instructions before use“	2	4	3	60
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	7	14	5	100
First part i) Formulation batch number or designation	7	14	2	40
Last part i) Expiry date relevant to normal conditions of storage	24	48	5	100
j) Period of time needed for the biocidal effect, if relevant	18	36	5	100

l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	6	12	5	100
<b>Average value for the following 10 questions (8 requirements):</b>		<b>15.4</b>		<b>72</b>

**Table 5.2.2-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple mathematical estimate useful for comparison between participating countries and products with and without legally binding provisions.**

#### **Active substances:**

49 examined products contained only 1 active substance, 6 products contained 2 active substances (5 in PT 18 and 1 in PT2). In total, 61 active substances were examined.

- 2 products in PT19 contained active substances only notified in ANNEX I.  
(Infringement with active substances not notified to specific product type in ANNEX II on 2 out of 55 products (3.6 %) or 2 out of 61 examined active substances 3.3 %)

#### **Enforcement**

Advice to enterprise was given with regard to 15 products, mainly because of inconsistency between the label, the safety data sheet and the packaging (language and text).

The indication of the environmental danger was not in compliance for 17 products, mainly in PT18 and PT2; those products were given sanctions in the form of warnings. The products which were removed from the market were those with no national authorisation.

Advice to enterprise	15
Removed from market	5
Sanctions (warning)	17

**Table 5.2.2-4: Results of enforcement of biocidal products in Belgium.**

Violations were found in (15+5+17=37), (65.7 %) of all examined products and those products were not in compliance with the BPD legislation in the Belgian approach.

## Results

Removed from market	5
Product prohibited after sanction	1
Product legalised after advice and sanctions	31

**Table 5.2.2-5: Results after 1<sup>st</sup> contact to enterprises/enforcement, January 2009.**

### 5.2.3 Denmark

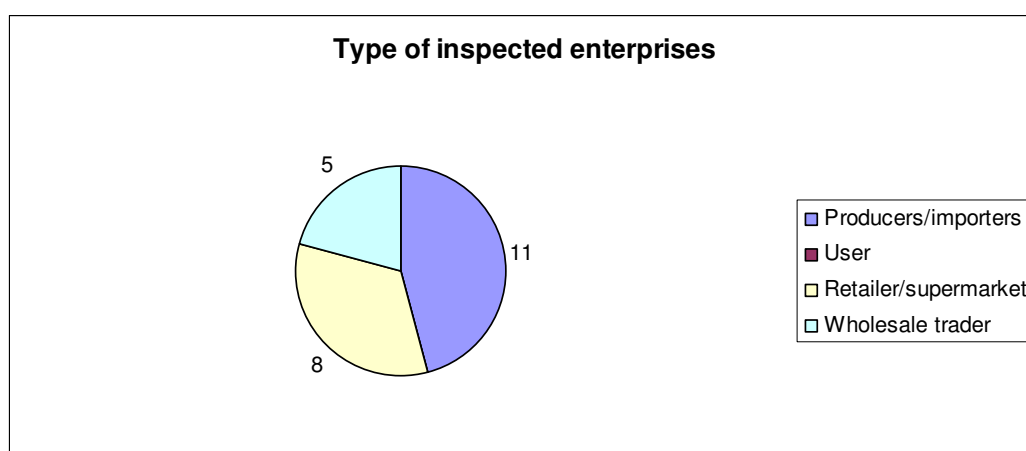
Denmark handed in **51 products** from the inspection in 24 enterprises.

Biocidal products were examined in 7 product types. The majority of the inspected products belonged to PT6, PT7 and PT8 and the remaining in PT2, PT10, PT18 and PT19.

Product type	Figures
PT2	5
PT6	7
PT7	22
PT8	7
PT10	5
PT18	2
PT19	2
Detergent agent	1

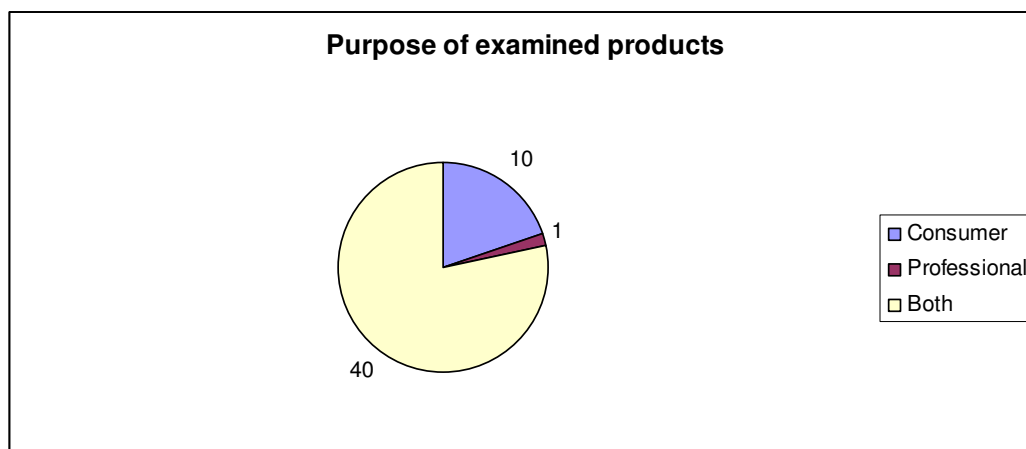
**Table 5.2.3-1: Number of biocidal products in relation to product types inspected in Denmark. 1 borderline product in the Danish approach claimed to be a detergent agent were examined in the project.**

The division in types of enterprises and purpose of the products was as shown in the figures below:



**Figure 5.2.3-1: Overview of types of enterprises inspected in the Danish project.**

24 enterprises were inspected. 11 producers/importers (45.8 %), 8 retailers/supermarkets (33.3 %) and 5 wholesale traders (20.8 %).



**Figure 5.2.3-2: Overview of the purpose of examined products in the Danish project.**

40 (78.4 %) of the examined products were intended for both consumers and professionals, 10 products were intended for consumers (19.6 %), and 1 product was intended for professionals.

2 different campaigns supplied data for the Danish project: a wood preservatives control (PT6, PT7 and PT8) and a biocidal products campaign of products collected from retailers and supermarkets (Consumer products).

10 importers/producers, 1 retailer/supermarket and 1 wholesale trader were visited during the Wood Protection Campaign in 2007, 33 products were examined in this approach. 8 retailers/supermarket and 4 wholesale traders were inspected in the Biocides in the Retail Chain Campaign and 18 products were collected. The wood protection enterprises were notified before inspection, but the retailer campaign was performed without notification to the enterprises.

Registration in Denmark is central and mandatory for all Biocidal products which according to BPD came into force in 2003.

Before the BPD entered into force and in the intermediate stage, a central national authorisation was a legal requirement for biocidal product types: PT2 (algae products, but not disinfectants), PT8 (wood protection), PT10 (Masonry preservatives claiming algae), PT14 (rodenticides), PT18 (insecticides) and PT19 (repellents). The Danish Environmental

Protection Agency was the responsible body for this authorisation. Those products were subject to a fee, at that point.

8 products without the demanded national authorisation were detected and therefore banned: 2 products in PT10, 3 products in PT8, 2 in PT19 and 1 in PT18.

### **Labelling and packaging**

1. Labelling, but not packaging was examined on 7 products from one specific enterprise which made "label-products".
2. 3 products had SDSs, but danger labelling was missing, 1 product had a leak or broken cap - the whole pallet in the supermarket was wet - and was pointed out.
3. No claim for wood protection on 4 products, but they contained high concentrations of active substances.
4. None of the examined products had misleading or exaggerated phrases, or low biocidal sentences etc.
5. 1 product in PT19 was Swedish (similar to a Danish product with a national authorisation); another product in PT19 was in Swedish and was unknown/illegal according to national authorisation.
6. Trade name was present on all products.
7. All examined products were preparations, no single active substances.
8. The 3 products without danger label did not have address information
9. 1 product was not a dangerous product
10. Chemical names were missing on 6 of the 42 examined products

### **SDS and chemical composition**

- 33 SDSs were available (9 requested)
- For 9 products the SDSs were requested at the inspection or following the inspection
- 8 products were not examined according to composition / chemical ingredients, because they did not have a national authorisation and were therefore prohibited.
- Chemical substances were examined in 47 products

### **Classification**

- None of the examined products were classified as very toxic T+ or toxic T
- 18 of the examined products were classified with Xn, 9 out of 22 in PT7 (40.1 %), 3 out of 7 in PT8 and PT6 (42.9 %)
- 4 products classified as corrosive were found in PT2, PT6, PT7 and PT10

- 7 products were classified as irritant, 5 of these were in PT7
- None of the examined products were classified as flammable or oxidative
- 1 product in PT18 were classified with N
- The examination detected that 7 of these products examined were missing N (environmental danger symbol). 4 in PT7, 2 in PT6 and 1 in PT8

Denmark PT	Examined products	T	T+	Xn	C	Xi	F+	F	O	N	Missing Authorisation/ Not applicable
2	5				1	1					/1
6	7			3	1						/3
7	22			9	1	5					/6
8	7			3							3/2
10	5			2	1	2					2/
18	2			1						1	1/
19	2										2
Deter- gents	1										/1
#	41			18	4	8				1	8/12

**Table 5.2.3-1: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized. (All PT10 products were examined)**

#### **Indication of danger (classification and labelling)**

- Mistakes with indication of danger (other than dangerous for the environment) were detected in 13 products, 3 in PT6, 6 in PT7, 3 in PT8 and 1 in PT10. (13 out of 42 examined products, 31 %). (Label and content of chemicals was inconsistent for products in PT8.)
- Mistakes with indication of safety-phrases in 8 out of 42 products (19 %), 1 in PT6, 3 in PT7, 3 in PT8 and 1 in PT19.
- Mistakes with indication of environmental danger were found in 19 out of 42 products, (45.0 %):
  - 4 products in PT2 (9.8 %), 3 in PT6 (42.9 %), 8 in PT7 (36.4 %), 3 in PT8 (42.9 %) and 1 in PT10 (20 %) of which 1 product in PT6, 4 products in PT7, 2 products in PT8 and 1 in PT10 should change from R52/53 to R51/53,

- 7 products were missing N; environmental danger symbols, 4 in PT7, 2 in PT6 and 1 in PT8; and
- R51/52 was missing in 4 products in PT2).

## Biocidal investigation

### Borderlines:

- 17 borderline cases were found in the Danish approach.
- 12 products had a borderline between PT6, PT7 and PT8. The distinction between products with fungicidal effect and surface products with active substances intended only for in-can preservatives (PT6) and film preservatives (PT7) has to be resolved.
- 4 products in PT2 were borderlines to detergents.
- 1 Mosquito spray was a borderline to a medical device, and was claimed as such – but was included to the BPD-scope in PT19.

### Specific BPD-rules for labelling:

National authorisation was not in force for these 46 examined products. Legally binding procedures were assumed not in force for the products examined in table 5.2.3-3. Worst “statistical calculation” (45.7 %) were found in question f concerning “side effects and any directions for first aid”.

Examined BPD-requirements:	Figures for products without authorisation	Percent (%) Not OK
	<b>No legal provision</b>	
First part a) Identity of every active substance	15	32.6
Last part a) Concentration in metric units	15	32.6
c) Indication of the type of preparation	3	6.5
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	21	45.7
g) If accompanied by a leaflet: Sentence „read instructions before use“	17	37,0
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	8	17.4
First part i) Formulation batch number or designation	6	13.0
Last part i) Expiry date relevant to normal conditions of storage	15	32.6

j) Period of time needed for the biocidal effect, if relevant	14	30.4
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	15	32.6
<b>Average value for the 10 questions (8 requirements):</b>		<b>28.0</b>

**Table 5.2.3-2: 8 Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (Always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple estimate useful for comparison between the participating countries.**

### Active substances:

Out of the 34 examined products, (48 examined active substances), 21 products contained only 1 active substance, 12 products contained 2 active substances (1 in PT6, 3 in PT7, 4 in PT8 and 5 in PT19) and 1 product in PT8 contained 3 substances..

- 2 products in PT10 contained fatty acids, for which a non-inclusion decision came into force 1 September 2006.
- 16 products were not examined, 8 products because national authorisation was missing, 2 products did not have a Danish label and some because of inconsistencies between information about the chemical content and the labels.

### Enforcement

Advice to enterprise was given to 11 products, mainly because of mistakes with the SDSs (inconsistencies between label and SDS), the packaging (language and text) and classification and labelling (mainly problems with environmental danger classification).

Environmental danger was not OK for 19 products, mainly in PT6, PT7 and PT8. 15 borderlines were detected in the same product types.

8 products did by mistakes not have a national authorisation and were therefore prohibited, 2 products contained non-inclusion active substances, and the other 3 were prohibited because danger labels were missing.

Advice to enterprise	11
Prohibited	13
Information to another Ministry	1

**Table 5.2.3-3: Results of enforcement of biocidal products in Denmark.**

Violations were found in (11+13+1= 35), 68.8 % of all examined products and those products were not in compliance with the BPD legislation in the Danish approach.

## Results

Removed from market	5
Product legalised after advice and prohibition	24
Further inspection necessary	12

**Table 5.2.3-4: Results after follow-ups to enterprises/enforcement, January 2009.**

The strategy for further biocidal enforcement in Denmark is the intention of performing at least one biocidal campaign every year. In 2009, Denmark participated in a joint Nordic Pool Chemicals Campaign and examined 92 pool chemicals (disinfectants) in PT2.

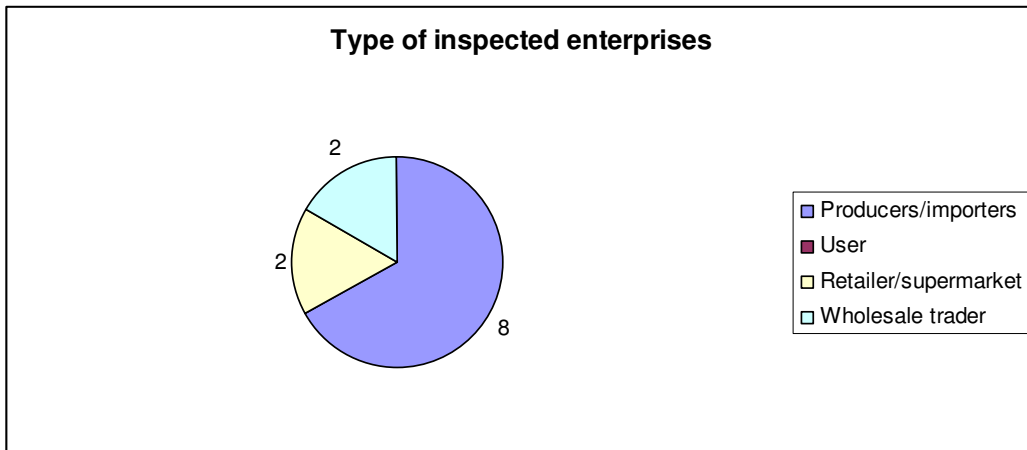
### 5.2.4 Estonia

Estonia handed in **82 products**. The biocidal products were examined in 10 product types, mainly represented with 24 disinfectants in PT2, 17 insecticides in PT 18 and 11 food and feed disinfectants in PT4.

Product type	Figures
PT1	1
PT2	24
PT3	5
PT4	11
PT8	8
PT11	1
PT14	5
PT18	17
PT19	8
PT20	2

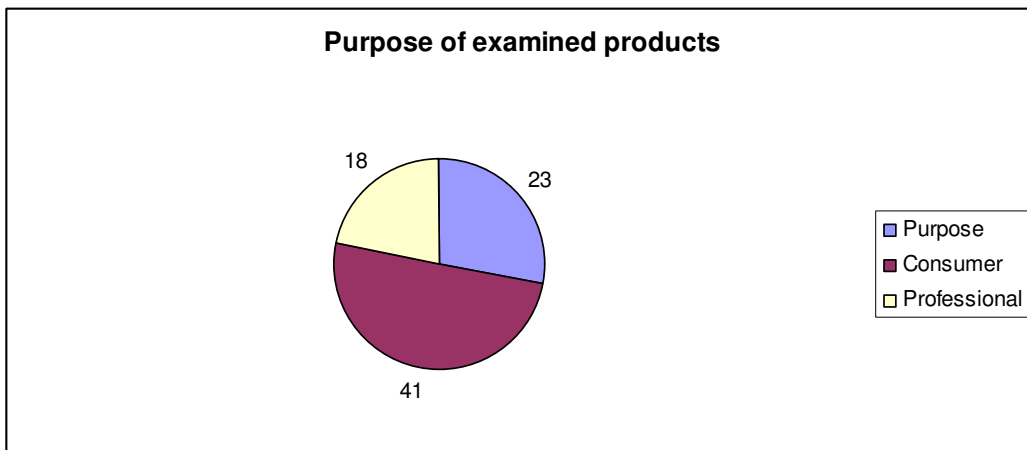
**Table 5.2.4-1: Number of biocidal products in relation to product types inspected in Estonia**

The division into types of enterprises and purpose of the products were as shown in the figures below:



**Figure 5.2.4-1. Overview of type of enterprises inspected in the Estonian project.**

12 enterprises were inspected in the Estonian approach. 8 (66 %) of the visited enterprises were producers and importers, 2 (17 %) were retailers and 2 (17 %) were wholesale traders.



**Figure 5.2.4-2: Overview of examined products in the Estonian project.**

The majority of the examined products in Estonia, 41 (50 %), were intended for professionals, 23 (28 %) products were intended for consumers, and 18 (22 %) for both.

All registered products were subject to a fee.

In 2009 the national register included about 3000 biocidal products.

**Labelling and packaging**

1. The labelling on 5 products was not examined; this was because the products could only be ordered in tanks (big containers).
2. The labelling was clear and indelible on all examined products

3. 1 product in PT2 had misleading phrases with “*Harmless for people staying in the room*”.
4. Name and address was insufficient on 5 products
5. 12 products were not dangerous
6. Chemical names were missing on 4 products

### SDS and chemical composition

- All SDSs were available and examined
- All active substances were examined

### Classification

Estonia PT	Products examined	T+	T	Xn	C	Xi	F+	F	O	N	Not applicable
1	1								1		
2	24		1	4	7	8	2		1	2	3
3	5			1		2		1		2	
4	11			1	7	2				2	
8	8			5		1		1		3	
11	1					1					
14	5			1							5
18	17		2			2	7	1		15	
19	8			1		2	2	3			2
20	2										2
#	82		3	13	14	18	11	6	2	24	12

**Table 5.2.4-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the number of indication of danger is given. Because some products are not dangerous and because some products contained more than one label there are differences when the results are summarized.**

- In PT18, 2 products contained toxic T substances:  
Permethrin (CAS nr. 52645-53-1) and Cypermethrin (CAS nr 52315-07-8) both collected from user intended for professional use. Another toxic substance was found in PT2 (Ethanol CAS 64-17-5), indented for professional use.
- 13 of the examined products were classified with Xn, the majority, 4 in PT2 and 5 in PT 8.
- 7 products classified as corrosive were found in both PT2 and PT4.

- 18 products were classified as irritant, found in 8 of the examined product types, but a majority 8 out of 21 (33 %) examined products in PT2)
- 11 products, (majority 7 out of 17 (41.2 %) in PT18) were classified very flammable
- 6 products of which 3 out of 8 (37.5 %) in PT19 were classified as flammable.
- 2 products, 1 in PT1 and 1 in PT2, were classified as oxidative.
- 24 products were classified with environmental danger, the highest numbers
- 15 out of 17 (88.2 %) examined in PT18, and 3 out of 8 (37.5 %) in PT8.
- 12 products were blank (not applicable), the same number as the
- not dangerous products.

#### **Indication of danger (classification)**

- Mistakes with indication of danger were detected for 2 products in PT2 and 1 product in PT4. (3 out of 82 products, 3.7 %)
- Mistakes with indication of safety-phrases for 2 products in PT2, 4 in PT4 and 1 in PT8 (7 out of 82 examined products, 8.5 %)
- Mistakes with indication of environmental danger for 1 product in PT2 and 1 product in PT8. (2 out of 82 examined products, 2.4 %)

#### **Biocidal investigation**

##### **Borderlines:**

- 9 borderline cases (11 %) were detected within PT2 in Estonia
- These were borderlines to detergents

##### **Specific BPD-rules for labelling:**

National authorisation was in force for 78 out of 82 examined products 4 products did not have authorisation, Products with and without legally binding procedure were shown in table 5.2.4-3.. Most products not in compliance were found in question g) about “reading the instruction before use”, indicating that around 29.5 % (grey in table 5.2.4-3) of the products with legally binding provision were not in compliance with at least 1 of the 8 specific BPD-requirements.

<b>Examined BPD-requirements:</b>	<b>Figures for 78 examined products with authorisation</b>	<b>Percent (%) Not OK</b>	<b>Figures for all 4 examined products without authorisation</b>	<b>Percent (%) Not OK</b>
	<b>Legal provision</b>		<b>No legal provision</b>	
First part a) Identity of every active substance	1	1.3	0	0
Last part a) Concentration in metric units	4	5.1	2	50
c) Indication of the type of preparation	6	7.7	1	25
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	0	0	2	50
g) If accompanied by a leaflet: Sentence „read instructions before use“	23	29.5	0	0
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	5	6.4	3	75
First part i) Formulation batch number or designation	5	6.4	0	0
Last part i) Expiry date relevant to normal conditions of storage	5	6.4	0	0
j) Period of time needed for the biocidal effect, if relevant	2	2.6	1	25
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	1	1.3	3	75
<b>Average value for the 10 questions (8 requirements):</b>		<b>6.7</b>		<b>30</b>

**Table 5.2.4-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (j) (always required on the label of a biocidal product with a national authorisation). The average calculation is a simple mathematical estimate useful for comparison between participating countries and products with and without legally binding provision**

### **Active substances**

34 products contained only 1 active substance, 29 products contained 2 active substances (most in PT2 and PT18), and 9 (most in PT2) contained 3 active substances, and 1 product in PT2 contained 4 active substances. In total, 123 active substances were examined.

- 2 products in PT2 with a minimum of 2 active substances contained active substances only notified in ANNEX I
- 2 products in PT4 with a minimum of 2 active substances contained active substances only notified in ANNEX I

### Enforcement

Sanction	29
Information to focal point	10
Advice to enterprises	1
None	42

**Table 5.2.4-4: Results of enforcement of biocidal products in Estonia.**

Violations were found in approximately (29 +10 +1=40) of all examined products (82) and those products were not in compliance with the BPD legislation in the Estonian approach.

Specific classification and labelling requirements for biocidal products as laid down in Article 20(2) of BPD were examined on all products in Estonia, and advice was given to the enterprises – the products given “information to focal point” have since been legalised as shown in table 5.2.3-5.

### Results

Further inspection necessary	29
Product legalised	10
None	0

**Table 5.2.4-5: Final results after follow-ups to enterprises/ enforcement in Estonia, January 2009.**

### 5.2.5 Finland

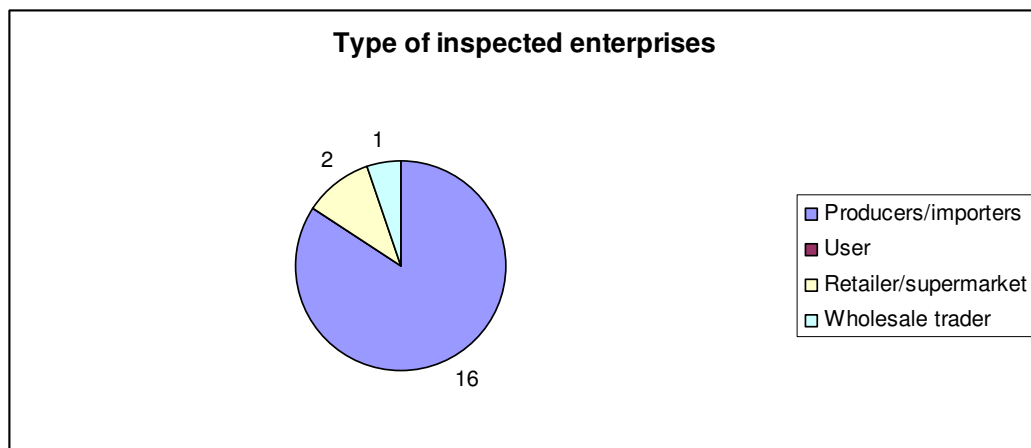
Finland handed in **70 products**.

Biocidal products were examined in 10 product types, mainly represented with 37 disinfectants in PT2.

Product type	Figures
PT1	3
PT2	37
PT3	3
PT4	6
PT6	2
PT8	3
PT10	1
PT18	8
PT19	3
PT21	4

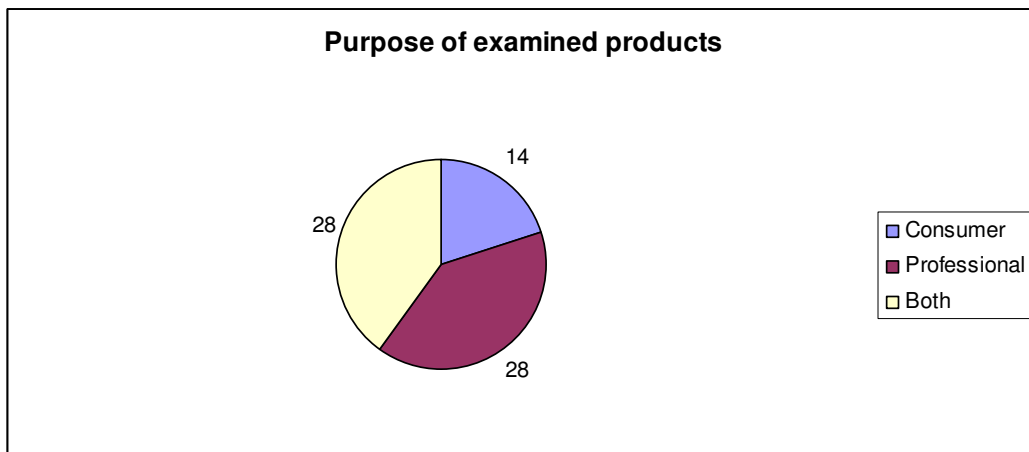
**Table 5.2.5-1: Number of biocidal products in relation to product types inspected in Finland**

The division into types of enterprises and purpose of the products were as shown in the figures below:



**Figure 5.2.5-1: Overview of type of enterprises inspected in the Finnish project.**

19 enterprises were inspected. 16 (84.2 %) of the visited enterprises were producers/importers, 2 were retailers/supermarkets (10.5 %) and 1 was a wholesale trader (5.3 %).



**Figure 5.2.5-2: Overview of the purpose of examined products in the Finish project.**

28 products (40 %) were intended for professionals, 28 products (40 %) were intended for both consumers and professionals, and 14 products (20 %) were intended for consumers in the Finnish project.

In Finland, registration in the National Product Register is central and mandatory for all biocidal products according to BPD.

Products in PT8, PT14, PT18, PT19 and PT21 were subject to national authorisation and a fee. Other examined products in PT1, PT2, PT3, PT4, PT6 and PT10 were not included in the national authorisation at that point.

### **Labelling and packaging**

1. The packaging on 9 products was not examined. Comments like “whole package not available at the time of inspection” were filled in to the datasheet.
2. For 61 examined labels, 7 were unclear and not indelible with comments like “symbol and font too small”, “label is to be removed before opening”, “label folded”, etc.
3. 1 product had an exaggerated impression/misleading sentence: “Does not irritate skin”.
4. Belittling, misleading and non harmless sentences were found on 1 product; the product was referred to as “harmless” on the packaging.
5. 4 products were only in Finnish, not in Swedish; on 2 products part of the Swedish text was missing and 2 products were only in Danish.
6. Trade names were generally present.
7. 1 enterprise with incomplete address and 1 with incomplete address and telephone number, in total 5 products.
8. All examined products were preparations, no single substances.
9. 3 products were not dangerous products.

10. Chemical names were on all products, if applicable, but inconsistencies were mentioned for 9 products: “wrong active substance mentioned on the label”, “only one chemical named”, “copper sulphate not mentioned”, “wrong CAS number”, “wrong INCI names on label”, “inconsistency with other information available”, etc.

### SDS and chemical composition

- 48 SDSs were available
- 15 SDSs were only available on request
- 13 SDSs were not examined

### Classification

Finland PT	Examined products	T	T+	Xn	C	Xi	F+	F	O	N	Blank/ not app.
1	3						1	1			
2	37			14	9	7		1	4	8	
3	3										/1
4	6				2	3				2	
6	2				2					2	
8	3			1							2
10	1				1					1	
18	8					2	2			5	/1
19	3					1		1			/1
21	4			3		1				4	
#	70			18	14	11	3	3	4	22	2/3

**Table 5.2.5-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized.**

- None of the products contained very toxic T+ and T substances
- 18 of the examined products were classified with Xn, 14 out of 37 (37.8 %) in PT 2
- 14 products were classified with C. 9 out of 37 in PT2 (21.6 %)
- 14 products were classified with Xi, 7 out of 37 in PT2 (18.9 %)
- 3 products were classified as very flammable, 2 in PT18 and 1 in PT2
- 3 products were classified as flammable, 1 in PT1, PT2 and PT19

4 products in PT2 were classified as oxidative

- 22 products were classified with environmental danger, the highest numbers, 8 out of 37 (21.7 %), in PT 2 followed by 5 out of 8 examined in PT18 (62.5 %) and 4 out of 4 examined in PT21.

### **Indication of danger (classification and labelling)**

- Mistakes with indication of danger were found for 26 out of 68 examined (38.2 %).
- The majority of mistakes were found in PT2, 20 products out of 37 examined (54.1 %)
- Uncertainty about indication for danger mentioned for 1 product in PT4
- Mistakes with indication of safety-phrases were found in 21 out of 68 products (30.9 %).
- The majority of mistakes, 15 out of 37, were found in PT2 (40.5 %).
- Uncertainty about indication of danger was mentioned for 2 products in PT3 and PT7
- Mistakes with indication of environmental danger were found for 2 products, 1 in PT2 and 1 in PT 3. (2 out of 75 examined products, 2.7 %)

### **Biocidal investigation**

#### **Borderlines:**

- 15 of the 70 examined products were mentioned as borderline cases (21.4 %),
- 10 products had a borderline to Detergents
- 2 products in PT3 had a borderline to Medical devices
- 2 products in PT1 had a borderline to Cosmetics
- 1 product in PT4 mentioned "other", which was feed regulation

### **Specific BPD-rules for labelling: (No data filled in for this question)**

#### **Active substances:**

- 14 active substances in 12 products, 7 in PT2, 3 in PT3 and 2 in PT4, were only notified in ANNEX I. (But 10 out of the 14 active substances in ANNEX I mentions "function of the substance in the product unclear", 5 in PT5, 3 in PT3 and 2 in PT4).
- 2 products in PT2 contained active substances only notified in ANNEX I

40 examined products contained only 1 active substance, 24 products contained 2 active substances (mainly in PT2 and PT8), and 6 in PT2 contained 3 active substances. In total, 106 active substances were examined.

## Enforcement

Advice to enterprise was filled in for 37 products, mainly because of mistakes with SDSs (inconsistency between label and SDS), packaging (language and text) and classification and labelling). 1 product with an Annex I substance was prohibited. Furthermore, enforcement to focal point was necessary for 8 products for which further inspections were necessary because the function of the active substances in the products was unclear.

Advice to enterprise	37
Enforcement to focal point	8
Product/substance prohibited	1

**Table 5.2.5-3: Results of the enforcement of biocidal products in the Finnish approach, January 2009.**

Violations were found in approximately (37+8+1=46); 65.7 % of all examined products and those products were not in compliance with the BPD legislation in the Finnish approach.

### 5.2.6 France

France handed in **10 products** from the inspection in 10 enterprises.

Product type	Figures
PT8	4
PT11	6

**Table 5.2.6-1: Number of biocidal products in relation to product types inspected in France**

10 enterprises were inspected. All enterprises (production sites) were in the category users and the products intended for professionals. There was no registration, nor fees in France on products in PT8: Wood preservatives and PT11: Preservatives for liquid-cooling and processing systems in 2007.

450 inspections were performed in enterprises categorised as biocides product users in PT8 and PT11. 10 of those products have been handed in to this project.

2 inspection authorities carried out the biocides inspections in France:

- the environmental inspectors carried out inspection in PT 8 and PT11
- the fraud office carried out inspections in PT2, PT3 and PT19.

The environmental inspectors carried out about 40 inspections in wood treatment facilities (PT 8); 10 of those inspections were carried out using the questionnaire in APPENDIX 8 of the EuroBiocides manual (4 were filled in).

More than 200 inspections were also carried out in PT11 (preservatives for liquid-cooling) for which a French questionnaire was used. This questionnaire, more and less, gives answers to 18 of the 30 questions in the EuroBiocides project questionnaire. Initially, PT11 was not included in the scope of the EuroBiocides project.

10 inspections in 10 enterprises were carried out using the questionnaire in APPENDIX 8 of the EuroBiocides manual.

### **Labelling and packaging**

1. The labelling and packaging was clear and indelible on all 10 products
2. No misleading or exaggerated sentences/phrases were detected
3. National name and trade name was OK
4. The products were all dangerous
5. Chemical name(s) missing on 5 products

### **SDS and chemical composition**

- All SDSs were available and examined,
- All active substances were examined.

### **Classification**

- 1 product in PT11 was classified as toxic T (EC number 259-709-0,
- Tetrakis(hydroxymethyl)phosphonium sulphate(2:1)) on the label, but Xn in the SDS, and was changed to Xn
- 2 products in PT11 were classified with C, corrosive products, 3 products in PT11 did not have a symbol but 2 of those were missing danger symbol Xn
- 1 examined product in PT8 was classified with Xn symbol, 1 with C and 2 with Xi, all 4 with N.

France PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N
8	4			1	1	2				4
11	6		1		2					
#	10		1	1	3	2				4

**Table 5.2.6-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized.**

#### **Indication of danger (classification)**

- Mistakes with indication of danger (other than dangerous for the environment) were found in 4 out of the 10 products, 40.0 % (all in PT11).
- Mistakes with indication of safety-phrases were found in 1 out of 10 products, 10.0 % (1 in PT11).
- No mistakes with indication of environmental danger were found in the products which were handed in.

#### **Biocidal investigation**

##### **Borderlines:**

- No borderlines were found in the products in PT8 and PT11.

##### **Active substances:**

The 10 products filled in contained at least 1 active substance, 6 products contained 1 active substance, 1 product (in PT8) contained 2 active substances, 1 product (in PT8) contained 3 active substances and 2 products contained 4 active substances. In total, 19 active substances were examined.

- All active substances were notified in the specific product type in ANNEX II and were legal

##### **Specific BPD-rules for labelling:**

National authorisation was not in force for the examined products. Legally binding procedures were assumed not in force for the products examined in table 5.2.6-3. Worst “statistical calculation” (70 %) were found in question c), f) and h).

<b>Checked BPD-requirements:</b>	<b>Figures for products without authorisation,</b>	<b>Percent (%) Not OK</b>
	<b>No legal provision</b>	
First part a) Identity of every active substance	4	40
Last part a) Concentration in metric units	5	50
c) Indication of the type of preparation	7	70
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	7	70
g) If accompanied by a leaflet: Sentence „read instructions before use“	4	40
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	7	70
First part i) Formulation batch number or designation	2	20
Last part i) Expiry date relevant to normal conditions of storage	4	40
j) Period of time needed for the biocidal effect, if relevant	6	60
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	4	40
<b>Average value for the following 10 questions (8 requirements):</b>		<b>50</b>

**Table 5.2.6-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple estimate useful for comparison between the participating countries.**

### **Enforcement**

Violation detected was filled in for 1 product, which was missing Xn. Further inspection was necessary for 2 products in PT11, which also included biocidal information and advice.

Approximately 4 (40 %) of all the examined products were not in compliance with the BPD legislation in the French approach.

Summary of the findings of the inspections in 2008 were as follows:

- Generally, the producers comply with the biocide regulations; and the active substances were in accordance with the regulation.
- The non-compliance points were: absence of some labelling indications, name of the active substance missing; concentration of the substance, no leaflet, presence of substance without a biocide claim, purpose in a biocide product. Regarding the last

point, “purpose in a biocide product”, the inspectors had to ask the producers for a written declaration that the substance was not in the product for its biocidal function

### 5.2.7 Germany

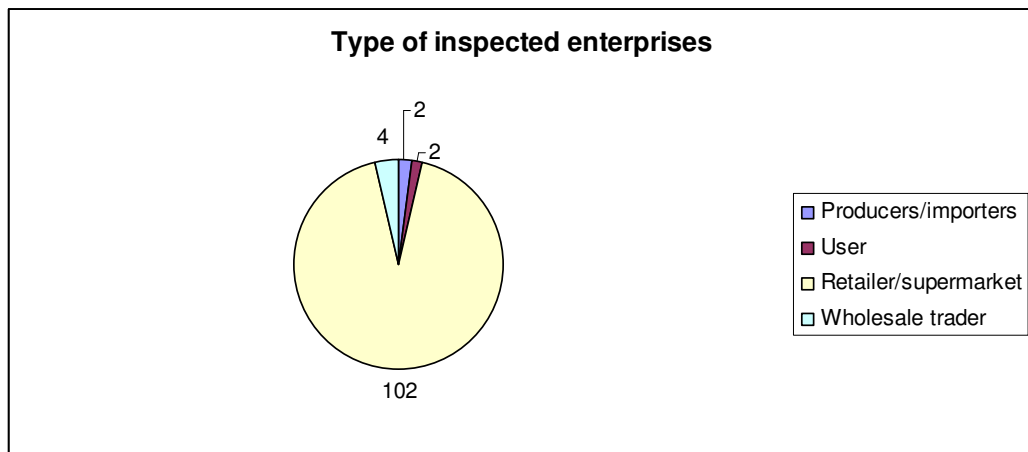
Germany handed in **353 products** from 5 of 16 federal states (Bundesländer). Some of the states decided not to join EuroBiocides because they had focused on biocidal products the previous two years.

Around 70 inspectors have been trained to examine biocidal products. The product types most represented were PT18: 109 insecticides; PT19: 87 repellents and PT2: 61 disinfections.

<b>Product type</b>	<b>Figures</b>
<b>PT1</b>	1
<b>PT2</b>	61
<b>PT3</b>	11
<b>PT5</b>	3
<b>PT8</b>	16
<b>PT9</b>	1
<b>PT10</b>	7
<b>PT14</b>	10
<b>PT16</b>	1
<b>PT18</b>	109
<b>PT19</b>	87
<b>PT21</b>	46

**Table 5.2.7-1: Number of biocidal products in relation to product types inspected in Germany**

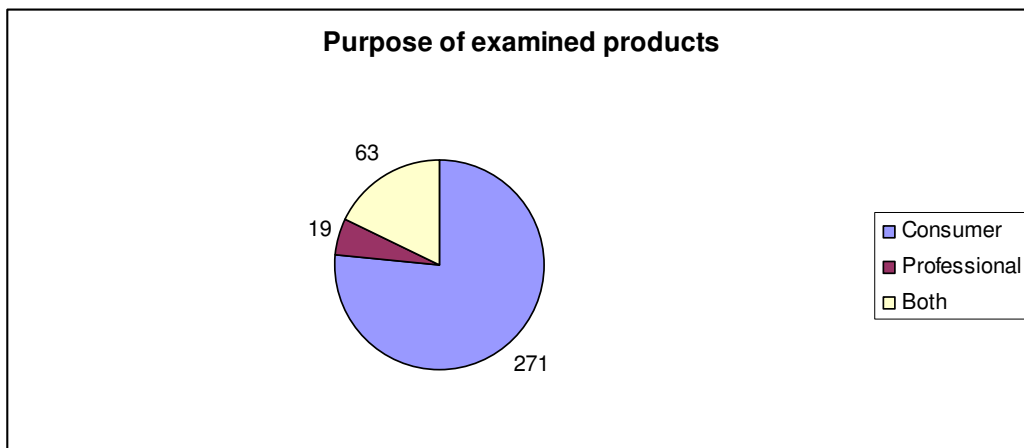
The division into types of enterprises and purpose of the products was as shown in the figures below:



**Figure 5.2.7-1: Overview of type of enterprises inspected in the German project.**

110 enterprises were inspected. Around 3 products were examined in each enterprise. The majority of the visited enterprises, 102 (92.7 %), were retailers and for that reason the majority of the examined products were intended for consumers.

4 enterprises were in the category wholesale trader, 2 were in the category users and 2 were in the category producer/importers.



**Figure 5.2.7-2: Overview of examined products in the German project.**

The majority of the examined products in the German project, 271 products (73.4 %) out of 353, were intended for consumers, 19 (5.4 %) were intended for professionals and 63 (17.1 %) were intended for both.

In Germany, it is mandatory for all biocidal products to obtain registration. At the moment biocidal products do not need a National authorisation and are not subject to a fee.

## **Classification and labelling**

1. The label on 1 product was unclear and not indelible; otherwise nothing was mentioned about labelling.
2. 21 products were blank/not checked.
3. 2 products had misleading sentences or gave an exaggerated impression, among those were mentioned: "Natural substances", "Naturally grown".
4. 35 products indicated low risk biocidal product, non-toxic, harmless or similar:  
Misleading: Natural active substances; only chloride; anti-allergic; insect free; no toxicity, biologically degradable; foodstuff to people, animal and plant harmless; harmless to health; different variations of no toxicity; without chemicals and preservatives; without danger to pets and persons; it is not corrosive and not toxic; no toxicity to person and animals; without toxic substances; 100 % natural. No danger to people, pets and animals, Winner of the green Chemistry award; absolute toxic free; harmless to farm animals, environmental friendly grit against insecticides at home, in barns and in bio-waste container; with low impact on man and environment against mould – "absolute ... non toxic", no impact on biological equilibrium, "no adverse effects when used appropriately", biologically degradable, not attractive to bees, bumble-bees and other useful insects, natural active substances.
5. 2 labels were not in German but in English only
6. 1 product had no trade name
7. 4 active substances were examined, all had substance name (applicable for single substances)
8. 126 products were incomplete with regards to company name, address and telephone number
9. 217 products were dangerous; uncertain was filled in for 23 products,
10. 113 products were not dangerous.
11. Chemical name(s) on the product were examined by comparing the declaration on the label, the SDSs and the German Biocidal Product Register, with the result that the information about substances on the label of 267 products were correct, missing in 35 cases and in 38 cases uncertain, 13 products were blank/not checked.

## **SDS and chemical composition**

- For 285 products no statistical results about inspection of SDSs were documented during the EuroBiocides project phase, also in cases when SDSs were not obligatory. Detailed inspections of 205 SDSs of biocidal products in 2006 led to a

factor of 64 % of non-compliance<sup>9</sup>. It is assumed that during EuroBiocides, the results would be comparable if a statistical data analysis had been done.

- Classification and labelling: in total 115 products were not dangerous preparations and therefore SDSs were mostly not necessary.
- Active substances were examined in all 353 products.

## Classification

- In PT2, 1 product contained very toxic T+ substances (Chlorine, CAS. No 7782-50-5) (Active substance intended for professional use) and the biocidal product was labelled with T+
- 3 product in PT18 were classified with Xn but T+ was required
- 1 toxic substance was found both in PT9 and PT18.  
PT9: Diphenoxarsin-10-yloxid (CAS No 58-36-6) was collected from a producer/importer and the biocidal product was labelled with T and was intended for professional use.  
PT18: Methomyl (CAS No 16752-77-5), Non-inclusion list, was found twice in a retailer/supermarket store; one intended for professionals and one intended for both professionals and consumers: The product for professional use was labelled with Xn and the one intended for both was labelled with T. 61 of the examined products were classified with Xn, the highest numbers (%) out of the examined products for PT21
- 9 products (in total) classified as corrosive were found in PT2 and PT3.
- 41 products classified with irritant were found, mainly in PT2
- 42 products, mainly in PT18, were classified as very flammable 16 products were classified as flammable, mainly in PT2 and PT18.
- No products were classified as oxidative.
- 79 products were classified with environmental danger; the highest numbers (%) were in PT18 followed by PT2.

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<sup>9</sup> Annual report of Ministry of Environment of the Federal State: Umweltministerium: Jahresbericht der Gewerbeaufsicht Baden-Wuerttemberg, 2006/2007  
<http://www.gaa.baden-wuerttemberg.de/servlet/is/17475/>  
[http://www.gaa.baden-wuerttemberg.de/servlet/is/17475/Informationen/Jahresberichte/Jahresbericht\\_06\\_07/Taetigkeitsberichte\\_Marktueberwachung.pdf](http://www.gaa.baden-wuerttemberg.de/servlet/is/17475/Informationen/Jahresberichte/Jahresbericht_06_07/Taetigkeitsberichte_Marktueberwachung.pdf)

Germany PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	uncertain/ blank /not applicable
1	1						1				
2	61	1		5	5	19	1	6		7	1/5/14
3	11			1	4	1		1		1	2/0/1
5	3										0/1/2
8	16			6						3	0/0/9
9	1		1							1	
10	7					4					1/0/3
14	10										0/0/4
16	1										1/0/0
18	109		1	12		9	36	6		32	12/1/24
19	87			1		4	3	3		5	14/4/55
21	46			36		4	1			30	5/0/5
<b>#</b>	<b>353</b>	<b>1</b>	<b>2</b>	<b>61</b>	<b>9</b>	<b>41</b>	<b>42</b>	<b>16</b>	<b>-</b>	<b>79</b>	<b>36/11/113</b>
<b>Percent (%)</b>		0.3	0.6	17.3	3.5	11.6	11.9	4.5	-	22.4	

**Table 5.2.7-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products are not dangerous and otherwise some products have to be labelled with more than one indication of danger, there are differences when the results are summarised.**

#### **Indication of danger (classification)**

- 113 products were mentioned as not applicable (113 products were not dangerous); not applicable was mainly found in PT18 (22 products) and PT19 (53 products),
- Indications of danger were not OK for 46 products (13 %), uncertainty mentioned for another 63 products. Not in compliance was mainly found in PT18 and PT2, shown in diagram
- Indication of safety was not OK for 76 (27.2 %) products, which were mainly found in PT18 and PT2.
- Indication of environmental danger was not OK for 33 products (9.3 %), mainly in PT18.
- 19 products were not OK, both for danger and for environmental danger, 12 of those, mainly in PT18, were missing both N and F+.

Germany	Examined dangerous products	Checked products	Indication of danger		Indication of safety	Environmental indication of danger	
			Not OK	Uncertain		Not OK	Uncertain
PT	(Except not applicable)	(Except blank)	Not OK	Uncertain	Not OK	Not OK	Uncertain
1	1	1					
2	44	61	11	6	19	5	1
3	11	11	2	3	3		
5	1	3		1			
8	9	16		1	1		
9	1	1			1		
10	5	7		2			
14	0	10					
16	1	1		1			
18	87	109	28	13	42	24	
19	35	87	4	20	5	3	
21	46	46	1	16	5	1	
#	240	353	46	63	76	33	1

Table 5.2.7-3: Examined products with mistakes in labelling for indication of danger including risk phrases (R-sentences), safety phrases (S-sentences) and environmental danger in Germany

## Biocidal investigation

### Borderlines:

5 borderline cases were found/discussed in Germany, but these cases were easily determined on the basis of the Manual of Decision.

- 4 products with 3 borderlines to cosmetics and 1 to plant protection agents were found in PT19
- In 1 product in PT2, a claim of external biocidal effect of an article was made but the manufacturer insisted that the product was not a biocidal product because the effect

could only be internal. But a study of the biocidal effect proved that it was external and therefore the requirements of BPD must be met.

### Specific BPD-rules for labelling:

At the moment biocidal products do not need a National authorisation. The BPD-requirements of classification and labelling according Article 20 are implemented in the national chemicals legislation. Legally binding provisions were in force for those 353 examined products, shown in table 5.2.7-4. Most of the products not in compliance were found in question last part i) about “expiry date”, indicating that around 33.4 % (grey in table 5.2.7-4) of the products were not in compliance with at least 1 of the 8 specific BPD-requirements.

Examined BPD-requirements	Figures for products without authorisation	Percent (%) (Not OK)
	<b>Legal provision (implemented in national legislation)</b>	
First part a) Identity of every active substance	35 (additional 38 uncertain)	9.9
Last part a) Concentration in metric units	66 (additional 58 in percentage)	18.7
c) Indication of the type of preparation	48	13.6
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	104	32.8
g) If accompanied by a leaflet: Sentence „read instructions before use“	35	9.9
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	94	26.6
First part i) Formulation batch number or designation	62	17.6
Last part i) Expiry date relevant to normal conditions of storage	118	33.4
j) Period of time needed for the biocidal effect, if relevant	56	15.9
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	71	20.1
<b>average value for the following 10 questions (8 requirements):</b>		<b>19.9</b>

**Table 5.2.7-4: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always necessary on the label of a biocidal product with a national authorisation). The average calculation is a simple estimate useful for comparison between participating countries and products with and without legally binding provision.**

**Active substances:**

319 products (except the 34 which were not checked / no information about active substances available) contained minimum 1 active substance, 159 products contained only 1 single substance, 116 products contained 2 active substances, 36 products contained 3 active substances, and 8 products contained 4 active substances or more. 531 active substances were examined.

- A total of 38 products contained active substances which are not listed in ANNEX II, not including the products which were not finally examined (not checked / no information available). The active substances were found in PT2(9), PT3(1), PT5(1), PT10(1), PT14(2), PT18(1), PT19(19) and PT21(4).
- 6 products contained more than 1 active substance, in total 44 active substances were not listed in ANNEX II.
- Not found was mentioned for 16 products for the 1<sup>st</sup> active substances (total: 24). This could be explained in different ways: One reason is that information about active substances is not detailed enough for substance identification purposes e.g. in cases of quaternary ammonia compounds or it may be “new substances” (also in cases of quaternary ammonia compounds).
- 16 substances were not checked/no information available (mostly because CAS numbers or other detailed information for substance identification purposes were not available).
- Non-inclusion substances were found in PT1(1), PT18(19) and PT19(2). In total, 22 active substances were included in non-inclusion decisions.

**ENFORCEMENT****OVERVIEW**

151 of the total of 353 biocidal products were removed from the market during the project phase because of illegal active substances and / or non-compliance with classification and labelling. In 21 cases of biocidal product inspections information was given to companies. Enterprises placing products on the market with insufficient information, or without any information about active substances on the label or in the SDS, were asked for clarification and / or re-labelling of the products in accordance with the BPD. These follow up actions were mostly not documented in the EuroBiocides because they went on beyond the project phase.

The inspection results in Germany are related to two main aspects: marketability of the inspected products e.g. in relation to active substances; and classification and labelling, (including misleading expressions).

- Related to marketability of the inspected products:

A significant number of products were not allowed placing on the market because they contained active substances which were not notified to their specific use/product type. In addition, for a significant number of products the information about the identity of active substances on the label was different from the information in the SDS and / or in the German Biocidal Products Register. Therefore, inspectors have examined the marketability of the products in a time consuming process both during the project phase and afterwards.

- Related to classification and labelling:

A significant number of non-compliances concerning labelling of dangerous biocidal products were found with regards to hazards information.

Furthermore, around 10 % of the products were labelled with forbidden misleading phrases like “non-toxic” or “harmless” or similar.

Violation was found in approximately 172 (48.7 %) of all examined products and those products were not in compliance with the BPD legislation in the German approach.

#### **5.2.7.1 Results and comparison with other results**

In 2005 in Germany, 928 biocidal products were examined<sup>10</sup> and statistically documented. In 2006/2007<sup>11</sup> during the follow up inspection project, a total of 1315 biocidal products were inspected. But because detailed statistical data was not available for all of these products the comparison is made in relation to the 353 products documented during inspections in North-Rhine Westphalia in those years.

When comparing these results with results from former biocidal product inspections a slight improvement was generally detected.

An obligation which is easily fulfilled, but no less important is the labelling with complete name and address on products; this is especially important in cases of poisoning or accidents. In

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<sup>10</sup> Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit (BLAC): Ergebnisse der Schwerpunkt-Überwachungsaktionen 2005: Biozid-Produkte im Handel, bei Herstellern und Verwendern, 26.07.2006  
<http://www.blac.de/servlet/is/2146/P-8a.pdf>

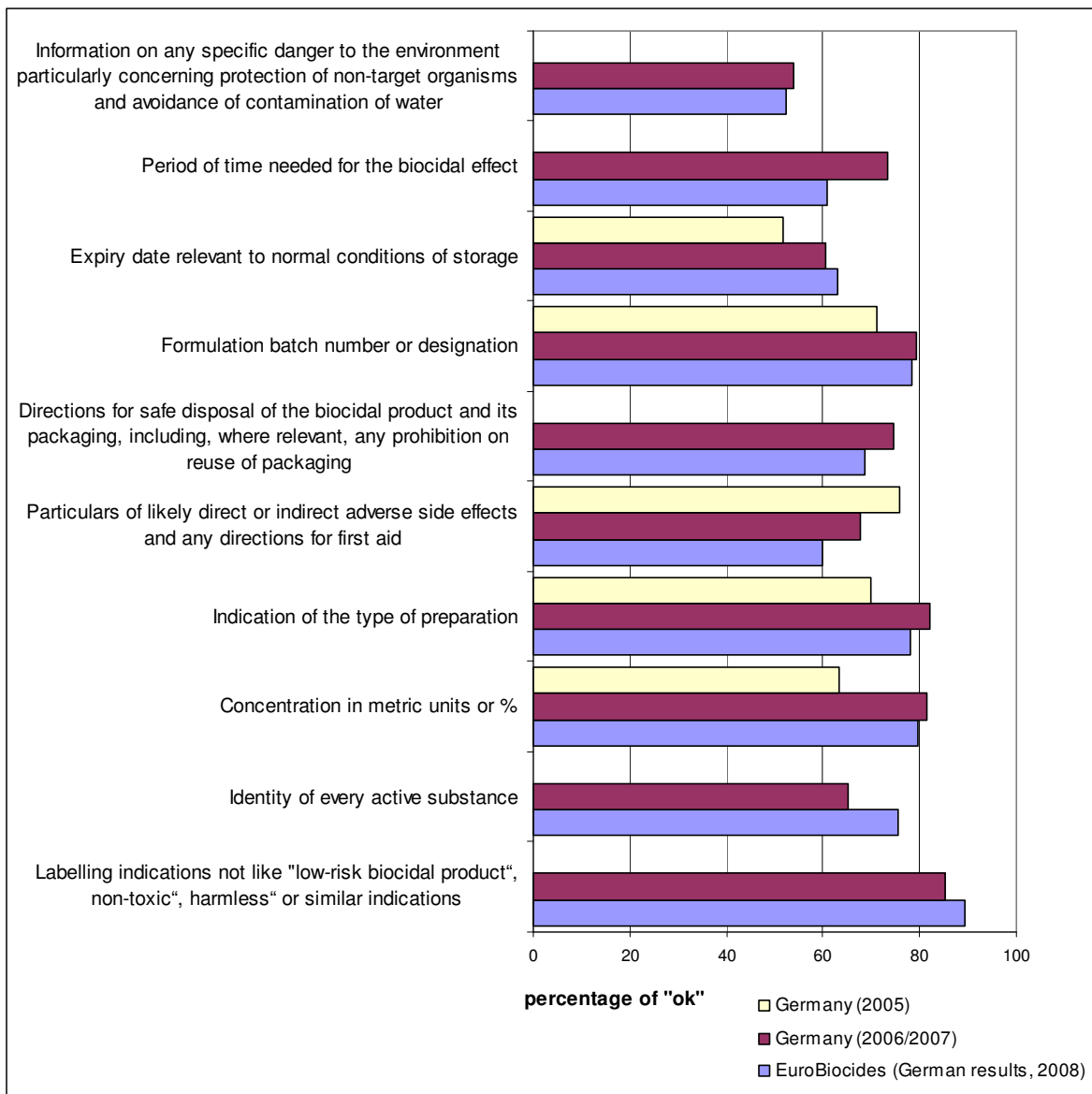
<sup>11</sup> Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit (BLAC): Ergebnisse der Schwerpunktüberwachungsaktionen 2006/2007 von Biozid-Produkten im Handel, bei Herstellern und Verwendern  
<http://www.blac.de/servlet/is/2146/P-8b.pdf>

2008, products labelled with complete address increased to 65 percent from 58 percent in 2006/2007 and 60 percent in 2005.

An improvement was also observed in relation to forbidden labelling with indications like "low-risk biocidal product", "non toxic", "harmless" or similar indications: In 2008, around 10 percent were labelled with forbidden expressions, compared to 14 percent in 2006/2007 (no statistical data available for 2005).

### **Labelling according to BPD**

The comparison of results during the EuroBiocides project phase with former results showed a clear trend concerning the degree of compliance e.g. between data from 2006/2007 and 2008. This could be explained in the following way: On the one hand, there is still a considerable degree of non-compliance, but on the other hand, the enforcement activities are well-directed in the relevant fields.



ds.

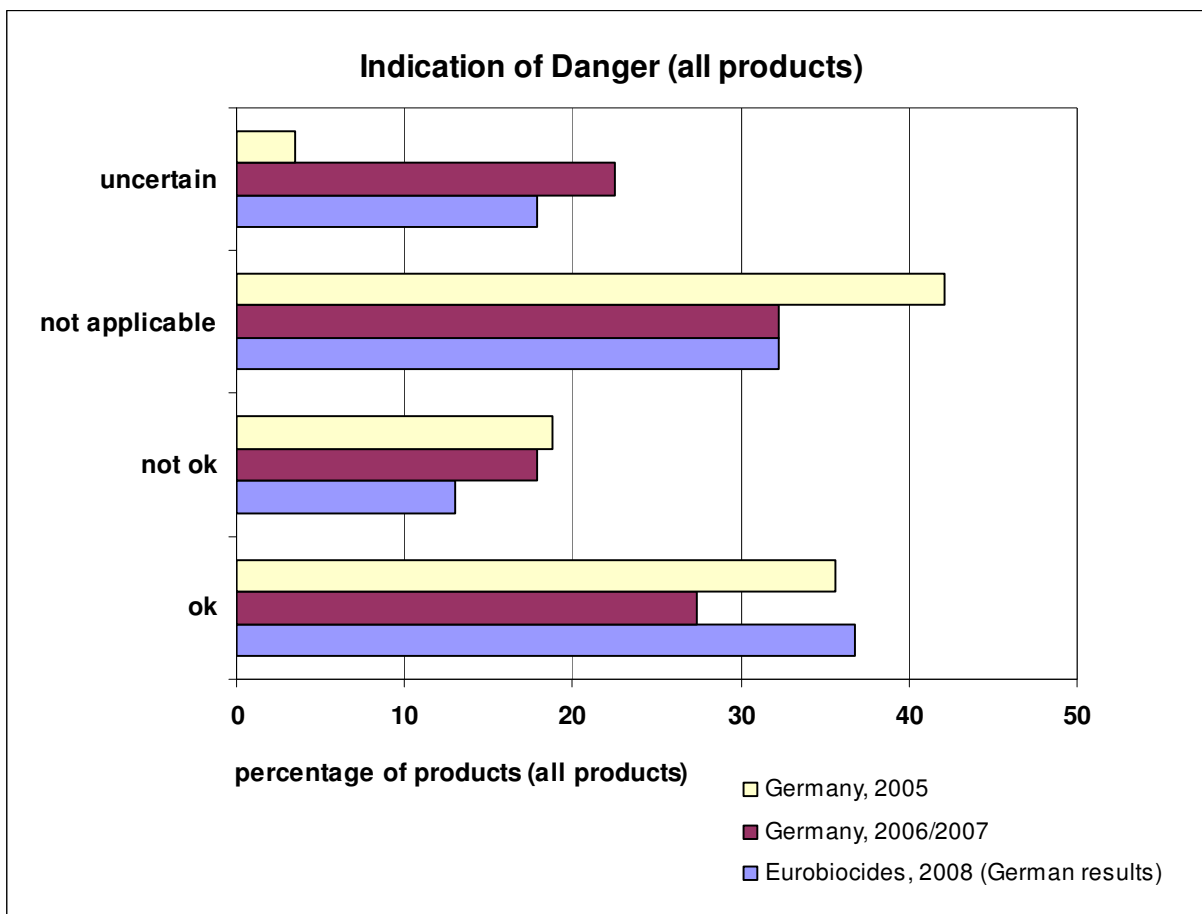
**Figure 5.2.7-5: Comparison of results of inspections of biocidal products in Germany 2005 (928 products), 2006/2007 (391 products)<sup>12</sup> and during EuroBiocides in 2008 (353 products). In some cases no statistical data are available for 2005. Concentrations of active substances given in percentages are counted as "ok".**

### Labelling according to 67/548/EEC and 1999/45/EC

The comparison of inspection results in Germany shows a tendency of improvement in compliance concerning classification and labelling with hazard symbols: The range of hazardous preparations of biocidal products was nearly the same in 2006/2007 and 2008, but the wrong labelling of the hazardous preparations decreased from 18 to 13 percent. In

<sup>12</sup> In 2005 in Germany 928 biocidal products were checked and statistically documented. In 2006/2007 during the follow up inspection project a total of 1315 biocidal products were checked. But for the reason that not for all of these products detailed statistical data are available the comparison is done in relation to the 353 products documented during inspections in North-Rhine Westphalia in those years.

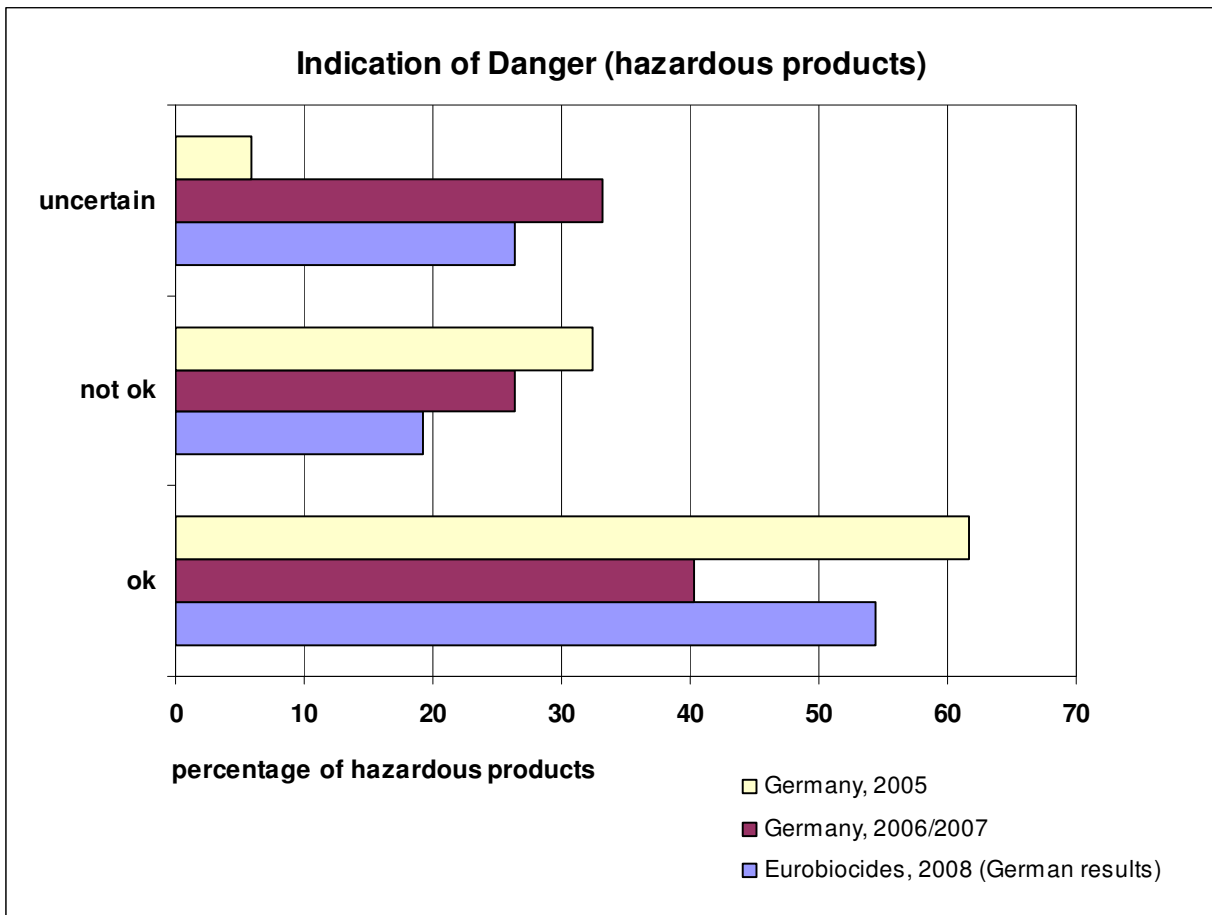
addition, the number of “uncertain” products (products with insufficient information for inspecting classification and labelling during project phase) decreased. This tendency may be explained by better or more consistent information given by companies about the content of preparations, but is still in the range of 18 %.



**Table 5.2.7-6: Comparison of results (all inspected products) of inspections of biocidal products in Germany 2005 (928 products), 2006/2007 (391 products)<sup>13</sup> and during EuroBiocides in 2008 (353 products). “Not applicable” means “no hazardous preparation”. “Uncertain” means that inspection of labelling could not be finalized during project phase because of missing, incomplete or inconsistent information given by companies about the content of preparations.**

When only focusing on the hazardous preparations, the percentage of wrong or missing indications of danger increases to the range of 20 %.

<sup>13</sup> In 2005 in Germany 928 biocidal products were checked and statistically documented. In 2006/2007 during the follow up inspection project a total of 1315 biocidal products were checked. But for the reason that not for all of these products detailed statistical data are available the comparison is done in relation to the 353 products documented during inspections in North-Rhine Westphalia in those years.



**Figure 5.2.7-7: Comparison of results of inspections (only hazardous preparations) of biocidal products in Germany 2005 (928 products), 2006/2007 (391 products)<sup>14</sup> and during EuroBiocides in 2008 (353 products). “Uncertain” means that inspection of labelling could not be finalized during project phase because of missing, incomplete or inconsistent information given by companies about the content of preparations.**

An even higher level of non-compliance can be determined, when the number of wrong indications is counted instead of the number of products, because in some cases more than one indication was wrong and/or missing.

The percentage of products not in compliance with the requirements of R-sentences and S-sentences is higher than the percentage of products not in compliance with the requirements of indication of danger, which is not really surprising because of subsequent errors.

The indication of danger on 13 % of the products was wrong or missing and the R-sentences on nearly 20 % of the products were wrong. For around 28 % of the products, inspectors were

<sup>14</sup> In 2005 in Germany 928 biocidal products were checked and statistically documented. In 2006/2007 during the follow up inspection project a total of 1315 biocidal products were checked. But for the reason that not for all of these products detailed statistical data are available the comparison is done in relation to the 353 products documented during inspections in North-Rhine Westphalia in those years.

unable to decide if the R-sentences were OK or not during the project phase, compared with 18% of indication of danger of the products.

A great increase in compliance of labelling with environmental indication of danger was observed: More than 65 % of the inspected products with environmental danger were labelled OK.

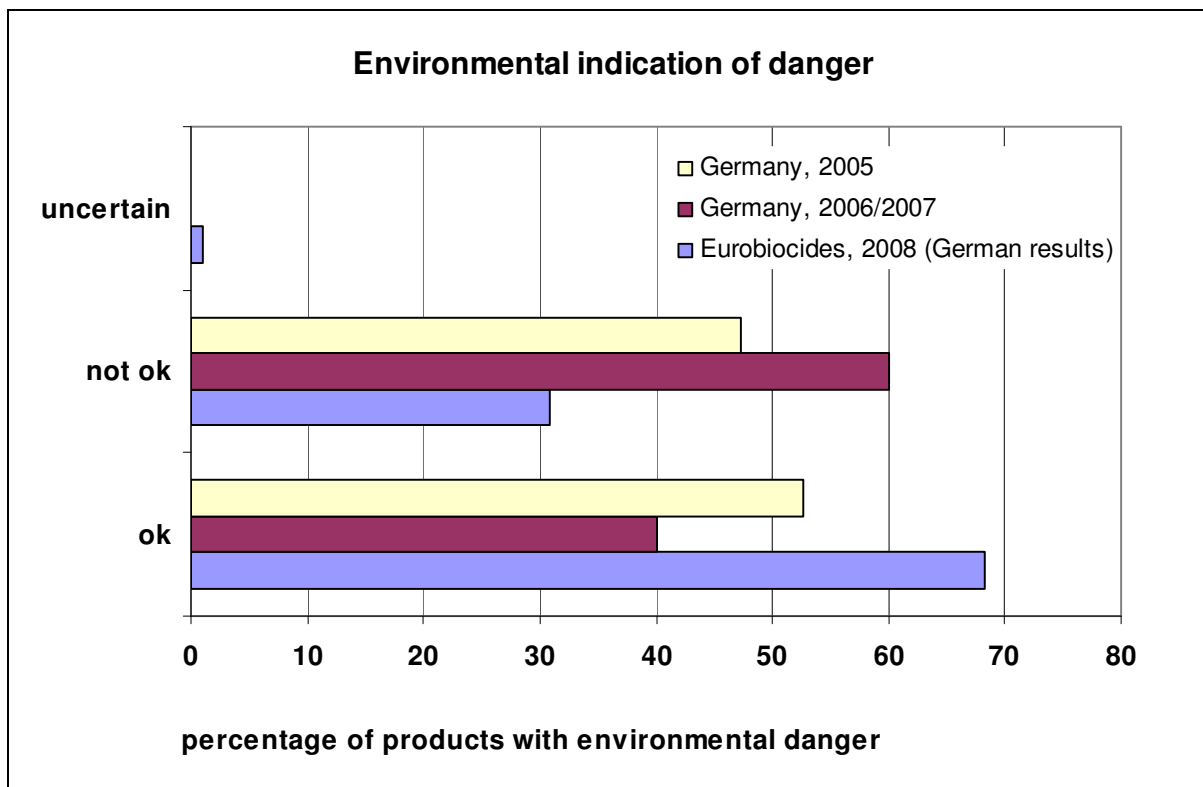


Figure 5.2.7-8: Comparison of results of inspections (only preparations with environmental danger) of biocidal products in Germany 2005, 2006/2007 and during EuroBiocides 2008.

## 5.2.8 Latvia

Latvia handed in **81 products**.

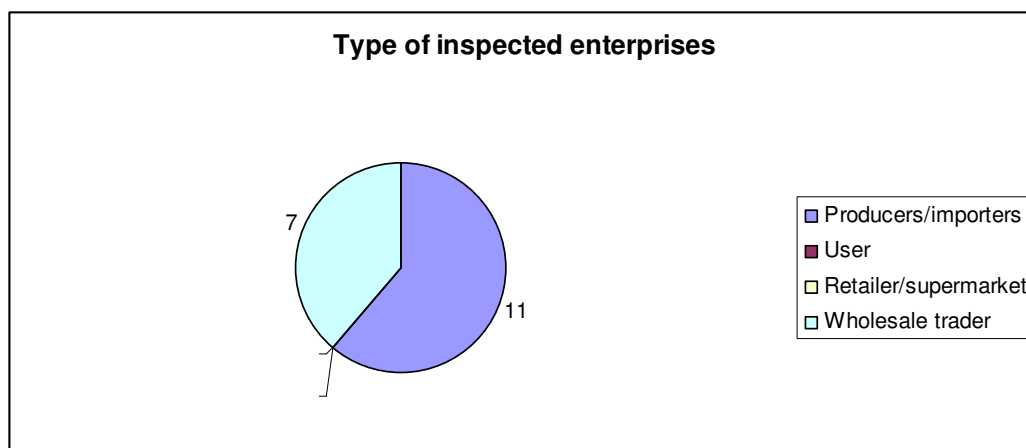
The biocidal products were examined in 5 products types, mainly represented with 27 disinfectants in PT2, 19 wood protection products in PT8 and 18 insecticides in PT18.

Product type	Figures
PT2	27
PT8	19
PT14	13
PT18	18
PT19	4

**Table 5.2.8-1: Number of biocidal products in relation to product types inspected in Latvia**

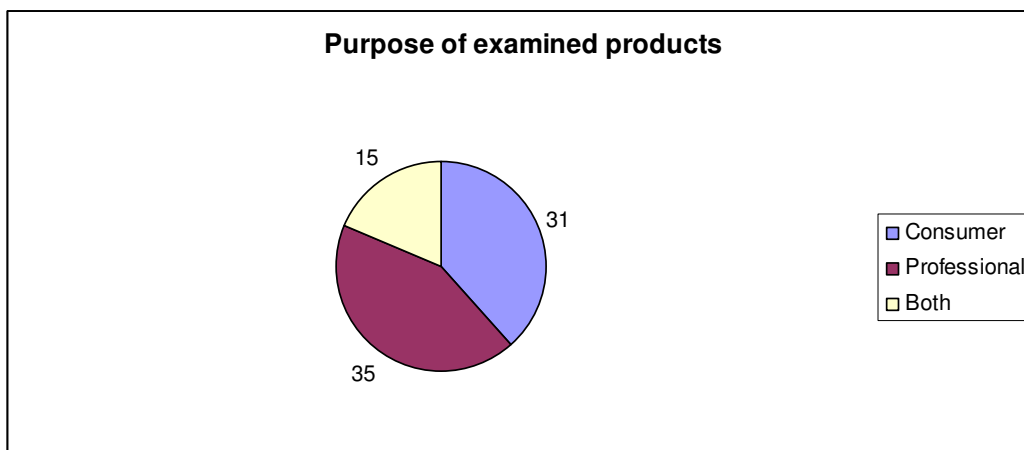
18 enterprises were inspected. Knowledge about the legislation and information about the products were satisfactory in 10 of the 18 inspected enterprises, and incomplete in 8 enterprises.

The division in types of enterprises and purpose of the products were as shown in the figures below:



**Figure 5.2.8-1: Overview of type of enterprises inspected in the Latvian project.**

11 (61.2 %) of the inspected products were collected from wholesale traders and 7 (38.8 %) from producers and importers.



**5.2.8-2: Overview of the purpose of examined products in the Latvian project.**

35 of the examined products (43.2 %) were intended for professionals, 31 for consumers (38.3 %) and 15 (18.5 %) for both.

National authorisation is in force for all biocidal products, but they are not subject to a fee.

### **Labelling and packaging**

1. 5 products were missing labels (not checked).
2. Nothing remarkable concerning packaging - clear and indelible labelling.
3. 2 products indicated “not dangerous for the environment”
4. 5 products had incomplete name and address
5. 20 products were not dangerous (3 in PT 18, 3 in PT14, 1 in PT8, 2 in PT2, 11 in PT19)
6. Chemical names were incomplete on 34 products

### **SDS and chemical composition**

- 68 SDSs were available and examined
- 13 SDSs were not available and not examined

### **Classification**

- 2 products in PT8 contained very toxic T+ substances (both with Disodium tetraborate, anhydrous, EINECS nr. 215-540-4)
- 1 toxic substance was found in both PT8 and PT18 (In PT18 Disodium tetraborate, anhydrous, EINECS nr. 215-540-4 and Bendiocarb; EINECS nr 245-216-8 in PT8)

- The 4 toxic and very toxic products were intended for professional use, and were collected from producers/importers.
- 11 of the examined products were classified with Xn: 3 in PT2, 6 in PT18 and 2 in PT8.
- 10 products classified as corrosive; 4 out of 27 (14.8 %) and 6 out of 19 (31.6 %) were found in PT2 and PT8.
- 22 products were classified as irritant, 16 out of 27 (59.3 %) in PT2
- 8 products, 6 out of 18 (33.3 %) in PT18 and 2 out of 4 in PT19 (50 %) were classified as very flammable
- 1 product in PT2 was classified as flammable.
- 2 products in PT2 were classified as oxidative.
- 31 products were classified with environmental danger; the highest numbers, 14 out of 18 products (77.8 %) in PT18, followed by 13 out of 19 (68.4 %) in PT8.
- 20 products were blanks (not applicable because they were not dangerous).

Latvia PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	Not applicable
2	27			3	4	16		1	2	4	3
8	19	2	1	2	6	2				13	1
14	13										13
18	18		1	6		3	6			14	3
19	4					1	2			0	
#	81	2	2	11	10	22	8	1	2	31	20

**Table 5.2.8-2: Labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous and because some products contained more than one symbol, there are differences when the results are summarized.**

#### **Indication of danger (classification)**

- Mistakes with indication of danger were found in 22 products, 13 in PT2, 7 in PT 18 and 2 in PT 8. (22 out of 81 examined products, 27.2 %)
- Mistakes with indication of safety-phrases, were found in 14 products in PT2 and 7 in PT9 (23 out of 81 examined products, 28.4 %)
- Mistakes with indication of environmental danger were found in 3 products, 2 in PT8 and 1 in PT2. (3 out of 81 examined products, 3.7 %)

## Biocidal investigation

### Borderlines:

- In total, 17 products out of 81 examined (21 %) had a borderline
- 13 products in PT2 were borderlines to detergents (horizontal legislation)
- 3 products in PT8 had borderlines to “others” because of VOC legislation.
- 1 product in PT19 was a borderline to a detergent

### Specific BPD-rules for labelling:

National authorisation was in force for 71 out of 81 examined products. 10 products did not have authorisation. Products with and without legally binding procedure were shown in table 5.2.8-3. Most products not in compliance were found in question g) about “ the sentence “read instruction before use”, indicating that around 22.5 % (grey in table 5.2.3-8) of the products with legally binding provisions were not in compliance with at least 1 of the 8 specific BPD-requirements.

<b>Examined BPD-requirements:</b>	<b>Estimates of Figures for 71 products with authorisation</b>	<b>Percent (%),  Not Ok</b>	<b>Figures for 10 examined products without authorisation</b>	<b>Percent (%)  Not OK</b>
	<b>Legal provision</b>		<b>No legal provision</b>	
First part a) Identity of every active substance	8	11.3	2	20
Last part a) Concentration in metric units	4	5.6	10	100
c) Indication of the type of preparation	5	7	2	20
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	5	7	4	40
g) If accompanied by a leaflet: Sentence „read instructions before use“	16	22.5	6	60
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	13	18.3	4	40
First part i) Formulation batch number or designation	11	15.5	1	10
Last part i) Expiry date relevant to normal conditions of storage	8	11.3	1	10

j) Period of time needed for the biocidal effect, if relevant	2	2.8	4	40
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	12	16.9	1	10
Average value for the following 10 questions (8 requirements) :		11.8		35

**Table 5.2.8-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l)(always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple estimate useful for comparison between participating countries and products with and without legally binding provision.**

### Active substances:

58 examined products contained at least 1 active substance, 11 products contained 2 active substances (most (12) in PT8), and 7 (most (6) in PT8) contained 3 active substances, and 3 products contained 4 active substances (in PT2 and PT8), 1 product in PT 18 contained 5 active substances, in total 120 active substances were examined.

- 2 products in PT18 contained active substances, which were only notified in ANNEX I.
- The same was the case for the 2nd listed active substance in another PT18 products.
- 1 product in PT18 contained 1 non-inclusion active substance (CAS nr. 204-029-1)
- No information for 1 product in PT1.

### Enforcement

The columns for enforcement and results have not been filled in the result form, but violation was detected in 40 products, 30 of these products can be compared to products which have insufficient classification and labelling as shown in the table above. 6 products concerned specific requirements to biocidal products, e.g. "Identity of active substances is not present on labelling", detergents and safety warnings.

The remaining 4 products not in compliance were the 4 active substances (3 only in ANNEX I and 1 with a non-inclusion decision)

Violations were found in approximately 40 (49.4 %) of all examined products and those products were not in compliance with the BPD legislation in the Latvian approach.

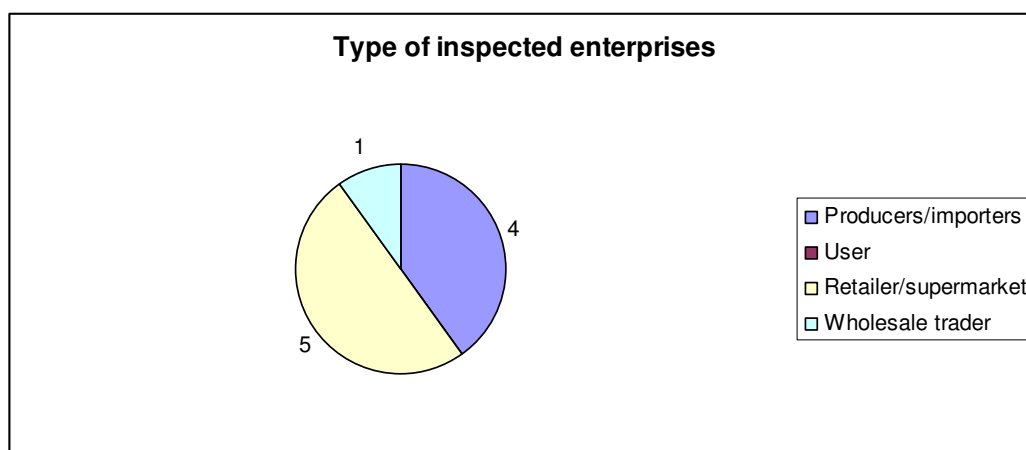
### 5.2.9 The Netherlands

The Netherlands handed in **50 biocidal products**. The products were examined in 5 product types with a majority in PT18: 23 insecticides; PT19: 12 repellents and PT2: 11 disinfectants.

Product type	Figures
PT1	2
PT2	11
PT3	2
PT18	23
PT19	12

**Table 5.2.9-1: Number of biocidal products in relation to product types inspected in the Netherlands.**

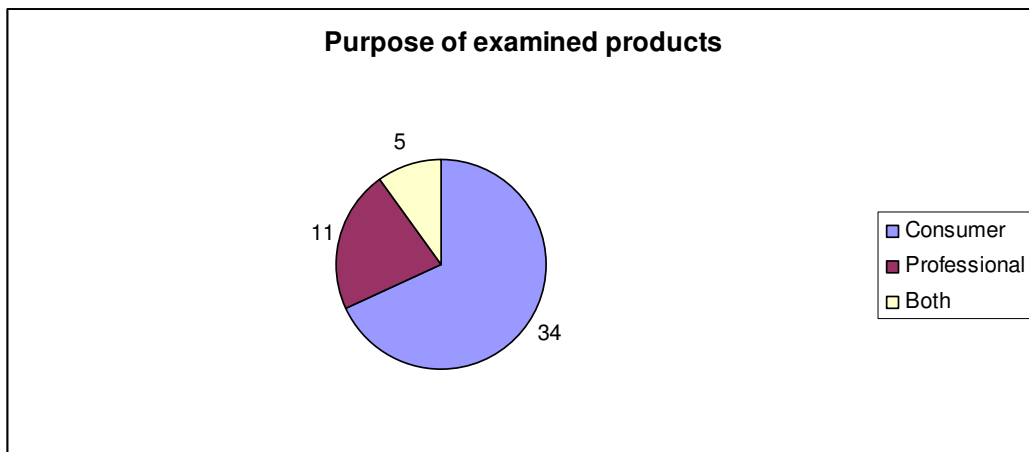
The division in types of enterprises and purpose of the products was as shown in the figures below:



**Figure 5.2.9-1: Overview of types of enterprises inspected in the Netherlands project**

10 enterprises were inspected; between 2 and 8 products were collected from each enterprise. 5 inspections took place at retailers/supermarkets (50 %). 4 at producers/importers (40 %) and 1 at a wholesale trader (10 %).

34 of the examined products (68 %) were intended for consumers, 11 products (22 %) for professionals and 5 products for both (10 %) as shown in figure 5.2.9-2.



**Figure 5.2.9-2: Overview of the purpose of examined products in the Netherlands project.**

The Netherlands has a central and mandatory registration for all Biocidal products according to the BPD. Nearly all product types were subject to national authorisation. However, the examined products in PT1 were not included in the national authorisation. Authorisation in the Netherlands was introduced prior to the BPD.

PT1 was not included in the authorisation, because at that time, the products were considered cosmetics or medicines. Following the transitional measures of Article 16 of the BPD, PT1 products in the Netherlands are now considered as biocides, but not included in the Netherlands authorisation. PT1 products are a subject of the European work programme and will become part of the authorisation when the active ingredients are incorporated in ANNEX I of the BPD.

An applicant for an authorisation of a biocidal product must pay for the costs of the authorisation request and the costs involved in the evaluation procedure of the authorisation process. After authorisation an annual levy of 1250.00 euro per authorised biocidal product is charged.

### **Labelling and packaging**

1. Packaging was examined on all products
2. Labelling was clear and indelible on all examined products
3. 6 products had misleading or exaggerated phrases like:  
 “quickly effective”, “radically scientifically proved”, “picture of a fly”, “natural fly spray”,  
 “working misleading name”, “20.000 flies?”, “Flowers on packaging”, “100 % natural  
 quick high efficiency and very low toxicity for mammals”
4. 5 products had “non-biocidal” claims like:

“Safe skin friendly”, “no pesticides”, “no added poison”, “100 % natural mild protection”, “Bio”, “no pesticides”, “Biologically degradable”, “not harmful for grass and plants”, “Safe and effective”, “100 % natural”, “Free of pesticides”, “safe for environment”

5. 15 products from 6 different enterprises were incomplete, without name and telephone number
6. 1 product was in Spanish, not in Dutch
7. 47 preparations and 3 active substances were examined, all active substances were on the labelling of the products
8. 19 products were not dangerous
9. Chemical names were on 30 of the examined dangerous products – some chemical names were also present on products which were not dangerous products

### SDS and chemical composition

- 49 SDSs were available and examined,
- All active substances were examined.

### Classification

The Netherlands PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	Not applicable (Not dangerous)
1	2										2
2	11			2	1	5			1	6	2
3	2				2				1		
18	23	1		2	1	2	10			16	5
19	12					3		2		1	9
#	50	1		4	4	10	10	2	2	23	19

**Table 5.2.9-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous and because some products contained more than one symbol, there are differences when the results are summarized.**

- 1 product in PT18 was classified as very toxic T+, (EC nr. cyfluthrin269-855-7/ CAS nr. 68359-37-5), intended for professional use collected from producer/importer
- 4 products, 2 in both PT2 and PT18 were classified with Xn
- 4 products were classified as corrosive, 1 in PT2, 2 in PT3 and 1 in PT18

- 10 products were classified as irritant, 5 out of 11 examined in PT2, 2 in PT18 and 3 in PT19
- 10 products were classified as very flammable, all 10 (43.5 %) in PT18.
- 1 product in PT2 and 1 in PT3 were classified as oxidative
- 23 products were classified with environmental danger (16 out of 23 examined products in PT18, 69.6 %, and 6 out of 11 products in PT2, 54.5 %)
- For 19 products the question in the questionnaire about classification was not answered, these products were not classified as dangerous and were mainly found in PT19 (9) and in PT18 (5)

### **Indication of danger**

- Mistakes with indication of safety-phrases were found in 7 out of 50 products (14.0 %), 3 in PT2, 3 in PT18 and 1 in PT8.
- Uncertainty about indication of danger was mentioned for 1 product in PT1 (lack of data)
- Mistakes with indication of environmental danger were not OK for 6 out of 50 products (12 %), 2 products in PT2 and 4 in PT18.
- 1 product in PT19 was not examined, and had no authorisation or SDS.

### **Biocidal investigation**

#### **Borderlines:**

- 17 borderline cases (of which 2 products in PT1 were borderlines, but considered cosmetics when the inspection took place) were detected in the Netherlands, corresponding to 34 % of examined products.
- "Others" were mentioned for 7 products in PT19 (14 %), 1 in PT18 and 2 in PT2.
- Detergent as a borderline was mentioned for 1 product in PT2.
- 2 borderlines between PT1 respectively 2 in PT19 to cosmetics were found.
- In PT18, 1 borderline to plant protection agents and 1 to medical devices were found

#### **Specific BPD-rules for labelling:**

National authorisation was in force for 32 out of 50 examined products. 18 products did not have authorisation. Products with and without legally binding procedure were shown in table 5.2.9-3. Most of the products not in compliance were found in the question: Last part i) Expiry date relevant to normal conditions of storage for those products with authorisation, indicating

that around 50 % (grey in table 5.2.9-3) of the products with legally binding provision were not in compliance with at least 1 of the 8 specific BPD-requirements.

<b>Examined BPD-requirements:</b>	<b>Estimates of (not ok) for 32 products with authorisation</b>	<b>Percent (%), Not Ok</b>	<b>Figures for 18 examined products without authorisation</b>	<b>Percent (%) Not OK</b>
	<b>Legal provision</b>		<b>No legal provision</b>	
First part a) Identity of every active substance	3	9.4	6	33.3
Last part a) Concentration in metric units	5	15.6	5	27.8
c) Indication of the type of preparation	3	9.4	9	50.0
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	0	0	13	72.2
g) If accompanied by a leaflet: Sentence „read instructions before use“	0	0	5	27.8
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	3	9.4	13	72.2
First part i) Formulation batch number or designation	4	12.5	9	50.0
Last part i) Expiry date relevant to normal conditions of storage	16	50	13	72.2
j) Period of time needed for the biocidal effect, if relevant	0	0	11	61.1
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	5	15.6	18	100
<b>Average for the following 10 questions (8 requirements):</b>		<b>12.2</b>		<b>56.7</b>

**Table 5.2.9-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple estimate useful for comparison between participating countries and products with and without legally binding provision**

**Active substances:**

- 6 active substances, which were only notified in ANNEX I, were found among 39 examined products (15.8 %), 1 in PT2, 2 in PT18 and 3 in PT19,
- 1 substance in PT2, 1 in PT18 and 1 in PT19 were not found, probably not active substances or “new substances”: Gesteentemeel (minerals), PT2 and Quaternary ammonia compounds, benzylkokosalkyldimethyl, chloriden (1)263-080-8 61789-71-7; PT2 and Alletrina, PT19
- 11 products, 6 in PT19, 2 in PT18, 2 in PT2 and 1 in PT1 were not examined

24 of the 39 examined products (53 examined active substances), contained only 1 active substance, and 13 products, (6 in PT18) contained 2 active substances.

**Enforcement**

In the Netherlands this project was not performed as an enforcement project. The project was discussed with the Platform Biocide<sup>15</sup> and it was decided to perform the project as an inventory project. The results were communicated to the enterprises to enable them to correct the errors on the biocides. Other biocides enforcement projects that year were carried out as planned.

Violations were found in approximately 23 (46 %) of all examined products and those products were not in compliance with the BPD legislation in the Netherlands approach.

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<sup>15</sup> Platform Biocide is the representative of all biocide associations in the Netherlands.

### 5.2.10 Norway

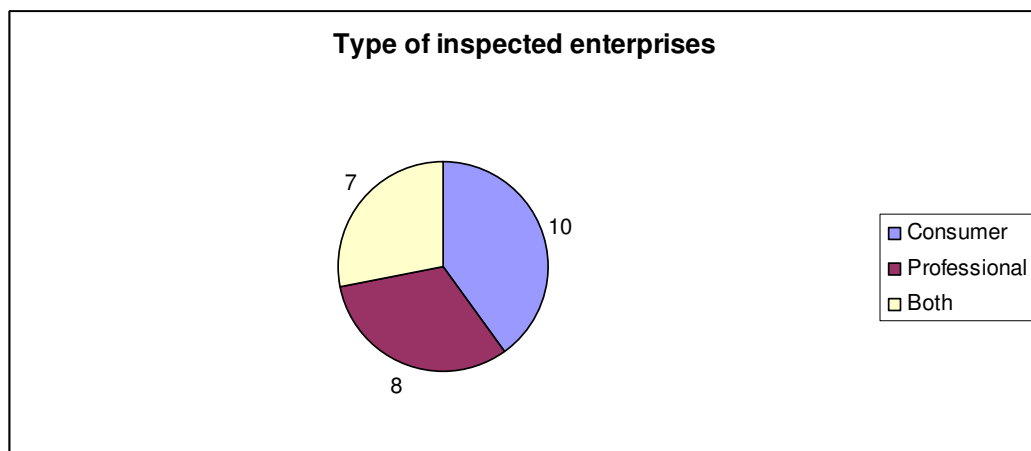
Norway inspected 5 enterprises and reported on **25 examined products** including PT2, PT14, PT18 and PT19, with a majority of products (16) in PT 18, insecticides and 7 in PT14, rodenticides.

Product type	Figures
PT2	1
PT14	7
PT18	16
PT19	1

**Table 5.2.10-1: Number of biocidal products in relation to product types inspected in Norway**

All enterprises were in the category producers/importers and 3 to 10 products were collected from each enterprise.

Purpose of the products was as shown in the Figures below:



**Figure 5.2.10-1: Overview of the purpose of examined products in the Norwegian project.**

10 (45.5 %) of the collected products were intended for professionals, 8 (36.4 %) products were intended for consumers and 7 (31.8 %) were intended for both

None of the products needed a National authorisation, neither were any of the products subject to a fee. Registration of biocides is mandatory in Norway.

## Labelling and Packaging

1. 20 of 25 labels were not ok regarding correct information on health and/or environmental hazards.
2. 1 company did not have phone number on the label
3. 1 product was not dangerous

## SDS and chemical composition

- All SDSs - except for 2 – were available.
- 5 of 25 SDSs were not checked regarding classification and labelling.
- There were variations in the quality of the SDSs. Especially part 12: Eco-toxicology was not satisfactory
- All active substances were examined

## Classification

- 1 product in PT14 was classified with T+ and 1 product in PT18 was classified with T
- 4 products in PT14 and 3 in PT18 were classified with Xn
- 2 products were classified with F+ in PT18
- 8 products out of 16 examined in PT18 were classified with N and 1 in PT19.
- 8 were missing N

Norway	Examined Products	T+	T	Xn	C	Xi	F+	F	O	N	Not applicable (not dangerous)
PT											
2	1					1					
14	7	1		4							
18	16		1	3			2			8	
19	1									1	1
#	25	1	1	7		1	2			9	1

**Table 5.2.10-2: Danger labelling of the examined biocidal products. The total number of examined Biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized.**

### **Indication of danger (classification)**

- Mistakes with indication of danger (wrong or missing danger symbols and/or risk phrases) were detected on 20 products out of 25 examined, 80 %. (16 in PT18, 64 % (mostly something missing))
- Mistakes with indication of danger were uncertain for 3 other products (2 in PT 18, 1 in PT2) due to conflicting information on label, SDS and/or Norwegian Product Register.
- Mistakes with indication of safety-phrases were not ok for 2 products in PT18, uncertainty about 1 product in PT2.
- Mistakes with indication of environmental danger were not ok for 13 out of the 20 incorrect labelled products, 60% (1 product in PT14 and 12 products in PT18 (incl. 2 with correct N, but wrong R-phrases)).

### **Biocidal investigation**

#### **Borderlines:**

- 1 product out of 25 examined products (4 %) was a borderline case to a plant protection product (in PT18).

#### **Specific BPD-rules for labelling:**

Since no products were authorised in Norway at that point, these provisions were not enforced.

#### **Active substances:**

- 1 examined product in PT2 contained 2 active substances, both in ANNEX II.
- 7 products in PT14 were examined, 6 contained only 1 active substance – these 6 substances were OK. 1 product contained 2 active substances of which the 2<sup>nd</sup> listed active substance were not in ANNEX II. (but notified in ANNEX I)
- The examined products in PT18 included in total 21 active substances - 10 different substances. 1 product in PT18 with 1 active substance were not notified to the specific product type in ANNEX II (but notified in ANNEX I)
- The product examined in PT19 contained 3 active substances; all OK at the time of inspection, but 2 will be phased out later.

Of the 25 examined products (39 examined active substances), 16 products contained only 1 active substance, 4 products contained 2 active substances, 5 products (all in PT18) included 3 active substances.

## Enforcement

All labels and SDSs which were not OK had to be updated by the companies - this is an obligation pursuant to Norwegian regulations.

For the 2 active substances only in ANNEX I, 1 product was an old product which was removed from the market and was subsequently changed and then legalised. For the other active substance only in ANNEX I, the SDS was not updated, so this substance had also been substituted.

Approximately 20 (80 %) of the examined products were not in compliance with the BPD or other chemical legislation in Norway. The main reason was the lack of knowledge in the companies on legislation regarding classification and labelling.

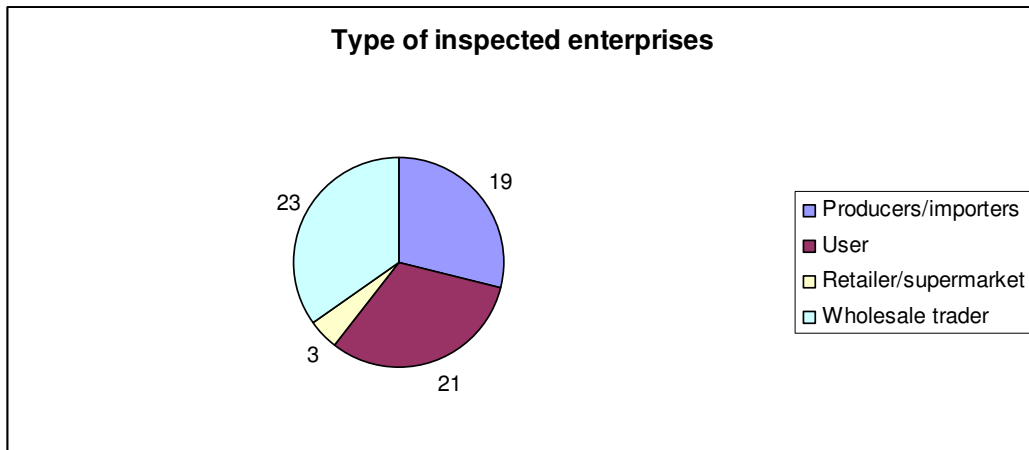
### 5.2.11 Poland

Poland handed in **80 products**. 10 product types were examined in the Polish project, mainly represented with 22 wood protection products in PT8, 18 disinfectants in PT4 and 10 disinfectants in PT2.

Product type	Figures
PT1	5
PT2	10
PT3	4
PT4	18
PT6	1
PT7	1
PT8	22
PT10	1
PT14	10
PT18	4
PT19	4

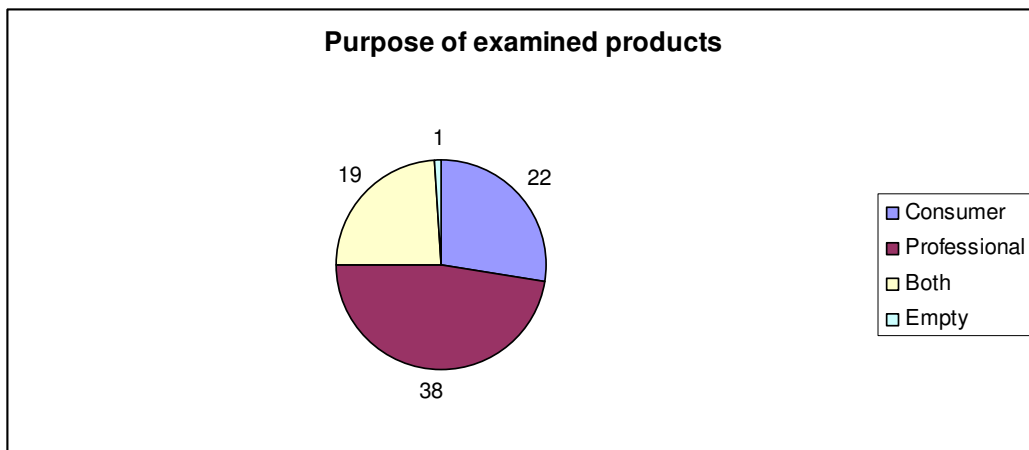
**Table 5.2.11-1: Number of biocidal products in relation to product types inspected in Poland**

66 enterprises were inspected. The division into types of enterprises and purpose of the products were as shown in the figures below:



**Figure 5.2.11-1: Overview of type of enterprises inspected in the Polish project.**

23 of the inspected enterprises were wholesale traders (34.8%), 21 were users (31.8%), 19 were producers/importers (28.8%) and 3 were retailers/supermarkets.



**Figure 5.2.11-2: Overview of the purpose of examined products in the Polish project.**

38 of the examined products (47.5 %) were intended for professionals, 22 products (27.5 %) were intended for consumers, 19 for both (23.8 %) and 1 was blank.

National authorisation/registration is mandatory for all biocidal products in Poland.

According to Article 16 (1) of Directive 98/8/EC in pursuance of Polish legislation, biocidal products shall be placed on the Polish market according to Article 54 of the Act of September 13, 2002 on biocidal products. Application form and attachments (labelling or information leaflet, efficacy data report, Safety Data Sheet (only information necessary for issuing authorisation)) document certifying legal status of the applicant and evidence of payment) are verified by the Polish CA (the Office for Registration of Medicinal Products Medical Devices and Biocidal Products). Charge shall be paid separately for each application.

It was difficult for the inspectors in this project to check if products were subject to a fee. The exception was the inspection of producers/ importers who had submitted documentation to the Polish CA (Office for Registration) and had copies of the documentation (including evidence of payment). In Poland, generally all authorisations are subject to a fee.

### **Labelling and packaging**

1. There were few remarks about labelling and packaging, 1 product was not examined and 3 products had labels with too small print.
2. 1 product had misleading phrases with "harmless to health".
3. All products had national language and trade name
4. 3 products had mistakes in address and name, telephone number etc.
5. 23 products were not labelled dangerous (mainly in PT8 and PT14)

2 products were not examined for being dangerous and uncertainty about dangerous was mentioned for 3 other products.

### **SDS and chemical composition**

- 74 SDSs were examined (question 3.2 d)
- 3 were not examined
- 3 were blank.

### **Classification**

- 2 toxic substances, 1 substance in PT2 (Formaldehyde / EINECS 200-001-8 / CAS nr. 50-00-0/ 37; concentration  $0\pm 1,0$  %) intended for both professionals and consumers and 1 substance in PT4 (Hydrogen peroxide/ 231-765-0/7722-84-1) intended for professionals.
- Another 2 toxic substances were found in PT8 (Copper oxide/ EINECS nr. 215-269-1 / CAS nr. 1317-38-0/ 10-25% and Chromium trioxide/ EINECS nr. 215-607-8/ CAS nr. 1333-82-0/ 25-40%) both intended for professionals.
- 11 of the examined products were classified with Xn, 3 in PT2 (30 %), 1 in PT4 and 5 in PT8 (62.5 %)
- 17 products were classified as corrosive, the highest numbers were 9 in PT4 (50 % of all examined) and 6 in PT8 (27.3 %)
- 16 products were classified as irritant, mainly in PT2 (27.8 %) and PT4 (50 %)
- 4 products in PT1 were classified as flammable.
- 3 products in PT4 were classified as oxidative (16.7 %)
- 7 products were classified with environmental danger, 4 out of 22 in PT8 (18.2 %)

- In PT14, 3 products were blank and 8 not applicable (not dangerous).

Poland PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	Not dangerous/ not applicable/ not checked
1	5					2		2		1	2
2	10		1	3	1	5					
3	4			1						1	2
4	18		1	2	9	5			3		1
6	1				1						
7	1					1					
8	22		2	5	6	1				4	6/1
10	1					1					
14	10										6/1
18	4									1	2
19	4					1					4
#	80		4	11	17	16		2	3	7	23/2

**Table 5.2.11-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized.**

#### Indication of danger (classification)

- For 23 products the question for indication of danger was not answered, these products correspond to those 23 products mentioned not dangerous in point 5 under **Labelling and Packaging**, mainly found for products in PT8 and PT14.
- There were mistakes with indication of danger for 5 products. 1 in PT2, 1 in PT3, 1 in PT4, 1 in PT8 and 1 in PT14 (5 out of 78 examined products, 6.4 %).
- Uncertainty about indication of danger for 2 products in PT8 and 1 in PT14
- Mistakes with indication of safety-phrases for 3 products, 2 in PT2 and 1 in PT8 (3 out of 78 examined products, 3.6 %)
- Uncertainty about indication of safety-phrases for 2 products in PT3 and PT7
- Mistakes with indication of environmental danger for 2 products, 1 in PT2 and 1 in PT 3. (2 out of 78 examined products, 2.6 %)

#### Biocidal investigation

##### Borderlines:

5 borderline cases were found in the Polish approach (6.3 % out of all examined *products*)

- 1 product in PT2, 1 in PT3 and 1 in PT4 were borderlines to detergents.
- 1 hand disinfectant in PT1 was a borderline to cosmetics
- 1 product in PT8 with a borderline not specified (others)

#### Specific BPD-rules for labelling:

National authorisation was in force for all the 79 examined products (legal provision), 1 product was blank. Products with legally binding procedure were shown in table 5.2.11-3. Most of the products not in compliance were found in question g) about “the sentence read instruction before use”, indicating that around 17.2 % (grey in table below) of the products with legally binding provision were not in compliance with at least 1 of the 8 specific BPD-rules.

<b>Examined BPD-requirements:</b>	<b>Figures for 80 products with authorisation</b>	<b>Percent (%), Not Ok</b>
	<b>Legal provision</b>	
First part a) Identity of every active substance	2	2.5
Last part a) Concentration in metric units	2	2.5
c) Indication of the type of preparation	2	2.5
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	12	15.2
g) If accompanied by a leaflet: Sentence „read instructions before use“	14	17.2
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	11	13.9
First part i) Formulation batch number or designation	4	5.1
Last part i) Expiry date relevant to normal conditions of storage	2	2.5
j) Period of time needed for the biocidal effect, if relevant	8	10.1
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	1	1.3
<b>Average value for the following 10 questions (8 requirements):</b>		<b>7.3</b>

**Table 5.2.11-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple mathematical estimate useful for comparison between participating countries and products with and without legally binding provision.**

### **Active substances:**

48 products contained only 1 active substance, 17 products contained 2 active substances (most in PT1, PT2, PT4 and PT8), and 10 (most in PT8) contained 3 active substances, and 2 products (1 in PT2 and 1 in PT8) contained 4 active substances, in total 120 ( 48+17\*2 + 10\*3 + 2\*4) active substances were examined.

- 2 products in PT8 contained active substances only identified in ANNEX I (CAS nr. 1333-82-0, Chromium trioxide), but the function of the substance in the product was not biocidal.
- In total 2 non-inclusion substances were found:  
1 in a PT4 product (Orthophosphoric acid/ CAS nr. 231-633-2/ EINECS nr 7664-38-2 / concentration: 75% - Commission decision 2008/809/EC) and 1 in a PT8 product (CAS Nr. 269-919-4 Quaternaire ammonium compounds, [Commission Regulation \(EC\) 1048/2005, phasing out 1 September 2010](#))
- “Not found” was filled in for 1 examined active substance in PT14; the name of the substance was not filled in.

### **Enforcement**

Enforcement and results have not been filled in the result form, but violation was reported for 29 products for which there were minor mistakes with name and address, print, classification and labelling etc on 5 products. Violation was also reported for 22 products for which specific biocidal requirements were missing, e.g. “direction for safe disposal of biocidal product”, “identity of active substance was not present on labelling”, “read instruction before use”, “first aid” etc.

The remaining 2 products not in compliance were the products in PT4 and PT8 which included active substances with a non-inclusion decision.

Violations were found in approximately 29 (36.3 %) of all the examined products (80) and those products were not in compliance with the BPD legislation in the Polish approach.

The following activities were undertaken by the inspectors:

- If a substance was only included in ANNEX I and not included in ANNEX II to Reg EC 1451/2007, an administrative decision was issued to the company with order to stop the placing on the market of the biocidal product containing substances from ANNEX I, not listed in ANNEX II

- If a product included non-inclusion substances, an administrative decision was issued ordering withdrawal of such product from the market. This information was forwarded to other regional inspectors to ensure harmonised enforcement.
- If a biocidal product was not in compliance with the specific BPD requirements (sheet question 2.16 to 2.25), advices were given for correct labelling. In case of serious non-compliance and in case of misleading labels, an administrative decision was issued.
- If the SDS of a biocidal product was incorrect or if the product had no safety data sheet, advices to correct the SDS or an administrative decision was issued.

### 5.2.12 Romania

Romania handed in **5 products** from the inspection in 3 enterprises/shops (retailer).

Product type	Figures
PT18	5

**Table 5.2.12-1: Number of biocidal products in relation to product types inspected in Romania**

None of the inspected products – all in PT18: insecticides – had a national authorisation nor were they subject to a fee.

The products were collected in connection with a Twinning project in Romania supported by German participants.

The 5 examined products were sold in 3 different retailers/supermarkets. All products were intended for consumers

#### Labelling and packaging

1. Labelling and packaging was clear and indelible
2. No misleading or exaggerated sentences/phrases were detected
3. National language and trade names were OK
4. The products were all dangerous; 2 products were not classified / labelled correctly and for 1 product the correctness of labelling could not be clarified.
5. 1 was a single substance, name of the substance was on the product
6. 1 product did not have the company address on the product
7. Chemical name was on all 5 products

## SDS and chemical composition

- No SDSs were available and for that reason not examined.

## Classification and labelling

Romania PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N
18	5	1	1			1				3

**Table 5.2.12-2: Labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products contained more than one symbol, there are differences when the results are summarized.**

- 1 product in PT18 was labelled with “poison” but it was not possible to determine if that meant very toxic, toxic or harmful (EC number 259-154-4) The symbol on the package is not legal in the EU; it was unclear if it means Xn, T or T+; it was also unclear if it contained naphthalene or only Empenthrin (Empenthrin, CAS 54406-48-3; not legally classified).
- 1 examined product in PT18 included a toxic substance (Chlorpyrifos legally classified as T, N. Additional information on the preparation was missing)
- 1 product was labelled as irritant and had environmental danger, but should have been classified as Xn, carcinogen category 3 (R40) and as environmentally dangerous.
- 3 products needed N, and for 2 additional products it was uncertain if N was needed

### Indication of danger (classification)

- Mistakes with indication of danger (other than dangerous for the environment) were found in 2 out of 5 examined products, 40 %.
- Uncertainty about R-sentences was found in 1 product (lack of data)
- Mistakes with indication of safety-phrases were found in 3 out of 5 products (60 %)
- Uncertainty about indication for Safety was mentioned for another 2 products.
- Mistakes with indication of environmental danger were missing on 4 out of 5 products (80 %)
- Uncertainty with indication of environmental danger was mentioned for another 2 products.

### Biocidal investigation

#### Borderlines:

- None of the products were borderlines, but all products were clearly intended to be insecticides

#### Specific BPD-rules for labelling:

National authorisation was not in force for the examined products. Legally binding procedures were not in force for the products examined in table 5.2.12-4.. Worst “statistical calculation” (100 %) were found among 3 question f, g and h.

<b>Examined BPD-requirements</b>	<b>Figures for 5 examined products without authorisation</b>	<b>Percent (%) Not OK</b>
	<b>No legal provision</b>	
First part a) Identity of every active substance	0	0
Last part a) Concentration in metric units	1	20
c) Indication of the type of preparation	2	40
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	5	100
g) If accompanied by a leaflet: Sentence „read instructions before use“	5	100
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	5	100

First part i) Formulation batch number or designation	3	60
First part i) Expiry date relevant to normal conditions of storage	0	0
j) Period of time needed for the biocidal effect, if relevant	2	40
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	3	60
<b>Average value for the following 10 questions (8 requirements):</b>		<b>52.0</b>

**Table 5.2.12-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple estimate useful for comparison between the participating countries**

### Active substances:

The 5 examined products contained at least 1 active substance, 4 products contained 1 active substance, 1 product contained 2 active substances. In total, 6 active substances were filled in.

- 1 product contained an active substance listed in ANNEX II for the relevant PT18
- 3 products in PT18 included non-inclusion active substances, 2 products with Chlorpyrifos – CAS no. 2921-86-2 phase out / banned since 22.08.2008 (KOM 2007/565/EG) and 1 with Esbiothrin - CAS no 584-79-2 phase out / banned since 22.08.2008 (KOM 2007/565/EG).
- 2 products contained active substances which were only listed in ANNEX I: naphthalene is only included in ANNEX I (also listed in ANNEX II but for PT19 and not for PT18) and 2,6-di-tert-butyl-p-creso (CAS nr. 128-37-0) and accordingly banned since 09-2006.

### Enforcement

Removed from market	5
---------------------	---

**Table 5.2.12-1: Results of enforcement of biocidal products in Romania.**

No further information about measures and enforcement was received, but according to the filled in result, all 5 products were removed from the market.

Violations were detected in all examined products (100 %) and the examined products were not in compliance with the BPD legislation in the Romanian approach.

### 5.2.13 Slovenia

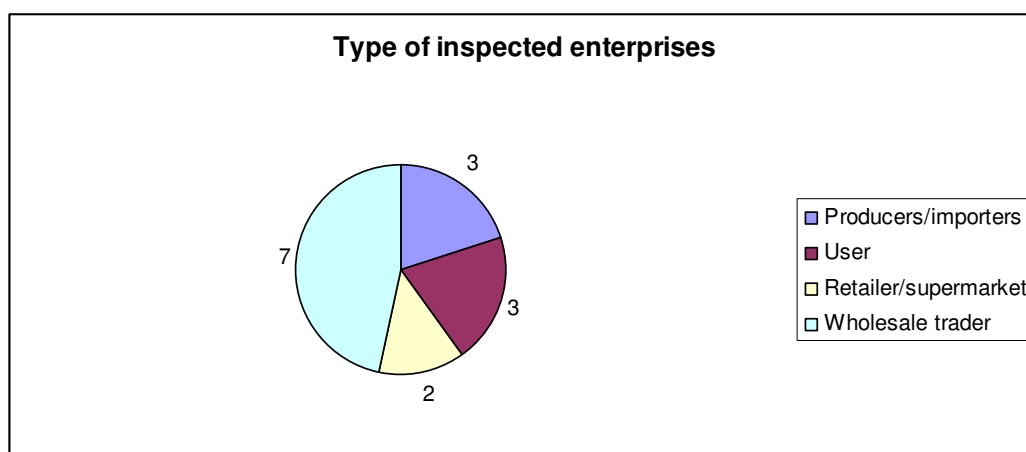
Slovenia handed in **45 products**.

Biocidal products were examined in 8 product types, a majority represented with 14 products in PT18, 8 in PT2 and 7 in PT8.

Product type	Figures
PT1	1
PT2	6
PT4	7
PT7	2
PT8	7
PT14	4
PT18	15
PT19	3

**Table 5.2.13-1: Number of biocidal products in relation to product types inspected in Slovenia**

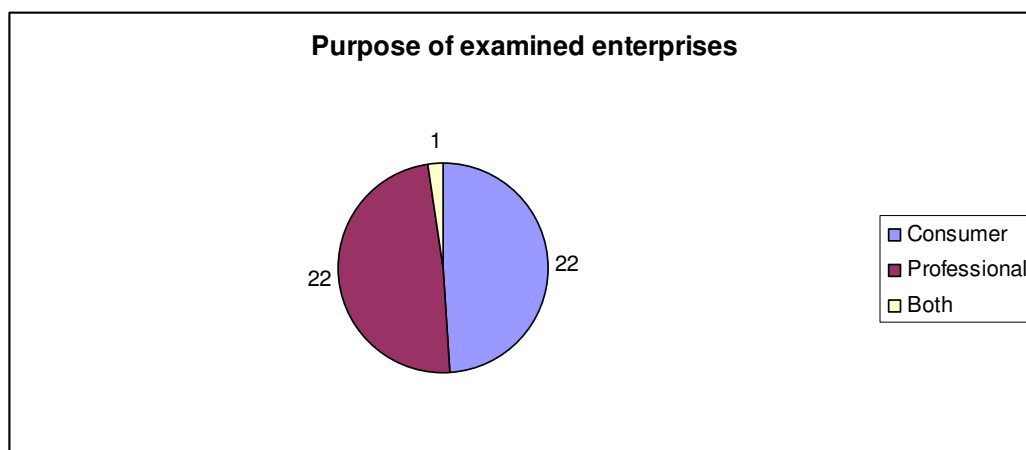
The division into types of enterprises and purpose of the products was as shown in the figures below:



**Figure 5.2.13-1: Overview of types of enterprises inspected in Slovenian project.**

15 enterprises were inspected. 7 of the inspections took place at wholesale traders (46.7 %). 3 at producers/importers (20%), 3 at users (20%) and 2 at retailers/supermarkets (13.3 %).

22 products were intended for consumers (48.9 %), 22 products were intended for professionals (48.9 %) and 1 product was intended for both as shown in figure 5.2.13-2.



**Figure 5.2.13-2: Overview of the purpose of examined products in the Slovenian project.**

All inspected product types have mandatory national authorisation and are subject to a fee.

### Labelling and packaging

1. Nothing remarkable was found; packaging and labelling were clear and inedible, name, address and trade name were all sufficient
2. No misleading phrases
3. 8 products were not dangerous
4. Trade name on 1 product was missing
5. Chemical names on 1 product were missing
6. All products were preparations

### SDS and chemical composition

- All SDSs were available and examined
- All 45 active substances were examined

### Classification

- 2 very toxic T+ substances were found in PT14 (deltametrin (EINECS 258-256-6)) and (Magnezijev fosfid (EINECS 235-02-7)) Both products were collected from users and were intended for professionals
- 12 of the examined products were classified with Xn, the majority 6 out of 14 examined (42.9 %) in PT18 and 2 in both PT14 and PT8 and 1 in both PT4 and PT2.
- 9 products were classified as corrosive, the majority 6 out of 7 (85.7 %) examined in PT4, 1 in PT2 and 1 in both PT1 and PT7.
- 8 products were classified as irritant, the majority 3 (37.5 %) out of 8 examined in PT2

- 3 products classified as very flammable were found: 2 in PT18 and 1 in PT19.
- 1 product classified as flammable was found in PT18
- 1 product classified as oxidative was found in both PT2 and PT4
- 13 products were classified with environmental danger, the majority 7 out of 14 (50 %) in PT18 followed by 4 out of 7 (57.1 %) in PT8 and 2 in PT2.
- 9 products were blanks (not dangerous products)

Slovenia PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	Not applicable
1	1				1						
2	6			1	1	3			1	2	1
4	7			1	6				1		
7	2				1	1					
8	7			2						4	3
15	4	1		2						1	1
18	15	1		6		3	2	1		7	2
19	3					1	1				1
#	45	2		12	9	8	3	1	2	14	8

**Table 5.2.13-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized.**

#### Indication of danger (classification)

- Mistakes with indication of danger (other than dangerous for the environment) were found in 1 product in PT18 (out of 45 examined products, 2.2 %)
- No mistakes with indication of safety-phrases and environmental danger were found.

#### Biocidal investigation

##### Borderlines:

- 5 borderlines out of the 45 products examined (11.1 %) were detected; 2 in PT2, 2 in PT18 and 1 in PT19
- products had a borderline to detergents; 2 in PT2 and 1 in PT19 – the examined products are in the scope of the BPD (horizontal legislation)
- 1 product in PT18 was a borderline to a plant protection agent
- 1 product in PT19 was a borderline to a cosmetic product

### Specific BPD-rules for labelling:

National authorisation was in force for 44 out of 45 examined products 1 product did not have authorisation. Products with and without legally binding procedure were shown in table 5.2.13-3. Most products not in compliance were found in question h) about “direction for safe disposal...”, indicating that around 18.2 % (grey in table 5.2.13-3) of the products with legally binding provision were not in compliance with at least 1 of the 8 specific BPD-requirements.

Checked BPD- requirements	Estimates of Figures for 44 products with authorisation	Percent (%), Not Ok	Figures for 1 product without authorisation	Percent (%) Not OK
	Legal provision		No legal provision	
First part a) Identity of every active substance	1	2.3	0	0
Last part a) Concentration in metric units	0	0	1	100
c) Indication of the type of preparation	1	2.3	0	0
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	3	6.8	0	0
g) If accompanied by a leaflet: Sentence „read instructions before use“	2	4.5	0	0
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	8	18.2	0	0
First part i) Formulation batch number or designation	4	9.1	0	0
Last part i) Expiry date relevant to normal conditions of storage	0	0	0	0
j) Period of time needed for the biocidal effect, if relevant	4	9.1	0	0
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	3	6.8	0	0
<b>Average for the following 10 questions (8 requirements):</b>		<b>5.9</b>		<b>10</b>

**Table 5.2.13-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple mathematical estimate useful for comparison between participating countries and products with and without legally binding provision.**

### **Active substances:**

Of the 45 examined products (72 examined active substances), 29 products contained only 1 active substance, 7 products contained 2 active substances, 6 products (3 in PT18) contained 3 active substances and 3 products contained 4 active substances (in PT18).

- 6 active substances out of 73 examined (8.2 %) - 4 products out of 45 (8.9 %) – included active substances which were not notified to the specific product type in ANNEX II (notified in ANNEX I). (1 product in PT14, 2 in PT18 and 1 in PT19).
- Not found active substances were mentioned for 5 active substances in 4 products (1 product in PT14, 2 in PT18 of which 1 product contained 2 “not found” substances).

### **Enforcement**

No detailed information about enforcement was given in the result form, but violation was reported for 2 products, 1 for which chemical names on the product were missing and 1 product for which trade name was missing on the label, 1 product in PT18 had mistakes with indication of danger, between 8 or 9 products had problems according to the specific BPD labelling requirements and 4 products were banned because they contained active substances which were not notified to the specific product type in ANNEX II.

Violations were enforced in approximately 14 (31.1 %) of all examined products and those products were not in compliance with the BPD legislation in the Slovenian approach.

#### **5.2.14 Spain**

In Spain 14 Autonomous Communities (Andalucía, Aragón, Islas Baleares, Islas Canarias, Castilla - León, Castilla – La Mancha, Cataluña, Extremadura, Galicia, Madrid, Murcia, País Vasco, La Rioja and Valencia) participated in the project, which was coordinated by the Ministry of Health and Social Policy (**MSPS**).

Before the BPD entered into force, a central national registration was a legal requirement for most of the biocidal product types: PT2, PT4, PT8, PT11, PT14, PT18 and PT19 were registered by the MSPS. Most of the biocidal PT1 was registered by the pharmaceutical body of the MSPS (nowadays “Agencia Española de Medicamentos y Productos Sanitarios”. The MARM (“Ministerio de Medio Ambiente y Medio Rural y Marino”, before “Ministerio de Agricultura, Pesca y Alimentación”) was responsible for PT3. These registrations were subject to a fee.

In order to perform the EuroBiocides Project in Spain, the following was agreed:

- 1) The first priority for inspections was to focus on biocidal PT2, PT4, PT8, PT11, PT14, PT18 and PT19, excluding within PT2, products for swimming pools.
- 2) PT6 and PT7 were also a priority, being the next product types to require national authorisation.
- 3) The most interesting biocidal products to inspect would be the borderline products interacting with other legislative chemical sectors.
- 4) Some variations were made to the project questionnaire (enterprises/ products), for example the size of enterprises inspected (Commission Recommendation of 6 May 2003. OJ L124, 20.5.2003, p. 36).
- 5) Training of the inspectors on biocidal products and legislation was required.
- 6) To organise the necessary coordination meetings as well as information exchange among regional/national coordinators to face the EuroBiocides project.

In Spain **369 biocidal products** were inspected in 131 enterprises and 253 public health inspectors (including coordinators) were involved. Biocidal product types 1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 14, 18, 19 and 21 were examined.

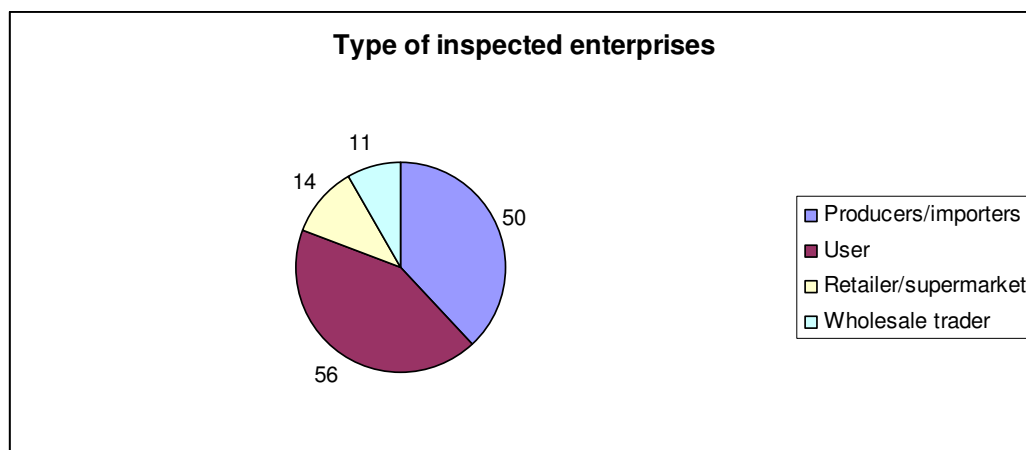
Out of 369 products, 321 (87 %) biocidal products had national authorisation; 45 (12 %) had no national authorisation and 3 (1%) were without data.

Of the 14 product types examined, a majority was represented with 122 (33 %) insecticides in PT18, 68 (18 %) rodenticides in PT14 and 56 (15 %) human disinfectants in PT2.

Product type	Figures
PT1	2
PT2	56
PT3	1
PT4	41
PT5	2
PT6	14
PT7	18
PT8	30
PT11	9
PT12	2
PT14	68
PT18	122
PT19	3
PT21	1

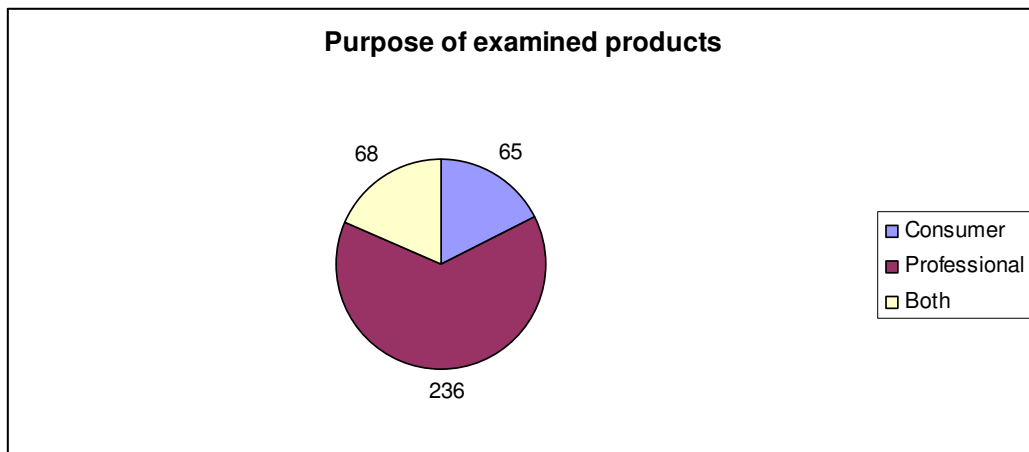
**Table 5.2.14-1: Number of biocidal products in relation to product types inspected.**

The division into types of enterprise and purpose of the products can be seen in the Figures below:



**Figure 5.2.14-1: Overview of type of enterprises inspected in the Spanish project.**

131 enterprises were inspected. 56 (42.7 %) enterprises were users, 50 (38.2 %) were producers/importers, 14 (10.7%) were retailers/supermarkets and 11 (8.4 %) were wholesale traders.



**Figure 5.2.14-2: Overview of examined products in the Spanish project.**

The majority of the examined products in the Spanish project, 236 products (64 %) out of 369, were intended for professionals, 65 (18.4.%) for consumers and 68 (19.2 %) of the examined products were intended for both.

### **Classification and labelling**

1. 8 products were not in compliance with the legislation, among these 1 product was without label, 1 product was a 20 litres packaging of high density polyethylene wrapping used on disinfectant intended to drinking water treatment.
2. Labelling was unclear and not indelible on 19 products; “text difficult to read”, “letter size”, “letters written vertical” and “easy to damage” were mentioned as mistakes.
3. 22 products had misleading sentences or gave an exaggerated impression, among those were: Misleading with bactericides, germicides, etc. advertised in such a manner that the product could be mistaken for a food or a veterinary product  
Unclear brand or name. It was unclear if the trade name was “Espectro total” or “germosan NOR”
4. 13 products indicated low risk biocidal product, non-toxic, harmless or similar:  
Misleading: “It kills and destroys quickly”, “high persistency”, “highly efficient”, “especially for pigsties and stables”, “natural solution”, “very powerful”, “super effective”, “does not cause damage to animals or persons”, “environmentally friendly”, “without re-entry period”, “with very low toxicity”, “suitable for domestic use”.
- 5 1 label was not in Spanish but in English only
- 6 All products had trade names, other than products for which it was not applicable
- 7 Substance names were not present on 3 products
- 8 42 products were incomplete with regards to company name, address and telephone number
9. 36 products were according to the label not dangerous

10. Chemical name(s) were not applicable on 31 products (not dangerous products)

### **SDS and chemical composition**

- 92 SDSs were available only on request.
- 1 product was not examined according to classification and labelling.
- All active substances were examined

### **Classification**

- Approximately 330 products were examined; 36 products were not applicable (not dangerous) and 39 were empty, among those 9 in PT2 and 23 in PT18 and between 1 and 2 products in the remaining product types were not examined.
- 1 product in PT12 (Slimicides) contained a very toxic T+ substance (EC number 228-652-3 Ethylene Dithiocyanate).
- 10 toxic substances were found in 5 different product types: PT6, PT7, PT12, PT14 and PT18.
- 159 (48.2%) examined products were classified with Xn, mainly in PT8, PT14 and PT18. 94.1 % of the products examined in PT14; 56. % of the examined products in PT8 and 39.3 % in PT18 were classified with Xn.
- 35 (10.6 %) of the examined products were classified as corrosive, the highest numbers were found in PT2 (19.6 %) and PT4 (22 %).
- 35 products were classified as irritant, mainly in PT2 (25 %) and PT4 (22.5 %)
- 35 products, mainly in PT18, (20.5 %) were classified very flammable.
- Another 17 products (9.1%), were classified as flammable, mainly in PT18 (7,4 %) and in PT3 (10 %).
- 7 products were classified as oxidative, 6 (14.6 %) in PT4 and 1 in PT18 (0.8 %),
- 96 products were classified with environmental danger; out of these 56.6 % of PT18 products, 33.3 % of PT8 and 16.1 % of PT2 had the environmental danger symbol

Spain PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	Blank/ not applicable
1	1					1					1
2	47			9	11	14	3	3		9	9/3
3	1						1				
4	40			6	14	9	2	1	6	1	1/3
5	2				1	1					
6	14		3	5	2	2		1		3	/3
7	18		2	5	3					2	/2
8	28			17	2		4	3		10	2/5
11	8			4	2	2					1
12	2	1	1								
14	66		1	64							2/9
18	99		3	48	3	6	25	9	1	69	23/7
19	3										/1
21	1			1							/1
<b>Sum #</b>	<b>330</b>	<b>1</b>	<b>10</b>	<b>159</b>	<b>38</b>	<b>35</b>	<b>35</b>	<b>17</b>	<b>7</b>	<b>94</b>	<b>39/36</b>
<b>Percent %</b>			3	48.2	11.5	10.6	10.6	5.2	2.1	28.5	

**Table 5.2.14-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the number of indication of danger are given. Because some products were not dangerous and because some products contained more than one symbol there are differences when the results are summarised.**

#### **Indication of danger (classification)**

- Indication of danger was not OK on 98 (29.7 %) products out of 330 examined
- Indication of safety was incorrect on 92 (27.9 %) products out of 330 examined
- Indication of environmental danger was not OK on 27 (8.2 %) products out of 330 examined

In-compliances regarding classification and labelling with danger and safety were particularly found in for example PT2, PT7 and PT8 as shown in the table below:

Spain PT	Examined Products (except blank)	Indication of Danger (Not OK)	Indication of Safety (Not OK)	Environmental Indication of danger, N (Not OK)
1	1			
2	47	24	16	3
3	1		1	
4	40	6	12	2
5	2	1	2	
6	14	7	4	2
7	18	12	11	6
8	28	12	4	1
11	8	2	1	1
12	2	1	1	1
14	66	4	6	1
18	99	25	31	8
19	3	3	2	2
21	1	1	1	
%	330	98 (29.7%)	92 (27.9%)	27 (8.2%)

**Table 5.2.14-3: Examined products with mistakes in labelling for indication of danger including, risk phrases (R-sentences), safety phrases (S-sentences) and environmental danger.**

## Biocidal investigation

### Borderlines:

- 33 (8.9 %) borderline cases out of 369 examined products were found in Spain.
- A majority of 14 products with a borderline to detergents was found in PT2.
- 2 products in PT1 and 4 in PT4 were also borderlines to detergents.
- 3 substances in PT6 had a borderline to cosmetics.
- 2 products with a borderline to “others” were found in both PT2 and PT4, and 1 in PT5 and PT11.
- 1 product with a borderline to plant protection products were found in both PT2, PT8 and PT18.
- 1 borderline to medical devices was found in PT19 (Mosquito repellent).

### Specific BPD-rules for labelling:

National authorisation was in force for 321 out of 365 examined products and 45 products did not have authorisation (3 were blank). 13 of the 45 products without national authorisation

were examined., Products with and without legally binding procedure are shown in table 5.2.14.-4. Most products not in compliance were found in question h) about “directions for safe disposal.....”, and last part i) “expiry date relevant to normal conditions of storage” indicating that around 53 % respectively 43.6 % (grey in table 5.2.14-4) of the products with legal binding provision were not in compliance with at least 1 of the 8 specific BPD-requirements..

<b>Examined BPD-requirements:</b>	<b>Figures for 321 products with national authorisation</b>	<b>Percent (%)  Not OK</b>	<b>Figures for 13 examined products without national authorisation</b>	<b>Percent (%)  Not OK</b>
	<b>Legal provision</b>		<b>No legal provision provided</b>	
First part a) Identity of every active substance	10	3.1	5	38.5
Last part a) Concentration in metric units	6	1.9	2	15.4
c) Indication of the type of preparation	64	19.9	2	15.4
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	33	10.3	4	30.8
g) If accompanied by a leaflet: Sentence „read instructions before use“	14	4.4	0	0
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	170	53.0	8	61.5
First part i) Formulation batch number or designation	33	10.3	5	38.5
Last part i) Expiry date relevant to normal conditions of storage	140	43.6	8	61.5
j) Period of time needed for the biocidal effect, if relevant	60	18.7	8	61.5
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	89	27.7	5	38.5
<b>Average value for the following 10 questions (8 requirements):</b>		<b>19.3</b>		<b>36.2</b>

**Table 5.2.14-4: 8 Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always necessary on the label of a biocidal product with a national authorisation). The average calculation is a simple mathematical estimate useful for comparison between participating countries and products with and without legally binding provision.**

### Active substances:

Among all 369 examined products, the findings were: 220 products with 1 active substance; 95 products with 2 active substances; 42 products with 3 active substances, 12 products with 4 active substances and 11 products not containing any identified active substance. In total, 595 ( $220 + 11 + 97 \times 2 + 43 \times 3 + 12 \times 4 = 595$ ) active substances were examined in Spain.

- All examined active substances in PT5 and PT12 were notified in ANNEX II (legal in products)
- 34 (9.2%) products contained active substances in ANNEX I, but not notified to specific product type in ANNEX II (illegal in products), highest number 9 in PT 14, 6 in PT2 and PT4, 5 in PT7, 4 in PT18, 2 in PT19 and 1 in PT6 and PT21. In total 39 active substances were found, because 4 examined products in PT2, PT4, PT7 and PT19 contained more than 1 active substance.
- Non-inclusion substances were found in product types 1, 2, 4, 6, 8, 18 and 19, a total number of 13 products in the check for 1<sup>st</sup> listed active substance. Check for 2<sup>nd</sup> listed active substance showed 3 non inclusion active substances (PT18 and PT19). 3<sup>rd</sup> listed active substance check showed 1 non inclusion substance (PT4), in total 17 active substances, 1 in each product.
- Not found and not checked was mentioned for 2 respective 3 products in 1st checked active substance.

### Enforcement

None	139
No answer/blank	56
Information to focal point	60
Further inspection necessary	36
Advice to enterprise	78

**Table 5.2.14-5: Results of enforcement of biocidal products in Spain.**

Violation was found in ( $60+36+78 = 174$ ); 47.2 % of the examined products (369) and those products were not in compliance with the BPD legislation in the Spanish approach.

The phrase “information to focal point” was used when information from the inspections lead to the following possibilities:

- (a) The active substance examined is illegal on the market (34 of 369 products inspected).
- (b) Further information was sent to inspectors

(c) Wrong classification and labelling was found.

The idea was to keep the National Focal Point informed. In Spain the National Focal Point is the Competent Authority for the Human Health sector of REACH (Ministerio de Sanidad y Política Social, MSPS). If necessary, the information will be distributed within the National Rapid Alert System for Chemicals (encrypted network: SIRIPQ/EUVICHEM). The MSPS coordinates the system which involves the Human Health Authorities of the Autonomous Communities (17 regions and two cities).

### **Overview of the project**

The results from the inspections in Spain were related to four main aspects: the inspected products, the companies' knowledge of the biocides legislation, the classification and labelling and the SDSs of the biocidal products.

- Related to inspected products:

Biocidal main function and a biocidal secondary function are concepts which are very difficult to apply, e.g.: in insecticides paints, in fungicide sealants. In these cases being a paint or a sealant may not be the main function, but the way in which the biocide is applied.

Differentiation between active substances (especially when there is more than one) and other components in the formulation has not been a straight forward issue. In most cases, inspectors have to rely on the information provided by the formulators.

Commercialised active substances specify a generic use in Heading 1 of the SDS, e.g. biocide, germicide, etc., but are often used for different types of biocidal products like PT6, PT7 or PT2, by those enterprises formulating chemical products, which are not aware of the biocides legislation because they are not provided with enough information.

Enforcing PT6 or PT7 active substances has the added problem of being basically inspected in non-biocidal mixtures, by chemical formulators who are not aware of the BPD.

- Related to the companies knowledge of the biocides legislation:

In general, inspected companies were not aware of the BPD and related legislation.

In the case of enterprises formulating chemical products, there was also unawareness of the legal implications of advertising their mixtures as mixtures with biocidal properties (antibacterial, disinfectants, etc.).

It has been found that especially advertising on the Web has not been done in accordance to the BPD.

- Related to classification and labelling of inspected products:

In some regions, a significant number of deficiencies concerning labelling of dangerous biocidal products have been found in regard to the hazards information.

Label requirements of the BPD have been found to be missing in many of the products inspected. The requirements in question concerned the next access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas.

- Related to the SDSs of the biocidal products

In general, deficiencies were found in Heading 3 (former 2) of the SDSs; related to id numbers of components and to classification.

Deficiencies in the management of the SDSs (non-compliance with Title IV of REACH) were found. No documented systems for providing SDSs, receiving SDSs or keeping them up-to-date.

In many cases, distributors of the biocidal products were not handing out SDSs to their customers.

### 5.2.15 Switzerland

Switzerland handed in **22 products**.

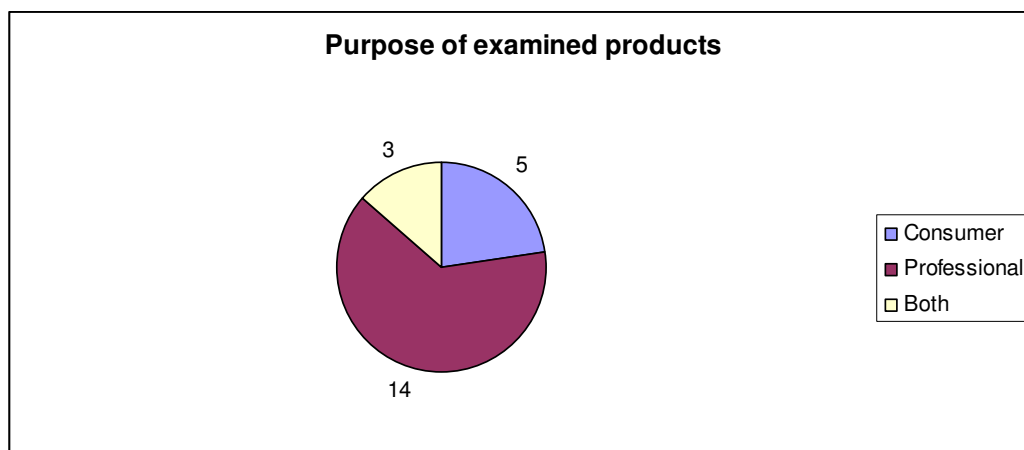
Biocidal products were examined in 8 different product types; the majority was 8 products in PT2 and 4 products in PT6

Product type	Figures
PT1	2
PT2	8
PT3	1
PT4	2
PT6	4
PT7	1
PT8	2
PT18	2

**Table 5.2.15-1: Number of biocidal products in relation to product types inspected in Switzerland**

15 enterprises were inspected. All were in the category importers/producers

Purpose of the products was as shown in the figures below:



**Figure 5.2.15-1: Overview of the purpose of examined products in the Swiss project.**

14 (63.6 %) of the collected products were intended for professionals, 5 (22.7 %) products were intended for consumers and 3 (13.6 %) were intended for both

Switzerland has a central and mandatory registration for all biocidal products according to the BPD.

All 300 products registered in the National Product Register were examined, but only products which had harmonised European labelling were handed in to the project

### **Labelling and packaging**

1. Packaging was not examined on 2 products out of the 22 products filled in.
2. 4 products had unclear and not indelible labels; the comments listed “too small letters”.
3. None of the examined products had misleading or exaggerated phrases, but 1 had low biocidal sentences saying “natural active substances”.
4. National language was not OK for 1 product (language not mentioned).
5. Trade name was present on all products.
6. All examined products were preparations, no single active substances.
7. 2 products were not dangerous.
8. Chemical names were on all 22 examined products

### **SDS and chemical composition**

- All SDSs were available and all were examined
- For 7 products several mistakes were found in the SDSs

### **Classification**

- 1 product in PT2 and 1 in PT8 were classified as toxic T
- 6 of the examined products were classified with Xn, 3 in PT2, 2 in PT6 and 1 in PT8
- 3 products classified as corrosive were found: 1 in PT2 and 2 in PT4
- 4 products were classified as irritant: 2 in PT1, 1 in PT3 and 1 in PT6
- 1 product in PT2 and 1 in PT18 were classified as very flammable
- 8 products, 1 in both PT1, PT7, PT8 and PT18 and 2 in both PT2 and PT6 were classified with N.
- 1 product in PT2 and 1 in PT8 were not applicable (not dangerous) to be examined.

Switzerland PT	Examined products	T+	T	Xn	C	Xi	F+	F	O	N	Not applicable (Not dangerous)
1	2					2				1	
2	8		1	3	1		1			2	1
3	1					1					
4	2				2						
6	4			2		1				2	
7	1		1							1	
8	2			1		1				1	1
18	2						1			1	
#	22		2	6	3	4	2			8	2

**Table 5.2.15-2: Danger labelling of the examined biocidal products. The total number of examined biocidal products and the indication of danger are given. Because some products were not dangerous or because some products contained more than one symbol, there are differences when the results are summarized.**

#### **Indication of danger (classification)**

- Mistakes with indication of danger (other than dangerous for the environment) were found in 3 out of 22 examined products, 13.6 %.
- R-sentences were uncertain in another 2 products in PT6
- Mistakes with indication of safety-phrases were found in 4 out of 22 products (18.2 %), 1 in PT2, PT6, PT7 and PT8.
- Mistakes with indication of environmental danger were found on 2 products, 1 in PT1 and 1 in PT2. 1 product had no data and the comment was uncertain, besides that, 1 product in PT6 was missing R53 and another was classified with N; R50/53 instead of R51/53

#### **Biocidal investigation**

##### **Borderlines:**

- Borderlines were not found among the examined products because the basis for the inspection was the Swiss Product Register with authorised biocidal products.

### Specific BPD-rules for labelling:

National authorisation was in force for all 22 products and shown in table 5.2.15-3. Most of the products not in compliance were found in question j) about “period of time needed for biocidal effects” and l) about any “specific danger to the environment” with authorisation, indicating that around 45.5 % (grey in table 5.2.15-3) of the products with legal binding provision were not in compliance with at least 1 of the 8 specific BPD-rules.

<b>Examined BPD- requirements</b>	<b>Figures for products with authorisation,</b>	<b>Percent (%) Not OK</b>
	<b>Legal provision</b>	
First part a) Identity of every active substance	1	4.5
Last part a) Concentration in metric units	0	0.0
c) Indication of the type of preparation	3	13.6
f) Particulars of likely direct or indirect adverse side effects and any directions for first aid	9	40.9
g) If accompanied by a leaflet: Sentence „read instructions before use“	6	27.3
h) Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging	1	4.5
First part i) Formulation batch number or designation	1	4.5
Last part i) Expiry date relevant to normal conditions of storage	8	36.4
j) Period of time needed for the biocidal effect, if relevant	10	45.5
l) Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water	10	45.5
<b>Average value for the following 10 questions (8 requirements):</b>		<b>22.3</b>

**Table 5.2.15-3: Specific BPD-rules for biocidal products, set out in Article 20(3), point (a) to (l) (always an obligation on the label of a biocidal product with a national authorisation). The average calculation is a simple estimate useful for comparison between participating countries and products with and without legally binding provision.**

**Active substances:**

22 products were examined and contained at least 1 active substance, 11 products contained 1 active substance, 10 contained 2 active substances (most in PT4), and 1 product in PT3 contained 3 active substances. In total, 34 active substances were examined.

- All examined active substances were notified in the specific product type in ANNEX II

**Enforcement**

Violation detected was filled in for 5 products. Advice about classification and labelling was given to the enterprises and all products were legalised.

In Switzerland all biocidal products must be authorised according to the biocidal regulation 98/8/EC. Therefore, theoretically, all products should be correct. To our astonishment we observed that several producers were not capable (or not willing) to transfer the classification and labelling correctly from the authorisation onto their products. This is one of the reasons why we continued with the EuroBiocides project in Switzerland. In the first part of this project, we inspected authorised products for correct labelling and we also did analytical tests to verify the indicated composition for the authorisation. In the second part, we specifically looked for hidden biocidal products such as cleaning products containing quats (quaternary ammonium cation) which have a biocidal claim.

Violations were found in 5 (22.7 %) of all examined products and those products were not in compliance with the BPD legislation in the Swiss approach

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## **6 Conclusions**

### **HARMONISED ENFORCEMENT**

The EuroBiocides project has through the exchange of enforcement experience between the 15 participating countries and examination of 1346 products, successfully ensured that enforcement of the BPD-regulation was carried out harmonised, and was uniformly reported for each country:

The EuroBiocides manual (finished April 2008) included training of inspectors and set ups for the national biocide projects or approaches. The manual has been a useful tool to ensure that the enforcement was harmonised in the participating countries; however, future common projects will be more focused with regards to workload, tools and enforcement issues and will be limited to specific product types.

The 15 national approaches for enforcement of the BPD were designed according to the working method in the EuroBiocides Manual, which recommended the selection criteria: “many borderlines”, “high volume” and “high risk”.

Analysing the specific product types was not an issue from the beginning, but as 6 product types PT2: Disinfectants (272), PT4: Food and feed area disinfectants (91), PT8: Preservations of wood (122), PT14: Rodenticides (127), PT18: Insecticides (382) and PT19: Repellents (138) represented 84.2 % of all examined products and were examined in between 7 and 13 countries, the results were assigned and mapped according to those so-called well documented product types.

### **REDUCING RISK TO HUMANS FROM USING BIOCIDAL PRODUCTS**

The biocidal products were examined according to the rules set up in the BPD regulation, including among others classification, labelling and packaging, the specific BPD labelling rules and legality of active substances in the EuroBiocides project.

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

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,

intensity regarding repetition of BPD enforcement, purpose of products and enterprises inspected.

In 6 countries: Romania, Norway, Denmark, Belgium, Austria and Finland the number of products not in compliance was between 10 and 50 % higher than the calculated average value. 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 came 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.

14 % of the examined products were either prohibited or removed from the market when the inspection phase finished in January 2009, and risk to human health and the environment from using biocidal products was in this cases reduced.

The large number of illegal products indicates, on the one hand that further enforcement of the BPD-regulation in the intermediate stage is necessary, not only in relation to BPD rules but also in relation to classification and labelling. On the other hand, enforcement is not responsible for the result but is an important measure to improve the companies knowledge of the legislation with the aim to reduce the large number of products not in compliance with the BPD legislation.

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 change of chemical contents in the products.

Furthermore, close cooperation and dialogue between the enterprises dealing with biocidal products and the enforcement authorities is essential in order to reduce the number of illegal products placed on the market.

The most significant results and observations of the EuroBiocides project were elaborated into recommendations to the Commission, the Competent Authorities and the enterprises.

## 7 Recommendations

According to the results and the assessment of products which were not in compliance with the regulation, the following recommendations to inspectors, enterprises, competent authorities and the Commission were elaborated:

### Inspectors

#### Examination of products:

- Be advised and take account of the results mapped in the projects, e.g. use the experiences of other countries with specific product types, borderlines, illegal substances, classification and labelling etc.
- Concentrate further projects on borderline issues and claims, because especially retailers are not aware that their products are included into the BPD.
- In general, products intended for consumers must have high priority, e.g. disinfectants, repellents and insecticides, but also other products either sold from retailers and/or intended for consumers. Enforcement on those products may for instance focus on classification and labelling, misleading sentences, risk communication and completion of address.
- Carry out enforcement for registration of biocidal products, which will support both borderline issues, further enforcement of active substances and, in the future, authorisation of all biocidal products.
- Pay more attention to product types inspected in many countries, but few (under 50 products) reported to the EuroBiocides project, e.g. PT1 (Human hygiene biocidal products), PT3 (Veterinary hygiene biocidal products), PT6 (In-can preservatives) and PT7 (Film preservatives) on a common and national level.
- Pay more attention to product types for which only few products have been examined, e.g. PT12 (slimicides) and PT13 (Metalworking-fluid preservatives) or be aware of specific industries or businesses on a national level, e.g. PT11 (anti-cooling systems offshore).
- Focus more on SDS quality and availability of SDSs; also focus on SDSs for not dangerous products, which should be available on request.

#### Examination of active substances:

- Prepare further inspections in the intermediate period towards legality of the active substances on the market included in the review programme, following the submission deadlines for the product types and non-inclusion decisions.

- Make a follow up on product types for which the EuroBiocides project has detected many findings with active substances not notified in the specific product type.

### **Enterprises**

- Generally be aware of the responsibility for reducing the amount of biocidal products not in compliance, of which many problems with classification and labelling, packaging, advertisements and legality of active substances were found in this project.
- Be aware of whether the chemical products are included in the BPD or not (borderlines).
- Be aware of the status of the active substances in biocidal products, Reg.EC N° 1451/2007, both with regards to notification in a specific product type and with regards to non-inclusion decisions.
- Producers and importers shall ensure that information about legality of the active substances is spread to all enterprises (users, wholesale traders and supermarkets) in the supply chain, businesses and organisations.
- Be aware of product types which already need authorisation (EU or national)/active substances with a decision on inclusion of the substance in ANNEX I, IA or IB of the BPD-directive, and the specific BPD classification and labelling rules for products with authorisation.
- Be aware of the specific rules for advertisement of biocidal products and give sufficient information about function of biocidal products to the intended users, and be aware that many biocidal products are intended for consumers who primarily receive information about danger from the leaflet information or labelling on the product.

### **Competent Authority**

- Use the information in the report to raise public awareness of existing problems in each country and highlight the need for public information and the general monitoring of biocidal subjects.
- Inform about legislation, borderlines, status on active substances and any other biocidal issues in a context which distinguishes between professionals and consumers. Information may be given by means of newsletters containing information about non-inclusion decisions, directed at both down stream users, professionals, retailers and wholesale traders.
- Support enforcement strategies and produce information which can bring down the number of products not in compliance with the BPD.

## **EU-commission**

Prepare guidelines, frames and reporting requirements for the BPD and new regulation in accordance with the EuroBiocides results, e.g.

- Highlight and update the Manual of Decision document for products in the intermediate stage, add examples of products with more than one or more active substances with biocidal and non biocidal functions.
- Publish statistical information about the progress of the review programme for the main groups' I-IV and each product type.
- Publish guidelines for the specific BPD labelling rules and efficacy tests of biocidal products for both inspectors and enterprises.
- Pay attention and set up working groups to deal with strategies and information about product types intended for consumers, for subjects such as classification and labelling, human exposure from biocidal products, misleading sentences, consumption etc.

Finally, the CLEEN Members encourage the European Commission to be aware of the EuroBiocides results and enforcement projects in general, and suggest among other things that the Commission includes a link to the CLEEN web site on their site.

## 8 APPENDIX

### 8.1 APPENDIX 1: Glossary

*Advice to enterprise* advice on legislation and of infringements

*ANNEX I* Reference to ANNEX I in Reg. EC N° 1451/ 2007.

*ANNEX II* Reference to ANNEX II in Reg. EC N° 1451/ 2007.

*APPENDIX* Reference to Appendices in the EuroBiocides report

*BPD* Biocidal Product Directive (EC)

*CPD* Cosmetic Product Directive

*CLEEN* Chemicals Legislation European Enforcement Network

*Further inspection necessary:*

Products for which not all information has been received, products in process

*“High risk”:* Dangerous products classified as corrosive; dangerous for health, dangerous or very dangerous (higher than irritant)

*“High volume”:* Voluminous (in litres and weight), but not necessary content of substances classified higher than irritant.

*Information to focal point:*

Not defined in total, but mainly used when information about illegal products was given to other than the enterprises inspected (mainly importers/professionals)

*Manual of Decisions:* Manual of Decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products.

*“Many borderlines”:* Biocidal product types in which many borderlines were expected.

*Not dangerous products:* Products with no danger symbols or R and S-phrases

*Product/ substance prohibited:* Sale prohibited

*PPPs* Plant Protection Products

*PT* Product type

*Removed from marked:* Marketability forbidden

*Sanction:* It is part of enforceability and country dependent (not specified)

*SDS* Safety Data Sheet

## 8.2 APPENDIX 2: Scope, Regulation related to Directive 98/8, Exempted

According to Article 1(2) of Directive 98/8/EC the following Directives/Regulations are exempted from the scope of the Biocides Directive:

<b>Product</b>	<b>Directive / Regulation</b>
Proprietary medicinal products	Directive 65/65/EEC, <b>repealed</b> by Directive 2001/83/EC, as last amended by Directive 2004/27/EC
Veterinary medicinal products	Directive 81/851/EEC, <b>now</b> : Directive 2001/82/EC, as last amended by Directive 2004/28/EC
Immunological medicinal products	Directive 90/677/EEC, <b>repealed</b> by Directive 2001/82/EC, as last amended by Directive 2004/28/EC
Homeopathic medicinal products	Directive 92/73/EEC, <b>repealed</b> by Directive 2001/83/EC, as last amended by Directive 2004/27/EC
Homeopathic veterinary medicinal products	Directive 92/74/EEC, <b>repealed</b> by Directive 2001/82/EC, as last amended by Directive 2004/28/EC
Active implantable medical devices	Directive 90/385/EEC
Medical devices	Directive 93/42/EEC
Food additives	Directive 89/107/EEC
Flavourings for use in foodstuffs and to source materials for their production	Directive 88/388/EEC
Food additives other than colours and sweeteners	Directive 95/2/EC
Food contact materials	Directive 89/109/EEC, <b>repealed</b> by Regulation (EC) No 1935/2004
Products used in treatment of raw milk, heat-treated milk and milk based products	Directive 92/46/EEC, <b>repealed</b> by Directive 2004/41/EC, these products now fall within the scope of Regulation (EC) No 853/2004
Products used in treatment of egg products	Directive 89/437/EEC, <b>repealed</b> by Directive 2004/41/EC, these products now fall within the scope of Regulation (EC) No 853/2004
Products used in treatment of fishery products	Directive 91/493/EEC, <b>repealed</b> by Directive 2004/41/EC, these products now fall within the scope of Regulation (EC) No 853/2004
Medicated feeding stuffs	Directive 90/167/EEC
Additives for use in animal nutrition	Directive 70/524/EEC, <b>repealed</b> by Regulation (EC) No 1831/2003

Products used in animal nutrition	Directive 82/471/EEC
Straight feeding stuffs	Directive 77/101/EEC
Cosmetic products	Directive 76/768/EEC
Products used in treatment of products of animal origin	Directive 95/5/EC
Plant protection products	Directive 91/414/EEC

### **8.3 APPENDIX 3: Product type**

#### **ANNEX V to BDP**

Biocidal product types and their description as referred to in Article 2(1) of the Biocide Directive. These product types exclude products when they are covered by the Directives mentioned in Article 1(2) of this Directive for the purposes of these Directives and their subsequent modifications.'

#### **MAIN GROUP 1: Disinfectants and general biocidal products**

These product types exclude cleaning products which are not intended to have a biocidal effect, including washing liquids, powders and similar products.

##### **Product type 1: Human hygiene biocidal products**

Products in this group are biocidal products used for human hygiene purposes.

##### **Product type 2: Private area and public health area disinfectants and other biocidal products.**

Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algacides. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other Substrates (in playgrounds).

##### **Product type 3: Veterinary hygiene biocidal products**

Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

##### **Product type 4: Food and feed area disinfectants.**

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipe work associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.

##### **Product type 5: Drinking water disinfectants**

Products used for the disinfection of drinking water (for both humans and animals).

#### **MAIN GROUP 2: Preservatives**

##### **Product type 6: In-can preservatives**

Products used for the preservation of manufactured products, other than foodstuffs or feeding stuffs, in containers by the control of microbial deterioration to ensure their shelf life.

##### **Product type 7: Film preservatives**

Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

**Product type 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.

This product type includes both preventive and curative products.

**Product type 9:** Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

**Product type 10:** Masonry preservatives

Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

**Product type 11:** Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the preservation of drinking water are not included in this product type.

**Product type 12:** Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

**Product type 13:** Metalworking-fluid preservatives

Products used for the preservation of metalworking fluids by the control of microbial deterioration.

**MAIN GROUP 3: Pest control****Product-type 14:** Rodenticides

Products used for the control of mice, rats or other rodents.

**Product-type 15:** Avicides

Products used for the control of birds.

**Product-type 16:** Molluscicides

Products used for the control of molluscs.

**Product-type 17:** Piscicides

Products used for the control of fish; these products exclude products for the treatment of fish diseases.

**Product-type 18:** Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).

**Product-type 19:** Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

#### **MAIN GROUP 4: Other biocidal products**

##### **Product-type 20: Preservatives for food or feedstocks**

Products used for the preservation of food or feedstocks by the control of harmful organisms.

##### **Product-type 21: Antifouling products**

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

##### **Product-type 22: Embalming and taxidermist fluids**

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

##### **Product-type 23: Control of other vertebrates**

Products used for the control of vermin.

## 8.4 APPENDIX 4: Important deadlines for relevant enforcement according to BPD

Deadline	General Rule for biocidal products	Legal Basis
<b>Advertisement</b> 14 May 2000	Advertising for biocidal products must be in conformity with Article 22 of Directive 98/8/EC.	Article 22 of Directive 98/8/(EC)
<b>Legal provision</b> 15 December 2003  New active substances	Biocidal products containing active substances that are not included in ANNEX I of Regulation (EC) No 1451/2007 cannot be placed on the market anymore. Not included biocidal substances must be treated as a “new substance”, and meet the requirement in Articles 3 and 5.	Article 4(3) of Regulation (EC) No 1451/2007.
<b>Classification and Labelling</b> 30 July 2004	Applicability of the new Preparations Directive. Biocidal products and active substances must be classified, labelled and packed according to the regulations of Directive 1999/45/EC.	Directive 1999/45/EC
<b>Safety Data Sheets</b> 30 July 2004	Safety Data Sheets must be available for biocidal products according to Directive 91/155/EEC, as amended by Directive 2001/58/EC (Safety Data Sheet Directive) <sup>4</sup> (footnote p.6). This means that a Safety Data Sheet must be available, if the biocidal product is a dangerous preparation under Directive 1999/45/EC and in case of professional use. For biocidal products not classified as dangerous a Safety Data Sheet must be available on request. This is mentioned on the package of the product.	Article 21 of Directive 98/8/EC

Deadline	General Rule for biocidal products	Legal Basis
<p><b>Placing biocidal product on the market</b></p> <p>1. September 2006</p>	<p>The following biocidal products may not be placed on the market anymore:</p> <p>a) Biocidal substances, not listed in ANNEX I may be treated as new active substances.</p> <p>b) Biocidal products containing active substances included in ANNEX II of Commission Regulation (EC) No 1451/2007 for product types not listed in the Annex.</p>	<p>Article 3 and 5, Directive 98/8/EC.</p> <p>Article 4 (1) Regulation (EC) No. 1451/2007.</p>
<p><b>Not included in ANNEX I – Phasing out substances (“assessment report”):</b></p> <p>1. September 2006</p>	<p>Existing substances withdrawn from the review programme, not to be included into ANNEX I, IA or IB in the Directive 98/8, concerning</p> <p>Existing active substances for which a decision of non-inclusion into ANNEX I or IA in the Directive 98/8 has been adopted without phasing out period<sup>16</sup>.</p> <p>Substances and product types for which no company or Member State indicated an interest in taking over the role of participant for. (apply from the day following its publication in official Journal of the European Union))<sup>17</sup></p>	<p>Article 9(2), Regulation (EC) No. 1451/2007</p> <p>Article 4(2) Regulation (EC) No 1451/2007.</p> <p>Article 16(2) of Directive 98/8/EC</p>
<p>Until 14 May 2014</p>	<p>End of transitional period. Only authorised products shall be on the market</p>	<p>Article 16 of Directive 98/8/EC</p>

<sup>16</sup> A list of non-including decisions is available at [http://ec.europa.eu/environment/biocides/pdf/list\\_dates\\_product\\_phasing\\_out.pdf](http://ec.europa.eu/environment/biocides/pdf/list_dates_product_phasing_out.pdf) under the menu “Review of existing substances”.

<sup>17</sup> Commission Decision of 14 August 2007 concerning the non-inclusion in Annex I, IA or IB to Directive 98/8/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0565:EN:NOT>

## 8.5 APPENDIX 5: Scope of borderline cases

Borderline cases on:

- Plant protection products
- Medical products
- Cosmetic products
- Commodities (including detergents)

<b>Plant protection products</b>	<p>NB: According to Article 2 No.1 of the Plant protection Product Directive 91/414/EEC, plant protection products are substances that are intended for</p> <ul style="list-style-type: none"> <li>a) protection of plants or plant products from harmful organisms</li> <li>b) protection of plants or plant from animals, plants or micro-organisms which are not harmful organisms</li> <li>c) influencing the life process of plants without serving there nutrition (growth regulators),</li> <li>d) inhibiting the germination of plant products</li> </ul> <p>The exceptions include water, fertilizers according to the meaning of the <i>Fertilizer Art. 2 No 1.2 of 91/414/EEC</i> and plant fortifying agents; substances not falling under a) or c) that are intended to kill off plants or inhibit or prevent the growth of plants are also considered to be plant protection products.</p>
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Due to the statutory provisions the following differences constitute the results for the application of the biocide and plant protection law:

Biocidal Products	Plant Protection Products
Biocidal products are active substances and preparations	Plant protection products are substances
Protection from harmful organisms via biological or chemical routes (no physical effect)	No differentiation with regard to the mode of action (also physical effect)
The effect is directed at the harmful organism, relatively independently of the protected asset (man, animal, environment)	The effect is limited to the protected asset: plants and plant products
All products must be able to be assigned to certain product types in ANNEX V (BPD)	Product types do not exist

When considering the 23 individual product types in ANNEX V to the Directive scope consideration to plant protection are listed for the following product types (in short: PT)

PT	Description of the PT	Example for biocidal products
3	Veterinary hygiene products	Disinfection for cattle transports in which plant products are also transported
4	Food and feed area disinfectants	Disinfectant in food enterprise to improve the general hygiene
7	Film Preservatives	Substances for the protection of cellulose for paper production
8	Wood preservatives	Wood protection from point of entry into the sawmill
14	Rodenticides	Rat control agents in greenhouses to prevent the transmission and spread of diseases that can be transmitted by rats to man
16	Molluscicides	Snail control in pipelines
18	Insecticides, acaricides and products to control other arthropods	Insect control agents in plant stores for reasons of hygiene
19	Repellents and attractants	Insect deterrents (not for the protection of plant and plant products)
20	Preservatives for food or feedstocks	Fumigation agent in stores; fumigation agents in stores for plant and parts of plants are, however, plant protection products

<b>Medical Products</b>	<p>According to Article 1 of the Medical Product Directive 2001/83/EC, medical products are substances and preparations from substances which are intended, through use or in the human or animal body;</p> <ul style="list-style-type: none"> <li>a) to heal, alleviate, prevent and identify disease, ailments, physical damage and complaints of illness,</li> <li>b) to permit the identification of the composition, the state of the function of the body or psychological states</li> <li>c) to replace active substances or body fluids produced by the human or animal body</li> <li>d) to deter, to remove or to render harmless pathogens, parasites or exogenous substances or</li> </ul> <p>to influence the composition, the state of the function of the body or psychological states</p>
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The following table reflects the current status of the discussion at EU level with regard to the delimitation of biocidal products from pharmaceuticals:

<b>Biocidal products are, for example</b>	<b>Pharmaceutical products are, for example</b>
Products for animals against flies, fleas and ticks which have a lethal effect and are not applied to the skin (products for the treatment of cages)	Products against flies, fleas and ticks which have a lethal effect are applied to the skin and are intended to have a medical effect. If the medical claim is not there, the product is a biocidal product.
Repellents: It is of no significance whether these agents are applied to the skin	

In general, products used on man or animals are authorised as pharmaceuticals or veterinary products with precise medical indications.

Scope considerations among human medical/veterinary medicinal products and the biocidal products constitute the results for the following product types:

<b>PT</b>	<b>Description of the PT</b>	<b>Example for biocidal products</b>
1	Human hygiene biocidal products	Disinfectants in the area relating to hairdressing for protective helmets, shoes, for walk-through baths
2	Private area and public health area disinfectants and other biocidal products	Wide-area disinfectants, disinfectants for swimming baths and humidifiers, products for chemical toilets, water beds, for waste removal.
3	Veterinary hygiene biocidal products	Products for use in fish farms, in dog collars to deter parasites, disinfectants for use in foot baths for animal.
4	Food and feed area disinfectants	Products for use in water containers, in sterilizers, in the food industry

<b>Cosmetic Products</b>	<p>According to Article 1(1) of the Cosmetic Directive 76/768/EEC, cosmetic agents are substances or preparations of substances that are intended to be applied to man externally or in his oral cavity to clean, care or influence the appearance or the body odour or to convey odoriferous impressions unless they are mainly intended to alleviate or top diseases, disorders, physical damage or pathological complaints.</p> <p>Both the cosmetic agents and the biocidal products are therefore substances and preparations. Cosmetic agents are applied externally and, in the process, come into contact with the various parts of the human body or with the teeth and the mucous membranes of the oral cavity, indeed doing so for the purpose of improving the appearance or cleaning or protecting the body. The agent does not serve to prevent or stop diseases (→ pharmaceuticals).</p> <p>Preservatives used exclusively in cosmetic products are not biocidal</p>
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	<p>products. The Cosmetics Directive 76/768/EEC names in ANNEX II substances which are not allowed in cosmetics, even though they fulfil restrictions laid down in the ANNEX III. In ANNEX VI preservatives are listed which may be added to cosmetic agents. These preservatives therefore come under the rules for cosmetic agents and are excluded from the scope of the Biocidal Products Act. If the same preservative is used in other areas (e.g. paints, cleaning agents) it is then a biocidal product.</p>
<p><b>Commodities</b></p>	<p>Commodities within examples of materials and articles which could possibly be treated with biocidal substances are:</p> <ol style="list-style-type: none"> <li>1. Articles that are intended to be used during the production, treatment, marketing or consumption of foodstuffs and, in the process, come into contact with the foodstuffs or have an effect on them;</li> <li>2. Packaging, containers or other wrappings which are intended to come into contact with cosmetic products or tobacco products;</li> <li>3. Articles that are intended to come into contact with the mucous membranes of the mouth;</li> <li>4. Articles that are intended for body care;</li> <li>5. Toys and joke articles;</li> <li>6. Articles that are intended to only come into contact with the human body temporarily, such as Articles of clothing, bed linen, masks, wigs, hair-pieces, artificial eyelashes, bracelets, spectacle frames;</li> <li>7. a) Cleaning and care agents b) Impregnation agents and other finishing agents for commodities which are intended for use in the home.</li> </ol>

Overlapping with the Commodities legislation, the Regulation of Detergents (648/2004/EC) as well as the Laundry and Cleaning Products (under Regulation of 648/2004/EC) affect, in particular, the product types 1, 2 and 3 in ANNEX V of the Directive. As a disinfectant cleaner which has a cleaning and a disinfectant effect represent one example, the question rose in connection with these combination cleaners what the main purpose of the product might be. If the product is mainly intended to have a cleaning effect, it is a commodity. If the product mainly has a disinfectant effect – without pursuing therapeutic aims – it is a biocidal product.

Detergents legislation:

The “horizontal” connection between requirement of Article 20(3) of the Biocides Directive and those of Regulation (EC) No 648/2004, Article 3(1) on detergents has otherwise also been answered in the Manual of Decisions, Paragraph 2.1.6 Detergent. The answer stipulates that whenever a detergent containing surfactants is placed on the market where it falls within the scope of both legislations, the surfactant shall be classified and labelled in accordance with the provisions of Directive 67/548/EEC and the Detergents in accordance

with the provision of Directive 1999/45/EC, the additional requirement of Article 20(3) of Directive 98/8/EC and ANNEX VII A of regulation 648/2004 shall also apply for the product.

## 8.6 APPENDIX 6: WORKING METHOD

Step	Activities	Comments/hints
1.	Select biocidal product or product types to be inspected: - Product type:	Selection criteria “high volume”, “high risk” and “borderline cases”
2	<b>Information to involved authorities and trade unions about the project.</b>  <b>Public awareness</b>	Who:  Where: Internet, homepages, other
3	<b>Enterprise selection</b> <ul style="list-style-type: none"> <li>• Selection of enterprises: Minimum 10 enterprises to be inspected and 5 different products/active substances in each product type.</li> </ul>	Information sources: Internet, catalogues etc.
4	<b>Collection of information to be used within the visit and preparation of the visit:</b> <ul style="list-style-type: none"> <li>• Collect information on the enterprise</li> <li>• Check if all information required is available</li> <li>• Financial laboratory or toxicology resources.</li> </ul>	Information sources: Internet, SDSs, internal knowledge, register of products etc.

Step	Activities	Comments/hints
5	<p><b>Preparation of the enterprise visit:</b></p> <p>If notified inspections:</p> <ul style="list-style-type: none"> <li>• Make an arrangement with the enterprise</li> <li>• Contact person</li> <li>• Ask for a list of biocidal products the enterprise is producing/importing/using/selling</li> <li>• Ask for other products that could be biocidal products (borderline cases)</li> <li>• Ask for the composition of biocidal products and SDS</li> <li>• Confirm the arrangement</li> </ul> <p>If not notified inspections:</p> <ul style="list-style-type: none"> <li>• Control the selected enterprises, traders etc, and take the steps above afterwards.</li> </ul>	Notified or non-notified inspections.
6	<p><b>Inspect enterprise</b></p> <ul style="list-style-type: none"> <li>• Check knowledge about biocidal relevant legislation</li> <li>• Check products selected <ul style="list-style-type: none"> <li>- Classification and labelling</li> <li>- Check SDS</li> <li>- Legality on the market</li> <li>- Advertisement</li> <li>- Active substances</li> <li>- Possible borderline cases</li> </ul> </li> </ul>	<p>Note: APPENDIX 8</p> <p>Note: APPENDIX 8</p>
7	<p><b>Further conversation/enforcement with the enterprise</b></p> <ul style="list-style-type: none"> <li>• First inspection results</li> <li>• Evaluation of legal provision enforceable</li> <li>• Further information/analyses necessary</li> <li>• Further information received</li> <li>• Analysis results available</li> </ul>	

Step	Activities	Comments/hints
8	<p><b>Results</b></p> <ul style="list-style-type: none"> <li>• Inspection results <ul style="list-style-type: none"> <li>- Enterprise</li> <li>- Product analysis</li> <li>- Active substances</li>   <li>- Legality on the market</li> <li>- Classification and labelling</li> <li>- SDS</li> <li>- Advertising</li> </ul> </li>   <li>• Violations <ul style="list-style-type: none"> <li>- Are there violations</li> <li>- Sanctions</li> <li>- Advice to the enterprise</li> <li>- Necessary further inspections</li> <li>- Information to focal point</li> </ul> </li> </ul>	<p>Fill in Report form, APPENDIX 8</p> <p>Further information received Analyses results available Borderline cases</p> <p>OK/not OK OK/not OK OK/not OK OK/not OK</p>
9	<p><b>Finish report Excel-form and send it to the management</b></p>	<p>E-mail the report to:</p>

## 8.7 APPENDIX 7: QUESTIONNAIRE ENTERPRISES

European Enforcement Project „EuroBiocides“

### Questionnaire Enterprises

(please fill in 1 questionnaire per enterprise inspected)

#### Section 1 – General information

- 1.1 Member State:  
1.2 Contact person:  
1.3 Address:  
1.4 Telephone number:  
1,5 E-mail address:  
1.6 Date of inspection:

#### Section 2 – Enterprise information and ID: (Country code, Product type; No (3 numbers))

**2.1. Enterprise name:** (please anonymise before handing in the results to the WG)

- 2.2 Contact person:  
2.3 Address:  
2.4 Telephone number:  
2.5 E-mail address:

2.2 Type of enterprise

- Producer / importer  
 Wholesale trader  
 Retailer/ supermarket  
 User (e.g. gastronome, food industry, market garden)

Please indicate user:

2.3 Member of an association of the biocides/chemicals sector or other professional associations

- yes    no    Other, Please indicate other:

2.4 Certificate

- yes, if yes indicate which    no

- ISO 9001    ISO 14001    EMAS    Nordic Swan  
 Other, Please indicate other:

2.5 Knowledge about classification / labelling / Safety Data Sheet is

- available in the enterprise  
 sourced out  
 not available

2.6 Knowledge about the regulations of Directive 98/8/EC

- good  
 incomplete  
 not available

### Section 3 – Other information

Is existing legislation comprehensible and sufficient?

Recommendations:

Other Comments:

## 8.8 APPENDIX 8: QUESTIONNAIRE PRODUCTS

European Enforcement Project EuroBiocides

### Questionnaire products

(please use as a checklist to every inspected product)

#### Section 1 – Information on the biocidal product

##### Enterprise ID:

**Please note: must be identical with ID number in headline in section 2 in the Questionnaire Enterprises**

Type of enterprise

- Producer / importer
- Wholesale trader
- Retailer/ supermarket
- User (e.g. gastronome, food industry, market garden)

Please indicate user:

##### Trade name of the biocidal product:

1.1  active substance \* preparation

1.2. Product type:

- 
- 

Intended use:

1.3. National Authorisation

- Yes
- no

1.4 Subject to a fee

- Yes
- no

Comments:

1.5. Purpose

- Consumer product
- Professional use
- both

**1.6 Borderline cases identified:**

yes     no

If yes, indicate which:

- Plant protection agents
- Medical devices / pharmaceuticals
- Cosmetics
- Detergents
- Other, please describe others:

**\* Section 2 – Results labelling / packaging**































No.		Legal basis/tips
<b>Packaging</b>		
2.1	Product packed in a way where the likelihood to mistake it for food, drink or feeding stuff is minimized? <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> not checked <input type="checkbox"/> uncertain (please indicate reason)  Comments:	Art. 20 (2) DIR 98/8/EC (see picture in manual)  <b>if possible, provide a digital picture</b>

<b>Labelling</b>		
2.2	Labelling clear and indelible? <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> not checked <input type="checkbox"/> uncertain (please indicate reasons) Comments:	Art. 23 (2) DIR 67/548/EEC, Art. 10 No. 2 DIR 1999/45/EEC, Art. 20 (3) DIR 98/8/EC
2.3	Labelling misleading or giving an exaggerated impression of the product? <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> uncertain (please indicate reason) Comments:	Art. 20 (3) DIR 98/8/EC (see picture in manual)  <b>if possible, provide a digital picture</b>

2.4	<p>Labelling indications like "low-risk biocidal product", non-toxic", harmless" or similar indications?</p> <p><input type="checkbox"/> yes</p> <p><input type="checkbox"/> no</p> <p><input type="checkbox"/> not checked</p> <p><input type="checkbox"/> uncertain (please indicate reason)</p> <p>Please document:</p>	<p>Art. 23 (4) DIR 67/548/EEC</p> <p>Art. 10 No. 5 DIR 1999/45/EEC</p> <p>Art. 20 (3) DIR 98/8/EC</p>
2.5	<p>National Language:</p> <p><input type="checkbox"/> ok</p> <p><input type="checkbox"/> not ok</p> <p>Comments:</p>	<p>Art. 20 No. 6 DIR 98/8/EC</p>
2.6	<p>Trade name (applicable in case of preparations only)</p> <p><input type="checkbox"/> present</p> <p><input type="checkbox"/> not present</p> <p><input type="checkbox"/> not applicable</p> <p>Comments:</p>	<p>Art. 10 No. 2.1 DIR 1999/45/EEC</p>
2.7	<p>Substance name (applicable in case of single substance only)</p> <p><input type="checkbox"/> present</p> <p><input type="checkbox"/> not present</p> <p><input type="checkbox"/> not applicable</p> <p>Comments:</p>	<p>Art. 23 (2a) DIR 67/548/EEC</p>
2.8	<p>Company name, complete address, telephone number</p> <p><input type="checkbox"/> ok</p> <p><input type="checkbox"/> not ok, why not ok:</p>	<p>Art. 23 (2 b) DIR 67/548/EEC</p> <p>Art. 10 No. 2.2 DIR 1999/45/EEC</p>

**\*Labelling of biocidal products being dangerous substances or preparations**

2.9	<p>The product is a dangerous substance or preparation</p> <p><input type="checkbox"/> yes</p> <p><input type="checkbox"/> no (go on with question 2.16)</p> <p><input type="checkbox"/> not checked (go on with question 2.16)</p> <p><input type="checkbox"/> uncertain (please indicate reason)</p> <p>Comments:</p>	<p><i>Information on composition of a preparation is needed</i></p>
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2.10	Chemical Name(s) of the components of the preparation <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> uncertain (please indicate reason) Comments:	Art. 10 No. 2.3 DIR 1999/45/EEC																																												
2.11	Danger symbols <input type="checkbox"/> ok <input type="checkbox"/> not ok <input type="checkbox"/> not applicable <input type="checkbox"/> uncertain (please indicate reason)  Comments:	Art. 23 (2 c) DIR 67/548/EEC Art. 10 No. 2.4 DIR 1999/45/EEC																																												
2.12	Indication of danger  <input type="checkbox"/> yes <input type="checkbox"/> no  if yes, please dig:  <table border="0" style="width: 100%; text-align: center;"> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Xn</td> <td>Xi</td> <td>C</td> <td>T</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>gesundheitsschädlich</td> <td>reizend</td> <td>ätzend</td> <td>giftig</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>T+</td> <td>O</td> <td>F</td> <td>F+</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>sehr giftig</td> <td>brandfördernd</td> <td>leichtentzündlich</td> <td>hochentzündlich</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td colspan="2"></td> </tr> <tr> <td>N</td> <td>E</td> <td colspan="2"></td> </tr> <tr> <td></td> <td></td> <td colspan="2"></td> </tr> </table> The indication of danger is: <input type="checkbox"/> ok <input type="checkbox"/> not ok (please indicate reason) <input type="checkbox"/> not applicable <input type="checkbox"/> uncertain (please indicate reason)  Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Xn	Xi	C	T					gesundheitsschädlich	reizend	ätzend	giftig	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	T+	O	F	F+					sehr giftig	brandfördernd	leichtentzündlich	hochentzündlich	<input type="checkbox"/>	<input type="checkbox"/>			N	E							Art. 23 para 2 c) DIR 67/548/EEC Art. 10 No. 2.4 DIR 1999/45/EEC
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N	E																																													
																																														

2.13	Risk phrases (R-Sentences) <input type="checkbox"/> ok <input type="checkbox"/> not ok <input type="checkbox"/> not applicable <input type="checkbox"/> uncertain (please indicate reason) Comments:	Art. 23 (2 d) DIR 67/548/EEC Art. 10 No. 2.5 DIR 1999/45/EEC <u>Notice:</u> <i>If package contains not more than 125 ml exemption acc. to Art. 23 (3) DIR 67/548/EEG or. Art. 10 No. 4 DIR 1999/45/EEC</i>
2.14	Safety phrases (S-Sentences) <input type="checkbox"/> ok <input type="checkbox"/> not ok <input type="checkbox"/> not applicable <input type="checkbox"/> uncertain (please indicate reason) Comments:	Art. 23 Abs. 2 e) DIR 67/548/EEC Art. 10 Ziff. 2.6 DIR 1999/45/EEC <u>Notice:</u> <i>If package contains not more than 125 ml: exemption according to Art. 23 (3) DIR 67/548/EEC or. Art. 10 No. 4 DIR 1999/45/EEC</i>
2.15	Classification as „dangerous for the environment“ <input type="checkbox"/> ok <input type="checkbox"/> not ok <input type="checkbox"/> not applicable <input type="checkbox"/> uncertain (please indicate reason) Comments:	Art. 10, ANNEX III DIR 1999/45/EEC

\*Labelling acc. to Directive 98/8/EC

**If Article 20 (3) is in national force, please answer the next questions.**

2.16	Identity of every active substance <input type="checkbox"/> present <input type="checkbox"/> not present <input type="checkbox"/> not applicable <input type="checkbox"/> uncertain (please indicate reason) Comments:	Art. 20 (3a) DIR 98/8/EC
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2.17	<p>Concentration in metric units</p> <p><input type="checkbox"/> present</p> <p><input type="checkbox"/> indicated in other units (e.g. percentage)</p> <p><input type="checkbox"/> not present</p> <p>Comments:</p>	Art. 20 (3a) DIR 98/8/EC
2.18	<p>Indication of the type of preparation</p> <p><input type="checkbox"/> present</p> <p><input type="checkbox"/> not present</p> <p><input type="checkbox"/> uncertain (please indicate reason)</p> <p>Comments:</p>	Art. 20 (3c) DIR 98/8/EC
2.19	<p>Particulars of likely direct or indirect adverse side effects and any directions for first aid</p> <p><input type="checkbox"/> present</p> <p><input type="checkbox"/> not present</p> <p><input type="checkbox"/> incomplete</p> <p><input type="checkbox"/> not applicable</p> <p><input type="checkbox"/> uncertain (please indicate reason)</p> <p>Comments:</p>	Art. 20 (3f) DIR 98/8/EC
2.20	<p><b>If accompanied by a leaflet:</b></p> <p>Sentence „read instructions before use“</p> <p><input type="checkbox"/> sentence present</p> <p><input type="checkbox"/> sentence not present</p> <p><input type="checkbox"/> not applicable</p> <p>Comments:</p>	Art. 20 (3g) DIR 98/8/EC
2.21	<p>Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging</p> <p><input type="checkbox"/> present</p> <p><input type="checkbox"/> not present</p> <p><input type="checkbox"/> incomplete</p> <p><input type="checkbox"/> not applicable</p> <p><input type="checkbox"/> uncertain (please indicate reason)</p> <p>Comments:</p>	Art. 20 (3h) DIR 98/8/EC

2.22	Formulation batch number or designation <input type="checkbox"/> present <input type="checkbox"/> not present Comments:	Art. 20 (3i) DIR 98/8/EC
2.23	Expiry date relevant to normal conditions of storage <input type="checkbox"/> present <input type="checkbox"/> not present Comments:	
2.24	Period of time needed for the biocidal effect ( <b>if relevant</b> )..... including <ol style="list-style-type: none"> <li>1. particulars concerning decontamination means and measures</li> <li>2. particulars concerning duration of necessary ventilation of treated areas,</li> <li>3. particulars for adequate cleaning of equipment,</li> <li>4. particulars concerning precautionary measures during storage</li> <li>5. particulars concerning precautionary measures during use and transport</li> </ol> <input type="checkbox"/> present <input type="checkbox"/> not present <input type="checkbox"/> incomplete <input type="checkbox"/> not applicable <input type="checkbox"/> uncertain (please indicate reason) Comments:	Art. 20 (3j) DIR 98/8/EC
2.25	Information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water <input type="checkbox"/> present <input type="checkbox"/> not present <input type="checkbox"/> incomplete <input type="checkbox"/> not applicable <input type="checkbox"/> uncertain (please indicate reason) Comments:	Art. 20 (3l) DIR 98/8/EC

\* Section 3 – Legality on the market and inspection of Safety Data Sheets (SDS)

Checking of SDS and classification

3.1	<p>a) SDS available</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>b) Available only on request</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>c) Content of chemical substances available on SDS</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>d) SDS Checked:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Comments:</p>	Art. 20 DIR 98/8/EC
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<p>3.2</p>	<p>Please indicate active substances and concentration; as well as EINECS / ELINECS / CAS-number (if available)</p> <p>1.</p> <p><input type="checkbox"/> ANNEX I  <input type="checkbox"/> ANNEX II listed for relevant PT  <input type="checkbox"/> non-inclusion list  <input type="checkbox"/> not found</p> <p>2.</p> <p><input type="checkbox"/> ANNEX I  <input type="checkbox"/> ANNEX II listed for relevant PT  <input type="checkbox"/> non-inclusion list  <input type="checkbox"/> not found</p> <p>3.</p> <p><input type="checkbox"/> ANNEX I  <input type="checkbox"/> ANNEX II listed for relevant PT  <input type="checkbox"/> non-inclusion list  <input type="checkbox"/> not found</p> <p>4.</p> <p><input type="checkbox"/> ANNEX I  <input type="checkbox"/> ANNEX II listed for relevant PT  <input type="checkbox"/> non-inclusion list  <input type="checkbox"/> not found</p> <p>5.</p> <p><input type="checkbox"/> ANNEX I  <input type="checkbox"/> ANNEX II listed for relevant PT  <input type="checkbox"/> non-inclusion list  <input type="checkbox"/> not found</p> <p>Comments:</p>	<p><b>If listed in ANNEX I:</b> Active substances identified</p> <p><b>If listed in ANNEX II:</b> Transitional arrangement; please note: currently marketable if listed for the relevant product type <small>(look up in note 6 and 7, decisions of non-inclusion)</small></p> <p>A consolidated list of existing active substances for which a decision of non-inclusion into ANNEX I or IA of Directive 98/8/EC has been adopted is available:  <a href="http://ec.europa.eu/environment/biocides/non_inclusions.htm">http://ec.europa.eu/environment/biocides/non_inclusions.htm</a></p> <p><b>If not listed in ANNEX II for the relevant product type:</b> Marketing forbidden<sup>1</sup>.</p> <p><b>If not listed in ANNEX I or II:</b> May be treated as a new active substance, premised biocidal efficiency and included into the Directive 98/8/EC</p> <p><u>Please note: Possibly national provisions!</u></p>
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* Section 4 – Biocide product advertisement		
4.1	<p>Is the product advertised?</p> <p><input type="checkbox"/> yes</p> <p><input type="checkbox"/> no (if no, no further questions are relevant)</p> <p><input type="checkbox"/> not checked</p> <p>Comments:</p>	
4.2	<p>Does advertisement refer to the product in a manner which is misleading in respect of the risks from the product to man or the environment?</p> <p><input type="checkbox"/> yes (if yes, please document)</p> <p><input type="checkbox"/> no</p> <p>please document:</p>	<p>Art. 22 (2) DIR 98/8/EC. (example: see manual)</p> <p><b>If available, please provide documents.</b></p>
4.3	<p>Is product accompanied by the sentence “Use biocides safely”. Always read the label and product information before use“?</p> <p><input type="checkbox"/> yes</p> <p><input type="checkbox"/> no</p> <p>Comments:</p>	<p>Art. 22 (1) DIR 98/8/EC</p>
4.4	<p>Is the sentence clearly distinguishable in relation to the whole advertisement?</p> <p><input type="checkbox"/> yes</p> <p><input type="checkbox"/> no</p> <p>Comments:</p>	<p>Art. 22 (1) DIR 98/8/EC</p>

#### APPENDIX 8: QUESTIONNAIRE PRODUCTS AND RESULT FORM

An Excel format, Questionnaire products and result form for compiling of data enclosed of the Manual of the EuroBiocides project, 16<sup>th</sup> April 2008)

## 8.9 APPENDIX 9: National project Co-ordinators and contact persons

National biocides project-coordinators and contact persons in the participating countries:

Country	Name	E-mail
Austria	Sabine Cladowa	<a href="mailto:sabine.cladowa@umweltbundesamt.at">sabine.cladowa@umweltbundesamt.at</a>
Belgium	Michel Leynen	<a href="mailto:Michel.Leynen@health.fgov.be">Michel.Leynen@health.fgov.be</a>
Denmark (Management/WG)	Annmette Carline Søgård	<a href="mailto:amj@mst.dk">amj@mst.dk</a>
	Birte Børglum	<a href="mailto:bb@mst.dk">bb@mst.dk</a> (contact person)
Estonia	Natali Promet	<a href="mailto:Natali.promet@tervisekaitse.ee">Natali.promet@tervisekaitse.ee</a>
Finland	Annette Eckman	<a href="mailto:annette.ekman@valvira.fi">annette.ekman@valvira.fi</a>
France (WG)	Stéphanie Viers	<a href="mailto:Stephanie.viers@ecologie.gouv.fr">Stephanie.viers@ecologie.gouv.fr</a>
Germany (WG)	Katrin Lütjen	<a href="mailto:Katrin.Luetjen@mlur.landsh.de">Katrin.Luetjen@mlur.landsh.de</a>
	Andrea Mayer- Figge	<a href="mailto:Andrea.Mayer-Figge@mags.nrw.de">Andrea.Mayer-Figge@mags.nrw.de</a>
Latvia	Kristīne Kazerovska	<a href="mailto:Kristine.kazerovska@vi.gov.lv">Kristine.kazerovska@vi.gov.lv</a>
	Parsla Pallo	<a href="mailto:Parsla.pallo@vi.gov.lv">Parsla.pallo@vi.gov.lv</a>
Netherlands (WG)	Sipke Havinga	<a href="mailto:Sipke.Havinga@minvrom.nl">Sipke.Havinga@minvrom.nl</a>
Norway	Beryl C. Nygreen	Beryl C. Nygreen [beryl-c.nygreen@klif.no]
Poland	Marta Osówniak	Marta Osowniak [M.Osowniak@gis.gov.pl]
Slovenia	Jeraj-Pezdir Mojca	<a href="mailto:Mojca.Jeraj-Pezdir@gov.si">Mojca.Jeraj-Pezdir@gov.si</a>
Spain (WG)	Rosario Alonso Fernández	<a href="mailto:ralonso@mpsi.es">ralonso@mpsi.es</a> <a href="mailto:ralonso@mpsi.es">ralonso@mpsi.es</a>
	María Tarancón Estrada	<a href="mailto:maria.tarancon@juntadeandalucia.es">maria.tarancon@juntadeandalucia.es</a>
Switzerland (WG)	Heribert Bürgy	<a href="mailto:heribert.buergy@bag.admin.ch">heribert.buergy@bag.admin.ch</a>
Romania	Mihaela Albulescu	<a href="mailto:Mihaela.albulescu@gmail.com">Mihaela.albulescu@gmail.com</a>

## 8.10 APPENDIX 10: Contact address and list of participating inspectors

### AUSTRIA

Name of inspector	Focal Point
Eugen Anwander	Sabine Cladrowa, Dr. Chemikalien/Chemicals Umweltbundesamt Spittelauer Lände 5/Spittelauer Laende 5 1090 Wien/Vienna Österreich/Austria
Günter Bauer	
Tamara Friedrich	
Heinz Götz	
Angelika Hold	
Rudolf Kaufmann	
Rosemarie Malicha	
Josef Wieser	
Eva Valdo	
Martin Rinderer	
Sabine Cladrowa	National project Co-ordinator

### BELGIUM

Name of inspector	All inspectors are working for
Yvette Meeus	Federal Public Service Health, Food Chain Safety & Environment DG Environment Inspection Place Victor Horta 40 Box 10 B-1060 Brussels, Belgium
Henri Dusart	
Thierry Dudek	
Philippe Marotte	
Kristof Van Den Driessche	
Walter Dobbeni	
Isabelle Meurant	
Isabelle Watelet	
Willem Klemans	
Katrien Maasen	
Fabrice Procureur	
Serge Smetz	
Michel Leynen	

### DENMARK

Name of inspector	All inspectors are working for
Annmette Carline Søgård	Danish Environmental Protection Agency Chemical Inspection Service
Annmette Carline Søgård	National project Co-ordinator

## ESTONIA

Department of Chemical Safety  
Chemicals and Product Safety Bureau, HEALTH BOARD, Paldiski road 81, 10617 Tallinn

Senior Public Health Officer Natali Promet (National project Co-ordinator)

Estonian Health Board inspectors, who participated in the EuroBiocides project in 2006-2009

Name of inspector	Health Board Service (Region)
Marianna Selivanova	Eastern Service (Virumaa Region)
Kaja Laursoo	Southern Service (Tartu Region)
Reelika Tammai	Western Service (Pärnu Region)
Tatjana Lihhuša	Northern Service (Harjumaa region)
Natalja Borel	Northern Service (Harjumaa region)
Jevgenia Rõõmusoks	Northern Service (Harjumaa region)

## FINLAND

Paula Haapasola, National Supervisory Authority for Welfare and Health  
Eeva Nurmi, Finnish Environmental Institute

In Finland the inspections were carried out by several inspectors at the Municipal Supervisory Authority for Chemicals.

## FRANCE

Name of inspector	Contact person and address
Anne PERREAU	Stéphanie Viers
Jean-Luc ROUSSEAU	Chargé de mission Animation des politiques de contrôles
Sébastien POTTE	Bureau des Substances et Préparations Chimiques DPPR / SDPD
Patrice CHEMIN	Ministère de l'Écologie, du Développement et de l'Aménagement Durables 20, avenue de Ségur - 75302 PARIS 07 SP FRANCE
Stéphanie VIERS	National project Co-ordinator

## GERMANY

Name of inspector	Focal point
- around 70 inspectors took part in the project.	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) Federal Institute for Occupational Safety and Health Fachbereich 5 "Bundesstelle Chemikalien, Zulassung Biozide" Division 5 "Federal Office for Chemicals, Authorisation of Biocides" , Stefan Frenzel, chemg@baua.bund.de
	National project Co-ordinator
Andrea Mayer-Figge	Ministry of Employment, Integration and Social Affairs
Katrin Lütjen	Ministry of agriculture, environment and rural areas,

## LATVIA

### The Health Inspectorate of the Republic of Latvia Products Control Division

	<i>Name</i>	<i>Surname</i>	<i>Position</i>
1.	Kristīne	Kazerovska	Head of Division
2.	Sintija	Elferte	Senior inspector
3.	Jeļena	Abo Dauda	Senior inspector
4.	Leva	Suse	Senior inspector
5.	Liene	Cepurīte	Inspector

Controls were performed in cooperation with the competent authority in the biocide area:

### Latvian Environment, Geology and Meteorology Agency Chemical Substance Division

	<i>Name</i>	<i>Surname</i>	<i>Position</i>
1.	Jolanta	Staško	Chemist
2.	Anta	Jantone	Chemist

## POLAND

### Department of Environmental Hygiene Chief Sanitary Inspectorate

ul. Długa 38/40  
00-238 Warszawa  
tel: +48 22 536 14 91  
fax: +48 22 826 50 63

Magdalena Nogańska  
Wojciech Szcześniak  
Marta Osówniak

### Voivodeship Sanitary Inspectors, City

Natalia Andrzejewska, Poznań  
Marek Duszyński, Poznań  
Mariusz Wójcik, Łódź

### County Sanitary Inspectors

#### -from Poznań Voivodeship

Name	Area
Mieczysław Drużga	Chodzież
Julita Pawłowska-Dudziak	Czarnków
Barbara Bultrowicz	Gniezno
Katarzyna Woźniak	Gostyń
Dorota Gnus	Grodzisk Wlkp.
Sławomira Gromadzińska	Jarocin
Anna Napierała	Kalisz
Mariola Hładzyńska	Kępno
Bernadeta Nowakowska-Kujawa	Koło
Krystyna Hofman-Bukowiecka	Konin
Katarzyna Nowak	Kościan
Ewa Wojciechowska	Krotoszyn
Zdzisław Rzeźniczak	Leszno
Małgorzata Mięzał	Międzychód
Alicja Kubicka	Nowy Tomyśl
Izabela Kłosowicz	Oborniki
Krzysztof Leszczyński	Ostrów Wlkp.

Monika Patławska	Ostrzeszów
Katarzyna Derezińska	Piła
Ewa Grzeszczak	Pleszew
Paweł Śliwa	Poznań
Lidia Wróblewska	Rawicz
Urszula Goślińska	Słupca
Danuta Gajzler	Szamotuły
Hanka Ratajczak	Śrem
Elżbieta Lobermajer	Środa Wlkp.
Halina Kostrzewa	Turek
Małgorzata Tchórzewska	Wągrowiec
Beata Wojtowicz	Wolsztyn
Grażyna Prokop	Września
Anna Sobbek	Złotów

**from Olsztyn Voivodeship**

<b>Name</b>	<b>Area</b>
Teresa Dziewałtowska-Gintowt	Olsztyn

**from Łódź Voivodeship**

<b>Name</b>	<b>Name</b>
Teresa Goch	Bełchatów
Barbara Karasińska	Bełchatów
Wiesław Łyszkiewicz	Brzeziny
Marianna Rączkiewicz	Kutno
Jolanta Wawrzyńczak	Kutno
Alicja Kmin	Łask
Elżbieta Klimczak	Łask
Anna Pietrzak	Łęczyca
Joanna Głodek	Łęczyca
Sławomir Mucha	Łowicz
Grażyna Stobiecka	Łowicz
Daniela Cisowska	Łódź
Ewa Boruszczak	Łódź
Renata Duszyńska	Łódź
Natalia Kacprzak	Łódź
Janusz Wojciechowski	Opatów
Bożenna Frydrych	Pabianice
Stefan Grzanka	Pabianice
Piotr Szczepaniak	Pabianice
Sławomira Tokarska	Pajęczno

Ewa Derendarz	Piotrków Trybunalski
Joanna Roll	Piotrków Trybunalski
Magdalena Pełka – Owczarek	Poddębice
Krystyna Włodarska	Poddębice
Helena Magdziarz	Radomsko
Jolanta Spychalska	Radomsko
Wiesława Dudek kierownik HP	Rawa Mazowiecka
Beata Stanisławczyk	Rawa Mazowiecka
Jolanta Szymańska	Sieradz
Jadwiga Nowak	Sieradz
Aldona Maciejak	Skierniewice
Maria Starzec	Skierniewice
Krystyna Zwolińska	Skierniewice
Matuszewska Elżbieta	Tomaszów Mazowiecki
Wojtaszek Krystyna	Tomaszów Mazowiecki
Kudła Małgorzata	Tomaszów Mazowiecki
Przemysław Drozdek	Wieluń
Agnieszka Gaszych	Wieruszów
Ewa Urbaniak	Zduńska Wola
Bogumiła Majewska	Zduńska Wola
Urszula Skonieczka	Zgierz
Zgierz	Teresa Machałowska

## SLOVENIA

Chemical Office of the Republic of Slovenia  
 Jeraj Pezdir Mojca (National project Co-ordinator)

Inspectors: No information

## SPAIN

### **MINISTERIO DE SANIDAD Y POLÍTICA SOCIAL (Madrid)**

Dirección General de Salud Pública y Sanidad Exterior  
 Subdirección General de Sanidad Ambiental y Salud Laboral

*Mr. Fernando CARRERAS VAQUER (Focal Point)*

*Ms. Rosario ALONSO FERNÁNDEZ (National Project Co-ordinator)*

### **COMUNIDAD AUTÓNOMA DE ANDALUCÍA**

Consejería de Salud

Dirección General de Salud Pública y Participación

*Ms. María TARANCÓN ESTRADA (Autonomous Communities Representative)*

**LIST OF PARTICIPATING PUBLIC HEALTH INSPECTORS FROM 14 AUTONOMOUS COMMUNITIES****COMUNIDAD AUTÓNOMA DE ANDALUCÍA**

Consejería de Salud

Secretaría General de Salud Pública y Participación

Servicio de Salud Ambiental (Sevilla)

Coordinator(\*): María TARANCÓN ESTRADA

AGS: Área de Gestión Sanitaria

DSAP: Distrito Sanitario de Atención Primaria

<b>ALMERÍA</b>		
<b>Name</b>	<b>Surname</b>	<b>Area</b>
IRENE	LAZARO JIMÉNEZ DE CISNEROS	AGS NORTE ALMERIA
VICTOR	ALFARO DORADO	AGS NORTE ALMERIA
CARMEN	DE OÑA BAQUERO	AGS NORTE ALMERIA
ANTONIA	CAYUELA PÉREZ	AGS NORTE ALMERIA
MARIA ISABEL	CAPARROS JIMÉNEZ	AGS NORTE ALMERIA
MARIA DOLORES	GUERRERO HARO	AGS NORTE ALMERIA
<b>CÁDIZ</b>		
<b>Name</b>	<b>Surname</b>	<b>Area</b>
ALICIA	PENDÓN MELÉNDEZ	AGS. CAMPO DE GIBRALTAR
JOSEFA	MEDINA MARTIN	AGS. CAMPO DE GIBRALTAR
M <sup>a</sup> ANGELES	DE SALAS SIERRA	AGS. CAMPO DE GIBRALTAR
MONICA	MUÑOZ BASCÓN	AGS. CAMPO DE GIBRALTAR
CARMEN	VICENTE ENAMORADO	AGS. CAMPO DE GIBRALTAR
M <sup>a</sup> ANGELES	ESPINOSA OLIVA	AGS. CAMPO DE GIBRALTAR
JACQUELINE	PENEDO LAVENU	AGS. CAMPO DE GIBRALTAR
HELENA	FRAMIÑÁN TORRES	AGS. CAMPO DE GIBRALTAR
ADELA	NAVARRO CAMACHO	AGS. CAMPO DE GIBRALTAR
CARMEN	PASTOR MATEO	AGS. CAMPO DE GIBRALTAR
AURORA	VELA LOPEZ	DSAP. BAHIA CADIZ-JANDA
ASUNCIÓN	MUÑOZ VELEZ	DSAP. BAHIA CADIZ-JANDA

CARMEN	PACHECO RODRIGUEZ	DSAP. BAHIA CADIZ-JANDA
JERONIMO	LOPEZ GONZALEZ	DSAP. BAHIA CADIZ-JANDA
PATRICIA	RODIRGUEZ BERNAL	DSAP. BAHIA CADIZ-JANDA
MARINA	ALCALA CASTILLA	DSAP. BAHIA CADIZ-JANDA
DOLORES	MORENO BADILLO	DSAP. BAHIA CADIZ-JANDA
LUIS FERNANDO	RUBIALES RAMÍREZ	DSAP. BAHIA CADIZ-JANDA
ROCIO	CARRASCO RAMIREZ	D.A.P. SIERRA DE CÁDIZ
MANUEL ANGEL	CHACÓN GONZÁLEZ	D.A.P. SIERRA DE CÁDIZ
Mª DEL MAR	GUITART DEL PRADO	D.P. DE SALUD DE CÁDIZ
<b>CÓRDOBA</b>		
<b>Name</b>	<b>Surname</b>	<b>Area</b>
Mª TERESA	ALVAREZ DE SOTOMAYOR MORALES	DS GUADALQUIVIR
Mª ESTHER	FUENTES-GUERRA CABALLERO	DS GUADALQUIVIR
DIEGO	GALAN ZURITA	DS GUADALQUIVIR
ELENA	GOMEZ-VILLALVA PELAYO	DS GUADALQUIVIR
Mª DOLORES	LUNA GOMEZ	DS GUADALQUIVIR
JOSE ANTONIO	RUIZ MURO	DS GUADALQUIVIR
Mª TERESA	SANCHEZ GONZALEZ	DS GUADALQUIVIR
Mª VERONICA	TEJEDOR GARRIDO	DS GUADALQUIVIR
RAFAEL	TOSCANO BENAVIDES	DS GUADALQUIVIR
CARMEN	NÚÑEZ GUTIERREZ	DS CÓRDOBA
ALEJANDRO	BLÁZQUEZ ROJAS-MARCOS	DS CÓRDOBA
ANA	RUBIO GARCÍA	DS CÓRDOBA
JOAQUÍN	GARABITO DURÁN	DS CÓRDOBA
MARIA TERESA	GALLEGO QUEVEDO	DP SALUD CORDOBA
FRANCISCA	CANO CAMPOS	DP SALUD CORDOBA
Mª PATRICIA	ARMARIO IBÁÑEZ	AS NORTE
Mª ANGELES	ROMERO PAREDES	AS NORTE
Mª ELISA	MEDINA ROMERO	AS NORTE
CARMEN	PÍRIZ SILVA	DISTRITO CÓRDOBA SUR
CARMEN	ROLDÁN PADILLA	DISTRITO CÓRDOBA SUR
Mª CARMEN	JIMÉNEZ JIMÉNEZ	DISTRITO CÓRDOBA SUR
ANTONIO	JODRAL SEGADO	DISTRITO CÓRDOBA SUR
REYES	MARTÍN LUCENA	DISTRITO CÓRDOBA SUR

FRANCISCA	RAYA RAYA	DISTRITO CÓRDOBA SUR
LOURDES	COBOS ORTIZ	DISTRITO CÓRDOBA SUR
CONSUELO	DE PRADO ALCALÁ	DISTRITO CÓRDOBA SUR
ROCÍO	MEDINA BAENA	DISTRITO CÓRDOBA SUR
MERCEDES	PONTES JIMÉNEZ	DISTRITO CÓRDOBA SUR
CARLOS	RODRÍGUEZ LÓPEZ	DISTRITO CÓRDOBA SUR
ELENA	MOHEDANO MOHEDANO	DISTRITO CÓRDOBA SUR
MANUEL J	ARRABAL FEIXAS	DISTRITO CÓRDOBA SUR
<b>GRANADA</b>		
<i><b>Name</b></i>	<i><b>Surname</b></i>	<i><b>Area</b></i>
LAURA	MOLINA GARCIA	DS GRANADA
MANUEL	MARTÍN PELEGRINA	DS METROPOLITANO
CONCEPCIÓN	BELLIDO BELLIDO	DS METROPOLITANO
ANA MARIA	HERNÁNDEZ JEREZ	DS METROPOLITANO
ELENA	YAÑEZ DE LARA	DS METROPOLITANO
MARGARITA	MENÉNDEZ NUÑEZ	DS METROPOLITANO
INMACULADA	MEGIAS CANO	DS METROPOLITANO
FRANCISCO	HERRERO MUÑOZ	DS METROPOLITANO
ARACELI	PULIDO RODRIGUEZ	DS METROPOLITANO
MARIA	MORALEDA SÁNCHEZ	DS NORDESTE
MARIA	NIETO JIMENEZ	DS NORDESTE
PILAR	FERNANDEZ SANCHEZ	DS NORDESTE
MARIA TERESA	VALENZUELA CLAROS	DS NORDESTE
ANA	DOUGNAC RODRIGUEZ	DS NORDESTE
ENCARNACIÓN	PÉREZ LÓPEZ	DS NORDESTE
ELISA	GARCIA RUIZ	AREA GESTION SANIT. SUR
ROSA	GARCIA MESA	AREA GESTION SANIT. SUR
FRANCISCO	CARRILLO HURTADO	AREA GESTION SANIT. SUR
ISABEL	ESTEBAN LEIVA	DELEGACIÓN PROVINCIAL
BELÉN	ILLA VALDIVIESO	DELEGACIÓN PROVINCIAL
<b>HUELVA</b>		
<i><b>Name</b></i>	<i><b>Surname</b></i>	<i><b>Area</b></i>
ÁNGELA	SÁNCHEZ-BLANCO IZQUIERDO	DS CONDADO-CAMPIÑA
CRISTINA	SARMIENTO FEDRIANI	DS CONDADO-CAMPIÑA
JOSÉ FERNANDO	HIDALGO CONTIOSO	DS CONDADO-CAMPIÑA
CRISTINA	PRADAS MONTILLA (TSSA)	DS CONDADO-CAMPIÑA
RAQUEL	HERNÁNDEZ SÁNCHEZ	DS HUELVA-COSTA

JOSÉ MARÍA	JURADO MARTÍNEZ	DS HUELVA-COSTA
MANUEL	GARCÍA ORDIALES	DS HUELVA-COSTA
EDUARDO	FORJÁN LOZANO	DS HUELVA-COSTA
ESTHER	GIL GALLARDO	DS HUELVA-COSTA
CAROLINA	HERNÁNDEZ VIAPLANA	DS HUELVA-COSTA
CARMEN	GARCÍA PRAT	DS HUELVA-COSTA
MARINA	MARTÍNEZ LEITGEB	DS HUELVA-COSTA
ROSARIO	GARRIDO DE LA SIERRA	DS HUELVA-COSTA
ROGELIO	LÓPEZ GONZÁLEZ	DS SIERRA-ANDÉVALO
ROSALÍA	LORCA CABALLERO	DS SIERRA-ANDÉVALO
PILAR	GONZÁLEZ DE CANALES GARCÍA	DS SIERRA-ANDÉVALO
ENRIQUE	NARANJO MÁRQUEZ	DS SIERRA-ANDÉVALO
<b>JAÉN</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
MARIA JESUS	OLLERO PALMA	DS JAEN-SUR
FRANCISCO	PERALES GODOY	DS JAEN-SUR
MONICA	DOÑA JIMÉNEZ	DS JAEN-SUR
MARIA CARLOTA	LOZANO IZQUIERDO	DS JAEN-NORDESTE
JULIA	FERNÁNDEZ FERNÁNDEZ	DS JAEN-NORDESTE
JOSE	MARTOS MOLINA	DS JAEN-NORDESTE
MIGUEL ANGEL	LOPEZ TORRES	DS JAEN-NORDESTE
LOURDES	FERNANDEZ CARAZO	DS JAEN-NORTE
ANA	ROLDAN GONZALEZ	DS JAEN-NORTE
LUIS	LANDA DEL CASTILLO	DS JAEN-NORTE
MILAGROSA	MARRON MORENO	DS JAEN
JUAN BOSCO	MUÑOZ LEÓN	DS JAEN
M <sup>a</sup> JOSÉ	LIÉBANA LIÉBANA	DS JAEN
CARLOS GABRIEL	MONTERO HERRERO	DS JAEN
LOURDES	GÓMEZ JIMÉNEZ	DS JAEN
LUIS MANUEL	TORRES PÉREZ	DS JAEN
ANA MARIA	FUENTES RUIZ	DS JAEN
<b>MÁLAGA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
CARLOS	CABEZAS GARCIA	D.S.AXARQUIA
AURORA	SANCHEZ PEREZ	D.S.AXARQUIA
ANA MARIA	TORO ZAYAS	D.S.AXARQUIA
RAFAEL	FERNADEZ ARRABAL	D.S.AXARQUIA
FRANCISCA	MACIAS GOMEZ	D.S.COSTA DEL SOL
MERCEDES	GARCIA MOURIÑO	
VANESA	TORRES SAURA	D.S.NORTE DE MALAGA
ESTHER	CASTILLO QUESADA	D.S.DE MALAGA
MANUEL	MACHUCA MEDINA	D.S.DE MALAGA
MAGDALENA	BLANCO TORRES	D.S.VALLE DEL

		GUADALHORCE
AMELIA	LOPEZ PARRA	D.S.VALLE DEL GUADALHORCE
M <sup>a</sup> DOLORES	MORALES SANCHEZ	D.S.VALLE DEL GUADALHORCE
<b>SEVILLA</b>		
<i><b>Name</b></i>	<i><b>Surname</b></i>	<i><b>Area</b></i>
BERTA	ALCÓN ÁLVAREZ	DS NORTE
ANA	FONSECA LAVADO	DS NORTE
VICTORIA	NIETO LÓPEZ	DS NORTE
PILAR	SÁNCHEZ DE MEDINA MARTÍNEZ	DS NORTE
GUADALUPE	RUEDA CABRERA	DS SEVILLA
ROCIO	ESCALONA NAVARRO	DS SEVILLA
JOSEFA	GARCÍA GARCÍA	DS SEVILLA
MATILDE	REVUELTA GÓNZALEZ	DS ALJARAFE
MERCEDES	MÉNDEZ MORENO	DS ALJARAFE
M <sup>a</sup> DEL CARMEN	ZAMBRANA CAYUSO	DS ALJARAFE
CONCHA	NÚÑEZ CASTAÍN	DS ALJARAFE
ALFREDO	MARTÍNEZ COGOLLOS	DS ALJARAFE
LOURDES	MORILLO MONTAÑÉS	DS ALJARAFE
CARMEN	GÓMEZ MARTÍN	DS ALJARAFE
M <sup>a</sup> DOLORES	BARRANCO MORENO	DS ALJARAFE
JOSÉ MANUEL	GIRÁLDEZ MARTÍNEZ	DS ESTE
ROCIO	LÓPEZ PÉREZ	DS ESTE

### **COMUNIDAD AUTÓNOMA DE ARAGÓN**

Departamento de Salud y Consumo

Dirección General de Salud Pública

SSAMA: Servicio de Seguridad Alimentaria y Medioambiental

SPSPZ: Subdirección Provincial de Salud Pública de Zaragoza

Coordinator (\*): María Iciar ALONSO URRETA (SSAMA)

<b>ZARAGOZA</b>		
<i><b>Name</b></i>	<i><b>Surname</b></i>	<i><b>Area</b></i>
ISABEL	BOSQUE PERALTA	SSAMA
EVA M <sup>a</sup>	MARZO LLEIXA	SPSPZ

### **COMUNIDAD AUTÓNOMA DE ISLAS BALEARES**

Consejería de Salud y Consumo

Dirección General de Salud Pública y Participación

Servicio de Protección de la Salud

Coordinator (\*)

<b>MALLORCA</b>
-----------------

<i>Name</i>	<i>Surname</i>	<i>Area</i>
MERCEDES	GUMÄ TORA (*)	Sector Palma de Mallorca

### COMUNIDAD AUTÓNOMA DE ISLAS CANARIAS

Servicio Canario de Salud

Dirección General de Salud Pública

Coordinator (\*): María Luisa PITA TOLEDO

(TSP) (\*\*): Técnico de Salud Pública

<b>SANTA CRUZ DE TENERIFE</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
ESTEBAB	CAMPOS TRUJILLO (**)	Sector Palma de Mallorca

### COMUNIDAD AUTÓNOMA DE CASTILLA - LEÓN

Consejería de Sanidad

Agencia de Protección de la Salud y Seguridad Alimentaria

Servicio de Evaluación de Riesgos y Gestión de Alertas

Coordinator (\*): Carlos PÉREZ VEGA (Valladolid)

HASA: Higiene de los Alimentos y Sanidad Ambiental

DF: Demarcación Farmacéutica

<b>BURGOS</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
ALEGRIA	ARIAS GOMEZ	HASA
JOSE MANUEL	VILLANUEVA ESTEBANEZ	DF BURGOS
<b>LEÓN</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
MARIA ANGELES	ANDRES TOVESCAMPOS TRUJILLO (**)	HASA
<b>PALENCIA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
MARTA	ARANGÜENA FANEGO	HASA
ANGELA	CASERO GONZALEZ	DF PALENCIA SUR
<b>SALAMANCA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
MANUELA	PLAZA NIETO	HASA
<b>SEGOVIA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
ISABEL	GALLARDO ALONSO	HASA
<b>SORIA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
VICTORIA	PASCUAL CACHO	HASA
MARIA PILAR	POZA MIRANDA	DF SORIA
<b>ZAMORA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>

JOSE MARIO	MARTINEZ DELGADO	HASA
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### COMUNIDAD AUTÓNOMA DE CASTILLA – LA MANCHA

Consejería de Salud y Bienestar Social

Dirección General de Salud Pública

Servicio de Sanidad Ambiental, Salud Laboral y Laboratorios de Salud Pública

Coordinator (\*): Marcial GÓMEZ ORRIOS

<b>ALBACETE</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
RICARDO	MARTINEZ FERRANDO	DP DE SANIDAD DE ALBACETE
MARIA	PASTOR ESCRIBANO	DP DE SANIDAD DE ALBACETE
ISABEL	MARTINEZ BLAZQUEZ	DISTRITO DE SALUD DE ALBACETE
<b>CIUDAD REAL</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
FELICIA	TORRES MANRIQUE	DP DE SANIDAD DE CIUDAD REAL
JOSE LUIS	SERRANO FERNANDEZ	DP DE SANIDAD DE CIUDAD REAL
CARMEN	GARCIA FUENTEVILLA	DP DE SANIDAD DE CIUDAD REAL
<b>CUENCA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
MARIA VICTORIA	YUNTA ARRIBAS	DP DE SANIDAD DE CUENCA
CRISTINA	BARCUÑAN MARTINEZ	DP DE SANIDAD DE CUENCA
BRUNO	MAGRO PRIEGO	DP DE SANIDAD DE CUENCA
FEDERICO	LEON ALARCON	DISTRITO DE SALUD DE BELMONTE
<b>TOLEDO</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
GUADALUPE	MARTINEZ JUAREZ	INSTITUTO DE CIENCIAS DE LA SALUD
RUBEN	RODRIGUEZ CORROCHANO	INSTITUTO DE CIENCIAS DE LA SALUD
VICTORIA	RUIZ –TAPIADOR CANO	DP DE SANIDAD DE TOLEDO
JOSE LUIS	LOPEZ GONZALEZ	DP DE SANIDAD DE TOLEDO
SUSANA	RODRIGUEZ – SOLANO MUÑOZ	DISTRITO DE SALUD DE ILLESCAS
NOELIA	DE LA CRUZ CHOZAS	DISTRITO DE SALUD DE ILLESCAS

### COMUNIDAD AUTÓNOMA DE CATALUÑA

Departamento de Salud. Generalidad de Cataluña

Agencia de Protección de la Salud

Coordinators (\*): Irene CORBELLA CORDOMI, Sara PRADOS LUQUE and M<sup>a</sup> Soledad GARCIA PRADO (División de Objetivos y Programas. Area de Salud Ambiental)  
 SR: Servicio Regional

<b>BARCELONA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
JOAN	SOLANICH BRUNET	AGENCIA SALUD PÚBLICA DE BARCELONA
NURIA	JULIACHS PETIT	SR BARCELONA
MONICA	PUENTE CASTIÑEIRA	SR BARCELONA
MONTSERRAT	MALATS RIERA	SR CATALUÑA CENTRAL
INMA	LLOPART LLOPART	SR BARCELONA
<b>GERONA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
JOSEP	MUÑOZ BATET	SR GIRONA
<b>LÉRIDA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
ANGEL	DEL RIO MONGE	SR LERIDA
<b>TARRAGONA</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
GLORIA	FERRUS SERRA	SR TIERRAS DEL EBRO
LAUREA	BLANCH ESCURRIOLA	SR TIERRAS DEL EBRO
M <sup>a</sup> JESUS	GOMEZ MUÑOZ	SR TARRAGONA

### **COMUNIDAD AUTÓNOMA DE EXTREMADURA**

Consejería de Sanidad y Dependencia

Dirección General de Salud Pública

Servicio Extremeño de Salud

Coordinators (\*) M<sup>a</sup> Dolores ZAMORA FERNÁNDEZ and M<sup>a</sup> Soledad ACEDO GRANDE

ISES: Inspector del Servicio Extremeño de Salud

CS: Centro de Salud

FEFS: Farmacéutico/a Escala Facultativa Sanitaria

<b>CÁCERES</b>		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
MILAGROS	TREMIÑO MEDINA	FEFS/ CS PLASENCIA
FRANCISCO JAVIER	DOMÍNGUEZ FELIPE	FEFS/ CS CORDOBILLA DE LACARA
M <sup>a</sup> MAR	FEU MOLINA	FEFS/CS MERIDA
INÉS M <sup>a</sup>	PAVÓN FERNÁNDEZ	FEFS/CS MERIDA
TERESA	LASO MARTÍNEZ	FEFS/ CS CORIA

ANASTASIA	BEJARANO CEBRIÁN	FEFS/ CS CORIA
ELENA	VICENTE MARTÍN	FEFS/ CS MIAJADAS
Mª EUGENIA	MARTÍNEZ DOMÍNGUEZ	FEFS/ CS NAVALMORAL DE LA MATA

### COMUNIDAD AUTÓNOMA DE GALICIA

Consejería de Sanidad

Dirección General de Salud Pública

Servicio de Sanidad Ambiental (Santiago de Compostela)

Coordinators: Manuel ÁLVAREZ CORTIÑAS and María de la Paz GULÍAS LAMAS

DP: Delegación Provincial

FISP: Farmacéutico/a Inspector/a de Salud Pública

TS: Técnico Superior

JS: Jefe/a de Servicio

LA CORUÑA		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
ANTONIO VICENTE	MARTINEZ CALVO	TS DP LA CORUÑA
ANA	PAZO VAZQUEZ	FISP DP LA CORUÑA
Mª VICTORIA	FENTE LOPEZ	FISP DP LA CORUÑA
LUGO		
ANA ISABEL	DELGADO GIL	TS DP LUGO
Mª DOLORES	FRAGA CANDO	FISP DP LUGO
ORENSE		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
CRISTINA	GONZALEZ DOMINGUEZ	FISP DP ORENSE
ANA ISABEL	GONZÁLEZ VILLAR	FISP DP ORENSE
PONTEVEDRA		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
Mª CARMEN	SANCHEZ BARRAL	JS DP PONTEVEDRA
Mª DEL PILAR	SANCHEZ CASTRO	FISP DP PONTEVEDRA

### COMUNIDAD AUTÓNOMA DE MADRID

Consejería de Sanidad.

Dirección General de Ordenación e Inspección.

Subdirección general de sanidad Ambiental y Epidemiología.

Servicio de Sanidad Ambiental (Madrid)

Coordinators (\*): Pilar DE BERNARDO ALONSO and Mercedes BUTTLER SIERRA

TSSP: Técnico Superior de Salud Pública

SSP: Servicio de Salud Pública

MADRID		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
CONCEPCIÓN	DE PAZ	TSSP/ SSP ÁREA I
BEATRIZ	ALVARO	TSSP/ SSP ÁREA III

PATRICIA	MARTINEZ	TSSP/ SSP ÁREA IV
RAQUEL	DOMENECH	TSSP/ SSP ÁREA V
SANTA	CONZÁLEZ	TSSP/ SSP ÁREA VI
TERESA	GARCÍA	TSSP/ SSP ÁREA VIII
SUSANA	GARCÍA	TSSP/ SSP ÁREA IX
MARÍA	CÁCERES	TSSP/ SSP ÁREA X
LUCINDA	PEÑA	TSSP/ SSP ÁREA XI

### COMUNIDAD AUTÓNOMA DE MURCIA

Consejería de Sanidad.

Dirección General de Salud Pública

Servicio de Sanidad Ambiental (Murcia)

Coordinator TRVA (\*): Félix TALAVERA MARTÍNEZ

TRVA: Técnico Responsable de Vigilancia Ambiental

FSP: Farmacéutico de Salud Pública

MURCIA		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
PEDRO F.	SÁNCHEZ LÓPEZ	FSP
PEDRO J.	ÚBEDA RUIZ	FSP

### COMUNIDAD AUTÓNOMA DEL PAÍS VASCO

Departamento de Sanidad

Viceconsejería de Sanidad

Dirección General de Salud Pública (DGSP)

Coordinator (DGSP): Koldo DE LA FUENTE CAMPOS

SGSP: Subdirección General de Salud Pública

ÁLAVA		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
NAGORE	IRAZABAL TAMAYO	SGSP ÁLAVA
RAQUEL	HERNÁNDEZ GARCÍA	SGSP ÁLAVA
M <sup>a</sup> DOLORES	UREÑA HERAS	SGSP ÁLAVA
ARANTZA	ARMENTIA ÁLVAREZ	SGSP ÁLAVA
GUIPÚZCOA		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
ELENA	SERRANO IBARBIA	SGSP GUIPÚZCOA
MÓNICA	OTAZUA FONT	SGSP GUIPÚZCOA
LORETO	SANTA MARINA RODRÍGUEZ	SGSP GUIPÚZCOA
VIZCAYA		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
M <sup>a</sup> EUGENIA	MOLINERO DE MIGUEL	SGSP VIZCAYA
JAVIER	GOROSTIAGA GARAY	SGSP VIZCAYA
KOLDO	USATEGUI DIAZ DE	SGSP VIZCAYA

	OTALORA	
ANA	ELORTEGI GABICAGOGEASKOA	SGSP VIZCAYA
YOLANDA	CUETOS TUÑON	SGSP VIZCAYA
MARTA	RODRIGUEZ JULIÁ	SGSP VIZCAYA
ANA	SALINAS AVELLANEDA	SGSP VIZCAYA

### COMUNIDAD AUTÓNOMA DE LA RIOJA

Consejería de Salud

Dirección General de Salud Pública y Consumo

Subdirección General de Seguridad Alimentaria y Consumo

Servicio de Seguridad Alimentaria y Sanidad Animal

Coordinator (\*)

LOGROÑO		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
EUGENIO	IBARRA CERVANTES	FSP (*)

### COMUNIDAD VALENCIANA

Consejería de Sanidad

Dirección General de Salud Pública

Servicio de Salud Laboral

Coordinators (\*): Valentín ESTEBAN and Ángela GARCÍA TORRES

CSP: Centro de Salud Pública

USLA: Unidad de Salud Laboral

TSL: Técnico/a de Salud Laboral

ALICANTE		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
JOSÉ ANTONIO	CARNERO PEÓN	TSL - USLA CSP DÉNIA
VALENCIA		
<i>Name</i>	<i>Surname</i>	<i>Area</i>
FERNANDO	ALMEDA VIVES	TSL – USLA CSP MANISES
LIDIA	FERRER BOSCH	TSL – USLA CSP VALENCIA
AMPARO	BARRUÉ DE LA BARRERA	TSL – USLA CSP VALENCIA

### SWITZERLAND

**Heribert Bürgy (Natal project Co-ordinator)**

<b>Name</b>	<b>Province</b>
Werner Friedli	Solothurn
Jürg Leu	Bern
Yves Parrat	Basel
Daniel Stahl	Zürich

Jürg Stehrenberger	Thurgau
Steve Steiger	Vaud