

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

BEF-1 Report

Report of the first harmonised
enforcement project on treated articles

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| Version | Changes | Date |
|---------|--|-------------|
| 2.0 | <p>The BEF-1 report (version 1.0) presented some mistakes concerning treated articles (TAs) containing the active substance C(M)IT/MIT "Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)" (CAS number 55965-84-9). It appeared that during the BEF-1 some national inspectors reported the active substance C(M)IT/MIT as two different active substances, i.e. 5-chloro-2-methyl-2H-isothiazol-3-one (CIT) (CAS: 26172-55-4); and 2-methyl-2H-isothiazol-3-one (MIT) (CAS: 2682-20-4), indicating the active substance CIT as an allowed active substance in TAs. This is effectively incorrect, since CIT is allowed in TAs only in combination with MIT to form the "Reaction mass of C(M)IT/MIT". In case the active substance CIT is included in TAs without the presence of the active substance MIT, CIT is considered to be a non-allowed active substance in TAs. Indeed, CIT is a new active substance under the BPR, which (at the time of this revision) is currently under evaluation. In this light, it was decided to revise the BEF-1 report when showing CIT and MIT as two different active substances. The revised BEF-1 report (i.e. tables n. 6; 7; 12; and 13) now indicates that the active substance CIT without MIT is non-allowed in TAs, and the active substance CIT in combination with MIT forms the "Reaction mass of C(M)IT/MIT".</p> | August 2021 |
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Title: Report of the first harmonised project on treated articles – BEF-1

Authors:

Chair of the BPRS Working Group BEF-1: Jenny KARLSSON (SE);
Members of the BPRS Working Group BEF-1: Francesca RAVAIOLI (IT); Heribert BURGY (CH);
Marianne BRAAM (NL); Jabik DE BOER (NL); Karin PFAFF (DE); Nadine GRISEL (CH); Fiona
TCHANAKIAN (FR).

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European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

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1. Executive summary

1.1. Project overview

The first harmonised enforcement project (BEF-1) that was held under the umbrella of the BPR Subgroup of the Forum for exchange of information on enforcement (BPRS) focused on the labelling obligations for treated articles (TAs), and the presence of legal or illegal active substances in TAs in accordance with the Biocidal Products Regulation (EU) No 528/2012 (BPR).

The objectives of the BEF-1 were to check compliance and to assess awareness and competences among the actors placing and making TAs available on the EU market.

Inspections were performed in the year 2019 mainly on treated articles with biocidal property claims, and on TAs containing active substances with specific labelling conditions reported in their Commission approval decisions.

The main module of the questionnaire that national inspectors filled in during their enforcement visits focused on the general obligations concerning TAs. Additionally, each participating country decided whether to check an optional module of the questionnaire, that paid attention to the biocidal products used to treat articles and mixtures at manufacturers/importers' sites, when TAs contained illegal active substances.

1.2. Results and conclusions

In the project, 22 countries reported on 1 187 inspected companies in which 1 844 treated articles (TAs) were checked.

National inspectors reported that 84 % of the visits were performed onsite, and 73 % of the inspected TAs were produced within the EU. The most inspected TAs were clothing, paints, bedding and chemical mixtures.

The results from BEF-1 showed that 64 % of checked TAs (both articles and mixtures treated with active substances and therefore considered TAs) had complete and correct labelling according to Article 58 (3) of the BPR. In particular, 58 % of the inspected articles (566 out of 978) were found with correct and complete labelling, while 77 % of the mixtures were compliant (358 out of 462).

The requirement for labels in the national languages was generally well met. Though for MSs with minor official languages incompliance was found higher.

For the inspected TAs, less than 2.5 % contain an illegal active substance and were, therefore, illegally on the market. This result is only based on company's declarations. Chemical analyses of the TAs were not systematically performed by the national enforcement authorities (NEAs). Consequently, the actual percentage of illegal active substances on the EU market could be higher.

The consumer's right for information seemed to be not very well known as less than 20 % of the companies had received a consumer request about their products.

53 % of the inspected TAs were mostly compliant and no actions were necessary. Written and verbal advice were the measures most frequently imposed by the NEAs.

1.3. Recommendations

Industry should increase their knowledge and raise awareness about responsibilities for

treated articles (TAs). In addition, industry should work more in order to improve the overall quality of labelling, especially for articles treated with biocidal products to become TAs.

National enforcement authorities (NEAs) should continue providing trainings and information campaigns for national inspectors and industry with the aim of improving knowledge about the legal obligations for TAs.

The Forum Subgroup for Biocides (BPRS) should consider repeating this project in a few years with the focus on TAs that are not easily identifiable in the EU market. In addition, chemical analysis should be performed by NEAs allowing the verification of substance declarations and the identification of TAs without biocidal property claims.

Overall, the BEF-1 results provide a clear picture of the current situation of TAs on the European market. Enforcement is crucial to create a level playing field with companies producing and importing TAs in the EU.

The BEF-1 also offered NEAs with a tool on how to manage and reduce non-compliances of TAs in the next years of enforcement activities.

2. Project description

2.1. Project overview

The BEF-1 was the first harmonised enforcement project of the BPR Subgroup of the Forum for exchange of information on enforcement (BPRS).

As decided at the third plenary meeting of the BPRS (i.e. BPRS-3), the aim of the project was to control the presence of correct and complete labelling of treated articles (TAs), and the legal presence of active substances in TAs according to the Biocidal Products Regulation (EU) No 528/2012 (BPR).

The project was prepared by a Working Group (WG) of the BPRS consisting of members and experts from the BPRS supported by the ECHA Secretariat.

A national coordinator was nominated to the project by each of the 22 participating country. The tasks of the national coordinators were to first provide information and guidance at national level on the project methodology, timing and targeting; and secondly, to collect information on the national results and report these to the Working Group of the BEF-1.

During the preparatory phase of the project in 2018, the BEF-1 WG prepared the manual and related questionnaire for inspections.

Inspections were then conducted in each participating country during the operational phase of the project in 2019. Finally, in 2020, the information collected by the national coordinators were submitted to the WG members, who performed the related analysis of the data and drafted the Final Report of the project. The report was consulted with the BPRS and the national coordinators of the BEF-1, prior its written adoption and publication on the ECHA website.

2.2. Scope

This project only addressed treated articles (TAs), not biocidal products. The focus was on TAs with biocidal property claims and containing active substances which require labelling because of the Commission approval decisions of the concerned active substances.

The scope of the BEF-1 was wide-ranging allowing all Member States to participate. Any type of TA was included in the project to be checked and reported by the national inspectors: a TA can be a substance, mixture or an article according to the definition outlined in Article 3 (1)(I) of the BPR.

The checked TAs were mainly articles for consumers (e.g. children's clothing, sports clothing), articles for the professional market (e.g. building products, swimming pool equipment, personal safety equipment), and chemical mixtures (e.g. paint, ink).

National inspectors were not required to take samples of the TAs inspected. The information stated on their labels or in marketing material were enough to find and possible enforce TAs. National enforcement authorities (NEAs) were nonetheless allowed to perform specific sample analysis if they identified the need.

The main module of the BEF-1 questionnaire focused on checking:

- the presence of labelling on the TAs;
- the correct and complete labelling of the TAs; and
- the legal/illegal presence of the active substances in the TAs.

In addition to the main objectives, the project also comprised of one optional module, which focused on the enforcement of the biocidal products used to treat the articles and mixtures inspected. The optional module was not conceived to be reported within the framework of the BEF-1, but as a tool to help EU inspectors carrying out additional evaluations while enforcing TAs.

2.3. Objectives

The objective of BEF-1 was to assess the awareness and competences among the target groups on the treated article (TA) requirements and the levels of compliance with the BPR regarding the legal presence of active substances in TAs and, when required, the labelling of TAs.

The project helped to gain insight into the EU market of TAs for monitoring purposes. Previous projects performed in EU focusing on TAs, e.g. the CLEEN project EuroBiocides III, the Swedish and Swiss projects, clearly showed the need of performing a common harmonised EU project (see details in Annex 3).

In addition, and where possible, the project examined whether the information obligations were generally met: where necessary to protect human health, animal health or the environment, a TA should always be accompanied by instructions including precautions. Furthermore, upon request by a consumer, any supplier of a TA should provide information about the biocidal treatment of the TA within 45 days.

A supplementary objective of this project was to improve the knowledge of national enforcement authorities (NEAs) on the requirements for TAs under the BPR, and to obtain more clarity on borderline issues between biocidal product and TAs, leading to more enforcement of these provisions and a greater harmonisation of approaches between MSs.

2.4. Legal obligations

The legal obligations in accordance with the BPR subject to BEF-1 inspections are:

| | |
|---|--|
| Article 3 (1) | Legal definitions of biocide, treated article, placing on the market, making available on the market. |
| Article 58 (1), (2), (3), (4), (5) and (6) | Placing on the market of treated articles. Obligation to label treated articles with complementary information. Consumer information rights. |
| Article 94 (1) and (2) | Transitional measures concerning treated articles. |

3. Project results

Some questions included in the main module of the BEF-1 questionnaire were not mandatory and, therefore, the response rate reported by the national coordinators to the Working Group varied. In this light, it is important to note that the total number of reported treated articles and companies were not always consistent between different questions.

3.1. Participation and number of inspections

In the BEF-1, 22 countries reported on 1 187 inspected companies in which 1 844 products were checked. 84 % of the controls included onsite inspections. It was possible for participating inspectors to examine more than one treated article (TA) per company, limited to a maximum of five TAs.

Each participating country decided how many inspections to conduct during the operational phase of the project during the year 2019, since a minimum number of inspections was not defined by the BEF-1 Working Group (WG).

Table 1 Reported number of inspections by country.

| Member States | Inspected companies |
|---------------|---------------------|
| BE | 19 |
| CH | 14 |
| CZ | 28 |
| DE | 223 |
| DK | 13 |
| EE | 13 |
| ES | 89 |
| FI | 23 |
| FR | 58 |
| HU | 98 |
| IE | 5 |
| IT | 7 |
| LT | 15 |
| LU | 9 |
| LV | 19 |
| NL | 32 |
| NO | 5 |
| PL | 132 |
| RO | 277 |
| SE | 71 |
| SI | 10 |
| SK | 27 |
| Total | 1 187 |

Table 2 Reported number of checked TAs in participating countries.

| Member States | Checked TA |
|---------------|--------------|
| BE | 54 |
| CH | 37 |
| CZ | 38 |
| DE | 365 |
| DK | 12 |
| EE | 25 |
| ES | 126 |
| FI | 25 |
| FR | 129 |
| HU | 108 |
| IE | 5 |
| IT | 7 |
| LT | 19 |
| LU | 25 |
| LV | 21 |
| NL | 30 |
| NO | 10 |
| PL | 181 |
| RO | 441 |
| SE | 107 |
| SI | 10 |
| SK | 69 |
| Total | 1 844 |

3.2. Data evaluation

During the evaluation performed by the BEF-1 Working Group (WG) two exclusion criteria were applied when selecting the data submitted by the national coordinators:

- Incorrect sample reports. In particular 12 samples had duplicate names; 8 samples presented mismatches in the definition of article and mixture (both considered TAs); 65 samples with inconsistent answers;
- Products placed on the market before 1 Sept 2013.

Before the BPR came into force on 1 September 2013, there was no obligation regarding treated articles (TAs) and which active substances they were treated with. After 1 September 2013, due to transitional rules, a TA containing an unapproved active substance could have been placed on the market until the 1 March 2017. Since 1 March 2017, it is no longer possible to place articles on the EU market treated with unapproved active substances. These TAs, however, can still be made available if, indeed, they were placed on the market before 1 March 2017.

During the BEF-1 inspections, the information of when a TA was placed on the market was only obtained in 52 % of cases; one-third of the TAs inspected were placed on the market after 1 March 2017.

The data reported by the national coordinators showed that 130 TAs were placed on the market before 1 September 2013. These were not considered in the evaluation performed by the WG since the BPR does not apply.

Table 3 When was the TA placed on the market?

| When was the TA placed on the market? | Number of samples | Remarks |
|---|-------------------|--|
| Before 1 Sept 2013 | 130 | |
| After 1 Sept 2013 but before 1 March 2017 | 153 | |
| After 1 March 2017 | 632 | |
| Unknown | 844 | |
| Total | 1 759 | This 1 759 samples corresponds to 1 012 companies putting them on the market |

Due to inconsistencies in the dataset, some entries had to be removed from the evaluation performed by the WG. Figure 1 shows the exclusion criteria. In total, 215 samples were not included in this report. 1 629 samples from 921 inspected companies were considered.

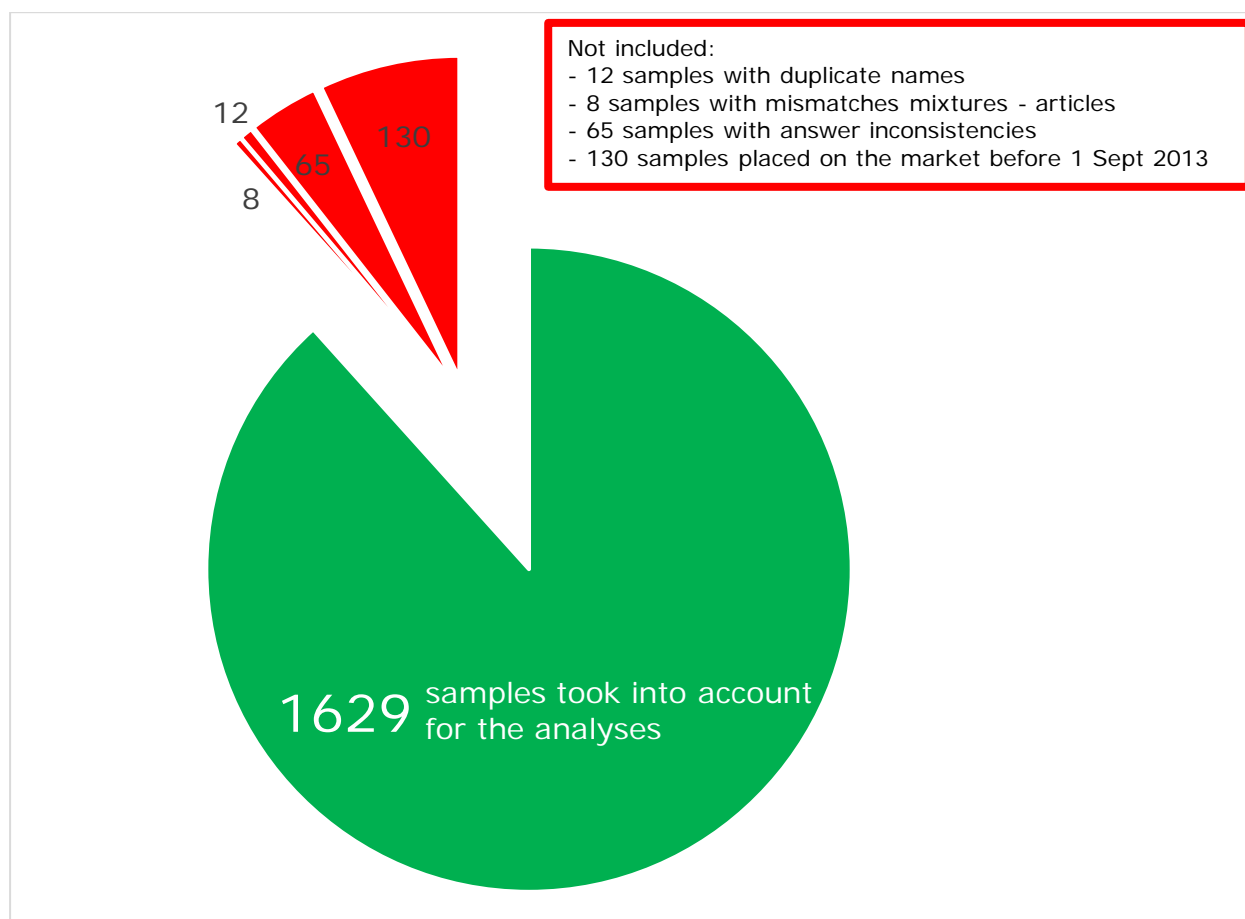


Figure 1 Description of the exclusion criteria and subsamples analysed.

3.3. Inspected companies

The national enforcement authorities (NEAs) had the possibility to perform inspections onsite, from the office (desktop inspections), or by web survey. Figure 2 shows that most of the inspections (84 %) were performed onsite.

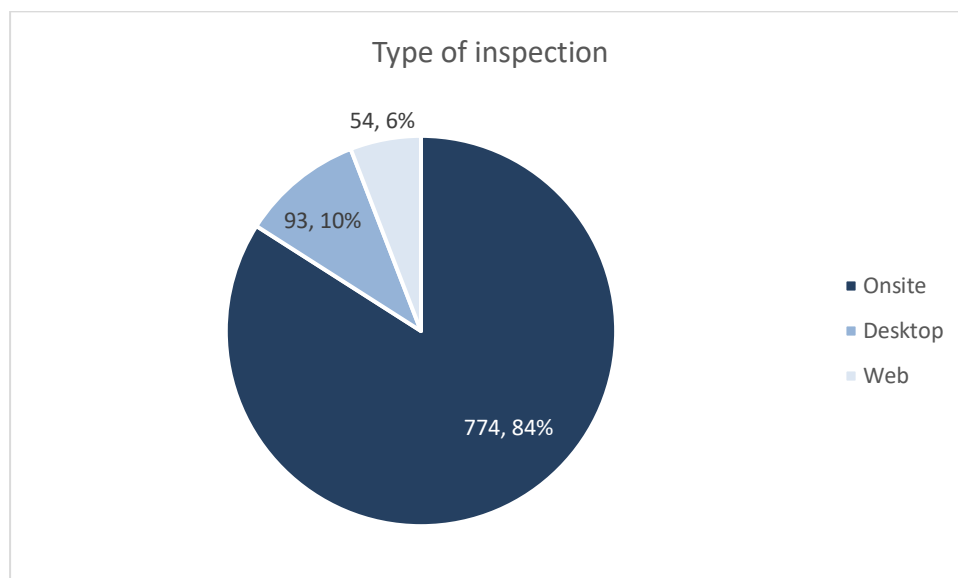


Figure 2 Type of inspection.

3.3.1. Role of companies

The target groups of this project were the actors in the supply chain that place treated articles (TAs) on the market (first making available) and make TAs available on the market (distribution).

The Member States were free to choose their targets. Most of the controlled companies were making TAs available on the market (Figure 3). In 16 % of the cases, controlled companies had dual roles, i.e. both placing and making available TAs on the market.

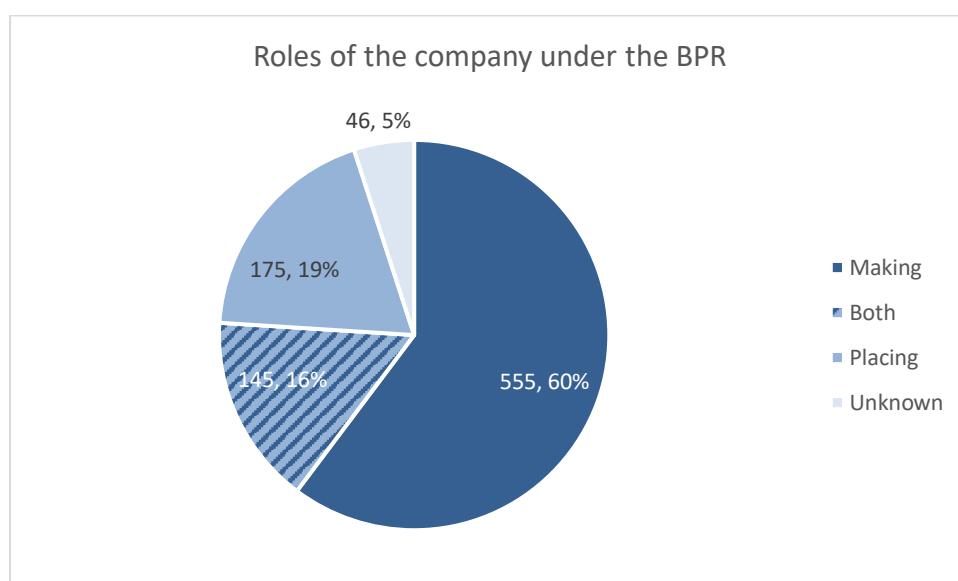


Figure 3 Roles of companies checked, placing or making TAs available on the market.

3.3.2. Company size

In the project, all sizes of companies have been controlled. The most controlled companies were micro-sized enterprises, followed by small- and medium-sized.

There is no difference in role compared to company size, even though slightly more micro-sized companies are making treated articles (TAs) available on the market rather than placing them on the market (Figure 4).

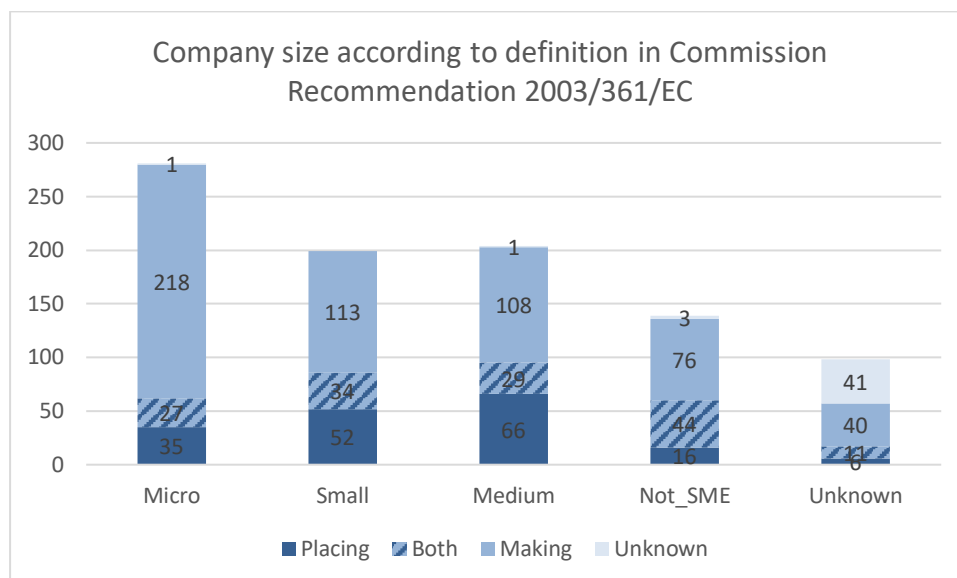


Figure 4 Role and size of the company. In the bars, absolute numbers are given.

3.3.3. Information request customer

According to Article 58 (5) of the BPR, a company selling treated articles (TAs), must provide information on the biocidal treatment within 45 days if the information is requested by a consumer.

Figure 5 shows that, in most cases, the companies had not received any questions from consumers about the specific product. Only less than 20 % of the companies inspected had received a consumer request for information about the treatment of TAs. If requests were received, over 75% of the companies responded to consumers' questions.

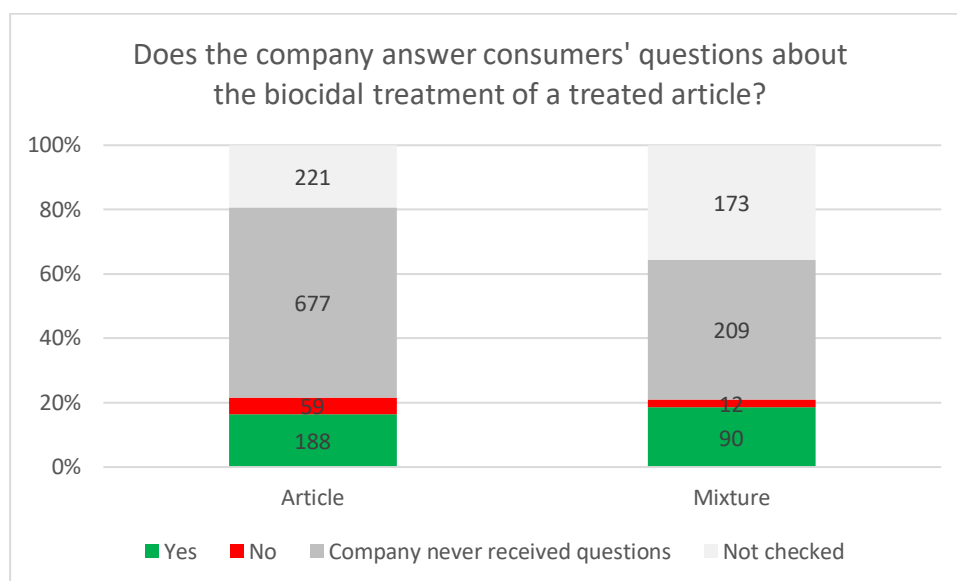


Figure 5 Number of companies with obligations checked and fulfilled. The answers are related to treated articles. In the bars, absolute numbers are given.

3.4. Inspected treated articles (samples, claims and labels)

In 70 % of the cases, the inspected treated article (TA) was an article. In this group, clothing was the most investigated type of article.

Regarding mixtures, there is almost a 50/50 ratio between paint and chemical mixtures that are not paints.

In 73 % of cases, the TAs checked were produced within the EU.

The majority of biocidal products used for treatment were linked to Product Types 2, 6 and 8.

The highest non-compliance on the labels was the lack of indication about the concerned active substances, relevant instructions for use, and biocidal property.

3.4.1. Types of treated articles

The total number of TAs considered for the following analyses is 1 629; which 70 % were articles and 30 % were mixtures (Figure 6).

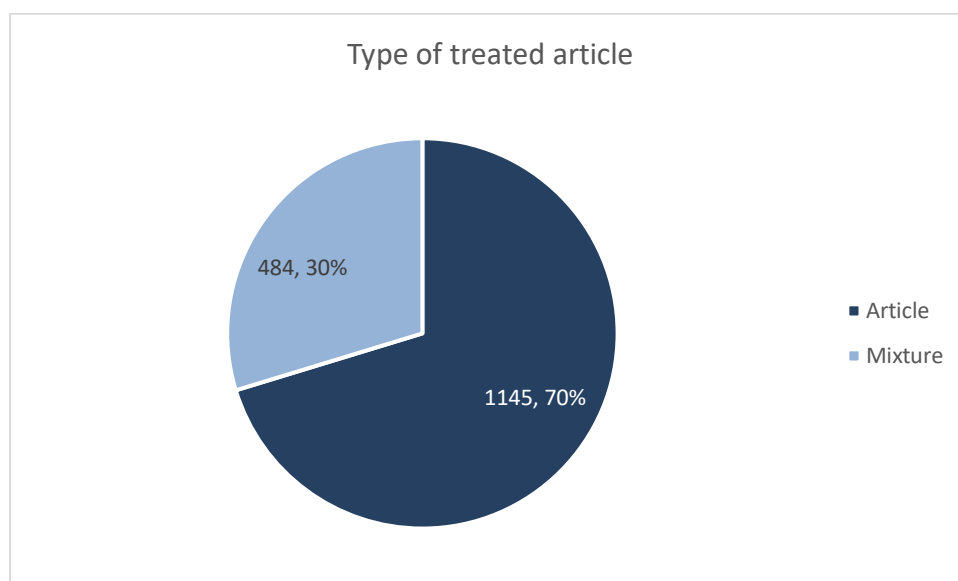


Figure 6 Type of treated article.

The national enforcement authorities (NEAs) reported multiple sources of information to search, determine and select treated articles (Table 4). The most used was the label followed by an investigation on the concerned website.

Table 4 Source of information used to determine treated articles.

| Source of information | Article | Mixture |
|------------------------------|---------|---------|
| Label | 820 | 421 |
| Advertisement | 100 | 9 |
| Website | 325 | 49 |
| On the shelf | 46 | 3 |
| MSDS | 119 | 182 |
| Information from distributor | 320 | 32 |
| Certificate of analysis | 35 | 1 |
| Analysis by authority | 2 | 1 |
| Others | 88 | 24 |

Each participating country was free to decide which type of TAs to control during the operational phase of the project (Figure 7).

The most controlled categories of TAs were:

- for articles: clothing (38 %) and bedding (19 %)
- for mixtures: paints (51 %) and chemical mixtures (42 %).

Some chemical mixtures and some paints were considered as articles, despite them being mixtures according to the BPR.

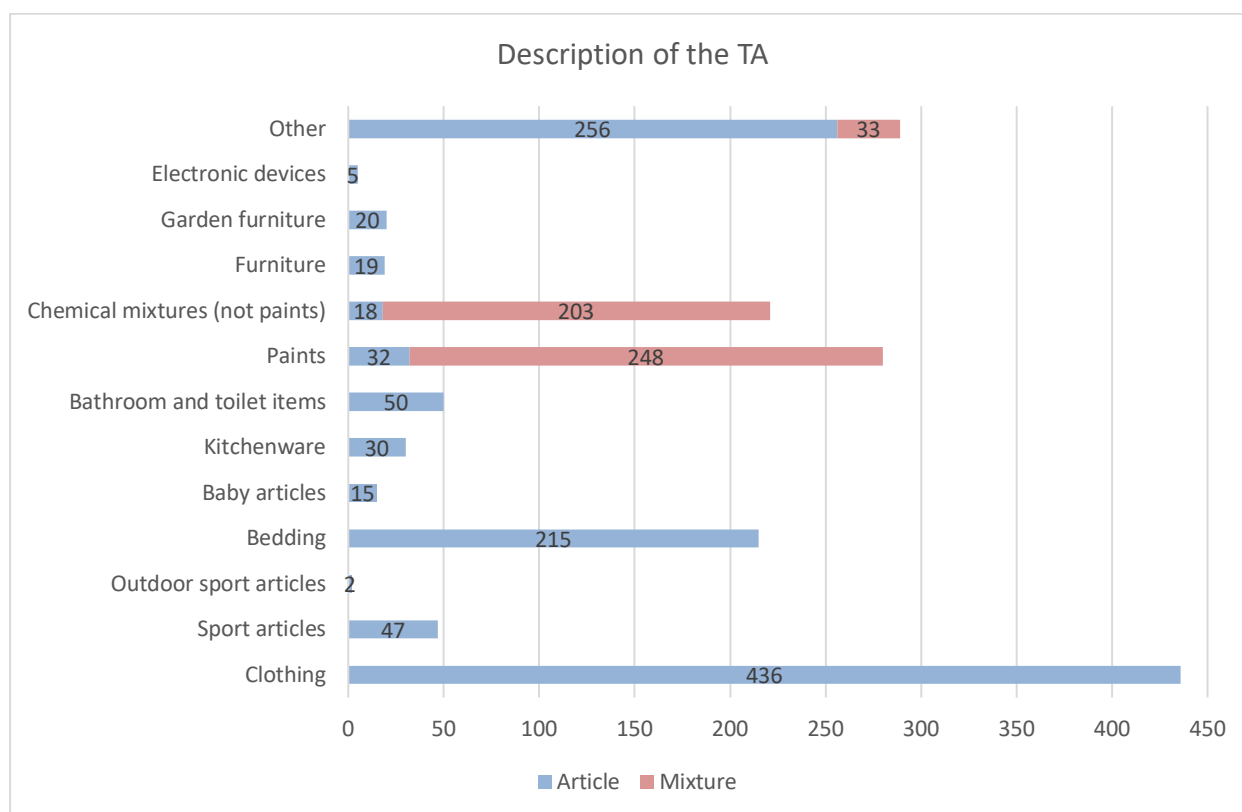


Figure 7 Description of treated articles. In the bars, absolute numbers are given.

3.4.2. Treated articles by product type

The product type (PT) of the treated articles (TAs) was indicated in 92 % of the samples inspected during the operation phase of the BEF-1 (see Annex 4 for details on the Product types as classified in Annex V to the BPR). For the remaining 8 % (128 samples), the product type was unclear (Figure 8). Two coexistent PTs (multiple PTs) were reported for 197 treated articles. The most found PTs for articles were PTs 2 and 9. For mixtures, PTs 6 and 7 were the most reported. Generally, these four PTs were found in 89 % of the inspected TAs.

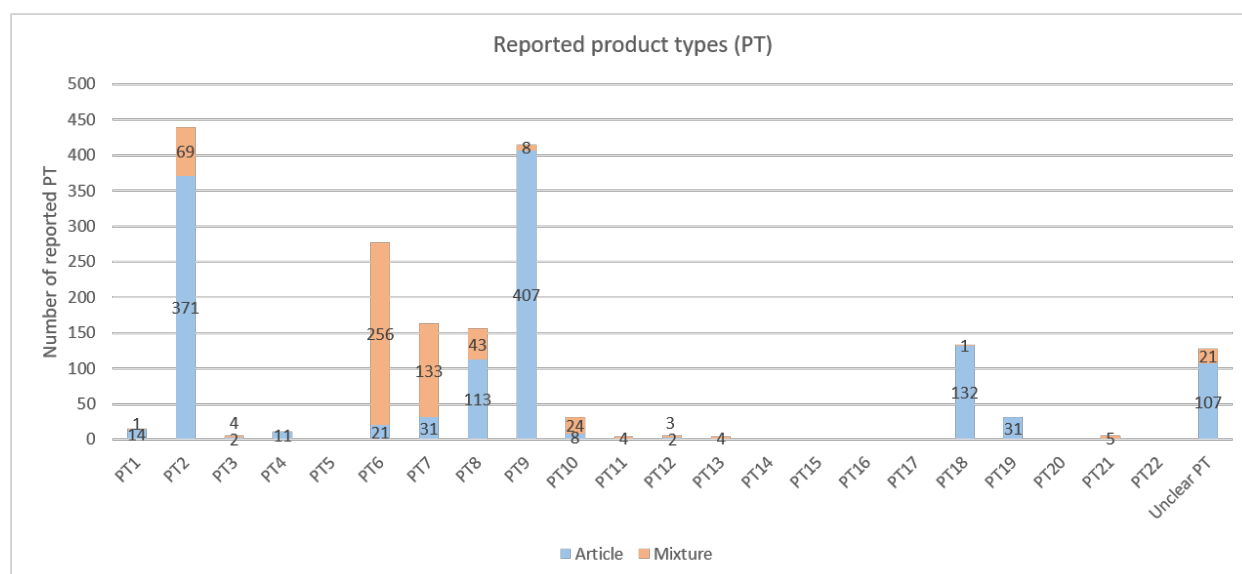


Figure 8 Reported product types for articles and mixtures (more than one PT/TA)

The matrix represents the different PT combinations reported for articles (Figure 9). For example, PT 1 combines only with PT 1. On the other hand, for PT 2, combinations were reported with PT 2, PT 3, PT 4, PT 9 and PT 18. The colours indicate the frequency of the combinations. Figure 10 shows a similar matrix for mixtures.

The most found PTs in articles were 2, 8, 9 and 18 indicated by the dark blue colours in Figure 9. For mixtures, the most found PTs were 6 and 7 (Figure 10).

The most found combinations of PTs were for articles 2 and 9; 9 and 18; and 18 and 19, whereas for mixtures, the most found combinations were 6 and 7; and 6 and 8.

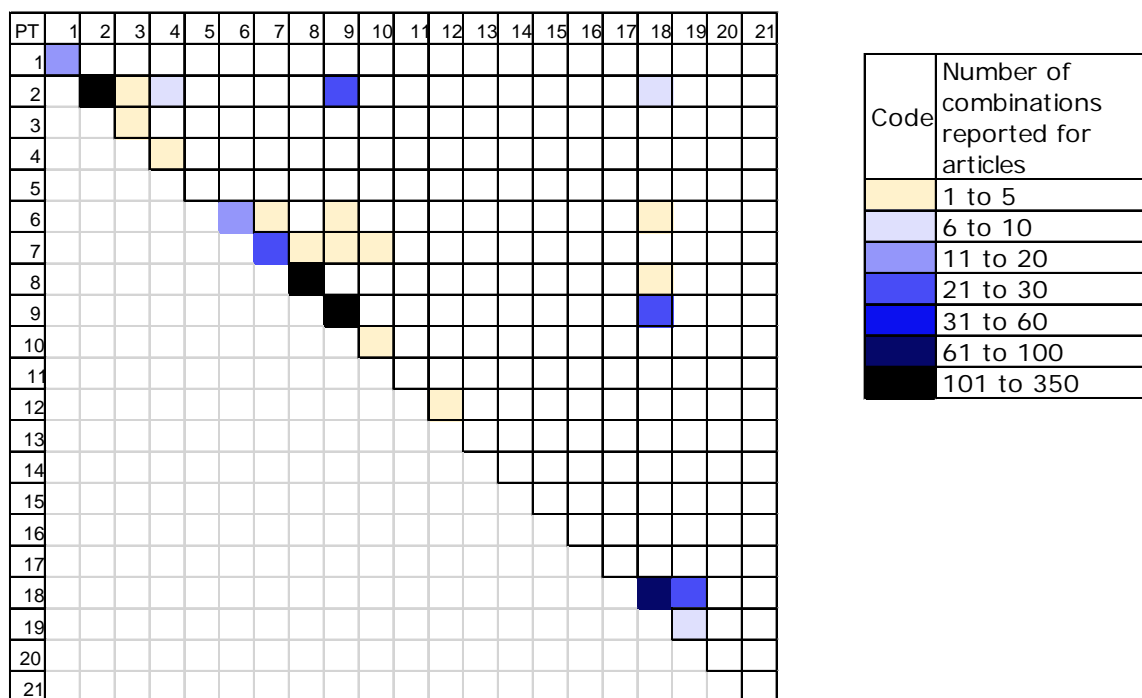


Figure 9 Representation of the product type combinations reported for articles.

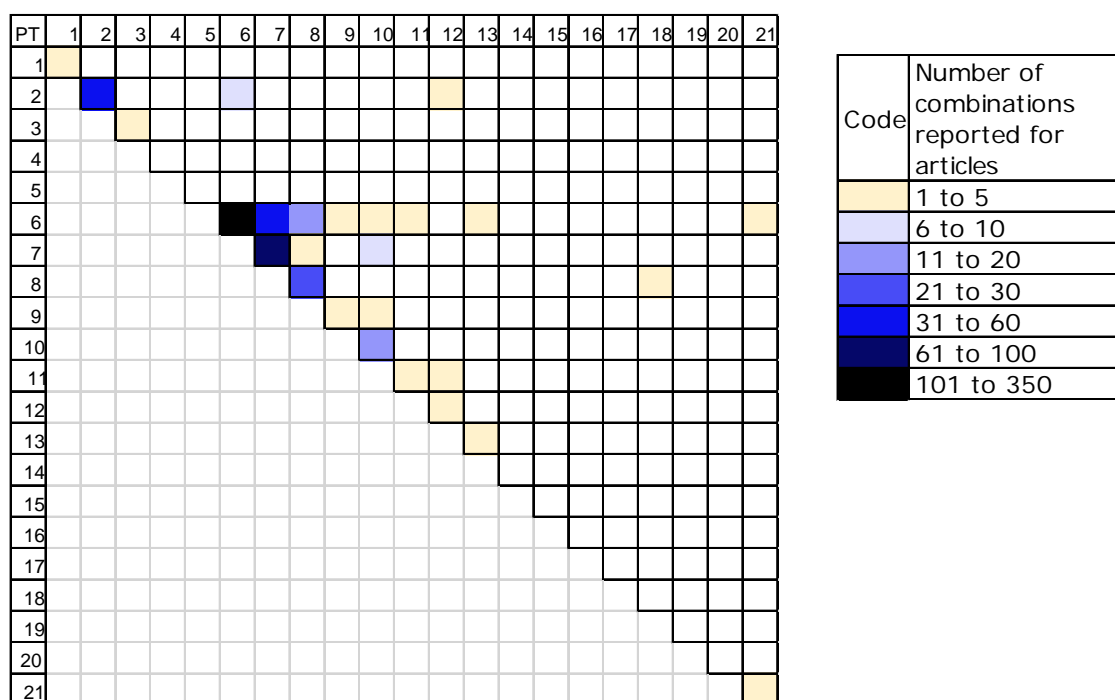


Figure 10 Representation of the product type combinations reported for mixtures.

3.4.3. Origin of treated article

Both for articles and mixtures, the majority (73 %) were manufactured within the EU. Only in 11 % of cases were the treated articles (TAs) imported. In 16 % of cases, the origin was unknown. The distribution is similar for articles and mixtures.

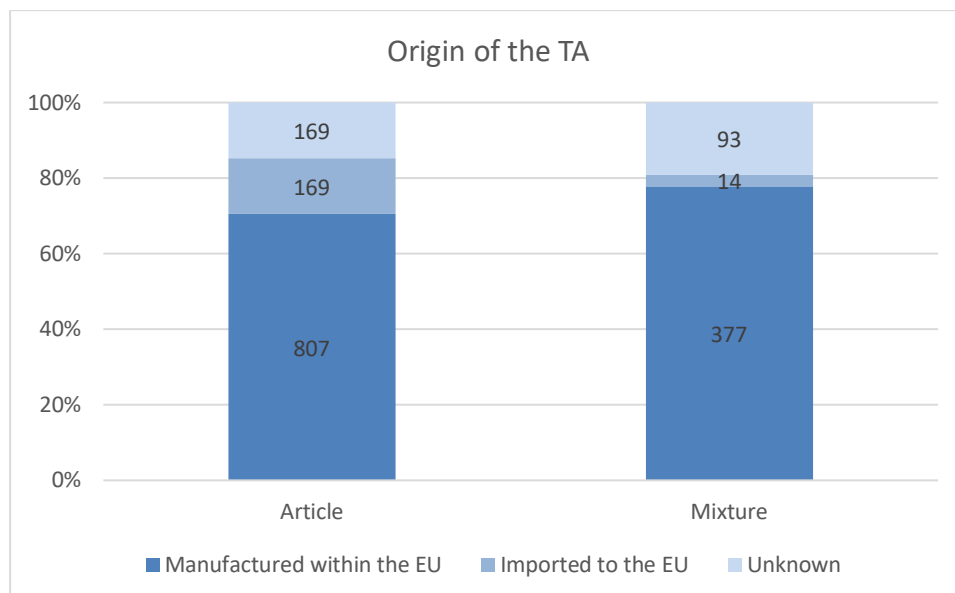


Figure 11 Origin of the treated articles (%). In the bars, absolute numbers are given.

3.4.4. Labelling

Figure 12 shows that 90 % of the treated articles (TAs) had to be labelled because they either had a biocidal property claim or contain an active substance with labelling requirements in the approval. For 10 % of the TAs, there was no labelling obligation. The labelling of the articles was triggered by the biocidal property claim for more than 65 %.

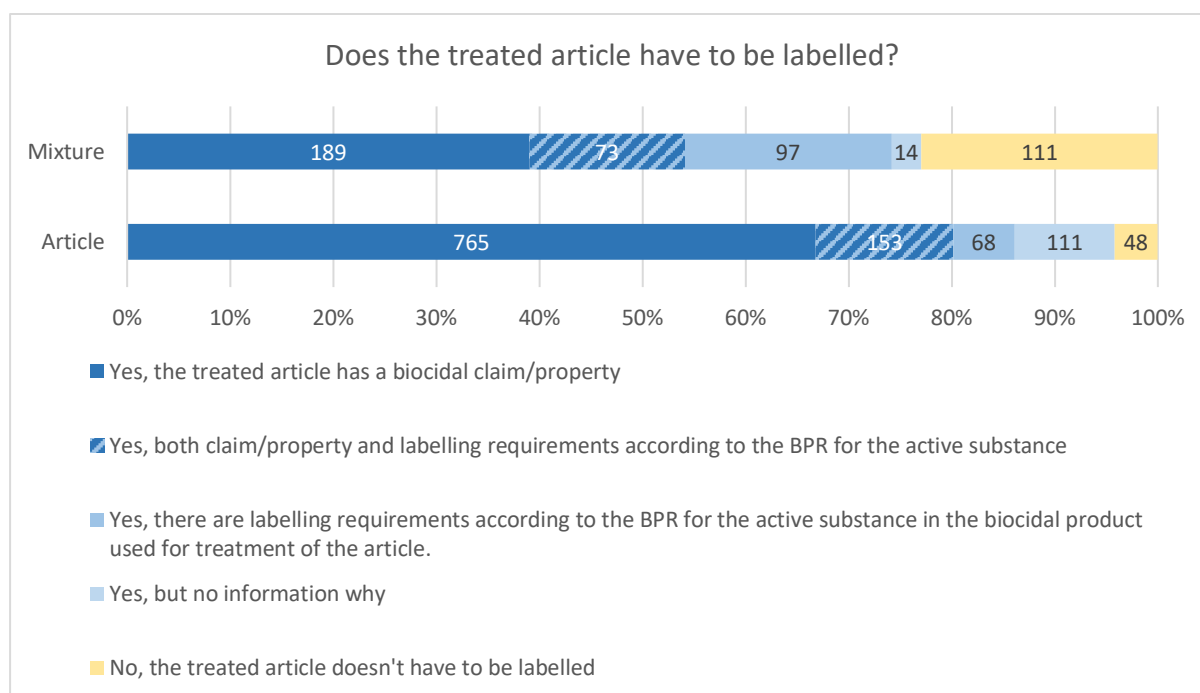


Figure 12 Does the treated article have to be labelled? In the bars, absolute numbers are given.

The compliance level is high for the presence of a label on the inspected TAs (Figure 13). In 90 % of cases, TAs that have labelling obligations were labelled. For mixtures, there is almost 100 % compliance.

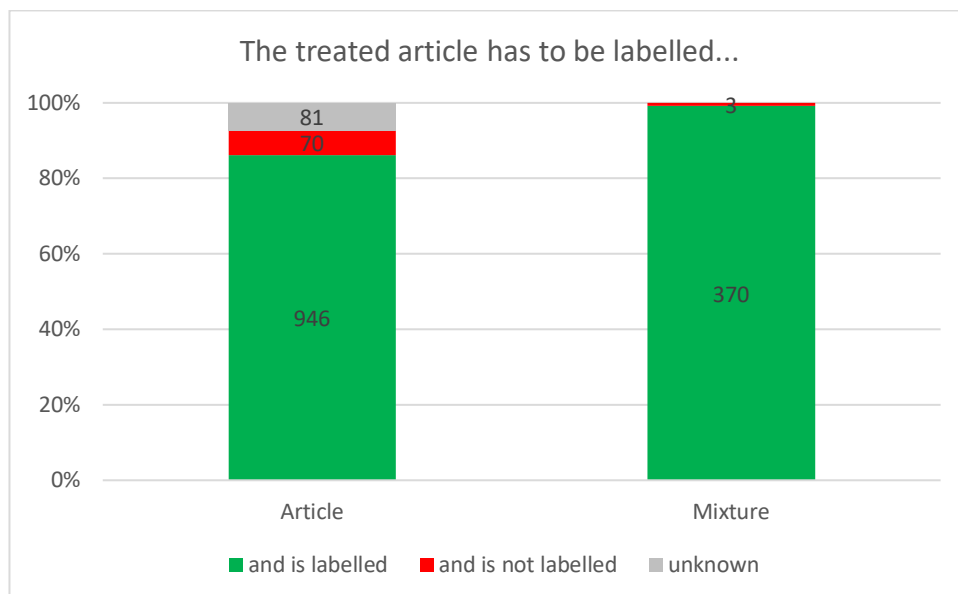


Figure 13 Presence of label on treated articles that must be labelled (reason: claim or active substance decision of approval) (%). In the bars, absolute numbers are given.

In almost all cases, the labelling was assessed to be clearly visible, easily legible and appropriately durable. The label durability of the TAs seemed to be more problematic for articles than for mixtures (Figure 14).

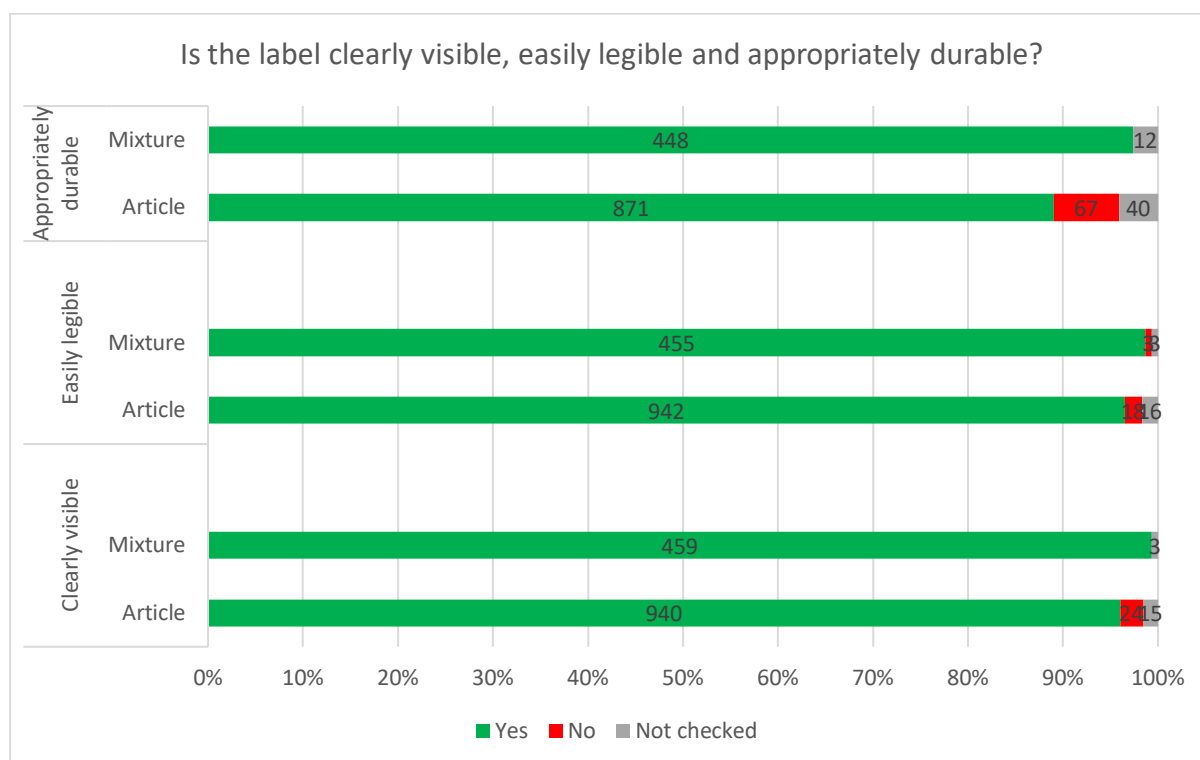


Figure 14 Number with labelling clearly visible, easily legible and appropriately durable (%). In the bars, absolute numbers are given.

According to Figure 15, the labels of all mixtures fulfilled the national requirements for languages. However, for 140 (17 %) of articles, the label was not compliant regarding the national languages.

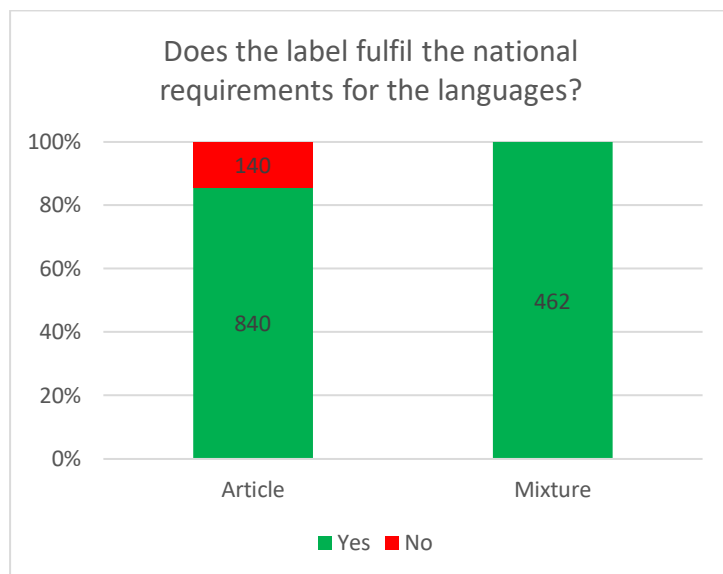


Figure 15 Fulfilment of the labelling requirements for the national languages (%). In the bars, absolute numbers are given.

When we look closer at these 140 articles with non-compliant labels regarding the languages, it appears that the non-compliance is distributed differently between participating Member States. For BE, EE, FI, NL, NO and SE, 40 % or more of the collected samples were not compliant.

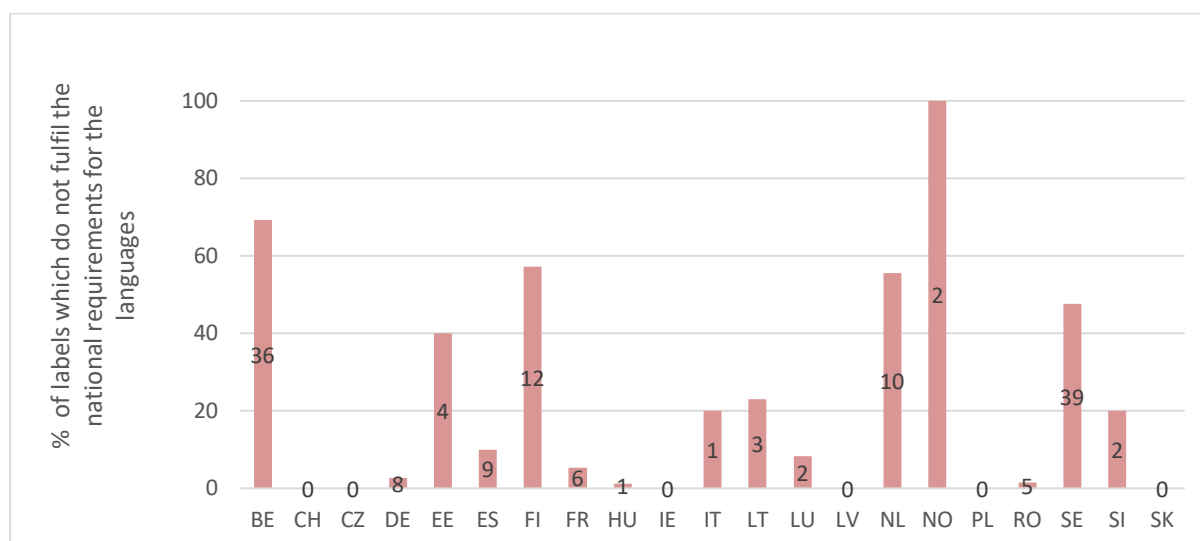


Figure 16 Percentage of labels which do not fulfil the national requirements for languages by country. In the bars, absolute numbers are given. Only articles were concerned. Only Member States that controlled articles with labelling obligations are reported.

For the obligations for sharing information on the labelling, there is a higher compliance rate for mixtures than articles. For articles, 58 % were compliant compared to 77 % for mixtures. In total, the compliance for the controlled TAs were 64 % (both articles and mixtures; Figure 17).

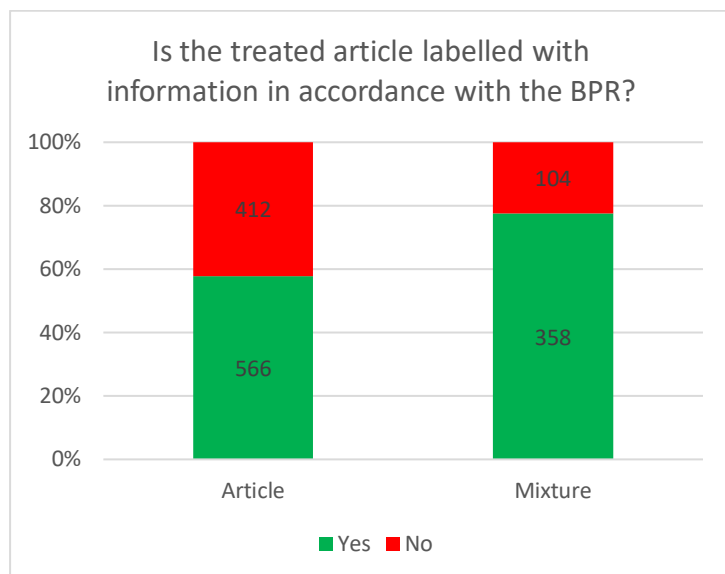


Figure 17 Compliance of the treated article labelling in accordance with the BPR (%). In the bars, absolute numbers are given.

The overview of errors and deficiencies on the label of the TAs show that the most common incompliances in the labelling are the name of the active substances, the relevant instructions for use, and the biocidal property claims (Figure 18).

There is a noticeable difference between articles and mixtures. The lack of the name of the active substances was the most common deficiency for articles (77 %; 316 out of 412), while only 17 % of mixtures lacked the name of the active substances (18 out of 104). For mixtures, it is about four times as common that they lack the biocidal property claims on the label compared to articles.

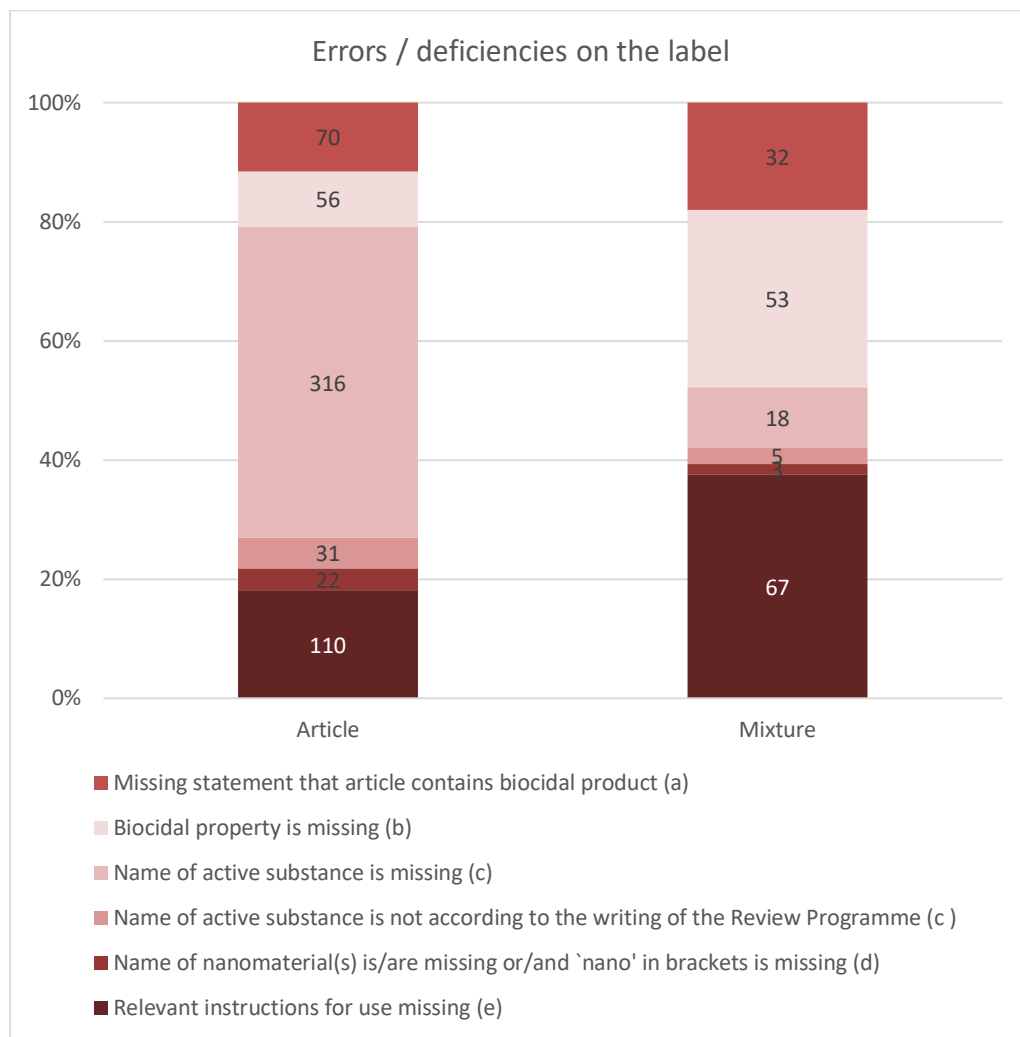


Figure 18 Errors and deficiencies on the label of the TAs (%). In the bars, absolute numbers are given. For one treated article, more than one error or deficiency could be reported. Therefore, the number of errors is higher than in Figure 17.

3.5. Active substances

In total, most of the controlled treated articles (TAs) contained only one active substance. Comparing articles and mixtures, it was more common that articles contained only one active substance, as opposed to the controlled mixtures, which usually contained more than one active substance (Figure 19). Overall, 129 different active substances were reported for the controlled TAs.

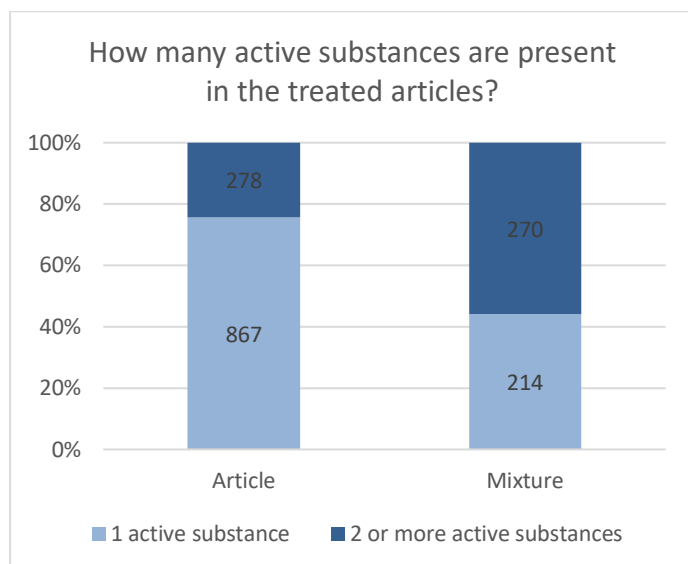


Figure 19 Number of active substances present in treated articles (%). Articles and mixtures are represented separately. In the bars, absolute numbers are given.

In the questionnaire, it was limited to report up to two active substances. Several of the checked TAs (especially the mixtures) contained more than two active substances. At least 11 TAs and 9 mixtures contained more than two active substances (Table 5). The absolute record was a mixture that contained seven active substances.

Table 5 Number of active substances. Note that this may not be complete as the information was not asked systematically and this represents the analysis of the supplementary information given by inspectors.

| Number of active substances | Articles | Mixtures |
|-----------------------------|-----------|----------|
| 3 | 8 | 7 |
| 4 | 2 | 0 |
| 5 | 1 | 1 |
| 7 | 0 | 1 |
| Total | 11 | 9 |

The tables containing the full list of active substances found in the controlled TAs are reported in Annex 2.

3.5.1. Allowed active substances in treated articles

In total, 90 different allowed active substances were found in articles, and 47 in mixtures.

The following tables show the 15 and 14 most found active substances allowed in treated articles (TAs) (Table 6 for articles and Table 7 for mixtures).

Pyrithione zinc was mostly found in articles (9 %) whereas 1,2-benzisothiazol-3(2H)-one was the most found active substance in mixtures (31 %).

Table 6 15 most found (of total 90 reported) allowed active substances in articles.

| Active substance name | Frequency | % of the inspected articles containing the active substance |
|---|-----------|---|
| Pyrithione zinc | 99 | 9 |
| Reaction mass of titanium dioxide and silver chloride | 70 | 6 |
| Permethrin | 60 | 5 |
| Tosylchloramide sodium (Chloramin T) | 58 | 5 |
| Geraniol | 49 | 4 |
| Silver phosphate glass | 47 | 4 |
| 1,2-benzisothiazol-3(2H)-one (BIT) | 44 | 4 |
| Alkyl (C12-16) dimethylbenzyl ammonium chloride / (ADBAC/BKC C12-C16) | 43 | 4 |
| Silver | 43 | 4 |
| Copper(II) carbonate-copper(II) hydroxide (1:1) | 40 | 3 |
| Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride | 39 | 3 |
| Silver chloride | 37 | 3 |
| 2-Octyl-2H-isothiazol-3-one (OIT) | 33 | 3 |
| Boric acid | 29 | 3 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (CAS 55965-84-9) (C(M)IT/MIT) | 30 | 3 |

Table 7 14 most found (of the 47 reported) common allowed active substances in mixtures.

| Active substance name | Frequency | % of the inspected mixtures containing the active substance |
|---|-----------|---|
| 1,2-benzisothiazol-3(2H)-one (BIT) | 149 | 31 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (CAS 55965-84-9) (C(M)IT/MIT) | 117 | 24 |
| 2-methyl-2H-isothiazol-3-one (MIT) (CAS: 2682-20-4) | 106 | 22 |
| 3-iodo-2-propynylbutylcarbamate (IPBC) | 84 | 17 |
| 2-Octyl-2H-isothiazol-3-one (OIT) | 70 | 14 |
| 4,5-dichloro-2-octyl-2H-isothiazol-3-one (DCOIT) | 58 | 12 |

| | | |
|--|----|---|
| Pyrithione zinc | 29 | 6 |
| Bronopol | 14 | 3 |
| Terbutryn | 12 | 2 |
| Propiconazole | 8 | 2 |
| Silver chloride | 7 | 1 |
| Permethrin | 6 | 1 |
| Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione /TMAD | 6 | 1 |
| Diuron | 5 | 1 |

3.5.2. Not allowed active substances in treated articles

In Tables 8 and 9, substances that have been reported as active substances that are not allowed to be used in articles and mixtures are respectively presented. This includes substances that are not active substances, i.e. they have not been included in the Review Programme, such as Melissa oil. It also includes substances that are allowed to be active substances but, in this case, have been used for the wrong product type.

In total 22 different not allowed active substances were found in articles and three in mixtures.

Table 8 Eight most found (of the 22 reported) common not allowed active substances in articles.

| Active substance name | Frequency | % of the inspected articles containing the active substance |
|-----------------------------------|-----------|---|
| Silver chloride | 9 | 2 |
| Silver | 5 | 1 |
| Melissa oil | 3 | 0.6 |
| Silver ion, not specified | 3 | 0.6 |
| Alcohols, C12-15, ethoxylated | 2 | 0.4 |
| 2-Octyl-2H-isothiazol-3-one (OIT) | 2 | 0.4 |
| Pyrithione zinc | 2 | 0.4 |
| Triclosan | 2 | 0.4 |

Table 9 Not allowed active substances found in mixtures (all the “not allowed active substances” found in the inspected mixtures are represented here).

| Active substance name | Frequency | % of the inspected mixtures containing the active substance |
|---------------------------------------|-----------|---|
| 1,2-benzisothiazol-3(2H)-one (BIT) | 2 | 0.4 |
| Bronopol | 1 | 0.2 |
| Alkylether sulphate 7 EO, sodium salt | 1 | 0.2 |

For 203 articles and 4 mixtures, the concerned active substances were reported as unknown (Table 10).

Table 10 Number of unknown active substances in the inspected treated articles (TAs).

| | Article | Mixture |
|----------------------------------|----------------|----------------|
| Unknown active substances | 203 | 4 |

The majority of the active substances used in the TAs were allowed, i.e. listed as "approved" or "under review" in the Review Programme for the relevant product types (Table 11).

In total, 43 active substances in 40 articles were not allowed, whereas only four mixtures contained active substances that were not allowed.

Table 11 Total number of reported allowed, not allowed and unknown active substances in articles and mixtures.

| Active substance status | In articles | In mixtures |
|--------------------------------|--------------------|--------------------|
| Allowed | 1 117 | 730 |
| Not allowed | 43 | 4 |
| Unknown | 272 | 57 |
| Total | 1 432 | 791 |

TAs that are mixtures had a higher compliance with reference to the declaration of the active substance on the label compared to articles (Figure 20). For example, only 51 % of the articles that needed to have a label due to a biocidal property claim had declared the active substance on the label, whereas for mixtures there was 97 % compliance.

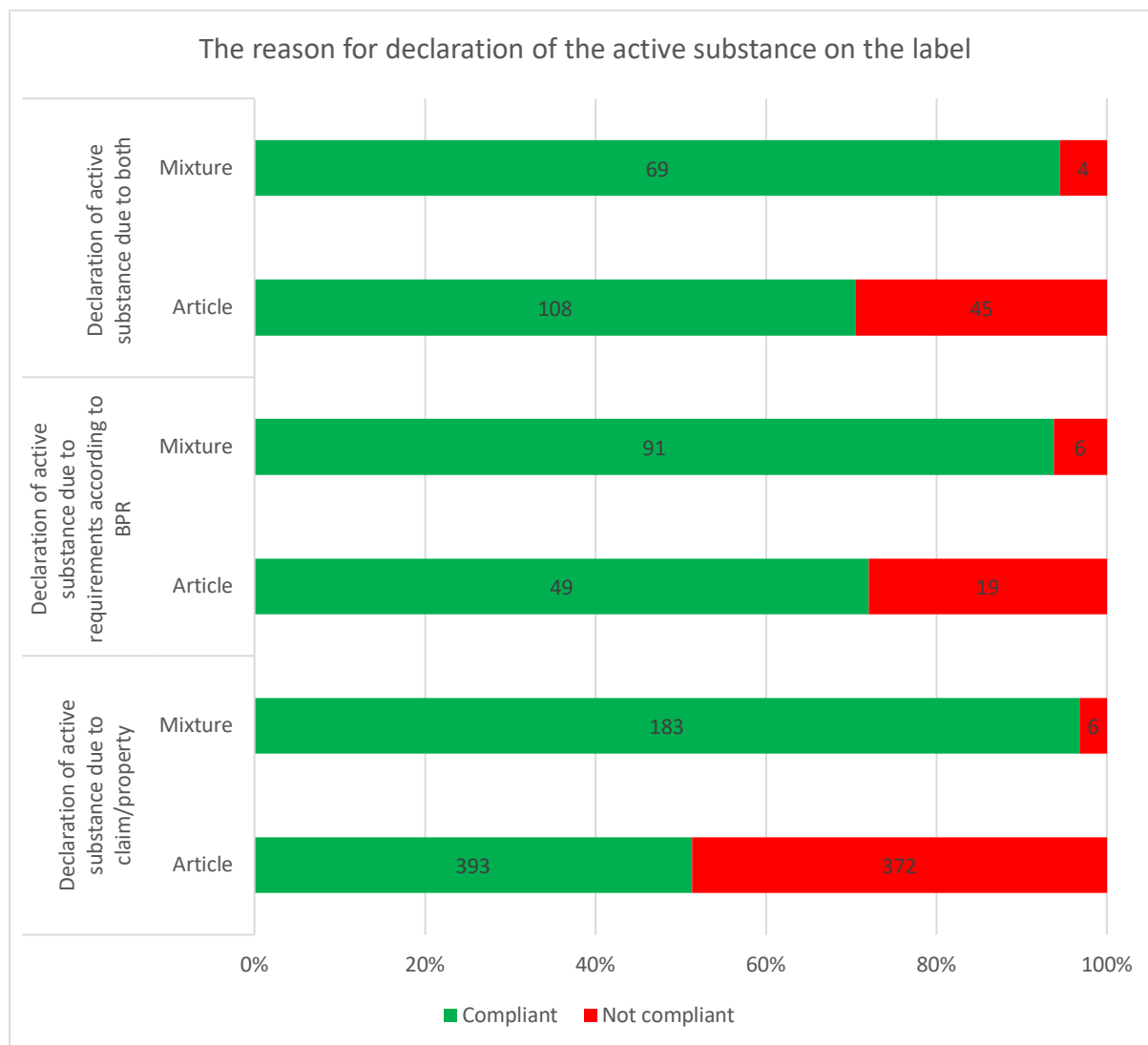


Figure 20 Number of treated articles requiring the declaration of the active substance on the label. (%). In the bars, absolute numbers are given.

3.6. Chemical analysis

Six Member States performed chemical analyses on the active substances for a total of 19 inspected treated articles (TAs).

In 12 of the 19 cases, the active substances found in the TAs corresponded to the declared active substances on the labels. In one case, the active substance did not correspond to what was declared on the label. In six cases, the active substance was not declared on the label.

3.7. Infringements and enforcement measures

As a result of the non-compliances found in treated articles (TAs), different measures have been imposed by the national enforcement authorities (NEAs). In some Member States more than one enforcement measure could be imposed for each non-compliance. In total, 615 measures were reported. The following figures are based on 1 012 companies (see Table 3).

The most common actions were written and verbal advice. 53 % of the companies were compliant and no actions were necessary.

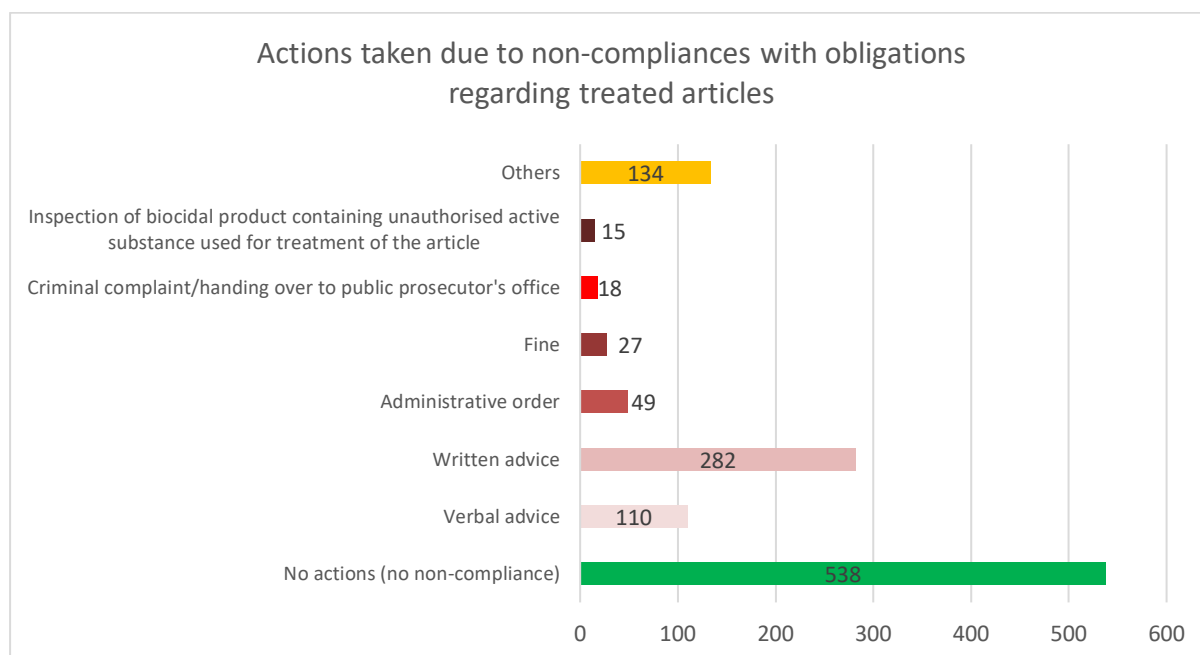


Figure 21 Action taken due to non-compliances with obligations regarding TAs

Figure 22 shows the distribution of the different actions taken by inspectors for each company size. The compliance rate (“no action taken”) was at approximately 50 % independent to the size of the company. Written advice followed by verbal advice were the actions taken most by inspectors.

Unapproved active substances were only found in companies of micro and medium sizes. Micro companies received the most fines.

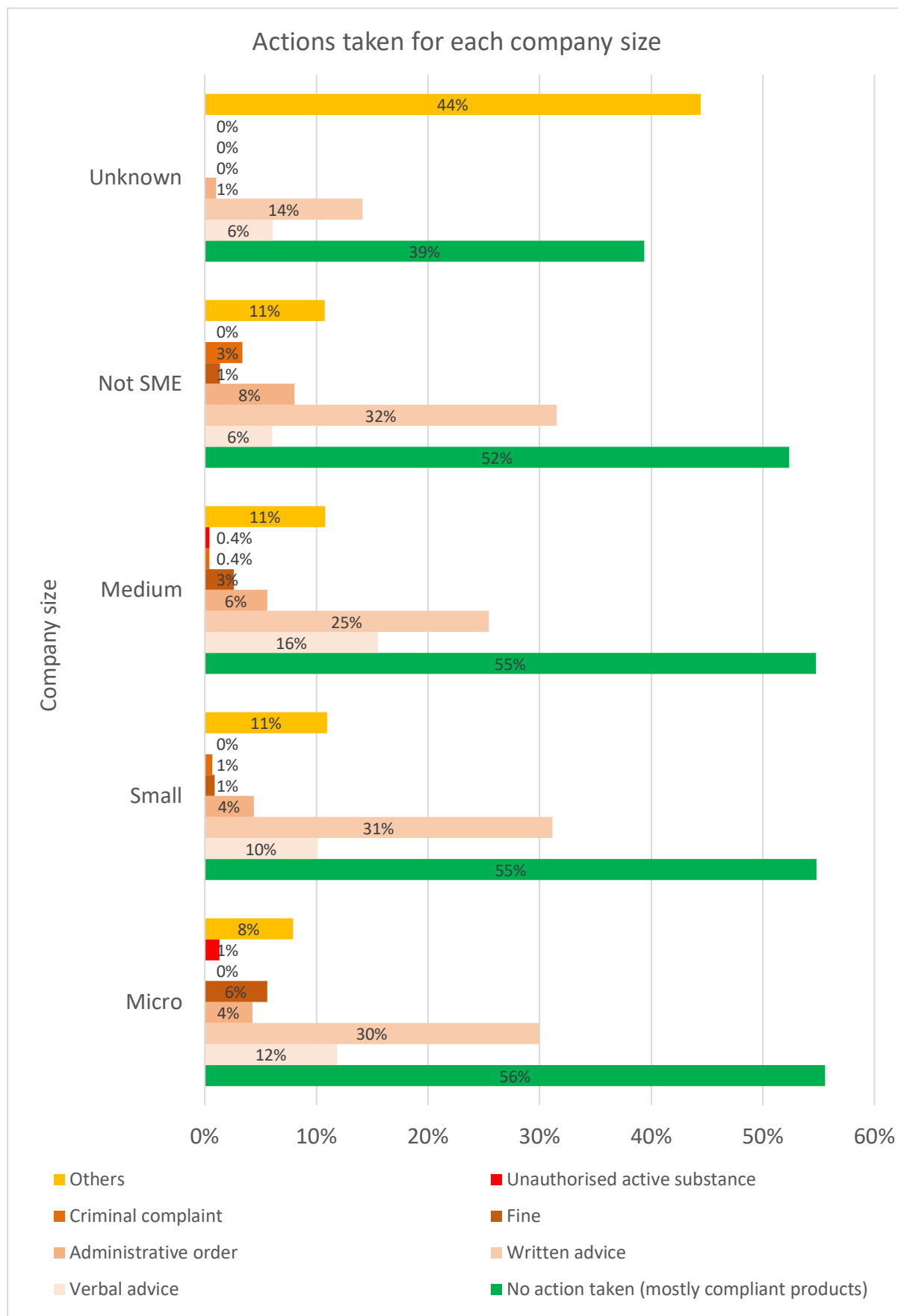


Figure 22 Action taken for each company size (%).

Figure 23 presents the reasons why companies were fined, received a criminal complaint, or an administrative order independent of their size. In more than 90 % of cases, these measures were related to labelling.

The most frequent incompliances leading to a sanction were that the information on the label did not comply with the requirements of the BPR, that the national requirements for languages were not fulfilled, or that the label on the TAs was missing.

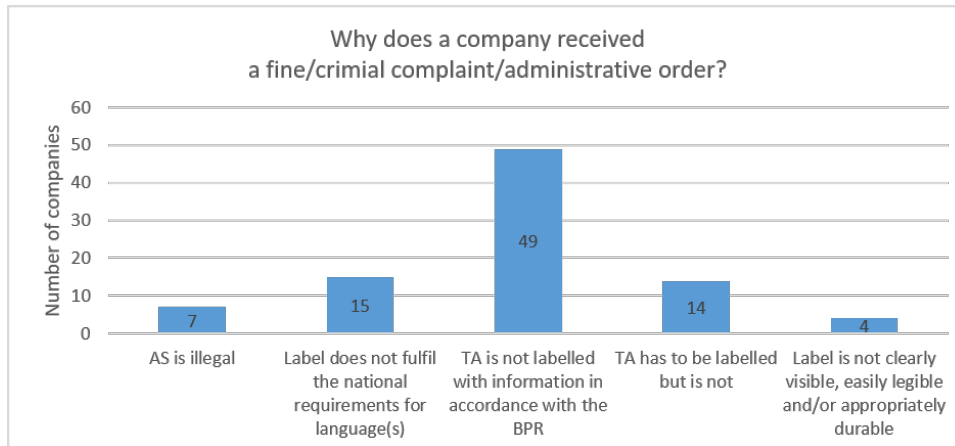


Figure 23 Reasons why companies were fined. In the bars, absolute numbers are given.

4. Conclusions and recommendations

The Working Group of the BEF-1 outlined the following conclusions and recommendations based on the inspections of treated article (TAs) performed by the national enforcement authorities (NEAs) during the operational phase of the project in the year 2019.

4.1. General considerations

Inspected **articles**, considered as treated articles, were mainly equipped with disinfectant properties and protective agents ([Figure 8](#)). For **mixtures**, considered as treated articles, the main area of application was storage and film protection. National enforcement authorities (NEAs) occasionally identified for these products potential problems of borderlines between treated articles (TAs) and biocidal products due to the primary biocidal functions of the concerned TAs. Companies might have used the provisions in place for TAs to circumvent biocidal product authorisations.

In 73 % of the inspected cases, the TAs were **produced within the EU**. For this reason, a good enforcement action is crucial to establish a level playing field with companies producing outside the EU.

The **consumers' right for information** seemed to be not very well known. Only every fifth company had received requests for information about the biocidal treatment ([Figure 5](#)).

The companies' knowledge on the responsibility for TAs was generally low. Often the whole supply chain of a TA had to be checked by the national enforcement authorities during their inspections.

The inconsistencies in the description of TAs (e.g. paints reported as articles and not as mixtures - [Figure 7](#)) highlighted that some national inspectors might have problems in understanding and interpreting the definition of TAs in accordance with the BPR. Describing a mixture as 'article' or 'article treated with a biocidal product' often led to misunderstandings.

Only one-third of the inspected TAs were placed on the market clearly after 1 March 2017. For half of the inspected TAs the date of the placing on the market was unknown ([Table 3](#)). This made enforcement rather difficult because the full applicability of the provisions is only given for the TAs placed on the market after 1 March 2017.

Companies can have two roles in marketing TAs: either they **place the TA on the market**, or they just **make them available on the market**. The legal responsibility for the compliance of TAs lies only with the first actors, the company placing TAs on the market. National enforcement authorities (NEAs) generally inspected TAs at selling points, mostly facing companies that made TAs available on the market. In this scenario enforcement is rather complex because national inspectors first needed to identify who place the concerned TAs on the market. Indeed, TAs can be widely distributed in many Member States from companies which make them available on the market. Complex supply chains make therefore enforcement problematic and time consuming.

Another problem in this context was the **language of the labels**, and the related responsibility for implementing this provision of the BPR when a TA is only made available in one Member State (and not placed on the market). In some MSs national legislations foresee sanctions for companies which make non-compliant TAs available on the market.

Often companies (at all stages of the supply chains) were found not aware of this duty.

4.2. Compliance with the BPR

The **labelling requirements** for the inspected treated articles (TAs) was generally fulfilled ([Figure 13](#)). However, this result might not be a reliable representation of the entire EU market of TAs, since the focus of the BEF-1 was on TAs with a biocidal property claim and thus clearly identified as TAs. The easiest way for national inspectors to find such products was indeed to select products with labels.

The **quality of the labels** for the inspected TAs was generally high, they were easy to read and durable ([Figure 14](#)). Also the requirements on the languages of the labels was generally well fulfilled ([Figure 15](#)). However, depending on the MSs, there was great variations and sometimes this provision was poorly met ([Figure 16](#)). MSs with minor official languages showed indeed higher incompliance.

The **quality of the information on the label** left much to be desired. Even the basic information on the biocidal active substances was often lacking ([Figure 20](#)), and in 77% of the cases articles missed this information. On the other hand, this information was met very well for mixtures, where two effects were likely to have been reinforced. On the one hand, manufacturers of mixtures are used to labelling their products and on the other hand many in-can preservatives require a declaration according to CLP, as well as the requirements of the BPR due to their sensitising properties. Across all control points, 36 % of labels showed deficiencies ([Figure 18](#)).

The interpretation of Article 58 (3) e) concerning the '**relevant instructions for use**' was perceived as difficult to determine by inspectors. For approved active substances such provisions can, in some cases, be found in the related Commission approval decisions. However, for active substances still under evaluation in the Review Programme, it is up to the national inspectors to decide whether this was applicable or not.

One of the central elements of the BPR, that only **allowed active substances** may be used to treat articles, seemed to be very well fulfilled. Less than 2.5 % of the products contained an illegal active substance. However, chemical analysis were not systematically performed and this number is only based on declared actives substances on the label ([Table 11](#)), or other sources such as the safety data sheet (SDS) and information from manufacturers.

Several MSs reported on articles that were marketed with **biocidal claims** but were found during inspections not to be treated with a biocidal product. The biocidal claim was indeed added along the supply chain as some companies seemed to consider it as beneficial in the marketing of the product.

Some companies chose to remove the biocidal claim when inspected to avoid having to comply with the biocidal legislation. This leads to unmonitored TAs on the market, making inspections more difficult (not declared TAs). This situation also makes it more difficult for consumers to make conscious choices when shopping.

One of the most used **combinations of biocidal product types (PTs)** in articles were PTs 9 and 18. These were mainly clothes treated with permethrin or a repellent. There were still differing views on these products. Some MSs considered them as biocidal products whereas others saw them as TAs.

Enforcement measures were taken by the NEAs against half of the companies inspected ([Figure 21](#)). These ranged from verbal advice to criminal prosecution.

There were no noticeable deviations in measures depending on the size of the company, except for fines. These appeared to have been more likely imposed on micro SMEs rather

than large companies ([Figure 22](#)).

4.3. Recommendations

Industry needs to **increase the knowledge and raise awareness** about the responsibilities on treated articles (TAs).

For 36 % of the checked TAs there was incompliance in the labelling. The different industry associations should be aware of the labelling requirements and inform their members about their responsibilities.

Member States with minor official language had the higher incompliance of national requirement for the **languages of the labels**. Therefore, the industry should raise awareness that TAs must be labelled in the national language(s) of the country where they are distributed.

Member States should continue providing **trainings and information campaigns** for both NEAs and industry, aiming at improving knowledge about the legal obligations for TAs.

Member States need to put more effort in clarifying that TAs can be mixtures as well as articles under the BPR.

The European Commission should better clarify the situation with clothes treated with insecticides or repellents in order to harmonise the enforcement between MSs. There is a need to update the guidance document on TAs including the Article 3 (3) decisions and the latest developments on TAs.

The BEF-1 was the first enforcement project of the BPRS, and it was focused on easily identifiable TAs in the EU market. A follow-up project under the umbrella of the BPRS could also cover unmonitored TAs, that are not simple to identify in the EU market. In this light, it would be crucial for the NEAs to perform more chemical analysis on TAs.

5. Annexes

Annex 1: Questionnaire for inspection

The document below was filled in by national inspectors as a checklist for both desktop and onsite enforcement visits during the year 2019. It was, at the same time, the tool for reporting data to the national coordinators of the BEF-1.

The questionnaire contains six different sections, which are divided into two parts. The first part constitutes the company-related information to be filled in once per company (Sections 1-3 and 6). The second part includes the article-related information to be filled in for every treated article that was inspected (Section 4). In the second part, an optional module was also included (Section 5).

Questions in white were obligatory to report. Questions in grey were not included in the reporting phase but were important to fill in for the national enforcement authorities' internal use, e.g. liaison with other national enforcement authorities for assistance and cooperation.

National inspectors were requested to only report treated articles and not biocidal products. If a TA was identified with a primary biocidal function, then the TA was marked as a biocidal product, and therefore the related information were not reported in this project. For further information on the concept of primary biocidal function see Article 3 (1) a) of the Biocidal Products Regulation (BPR) and the European Commission Guidance document on treated articles¹.

The questionnaire was intended only for the use of authorities and was not distributed to inspected companies.

| Section 1 – General information | | | |
|---------------------------------|---|--------|--|
| No | Question | Answer | Remark |
| 1 | Participating Member State | | |
| 2.1 | Company | | For your own internal use. |
| 2.2 | Address | | |
| 2.3 | Contact person | | |
| 2.4 | Telephone | | |
| 2.5 | Email (contact person) | | |
| 2.6 | Web address (if web survey/inspection) | | |
| 3 | Inspection date | | For your own internal use. |
| 3.1 | Inspector | | |
| 3.2 | Telephone (authority) | | |
| 3.3 | Email (authority) | | |
| 4 | File reference | | The file reference needs to match the file reference in Section 4 for the articles inspected. You could use your |

¹ The European Commission guidance document on treated articles:
<https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22>

| | | | |
|---|--|--|---|
| | | | country code and a number for the inspection. An example could be 'SE1' for your first inspection of company 1 and 'SE2' for your second inspection of company 2 (Sweden, SE, reporting). |
| Section 2 – Company-related information | | | |
| 5 | <p>Inspection type:</p> <p><input type="radio"/> Onsite inspection</p> <p><input type="radio"/> Desktop inspection</p> <p><input type="radio"/> Web survey</p> | | <p>Onsite inspection: When you are, for example, at the premises of a manufacturer of a treated article or in a shop selling treated articles.</p> <p>Desktop inspection: No visit to the company. All information is sent in by the company.</p> <p>Web survey: If you only wish to scan the market and don't perform any inspection.</p> |
| 6 | <p>Roles of the company under the BPR:</p> <p><input type="radio"/> Placing treated articles on the market in the Member State.</p> <p><input type="radio"/> Making treated articles available on the market in the Member State.</p> <p><input type="radio"/> Both placing and making available on the market</p> <p><input type="radio"/> Unknown, when web survey</p> | | Placing on the market includes both manufacturers and importers of treated articles to the EU. Making available is the distribution of articles within the EU. |
| 7 | <p>Company size according to definition in Commission Recommendation 2003/361/EC:</p> <p><input type="radio"/> Micro</p> <p><input type="radio"/> Small</p> <p><input type="radio"/> Medium</p> <p><input type="radio"/> Not an SME</p> <p><input type="radio"/> Unknown</p> | | <p>Micro: <10 employees and ≤ EUR 2 million annual turnover.</p> <p>Small: <50 employees and ≤ EUR 10 million annual turnover.</p> <p>Medium: <250 employees and ≤ EUR 50 million annual turnover.</p> |
| Section 3 – Company audit/inspection: routines and knowledge about treated articles | | | |
| 8 | <p>Was an onsite inspection carried out?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No – Go to Section 4.</p> | | |
| Use the questions in this section for onsite inspections . All questions are optional to ask and you can also ask fewer and/or other questions. The aim of the questions is to facilitate discussions between the inspector and the company. | | | |
| 9 | <p>Does the company have a policy regarding treated articles?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Comments: -----</p> | | Does the company have any thoughts regarding their sale of treated articles (future sale, intention to phase out such articles, etc.)? |
| 10 | Is there competence within the company to handle questions regarding chemicals in articles/treated articles? | | |

| | | |
|----|---|---|
| | <input type="checkbox"/> Yes <input type="checkbox"/> No Comments: ----- | |
| 11 | Does the company have any contract with suppliers of treated articles? <input type="checkbox"/> Written contract <input type="checkbox"/> Verbal contract <input type="checkbox"/> No contract Comments: ----- | It is important to have requirements for suppliers of treated articles to ensure that the articles are compliant with EU regulations. A way to do so is to include requirements on labelling, authorised active substances etc., in the contract. |
| 12 | What kind of information does the company get about the treated articles from their suppliers? ----- | The company will need information about the biocidal treatment of the article to be able to answer questions from consumers within 45 days as referred to in Article 58 (5) of the BPR. |
| 13 | How does the company handle the questions from consumers under Article 58(5) of the BPR? ----- | Use the answer to fill in question number 31. |
| 14 | Does the company ensure that the treated articles contain an <u>approved</u> active substance? <input type="radio"/> Yes <input type="radio"/> No - Go to question 16 | The active substance has to be on the Article 94 list under the same product type as used in the treated article. |
| 15 | How does the company ensure that the treated articles contain an <u>approved</u> active substance? <input type="checkbox"/> Performs own analysis. <input type="checkbox"/> Asks the supplier. <input type="checkbox"/> Does nothing special, fully trusts the supplier. <input type="checkbox"/> Other: ----- | |
| 16 | Who is responsible for the compliance of the labelling of the articles in the company? Name: ----- | The person placing a treated article on the market is responsible for the labelling. However, also a distributor should not supply treated articles that are not compliant with the BPR ² . It is, therefore, important to have someone responsible for the labelling of |

² More information can be found in the paper on the “Concepts of placing and making available on the market in the context of Regulation (EU) No 528/2012” (CA-Sept15-Doc.7.6 – Final, SANTE 2015-10467).

| | | |
|--|---|---|
| | | treated articles also at distribution level. |
| 17 | <p>Does the company check the labels of the treated articles before selling them?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments: -----</p> | One way of checking is to do random sampling to make sure that the articles are labelled correctly before sale. |
| <p>Section 4 – Inspection of treated articles (article-related information, questions 18-39) – Go to section to complete.</p> | | |
| <p>Section 5 – Non-allowed active substances in treated articles (optional module) Questions 40-47 – Go to section to complete.</p> | | |
| <p>Section 6 – Actions taken after inspection (company related)</p> | | |
| 48 | <p>Due to non-compliance with obligations regarding treated articles, which actions have you taken?</p> <p><input type="checkbox"/> No actions, as there was no non-compliance <input type="checkbox"/> Verbal advice <input type="checkbox"/> Written advice <input type="checkbox"/> Administrative order <input type="checkbox"/> Fine <input type="checkbox"/> Criminal complaint/handing over to public prosecutor's office <input type="checkbox"/> Inspection of biocidal product containing unauthorised active substance used for treatment of the article <input type="checkbox"/> Others – Please specify: -----</p> | If you have performed an inspection according to optional module (Section 5), mark 'Inspection of biocidal product containing unauthorised active substance used for treatment of the article'. |
| 49 | <p>Are the follow-up activities completed or ongoing?</p> <p><input type="radio"/> Completed <input type="radio"/> Ongoing</p> | If you answered 'No actions, as there was no non-compliance' to question 48, you can answer 'Completed'. |
| 50 | <p>Have any cases been forwarded to other Member States?</p> <p>Yes, to:</p> <p><input type="checkbox"/> the national coordinator of the project in the Member State. <input type="checkbox"/> the BPRS member representing the other Member State. <input type="checkbox"/> a relevant authority through ICSMS. <input type="checkbox"/> other – Please specify:</p> <p><input type="radio"/> No</p> | |
| 51 | <p>Other observations made during the inspection that you think can be useful to share with the other Member States:</p> <p>-----</p> | |
| <p>Section 4 – Inspection of treated articles (article-related information)</p> | | |
| <p>Questions about specific treated articles to be filled in for each article</p> | | |
| No | Question | Remarks |

| | | | |
|----|--|--|--|
| 4 | File reference | | The file reference needs to match the file reference in Section 1 so that the information about the checked article can be connected to the information about the company. For Sweden, this would be 'SE1'. See question 4 in Section 1. |
| 18 | Name of treated article | | For your own internal use |
| 19 | Internal identifier for the checked treated article | | For example, '1' for the first article inspected, '2' for the next. When you save/send the questionnaire, you can name the file according to the file reference with the internal identifier as a suffix. For Sweden, these would be 'SE1-1' and 'SE1-2' respectively for two articles checked during the same inspection. |
| 20 | Type of treated article: <input type="radio"/> Article <input type="radio"/> Mixture | | The definitions laid down in Article 3 of REACH shall apply for the terms in the BPR, as defined in Article 3(2) of the BPR. |
| 21 | Product type (PT) according to the BPR for the given biocidal property of the treated article: <input type="checkbox"/> PT____ <input type="checkbox"/> PT____ <input type="checkbox"/> Unclear PT | | Up to two product types can be provided in the answer. See Annex 8 to this manual for a description of product types ³ according to Annex V to the BPR. |
| 22 | Description of treated article: <input type="checkbox"/> Clothing <input type="checkbox"/> Sport equipment <input type="checkbox"/> Bedding <input type="checkbox"/> Baby articles <input type="checkbox"/> Kitchenware <input type="checkbox"/> Bathroom and toilet items <input type="checkbox"/> Paints <input type="checkbox"/> Chemical mixtures (not paints) <input type="checkbox"/> Furniture <input type="checkbox"/> Garden furniture <input type="checkbox"/> Electronic devices <input type="checkbox"/> Other | | For example, 'clothing', 'sports equipment', 'paint'. Sports equipment will include, for example: tents, boxing gloves, yoga mats etc. Shoes and workout clothes should be included in the option "clothing". |
| 23 | Origin of treated article: | | |

³ Some common treated articles are shoes and clothing where the biocidal property of the articles is antibacterial, to prevent the development of odour by such microorganisms. Such articles are treated with/contain biocidal products in PT 9.

| | | |
|----|--|--|
| | <input type="radio"/> Manufactured within the EU <input type="radio"/> Imported to the EU <input type="radio"/> Unknown | |
| 24 | <p>When was the article placed on the market?</p> <input type="radio"/> Before 1 Sept 2013 <input type="radio"/> After 1 Sept 2013 but before 1 March 2017 <input type="radio"/> After 1 March 2017 <input type="radio"/> Unknown | <p>A treated article that contains an unapproved active substance can still be made available on the market depending on the date it is placed on the market. This is due to transitional rules in the BPR⁴. If the article was placed on the market before 1 September 2013, the BPR is not applicable and the article should not be reported.</p> <p>For more information on the transitional rules in the BPR, refer to Annex 3 to the manual, i.e. Article 94 of the BPR.</p> |
| 25 | <p>Does the treated article have to be labelled?</p> <input type="radio"/> Yes <input type="checkbox"/> The treated article has a biocidal claim/property. <input type="checkbox"/> There are labelling requirements according to the BPR for the active substance in the biocidal product used for treatment of the article. <input type="radio"/> No, there is no labelling requirement according to Article 58 of the BPR. | <p>Treated articles without a biocidal claim but which contain an active substance with a condition regarding treated articles in the decision of approval need to fulfil the labelling requirements as defined in Article 58 (3) of the BPR.</p> <p>Note that the article may also have to be labelled with relevant instructions for use if this is necessary to protect humans, animals and the environment, as provided in Article 58 (4) of the BPR.</p> |
| 26 | <p>What is the source of information used to determine if it is a treated article?</p> <input type="checkbox"/> Label <input type="checkbox"/> Advertisement <input type="checkbox"/> Website <input type="checkbox"/> On the shelf <input type="checkbox"/> MSDS <input type="checkbox"/> Information from distributor <input type="checkbox"/> Certificate of analysis | |

⁴ Even treated articles containing an active substance with a decision of non-approval could be placed on the market until 1 March 2017 if the decision was taken before 1 September 2016. An example of this is Triclosan, which got a decision of non-approval in 2014. This is due to the transitional rules – see Annex 3 for more information.

| | | |
|----|--|--|
| | <input type="checkbox"/> Analysis by authority <input type="checkbox"/> Other | |
| 27 | <p>What is the name of the active substance?</p> <p>Active substance 1: Name: _____</p> <input type="checkbox"/> Unknown | <p>Please write the common name, if possible, e.g. 'ethanol'.</p> |
| | <p>What is the CAS number of the active substance?</p> <p>CAS number: _____</p> <input type="checkbox"/> Unknown | |
| | <p>Is the name of the active substance on the label?</p> <input type="radio"/> Yes <input type="radio"/> no | |
| 28 | <p>Is there a second active substance?</p> <input type="checkbox"/> Yes - Go to question 29 <input type="checkbox"/> No - Go to question 30 | |
| 29 | <p>Active substance 2 (if inspecting more than one substance):</p> <p>Name: _____</p> <input type="checkbox"/> Unknown | |
| | <p>What is the CAS number of the active substance?</p> <p>CAS number: _____</p> <input type="checkbox"/> Unknown | |
| | <p>Is the name of the active substance on the label?</p> <input type="radio"/> Yes <input type="radio"/> no | |
| 30 | <p>Is/are the active substance(s) mentioned above <u>allowed to be used</u> in the treated article?</p> <p>Active substance 1:</p> <input type="radio"/> Yes <input type="radio"/> No ⁵ <input type="radio"/> Unknown | <p>The active substance has to be on the Article 94 list under the same product type as used in the treated article.</p> |
| | <p>Active substance 2 (if applicable):</p> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown | |
| 31 | <p>Does the company answer consumers' questions about the biocidal treatment of a</p> | <p>As provided in Article 58(5) of the BPR, a company</p> |

⁵ If the treated article is placed on the market in your Member State, you can continue with inspection of the biocidal product used for treating the article if you wish (optional module). You can use Section 5 for that purpose.

| | | |
|----|--|---|
| | <p>treated article?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Company never received questions</p> <p><input type="radio"/> Not checked</p> | <p>selling treated articles must, upon request by a consumer, provide information about the biocidal treatment within 45 days. This question could also be asked when performing a desktop inspection.</p> |
| 32 | <p>Does the treated article have a label?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No – Go to question 38.</p> <p><input type="radio"/> Unknown – Go to question 38.</p> | <p>See Article 58(3) of the BPR.</p> |
| 33 | <p>Does the label fulfil the national requirements for the language(s)?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> | <p>The label information shall be provided in the official language or languages of the Member State of introduction. In some Member States, there may be more than one official language.</p> <p>Article 58(6) of the BPR.</p> |
| 34 | <p>Is the treated article labelled with information in accordance with the BPR?</p> <p><input type="radio"/> Yes – Go to question 36.</p> <p><input type="radio"/> No</p> | <p>The label needs to provide information for consumers to make informed choices and for users to safely handling the article.</p> <p>Article 58(3)(a-e) of the BPR.</p> |
| 35 | <p>Please specify the errors/deficiencies in the labels of the treated article in the table below:</p> <p><input type="checkbox"/> Missing statement that article contains biocidal product (a)</p> <p><input type="checkbox"/> Biocidal property is missing (b)</p> <p><input type="checkbox"/> Name of active substance is missing (c)</p> <p><input type="checkbox"/> Name of active substance is not according to the writing of the Review Programme⁶..... (c)</p> <p><input type="checkbox"/> Name of nanomaterial(s) is/are missing or/and 'nano' in brackets is missing (d)</p> <p><input type="checkbox"/> Relevant instructions for use missing (e)</p> | <p>It may be difficult to differentiate between some of the requirements, for example, the statement that the article contains a biocidal product and the biocidal property of the article. The biocidal property could be 'antibacterial', while a statement could be 'this article contains a biocidal product'. (Article 58(3) of the BPR)</p> |
| 36 | <p>Where is the label placed on the article?</p> <p><input type="checkbox"/> On the article itself.</p> | <p>The label should preferably be placed on the article itself. In some cases, this is</p> |

⁶ Commission Delegated Regulation (EU) No 1062/2014 on the work programme for the examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012. ECHA's Article 94 list:
https://echa.europa.eu/documents/10162/17158507/treated_art94_data_en.pdf

| | | |
|----|---|--|
| | <input type="checkbox"/> On the packaging. <input type="checkbox"/> On the instructions for use. <input type="checkbox"/> On the warranty. <input type="checkbox"/> The label information is given in another way. | <p>not possible and the label can be placed on, for example, the packaging. This will have to be decided on a case-by-case basis.</p> <p>Article 58(6) of the BPR.</p> |
| 37 | <p>Is the label clearly visible, easily legible and appropriately durable?</p> <p>Clearly visible: <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not checked</p> <p>Easily legible: <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not checked</p> <p>Appropriately durable: <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not checked</p> | <p>Whether the label is clearly visible, easily legible and appropriately durable will have to be decided on a case-by-case basis. It can, for example, be difficult to make a durable label on a shoe due to the use of the shoe.</p> <p>Article 58 (6) of the BPR.</p> |
| 38 | <p>Do you have information about the composition of the treated article?</p> <p><input type="radio"/> No – Go back to main questionnaire <input type="radio"/> Yes</p> <p><input type="checkbox"/> safety data sheet (MSDS) <input type="checkbox"/> certificate of analysis <input type="checkbox"/> chemical analysis by enforcing authority <input type="checkbox"/> other: _____</p> | |
| 39 | <p>Do the active substances found in the article correspond to the declared active substances?</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Active substance not declared</p> | |

| Section 5 – Non-allowed active substances in treated articles (optional module) | | | |
|--|---|-----------------------|---|
| You can use this section if you find a non-allowed active substance in a treated article placed on the market in your Member State and you wish to continue the inspection with regard to the <i>biocidal product</i> used for treating the article. | | | |
| No | Question | Answer | Remarks |
| 40 | Name of active substance | | Please write the common name, if possible (e.g. 'ethanol'). |
| 41 | CAS number of active substance | | |
| 42 | Reason that substance is deemed non-allowed: <input type="checkbox"/> The substance is not on the Article 94 list. <input type="checkbox"/> The substance in the product used to treat the article is used in a non-approved product type. Comments: | | |
| 43 | Name of the biocidal product used for treatment | | |
| 44 | Product type | | See Annex 8 of this manual for a list of the product types under the BPR. The product types are more thoroughly described in Annex V to the Regulation. |
| 45 | Contact information of company making the biocidal product available on the market | Name: Address: | |
| 46 | Manufacturer of biocidal product | | |
| 47 | Country of origin of the biocidal product used | | |

Annex 2: Active substances reported in treated articles

Allowed active substances are here defined as active substances identified for an active substance/PT combination notified in the Review Programme or with a Commission decision of approval (Tables 15 and 16).

On the contrary, not allowed active substances are active substances identified for an active substance/PT combination that are not notified in the Review Programme. In some cases, a decision of non-approval was taken for an active substance/PT combination. These indications are in the footnotes.

Table 12 Allowed active substances found in inspected articles.

| Active substance name | Frequency of active substance in articles |
|---|---|
| Pyrithione zinc | 99 |
| Reaction mass of titanium dioxide and silver chloride | 70 |
| Permethrin | 60 |
| Tosylchloramide sodium (Chloramin T) | 58 |
| Geraniol | 49 |
| Silver phosphate glass | 47 |
| 1,2-benzisothiazol-3(2H)-one (BIT) | 44 |
| Alkyl (C12-16) dimethylbenzyl ammonium chloride / (ADBAC/BKC C12-C16) | 43 |
| Silver | 43 |
| Copper(II) carbonate-copper(II) hydroxide (1:1) | 40 |
| Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride | 39 |
| Silver chloride | 37 |
| 2-Octyl-2H-isothiazol-3-one (OIT) | 33 |
| Boric acid | 29 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (CAS 55965-84-9) (C(M)IT/MIT) | 30 |
| Didecyl dimethylammonium chloride / DDAC (C8-10) | 20 |
| Ethanol | 17 |
| Propiconazole | 17 |
| Polymeric betaine | 16 |
| Copper (II) hydroxide | 15 |
| 2-Thiazol-4-yl-1H-benzimidazole (Thiabendazole) | 14 |
| Dimethyltetradecyl[3-(trimethoxysilyl) propyl] ammonium chloride | 14 |
| Glutaraldehyde | 14 |
| Bis[1-cyclohexyl-1,2-di(hydroxy-.kappa.O)diazeniumato(2-)]-copper | 13 |
| Silver sodium hydrogen zirconium phosphate | 13 |
| 3-iodo-2-propynylbutylcarbamate (IPBC) | 12 |
| 2-methyl-2H-isothiazol-3-one (MIT) (CAS: 2682-20-4) | 12 |
| N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine) | 12 |
| Propan-1-ol | 12 |
| Propan-2-ol | 12 |
| Glyoxal | 11 |
| Silver nitrate | 12 |
| Tebuconazole | 11 |
| Margosa extract from cold-pressed oil of Azadirachata Indica seeds without shells (kernel) extracted with super-critical carbon dioxide (sCO ₂) | 10 |

| Active substance name | Frequency of active substance in articles |
|--|---|
| Pentapotassium bis(peroxymonosulfate) bis(sulphate) (KPMS) | 9 |
| 4,5-dichloro-2-octyl-2H-isothiazol-3-one (DCOIT) | 8 |
| Formaldehyde | 7 |
| Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18)) | 6 |
| Active chlorine released from sodium hypochlorite (hereafter referred to as 'sodium hypochlorite') | 5 |
| Biphenyl-2-ol | 5 |
| Ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate (Fenoxycarb) | 5 |
| Hydrogen peroxide | 5 |
| Silver ion, not specified | 5 |
| Silver zinc zeolite | 5 |
| Formaldehyde released from (Ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm)) | 4 |
| Silver adsorbed on silicon dioxide (HeiQ AGS-20) | 4 |
| Silver, nano form | 4 |
| 2-Phenoxyethanol | 3 |
| Chlorocresol | 3 |
| Folpet | 3 |
| Peracetic acid | 3 |
| PHMB (1600; 1.8) (polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1600 and a mean polydispersity (PDI) of 1.8) | 3 |
| Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (ADBAC (C12-C14)) | 3 |
| Substance not identifiable | 3 |
| Poly(oxy-1,2-ethanediyl), .alpha.-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate (salt) (Bardap26) | 2 |
| Cypermethrin | 2 |
| Diuron | 2 |
| Eucalyptus citriodora oil, hydrated, cyclized | 2 |
| Lavender oil | 2 |
| Oxygen ⁷ | 2 |
| Peppermint oil | 2 |
| (Benzothiazol-2-ylthio) methyl thiocyanate (TCMTB) | 2 |
| Terbutryn | 2 |
| No AS reported | 2 |
| 2-aminoethanol ¹⁰ | 1 |
| 2-hydroxy-.alpha.,.alpha.,4-trimethylcyclohexanemethanol | 1 |
| 5-chloro-2-(4-chlorophenoxy)phenol (DCPP) | 1 |
| Alkyl-benzyl-dimethylammonium chloride/Benzalkonium chloride [1] | 1 |
| Bronopol | 1 |
| Butan-2-ol ¹⁰ | 1 |
| Carbendazim | 1 |
| Chrysanthemum cinerariaefolium, ext. | 1 |
| Citric acid | 1 |
| Copper (II) oxide | 1 |
| Copper carbonate ¹⁰ | 1 |
| D-gluconic acid, compound with N,N'-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (CHDG) | 1 |

⁷ Not an active substance, i.e. not included in the Review Programme.

| Active substance name | Frequency of active substance in articles |
|---|---|
| Disodium tetraborate (pentahydrate) | 1 |
| Disodium tetraborate, anhydrous ⁸ | 1 |
| Docusate sodium ¹⁰ | 1 |
| Ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate (Fenoxycarb) | 1 |
| (+/-)-cis-4-[3-(p-tertbutylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine (fenpropimorph) | 1 |
| Glycolic acid | 1 |
| Polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1415 and a mean polydispersity (PDI) of 4.7 (PHMB (1415;4.7)) | 1 |
| Quaternary ammonium compounds, benzyl-C10-16-alkyldimethyl, chlorides [1] | 1 |
| Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, salts with 1,2-benzisothiazol-3(2H)-one 1,1-dioxide (1:1) (ADBAS) | 1 |
| Quaternary ammonium compounds, coco alkyltrimethyl, chlorides [3] (ATMAC/TMAC) | 1 |
| Silver salt, not specified | 1 |
| Silver zeolite | 1 |
| Sodium pyrithione | 1 |
| Total | 1116 |

Table 13 Allowed active substances found in inspected mixtures.

| Active substance name | Frequency of active substance in mixtures |
|---|---|
| 1,2-benzisothiazol-3(2H)-one (BIT) | 149 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (CAS 55965-84-9) (C(M)IT/MIT) | 117 |
| 2-methyl-2H-isothiazol-3-one (MIT) (CAS: 2682-20-4) | 106 |
| 3-iodo-2-propynylbutylcarbamate (IPBC) | 84 |
| 2-Octyl-2H-isothiazol-3-one (OIT) | 70 |
| 4,5-dichloro-2-octyl-2H-isothiazol-3-one (DCOIT) | 58 |
| Pyrithione zinc | 29 |
| Bronopol | 14 |
| Terbutryn | 12 |
| Propiconazole | 8 |
| Silver chloride | 7 |
| Permethrin | 6 |
| Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione / TMAD | 6 |
| Diuron | 5 |
| Silver phosphate glass | 5 |
| (benzyloxy)methanol | 4 |
| 2-Phenoxyethanol | 4 |

⁸ Decision of non-approval: Commission Decision 2010/72/EU.

| Active substance name | Frequency of active substance in mixtures |
|---|---|
| Alkyl (C12-16) dimethylbenzyl ammonium chloride / (ADBAC/BKC C12-C16) | 4 |
| 2-butyl-benzo[d]isothiazol-3-one (BBIT) | 3 |
| Carbendazim | 3 |
| Formaldehyde released from (Ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm)) | 3 |
| 3-(4-isopropylphenyl)-1,1-dimethylurea (Isoproturon) | 3 |
| 1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione / (DMDMH) | 2 |
| Propan-2-ol | 2 |
| Reaction mass of titanium dioxide and silver chloride | 2 |
| Tebuconazole | 2 |
| Magnesium nitrate ¹² | 1 |
| 2,2'-oxydiethanol ⁹ | 1 |
| 2-Thiazol-4-yl-1H-benzoimidazole (Thiabendazole) | 1 |
| 3-(4-Isopropylphenyl)-1,1-dimethylharnstoff / Isoproturon | 1 |
| active chlorine released from sodium hypochlorite (hereafter referred to as 'sodium hypochlorite'). | 1 |
| Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18)) | 1 |
| Allyl isothiocyanate | 1 |
| Benzyl Alcohol | 1 |
| Biphenyl-2-ol ¹⁰ | 1 |
| Butanone oxime | 1 |
| Calcium dihydroxide (hydrated lime) | 1 |
| Chlorocresol | 1 |
| Cypermethrin | 1 |
| 2,2'-dithiobis[N-méthylbenzamide] (DTBMA) | 1 |
| N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine) | 1 |
| Polymeric betaine | 1 |
| Silver | 1 |
| Sodium benzoate | 1 |
| Sodium hydroxide ⁷ | 1 |
| Sodium N-(hydroxymethyl) glycinate | 1 |
| α,α',α''-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT) | 1 |
| Total | 729 |

Table 14 Not allowed active substances found in inspected articles

| Active substance name | Frequency of active substance in articles |
|---------------------------|---|
| Silver chloride | 9 |
| Silver | 5 |
| Melissa oil ¹³ | 3 |

⁹ This substance is not considered an active substance, i.e. not included in the Review Programme.

¹⁰ This substance is not considered an active substance, i.e. not included in the Review Programme.

| Active substance name | Frequency of active substance in articles |
|---|---|
| Silver ion, not specified | 3 |
| Alcohols, C12-15, ethoxylated ¹³ | 2 |
| 2-Octyl-2H-isothiazol-3-one (OIT) | 2 |
| Pyrithione zinc | 2 |
| Triclosan | 2 |
| Active bromine generated from bromine chloride | 1 |
| Alkyl (C12-16) dimethylbenzyl ammonium chloride / (ADBAC/BKC C12-C16) | 1 |
| Alkyl (C12-18) dimethylbenzyl ammonium chloride / (ADBAC C12-18) | 1 |
| 1,2-benzisothiazol-3(2H)-one (BIT) | 1 |
| Docusate sodium ¹³ | 1 |
| Gold ¹³ | 1 |
| Hydrogen peroxide | 1 |
| Methanol ¹³ | 1 |
| Permethrin | 1 |
| Polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1415 and a mean polydispersity (PDI) of 4.7 (PHMB (1415;4.7)) | 1 |
| Silver phosphate glass | 1 |
| Silver, nano form | 1 |
| Silver-zinc-aluminium-boronphosphate glass/Glass oxide, silver- and zinc-containing | 1 |
| Zinc oxide ¹¹ | 1 |
| No AS reported | 1 |
| Total | 43 |

Table 15 Not allowed active substances found in inspected mixtures.

| Active substance name | Frequency of active substance in mixtures |
|---|---|
| 1,2-benzisothiazol-3(2H)-one (BIT) | 2 |
| Bronopol | 1 |
| Alkylether sulphate 7 EO, sodium salt ¹² | 1 |
| Total | 4 |

¹¹ Decision of non-approval: Commission Regulation (EC) 1048/2005.

¹² Not an active substance, i.e. not included in the Review Programme.

Annex 3: Previous projects on treated articles

- EuroBiocides III: Project on treated articles, CLEEN 2017
- Project report Biocidal substances in textiles [English summary], Federal office of public health, Switzerland.
<https://www.anmeldestelle.admin.ch/dam/chem/en/dokumente/download-listen/chemikalien-kampagnen/projektbericht-wirkstoffe-in-textilien.pdf.download.pdf/projektbericht-wirkstoffe-in-textilien-de.pdf>
- Project report Biocidal products in facade coatings [English executive summary], Federal office of public health, Switzerland.
<https://www.anmeldestelle.admin.ch/dam/chem/en/dokumente/download-listen/chemikalien-kampagnen/bericht-kampagne-biozide-in-fassaden-2016-2017.pdf.download.pdf/report-biocidal-products-in-facade-coatings-campaign-2016-2017.pdf>
- Biocide treated articles – An internet survey, Swedish Chemicals Agency
<https://www.kemi.se/download/18.6df1d3df171c243fb23960bd/1591097405450/pm-2-12-biocide-treated-articles.pdf>
- Biocide treated articles – assessing knowledge levels, Swedish Chemicals Agency,
<https://www.kemi.se/download/18.6df1d3df171c243fb23960c5/1591097407460/pm-10-12-biocide-treated-articles.pdf>
- Market survey on articles treated with biocides, Swedish Chemicals Agency,
<https://www.kemi.se/download/18.60cca3b41708a8aecdbb6a8c/1586793296149/pm-6-16-market-survey-on-articles-treated-with-biocides.pdf>

Annex 4: Product types as defined in the BPR

Main group 1: Disinfectants

- PT 1 Human hygiene
- PT 2 Disinfectants and algaecides not intended for direct application to humans or animals
- PT 3 Veterinary hygiene
- PT 4 Food and feed area
- PT 5 Drinking water

Main group 2: Preservatives

- PT 6 Preservatives for products during storage
- PT 7 Film preservatives
- PT 8 Wood preservatives
- PT 9 Fibre, leather, rubber and polymerised materials preservatives
- PT 10 Construction material preservatives
- PT 11 Preservatives for liquid-cooling and processing systems
- PT 12 Slimicides
- PT 13 Working or cutting fluid preservatives

Main group 3: Pest control

- PT 14 Rodenticides
- PT 15 Avicides
- PT 16 Molluscicides, vermicides and products to control other invertebrates
- PT 17 Piscicides
- PT 18 Insecticides, acaricides and products to control other arthropods
- PT 19 Repellents and attractants
- PT 20 Control of other vertebrates

Main group 4: Other biocidal products

- PT 21 Antifouling products
- PT 22 Embalming and taxidermist fluids

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