Forum Subgroup for exchange of information on enforcement of the BPR - **BPRS**

Second harmonised enforcement project on biocidal products with approved/non-approved active substances - **BEF-2**

Project report

Adopted on 6 November 2023

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This report presents the results of inspections made under the BPRS enforcement project. Duty holders and biocidal products selected for checks were those that were relevant for the scope of the project. The project was not designed as a study of the EU-EEA market. The number of inspections for individual countries is varied. Accordingly, the results presented in the report are not necessarily representative of the situation in the EU-EEA market as a whole.

BPRS BEF-2 Project report on enforcement of biocidal products with approved/non-approved active substances.

Reference: ECHA-23-R-10-EN
ISBN: 978-92-9468-323-6
Cat. Number: ED-02-23-113-EN-N
DOI: 10.2823/494395
Publication date:
Language: EN

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European Chemicals Agency
Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Telakkakatu 6, Helsinki, Finland

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Glossary

Term	Description
BPR	Biocidal Products Regulation (EC) No 528/2012 concerning the making available on the market and use of biocidal products
CLP	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures
'EU Biocidal product'	Biocidal products authorised in line with Article 17(1) of the BPR
'Transitional biocidal product'	Biocidal products made available on the market under national transitional measures, as per Article 89 of the BPR
'Non allowed active substance'	Active substances subjected to non-approval decisions, active substances used in wrong product types, or substances that are not identified as biocidal active substances
EEA	European Economic Area
BPRS	Forum Subgroup for exchange of information on enforcement for the BPR in the EU, Norway, Iceland, Switzerland and Liechtenstein
MS	Member State
NEA	National Enforcement Authority
SDS	Safety Data Sheet
SPC	Summary of Biocidal Products Characteristics reporting information as per Article 22(2) of the BPR. SPCs are available on ECHA website in national languages.
Advertisement	Means of promoting the sale or use of biocidal products by printed, electronic or other media (Article 3(1)(y) of the BPR)
Making available on the market	Any supply of a biocidal product or treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge (Article 3(1)(i) of the BPR).
Placing on the market	The first making available on the market of a biocidal product or treated article (Article 3(1)(j) of the BPR).
'Major deficiencies'	Non-compliances affecting the proper and safe use of biocidal products. E.g. lack of authorisations, presence of non-allowed active substances in biocidal products, severe non-compliances related to labelling/advertisement. 'Major deficiencies' usually led to the withdrawal of concerned biocidal products from the market.
'Minor deficiencies'	Less severe non-compliances than 'major deficiencies', not affecting the safe use of biocidal product. E.g. missing contact information in biocidal product documentation.

Executive summary

BEF-2 Project

The Forum Subgroup for exchange of information on enforcement of the BPR (i.e. BPRS) conducted an EU wide enforcement project on biocides during 2022 (i.e. BEF-2).
The scope of the harmonised project focused on biocidal products containing approved/non-approved active substances as made available on the EEA and Swiss markets under the BPR or according to national transitional measures.

The BEF-2 included horizontal obligations such as Article 95, advertisement, labelling and packaging of biocidal products. Sections on disinfectant products (product types 1, 2, and 4) and chemical analysis were also considered.
National inspectors autonomously selected companies, biocidal products, and active substances during their enforcement activities.

The BEF-2 aimed at raising awareness on different legal provisions of the BPR and national legislations. The objective of BEF-2 was to lead to a safer market of biocidal products and a level playing field among companies in the EU.
The findings of the enforcement project were included in the BEF-2 report, which was adopted by the BPRS and published on ECHA website in November 2023.

Key results

The National Enforcement Authorities in **29 countries** checked **3548 biocidal products**, namely 798 biocidal products defined as 'EU biocidal products' (authorised in line with Article 17 of the BPR) and 2750 'transitional biocidal products' (available under national transitional measures, as per Article 89 of the BPR).

The BEF-2 inspections generally identified a wide spectrum of non-compliances. Specifically, **18%** (652) of the inspected biocidal products presented **major non-compliances**, which were assessed to affect their proper and safe uses. Most non-compliant biocidal products were disinfectants (product type 1 and 2), insecticides (product type 18), and repellents/attractants (product type 19). Non-compliances indicated lack of authorisations, presence of non-allowed active substances[1], and severe non-compliances related to labelling and advertisement. In particular, about 60 non-allowed active substances were found in biocidal products available on the market, most commonly in product type 19.
19% (661) of the inspected biocidal products in BEF-2 were identified with **minor non-compliances**, such as suppliers' missing contact information.

Among the biocidal products inspected in the BEF-2, 1849 were disinfectants. **265 disinfectants** were assessed **with major non-compliances**. Those were mostly related to the lack of authorisations.

[1] The Working Group members of the BEF-2 defined 'non-allowed active substances' as active substances subjected to non-approval decisions, active substances used in wrong product types, or substances that are not identified as biocidal active substances.

20% of the inspected **'EU biocidal products'** in BEF-2 presented **labelling non-compliances** concerning Article 69(2) of the BPR. **18%** of **'transitional biocidal products'** showed labelling non-compliances in line with national measures.
11% of the inspected **'EU biocidal products'** presented **misleading advertisement** in respect to risks for human health, animal health, environment, and biocidal product efficacy. 8% of the inspected 'EU biocidal products' had misleading labels.

Article 95 obligations were checked for a total of 973 biocidal products, and only **4%** of those did not fulfil the concerned obligations.

Finally, authorities performed **chemical analysis** on 285 biocidal products. **25%** of the tested biocidal products presented **concentration of active substances higher or lower than the indications** provided in concerned documentations.

Main conclusions and recommendations

The BEF-2 indicated a general **high level of non-compliance with the BPR and national transitional measures.**

Critical is the situation with the **number of non-compliant biocidal products** affected by major deficiencies. Lack of authorisations, presence of non-allowed active substances, and severe non-compliances related to labelling and advertisement might affect the proper and safe use of biocidal products. National Enforcement Authorities generally considered withdrawing those biocidal products from the EU market, and in some cases criminal complaints or fines were issued. In this light, prompt actions from industry to comply with the concerned obligations are highly recommended. Regarding biocidal products identified with minor deficiencies, authorities generally delivered advice or administrative orders.

Chemical analysis of biocidal products indicated that deviations from nominal concentrations might occur. It is important that industry ensure correctness of active substance concentrations before the making available on the market of biocidal products.

Misleading labelling and advertisement showed an inadequate situation in terms of information for consumers. Targeting actions from industry's side are also in this instance highly recommended.

To conclude, authorisation processes for biocidal products, both under the BPR and national transitional measures, play an important role in ensuring a safe market and a level playing field among companies in the EU. Only when relevant hazard and risk assessments are duly performed, consumers can use safe biocidal products. **Industry** should increase their level of knowledge and awareness about the legal responsibilities in making available biocidal products on the EU market. The high number of biocidal products with deficiencies is a crucial finding of the BEF-2, and industry are key actors to ensure future improvements.

Finally, the BPRS highlighted the importance for the **Member State Competent Authorities** as main actors of the review, and the **European Commission** as the guardian of the treaties, as well as the industry as the actor responsible for information on active substances, to take appropriate actions to conclude the review programme of active substances. The current coexistence of the BPR and transitional authorisations creates unclarity and difficulties in harmonising enforcement actions in EU and results in a lack of level playing field for companies.

1. Introduction

The scope of the second harmonised enforcement project (**BEF-2**) which was held under the umbrella of the Forum Subgroup for exchange of information on enforcement of the BPR (**BPRS**) focused on biocidal products containing approved/non-approved active substances.

The project aimed to check compliance with obligations under the **Biocidal Products Regulation** (BPR) and under **national legislations** concerning the placing and making available of biocidal products on the EU market. The scope of BEF-2 was intentionally conceived as wide-ranging, allowing most National Enforcement Authorities (NEAs) to participate in the project.

BEF-2 included horizontal obligations such as Article 95, advertisement, labelling and packaging. *Ad hoc* sections on disinfectant products and chemical analysis were also considered.

The BPRS members mandated the BEF-2 Working Group (WG) with the practical execution of the BEF-2 project. The WG was composed of BPRS members and alternates, invited experts from National Enforcement Authorities/Competent Authorities, and representatives from ECHA's Harmonised Enforcement Team (HET). When needed, the WG cooperated with the European Commission (i.e. DG SANTE).

National inspectors autonomously selected companies, biocidal products, and active substances to be inspected during their enforcement activities, which took place during the operational phase of the BEF-2 (year 2022).

The WG was tasked to analyse the data and elaborate the BEF-2 project report based on the data submitted by NEAs. The BEF-2 report was adopted by the BPRS members in November 2023.

Overall, BEF-2 aimed at raising awareness on different legal provisions of the BPR and national legislations. The final objective of BEF-2 was to lead to a safer market of biocidal products and a level playing field among companies in the EU.

1.1 Legal obligations

The Biocidal Products Regulation (BPR) defines biocidal products as any substance or mixture consisting of, containing, or generating one or more active substances, with the intention of destroying, deterring, rendering harmless any harmful organism by any means other than mere physical or mechanical action[2]. Therefore, the general characteristics of biocidal products can be summarised as follows: i) containing active substances[3] (substances, mixtures, or micro-organisms); ii) having an effect that is not purely physical or mechanical; iii) having an effect against harmful organisms.

Biocidal products should not be made available on the EU market unless they are **authorised** in line with Article 17(1) of the BPR. Biocidal products containing active

[2] For legal definitions see Article 3 of the BPR.

[3] Active substance according to Article 9 of the BPR or under the review programme.

substances under the review programme[4], and not yet approved, may be made available on the market under national transitional measures (as *per* Article 89 of the BPR).

Companies placing and making biocidal products available on the EU market are responsible for their **labelling** either under the BPR or under national legislations. Generally, labels of biocidal products should include authorisation numbers[5], directions for use, and the identity of the concerned active substances. Label elements should be displayed clearly, indelibly, and should not be misleading.

Advertisement of biocidal products should always include a reference to use products safely. This information should be clearly readable in the product advertisement. Statements that lead to the underestimation of hazards of biocidal products cannot be used in advertisements.

The obligations outlined in **Article 95** of the BPR aim to ensure equal treatment of persons/legal entities placing active substances on the market and establishing a level playing field. To achieve this, ECHA publishes a list of relevant active substances and suppliers (substance and product). Since 1 September 2015, a biocidal product (consisting of, containing, or generating one or more active substances) cannot be made available on the EU market if the substance supplier or product supplier is not included in the Article 95 list (for the product types to which the product belongs).
The overview of the legal provisions covered by the scope of BEF-2 are reported in table 1. Annex 1 to the BEF-2 report includes the complete legal text.

Table 1. Legal obligations subjected to BEF-2 inspections.

BPR legal provisions	Summary
Article 3(1)	Legal definitions of active substance, biocidal product, placing on the market, making available on the market, advertisement
Article 17(1)	Authorisation requirement for biocidal products
Article 22(1) and (2)	Content of the authorisation and the Summary of Product Characteristics (SPC)
Article 55(1)	Derogation from the authorisation requirement: temporary authorisations
Article 69(1) and (2)	Classification, packaging and labelling requirements for biocidal products
Article 72	Advertisement requirements
Article 89(2)	Transitional period of the BPR: national measures may apply
Article 95(1) and (2)	The 'Article 95-list' of relevant persons bringing active substances on the EU market

[4] Annex II to Commission Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products.
[5] Authorisation number means either the number given during the authorisation procedure or the number given according to the relevant national system.

For evaluation purposes, the BEF-2 Working Group members conducted a survey among the BPRS members to better understand the situation concerning the transitional regime for obligations related to Articles 69(2) and 72 of the BPR. The following questions were raised (results reported in table 2 below):
- Is it mandatory for biocidal products available in your Member State under transitional measures to have authorisation or registration numbers reported on labels?
- Is it mandatory for biocidal products available in your Member State under transitional measures to have additional information on labels similar to Article 69(2) of the BPR (besides CLP labelling information)? (alternatively, information can be in accompanying leaflet)
- Is it mandatory for biocidal products available in your Member State under transitional measures to observe specific advertising provisions similar to Article 72 of the BPR?

Table 2. National transitional arrangements under Article 89 of the BPR (status June 2023).

Member State	Authorisation or registration number mandatory on label	Label obligations similar to Article 69(2) of the BPR	Advertising obligations similar to Article 72 of the BPR
Austria	No	Yes	Yes
Belgium	Yes	Yes	Yes
Bulgaria	Yes	Yes	Yes
Croatia	Yes	Yes	Yes
Cyprus	Yes	No	No
Czech Republic	Yes	Yes	Yes
Denmark	Partly	Yes	Yes
Estonia	Yes	Yes	Yes
Finland	Partly	Partly	Yes
France	No	Yes	Yes
Germany	Yes	Yes	Yes
Greece	Yes	Yes	Yes
Hungary	Partly	Yes	Yes
Iceland	No	No	No
Ireland	Yes	Yes	Yes
Italy	Yes	Yes	Yes
Latvia	Yes	Yes	Yes
Liechtenstein	Yes	Yes	Yes
Lithuania	Yes	Yes	Yes
Luxembourg	No	Yes	Yes
The Netherlands	Yes	Yes	Yes
Malta	No	Yes	Yes
Norway	No	No	Yes
Poland	Yes	Yes	Yes

Portugal	Yes	Yes	Yes
Romania	No	Yes	No
Slovakia	Yes	Yes	Yes
Slovenia	No	Yes	Yes
Spain	No	Yes	Yes
Sweden	Partly	Yes	Yes
Switzerland	Yes	Yes	Yes

2. BEF-2 results

The BEF-2 Working Group members elaborated four questionnaires that national inspectors used during the enforcement activities under the BEF-2 (see BEF-2 questionnaires in Annex 2). The questionnaires targeted the following biocidal products:

1) Biocidal products under **Article 17 of the BPR with authorisation numbers**

2) Biocidal products under transitional measures according to **Article 89 of the BPR with authorisation or registration numbers**

3) **Hand and surface disinfectants** belonging to product types 1, 2 and 4 (both authorised under the BPR and national transitional measures, plus specific national/European derogations)[6]

4) **Other biocidal products**, namely biocidal products without authorisation numbers under the BPR, or national transitional authorisation or registration numbers. Biocidal products reported under questionnaire four were: i) biocidal products for which national transitional authorisation systems did not require authorisations or registrations numbers (note that those biocidal products were supposedly placed on the market in line with the national legislations); ii) biocidal products that should have presented BPR authorisation numbers, or national authorisation or registration numbers (those biocidal products were certainly presenting non-compliances).

BEF-2 results are based on the analysis of the data submitted by national inspectors via the four questionnaires. Since questions were not always mandatory to answer, different numbers of biocidal products appeared when elaborating the BEF-2 statistics. For this reason, figures in the BEF-2 project report do not have the same total number of biocidal products (note that the number of biocidal products is indicated in the descriptions of the figures).

The biocidal products made available on the EU market under Article 17 and Article 89 of the BPR, are referred in the BEF-2 report as **'EU biocidal products'** and **'transitional biocidal products'**, respectively. This terminology was designed by the BEF-2 Working Group members to better describe the project findings. This terminology is not reflected in any reference of the legal text of the BPR, and it serves only for reporting purpose.

BEF-2 results are grouped into five sections:

Chapter 2.1 describing the overall results for all inspected biocidal products
Chapter 2.2 focusing on 'non-compliant biocidal products lacking authorisations'
Chapter 2.3 describing the findings for 'EU biocidal products'
Chapter 2.4 analysing 'transitional biocidal products'
Chapter 2.5 including results concerning disinfectants for product types 1, 2 and 4

[6] Note that pool chemicals and roof cleaning products were not reported under questionnaire 3, but under questionnaires 1, 2 or 4.

2.1 Overall results

The following section of the BEF-2 report focuses on the overall results for all biocidal products inspected during the operational phase of the BEF-2.

2.1.1 Participating countries and number of inspections

In BEF-2, **29 countries** reported in total **3548 inspected biocidal products** which were available on the EU market during the year 2022. Of those products, 2750 (78%) were 'transitional biocidal products' and 798 (22%) were 'EU biocidal products'. Each participating country decided how many inspections to conduct and which companies to target during the operational phase of the project.

Table 3. Number of inspected biocidal products *per* country.

Member State	Number of inspected biocidal products
Austria	44
Belgium	79
Croatia	100
Cyprus	92
Czechia	161
Denmark	5
Estonia	57
Finland	14
France	77
Germany	913
Greece	13
Hungary	21
Iceland	20
Ireland	30
Italy	15
Latvia	30
Liechtenstein	26
Lithuania	95
Luxembourg	295
The Netherlands	66
Norway	16
Poland	169
Portugal	1
Romania	670
Slovak Republic	46

Slovenia	10
Spain	254
Sweden	107
Switzerland	122
Total	**3548**

The National Enforcement Authorities had the possibility to perform inspections **on-site**, from the office (**desktop inspections**), or by **web survey**. Most inspections were performed on-site (80%).

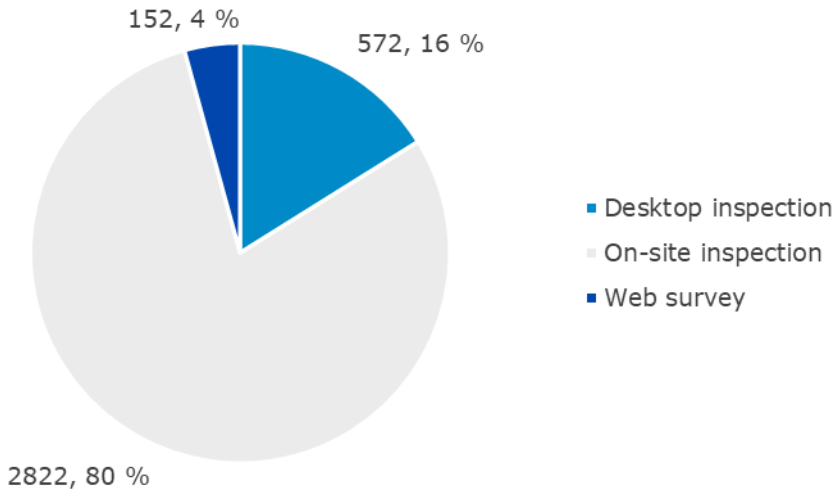


Figure 1. Type of inspections in BEF-2 (number of biocidal products=3546).

2.1.2 Distribution of product types and user categories

A biocidal product can belong to several product types. That is mainly relevant for disinfectants, preservatives, and insecticides/repellents/attractants. Those biocidal products inspected in BEF-2 often belonged to more than one product type. In this light, the total number of checked product types resulted higher than the total number of controlled biocidal products.

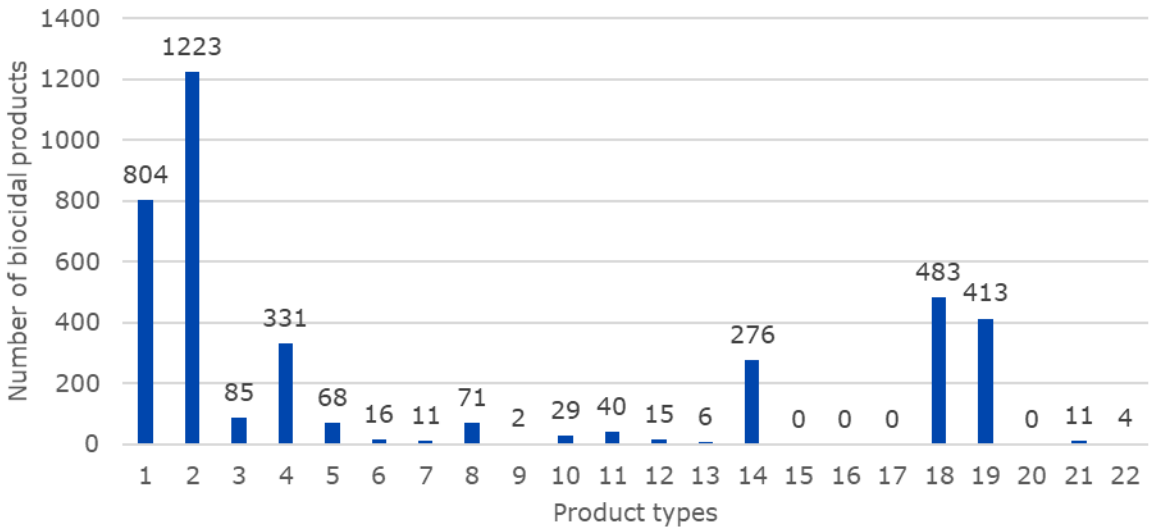


Figure 2. Distribution of product types in BEF-2 (number of biocidal products=3421). The user category identifies who uses biocidal products. For biocidal products subject to authorisations user categories must be reported. Biocidal products can be authorised for several user categories. For this reason, the total number for all user categories reported in BEF-2 is higher than the number of inspected biocidal products.

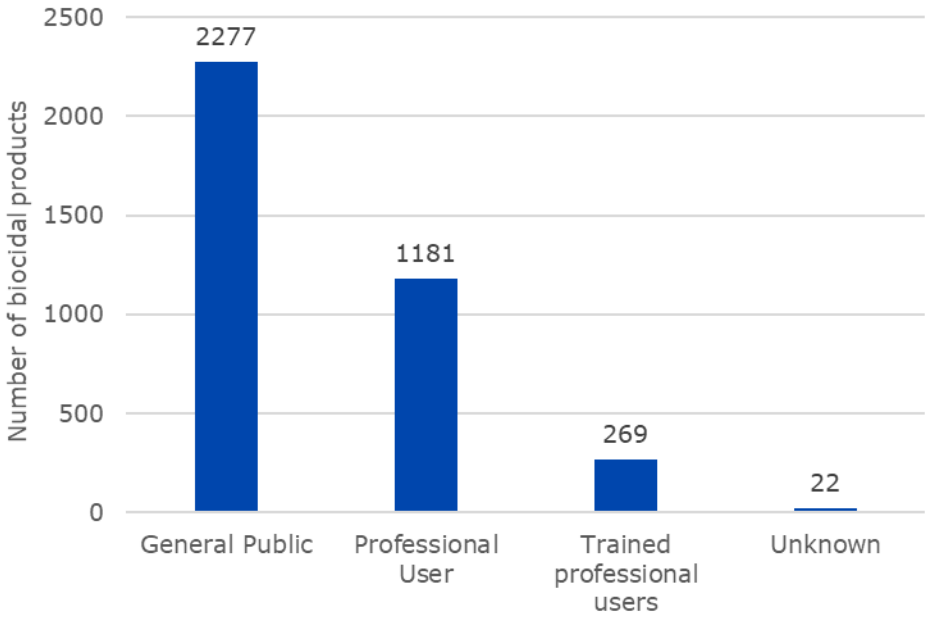


Figure 3. User category for inspected biocidal products in BEF-2 (number of biocidal products=2871)

2.1.3 Roles of companies

The target groups of the BEF-2 project were the actors involved in the supply chain of biocidal products. Participating countries identified the actors to be inspected. The majority of controlled biocidal products were sampled at distribution level. Many of the companies inspected had several roles in their supply chains. Note that authorisation holders are legally responsible for the compliance of biocidal products available on the market.

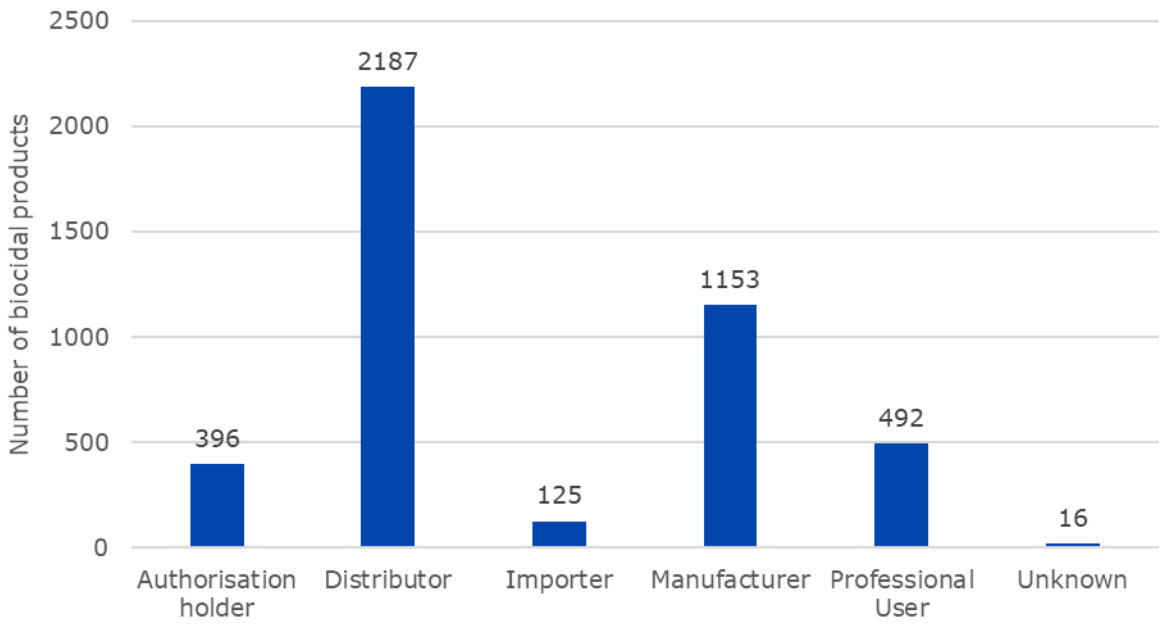


Figure 4. Roles of companies in BEF-2. Note that companies might have more than one role for inspected biocidal product (number of biocidal products=3542).

2.1.4 Active substances in biocidal products

The majority of the biocidal products inspected in BEF-2 contained only one active substance.

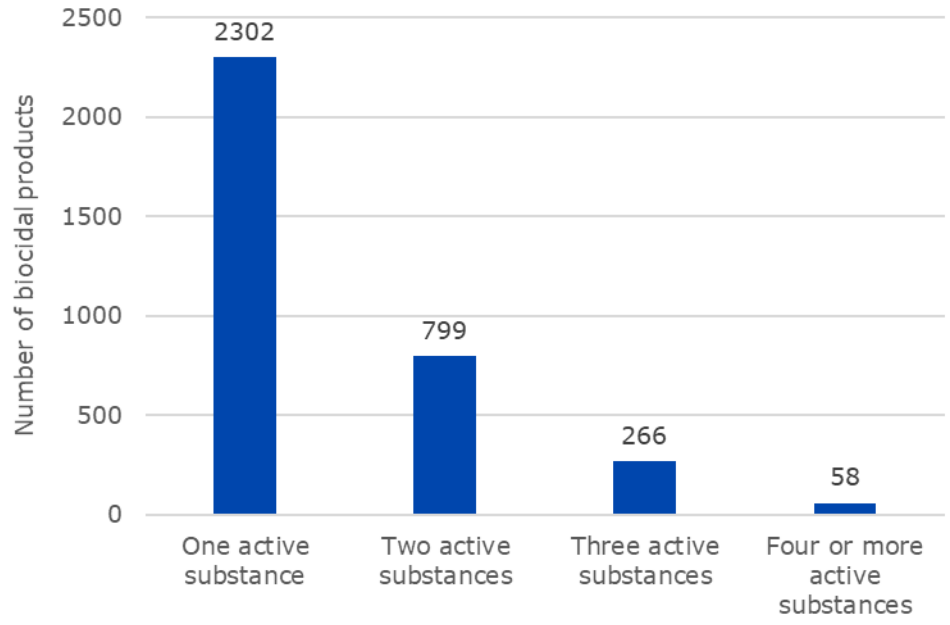


Figure 5. Number of active substances in inspected biocidal products (number of biocidal products=3425)

In total, 219 different active substances were reported in BEF-2. In addition, about 35 substances could not be identified due to a mismatch between names and CAS numbers, lack of proper identification during inspections, or reporting issues.

Table 4 reports the most common **allowed active substances** found in BEF-2 (mainly identified in disinfectants). The BEF-2 Working Group members defined 'allowed active substances' as active substances either approved under the BPR or included in the review programme in the appropriate product type.

Table 4. Most common allowed active substances found in inspected biocidal products.

Active substance	CAS	Number of inspected biocidal products
Ethanol	64-17-5	848
Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))	68424-85-1	407
Propan-2-ol	67-63-0	325
Didecyldimethylammonium chloride (DDAC)	7173-51-5	269
Active chlorine released from sodium hypochlorite	7681-52-9	214
Permethrin	52645-53-1	119
2-(2-butoxyethoxy)ethyl 6-propylpiper-onyl ether (Piperonyl butoxide/PBO)	51-03-6	97
Geraniol	106-24-1	96
Eucalyptus citriodora oil, hydrated, cyclized	1245629-80-4	94
D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine(2:1) (CHDG)	18472-51-0	91
Hydrogen peroxide	7722-84-1	89
Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18))	68391-01-5	83
2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin)	23031-36-9	81
(RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin)	52315-07-8	81

In total, about 60 **non-allowed active substances** were identified in BEF-2. The BEF-2 Working Group members defined 'non-allowed active substances' as active substances subjected to non-approval decisions, active substances used in wrong product types, or substances that are not identified as biocidal active substances.

Table 5 below reports the most common non-allowed active substances inspected in BEF-2. Note that 'not approved' refers to non-approval decisions issued by Commission (risk-based or due to missing documentation).

Some of the substances reported in table 5 were found in more than one biocidal product. It should also be noted that some of these substances may have other functions, e.g. fragrances.

Table 5. Most common non-allowed active substances found in inspected biocidal products.

Active substance	CAS	Number of biocidal products	Non-compliances
Citronella oil	8000-29-1	17	Not allowed in biocidal products as active substance[7]
(RS)-3-Allyl-2-methyl-4-oxocyclopent-2- enyl (1R,3R)-2,2-dimethyl-3-(2-methyl prop-1-enyl)-cyclopropanecarboxylate (mixture of 2 isomers 1R trans: 1R/S only 1:3) (Esbiothrin)	260359-57-7	12	Not approved for product type 18
(RS)-2-methyl-4-oxo-3-(prop-2-en-1-yl)cyclopent-2-en-1-yl (1R)-cis,trans-2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate (d-allethrin)	231937-89-6	7	Not approved for product type 18
Cymbopogon nardus oil	-	4	Not allowed in biocidal products as active substance
Rosemary essential oil	-	3	Not allowed in biocidal products as active substance
Butanone	78-93-3	2	Not allowed in biocidal products as active substance
4-chloro-3,5-xylenol	88-04-0	2	Not allowed in biocidal products as active substance

[7] The Commission Regulation (EC) No 2032/2003 provide lists of existing active substances. Identified substances listed in Annex III of the Commission Regulation may not be used in biocidal products since September 2006, while notified active substances in Annex II were included in the review programme for active substances.

2.1.5 Article 95 obligations

In total, 973 biocidal products were controlled concerning Article 95 obligations under the BPR. Only 36 products (4%) were identified as non-compliant, i.e. the product or active substance supplier was not indicated on the so-called 'Article 95 list' publicly available on ECHA website. Of those non-compliant biocidal products, 28 were 'transitional biocidal products'.

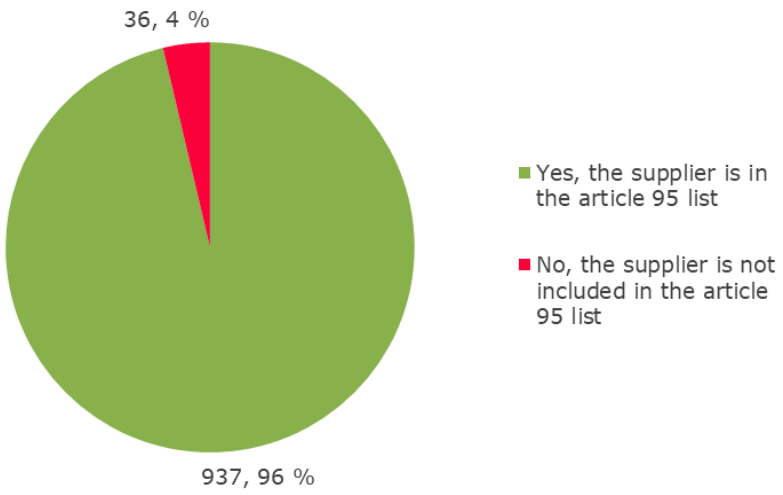


Figure 6. Article 95 obligation – list of suppliers (number of biocidal products=973)

The assessment of whether a company fulfils the Article 95 obligations was based on different types of documentation or written/verbal information presented by companies inspected in BEF-2. Figure 7 shows that in almost a third of the controls only written/verbal information presented by companies was considered. It is important to note that the nature of the written information was not specified by the National Enforcement Authorities. In 15% of the cases, the option ´other´ was chosen by national inspectors. This might include supplier information in SDS and SPC, or supplementing documentation.

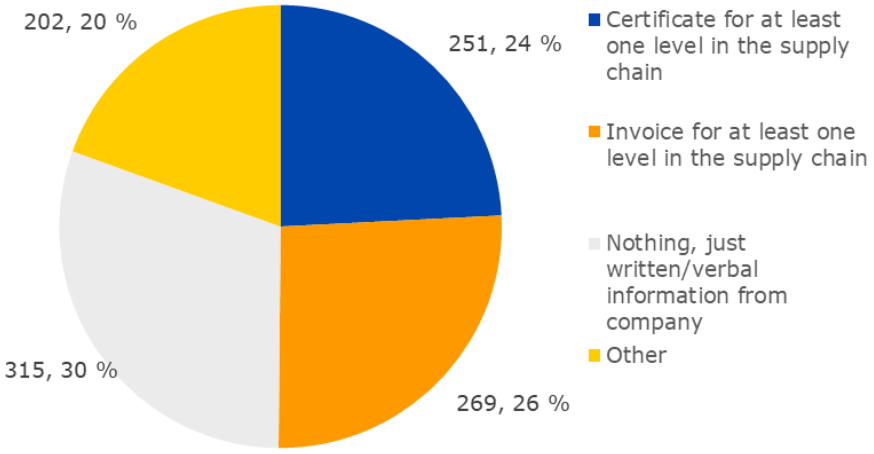


Figure 7. Article 95 documentation presented by suppliers included on the Article 95 list (number of biocidal products=932).

A certificate or an invoice are generally considered as strong evidence. Written/verbal information are considered less clear sources. In this light, the overall compliance rate of 96% reported in figure 6 might be considered overly optimistic.

2.1.6 Labelling obligations

In total, 2506 biocidal products (i.e. 501 'EU biocidal products' plus 2005 'transitional biocidal products') were controlled on national languages obligations. Only 36 products (1%) did not have labels in corresponding national languages.

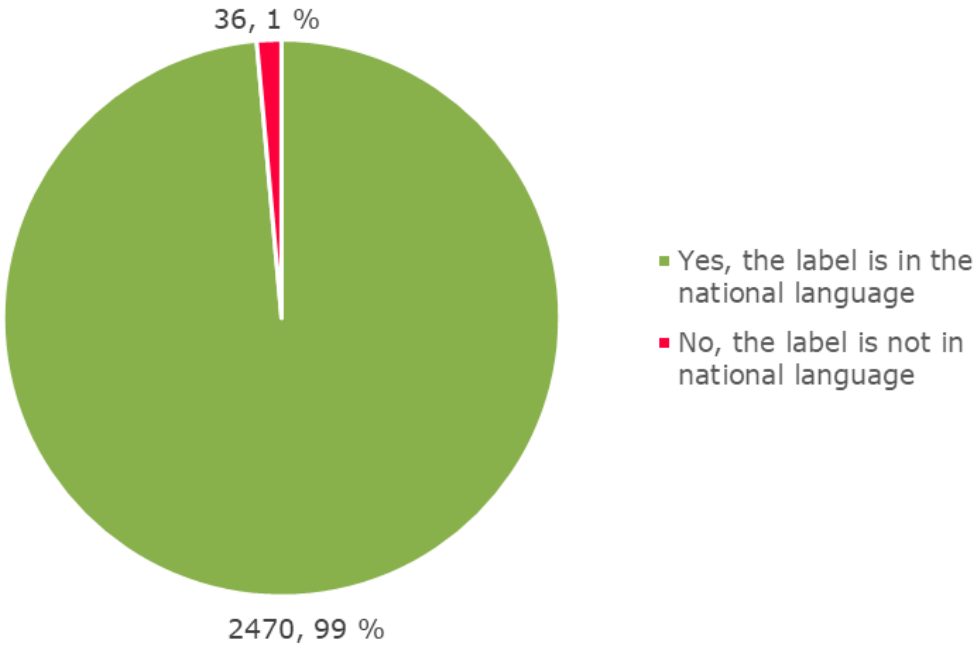


Figure 8. Labelling obligation - national languages (number of biocidal products=2506).

In total, 2463 biocidal products (464 'EU biocidal products' and 1999 'transitional biocidal products') were checked on labelling requirements, either with reference to Article 69(2) of the BPR or to the corresponding labelling requirements in national transitional measures (see table 2 for details).
Overall, 455 of those biocidal products did not fully cover labelling requirements. No relevant differences were identified in term of non-compliances between EU and transitional biocidal products.

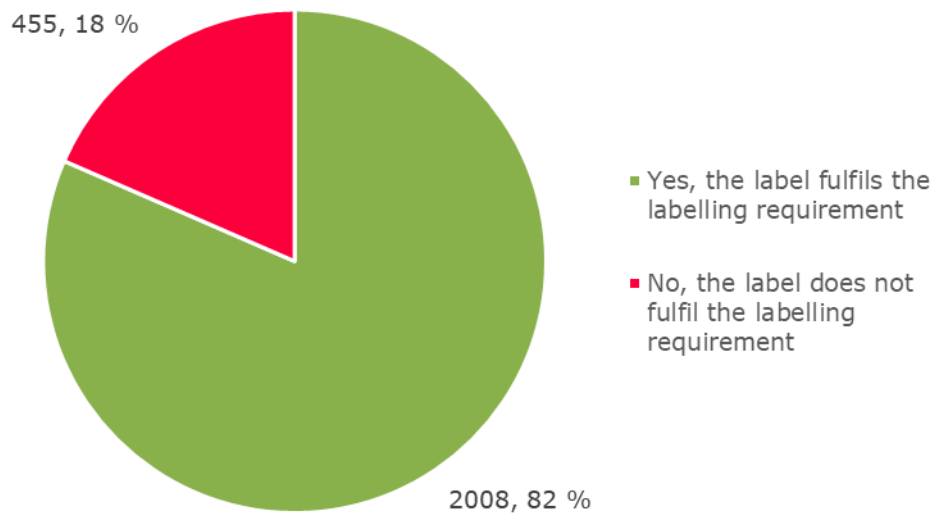


Figure 9. Labelling requirement (number of biocidal products=2463).

2.1.7 Advertisement obligations

In total, 544 biocidal products were controlled with reference to advertisement requirements (i.e. 132 'EU Biocidal products' plus 412 'transitional biocidal products' mainly reported by countries where transitional legislations were identical or similar to Article 72 BPR. See table 2 for details). In all, 42% of those controlled biocidal products were not fulfilling all advertisement requirements.

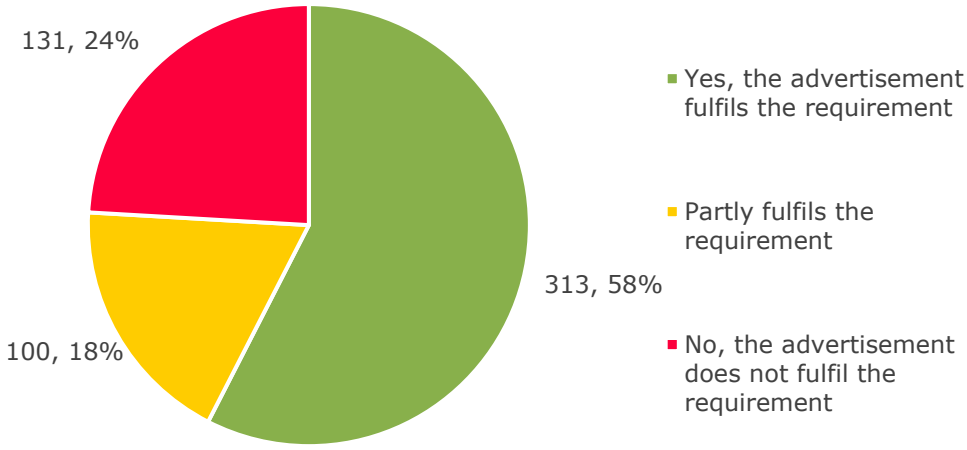


Figure 10. Advertisement obligations (number of biocidal products=544).

2.1.8 Chemical analysis

In all, 19 countries performed chemical analysis for a total of 285 biocidal products (77 'EU biocidal products' and 208 'transitional biocidal products'). The majority of the chemical analysis (56%) were performed on disinfectants in product types 1, 2 and 4. Four countries performed 75% of the chemical analysis, therefore the below data might not reflect the entire situation of the EU-EEA market.

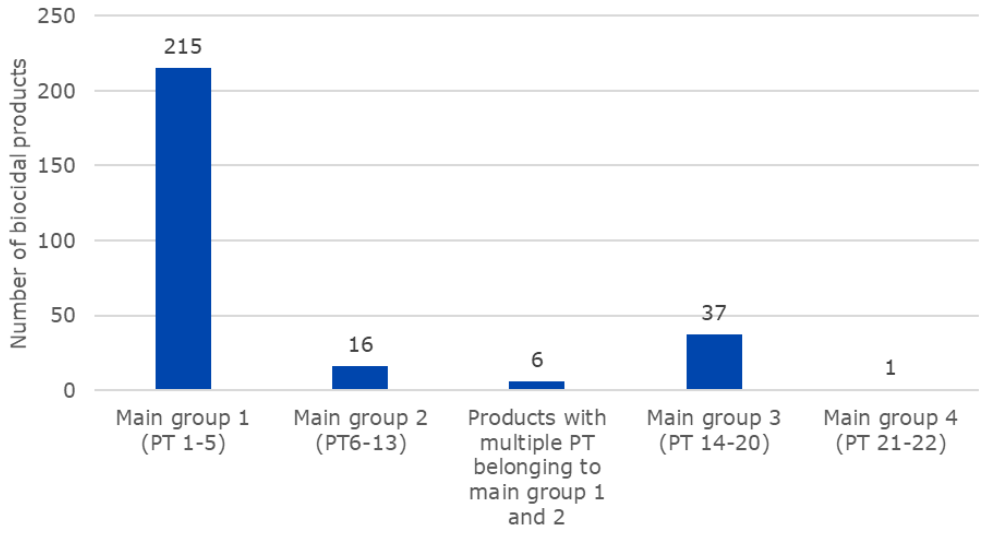


Figure 11. Number of chemical analysis *per* group of product types (number of biocidal products=285)

Figure 12 shows the relation between chemical analysis and relevant documentation. The majority of biocidal products (96%) were considered compliant, i.e. they contained the active substance stated in the documentation. In six biocidal products, active substances were not detected even though the concerned documentation mentioned their presences. Six biocidal products presented active substances that were not indicated in the documentation.

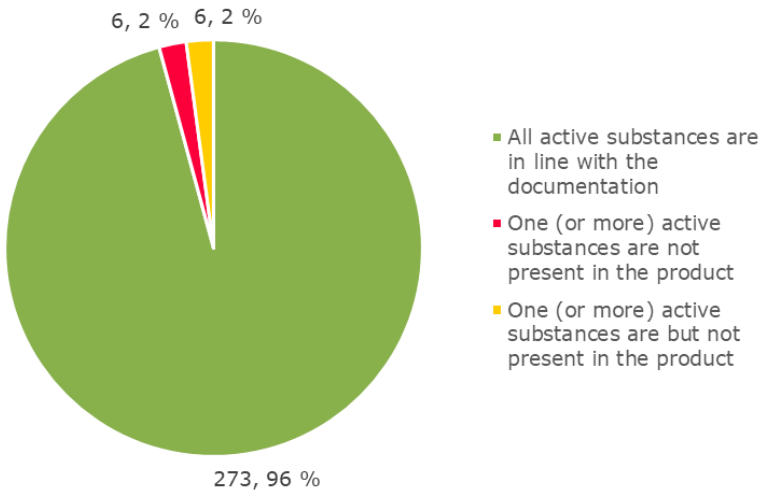


Figure 12. Number of biocidal products containing active substances as stated in SPC, national transitional authorisations, labels, safety data sheets (number of biocidal products=285)

In all, 25% of the analysed biocidal products did not contain the correct active substance concentration stated in the concerned SPC, labels, safety data sheets, or national transitional authorisations. Among those biocidal products, 4% contained higher concentration of active substances, while 21% lower concentration. The majority of biocidal products with lower concentration of active substances were biocidal products under national transitional measures. However, chemical analysis on 'EU biocidal products' showed lower concentrations of active substances compared to the indications reported in documentations for 12% of the analysed products.

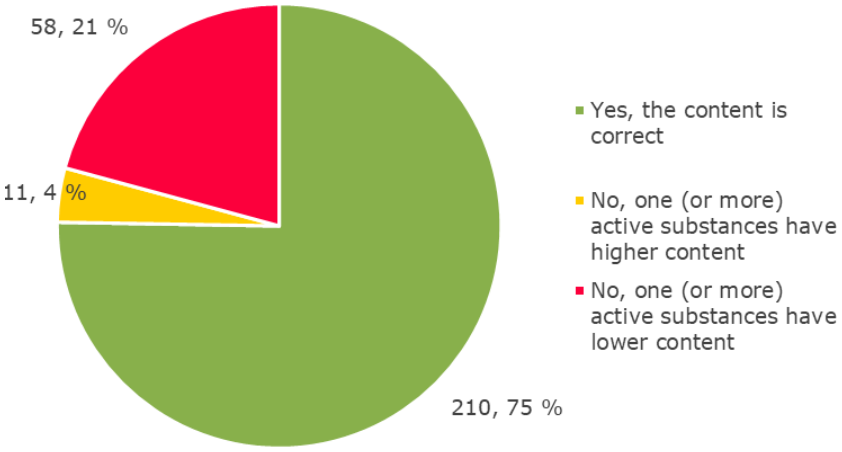


Figure 13. Correctness of active substance concentrations (within tolerance interval[8]) compared to concerned documentations (number of biocidal products=279)

[8] See table 5 of the BPR guidance: Volume I Parts A+B+C Version 2.0 May 2018

2.1.9 Non-compliant biocidal products on the market

In all, 18% of the inspected biocidal products in BEF-2 presented non-compliances that would impact on their making available on the market. This corresponded to 652 biocidal products (i.e. 212 'EU biocidal products' and 440 'transitional biocidal products'). National inspectors considered those non-compliances as '**major deficiencies**', i.e. lack of authorisations, presence of non-allowed active substances in biocidal products, and severe non-compliances mainly related to labelling and advertisement. As 'major deficiencies' affected the proper and safe use of biocidal products, National Enforcement Authorities considered withdrawing them from the market.

On the other hand, '**minor deficiencies'** identified less relevant non-compliances, e.g. missing contact information in biocidal product documentations. 'Minor deficiencies' did not usually lead to the withdrawal of concerned biocidal products from the market. In total, 661 biocidal products in BEF-2 were identified with minor deficiencies.

Figure 14 shows that 37% (i.e. 1313) of the inspected biocidal products in BEF-2 were non-compliant, presenting either major or minor deficiencies.

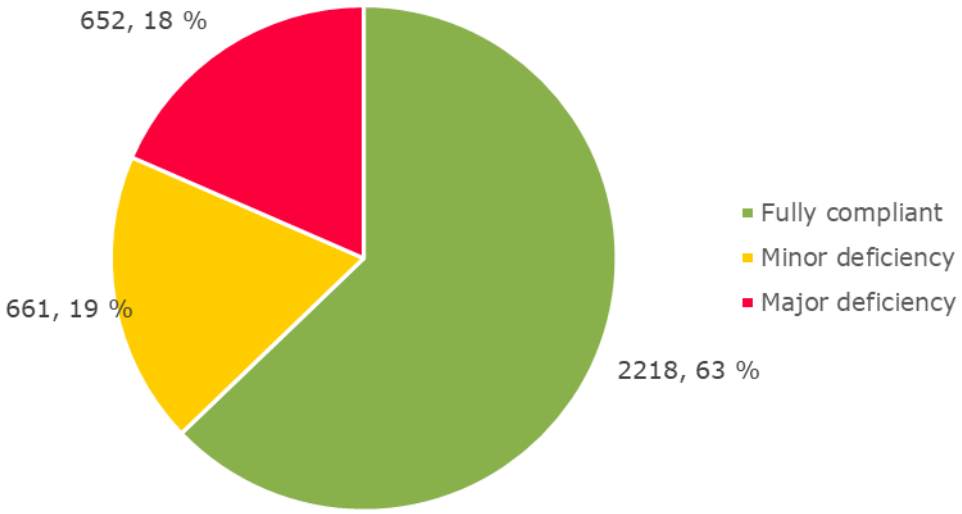


Figure 14. Overview of non-compliant biocidal products in BEF-2 (number of biocidal products=3531)

Figure 15 presents the identified non-compliances related to authorisations of EU and transitional biocidal products (disinfectants excluded). The figure shows that 79% of the biocidal products that needed authorisations according to the BPR (i.e. 'EU biocidal products') presented correct authorisations. The 'EU biocidal products' that presented non-valid authorisations according to the BPR (i.e. expired or non-valid in concerned Member States) were 16. The 'EU biocidal products' without authorisations were 121. Regarding 'transitional biocidal products', 86% presented correct authorisations or did not need authorisation according to national transitional legislations. Finally, 43 'transitional biocidal products' reported non-valid authorisations, and 105 'transitional biocidal products' did not

present authorisations (even though it was required according to national transitional legislations).

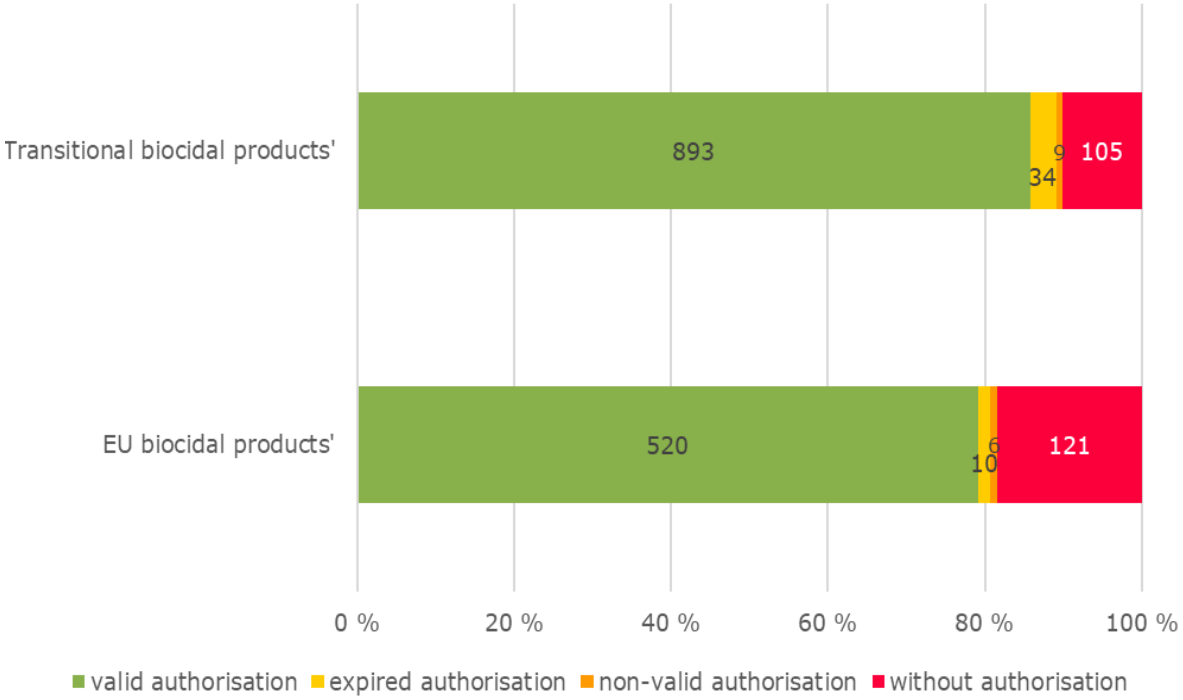


Figure 15. Non-compliances related to 'EU biocidal products' (number of biocidal products=657) and 'transitional biocidal products' (number of biocidal products=1041) concerning authorisations (disinfectants excluded).

In all, 31 'EU biocidal products' and 20 'transitional biocidal products' (disinfectants excluded) contained non-allowed active substances (either non-approved, or not allowed for concerned product types, or not identified as active substances), the majority belonging to product type 19.

2.1.10 Overview of enforcement measures for non-compliant biocidal products

In all, 2218 biocidal products inspected in BEF-2 were considered fully compliant and, consequently, no actions to concerned companies were taken by the National Enforcement Authorities. For the remaining 1320 biocidal products, different measures were imposed to inspected companies (note that more than one measure could be imposed *per* inspected biocidal product). Written advice was the most frequent measures implemented (45%).

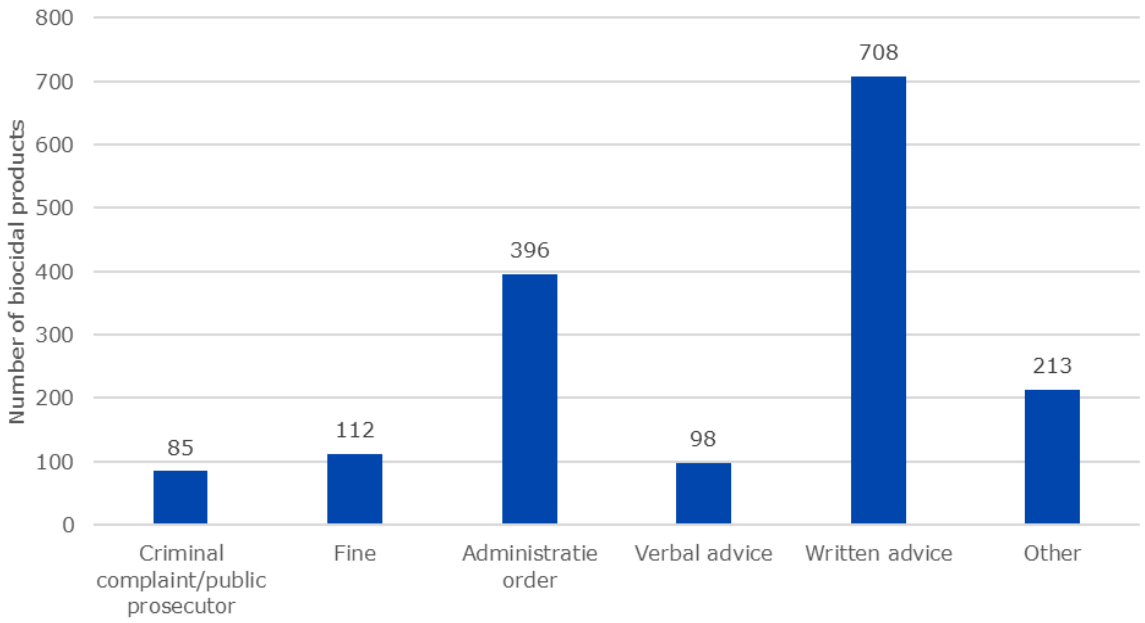


Figure 16. Actions taken by National Enforcement Authorities due to non-compliances (number of biocidal products = 1320)

2.2 Non-compliant biocidal products lacking authorisations

National inspectors reported that among the inspected biocidal products in BEF-2, 121 biocidal products were never subject to authorisation processes according to the BPR, and 105 biocidal products were not in line with the respective national transitional authorisation or registration processes (disinfectants are not considered in this statistic due to incompatibility of data). Out of those 226 non-compliant biocidal products, the biocidal products lacking proper authorisations and available for private users were 204 (i.e. so-defined as 'general public'); for 'professional users' were 23; and only three biocidal products were available for 'trained professional users'. Note that some biocidal products can have more than one user category.

2.2.2 Active substances in non-compliant biocidal products lacking authorisation

Figure 17 shows inspected biocidal products in BEF-2 in function of the active substances they contain. When analysing data, the BEF-2 Working Group members elaborated the following categories:

1) Biocidal products containing only approved active substances;
2) Biocidal products containing notified active substances that might be also approved active substance;
3) Biocidal products containing new active substances;
4) Biocidal products containing at least one active substance with non-approval decision;
5) Biocidal products containing at least one non-allowed active substance related to its product type;
6) Biocidal products containing at least one active substance which was neither notified, nor approved, nor considered as new active substance.

In this light, approximately 80% of the biocidal products lacking authorisations contained allowed active substances.
In all, 41% of the biocidal products lacking authorisations contained only approved substances (that led to authorisations according to Article 17 of the BPR).
Figure 17 shows that only 1% of the inspected biocidal products lacking authorisations in BEF-2 contained at least one active substance that was non-allowed in relation to its product type. 3.5% of the inspected biocidal products lacking authorisations included active substances with non-approval decisions, and 15% contained active substances that were neither notified, nor approved, nor classified as new active substances.

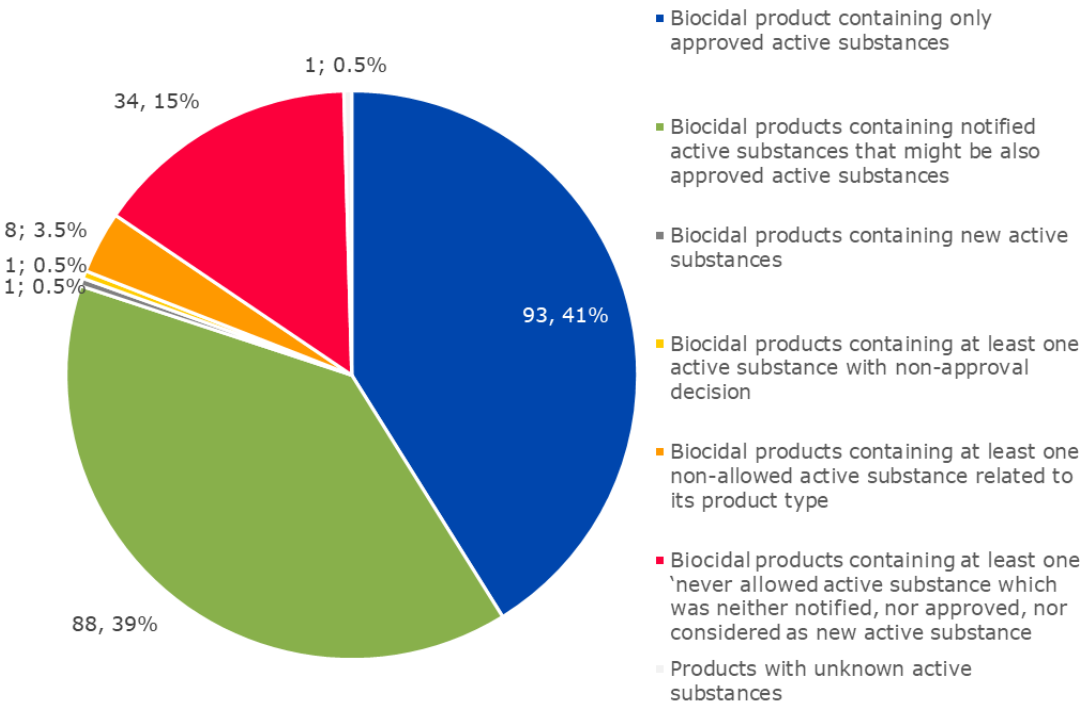


Figure 17. Distribution of biocidal products lacking authorisations in function of the active substances they contain (number of biocidal products=226)

2.2.3 Distribution of product types for non-compliant biocidal products lacking authorisations

The majority of the biocidal products lacking authorisations belonged to product types 2, 18 and 19. Those biocidal products were frequently intended for used by the general public. Note that in figure 18 biocidal products can belong to more than one product type.

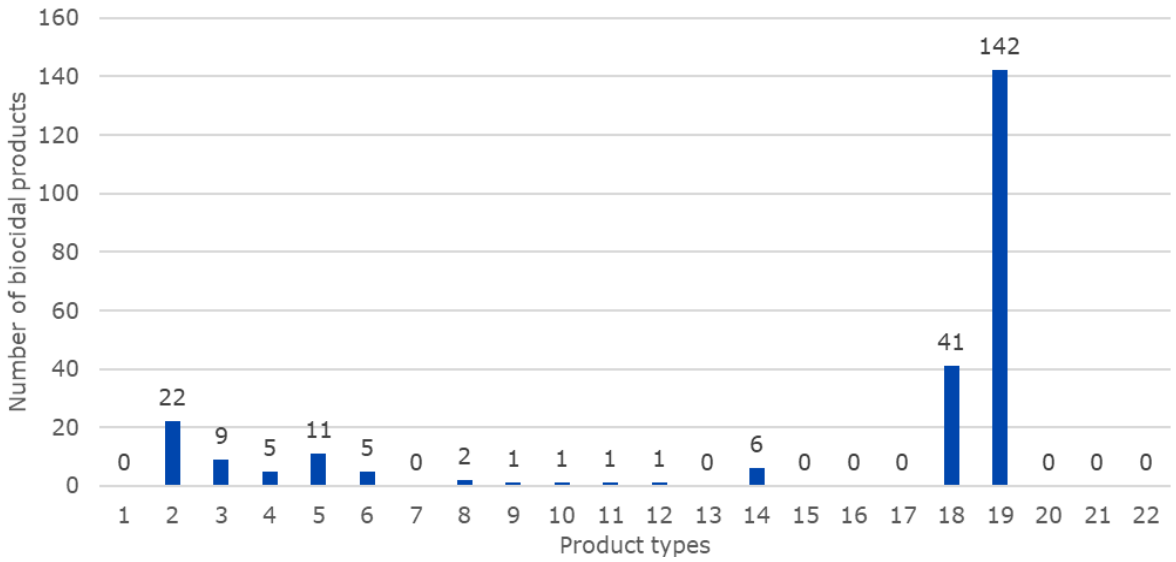


Figure 18. Distribution of product types for non-compliant biocidal products (number of biocidal products=226)

2.2.4 Active substances in biocidal products of product type 2, 18, 19 lacking authorisations

A total of 22 biocidal products of **product type 2**, did not have authorisation according to the BPR, or did not present national transitional authorisations or registrations. Only two non-compliant biocidal products of product type 2 contained non-allowed active substances that were neither notified, nor approved, nor considered as new active substances. Those two substances were: fluconazole (CAS 86386-73-4), and sodium hydroxide (CAS 1310-73-2).

A total of 41 biocidal products belonging to **product type 18** did not have authorisations according to the BPR or did not present national transitional authorisations or registrations. Four non-compliant biocidal products contained active substances with non-approval decisions (see more details in table 7). Two biocidal products contained two non-allowed active substances which were neither notified, nor approved, nor considered as new active substances. Those substances were: artemisia absinthium (CAS 84929-19-1) and unknown substance. The remaining 35 biocidal products contained approved active substances, notified active substances, or a mix of both.

Table 7. Active substances with non-approval decisions in biocidal products of product type 18 lacking authorisations.

Active substance name	CAS	Commission decision
(S)-3-allyl-2-methyl-4- oxocyclopent-2-enyl(1R,3R)-2,2- dimethyl-3-(2-methylprop-1-enyl)- cyclopropanecarboxylate (only 1R trans, 1S isomer) / S-Bioallethrin	28434-00-6	2007/565/EC
(RS)-3-Allyl-2-methyl-4-oxocyclopent-2-enyl (1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate	260359-57-7	EU 2021/98

(mixture of 2 isomers 1R trans: 1R/S only 1:3) / Esbiothrin		
Propoxur	114-26-1	2009/324/EC
Boric acid	10043-35-3	2008/681/EC

In all, 142 biocidal products belonging to **product type 19** did not have authorisations according to the BPR or did not present national transitional authorisations or registrations. The biocidal products containing only approved active substances were 44 (mainly for the general public and distributors). Only two biocidal products contained substances with non-approval decisions. Those substances are indicated in table 8.

Table 8. Active substances with non-approval decisions for biocidal products of product type 19 lacking authorisations.

Active substance name	CAS	Commission decision
2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether / Piperonyl butoxide / PBO	51-03-6	2008/681/EC
Melaleuca alternifolia, ext./Australian Tea Tree Oil	85085-48-9	2007/565/EC

A total of 28 biocidal products presented, at least, one non-allowed active substance, which was neither notified, nor approved, nor considered as new active substance. The three most frequent substances are reported in table 9.

Table 9. Non-allowed active substances neither notified, nor approved, nor considered new active substances, as found in biocidal products of product type 19 lacking authorisations.

Active substance name	CAS	Number of biocidal products lacking authorisations containing non-allowed active substances
Citronella oil	8000-29-2	17
Cedarwood oil	8000-27-9	2
Rosemary oil	-	2

2.2.5 Actions taken on biocidal products lacking authorisations

When enforcing biocidal products lacking authorisations, National Enforcement Authorities mainly issued administrative orders/injunctions (128 cases), criminal complaints/public prosecutors (63 cases), and written advice (59 cases).
Other actions reported in BEF-2 generally consisted in removing biocidal products from online platforms, and custom blocks.
In figure 19 'no action' refers to five cases when active substances were approved before 2020, and companies timely submitted applications under BPR, but the granting of

authorisations was still pending at the time of the enforcement visits[9]. Note that more than one measure could be imposed *per* non-compliant biocidal product.

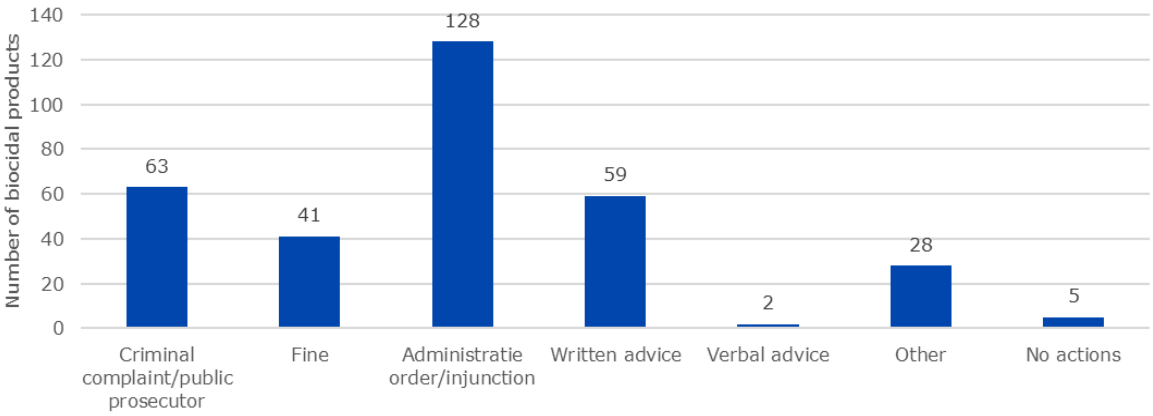


Figure 19. Actions taken when enforcing biocidal products lacking authorisations (number of biocidal products=226).

[9] Article 89(3) of the BPR states the following: [..] Member States shall ensure that authorisations for biocidal products are granted within three years of the date of active substance approval [..].

2.3 'EU biocidal products'

This section of the BEF-2 includes results concerning biocidal products that at the time of inspections were available on the market according to **Article 17 of the BPR** (so-defined by the BEF-2 Working Group members as 'EU biocidal products'). In total, 798 'EU biocidal products' were inspected in BEF-2.
In this section of the report, biocidal products containing substances not defined as active substances were also included (national inspectors initially considered those biocidal products as 'EU biocidal products'. For details see Annex 2, in particular the decision tree for inspections).

2.3.1 Labelling obligations

Only three 'EU biocidal products' did not present labels in the correct national languages.

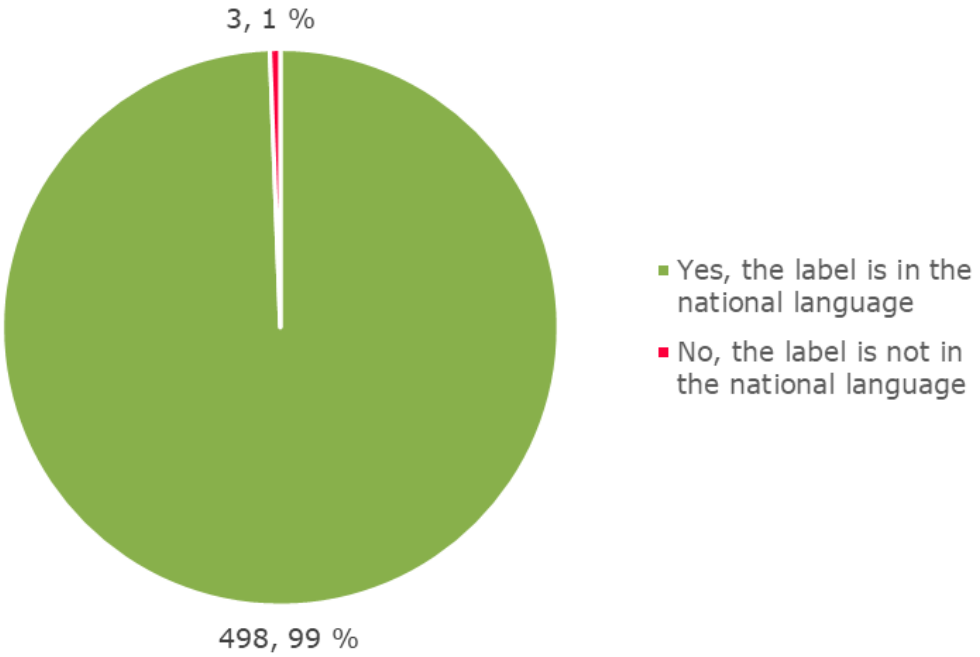


Figure 20. Labels in national languages (number of biocidal products=501)

Figure 21 shows that 5% of the labels checked on 'EU biocidal products' did not correspond to the concerned CLP classification stated in the SPC.

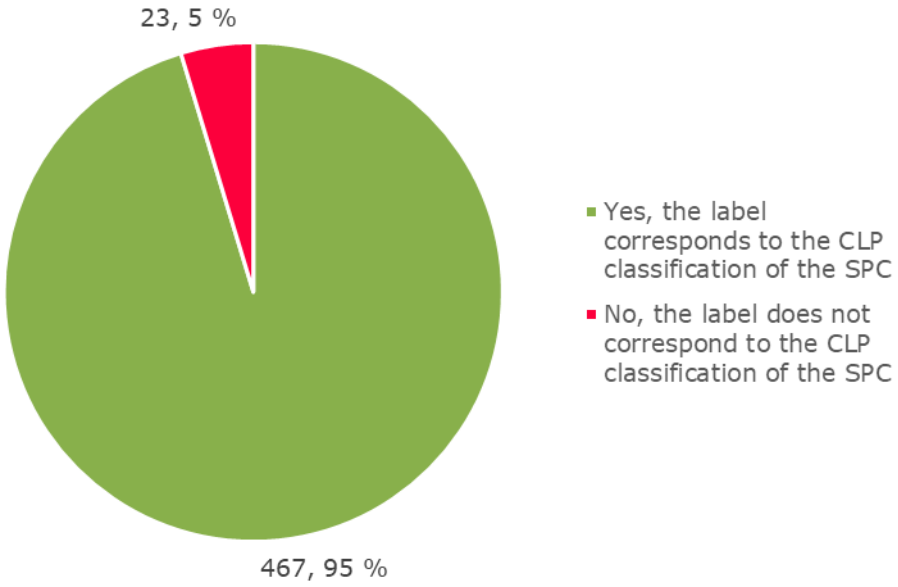


Figure 21. Labels in line with CLP classification as *per* SPC (number of biocidal products=490)

Figure 22 shows that the labels of 80% of the inspected 'EU biocidal products' reported all mandatory points concerning Article 69(2) from letter (a) to (o) of the BPR.

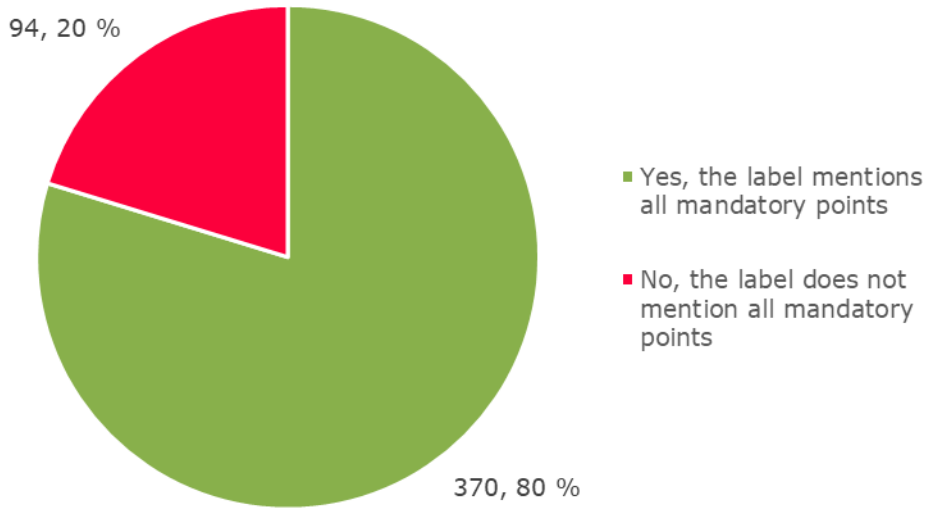


Figure 22. Labelling obligations - Article 69(2) of the BPR (number of biocidal products=464)

Regarding the labels of 'EU biocidal products' that did not present all mandatory points of Article 69(2) (i.e. 94 inspected biocidal products), the following results (together with figure 23) outline which points were missing on labels:

- Article 69(2)(c) Authorisation number (23 cases)
- Article 69(1)(d) Information on authorisation holder (24 cases)

- Article 69(1)(g) Directions for use (24 cases)
- Article 69(1)(h) Side effects and first aid (26 cases)
- Article 69(1)(l) Instruction for use (28 cases)
- Article 69(1)(n) Danger to the environment and non-target organisms (24 cases)

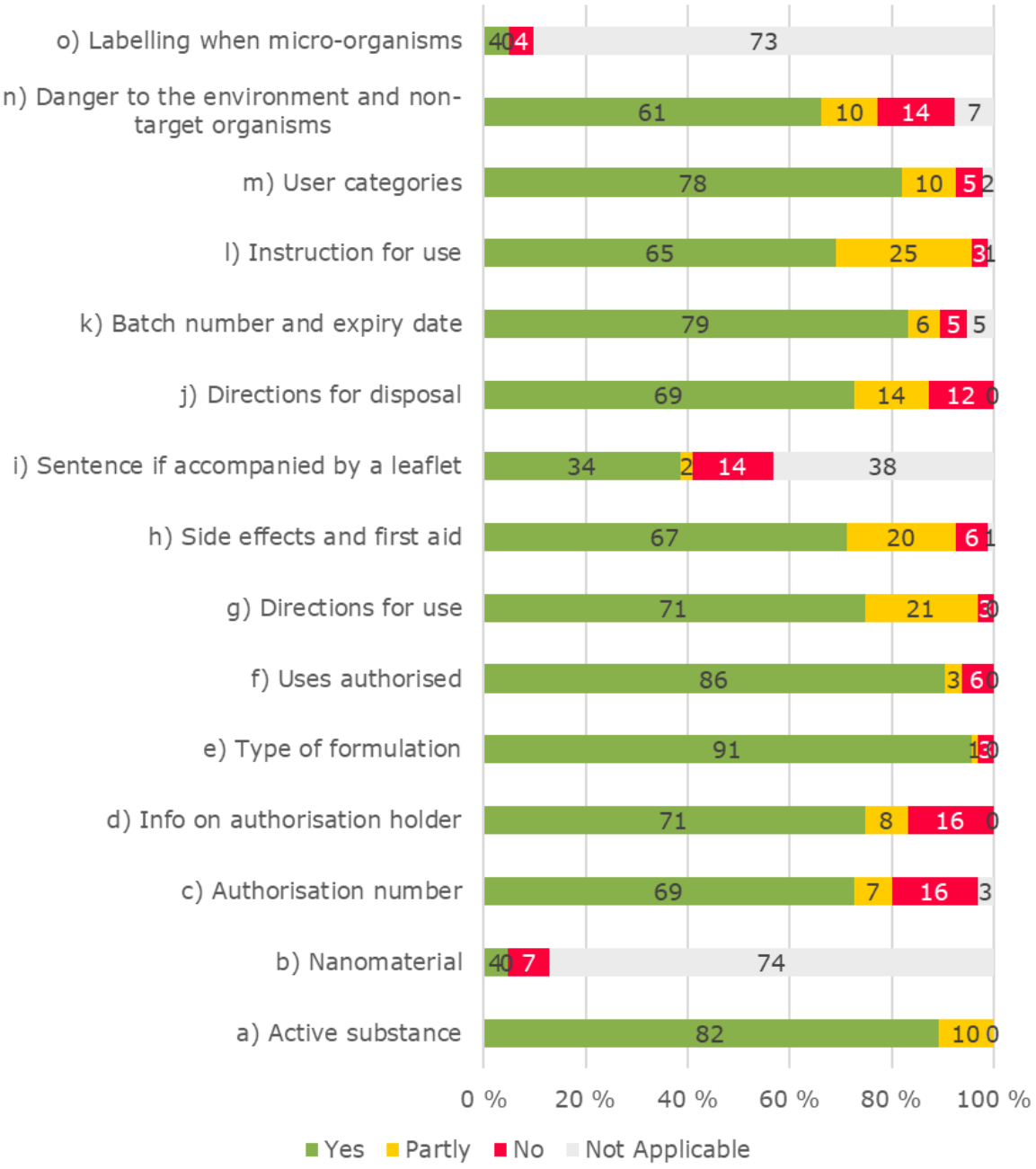


Figure 23. Labelling compliance with reference to Article 69(2) of the BPR. Bars shows specific number of biocidal products (number of biocidal products=171)

According to Article 69(2) of the BPR, labels of 'EU biocidal products' should not be misleading in respect of risks to human health, animal health or the environment; and biocidal product efficacy. Moreover, labels should not mention 'low-risk biocidal products', 'non-toxic', 'harmless', 'environmentally friendly, 'animal friendly' or any similar indications. Figure 24 shows that 8% of the inspected 'EU biocidal products' presented misleading labels.

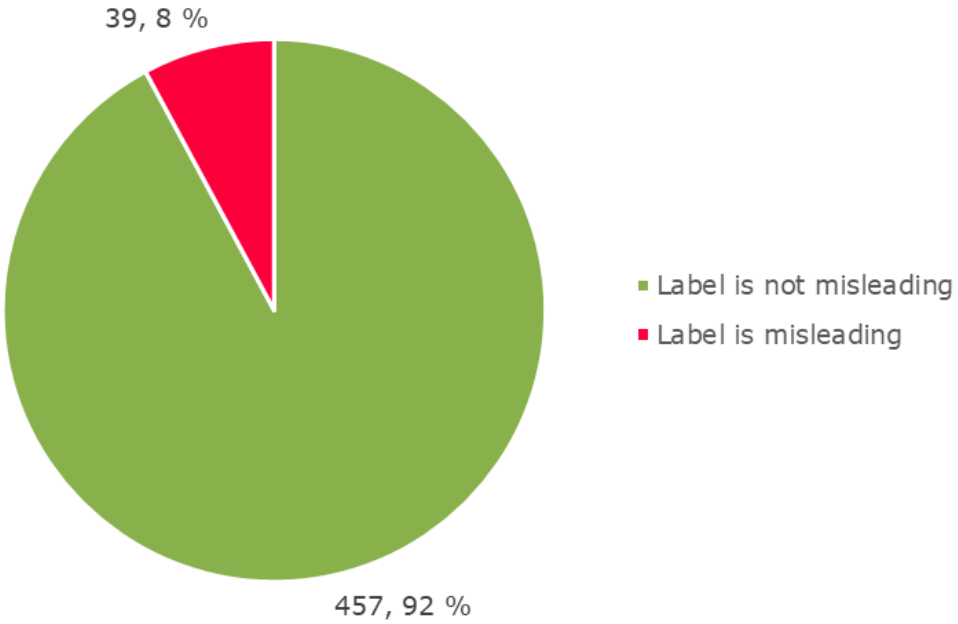


Figure 24. Misleading labels according to Article 69(2) of the BPR (number of biocidal products=496)

In all, 2% of the inspected 'EU biocidal products' did not correspond to the packaging indication as stated in their SPC.

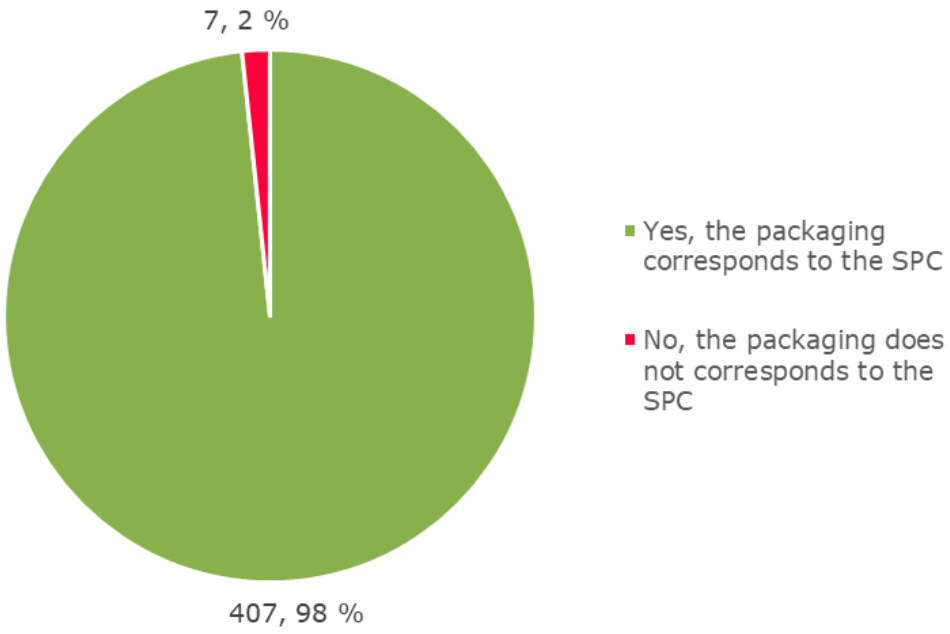


Figure 25. Packaging obligation according to SPC (number of biocidal products=414)

2.3.2 Advertisement obligations

Inspected 'EU biocidal products' should comply with Article 72 of the BPR. Namely, advertisements of biocidal products should report the following obligatory phrase: 'Use

biocides safely. Always read the label and product information before use'. That sentence should be clearly distinguishable.

Figure 26 shows that 39% of the inspected 'EU biocidal products' did not comply with the Article 72 provisions.

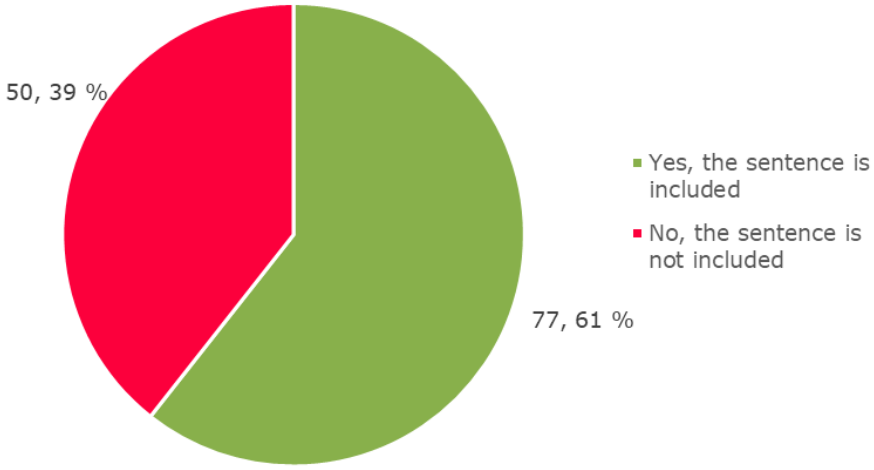


Figure 26. Advertisement obligations - Obligatory phrase 'Use biocides safely. Always read the label and product information before use' (number of biocidal products=127).

Figure 27 shows that 5% of the inspected 'EU biocidal products' did not have the sentence 'Use biocides safely. Always read the label and product information before use' clearly distinguishable in their advertisement

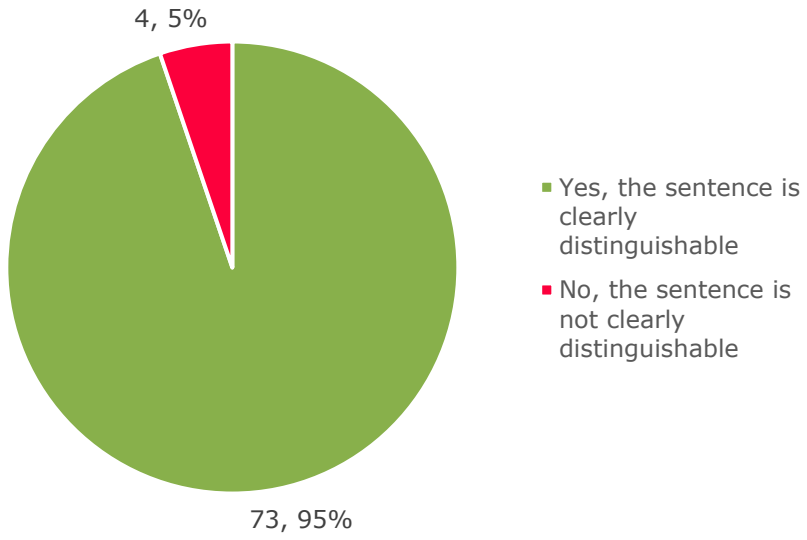


Figure 27. Advertisement obligations - Obligatory phrase 'Use biocides safely. Always read the label and product information before use' clearly distinguishable on labels (number of biocidal products=77)

Article 72(3) of the BPR states that advertisements should not be misleading in respect to human health, animal and environment health, or the efficacy of the biocidal product. Therefore, advertisement should not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indications. Figure 28 reports the level of compliance with reference to Article 72(3).

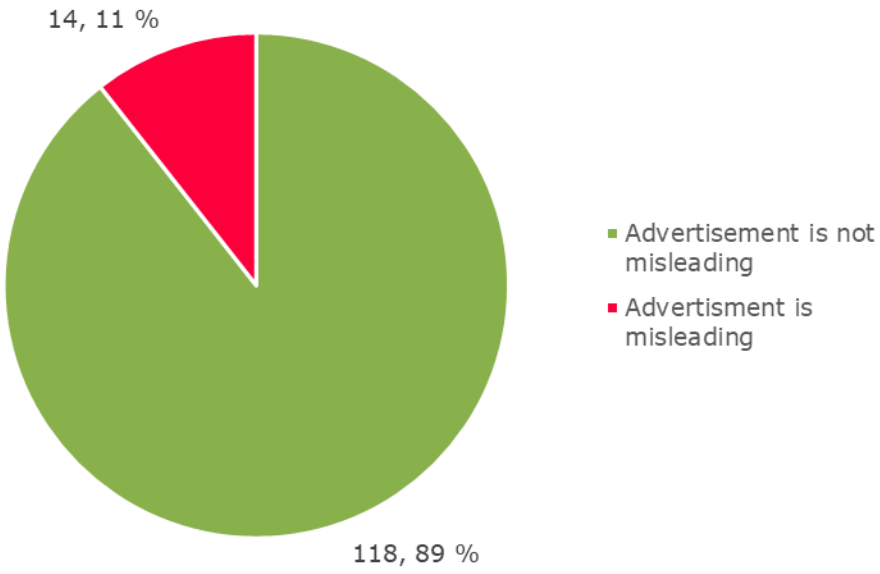


Figure 28. Misleading advertisement according to Article 72(3) of the BPR (number of biocidal products=132)

Figure 29 shows the overall situation with the advertisement provisions of the BPR concerning the inspected 'EU biocidal products'.

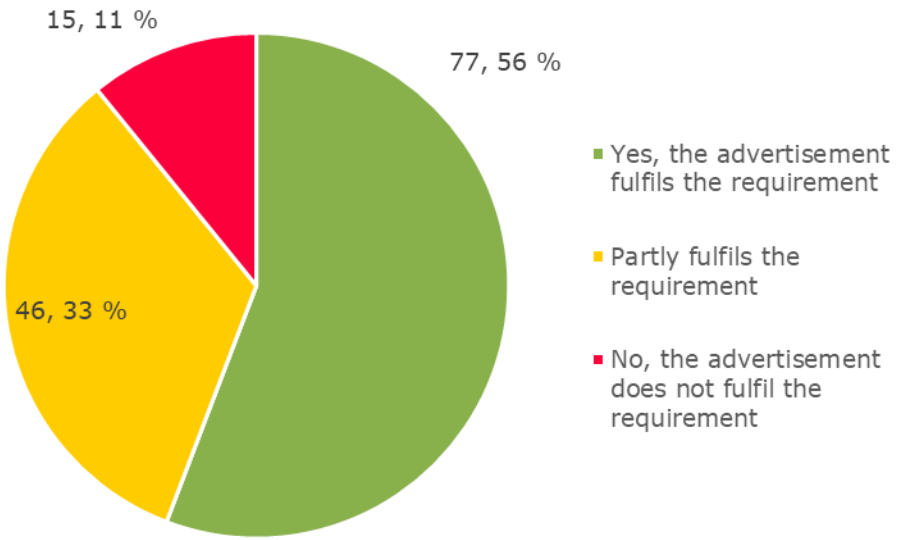


Figure 29. Advertising obligations – overall results for 'EU biocidal products' (number of biocidal products=132)

Finally, figure 30 shows that national inspectors mainly controlled advertisement of 'EU biocidal products' online. In some circumstances company product catalogues were taken into account.

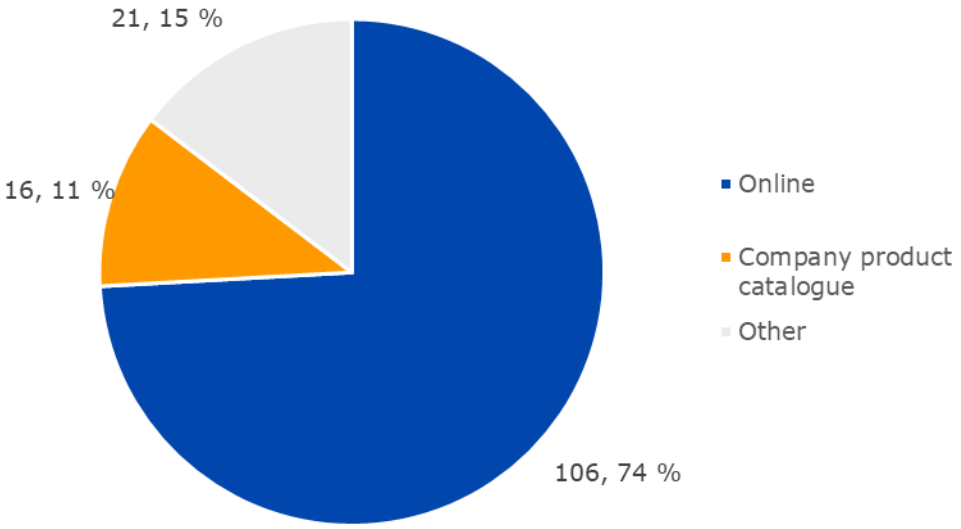


Figure 30. Source of advertisement for 'EU biocidal products' (number of biocidal products=132)

2.4 'Transitional biocidal products'

This section of the BEF-2 report focuses on what the BEF-2 Working Group members defined as 'transitional biocidal products', i.e. biocidal products that at the time of BEF-2 inspections were made available on the national market under transitional measures according to Article 89 of the BPR.
In total, 2750 'transitional biocidal products' were inspected during the operational phase of the BEF-2.
The transitional measures in place in the countries participating to the BEF-2 applied in different modalities (see also table 2):
- 18 countries require authorisations or registration numbers on labels for all transitional biocidal products/product types (national transitional authorisations or registrations). 13 countries do not require authorisations or registration numbers on labels at least for some specific product types.
- 27 countries require labelling obligations for transitional biocidal products in line with Article 69(2) of the BPR (or similar). Four countries do not require labelling obligations in line with Article 69(2).
- 28 countries apply advertisement requirements for transitional biocidal products according to Article 72 of the BPR (or similar). Three countries do not apply advertisement requirements in line with Article 72.

The BEF-2 Working Group members took into account those differences when analysing the BEF-2 enforcement results.

2.4.1 Labelling obligations

The majority of the inspected 'transitional biocidal products' fulfilled the related national labelling requirements. In all, 18% of inspected 'transitional biocidal products' were not (or partly) compliant.

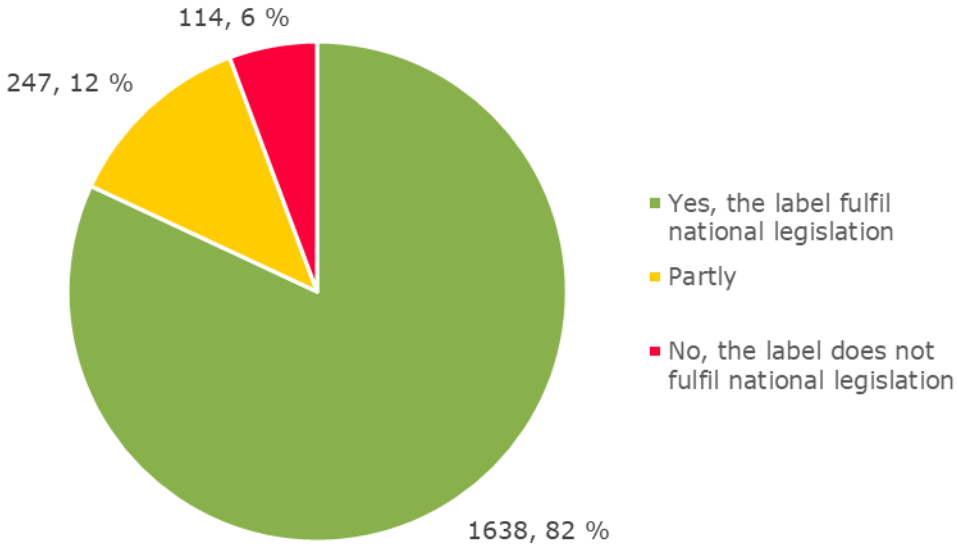


Figure 31. Labelling obligations according to national legislations (number of biocidal products=1999)

Only 2% of the inspected 'transitional biocidal products' presented labels that were not in the correct national languages.

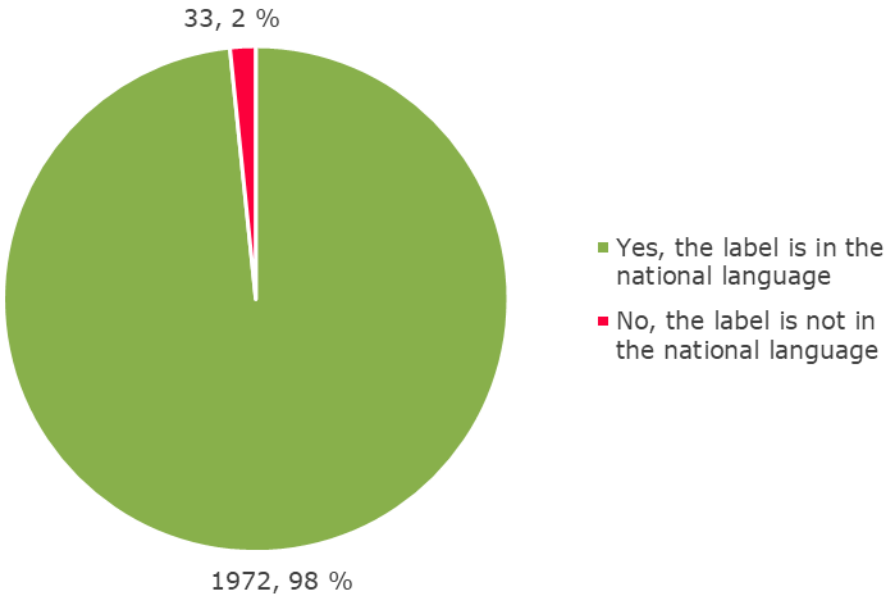


Figure 32. Label in national languages (number of biocidal products=2005)

2.4.2 Advertisement obligations

In all, 25% of the 'transitional biocidal products' presented non-compliances concerning advertisements.

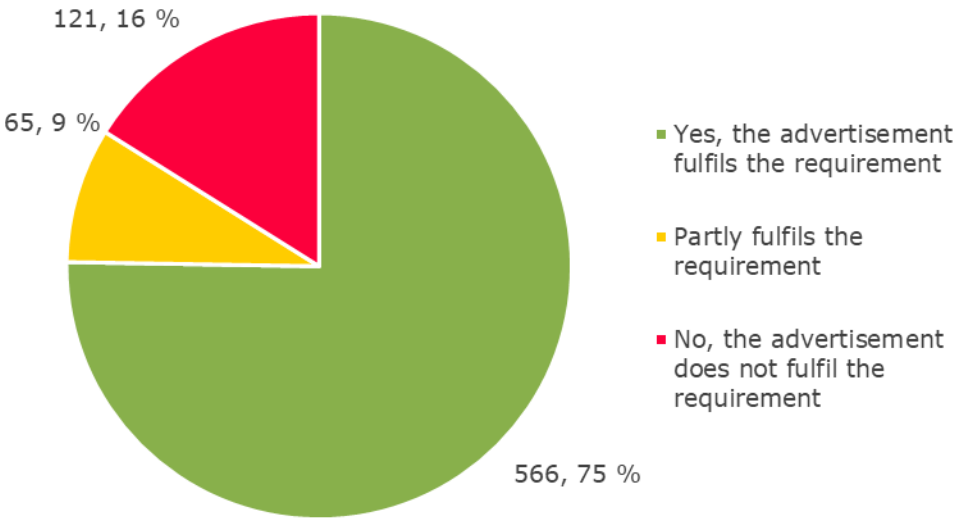


Figure 33. Advertising obligations – overall results for 'transitional biocidal products' (number of biocidal products=752)

National Enforcement Authorities reported to have used multiple sources when controlling advertisement of 'transitional biocidal products'.

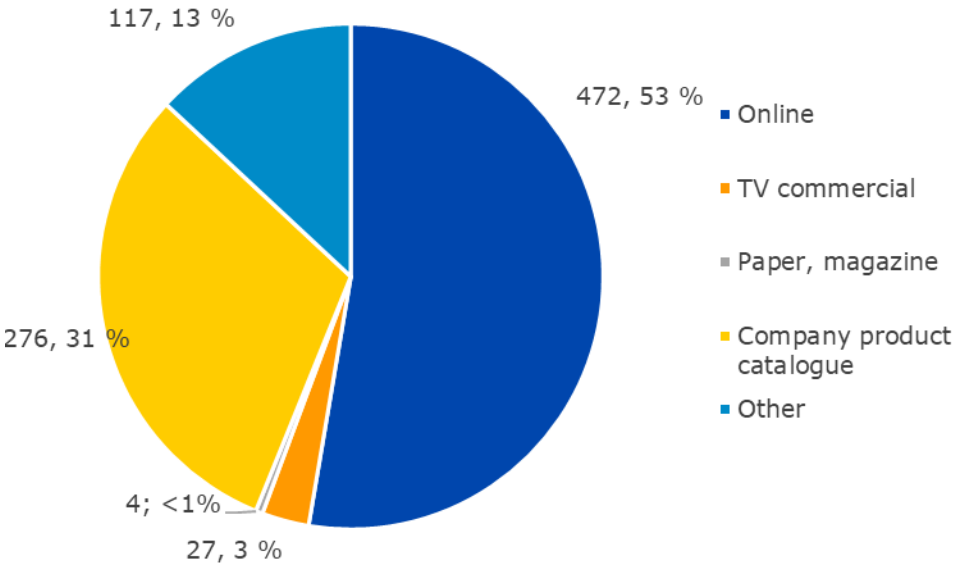


Figure 34. Source of advertisement for inspected 'transitional biocidal products' (number of biocidal products=752)

2.5 Disinfectants

This section of the BEF-2 report focuses on disinfectants. In the below analysis disinfectants belong to product types 1, 2 (algicides not included) and 4.
National inspectors controlled disinfectants made available on the market either as 'EU biocidal products' (under Article 17 of the BPR) or 'transitional biocidal products' (under national transitional regimes as *per* Article 89 of the BPR).
In total, 1849 disinfectants were inspected in BEF-2, namely 141 'EU biocidal products' and 1708 'transitional biocidal products'.

It is important to note that disinfectants were inspected shortly after the COVID-19 pandemic. The presence on the market of non-compliant disinfectants might be attributable to biocidal products made available on the market at early stages of the pandemic, where (new) manufacturers started producing, on short notice, (new) biocidal products. Often those disinfectants were indeed not fully compliant.

Overall, 91% of inspected disinfectants were compliant with the BPR or national transitional measures. The provision controlled by national inspectors focused on valid authorisations (Figure 35). Among the compliant disinfectants, the BEF-2 Working Group members also included disinfectants available on the market in countries whose national transitional legislations did not require any authorisation for disinfectants.

In all, 60 disinfectants had been granted temporary permits, and 125 disinfectants contained approved active substances with related authorisation applications duly submitted to authorities (there were also cases of biocidal products available on the market within the 180-day phase-out period according to Article 52 of the BPR).

A total of 160 disinfectants (i.e. 35 'EU biocidal products' and 125 'transitional biocidal products') were non-compliant mainly due to the lack of authorisations either according to Article 17 of the BPR or according to national legislations (those biocidal products mainly contained ethanol).

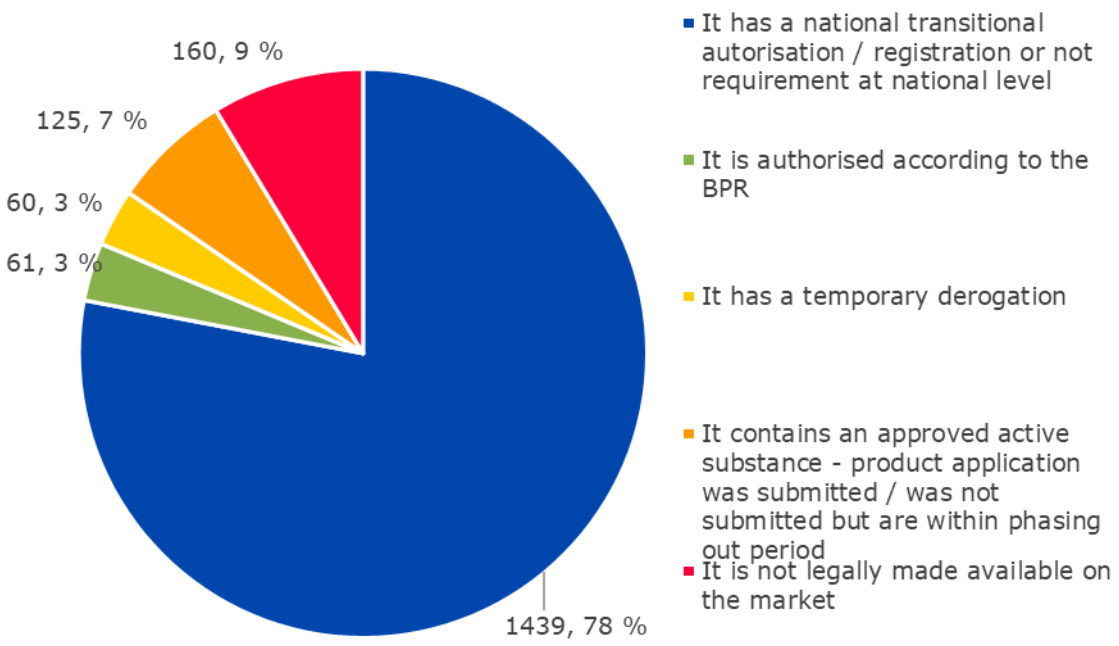


Figure 35. Overall compliances / non-compliances for inspected disinfectants based on allowed active substances and valid authorisations (labelling and advertisement are not considered in this figure) (number of biocidal products=1845)

In all, 265 disinfectants (35 'EU biocidal products' and 230 'transitional biocidal products') were considered to have 'major deficiencies' when also other non-compliances in labelling and advertisement were considered. Major deficiencies affected the proper and safe use of biocidal products, and usually led to the withdrawal of the disinfectants from the market.

Note that information on advertisement compliance for disinfectants are reflected in the overall results of the BEF-2.

2.5.1 Active substances

In total, 80 different active substances were reported for inspected disinfectants. Some were non-allowed active substances, while others were not approved for the use in biocidal products of product type 1, 2 or 4.
The most common active substance in disinfectants was ethanol.

Table 10. Most common allowed active substances found in inspected disinfectants.

Active substance	CAS	Number of inspected disinfectants
Ethanol	64-17-5	840
Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))	68424-85-1	348
Propan-2-ol	67-63-0	315

Didecyldimethylammonium chloride(DDAC)	7173-51-5	239
Active chlorine released from sodium hypochlorite	7681-52-9	135
D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine(2:1) (CHDG)	18472-51-0	87
Hydrogen peroxide	7722-84-1	76
Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18))	68391-01-5	76
Propan-1-ol	71-23-8	56
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine)	2372-82-9	51

14 different substances were identified as non-allowed for use in disinfectants and are presented in table 11.

Table 11. Non-allowed active substances/not approved found in inspected disinfectants for the use in product type 1, 2, and 4.

Active substance	CAS	Number of inspected disinfectants
Sodium hydroxide	1310-73-2	3
Butanone	78-93-3	2
4-chloro-3,5-xylenol	88-04-0	2
Geraniol[10]	106-24-1	1
Probiotica	-	1
Cyclohexane	110-82-7	1
Clorophene (Chlorophene)	120-32-1	1
Decan-1-ol, ethoxylated	26183-52-8	1
2-octyl-2H-isothiazol-3-one (OIT)	26530-20-1	1
Isotridecanol, ethoxylated	69011-36-5	1
Copper	7440-50-8	1
2-methylpropan-1-ol	78-83-1	1
Terpineol	8000-41-7	1
Poly(hexamethylenbiguanid)-hydrochlorid	91403-50-8	1

[10] Note that Geraniol might be present in disinfectants as fragrance.

2.5.2 Labelling obligations

In all, 28 disinfectants did not present labels in the correct national languages.

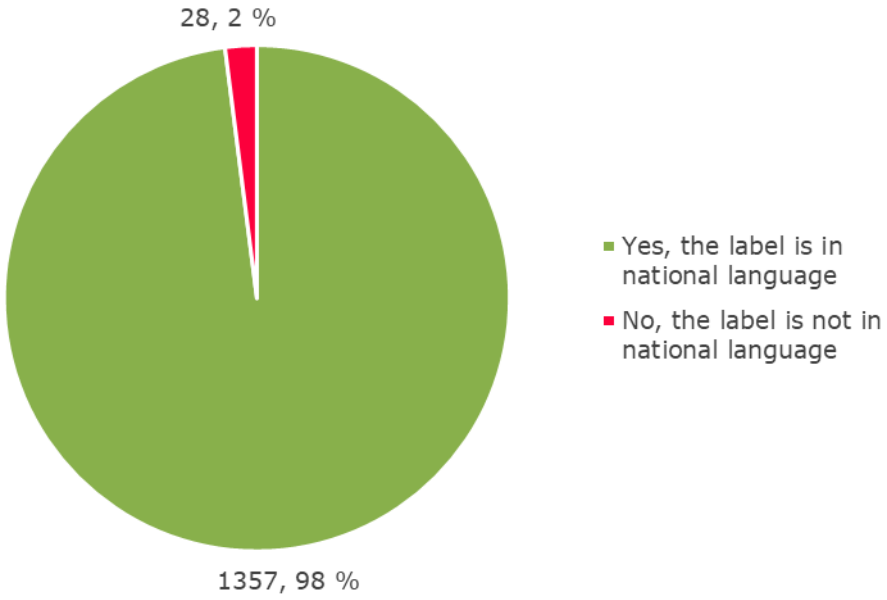


Figure 36. Label in national languages (number of biocidal products=1385)

In figure 37 different aspects of labelling requirements concerning 'EU biocidal products' are presented.

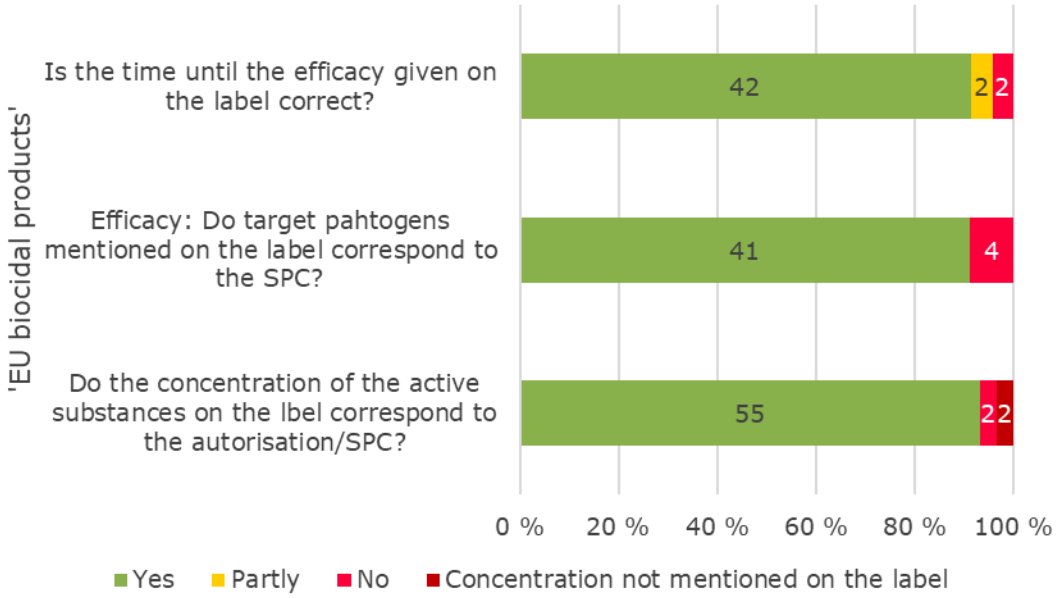
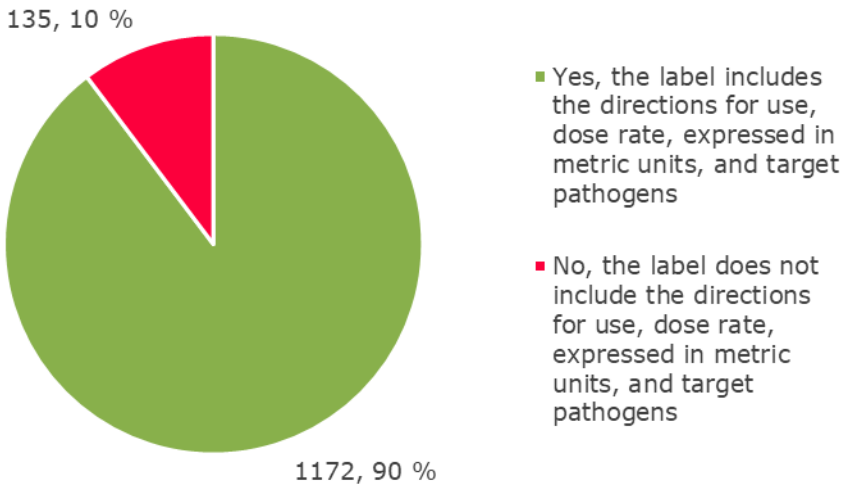


Figure 37. Labelling of disinfectants - information about efficacy, target organism, concentration for 'EU biocidal products' (bars show number of biocidal products)

In all, 10% of the inspected disinfectants presented labels lacking directions for use, dose rate expressed in metric units, and target pathogens.



Figures 38. Labelling of disinfectants - information directions for use for 'EU biocidal products' and 'transitional biocidal products' (number of biocidal products=1307)

2.5.3 Chemical analysis

In total, 160 disinfectants (i.e. 16 'EU biocidal products' plus 144 'transitional biocidal products') were analysed for their chemical composition.
Figure 39 shows that 96% of analysed disinfectants contained all active substances in line with the concerned documentation. Only four biocidal products did not contain active substances stated in the related documentation, while three biocidal products contained active substances that were not indicated in the related documentation.

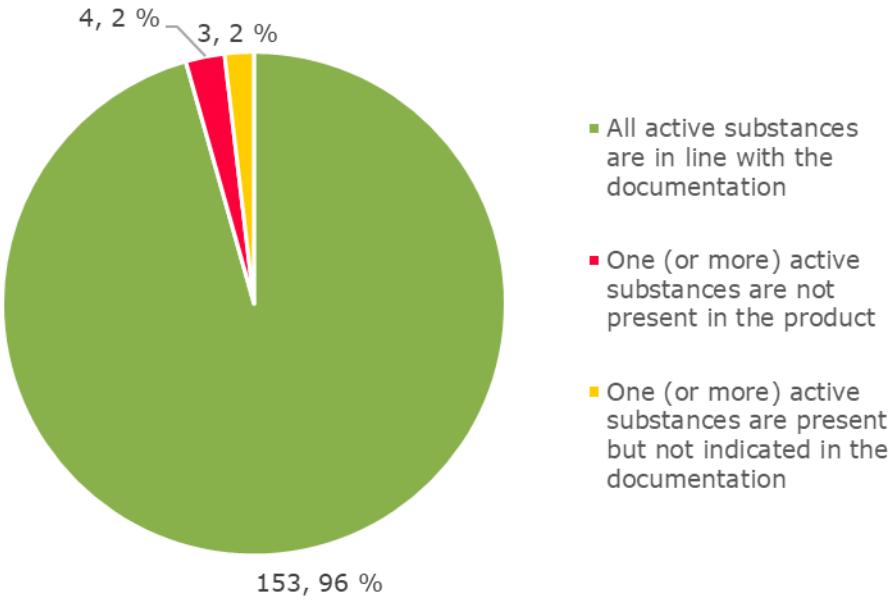


Figure 39. Chemical composition, active substances (number of analysed disinfectants=160)

Figure 40 indicates that 22% of the analysed disinfectants reported incorrect active substance concentrations (higher or lower than values reported in documentations).

In all, 28 disinfectants reported concentration of active substances with lower content than values reported in documentations (26 of them were disinfectants available on the market as 'transitional biocidal products').
In 23 disinfectants the active substance ethanol was detected in lower concentrations compared to what was indicated in the documentation, and four disinfectants presented active chlorine in lower concentrations than expected.
In 105 disinfectants, the chemical analysis targeted the detection of methanol, detecting it only in one biocidal product.

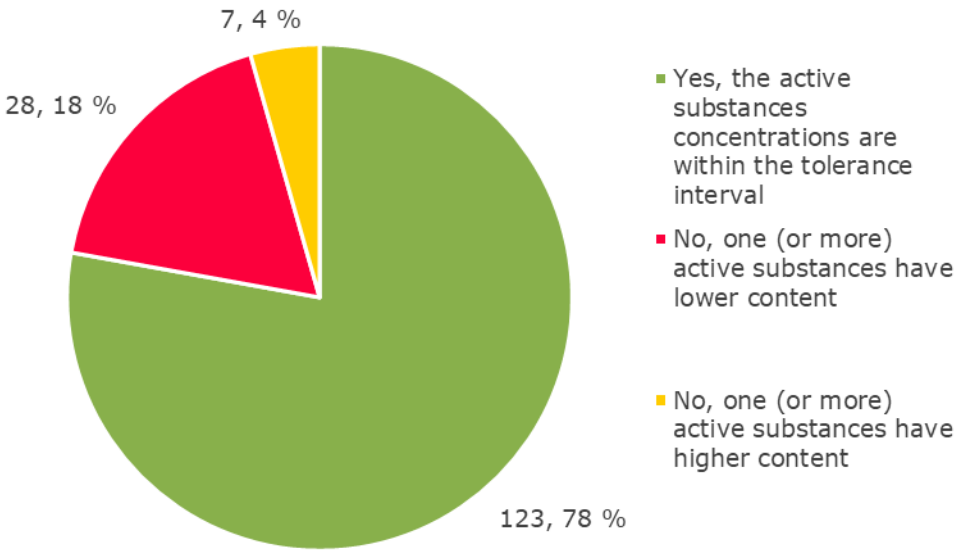


Figure 40. Correctness of active substance concentrations within the tolerance interval (number of analysed disinfectants=158)

In 4 % of the analysed disinfectants other active substances were detected than had been declared in the related authorisations, SPC and labels[11].

[11] Note that some active substances can overlap with the use for denaturation purpose (e.g. propanol).

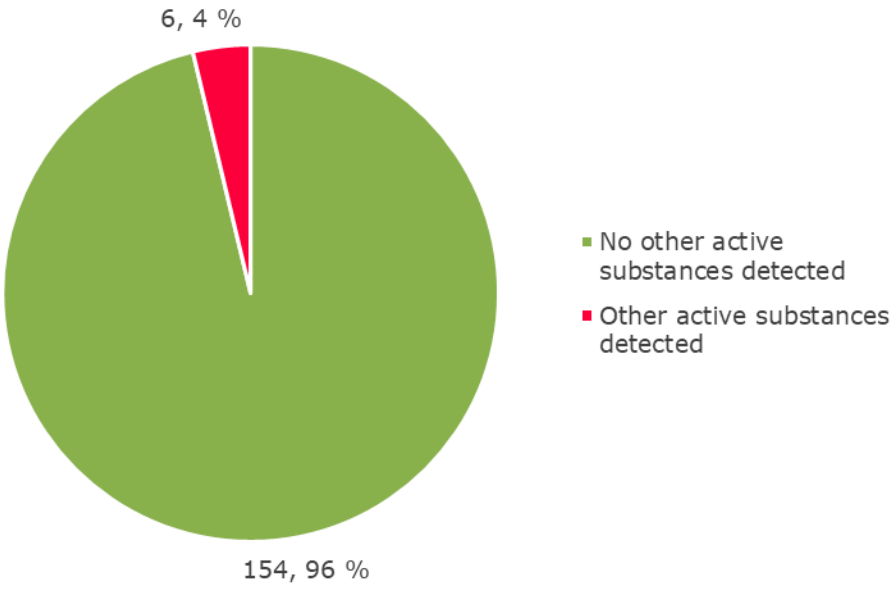


Figure 41. Detected active substances as declared in authorisation/SPC/label (number of analysed disinfectants=160)

3. Comparison with previous enforcement projects

"*Eppur si muove*[12]" Galilei is said to have muttered as he left the Inquisition Court - whether this also applies to the biocide market is presented in this chapter.

Table 12. Previous enforcement projects on biocidal products.

Name	Operational Phase Key aspects	Description	Report
EuroBiocides 2008	Year 2008 15 countries 1346 biocidal products 480 companies	General enforcement of biocidal products	CLEEN, 2011
EuroBiocides 2017	Year 2017 5 countries 211 biocidal products	Focus on biocidal products without BPR authorisation available on the market	CLEEN, 2017
REF-6 2018	Year 2018 24 countries 760 biocidal products	Focus on classification and labelling of mixtures. Specific module on biocidal products	FORUM, 2019
REF-8 2019	Year 2019 22 countries 1153 biocidal products	Enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold online	FORUM, 2021

[12] "*And yet it does move*": https://en.wikipedia.org/wiki/And_yet_it_moves

CASPCorona 2020	Year 2020 22 countries 39 biocidal products	General compliance for disinfectants	CASP, 2021

In the following section, some aspects of the BEF-2 results are compared with previous enforcement projects. Note that some adaptations were made to compare different databases. Therefore, the following figures should be carefully interpreted. They provide an indication of the real situation.

3.1 Compliance ratio for biocidal product authorisations

In figure 42, 'legally BPR' stands for biocidal products available on the market with an authorisation according to Article 17 of the BPR. 'Legally Transitional' for biocidal products available on the market with national transitional authorisations. 'Lack of Authorisation BPR' includes biocidal products that should have presented authorisations in line with Article 17 of the BPR but lacked it. 'Lack of Transitional' stands for biocidal products that should have presented transitional national authorisations but lacked it.
Note that data concerning BPR and transitional authorisations were combined with reference to REF-8 project.

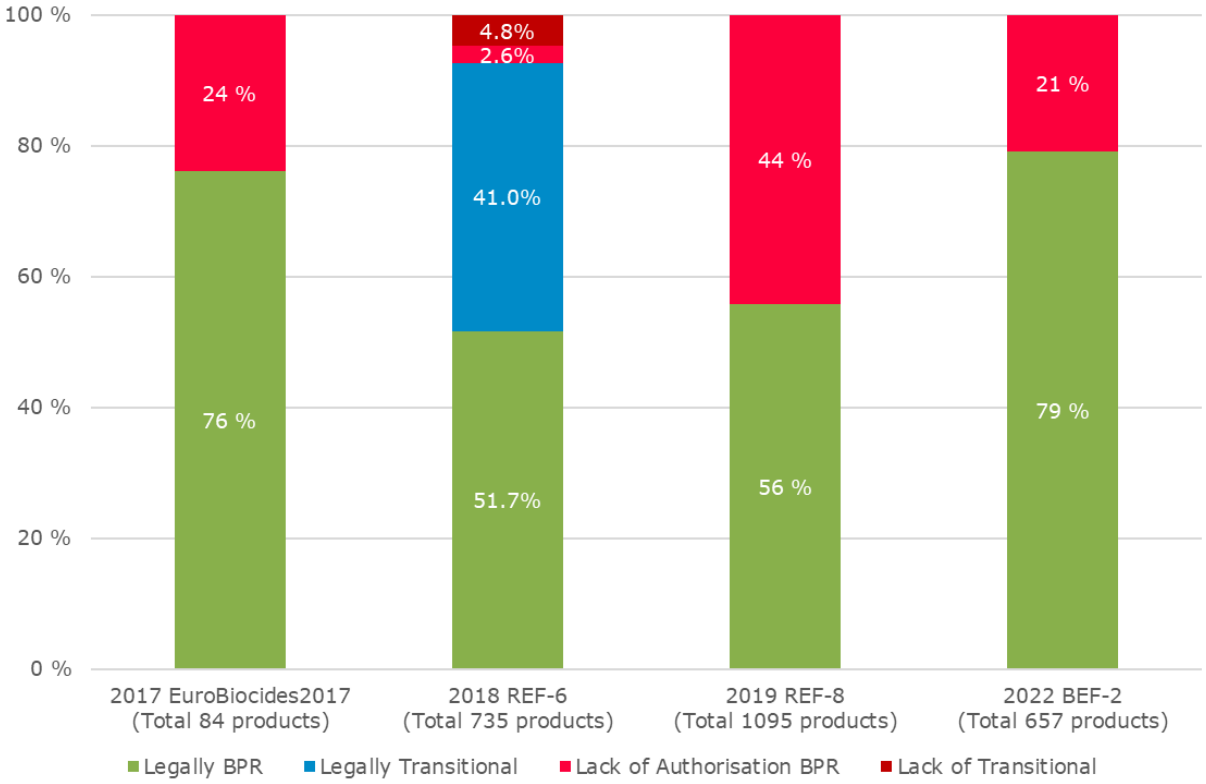


Figure 42. Overall compliance ratio concerning biocidal product authorisations in selected projects (year of operational phase indicated under the bar).

The ratio of authorised/unauthorised biocidal products inspected in different projects resulted different due to their goals and setups[13]. Overall, the high ratio of non-compliant biocidal products in REF-8 can be justified by its main focus on online sale. Web shops often sold online biocidal products without clarifying the concerned legal obligations (some web shops *de facto* control obligations only if requested by customers).
In REF-6 project the low number of biocidal products available on the market without authorisations can be linked to the fact that National Enforcement Authorities mainly targeted authorised biocidal products suspected to present other non-compliances.
Regarding EuroBiocides 2017 the selection of 'EU biocidal products' to be inspected was mainly arbitrary (in line with the BEF-2 project), and almost 24% of inspected 'EU biocidal products' were lacking authorisations. The findings of EuroBiocides 2017 are comparable with BEF-2 results, confirming that 20-25% of 'EU biocidal products' currently available on the EU market are not authorised.

3.2 Labelling obligation concerning national languages

Figure 43 reports the overall compliance data for EuroBiocides 2008 and BEF-2 concerning labels in correct national languages.

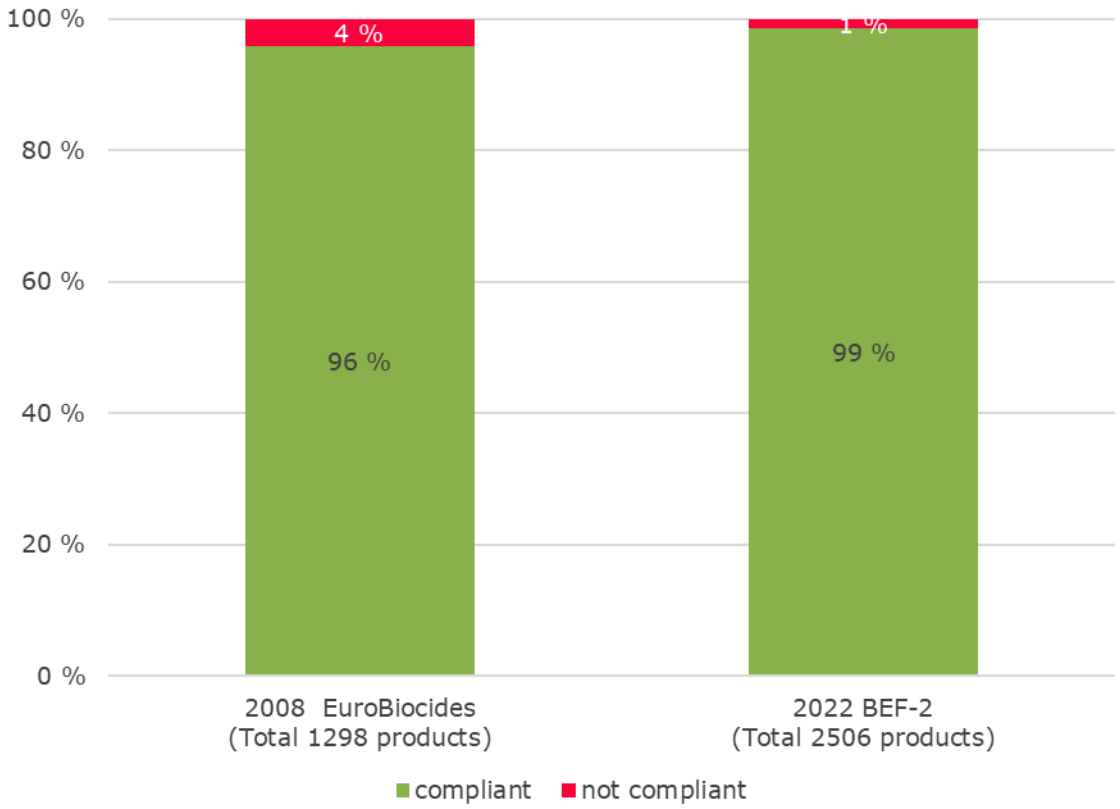


Figure 43. Comparison between EuroBiocides 2008 and BEF-2 concerning compliance of labels in national languages

[13] In EuroBiocides 2008 results authorisations were not a major issue yet, as most biocidal products were available on the market under transitional regime. For this reason, the comparison between the results of EuroBiocides 2008 and BEF-2 is not possible.

In EuroBiocides 2008 only 4% of biocidal products were not labelled in the correct national languages. In BEF-2 the situation improved to 1%. This finding can be probably linked to marketing aspects. Consumers tend to avoid buying products which are not labelled in their national languages.

3.3 Overall labelling compliance

Due to different focuses of enforcement projects, no relevant comparison can be made concerning labelling obligations. The only aspect that can be highlighted refers to EuroBiocides 2008, which presented overall results similar to BEF-2, with no significant improvement.
The high ratio of non-compliances in CASP 2020 can be linked to the focus of the project on disinfectants during the COVID-19 Pandemic. New manufacturers making available new biocidal products on short notice, without legal awareness of the BPR/national legislations.
A relevant comparison between labelling non-compliances between EuroBiocide 2008 and BEF-2 can be made since data were collected under similar circumstances and specifications (at the time of the Biocidal Products Directive labelling requirements in line with the current Article 69(2) of the BPR were already in place).

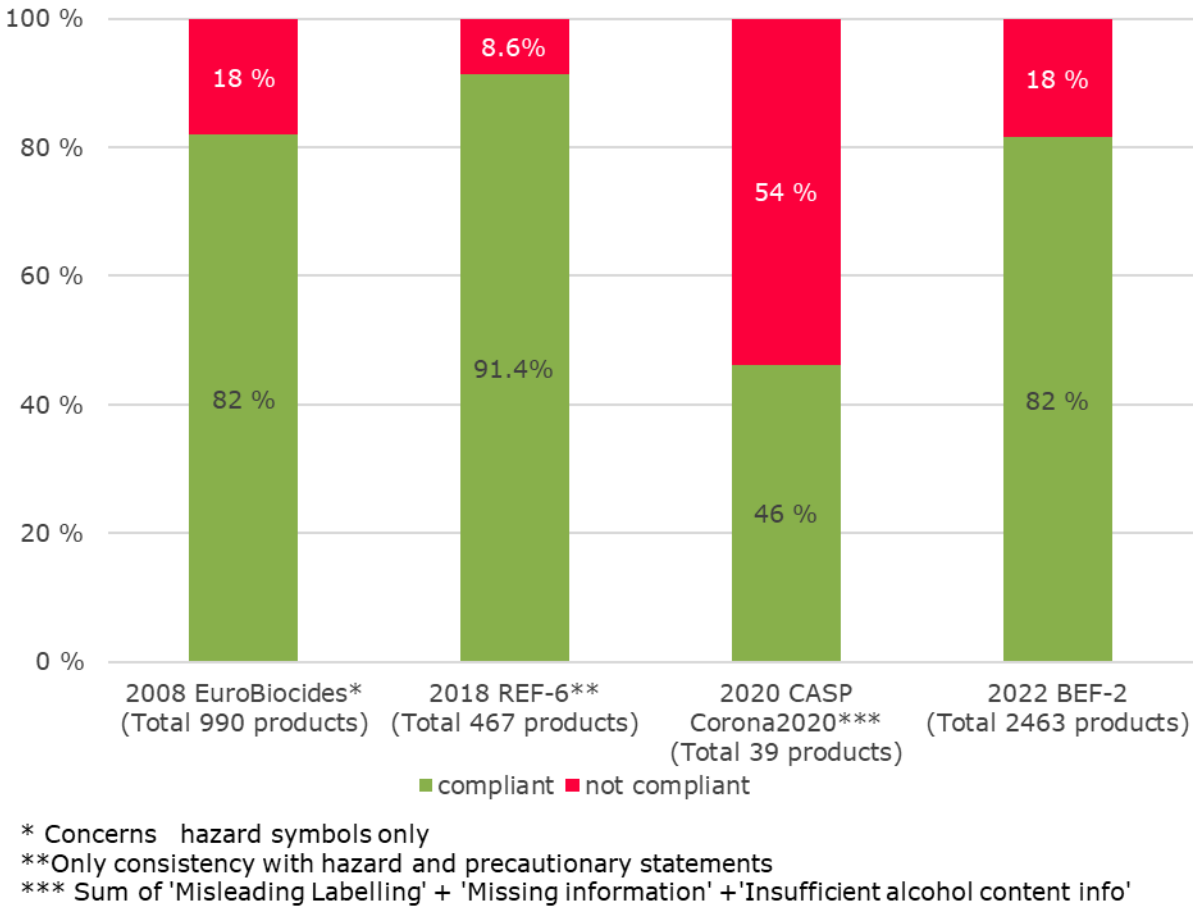


Figure 44. Labelling compliances in different enforcement projects.

In figure 45, BEF-2 results are reported only for biocidal products under Article 17 of the BPR (note that 'transitional measures products' were not considered in the statistic). The

figure shows compliance for disinfectants, BEF-2 general biocidal products, and the sum of both (i.e. 'BEF-2 total').

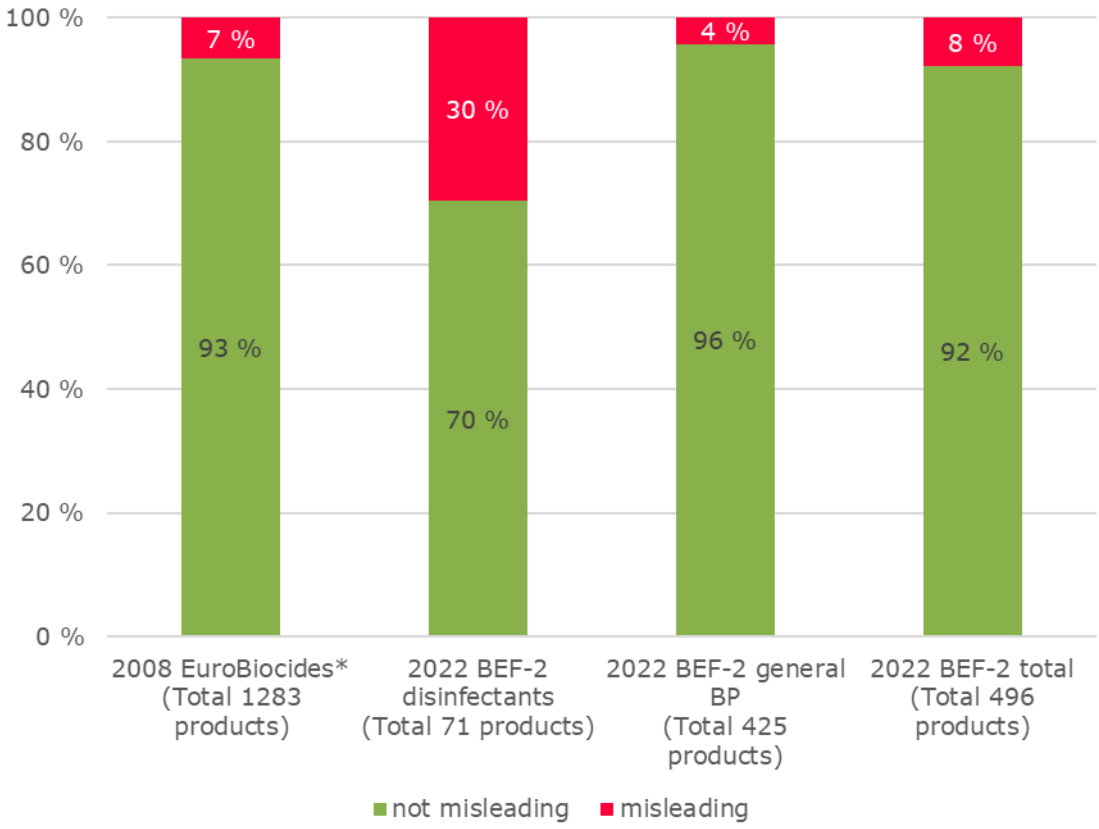


Figure 45. Labelling obligations - Article 69(2) of the BPR – misleading labels

Overall, no improvement in term of compliances can be highlighted between EuroBiocides 2008 and BEF-2. BEF-2 disinfectants show significantly higher ratio of non-compliance, i.e. 30% of inspected disinfectants had misleading information on labels.

Regarding 'general biocidal products' (i.e. biocidal products under Article 17 of the BPR, disinfectants excluded), the misleading claims do not pose a major problem due to the low number of non-compliant biocidal products available on the market. Nevertheless, misleading and trivialising claims should not be underestimated since they might lead consumers to handle biocidal products less carefully.

3.4 Advertisement compliance

Both under the Biocidal Products Directive (in place in 2008) and the BPR, advertisement obligations for biocidal products required indications about safe use and clarity concerning potential misleading terms.
Figure 46 shows the results for the indication 'Use biocides safely [..]. Enforcement data for EuroBiocides 2008 and BEF-2 were collected under similar circumstances and specifications, and their comparison shows a slight improvement in term of compliances

(even though the overall results still highlight an insufficient situation). REF-8 data cannot be directly compared due to its focus on online sale.

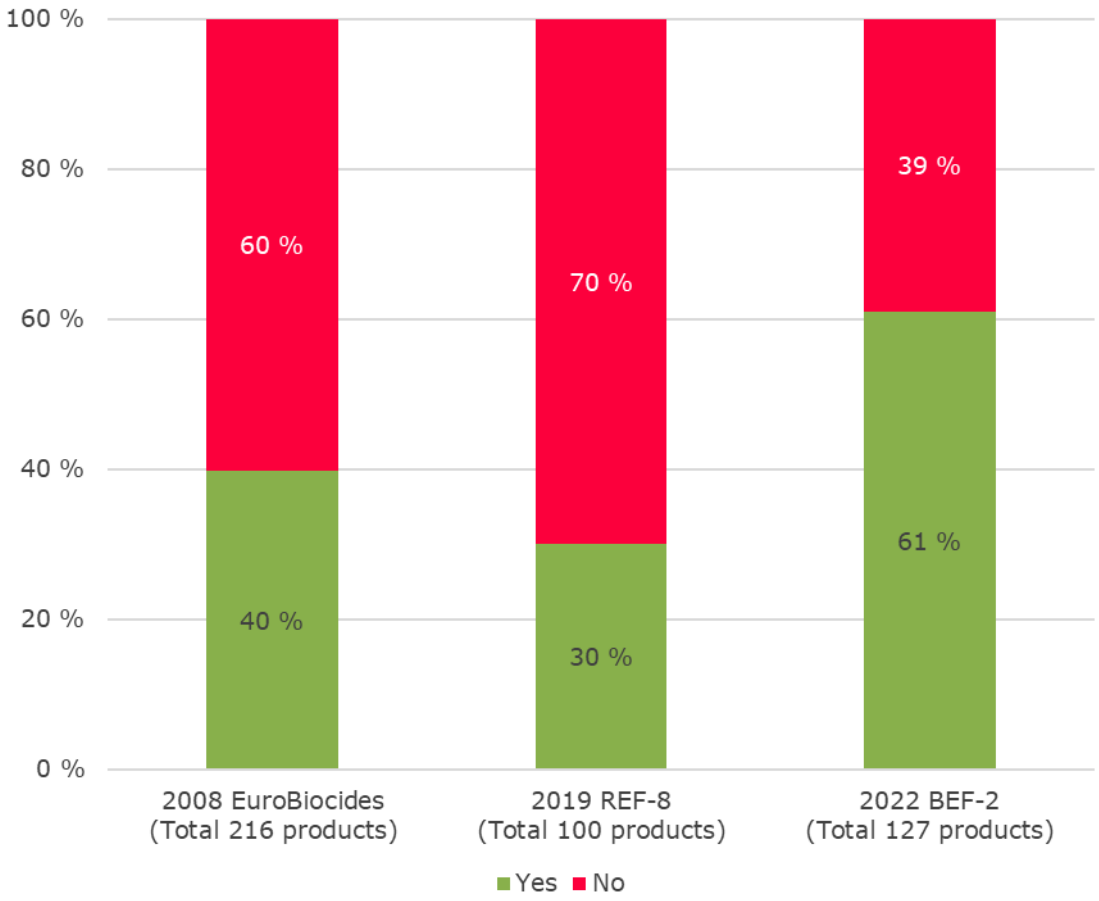


Figure 46. Advertisement obligations - Article 72(1) of the BPR (presence of sentence 'Use biocides safely [..]')

Figure 47 shows the results concerning misleading advertisements between EuroBiocides 2008 and BEF-2. Overall, misleading advertisements non-compliances increased. This finding can be linked to the use of terms as 'ecological', 'natural origin', and 'organic'. REF-8 results confirmed the situation concerning online sale.

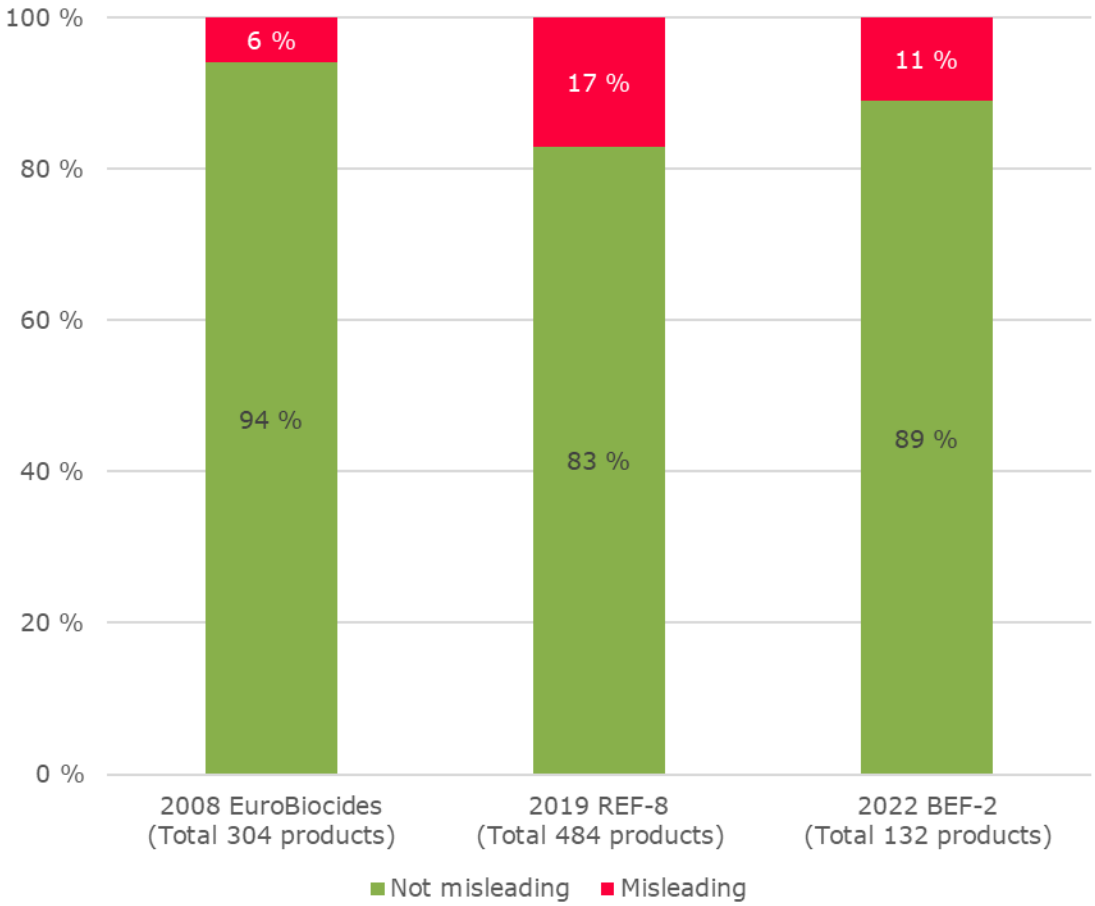


Figure 47. Advertisement obligations - Article 72(3) of the BPR – misleading advertisement

While EuroBiocides 2008 generally showed comparable findings about misleading advertisement claims and labels, BEF-2 reported relevant differences (namely 8% for non-labelling non-compliances and 11% about advertisement non-compliances).

Yes, *eppur si muove* – the compliance of the biocidal products, but not only to the better, but also to the worse or not at all.

4. Conclusions and recommendations

4.1 Conclusions

The BEF-2 Working Group members drawn the below conclusions and recommendations based on the analysis of project findings.

Table 13 shows the overall evaluation performed by the Working Group members on the BEF-2 results.

Table 13. Overall evaluation of BEF-2 findings[14].

Topic	Good	Medium	Poor
Non-compliant biocidal products lacking authorisations			
Presence of allowed active substances in biocidal products			
Chemical analysis and correctness of active substance concentrations			
Labels in national languages			
Labelling requirement in line with Article 69(2) points a) to o) of the BPR			
Misleading labelling			
Advertisement requirements indicating the obligatory phrase 'use biocides correctly [..]'			
Misleading advertisement			
Compliance with Article 95			

The main legal tool to regulate and ensure the safe use of biocidal products is **authorisation**. Only 79% of inspected 'EU biocidal products' met this requirement in BEF-2 (see figure 15). This finding shows an evident problem. Moreover, the comparison with previous enforcement projects confirmed that no improvement was made over 15 years (see details in chapter 3 of the report).
The reasons behind this situation could be connected to the high costs for biocidal product authorisations, together with the relevant efforts for companies to comply with biocides legislations. The coexistence of the BPR and transitional authorisations also creates unclarity.
In BEF-2 only 22% of the inspected biocidal products were in line with the BPR. The remaining 78% of the inspected biocidal products were available on the market under national transitional measures. That might be an indication of a less extensive evaluation of active substances and biocidal products. In this light, ensuring a swift progress of the

[14] The evaluation was carried out by the Working Group members considering the following aspects: i) Extent – number of biocidal products affected by non-compliances; ii) Impact - impact of non-compliances on the safe use of biocidal product, and related hazard to human health and the environment; iii) Protection goals - were the protection goals of the legislations undermined?; iv) Economic situation - potential market distortions concerning level playing field.

review programme for active substances (leading to their approval/non-approval) is crucial for a safer market.

The most relevant tools to convey necessary information for the safe use of biocidal products are **labels**. BEF-2 showed a good level of compliance with reference to national language requirements on labels (see figure 8). On the other hand, BEF-2 results also showed that the technical information reported on labels (e.g. exposure time) are not always sufficient. The high number of misleading labels poses a critical situation (see figure 24 - 'EU biocidal products'). The overall labelling non-compliances found in BEF-2 (i.e. 18%) are similar to the findings of a previous project named EuroBiocides 2008, which indicates little changes over 15 years (see figure 9).

Advertising for biocidal products must not be misleading and must contain specific information on their safe use. Very critical is the ratio of non-compliances found in BEF-2 (i.e. 42% for both EU and transitional biocidal products - see figure 10). A total of 11% of advertisement inspected concerning 'EU biocidal products' was assessed as misleading. That identifies a serious situation and confirms the general tendency for actors involved in supply chains in using attention-grabbing elements and terms in order to promote sales of biocidal products (see figure 28).

Article 95 obligations were only checked in 25% of the inspected biocidal products in BEF-2, though the results showed good compliances (see figure 6).

Regarding **chemical analysis** performed on biocidal products inspected in BEF-2, results shows that active substances stated in concerned documentations were typically found in biocidal products, and only in few cases different active substances were identified. Regarding concentrations of active substances, about 25% of the analysed biocidal products reported deviations from nominal concentrations (see figure 13).

In all, 18% of the inspected biocidal products in the BEF-2 were considered **non-compliant** presenting **'major deficiencies'** (as defined by the Working Group members with reference to authorisations, active substances, labelling and advertisement). Those non-compliances impacted on the making available on the market of the concerned biocidal products (see figure 14). Most non-compliant biocidal products belonged to **product types** 1, 2, 18 and 19.

Different **enforcement measures** were taken by the National Enforcement Authorities concerning non-compliant biocidal products in BEF-2. Those actions varied from verbal advices to criminal prosecutions (see figure 16).

4.2 Recommendations

The **ECHA website** disseminates valuable and important information concerning active substances and biocidal products authorised under the BPR. It was a key tool for national inspectors involved in BEF-2 activities. It is indeed very important that information on the ECHA website are updated regularly, for example the status of active substances.

Industry should increase their level of knowledge and awareness about the legal responsibilities in making available biocidal products on the EU market. The high number

of biocidal products with deficiencies is a crucial aspect of the biocides market, and industry are the key actors to ensure improvements.

Member states should continue providing training and information campaigns to both National Enforcement Authorities and industry, aiming at improving their knowledge on BPR requirements. General knowledge of Member States about biocidal products and active substances should be updated.

The BPRS highlighted the importance for the **Member State Competent Authorities** as main actors of the review, and the **European Commission** as the guardian of the treaties, as well as the industry as the actor responsible for information on active substances, to take appropriate actions to conclude the review programme of active substances. The current coexistence of the BPR and transitional authorisations creates unclarity and difficulties in harmonising enforcement actions in EU and results in a lack of level playing field for companies.

Annex 1 - Legal obligations inspected in BEF-2

Legal provisions of the BPR	Comments from BEF-2 Working Group members
Article 17 **Making available on the market and use of biocidal products** 1. Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation. (…) 5. Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69. Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken. (…) 6. The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission. (…)	Only biocidal products that are authorised, either on EU level, either on the national level, may be placed on the market and used. Biocidal products may only be used in compliance with the terms and conditions of the authorization and with the legal labelling and packaging requirements. Notification requirement for the authorization holder (either national, either EU authorization) at least 30 days before placing it on the market of the authorized biocidal product.
Article 22 **Content of an authorisation** 1. An authorisation shall stipulate the terms and conditions relating to the making available on the market and use of the single biocidal product or the biocidal product family and include a summary of the biocidal product characteristics (SPC). 2. Without prejudice to Articles 66 and 67, the summary of the biocidal product characteristics for a single biocidal product or, in the case of a biocidal product family, the biocidal products within that biocidal product family, shall include the following information:	SPC is integral part of the authorisation act. Mandatory contents of an SPC to be checked

(a) trade name of the biocidal product; (b) name and address of the authorisation holder; (c) date of the authorisation and its date of expiry; (d) authorisation number of the biocidal product, together with, in the case of a biocidal product family, the suffixes to apply to individual biocidal products within the biocidal product family; (e) qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products; and in the case of a biocidal product family, the quantitative composition shall indicate a minimum and maximum percentage for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0 %; (f) manufacturers of the biocidal product (names and addresses including location of manufacturing sites); (g) manufacturers of the active substances (names and addresses including location of manufacturing sites); (h) type of formulation of the biocidal product; (i) hazard and precautionary statements; (j) product-type and, where relevant, an exact description of the 57authorized use; (k) target harmful organisms; (l) application doses and instructions for use; (m) categories of users; (n) particulars of likely direct or indirect adverse effects and first aid instructions and emergency measures to protect the environment; (o) instructions for safe disposal of the product and its packaging; (p) conditions of storage and shelf-life of the biocidal product under normal conditions of storage; (q) where relevant, other information about the biocidal product.	
Article 55 **Derogation from the requirements**	

1. By way of derogation from Articles 17 and 19, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means. (…)	Temporary authorisation of a non-authorised biocidal product for a period not exceeding 180 days.
Article 69 **Classification, packaging and labelling of biocidal products** 1. Authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2), and with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008. In addition, products which may be mistaken for food, including drink, or feed shall be packaged to authorize the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children. 2. In addition to compliance with paragraph 1, 58authorization holders shall ensure that labels are not misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy and, in any case, do not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications. In addition, the label must show clearly and indelibly the following information: (a) the identity of every active substance and its concentration in metric units; (b) the nanomaterials contained in the product, if any, and any specific related risks, and, following each reference to nanomaterials, the word 'nano' in brackets; (c) the authorization number allocated to the biocidal product by the competent authority or the Commission; (d) the name and address of the authorization holder; (e) the type of formulation;	Forbidden mentions Mandatory information to be mentioned clearly and indelibly on the label.

(f) the uses for which the biocidal product is authorised; (g) directions for use, frequency of application and dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user, for each use provided for under the terms of the authorised; (h) particulars of likely direct or indirect adverse side effects and any directions for first aid; (i) if accompanied by a leaflet, the sentence 'Read attached instructions before use' and, where applicable, warnings for vulnerable groups; (j) directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging; (k) the formulation batch number or designation and the expiry date relevant to normal conditions of storage; (l) where applicable, 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, or the next access by humans 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; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use and transport; (m) where applicable, the categories of users to which the biocidal product is restricted; (n) where applicable, information on any specific danger to the environment particularly concerning protection of non- target organisms and avoidance of contamination of water; (o) for biocidal products containing micro-organisms, labelling requirements in accordance with Directive 2000/54/EC. By way of derogation from the first subparagraph, where this is necessary because of the size or the function of the biocidal product, the information referred to in points €, (g), (h), (j), (k), (l) and (n) may be indicated on the packaging or on an accompanying leaflet integral to the packaging. (…)	
Article 72	

Advertising 1. Any advertisement for biocidal products shall, in addition to complying with Regulation (EC) No 1272/2008, include the sentences 'Use biocides safely. Always read the label and product information before use.'. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement. 2. Advertisers may replace the word 'biocides' in the prescribed sentences with a clear reference to the product-type being advertised. 3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication.	Mandatory information to be mentioned clearly distinguishable and legible on any advertisement. Forbidden mentions.
Article 89 **Transitional measures** (…) 2. By way of derogation from Article 17(1), Article 19(1) and Article 20(1) of this Regulation, and without prejudice to paragraphs 1 and 3 of this Article, a Member State may continue to apply its current system or practice of making a given biocidal product available on the market until three years after the date of approval of the last of the active substances to be approved in that biocidal product. It may, according to its national rules, authorise the making available on the market in its territory only of a biocidal product containing existing active substances which have been or are being evaluated under Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work program referred to in Article 16(2) of Directive 98/8/EC, but which have not yet been approved for that product-type. By way of derogation from the first subparagraph, in the case of a decision not to approve an active substance, a Member State may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1. (…)	During the transitional period of the BPR, Member States may continue to apply their own national rules on authorizing biocidal products. Main criterium: approval status of the active substance(s) *<work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC: "10-year work programme" – "review program"* (last) active substance of the biocidal product EU approved : => BPR applies ("EU-products/authorisations") active substance(s) of the biocidal product not yet EU approved : => National legislation

	applies (national authorisation/registration/notification system, …)
Article 95 **Transitional measures concerning access to the active substance dossier** 1. As of 1 September 2013, any person wishing to place active substance(s) on the Union market on its own or in biocidal products (the 'relevant person') shall, for every active substance that they manufacture or import for use in biocidal products, submit to the Agency: (a) a dossier complying with the requirements of Annex II or, where appropriate, with Annex IIA to Directive 98/8/EC; or (b) a letter of access to a dossier as referred to under point (a); or (c) a reference to a dossier as referred to under point (a) and for which all data protection periods have expired. If the relevant person is not a natural or legal person established within the Union, the importer of the biocidal product containing such active substance(s) shall submit the information required under the first subparagraph. For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, Article 63(3) of this Regulation shall apply to all toxicological and ecotoxicological studies including any toxicological and ecotoxicological studies not involving tests on vertebrates. The relevant person to whom a letter of access to a dossier on the active substance has been issued shall be entitled to allow applicants for the authorisation of a biocidal product containing that active substance to make reference to that letter of access for the purposes of Article 20(1). By way of derogation from Article 60 of this Regulation, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but not yet approved under this Regulation shall end on 31 December 2025. 2. The Agency shall make publicly available the list of persons that have made a submission in accordance with paragraph 1 or for whom it has taken a decision in accordance with Article 63(3). The list shall also contain the names of persons who are participants in the work programme established under the first subparagraph of Article 89(1)	

or have taken over the role of the participant. (…)	

Annex 2 – BEF-2 questionnaires for inspections

BEF-2 Questionnaires.docx

EUROPEAN CHEMICALS AGENCY
TELAKKAKATU 6, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU