



FINAL REPORT

EuroBiocides 2017

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Inspection and law enforcement were conducted under the regulatory framework existing during the EuroBiocides inspection campaign (2017).

Published in 2018 by:
CLEEN network

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1 INTRODUCTION

Coordinating and carrying out enforcement of the biocides related legislation on the European level has been an area of work of the voluntarily network of enforcement authorities CLEEN for over a decade until the year 2016. As an official European body, tasked with initiating and supervising the BPR¹ enforcement in the future, was established in 2016, it was clear that CLEEN would withdraw from this subject. In order to maintain surveillance during the period until the new BPRS would become operational and take over, a final enforcement campaign related to biocides was proposed and performed by CLEEN: *EuroBiocides 2017*.

1.1 Intention of the EuroBiocides 2017 project

Products with active substances already in the union list of approved active substances according to article 9 (2) BPR should either have an authorization or an application should have been submitted. Some MS already had a system of transitional national authorizations under the transitional rules. But in most MS this is a new duty for the producers. The EuroBiocides 2017 project was designed to get an indication of the share of unauthorized biocides on the market. The internet trade was monitored for unauthorized biocides.

1.2 General Procedure

Internet monitoring usually is most efficient if it is conducted by a single central authority per participating Member State. It is up to each participating Member State how prosecution is organized in cases when illicit products are found.

1.3 Resources

As investigations can be done by one central point the needed resources are small.

1.4 Tools

Tools for reporting cases and preparing statistics had been developed during previous e-Commerce projects jointly by some MS that are active in Internet surveillance. These tools were ready to be used and suitable for the purpose of the current project.

It was up to the participating MS to either report each single case by means of the CLEEN *iCase Report Form* module or by means of a special summary report table for the *EuroBiocides 2017* campaign.

¹ REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products

1.5 Period

The project started at the beginning of 2017 and finished in the middle of the year. The draft report was presented at the CLEEN meeting in fall 2017.

2 RESULTS

2.1 Participating countries

Five countries of the CLEEN network participated in the *EuroBiocides 2017* project: Finland (FI), Germany (DE), Spain (ES), Switzerland (CH) and the Netherlands (NL).

CH, ES and NL have established a system of national transitional authorisations and assessment of the biocidal products. In FI only PT8 products need a national authorisation.

2.2 Analysis of the results

	Number of products found	Number of products with all active substances approved	Number of products with authorisation (or applied for)	Number of products without authorisation but which would need one
Total	211	84	59	20 (24%)

Table 1: Overview of the results.

Table 1 gives the summary of the results. The biocidal products found belonged to the following product types: PT1, PT2, PT7, PT8, PT14, PT18 and PT19.

211 products were assessed in total; thereof 84 already contained only approved active substances.

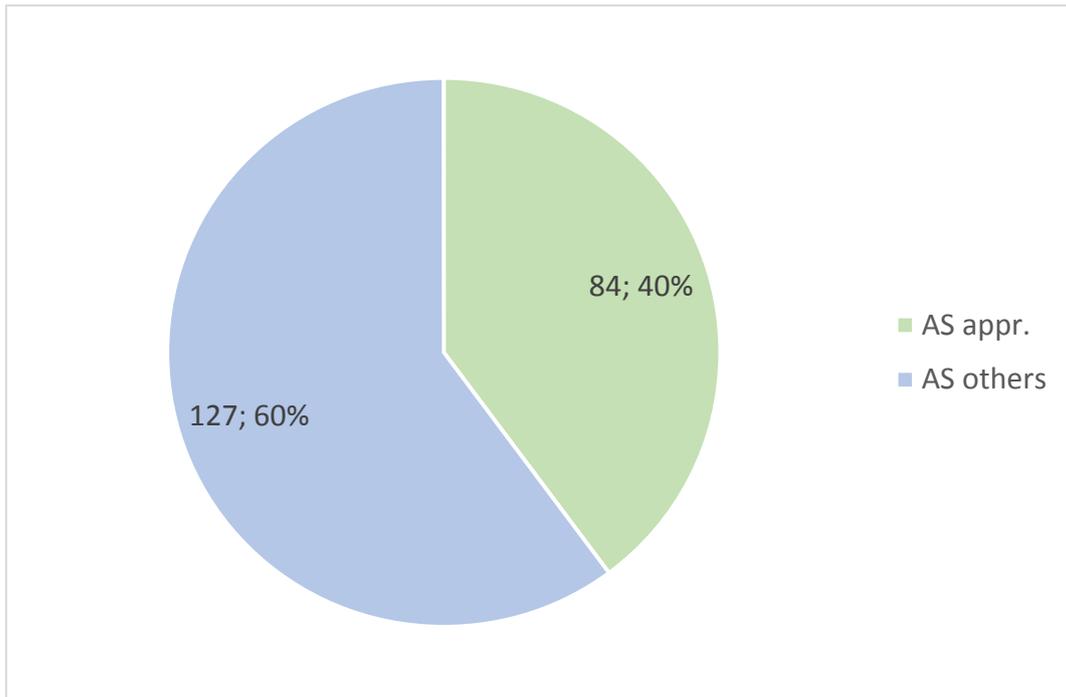


Figure 1: In total 211 biocidal products were found, thereof 84 had all active substances approved.

The results of the products with all active substances approved are listed in table 2. The rate of products with missing authorisation is 20 of 84 (24%).

	Number of products with all active substances approved	Number of products with authorisation (or applied for)	Number of products without authorisation and which need no authorisation yet	Number of products without authorisation but which would need one
PT8	81	57	5	19
PT14	3	2	0	1
Total	84	59	5	20

Table 2: Overview of the results regarding PT8 and PT14.

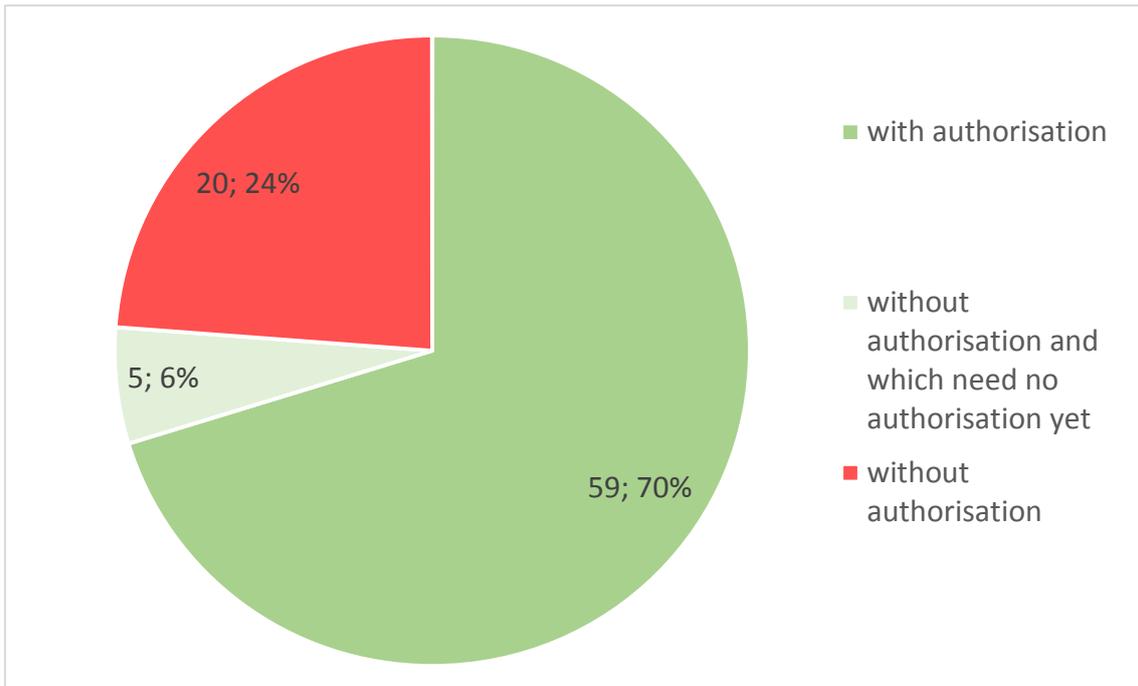


Figure 2: Figure of the products with all active substances approved. Nearly a quarter (24%) is illicitly on the market (without authorisation).

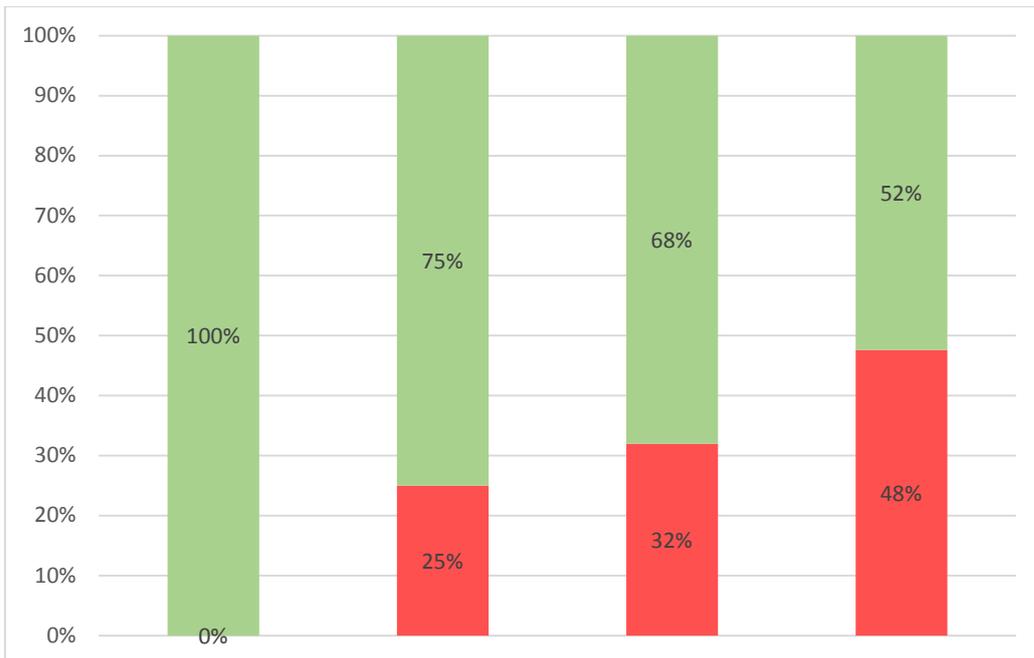


Figure 3: Distribution of the fraction of illicit biocides on the market in the different MS. It varies from 0% up to 48% of biocides without authorisation.

3 CONCLUSIONS & CONSIDERATIONS

Core elements of the BPR are the use of only approved active substances and that biocidal products undergo a process of authorisation.

In the EuroBiocides 2017 project the focus was set on the two questions: "Do the biocidal products on the market already need an authorisation according the BPR?" and if so "Do they have it?".

Of the PT8 and PT14-products a substantial percentage (24%) is on the market without the required authorisation according to the BPR (most active substances for these product types have already been granted an approval). The rate of unauthorized biocidal products on the market ranged from 0% up to 48%.

The objective of the BPR – protection of human health and the environment - can only be achieved if the biocidal products on the market have undergone the authorization process with its evaluation of the dangers and risks. With an average of 24% unauthorized products this goal has not been attained. Moreover unauthorized products enjoy an unfair advantage in competition because obtaining the authorization is a costly process and enterprises need resources for preparing authorization dossiers.

Therefore monitoring the market for unauthorized biocidal products further on and enforcing compliance with the provisions will be crucial to assure the BPR is functioning and meets its target in the future.