Forum Biocidal Products Regulation Subgroup (BPRS)

BEF-3 harmonised enforcement project report

Control of biocides labels, elements of the Safety Data Sheets and the use of information from the Summary of Product Characteristics – **BEF-3**

Operational phase: 2025

Adopted on 12 November 2026

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This report presents the results of inspections carried out 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 varied considerably between countries. Accordingly, the results presented in the report are not necessarily representative of the situation in the EU-EEA market as a whole.

BPRS BEF-3 project report on control of biocide labels, elements of the Safety Data Sheet and the use of information from the Summary of Product Characteristics

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Glossary

Term	Description
Advertisement	Means of promoting the sale or use of biocidal products by printed, electronic or other media (Article 3(1)(y) of the BPR)
BPR	Biocidal Products Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products
BPRS	BPR Subgroup of the Forum for exchange of information on enforcement. It is a network of authorities responsible for enforcement of BPR in the EU, Norway, Iceland, Switzerland and Liechtenstein
CLP Regulation	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures
EEA	European Economic Area
Forum	Forum for exchange of information on enforcement. Network of enforcement authorities established under the REACH Regulation.
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).
MS	Member State
NEA	National Enforcement Authority
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).
REACH Regulation	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency
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.

Executive summary

BEF-3 project

The Forum Subgroup for exchange of information on enforcement of Regulation (EU) No 528/2012 (i.e. BPRS) conducted an EU-wide enforcement project on biocides during 2025 (i.e. BEF-3).
The harmonised project focused on inspections of the labels of biocidal products and the use of information from the Summary of Product Characteristics (SPC). Assessment of the quality of the SPCs, controls of elements of Safety Data Sheets (SDS) and chemical analysis were also included as optional within the scope of the project.

The objective of the BEF-3 was to harmonise the enforcement of requirements concerning the use of information from the SPC in the labels and SDS of the biocidal products available in the EU market.

BEF-3 targeted only biocidal products authorised according to the Regulation (EU) No 528/2012

(BPR) and therefore provided with an SPC. Inspectors checked national authorisations, Union authorisations, and simplified authorisations. The use of biocidal products was not assessed within the project.

Biocidal products made available on the market under national transitional measures (Article 89 of the BPR) are not covered under the scope of the BEF-3 project.

National inspectors autonomously selected companies and biocidal products during their enforcement activities.

BEF-3 aimed to raise awareness on the importance of the content of the SPC, which must always be included in the authorisation. In line with Article 69 of the BPR, biocidal products are to be classified, packaged and labelled by authorisation holders in accordance with the approved SPCs. In addition, CLP Regulation provisions also apply.

Key results

The National Enforcement Authorities in 27 countries inspected 2053 biocidal products. Only biocidal products authorised according to the BPR were checked. These included products authorised by national, Union and simplified authorisation, but excluded products currently under transitional measures (Article 89 of the BPR).

Inspections concerned different actors along the supply chain of biocidal products, but the largest proportion of products (37%) was checked among distributors.
Overall, 24% of the inspected products were found by the inspectors to be non-compliant with regard to at least one of the BPR requirements. For 4% of the inspected products, inspectors considered at least one non-compliance sufficiently serious to prevent the product from being legally made available on the market. Where inspectors detected non-compliance, they took enforcement measures to rectify the situation – in most cases issuing advice or administrative orders.

Regarding the consistency between the SPC and product labels, packaging and leaflets, inspectors assessed, 20% of product as not fully compliant resulted with the SPC (at different extent). This relatively high non-compliance rate should be interpreted in light of the varying severity of the issues identified, as many of the non-compliances did not prevent the products from being made available on the market.

For products classified in accordance with the CLP Regulation, 13% of the inspected products showed at least one non-compliance with regard to CLP elements on the label.

Among all the SDSs checked by the inspectors, 18% were assessed as being non-compliant with the SPC to varying degrees.

Only 63 products were analysed to check the active substance concentration against the information in the authorisation. Only one product did not comply.

Finally, the quality of the SPC was assessed for nearly two thirds of the products. For 14% of products, issues were identified in the content of the SPC. These included unclear terminology, conflicting information or lack of practical and implementable instructions.

Main conclusions and recommendations

BEF-3 found a relatively high non-compliance with the BPR requirements, with almost one in four products failing to comply with at least one requirement. However, only 4 % of the inspected products showed major non-compliances, which would affect their making available on the market.

BEF-3 showed that labelling non-compliances are common among authorised products, even though the authorisation documentation provides the authorisation holder with all the

information needed to ensure that the product is correctly labelled. It is therefore recommended that the industry implements processes that would prevent non-compliances of biocidal product labelling and packaging. BPRS recommends that the Commission, together with the Competent Authority should reflect on the possibility to simplify the structure of the SPC to facilitate the transfer of the information from the SPC to the label for the economic operators.

For a notable proportion of the products checked, statements that were lacking clarity, coherence, feasibility and enforceability were found in the SPC. It is proposed that ECHA should consider the possibility of supporting the development of standardised information and definitions to be used in the SPC as well as the development of guidelines for an improved SPC structure. Also, it is important that the Member States Authorising authorities check more carefully the SPC for clarity, repetitions, simple language and translation accuracy (some of these problems may also arise from translation errors).

Chemical analysis of authorised biocidal products indicated that deviations from the active substance concentration in the SPC were uncommon.

1. Introduction

The scope of the third harmonised enforcement project (**BEF-3**), which was conducted under the umbrella of the Forum for exchange of information on enforcement Subgroup of the BPR (**BPRS**), focused on the SPC and related information on biocidal products' labels. In addition, the project also included checks of certain information in the Safety Data sheets (SDS) and, to a limited extent, chemical analysis.

The project aimed at checking compliance with obligations under the **Biocidal Products Regulation** (BPR) concerning the making available and use of biocidal products on the EU market. The scope of BEF-3 was intentionally broad, enabling most National Enforcement Authorities (NEAs) to participate in the project.

Since BEF-3 only targeted biocidal products authorised according to the BPR - and therefore provided with an SPC - biocidal products made available on the market under national transitional measures (pursuant to Article 89 of the BPR) were not covered by the scope of this project.
Furthermore, the use of biocidal products was not assessed within the project.

The BPRS members mandated the BEF-3 Working Group (WG) to implement the BEF-3 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). Where necessary, the WG cooperated with the European Commission (i.e. DG SANTE).

National inspectors autonomously selected companies and biocidal products to be inspected during their enforcement activities, which took place during the operational phase of the BEF-3 (year 2025). BEF-3 aimed to cover all actors in the biocidal products supply chain, i.e. importers, authorisation holders, manufacturers, distributors, etc.

The WG analysed the results of inspections submitted by NEAs and elaborated the BEF-3 project report, which was adopted by the BPRS in November 2026.

Overall, BEF-3 aimed at raising awareness on the legal provisions of the BPR governing the content of authorisations, particularly the content of the SPC, and the labelling of biocidal products. The objective of BEF-3 was to harmonise enforcement of requirements concerning the use of SPC information on product labels and in SDSs of the biocidal products available in the

EU market. The goal is to contribute to a safer market for biocidal products and a level playing field for companies in the EU.

1.1 Legal obligations

The legal provisions (and definitions) of the BPR covered under the BEF-3 are reported in the table below.

Table 1: Legal obligations covered by the BEF-3 project

BPR Legal provisions	Description
Article 3(1)	Legal definitions of biocidal product, placing and making available on the market, use of biocidal product, authorisation, national or Union authorisation, single biocidal product, biocidal product family
Article 17(1)	Obligation for biocidal products to be authorised in accordance with the BPR in order to be made available on the market or used.
Article 22(1) and (2), (a) to (q)	Content of a biocidal product authorisation, including terms and conditions relating to the making available on the market and use and the SPC. The provision also describes the content of the SPC.
Article 67(2)(b)	SPCs of authorised products are publicly available and free of charge
Article 69(1) and (2)	Duty to classify and label biocides. Biocidal products must be classified, labelled and packaged in accordance with the SPC– mandatory information to be mentioned on the label. Article 69 of the BPR regulates content of the label, requires that it is not misleading and includes indication of statements forbidden on the label. The assessment of misleading elements is not in the scope of BEF-3
Article 70	SDS of active substances and biocidal products
Article 71(6)(b)	SPC to be introduced into the Register for Biocidal Products

Article 17(1) of the BPR sets out that biocidal products cannot be made available on the market and used unless authorised in line with the BPR.

Biocidal products are defined as:

- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,
- or any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Biocidal products containing active substances included in the review programme, and not yet

approved, may be made available on the market under national transitional measures as per Article 89 of the BPR. The same applies for products containing approved active substances and for which an application for authorisation was submitted before the approval date of the active substance, but the application is still under assessment. These biocidal products are not included in the scope of the BEF-3 project.

Biocidal products authorisations stipulate terms and conditions relating to the making available on the market and uses of biocidal products (single biocidal products or biocidal product families). Authorisations (national, Union, and simplified authorisations) must always include the approved **Summary of Product Characteristics (SPC)**.

SPCs for biocidal products (or biocidal product families) must include the information stated in Article 22(2)(a) to (q) of the BPR[1].

SPCs of authorised biocidal products are made publicly available on the ECHA dissemination website as of the date of authorisation of the biocidal products.

In line with Article 69 of the BPR, biocidal products have to be classified, packaged and labelled by authorisation holders in accordance with the approved SPCs. Regarding the classification and labelling of the product, the SPC indicates only the hazard and precautionary statements and not all CLP hazard label elements. Hazard and precautionary statements[2] must be also in line with the applicable provisions of the CLP Regulation (more information about the role of the SPC in the hazard classification and labelling are reported in the document CA-May13-Doc.5.4.rev1[3]).

Safety data sheets (SDS) for active substances and biocidal products are to be prepared and made available in accordance with Article 31 and Annex II of REACH, where applicable.

The BEF-3 project did not cover other aspects and obligations of the BPR, such as misleading labels, advertisement, Article 95 listing and others. However, national inspectors had the possibility to control those aspects during their inspections and include in the answers to the questionnaire comments on the overall compliance of the inspected products.

2. BEF-3 results

The BEF-3 Working Group members developed a common questionnaire that national inspectors used during the enforcement activities under the BEF-3 (see Annex 1). The questionnaire aimed to help inspectors in evaluating the conformity of the product labels, SDS and chemical composition with the information listed in the SPC. In addition, it included an assessment of the quality of the SPCs. BEF-3 project results are based on the analysis of the data submitted by national inspectors via the questionnaire. Some sections in the questionnaire were optional, including those concerning SDSs and chemical analysis. Therefore, the number of products assessed (and answers) varied between questions, and this is reflected in the final figures in the BEF-3 project report. Note also that the number of biocidal products checked for specific aspect is indicated in the descriptions of the figures.

2.1 Participating countries and number of inspections

In the BEF-3 project, inspectors from 27 countries reported inspections of 2053 biocidal products which were available on the EU market during the year 2025. Each participating country decided how many inspections to conduct and which companies to target during the operational phase

[1] Without prejudice to the Articles 66 and 67 of the BPR (i.e. confidentiality and dissemination).
[2] As referred to in Article 22(2)(i) of the BPR.
[3] Available at https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/f7ba3aa6-33fe-4c61-9411-230b31ffbdaf/details

of the project. Four countries, (i.e. Germany, Hungary, Romania and Spain), conducted the majority of the total number of inspections (65%). It was also noted that in some Member States, especially the ones with a high number of inspections, same biocidal products were in some cases inspected more than once by different inspectors.

Table 2: Number of inspections per country.

Member State	Number of inspected biocidal products
Austria	60
Belgium	34
Croatia	49
Cyprus	27
Czechia	34
Denmark	10
Estonia	8
Finland	22
France	91
Germany	284
Greece	1
Hungary	332
Iceland	10
Ireland	9
Italy	26
Latvia	22
Lithuania	32
Luxembourg	19

The Netherlands	43
Norway	15
Poland	113
Romania	394
Slovak republic	23
Slovenia	18
Spain	326
Sweden	31
Switzerland	20
Total	**2053**

The National Enforcement Authorities had the possibility to perform inspections **on-site** or from the office (**desktop inspections**). Most inspections were performed on-site (66%).

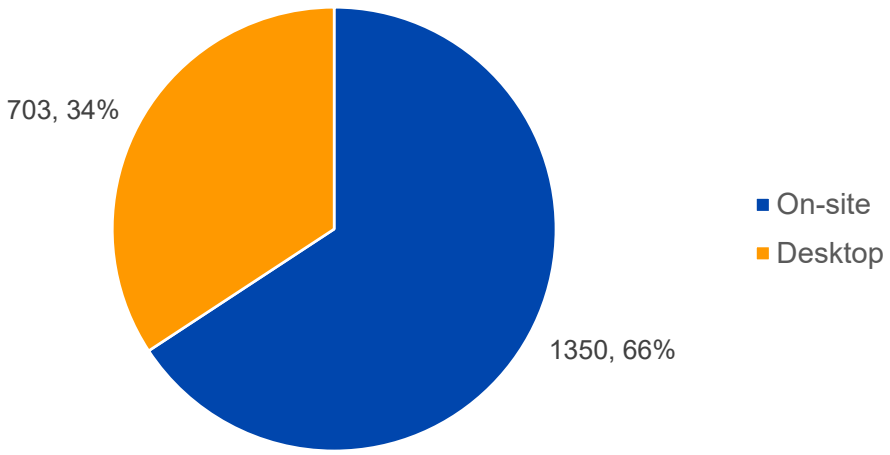

Figure 1 Type of inspection (number of products = 2053).

2.2 Roles of companies

The data from the BEF-3 inspections carried out across most EU Member States (plus Iceland, Norway and Switzerland), cover onsite and desktop checks of authorisation holders, distributors, retailers, professional users and manufacturers.

The target groups of the BEF-3 project were the actors involved in the supply chain of biocidal products. Participating countries identified the actors to be inspected. A high percentage of the inspected biocidal products were sampled at distribution level (37%). Many of the inspected companies performed several roles in the supply chain; in such cases, only the role considered to be at the 'highest level' of the supply chain was reported.

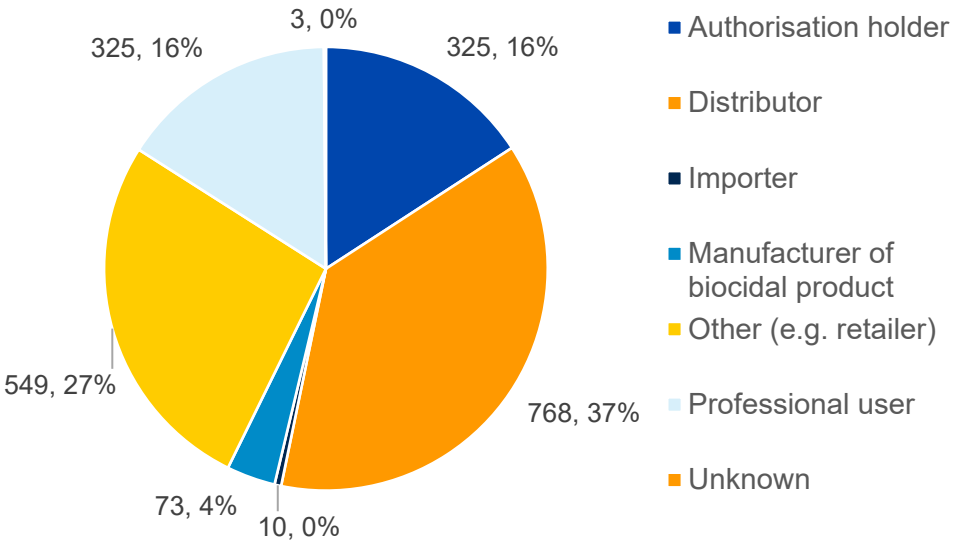

Figure 2 Roles of the companies (number of products = 2053).

2.3 Correspondence between SPC and label or packaging

SPCs are an essential part of biocidal product authorisations as they contain the general information about the biocidal product and conditions for making it available on the market and its use. The information from the SPC has to be reflected in the labelling of the product.

The role of the evaluating Competent Authorities in ensuring clarity and compliance concerning P-statements in the SPC is clarified in specific documents agreed by the Competent Authorities. This concerns in particular the omission of unnecessary P-statements in the CLP information in Section 3 of the SPC as a result of the risk assessment and ensuring coherent and non-contradictory risk mitigation measures required in Sections 4.1.2 and 5.2 of the SPC as a result of the risk assessment for the biocidal product (see CA-June22-Doc.4.6[4]).

The inspection results show that, in most cases, the information on labels, leaflets and packaging corresponded to the information in the SPC, although considerable room for improvement remains.

CLP labelling requirements for biocides

Regarding the CLP labelling obligations under Article 69(1) of the BPR, the detailed results show that labels of 8% of the checked products were non-compliant with the requirement to include precautionary statements (P statements). In 5% of the checked products the information on the labels regarding hazard pictograms and H-statements was non-compliant (see Figure 3 below).

There were therefore slightly higher non-compliance rates for the requirement of the biocidal label to include the P-statements compared to the H-statements and also hazard pictograms. Normally, in accordance with Article 28(3) of the CLP Regulation, no more than six P-statements

[4] Available at https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/165ba36f-0076-49eb-90d5-3a87c2e0e449/details

must appear on the label, unless necessary to reflect the nature and the severity of the hazards. In the SDS more P-statements can be indicated, but it does not mean they have to be indicated also on the label[5]. It may be useful for industrial and professional uses to include special P-statements into the appropriate sections of the SDS main body in order to reduce the number of P-statements on the label[6].

In addition, in section 3 of the SPC (classification and labelling information) more than six P-statements can be indicated. The authorisation holder must then select the most relevant statements required on the label in accordance with its obligations under the CLP Regulation[3]. However, if P-statements are included in sections 4.1.2 or 5 of the SPC in the form of a risk mitigation measures as a result of the risk assessment for the biocidal product, then these statements must be included on the label in all cases. It remains the obligation of the authorisation holder to ensure that P-statements from the SPC are included in the label in a coherent way (e.g. avoiding statements which contradict each other). At the same time, it is the role of the evaluating Competent Authorities to ensure that P-statements in the SPC are coherent and non-contradictory (as reported later, in chapter 2.6).

The differences between the hazard statements in the SPC on the one hand and on the label (and also in the SDS) on the other hand can be caused by changes in the hazard classification of the product based on new data. Relevant examples include changes in hazard classification of ingredients that results into a change of the classification of the mixture or some new test results. Changes in classification can be triggered by the inclusion of a substance contained in the product in Annex VI to the CLP Regulation by an Adaptation to Technical Progress (ATP). In this case a new or amended harmonised classification applies to that substance.

Following a new or revised hazard classification, in case the change impacts the classification of the product it is mandatory to update the SDS and apply for a change of the authorisation, that would lead to a change of the SPC and of the label.

Transitional periods for the application of a changed hazard classification are included in each ATP. As a rule, a transitional period of 18 months is set for the implementation of a new harmonised classification by economic operators. After the expiry of this period (i.e. the voluntary application period), the application of the new/revised hazard classification is mandatory.

Guidance and recommendations are available (see CA-May13-Doc.5.4.rev1[7]) to clarify situations where harmonised hazard classification of active substances or co-formulants in the biocidal product has been established or updated, triggering changes in the hazard classification and labelling of the authorised biocidal product. These situations include regulatory changes in Annex VI of the CLP Regulation or proposed harmonised classification and labelling for which an adopted ECHA RAC opinion exists.

While it is possible to update the SDS and the label during the transitional period, this period is often not enough for the Competent Authority to process the application for a change.

It should be noted that the requirements of both CLP and BPR regulations must be fulfilled in order for a biocidal product to be compliant and therefore legally available on the market (Art. 69(1) of the BPR).

It should also be noted that in some cases, the changes in the hazard classification stipulated in an ATP can even lead to a biocidal product not being allowed to be made available on the market for the general public anymore. For example, products containing the active substance

[5] *Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008,* Section 7 (page 84-190).

[6] *Guidance on the compilation of safety data sheets*, version 4.0 December 2020, page 43-44.

[7] Available at https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/f7ba3aa6-33fe-4c61-9411-230b31ffbdaf/details

transfluthrin may or may not be allowed to remain authorised for the general public, depending on its concentration. As a consequence of the ATP 21, transfluthrin as an active substance in biocidal products (often present in moth traps) leads to a classification of the product as STOT SE 1 when it is present in concentrations ≥10 %. In that case the biocidal product should not be authorised for making available on the market for the general public and the authorisation needs to be revoked or amended by the Competent Authority in accordance with Article 48(1) of the BPR.

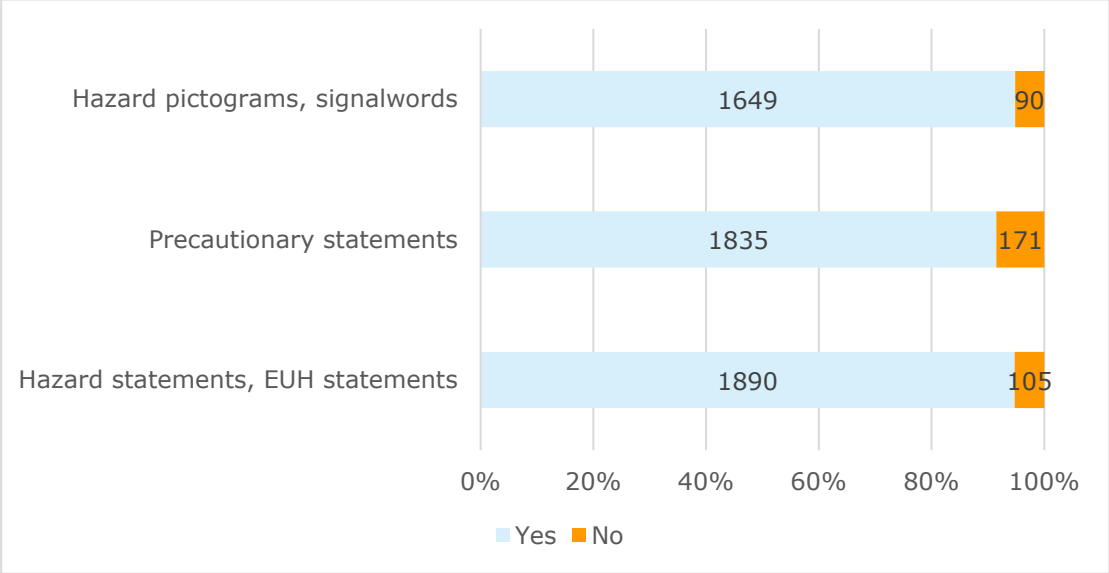

Figure 3: Numbers of labels compliant with CLP and consistent with the SPC (hazard statements, 1995 products inspected, precautionary statements 2006 products inspected and Hazard pictograms 1739 products inspected).

Tradename, pack size, packaging material and conditions of storage and shelf-life

Regarding the obligations in Article 69(1) of the BPR concerning the pack size and packaging material and the inclusion on the label of the information about tradename, conditions of storage and shelf-life, the compliance rates are between 93 to 99 % (Figure 4).

It is noted that there is a higher non-compliance rate (7%) with regards to the duty to include on the label information on conditions of storage and shelf-life compared to the obligations about pack size and packaging material (close to 1.5% each). This specific obligation covers two elements, i.e. conditions of storage and shelf-life, which could explain the higher non-compliance. Also, in the SPC there is usually a lot of information regarding the storage conditions, which has to be reflected on the label.

For the inspectors, there also seems to be some confusion between the shelf-life and expiry date. The shelf-life indicates the period of time a product maintains its quality and function and is indicated in the SPC under section 5.5 in years or months. Data are required to demonstrate that the biocidal product is stable during storage under the conditions and the specified packaging for the shelf-life claimed for the product. The expiry date is ultimately derived from the shelf-life of the biocidal product.

The expiry date will not be indicated in the SPC, since it will change with every batch of the product. For the inspector to be able to control and calculate the shelf-life, both the manufacturing date and an expiry date should be indicated on the label. However, the manufacturing date is not required on the labels in accordance with Article 69 of the BPR.

Cases of packaging material or size (i.e. packaging formats and volume) which differ from those included in the SPC were also reported. Inappropriate pack sizes (i.e. not in accordance with what was indicated in the SPC) used for consumer products may potentially increase exposure risks.

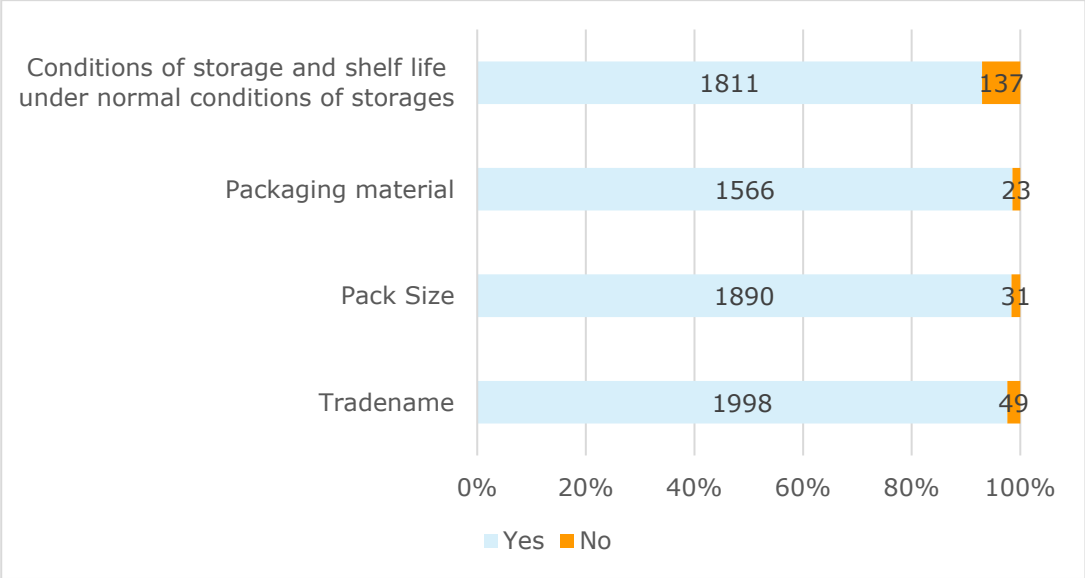

Figure 4 Compliance with labelling obligations referred to in Article 69(1) of the BPR regarding trade name (2047 products inspected), pack size (1921 products inspected), packaging material (1589 products controlled) and conditions of storage and shelf-life under normal conditions of storage (1948 products inspected).

Biocide label elements required in Article 69(2)

For the label elements prescribed in Article 69(2) of the BPR, a level of non-compliance similar to those mentioned above was observed.

Five of the labelling elements showed a slightly higher non-compliance, and these were:

- g) directions for use (7%),
- h) side effects and first aid (7%),
- i) sentence "Read attached instructions before use" if accompanied by a leaflet (9%),
- j) directions for disposal (6%) and
- l) instructions for use[8] (7%).

Concerning biocide label elements at Article 69(2)(g), (h), (j) and (l) of the BPR, in general Sections 4 and 5 of SPCs include numerous individual elements of a direction or of an instruction, which ultimately need to be reflected in these four label elements. The obligation to cover on the biocide label this high number of related directions or instructions provided in the SPC is a practical challenge.

[8] By "instruction for use" it is meant instructions such as 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, etc.

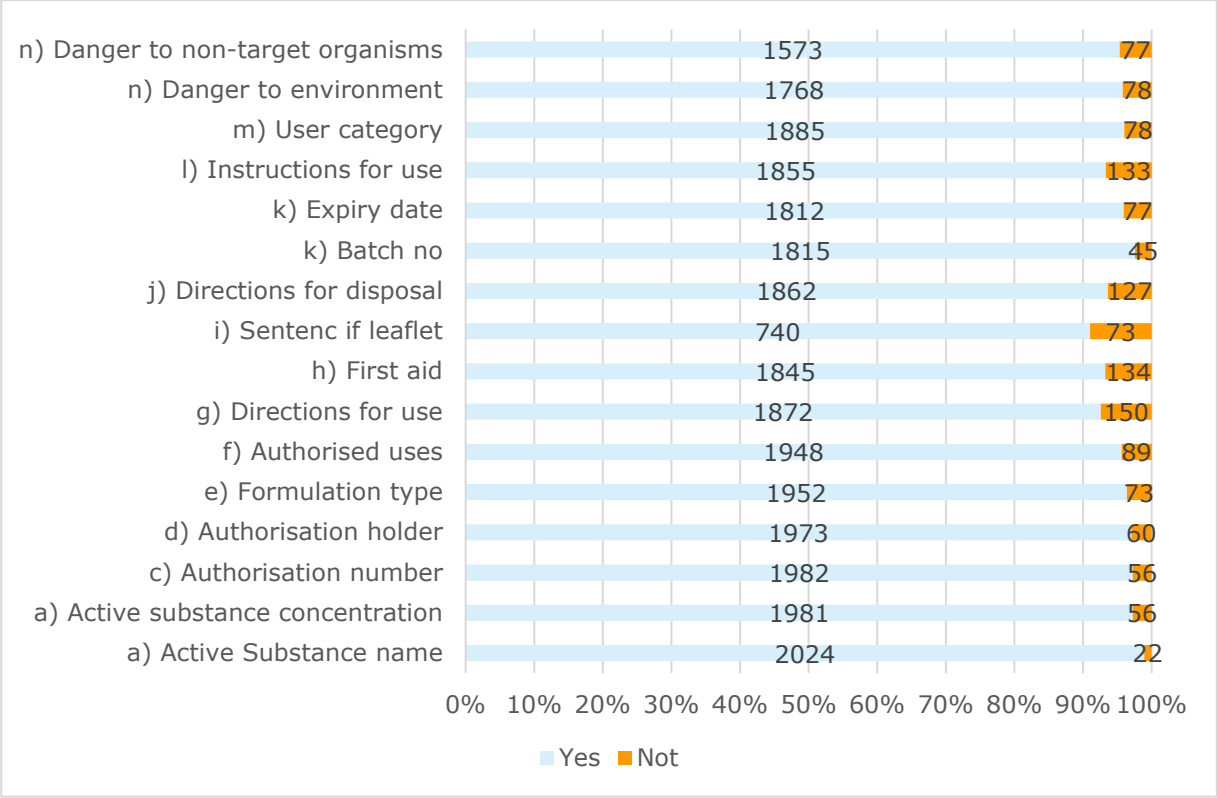

Figure 5 Labelling compliance with reference to Article 69(2) of the BPR. Bars show specific number of biocidal products (number of checked biocidal products variable across the Article 69(2) elements, between 2046 and 813)

Sections 4 and 5 of the SPC are the sections with the most text in the SPC, which is relevant in its entirety for the product label elements listed in Article 69(2)(g) and (l) of the BPR. However, the structure of the two SPC sections is not very clear in relation to these label elements. There can be a lot of repetitions in the labelling element at Article 69(2)(l) of the BPR concerning instructions of use; for example, one can find some relevant parts under Section 4 and other relevant parts under Section 5 of the SPC.

In addition, the numerous individual elements of directions or instructions in Sections 4 and 5 of an SPCs are not all clearly earmarked in a standardised form for their relevance for each individual label element at Article 69(2)(g), (h), (j) and (l) of the BPR. This poses challenges when composing the product label while ensuring a full coverage of all the relevant elements of the SPC in the product label.

The structure of the sections in family SPCs and their complex interplay in defining the relevant information for one individual family member biocidal product from which the content of its product label needs to be derived adds to these challenges.

This additional challenge consists in the fact that, for members of biocidal product families, elements from the information levels 1 to 3[9] need to be combined in a coherent manner based on the information in the SPC when the content of the product label is derived.

Given all the challenges mentioned, it is sometimes difficult for both authorisation holders and inspectors to assess and decide what exactly should be written on the label. Inspectors have in fact reported some concrete observations when investigating the alignment of labels with the SPC. For example, the instructions for disposal are often not specified in the SPC in enough

[9] Family SPC information is structured in 3 information levels (CA-May15.Doc.4.6.a-Final).

detail. Many times, for waste disposal the SPC refers only in a generic form to the national legislation.

Together, these challenges can result in inconsistencies between the content of the label and the content of the SPC, that are identified by the inspectors as non-compliances.

One of the main factors contributing to inconsistencies between labels of the biocidal product, SPC and the SDS is the complexity of this matter (generally intended as identification of information to be included in the SPC, SDS and label for the same product).

The observations reported by the inspectors show truncated or inconsistent P-statements, as well as wording mismatches.

In addition, many inspectors reported that the SPCs or label/SDS are partially in a different language, H- and P-statements are untranslated or present machine translation errors that create ambiguity. Also, P-statements for consumer products, such as P101 and P102, are listed in the SPC even though the product is for professionals only, which makes it complex to enforce the required omission of these unnecessary P-statements on the label.

Language and legibility issues can affect compliance, for instance when the label is not provided in the official language(s) required by the Member State or mandatory information is poorly legible, incomplete, or obscured by design elements. This affects user understanding and proper implementation of safety instructions.

In those cases where the label does not include all information required by Article 69 (such as authorisation number, instructions for use, risk mitigation measures or required hazard statements and precautionary statements) the consequence is that users are not adequately informed to ensure safe and correct use of the product.

2.4 Correspondence between SPC and Safety Data Sheet (SDS)

The Safety Data Sheet is an important tool for providing professional with all the necessary technical, toxicological, and safety information to manage the product responsibly throughout its life cycle.

One of the purposes of the SDS, as stated in REACH Regulation[10], is to communicate hazard and safe handling information to workers, distributors and emergency responders across the entire supply chain.

In accordance with the BPR, the authorisation of a biocidal product specifies the conditions of use of the biocidal product, with the SPC being part of the authorisation.

This means that the two documents have different objectives, scopes and audiences, even if some of the information they are to report is the same.

Completion of the questionnaire section concerning the SDS and its correspondence with the SPC was optional. The questions in the questionnaire covered six information elements that are included in the first three sections of an SDS: trade name, user categories, hazard statements, precautionary statements, active substance name and concentrations. Although many of the inspectors answered these questions, the number of checked products may vary across the different controlled parameters (and therefore the number of replies to the different questions). The questions about SDS had been answered, to some extent, for 1558 controlled biocidal products.

The highest non-compliance rate was found with regards to information on user categories, with 10% of products non-compliant. It should be noted that the user category must be stated under section 1 of the SDS only for products intended for professional or trained professional use, while if the product is for the general public, the user category does not have to be indicated. For 9%

[10] Article 31 and Annex II of Regulation 1907/2006

of the inspected products, the P-statements did not correspond and for 6% of the products the H-statements or EUH statements did not correspond between the SDS and SPC.

Only between 2% and 3% of the inspected products showed a lack of correspondence between the SPC and SDS in relation to trade name and active substance.

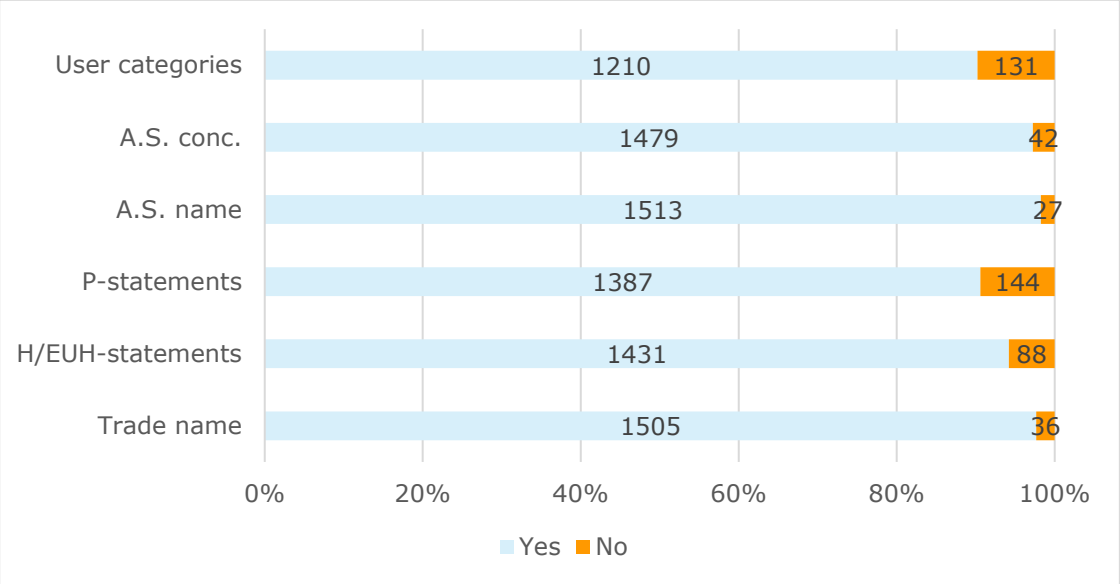

Figure 6 Correspondence of the SDS with the SPC regarding trade name (1541 inspected products), H-statements (1519 inspected products), P-statements (1531 inspected products), active substance (1521 inspected products for the name and 1540 for the concentration) and user categories (1341 inspected products).

The results for user category indicate a direct inconsistency between the official SPC and the Safety Data Sheet presented by the company. This inconsistency may have different causes. The SPC may not include clear user categories, the SDS may not have been updated after a SPC change, or conversely SDS could have been prepared with user categories not matching the SPC included in the authorisation. Additionally, there could also be a misunderstanding or inconsistent application of the "user categories" field among manufacturers/distributors/retailers.

When user categories on the SDSs do not match the SPC, this poses potential downstream safety and misuse risks - users may lack correct information on allowed or prohibited user groups. Inconsistencies in this information at retail and distributor level are particularly important, because these actors communicate product information to final users and handle packaging and point -of sale- documentation.

2.5 Chemical analysis

In total, 64 biocidal products were analysed for their chemical composition. Figure 7 shows that 100% of the analysed products contained all active substances in line with the authorisation.

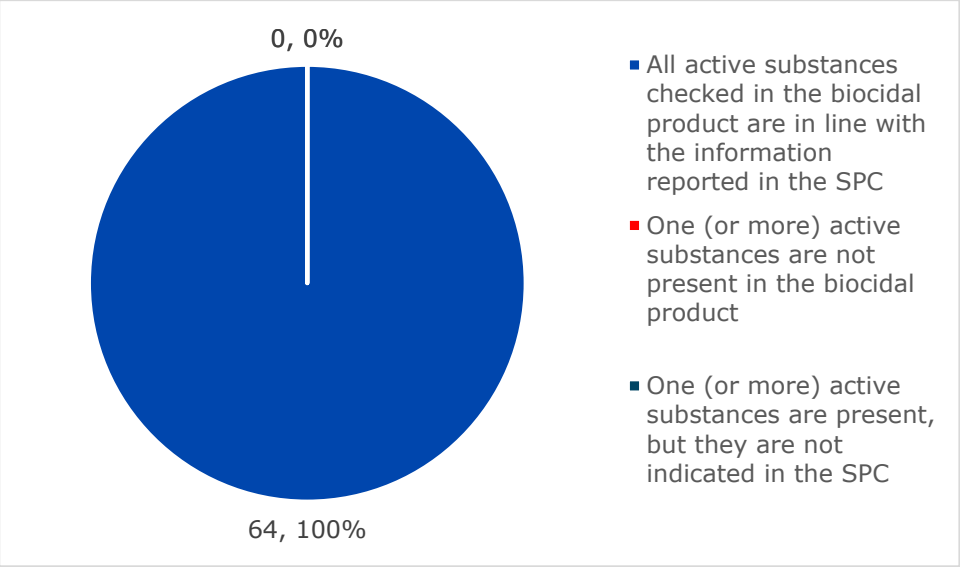

Figure 7 Chemical composition, active substances (number of analysed products=64).

For 63 products, the active substance concentration was analysed. Figure 8 shows that only one of the analysed products had lower active substance concentration than reported in the SPC.

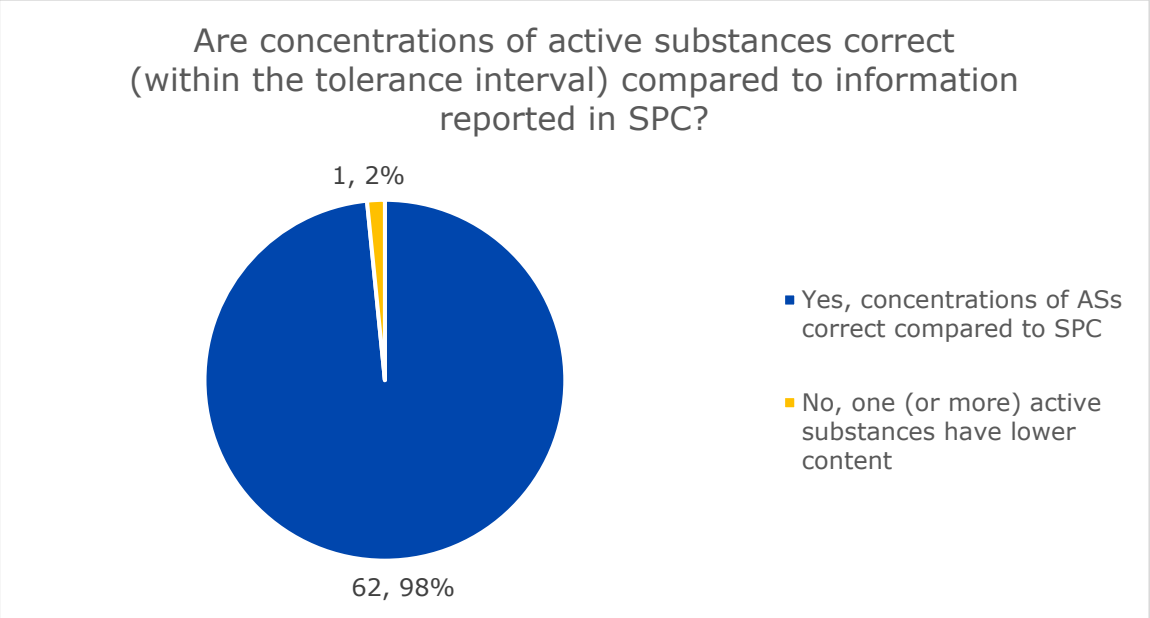

Figure 8 Products for which active substance concentrations are within the tolerance interval (number of analysed biocidal products= 63).

2.6 Quality of SPC content

As a part of the authorisation, the SPC should contain all the important information about the authorised biocidal product needed by industry to prepare the biocidal product label. Through the label this information is passed to the user, especially the general public.

The SPC is the basis for the enforcement activity by the inspectors when assessing the content of the product label. Without the SPC it is not possible to check if the label includes all the relevant information and is compliant with the authorisation. Without the SPC it would therefore be impossible to determine whether the biocidal product can be lawfully made available on the market or used.

This chapter of the report summarises key observations reported by the inspectors regarding the information relevant to labelling contained in the SPC included in the authorisation. The quality of the information in the SPC has been checked in 61% of the inspected products.

The findings highlight inconsistencies, clarity issues, and potential regulatory non-compliances that need to be addressed to ensure safe and effective use by consumers and professionals alike.

Inspectors reported statements in the SPC that were lacking clarity, coherence, feasibility or enforceability for 14% of the checked biocidal products (Figure 9).

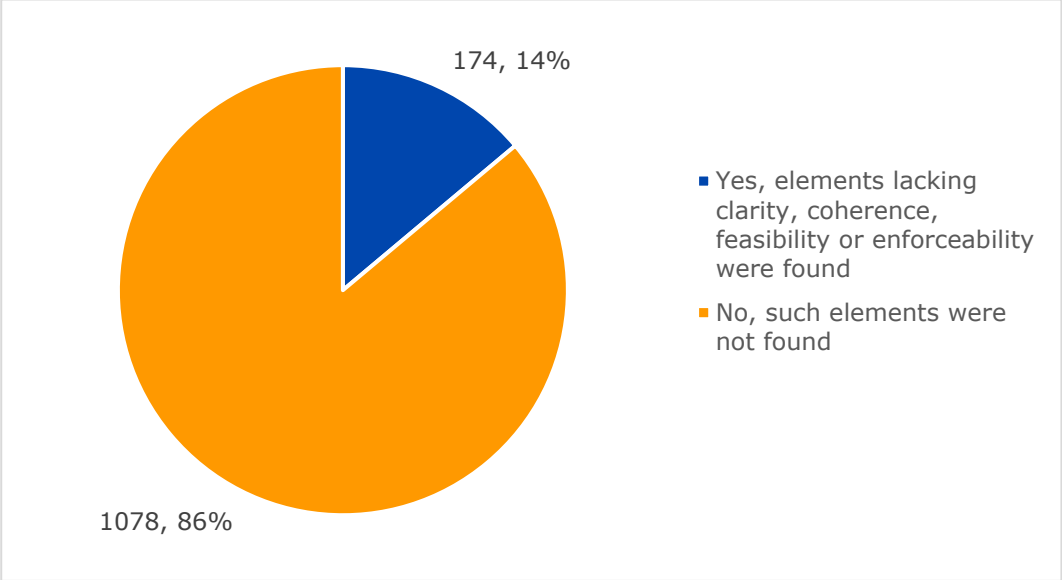

Figure 9 Quality issues in the content of the SPC (statements which are lacking clarity, coherence, feasibility or enforceability; number of products = 1252).

Due to the open structure of this part of the questionnaire of the BEF-3 project, the provided observations also included elements that are more appropriately addressed under other questions of this BEF-3 project.

For the sake of clarity, answers provided by inspectors have been considered in the relevant chapter in this report, where possible. For example, observations about P-statements in the SPCs that were found to be truncated or inconsistent with those in the SDS, leading to confusion regarding necessary safety measures, have been covered in chapter 2.3 of this report. Other observations on the quality of the SPC are summarised below.

User Categories and Definitions:
The inspectors reported some ambiguity in terminology. For example, the distinction between "professional users" and "trained professionals" is unclear, leading to confusion about who is permitted to use these products, as there is no clear definition of these terms.

There are also terms used in the SPCs that are not explained, such as “near”, “nearby”, “large surface”, “large buildings”.

Furthermore, terms such as “low infestation” and “high infestation” are not explained in the SPC or in the legislation. This leaves the terms open to interpretation by the user and could result to overuse of biocides.

Conflicting Information:
Many labels are produced with help of some form of machine translation. In some cases, this can lead to potentially confusing situations, for example for some rodenticides the type of formulation in section 2.2. in the SPC has been translated to “Ready-to-use fish bait”. Such mistranslations may leave users unclear about the intended use of the product.

Some inspectors found contradictory information between the different sections in the SPC. For

example, section 3 contains the P-statement "P501- *Deliver to a hazardous waste collection point or an authorised hazardous waste collector*" while section 5.4 contains a contradicting statement "*At the end of treatment, collect the bait boxes and dispose of them with household waste*".

In some cases, inspectors found it confusing that a product which is not classified as hazardous according to the CLP Regulation, nevertheless has a broad range of first aid measures listed in the SPC and therefore also on the label. This is due to the fact that also non-hazardous products require first-aid instructions in accordance with the BPR.

Lack of practical or complete instructions:
Several inspectors reported unclear application instructions, especially concerning rodenticides. For example, in the SPC it is stated that application should be 30 g bait per bait station, but the label states 25 g bait per bait station. The individual sachets of bait are 25 g, which makes it unclear and not feasible to put 30 g of bait per bait station.

Vague Language and Technical Jargon:

Many SPCs contain technical language that is not easily understood by non-professional users, complicating effective communication to the end user. For example, on a consumer product it is mentioned that a pest controller should be contacted if the infestation is large or widespread. It might be difficult for a consumer to assess if the infestation is large or widespread.

The instructions on the frequency of application are in some cases vague and might hinder the users' ability to comply effectively. For example, stating that the time between biocide applications depends on other actions (e.g. cleaning) without precise criteria may lead to confusion.

On some labels, instructions for "Use-specific risk mitigation measures" or "Instruction for use" start with the verb "consider" (e.g. "*consider the replacement of bait points to further places and the possibility to change to another bait formulation"* or "*…it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide"*). Instructions on how to use the products should be clear and easy to follow, particularly if the product is intended for the general public. This wording assumes that the person using the product is familiar with the terminology. For products intended to the general public, clearer information is required.

2.7 Overall evaluation of compliance

This chapter addresses the overall evaluation by inspectors of the compliance for all requirements checked for a product during the inspections under the BEF-3 project.

2.7.1 Compliance of label, packaging or leaflet with the SPC

For 20% of the inspected biocidal products, inspectors considered that the label, packaging and leaflet were not complete and consistent with the SPC.

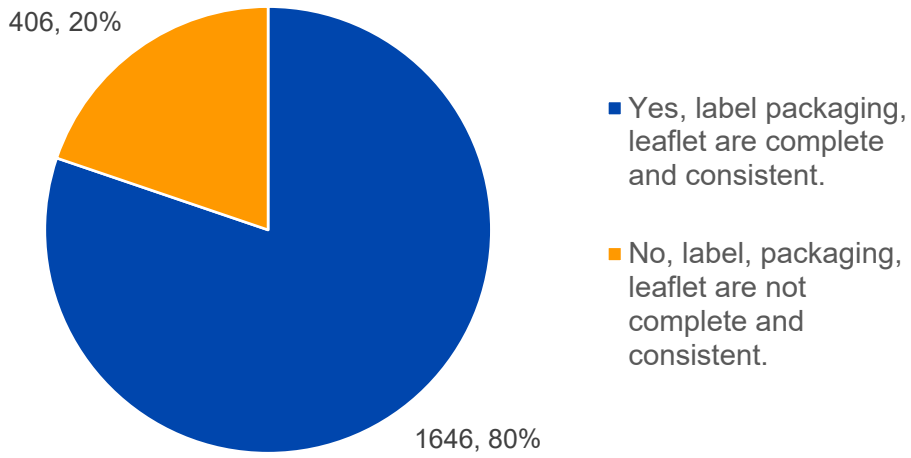

Figure 10 Consistency and completeness between label, packaging and leaflet (number of products = 2052).

2.7.2 Compliance of SDS and SPC

For 18 % of the checked biocidal products, the inspectors considered that the SDS was not fully compliant, consistent and in line with the SPC in relation to what has been checked.

The differences between SDS and SPC could be due to the fact that the SPC does not necessarily consider the information which is required to be included in the SDS, even though the SDS should always be aligned with the SPC.

There are also different legal bases for the two documents. The purpose of the SDS is to communicate the hazards associated with a product and to provide information on its safe handling and use by professional users. In contrast, the SPC forms part of the product's authorisation and provides information on the authorised use of the product.

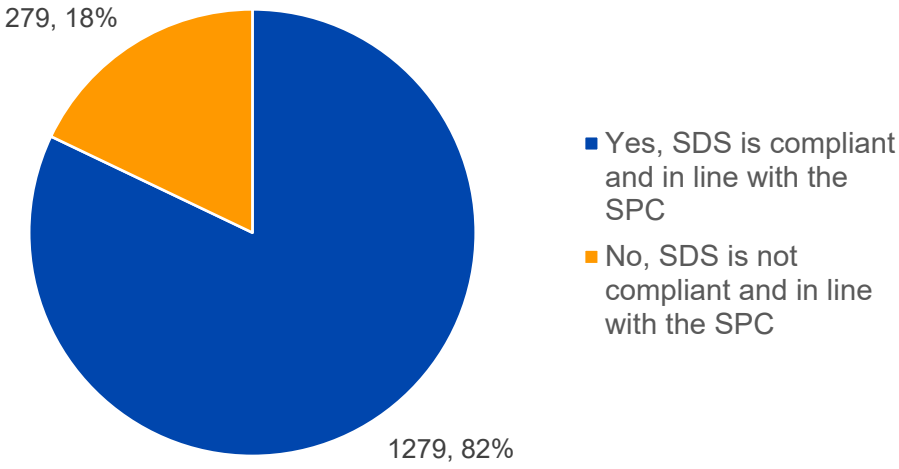

Figure 11 Compliance and consistency of the SDS compared to SPC with parameters checked (number of products = 1558).

2.8 Overview of enforcement measures for non-compliances

In this section the numbers on non-compliances and on enforcement measures include an overall evaluation of all aspects of the biocidal products checked during the enforcement, i.e. not only what has been checked in the narrow focus of the BEF-3 questionnaire. On this basis, inspectors reported that 24% of the checked biocidal products (498 out of 2053), including their SDSs, showed at least one non-compliance, while 76 % of the inspected biocidal products (1555 out of 2053) were considered compliant (Figure 12).

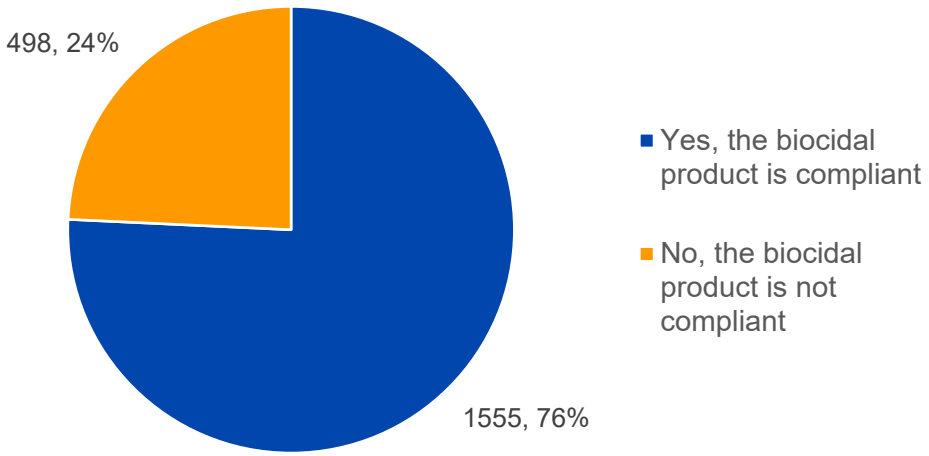

Figure 12 Number of non-compliant products (number of products = 2053).

For these non-compliant products different measures were taken, as presented in Figure 13. It was possible to choose more than one measure for one product, therefore the total number of measures (521) is higher than the number of affected products (498). The most common actions were written and verbal advice.

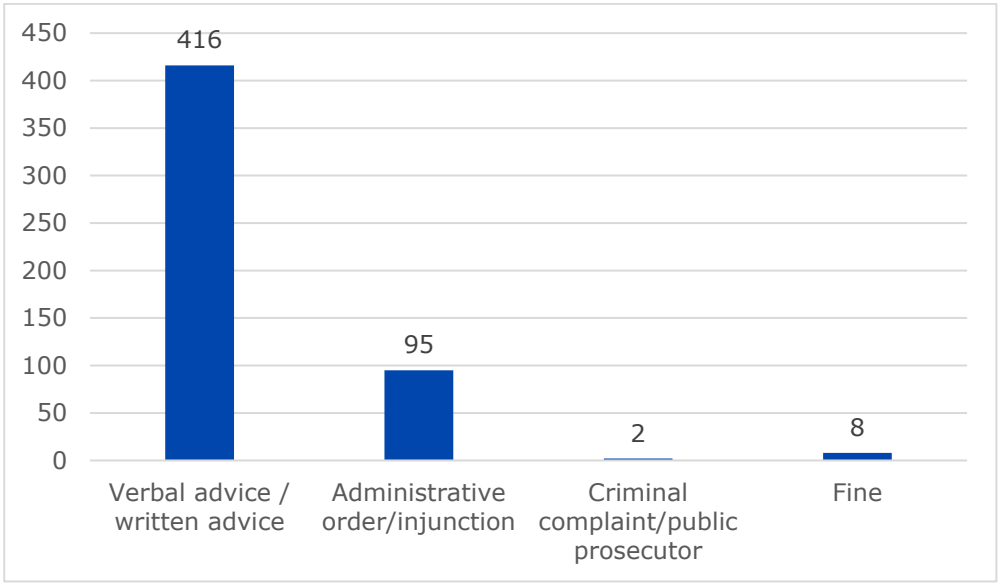

Figure 13 Actions taken due to non-compliances, based on 498 non-compliant products.

Non-compliances such as missing national language on the label, expired products and discrepancies between the actual packaging size and the size specified in the SPC were reported.

For approximately 4% (90 products) of the inspected biocidal products inspectors considered that the severity of non-compliances would impact their making available on the market.

Other non-compliances related to CLP were also identified, such as the absence of tactile warning.

3. Comparison with BEF-2 project

In this chapter some aspects of the BEF-3 results are compared with the previous BEF-2 project's results[11].

The BEF-2 project, which focused on biocidal products containing approved and non-approved active substances, included also elements other than those checked during the BEF-3.

3.1 Comparison concerning CLP labelling

In the BEF-2 project, 5% of the labels did not correspond to the respective CLP labelling stated in the SPC. In the BEF-3 project, the result of the inspections showed a higher non-compliance with regards to CLP labelling requirements where 13% of the biocidal product labels showed at least one non-compliance when the product label was compared with the SPC. In the BEF-3 project, around three times as many products were inspected for this requirement, which could explain the difference in compliance rates.

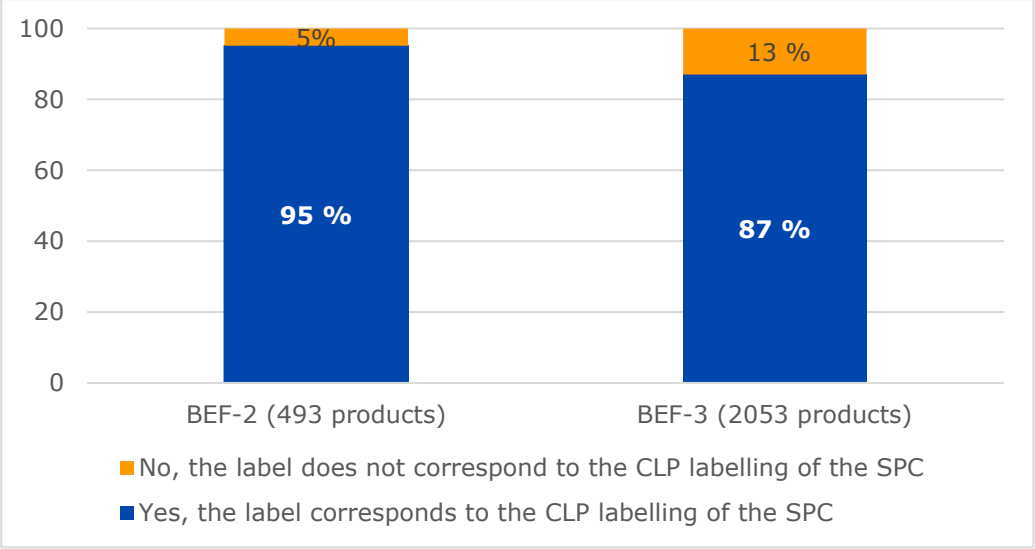

Figure 14 Comparison of CLP labelling compliances (Art.69(1) of the BPR) in BEF-2 and BEF-3 enforcement projects.

3.2 Comparison concerning labelling obligations in Art 69(2)

The overall results in BEF-2 regarding labelling requirements for biocidal products regulated under the BPR, showed that 19% of the inspected products did not fully fulfil the labelling requirements in Art. 69(2). The corresponding result for BEF-3 is similar to that showing a 25% non-compliance (Figure 15).

In the BEF-2 project there were fewer inspected products with regard to labelling obligations,

[11] For this chapter about the comparison with BEF-2, the non-compliance rates referring to BEF-3 are calculated by combining the results on each single relevant element.

but the same trend was observed as in the BEF-3 project with regard to specific non-compliances. A higher non-compliance was observed in relation to the following points of Article 69(2) of the BPR: (g) directions for use, h) side effects and first aid, j) directions for disposal and l) instructions for use.

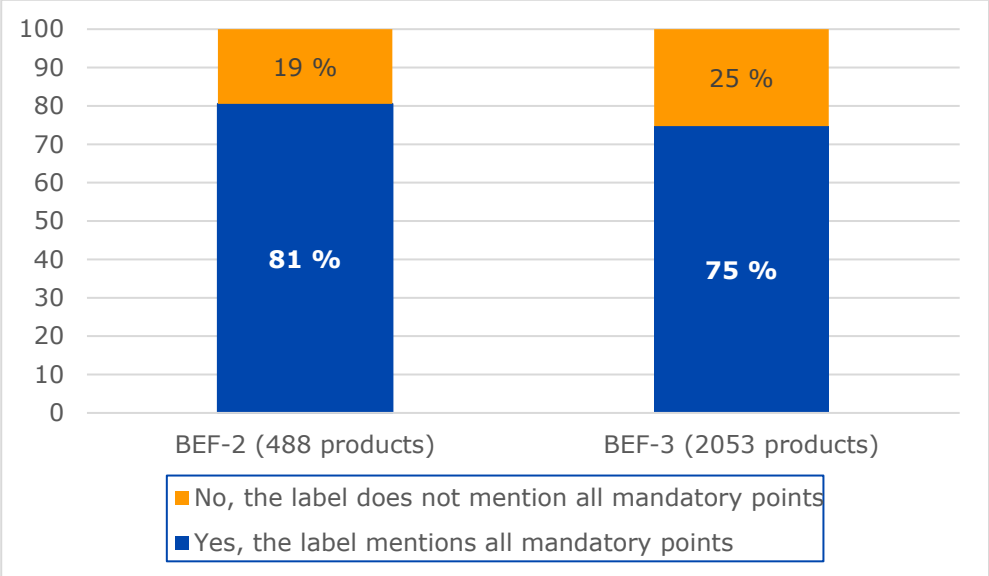

Figure 15 Comparison of labelling obligations according to Art. 69(2) of the BPR in BEF-2 and BEF-3 enforcement projects.

3.3 Comparison concerning chemical analysis

In the BEF-2 project, 25% of the inspected products were non-compliant regarding the concentration of the active substance. This percentage includes both biocidal products made available on the market under the transitional measures pursuant to Article 89 of the BPR and products regulated under the BPR. Considering only biocidal products regulated under the BPR, the non-compliance was 13%.

The higher non-compliance observed for biocidal products regulated under the BPR in the BEF-2 project compared to the BEF-3 is likely attributable to the fact that also non-authorised products were analysed (e.g. disinfectants benefiting from exemptions under Article 55 in the BPR were also included). These products were included in the project because its operational phase coincided with the COVID-19 pandemic.

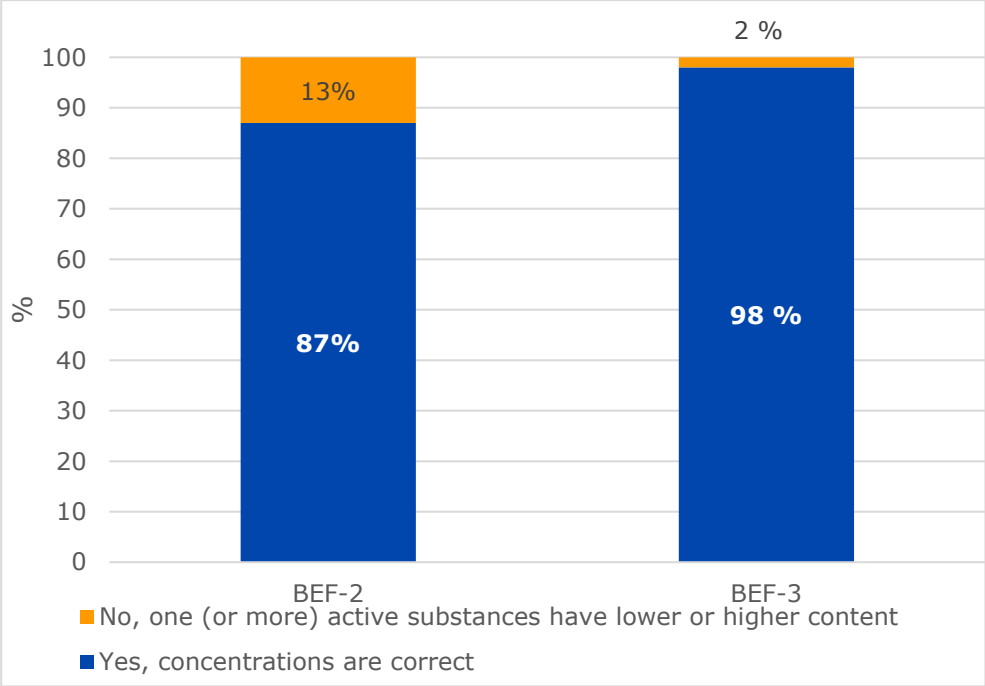

Figure 16 Comparison of the results of the substance active analyses in the biocidal products in BEF-2 and BEF-3 projects.

3.4 Comparison concerning overall non-compliances

In the BEF-2 project, 37% of the inspected biocidal products were found to be non-compliant, compared with 24% in the BEF-3 project (which refers to the overall estimation from the inspectors). The lower percentage of non-compliant products observed in the BEF-3 project may be explained by differences in the product selection criteria between the two projects. The BEF-2 project included authorised products, products made available under transitional measures (pursuant to Article 89 of the BPR), and products containing non-approved active substances.

In the BEF-3 project, only 4% of the checked products showed non-compliances that inspectors considered significant enough to affect their making available on the market and use. The corresponding non-compliance rate in the BEF-2 project was substantially higher, at 18%. This difference may again be attributed to the different product selections in the two projects. The relatively low percentage of products with serious non-compliances in the BEF-3 project is likely due to the fact that only authorised products were included, which would generally be expected to exhibit fewer compliance issues.

4. Conclusions and recommendations

The BEF-3 Working Group members drew the following conclusions and recommendations based on the analysis of project findings.

4.1 Conclusions

Table 3 shows the overall evaluation performed by the Working Group members on the BEF-3 results.

Table 3 Overall evaluation of the BEF-3 findings[12]

Topic	Good	Medium	Poor
Correspondence of labelling and SPC		√	
Correspondence of SDS and SPC		√	
Quality of SPC		√	
Chemical analysis and correctness of active substance concentrations	√		
Overall compliance of BP with BPR		√	

Biocidal products are extremely useful in many areas. However, by definition, they are manufactured with the intention of destroying, repelling or rendering harmful organisms harmless. As a consequence, their placing on the market is strictly regulated. The authorisation process for these products was introduced to minimise the risks associated with their use and ensure that they are effective against the target organism(s) they are meant to control. The terms and conditions related to making available on the market and use of the products are stipulated in the authorisation. These are important because, when fulfilled, they allow biocidal products to be used effectively under certain conditions with level of risk considered acceptable.

Since all the instructions and information required for the product's label to be compliant with the legal provisions are provided in the authorisation, a low rate of non-compliance would therefore be expected.

Nevertheless, although BEF-3 project targeted exclusively authorised biocidal products, the overall non-compliance was relatively high.

The project identified a number of challenges (mentioned in the different sections of the report) which makes it sometimes difficult for both authorisation holders and inspectors to assess and decide what exactly should be written on the label or if the label is fully in compliance. Examples are (i) the potential high number of directions and instructions which can be included in the SPC, (ii) potential repetitions in Sections 4 and 5 of the SPC, or (iii) the selection of P-statements.

Labelling

Labelling is an important tool to communicate necessary information about the safe use of biocidal products. Inspectors considered that for 20% of the inspected biocidal products, the label, packaging and leaflet were not complete and consistent with the SPC.

Even though the non-compliance rate is relatively low for the individual label elements in Article 69(2) of the BPR, there were some label elements concerning safe use such as g) directions for use, h) first aid and l) instructions for use, that showed a non-compliance rate of 7%. This non-

[12] 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 - whether the protection goals of the legislations could be undermined; iv) Economic situation - potential market distortions concerning level playing field.

compliance rate especially on the elements concerning directions for use (Article 69(2)(g) of the BPR), side effects and first aid (Article 69(2)(h) of the BPR) and instructions for use (Article 69(2)(l) of the BPR), are of particular concern because the relatively high risk for an unsafe use of biocidal products, especially for the general public.

The label elements directions for use (Article 69(2)(g) of the BPR) and instructions for use (Article 69(2)(l) of the BPR) typically include a lot of information and repetition in sections 4 and 5 of the SPC, which can make the obligation to cover on the biocide label a high number of related directions or instructions provided in the SPC a practical challenge.

Safety Data Sheet

The SDS is an important tool to communicate hazards and safe handling information to professional users. Among the SDSs that were checked for correspondence with SPC, 18% were found by the inspectors to be (partly) non-compliant. The non-compliance rate concerning the individual checked information elements in the SDS is relatively low, with rates between 2 and 10% for the six checked elements (see figure 6).

Summary of Product Characteristics

The SPC serves as the primary basis for inspectors when assessing whether a label complies with the conditions of the authorisation and whether the product can be legally made available on the market. However, many inspectors consider the structure and content of the SPC to be inadequate, particularly with regard to the family-SPCs.

Inspectors reported that for 14% of the inspected biocidal products, the SPC contained statements that lacked clarity, consistency, feasibility, or enforceability. Such statements are reported from the SPC to the label of products. As the label plays a crucial role in ensuring the safe use of products by general public (but not only), it is essential that the information provided in the SPC is clear, coherent, and easy to understand.

It should be noted that some of the issues identified in relation to unclear statements in the SPC may be associated with older authorisations and may already have been addressed for newer authorisations.

Chemical analysis

For chemical analysis performed on biocidal products inspected in BEF-3, results show that active substances stated in the SPC were normally correctly found in biocidal products. Regarding concentrations of active substances, deviations from the nominal active substance concentrations were identified in only one of the 63 products analysed (2%).

Overall compliance and enforcement

Overall, 24% of the inspected biocidal products in the BEF-3 project were assessed by the inspectors to be not fully compliant with the requirements for biocidal products. Among these, only 4 % presented non-compliances impacting the making available on the market of the concerned biocidal products such as labels with missing national language or products being expired.

Different enforcement measures were taken by the National Enforcement Authorities concerning non-compliant biocidal products in BEF-3. Those actions varied from verbal advice to criminal prosecutions (see figure 13).

4.2 Recommendations

4.2.1 For the inspectors/National enforcement authorities

It is recommended that **Member States** continue providing training and promoting information campaigns for both National Enforcement Authorities and industry, to improve their knowledge on BPR requirements, the role and legal status of the SPC and consequences of non-compliance.

4.2.2 Member States Competent Authorities/Authorising Authorities

It is recommended that **authorising authorities** check more carefully the SPCs for clarity, repetitions, simple language and translation accuracy for the official language(s) of the respective Member State. In particular, descriptions of the directions for use, instructions for use, adverse effects and first aid should be accurate and as concise as possible. To enhance the clarity and consistency of the SPC and ultimately safety of biocidal products on the market, the following actions are recommended:

- **Standardise information and definitions**: Ensure consistency across SPC and labels.
- **Simplify Language**: Use plain language where possible, to make safety and handling instructions comprehensible to a non-professional audience (if relevant).
- **Define User Categories Clearly**: Provide explicit definitions for all user categories, to eliminate ambiguity regarding use permissions.

It is recommended that the Competent Authorities together with the Commission should reflect on possibilities to simplify the structure of the SPC, especially the structure of the family SPCs/Meta SPCs. This would facilitate the transfer of the information from the SPC to the label for the economic operators. A potential solution is to create a better structure of the SPC, possibly with reference to the structure of Article 69(2) of the BPR listing all label elements. An SPC should only include what is really needed for the label. For example, first aid information may not be needed for unclassified products. For classified products, only P-statements to be placed on the label could be indicated.

4.2.3 For industry

It is recommended that **industry** engage to increase their level of knowledge and awareness about the legal responsibilities in making available biocidal products on the EU market.

The applicant should create the draft of the SPC, which will be submitted to the authorising authorities, paying attention to those points that the authorising authority should consider, i.e. clarity, no repetitions, simple language and translation accuracy for the official language(s) of the Member State(s) where they intend to place their product on the market. In particular it is recommended the use of qualified translators who understand both technical terminology and legal nuances, to ensure accurate translations.

As mentioned above, the SPC should only include what is strictly required by the BPR avoiding for example unnecessary P-statements (e.g. in case of unclassified products). For classified products, only P-statements to be placed on the label could be indicated.

Companies implement systems or processes that would prevent non-compliance of biocidal product labelling and packaging. Such systems or processes (e.g. label quality control) should ensure consistency between information on the label and the SPC and ensure full regulatory consistency of all product information.

4.2.4 For ECHA

It is recommended that **ECHA** consider supporting the development of standardised information and definitions that should be used in SPCs in all languages as well as guidelines for an improved structure of the SPCs.

It is also recommended to consider the possibility to develop guidance on the interlinks and

dependencies between label and SPC, and SDS and SPC.

4.2.5 For the Commission

It is recommended that the **Commission**, together with Competent Authorities should reflect on possibilities to simplify the structure of the SPC, especially the structure of the family SPCs/Meta SPCs. This would facilitate the transfer of information from the SPC to the label for the economic operators.

Appendix 1. BEF-3 questionnaire for inspections

1. General information	
1.1 Member State: (list for selection)	
1.2 Inspection type □ On-site inspection □ Desktop inspection	On-site inspection: when national inspectors are at the premises of manufacturers, or companies selling biocidal products. Desktop inspection: when no visit to companies take place. Inspectors request documentation from companies and check it remotely. Companies might send information directly to authorities.

1.3 Roles of the inspected company/entity for the inspected product in the supply chain? □ Authorisation holder □ Manufacturer of biocidal product □ Importer □ Distributor □ Professional user □ Other (e.g. retailer) □ Unknown	Only one option possible. If the company/entity inspected has several roles, please use the 'highest level' in the supply chain for the inspected biocidal product, or mark 'authorisation holder'. Authorisation holder: The person established within the Union who is responsible for placing a biocidal product on the market in a Member State (or in the Union) as indicated in the biocidal product authorisation (Article 3 (1) (p) of the BPR). Manufacturer: The BPR is not explicitly defining the role of manufacturers of biocidal products. The Working Group members agreed to use the term manufacturer in the framework of the BEF-3 as any natural or legal person who manufactures a biocidal product. Importer: The BPR is not explicitly defining the role of importers of biocidal products. The Working Group members agreed to use the term importer in the framework of the BEF-3 as any natural or legal person established within the Community who places a biocidal product from a third country on the Community market. Distributor: The BPR is not explicitly defining the role of distributors of biocidal products. The Working Group members agreed to use the term distributor in the framework of the BEF-3 as any natural or legal person in the supply chain, other than the manufacturer or the importer, who is established within the Community and makes a biocidal product available on the market. Professional user: a user of biocidal products in course of his/her professional activities (e.g. use of preservatives in liquid cooling and processing systems)

1.4 Identification Trade Name: free text Authorisation number: free text Date of inspection: free text Inspector name: free text Inspection authority: free text Name of inspected company: free text National reference for company/biocidal product: free text	Optional. For authorities' internal use only. Not included in the BEF-3 report. Authorisation number: as reported on ECHA dissemination website. National reference for company/biocidal product: internal number of the file that inspectors assign concerning the inspection/company/biocidal product. National coordinators to decide how to structure the number.

2. Do label, leaflet, and packaging correspond with the Summary of Product Characteristics (SPC) of the biocidal product?

Parameters	**Section of SPC(*)**	**Yes**	**No**	**Not Applicable / not checked**
Article 69(1) of the BPR				
Trade name	1.1 / 7.1			
Hazard (H)-statements, EUH-statements	3			
Precautionary (P)-statements	3			
Hazard pictograms, signal word	-			
Pack size	4			
Packaging material	4			
Conditions of storage and shelf-life under normal conditions of storage	5.5/5.6			
Article 69(2) of the BPR				
a) Active substance name	2.1/7.1			
Active substance concentration				
c) Authorisation number	1.2 / 7.1			
d) Authorisation holder	1.2 / 1.3(**)			
e) Type of formulation	2.2			
f) Uses authorised	4 and 5			

(*) Entries with one reference refer to sections in a single-SPC, in a member-SPC or in the second information level (part II, meta SPC) of a family-SPC. Information in differing sections of a meta SPC in a family-SPC is indicated with a second reference (e.g. 1.1 / 7.1). Please refer in the family-SPC to the meta SPC corresponding with the biocidal product under investigation.
(**) Section 1.3 of the first information level (part I) of the family-SPC

Yes = fully compliant

No = Not (/partially) compliant with SPC

Trade name: Article 69(2) does not explicity require trade names on labels, however Article 69(1) states that labels should be in line with the SPC. In SPC more than one trade names can be stated, but only one of them should be reported on labels.

g) Directions for use etc.	4 and 5			
h) Side effect and first aid	4 and 5			
i) Sentence if accompanied by a leaflet	-			
j) Directions for disposal	4 and 5			
k) Batch number	4 and 5			
Expire date				
l) Instruction for use	4 and 5			
m) User categories	4			
n) Danger to the environment	4 and 5			
Danger to non-target organisms				

Hazard pictograms and signal words are derived from hazard statements. They are not indicated in a SPC. In case of an unclassified products, option "Yes" should be chosen if the label does not contain H- and P- statements. This is correct since it is an unclassified products and it should not include such statements.

In case the label of an unclassified products contains GHS hazard labelling (H- and P-statements, hazard pictograms, signal words), option "No" should be chosen since the label is not in compliance with the SPC.

Packaging material: inspectors might need to check the product concerning symbols and indications on specific plastic/material to correctly assess the packaging material used to contain biocidal products.

Conditions of storage should be complete and correctly indicated.

The information in points e), g), h), j), k), l) and n) might also be found on leaflets (in line with Article 69 (2) of the BPR).

a) Active substance name:
The designation of all active substances must correspond to the designations in the product authorisations (SPC), in the approval decisions or as stated on the ECHA dissemination website.
Answer is 'No' when at least one of several active substances is not in the correct designation according to the product

	authorisation (SPC) or the ECHA dissemination website. b) Active substance concentration: The indication in % (mass-%) is also considered a metric unit. Answer is 'No' when: • at least one active substance concentration is not in metric units • all concentrations are not correct • at least one active substance concentration is not correct • no concentration is indicated • at least one concentration is missing • some of the concentrations are not correct and others are missing c) Authorisation number: In case of family member biocidal product, the family-SPC section 7.1 is reporting the family member authorisation/asset number. d) Authorisation holder: Answer is 'No' when: authorisation holder is not indicated; another company name; address is not correct. e) Formulation type Formulation type as part of the trade name can be considered compliant. f) Uses authorised Target organisms stated on the label must be mentioned in the SPC. However, not all target organisms mentioned in the SPC need to be mentioned on the label.

<table>
<tr><td></td><td>m) <u>User category</u>:
If the user categories are restricted to professional or trained professional users, only then it must be indicated on the label.
If a product has different uses and there are different user conditions for general and professional user, it must be clearly specified on the label.</td></tr>
<tr><td>3. Was the SDS checked?

□ Yes (go to 3.1)
□ No (go to section 4)</td><td>Optional module</td></tr>
<tr><td>3.1 Does the following information of the SDS correspond with the SPC?

<table>
<tr><th>Parameters [in brackets section of the SDS]</th><th>Section of SPC(*)</th><th>Yes</th><th>No</th><th>Not Applicable / not checked</th></tr>
<tr><td>Trade name [1.1]</td><td>1.1 / 7.1</td><td></td><td></td><td></td></tr>
<tr><td>Hazard (H)-statements, EUH statements [2.2]</td><td>3</td><td></td><td></td><td></td></tr>
<tr><td>P-statements [2.2]</td><td>3</td><td></td><td></td><td></td></tr>
<tr><td>Active substance name [3.2]</td><td>2.1</td><td></td><td></td><td></td></tr>
<tr><td>Active Substance concentration [3.2]</td><td>2.1</td><td></td><td></td><td></td></tr>
<tr><td>User categories [1.2]</td><td>4</td><td></td><td></td><td></td></tr>
</table>
</td><td>(*) see the related note in question 2

SPC provisions that are reported in a SDS should comply with Article 31 and Annex II to the REACH Regulation.

<u>Active substance concentration</u>: Note that in the SDS active substance concentration in section 3.2 might be stated in volume percentage and might be only provided as a concentration range (in line with Annex II of the REACH Regulation).

<u>User categories</u>: If the user categories are restricted to professional or trained professional users only, then it must be indicated in the SDS. If a product has different uses and there are different user conditions for general and professional users, that must be clearly specified in the SDS.
If the checked product is a consumer product, then option ‘Not applicable/not checked’ should be chosen in the questionnaire.</td></tr>
</table>

4. Was chemical analysis performed? □ Yes (go to 4.1 and 4.2) □ No (go to section 5)	**Optional module**
4.1 Do the active substances detected correspond to those listed in the SPC? □ All active substances checked in the biocidal product are in line with the information reported in the SPC □ One (or more) active substances are not present in the biocidal product □ One (or more) active substances are present, but they are not indicated in the SPC	
4.2 Are concentrations of active substances correct (within the tolerance interval) compared to information reported in SPC? □ Yes □ No, one (or more) active substances have lower content □ No, one (or more) active substances have higher content □ Concentration not checked	ECHA guidance document on the BPR: Volume I Parts A+B+C Version May 2.0 May 2018, table 5 (i.e. tolerance interval).
5. Did you assess the quality of the content of the approved SPC □ Yes (go to 5.1 and 5.2) □ No (go to section 6)	**Optional module**
5.1 Did you find statements (e.g. use descriptions, instructions, directions) in the SPC that are lacking clarity, coherence, feasibility or enforceability? □ Yes □ No	Please write the free text in English. Observations on clarity, coherence, feasibility, absence of conflicting statements or on enforceability are most likely to be found in sections 4 and 5 of a single-SPC / member-SPC or of a meta SPC of a family-SPC Observations might cover the general clarity of information for inspections; coherence and suitability of SPCs; difficulties encountered during the inspections; enforceability/feasibility of the risk mitigation measures; etc.
5.2 Please explain the observation/assessment: free text	

	See the examples in the section on SPCs in the BEF-3 manual
6. Evaluation (overall) of inspections on label, SDS and chemical analysis	
6.1 Are label, packaging, leaflet complete and consistent? □ Yes □ No	Note that these questions are an overall evaluation of all aspects checked during the enforcement (not only the aspects checked in the BEF-3 questionnaire). Other aspects like misleading labels, language of labels might also lead to non-compliant biocidal products.
6.2 Is the SDS compliant, consistent and in line with the SPC in relation to what has been checked? □ Yes □ No □ Not checked	
6.3 Did chemical analysis confirm compliance with SPC? □ Yes □ No □ Not checked	
7. Enforcement measures – overall evaluation for the biocidal product	
7.1 Is the biocidal product compliant in relation to what has been checked? □ Yes □ No (go to 7.2 and 7.3)	Note that this question is an overall evaluation of all aspects of a biocidal product checked during the enforcement (not only the aspects checked in the BEF-3 questionnaire). Other aspects like misleading labels, language of labels, Article 95 obligations, advertisement, etc. might lead to non-compliant biocidal products. Do not include checks on proper use of biocidal products.
7.2 Due to identified non-compliances which action were taken?	Multiple choice question.

[] Verbal advice / written advice [] Administrative order/injunction [] Fine [] Criminal complaint/public prosecutor	Note that this question is an overall evaluation of all aspects of a biocidal product checked during the enforcement (not only the aspects checked in the BEF-3 questionnaire).
7.3 Do you consider at least one of the non-compliances enough to impact on the making available of the biocidal product (e.g. withdrawal from market)? □ Yes □ No	Note that this question is an overall evaluation of all aspects of a biocidal product checked during the enforcement (not only the aspects checked in the BEF-3 questionnaire).
7.4 Are follow-up activities still ongoing? □ Yes □ No	
7.5 Other remarks: free text	Please write in English Please report reasons or additional non-compliances that were found during the inspections besides the aspects checked in the BEF-3 questionnaire (for example professional products sold to general public; misleading advertisement; language of labels; Article 95; etc.)

Appendix 2. Document history

Version	Date	Changes
1.0	November 2026	

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