FINAL REPORT

EUROBIOCIDES III

TREATED ARTICLES

2017

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CONTENT

1 INTRODUCTION

The Chemical Legislation European Enforcement Network (CLEEN) is a voluntary network of inspectorates situated in the European Union, Norway and Switzerland which aims to coordinate the enforcement of EU chemical legislation by developing common strategies and tools for the inspectors in the member countries. It is a forum for information exchange and it performs inspection projects as proposed by its members. The network's mission is to enhance the effectivity and the harmonisation of enforcement and to advance enforcement efforts especially in those areas of chemical legislation that have not been sufficiently covered yet.

In 2005-2010 the CLEEN-network undertook a major project, *EuroBiocides I*. It focused on the authorization and the placing on the market of biocidal products. The project showed a lot of non-compliance in the participating member states. This was followed-up in the *EuroDeter* project (borderlines detergent-disinfectants), the *e-commerce II* project (online sales of biocide product types (PTs) 14, 18 and 19 products) and an intention to make an inventory of enforcement tools used in the member states (ongoing). This follow-up is being referred to as the *EuroBiocides II* project.

At the 14th CLEEN conference in London, 2013, the proposed *Eurobiocides III* project received great interest among the attending Member States and was adopted. Eventually nine countries joined the common campaign. The enforcement focus lay on articles treated with biocides and the objective was to make traders and producers aware of the new obligations and to develop harmonized enforcement tools. The project was managed by Human Environment and Transport Inspectorate of the Netherlands and the Swedish Chemicals Inspectorate KEMI.

2 SUMMARY

Nine countries reported details and results from inspections at 330 different companies and fed their data sets online into the project's database that was hosted by Switzerland. In total 584 investigated articles were recorded of which 361 were regarded as treated articles and being subject to legal regulations on labelling. The presented results deal only with those 361 articles. Most products reported were treated with biocides belonging to the following categories:

- PT2 (disinfectants and algaecides not intended for direct application to humans or animals)
- PT9 (fibre, leather, rubber and polymerised materials preservatives)
- PT1 (human hygiene)
- PT8 (wood preservatives).

62 percent of the checked treated articles were on the market in breach of the Biocides Products Regulation (EU) No 528/2012 and the responsible companies received

corresponding information. In some cases orders to label products correctly were awarded. Among the compliant articles those treated with PT8 (wood preservatives) and articles treated with PT10 (construction material preservatives) had the highest rate of correct labels.

Some of the active substances were not listed or listed as not allowed on the Review Programme Regulation (EU) No 1062/201.

3 LEGAL BACKGROUND

The Biocidal Products Directive 98/8 of the European Parliament and of the Council had been in force for 14 years when it was substituted by the Biocides Products Regulation (EU) No 528/2012 (BPR) in 2013. The BPR has as a main objective the free movement of biocidal products and treated articles on the internal market while ensuring a high degree of protection of humans, animals and the environment. With this regulation an information obligation applying to treated articles was introduced. The information is supposed to give the customers the possibility to make a choice before purchasing a treated article. This particular information and labelling obligation was a completely new legal field for most enforcement agencies as well as for the industry. Accordingly, the project's main focus was to make the companies aware of the regulation. Although some transitional provisions for placing treated articles on the market existed, the last one ended on 1 March 2017. From this point on, all treated articles containing active substances and having a claim about their effects that is not in line with the provisions of the BPR, will not be allowed on the EU-market anymore.

4 PROJECT DESCRIPTION

An enforcement project was undertaken focussing on articles treated with biocides. The objectives were:

- Making the trade and producers aware of the new obligations
- Developing and using harmonized enforcement tools

Where non-compliance was found the intention was to provide information and advice to the traders and responsible producers rather than taking direct enforcement action. The information and advice was provided by awarding so called 'yellow cards' with a collection of facts about the labelling requirements. Some Member States chose a further-reaching enforcement approach, in which case orders on how to label were sent to the responsible companies.

Most of the inspections have been desk top inspections, but also many on-site inspections were conducted. Both conventional, location-based retailers as well as internet sale was inspected.
An extensive manual of the project was prepared by the Netherlands. Germany

contributed with a revision and adjustments to legal changes, the manual can be found in Annex 1. The Swiss Enforcement Unit provided the project with other valuable tools such as a database along with an online-interface for collecting the inspection reports from the participating inspectors.

The inspected articles were subdivided into three categories: "Biocidal Products", "Treated Articles with a claim" and "Treated Articles without a claim".
where a biocidal claim is made regarding the biocidal properties of the treated article

4.1 The labelling obligations in short

Treated articles that are placed on the market with a claim regarding biocidal properties, like "odourless", "antiseptic", "antibacterial" etc. are supposed to be labelled according to Article 58. This means that:

- The substance used for the treatment has to be included in the list of approved active substances for the relevant product type
- The person first placing the article on the market has to ensure that a label on the article provides certain relevant information. Labelling is also necessary if the approval conditions of the active substance(s) in the used biocide require it.
- The Regulation makes clear that where necessary to protect human health, animal health or the environment, a treated article should always be accompanied with instructions, including precautions. Furthermore, at a consumers request any supplier of a treated article has to provide information about the biocidal treatment of the treated article within 45 days.
- The labels of such treated articles should provide the following information:
  - a statement that the treated article incorporates biocidal products
  - where substantiated, the biocidal property attributed to the treated article
  - the name of all active substances
  - if relevant, the name of all nano-materials ('nano' in brackets)
  - any relevant instructions for use, including any precautions

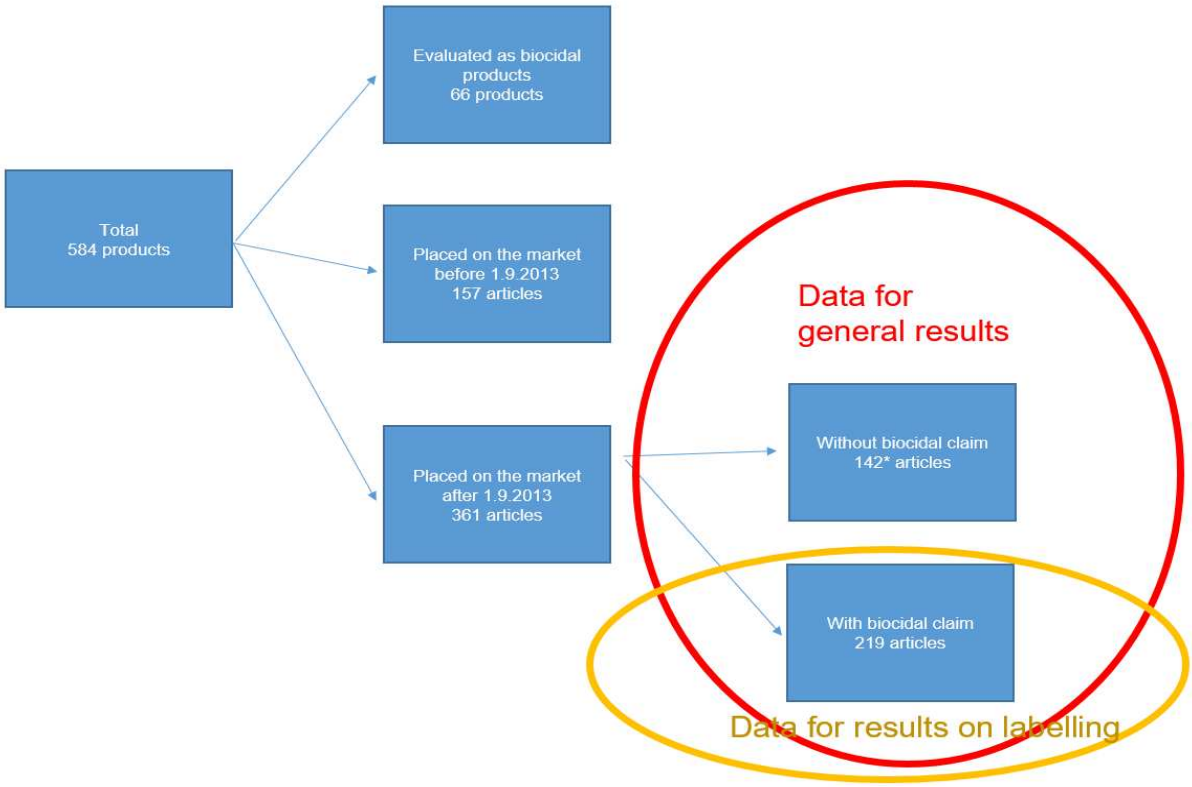
For further information about the working method and the legislation, please see the Project Manual in Annex 1 of this report.

There have been some transitional provisions regarding the choice of active substances, when treating and placing treated articles on the market. However, this topic has not been in the scope of this project. Information about where to find a list of approved biocides or biocides under review could instead be given when a yellow card was awarded. With March 1st, 2017 the period of transitional provisions has come to an end and now stricter conditions apply as to which substances that can be used for treating the different articles.

5 RESULTS

The project ended in December 2015 and nine countries had reported data from their inspections. In total 330 company inspections were performed and 584 articles were reported into the database.

After subtracting articles placed on the market before 1 September 2013 (157) and articles that were biocidal products[1] (66) a total of 361 products remained that were identified as treated articles (Fig. 1). Those are the base for the rest of the figures and statistics presented in this report. However, all companies subject of an inspection were contacted and received the necessary information about labelling.



*also includes articles for which the presence of a claim was not known/unsure or uncertain according to the survey results.

Fig. 1 A part of the reported articles were regarded as treated articles.

[1] Treated articles which are toys are exempt from the regulation. Reports on such products were therefore excluded from the analysis. Treated articles having a primary biocidal function shall be considered biocidal products. Data on these was excluded from the material as well, for example: mosquito repellent cloth, tick repellents, disinfecting tissues and mosquito coils.

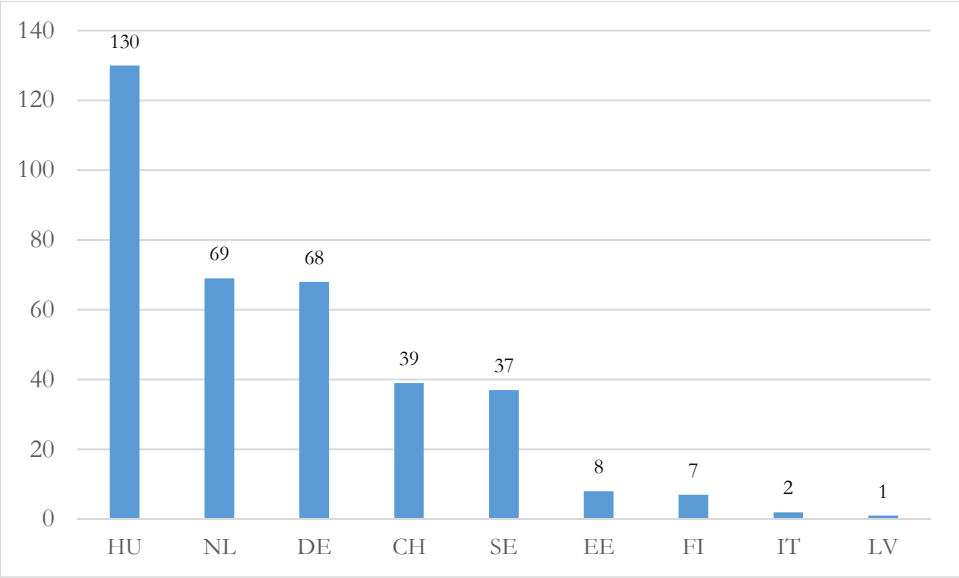


Fig. 2 Number of inspected articles per country

Figure 3 shows the range of product types (PT) in the inspected sample of treated articles. Most commonly seen PTs were PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals), PT 9 (Fibre, leather, rubber and polymerised materials preservatives), PT 1 (Human hygiene) and PT 8 (Wood preservatives).

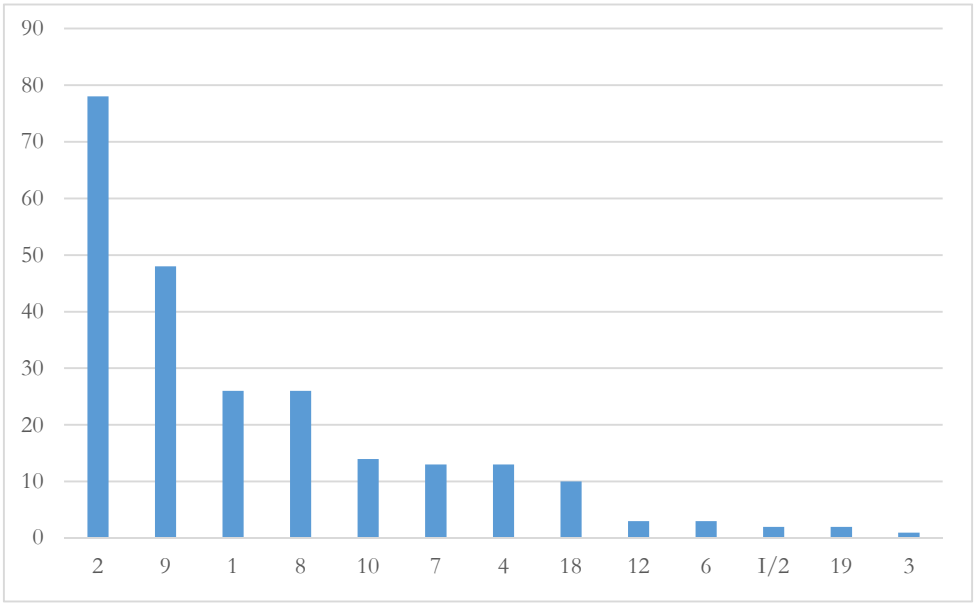


Fig. 3 Number of inspected articles per product type. Product type 1/2 contains articles reported to belong to either of the product types 1 or 2 by the inspector.

In total 62% (224) of the assessed articles were not correctly on the market and the responsible companies got an information leaflet (yellow card). In some cases orders were imposed to label products in a compliant way or products were taken off the market (Fig 4). The remaining 119 articles were reported to have a sufficient label and were therefore correctly on the market.

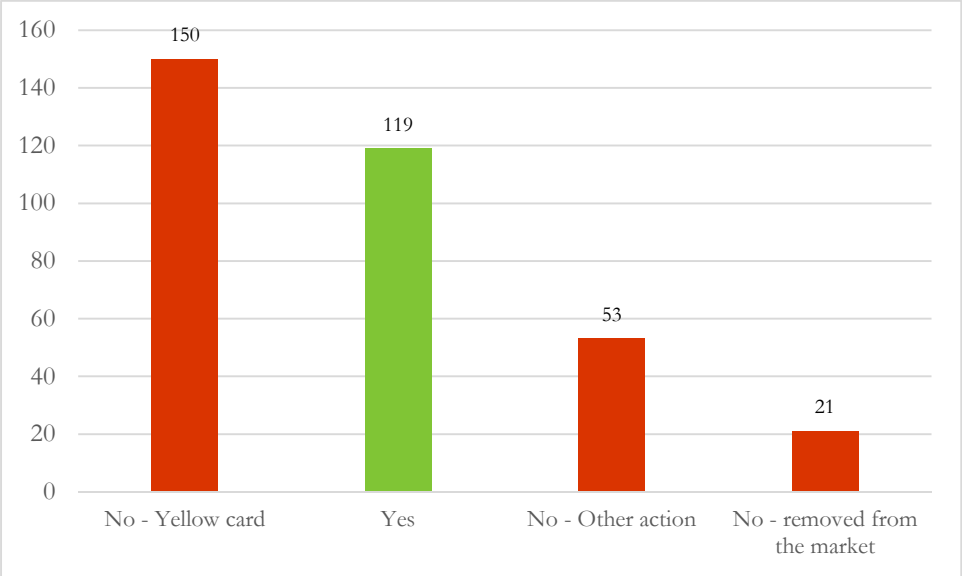


Fig 4 *Approved quality of labelling of treated articles on the market (green) and resulting action by the inspectorates in case of insufficiently labelled articles (red).*

More than 90% of the treated articles had a biocidal claim (Fig. 5). Two thirds of those had a label fulfilling at least some of the obligations. 28 treated articles without a claim were reported in the course of the project.

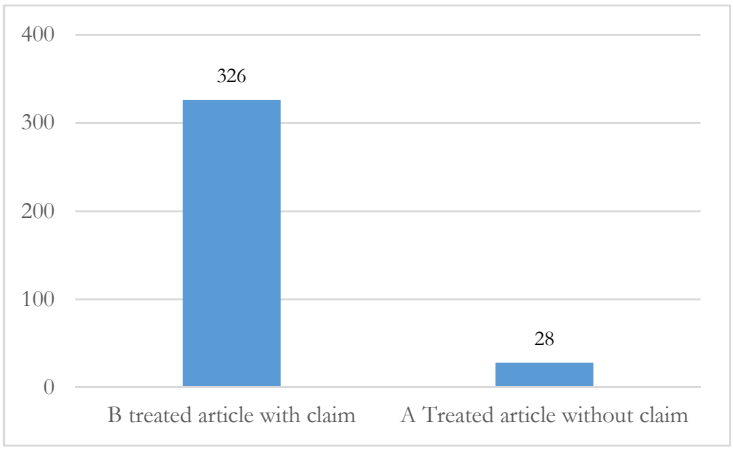


Fig. 5 *Frequency of biocidal claims in the sample of treated articles*

Figure 6 shows that 63% of the treated articles with a biocidal claim had a label. For 20% of the assessed articles inspectors stated that it was uncertain whether or not a label existed. Most of these articles were controlled on the internet and the label could not be examined.

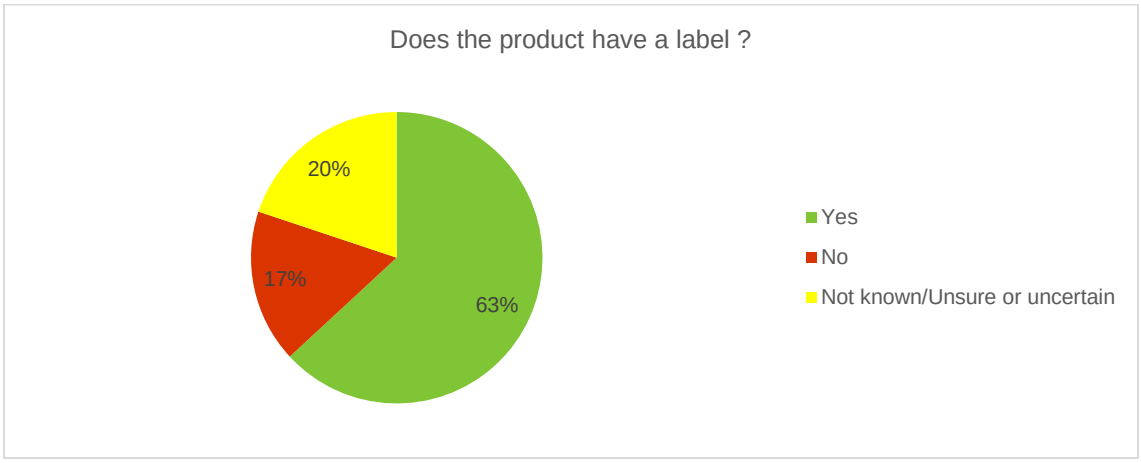


Fig. 6 Presence of a label on treated articles with a claim about a biocidal property (n = 219).

Among the compliant treated articles the best level of correctness was seen for articles treated with biocides belonging to PT 8, 10, 18, 7 and 2 (fig. 7). This indicates that treated wood and other treated construction material was better labelled than other articles.

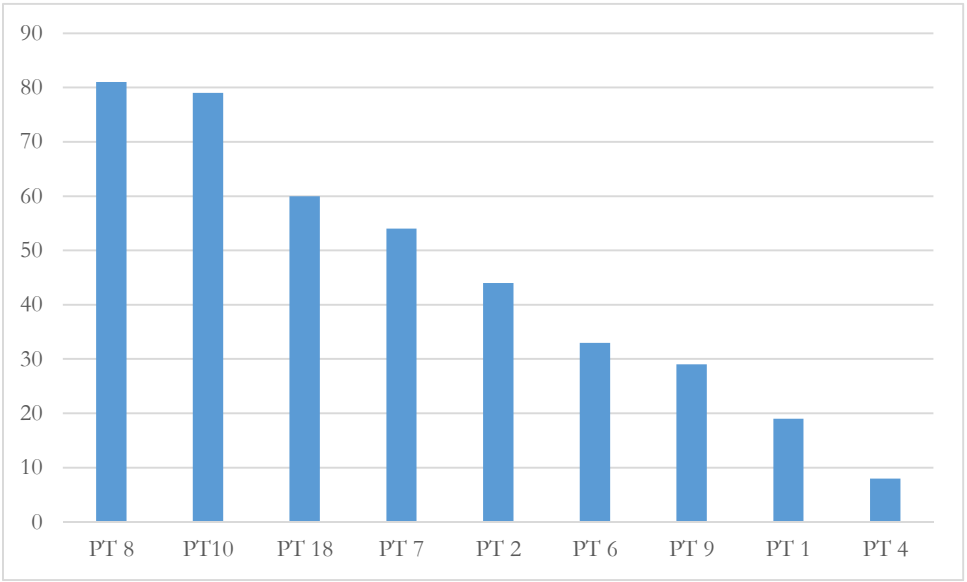


Fig. 7 Percentage of articles with correct label per PT

Of all the active substances found to be used, the majority was among those listed as "approved" or "under review" in the Review Programme of Regulation (EU) No 1062/201, and therefore was allowed to be used. However, whether or not the use of the active substances was approved for the particular PTs was not checked. If this parameter would have been checked it might have increased the number of not allowed substances. A few substances in the inspected articles were not listed at all or listed as "not allowed". A few reported substances might not act as biocides but in other ways, for example active carbon.

The active substances occurring most frequently in the sample articles are listed below. Silver chloride had the highest rate among the "not approved" substances.

- Silver (different salts) and silver zeolite
- Boric acid
- Copper and copper HDO
- OIT and DCOIT
- IPBC
- Permethrin
- Zink pyrithione
- Tebuconazole
- Geraniol

5.1 Content of the label

The information that must appear on the label of a treated article has also been subject of the checks (article 58 BPR). However, most of these articles were assessed on the internet and the label could not always be fully examined.

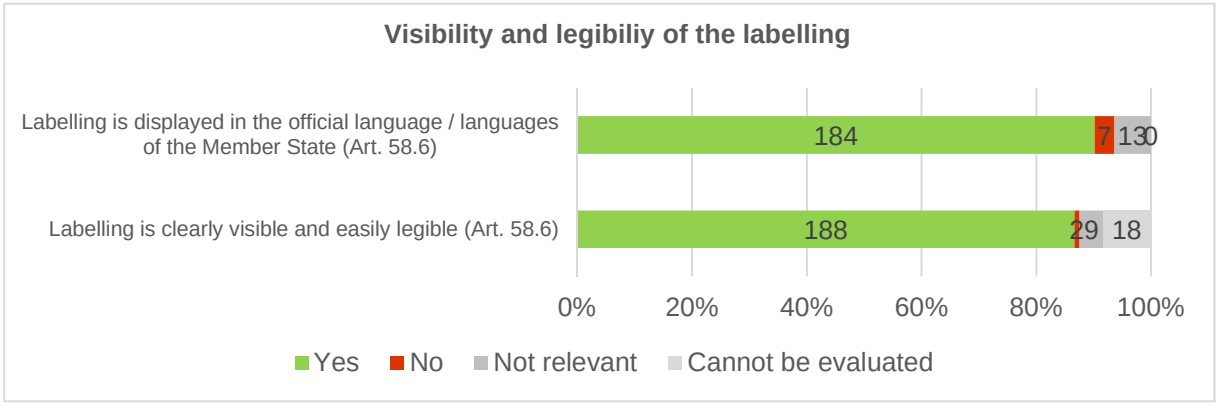


Fig. 8 Visibility and legibility of the labelling (subsample of articles (n = 219) meeting the following criteria: with a biocidal claim and being put on the market "After the 1st of September 2013". Occurring differences between total and sample size 'n' in rows represent the missing responses of inspectors to the given question).

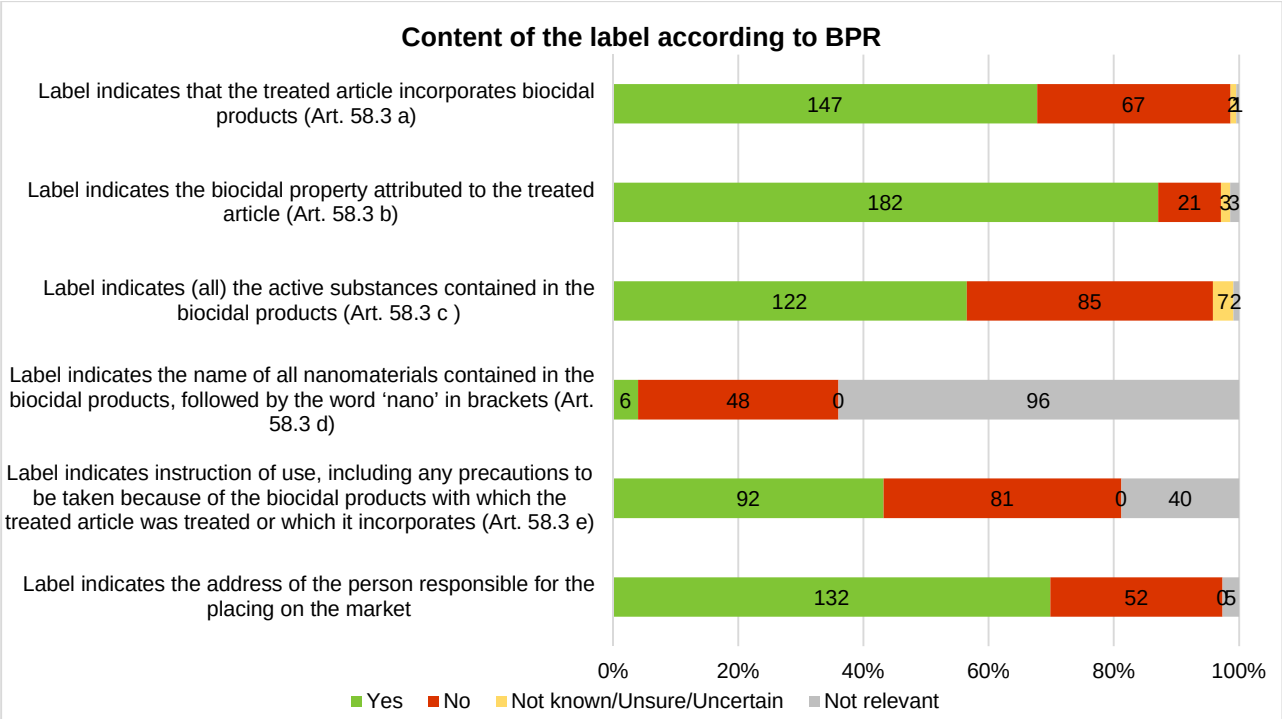


Fig. 9 *Presence of required content on the label (subsample of articles (n = 219) meeting the following criteria: with a biocidal claim and being put on the market "After the 1st of September 2013". Occurring differences between total and sample size 'n' in rows represent the missing responses of inspectors to the given question).*

6 DISCUSSION

One of the aims of the project was to inform the companies on the market about the new legislation and the demand on labelling. The project reached out to 330 companies selling treated articles and biocides. Most of the inspections seems to have been done on companies responsible for producing the label, but also many other actors on the European market, like retailers, have been contacted. In this way many actors have been reached with the information.

During the visits / contact with the retailers, the inspectors have also noticed that a lot of retailers are not aware of what a treated article is and the obligations related.
The other main purpose of the project was to coordinate the enforcement and the development of common strategies. This started with an extensive manual and with repeated discussions on the annual meetings of the enforcement group. The Treated Articles guidance document on ECHAs web page has also been used frequently.

The reporting of PT for the treated article might not have been done in a uniform way, since this was usually not given on the product and had to be decided with an expert judgement. For example a treated sock and an insole was reported as treated with biocides from PT1, PT2 or PT9 by three different inspectors.

The high amount of accepted labels in articles treated with biocides such as wood preservatives and Construction material preservatives might at least to a part be explained with already existing procedures of information/labelling for this branch. This was not further investigated.

The frames of the project and also some results have been presented to the industry and media in Mainz at the 14th international Fresenius conference in 2014 and in Ljubljana at a conference arranged by Chemicals Watch/Biocides Hub.

ANNEX 1 MANUAL WITH QUESTIONNAIRE

CLEEN project – Eurobiocides III

December 2014

An enforcement project is undertaken which focuses on articles treated with biocides. The purpose is to:

- Make the trade and producers aware of the new obligations
- Develop harmonized enforcement tools

Where non-compliance is found it is intended to provide information and advice to the traders and responsible producers rather than to take direct enforcement action. The information and advice may be provided, for example, by distributing so called 'yellow cards'. Member States may choose a farther-reaching enforcement approach.

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1. Introduction

In 2005-2010 the CLEEN-network undertook a major project called Eurobiocides I. It focused on the authorization and the placing on the market of biocidal products. The project showed a lot of non-compliance in the participating member states. This was followed-up in the Eurodeter project (borderlines detergent-disinfectants), the e-Commerce II project (online sales of biocide product types (PTs) 14, 18 and 19 products) and an intention to make an inventory of enforcement tools used in the member states (ongoing). This follow-up can be seen as Eurobiocides II.

At the 14-th CLEEN conference in London the proposed Eurobiocides III project was adopted. Most of the participating member states showed interest in participating in the project, especially if a stronger focus on some treated articles is provided.

With this document the project moves to its next phase.

This document gives not only the information provided in an earlier phase, it also provides more detailed information about the possible inspections and the follow-up procedures. Furthermore, text is included which member states can use to provide companies with information and advice about placing treated articles on the market.

2. Background information on biocides

Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. However, biocidal products can cause risks to humans, animals and the environment due to their intrinsic properties and associated use patterns. Therefore there is legislation in the European Union to minimize these risks. The *Biocidal Products Directive* (98/8/EC) has been in force since 1998. In 2013 it was replaced by the *Biocidal Products Regulation* (EU) No 528/2012 (the BPR) which is directly applicable.

The BPR has as main objective the free movement of biocidal products and treated articles in the internal market while ensuring a high degree of protection of humans, animals and the environment.

Biocidal products are '*any substance or mixture, in the form it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, 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'*. Even '*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, 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'* are considered to be biocidal products. Furthermore '*treated articles with a primary biocidal function' are also considered to be biocidal product*s.

The general principle of the BPR is that biocidal products shall not be made available on the market or used unless authorized in accordance with the BPR.

3. Background on Treated articles

Chapter XIII of BPR (Article 58) deals with 'Treated articles'. These are articles treated with one or more active substances. Treated articles with a primary biocidal function are considered to be biocidal products. The borderline between treated articles – biocidal products is still the subject of discussion, but might be clarified before Eurobiocides inspection activities start.

Articles, such as premises or containers used for storage or transport, which were solely fumigated or disinfected and that are not expected to have residues remaining from that treatment, are not considered to be treated articles and thus excluded from Article 58.

'Treated articles' are a new phenomenon in biocides legislation. They represent a completely new legal field for most enforcement agencies as well as for the industry. For this reason, the CLEEN-network puts some effort into providing advice and information on the legal requirements for this category of products.

Transitional provisions

The BPR entered into force on 1 September 2013. However, there are some transitional provisions, e.g. for placing treated articles on the market. According to Article 94 BPR, treated articles may continue to be placed on the market until the date of the decision concerning the approval for the relevant product-type/active substance (PT/AS-) combination, if the application for approval is submitted before 1 September 2016. From 1 March 2017 on treated articles containing active substances that are not in line with the provisions of the BPR are not allowed on the EU-market anymore..

Labelling obligations

The BPR prohibits the placing on the market of a treated article *unless the active substances contained in the biocidal products that it was treated with or incorporates* are included in the list of approved active substances for the relevant product type and use (PT/AS-combination).

In addition, where a biocidal claim is made regarding the biocidal properties of the treated article, the responsible person for the placing on the market (defined as first placing on the market) of such an article) has to ensure that a label on the article provides certain relevant information. Labelling is also necessary if the approval conditions of the active substance(s) require it.

The Regulation makes clear that where necessary to protect human health, animal health or the environment, a treated article should always be accompanied with instructions, including precautions. Furthermore, at a consumers request any supplier of a treated article has to provide information about the biocidal treatment of the treated article within 45 days.

Types of treated articles:	**Labelling requirements**
Treated article without biocidal claim (e.g. paint or ink containing in-can preservatives)	No labelling requirements (unless laid down differently in the approval of contained active substances or other legislation applies)
Treated article with a biocidal claim arising from treatment with a biocidal product. (e.g. tent cloth incorporating an insect repellent)	Labelling is required as specified in art 58(3) of BPR, unless equivalent provisions are required in other EU legislation
Treated article with a primary biocidal claim (e.g. a mosquito net equipped with a biocide)	Labelling is required as part of authorization (see also art 22. BPR)

The labels of such treated articles should provide the following information:

→a statement that the treated article incorporates biocidal products;
→where substantiated, the biocidal property attributed to the treated article;
→the name of all active substances;
→if relevant, the name of all nano materials ('nano' in brackets);
→any relevant instructions for use, including any precautions.

If other labelling requirements exist that provide the same level of information, those requirements are considered sufficient and the ones mentioned above do not apply. However, the person responsible for placing a treated article on the market has to include on the label any other relevant information for safe use (Article 58(4)). In addition, the person placing the treated article on the market has to provide to consumers on request information about the biocidal treatment of the treated article. This information has to be provided within 45 days of the request (Article 58(5)).

A proposed information leaflet is given in the Annex. The leaflet provides further information about the treated articles, the transitional periods and the labelling requirements. It can be used to inform companies about treated articles.

4. Goals of the project

The primary goal of this project is to contribute to the implementation of the BPR by inspection, communication and, if necessary, enforcement as well as to evaluate the level of compliance with the regulation. Improving the level of compliance is also an objective, although presently there is no insight into current compliance levels.

Another goal of the project is the development of harmonized inspection tools.

The project focuses on treated articles because these requirements are new and because Article 58 of the BPR applies from 1 September 2013 in regard to labelling.

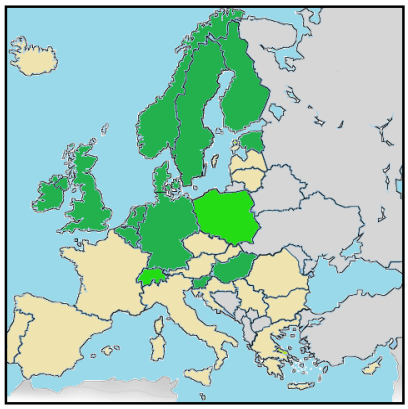
Treated articles can be found almost everywhere. Examples are products such as paints, glues, wood that incorporate preservatives, clothes (insecticides) and textiles (disinfectants, fiber preservatives), refrigerators, boots, ….

The project covers all treated articles but sets the focus on treated articles with no primary biocidal claim.

In the operational phase all participating MS will have 'yellow-cards' for the treated articles that they find on their market. A 'yellow-card' (or an equivalent) may be sent to the distributor and/or importer and/or producer concerned. A copy of the 'yellow-card' should be sent to the member state, in which the producer is situated. Returns from the MS will provide insight into the current level of compliance with the BPR requirements in regard to treated articles, including labelling. The 'yellow-cards' (or other advisory action) shall serve as a warning to induce companies to inform themselves and take necessary actions for complying with the BPR requirements within due time.

5. Project set-up

The following member states have shown interest in the project:



Participating MS

Participating MS in 2015

Other CLEEN-members

Member State	Focal Point	Remark
Denmark	(Dorrit Skals)	Project group
Estonia	(Natali Promet)	
Finland	(Päivi Karnani)	
Germany	(Stefan Frenzel / Lutz Erdmann)	Participation in 2015
Hungary	(Miklos Czékus)	
Ireland	(John Harrison)	
Latvia	(Kristīne Kazerovska)	
Norway	(Jorun Holme)	
Poland	(Marta Osowniak)	Participation in 2015
Slovenia	(Stanislav Krapež)	
Sweden	(Margareta Daho)	Project group
Switzerland	(Heribert Buergy)	Participation in 2015
The Netherlands	(Ida Scheijgrond)	Project group
United Kingdom	(Robin Foster)	

6. Time-table

The project continues until the end of 2015. This gives the project management the opportunity to make a report for the CLEEN-conference in 2016. MS still can use the available tools after this date if they want to. The returns available at the beginning of 2015 will be used to make an interim report.

7. Ways of participation

The project offers various ways of participation. It is up to a participating MS to choose one or a combination of ways:

1. On-site inspections with focus on special kinds of treated articles
2. Internet surveys → web shops
3. Internet surveys → special search terms
4. Inspections within a defined period
5. Reactive or secondary inspections

Recital 53 of the BPR notes that it is important to enable consumers to make informed choices and that therefore treated articles should be appropriately labelled. For this reason the project focuses on the production and placing on the market of consumer goods in the following product types:

PT2 Private area and public health area disinfectants
PT4 Food and Feed area disinfectants
PT9 Fiber, leather, rubber and polymerized materials preservation

However, each member state is free to set its own national focus by selecting treated articles.

The following industries may be involved:

- Cleaning devices and equipment (trolleys, boots, swabs…)
- Swimming pool equipment (filters, plumbing, pumps….)
- Air conditioning systems and devices (filters, condensers…)
- Toilet and other sanitary equipment and devices (seats, furniture, fittings…)
- Floor and wall panels (tiles, laminates, carpets…)
- Kitchen equipment and devices (chopping boards, knives, waste bins/bags…)
- Clothes and garments (t-shirts, trousers, socks, shawls, gloves…)
- Personal safety equipment (earplugs, gauntlets, boots…)

1. On-site inspection with focus on particular types of treated articles.
On-site inspections are possible. However the aim of the project mainly is to inform producers and retailers. MS should take into consideration that such inspections might not be a reasonable use of resources in this early phase of implementing the new obligations. Although on-site inspection is the best way to provide information and advice, it is also very time-consuming.

However, if a Member State chooses to participate by on-site inspections, they shall be conducted on the premises of producers and traders of products mentioned above. Alternatively, other treated articles may be selected in accordance with national interests. It certainly is possible to further narrow the focus of inspections, e.g. to target only producers of tiles or sanitary products.

2. Internet surveys → webshops
For Internet surveys all products are recommended. Within the project the focus is on web shops. Apart from pure virtual shops also companies should be targeted that are operating conventional shops at a physical base as well. The advantage of the latter inspection approach is that it is less time demanding.

The project management can't provide a list of web shops because many of them are only active in some countries, and some market different products in different countries. However, once

appropriate treated articles have been detected a simple Internet search may identify additional online suppliers (see below).

3. Internet surveys → special terms

The internet provides us with tools by which we can search on certain terms e.g. antibacterial or disinfecting. When the right terms are used a lot of hits will occur. Every hit needs a quick validation, but in many cases a treated article is involved.

Useful search terms are:

- Anti-bacterial
- Anti-microbiologic / -microbial
- Anti-fungus / moulds
- Insect (-icide)
- Algae (algicide)
- (Anti-) bugs
- Prevent / reduce / inhibit (-ing) odors
- (Anti-) allergen / allergic

4. Inspection within a certain period

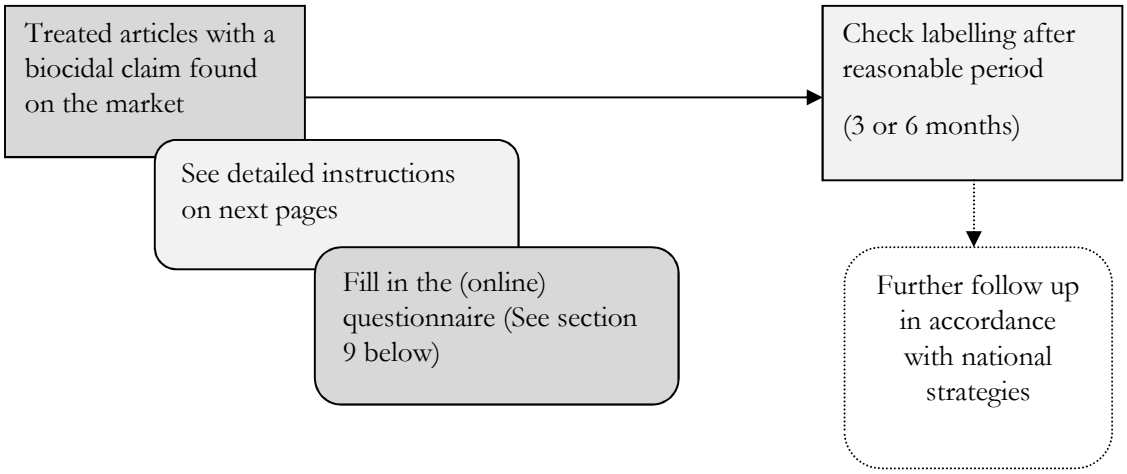
Some MS may only be able to participate during a certain period. The relatively long duration of the project allows every MS to choose a convenient period. The inspections undertaken may be on-site or Internet based as described above.

5. Reactive or secondary inspection

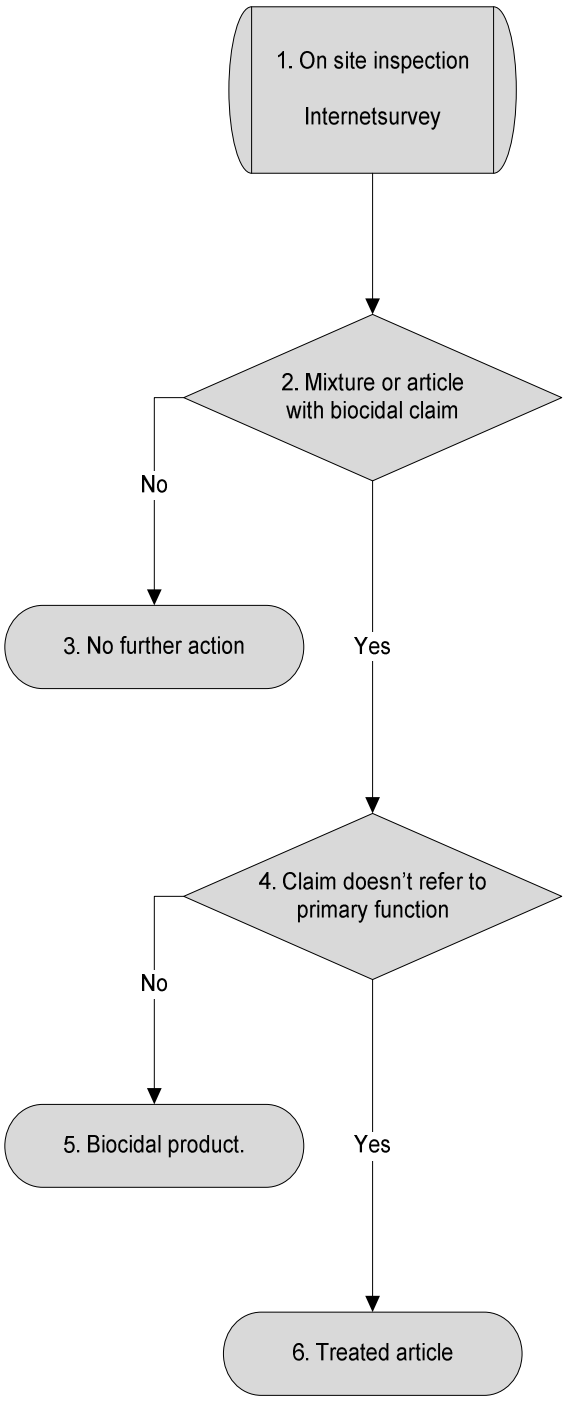
It is possible to undertake the project reactively alongside regular work. Inspectors can be alerted to finding treated articles in their daily work. If they come across treated articles, they can use the tools available in this project.

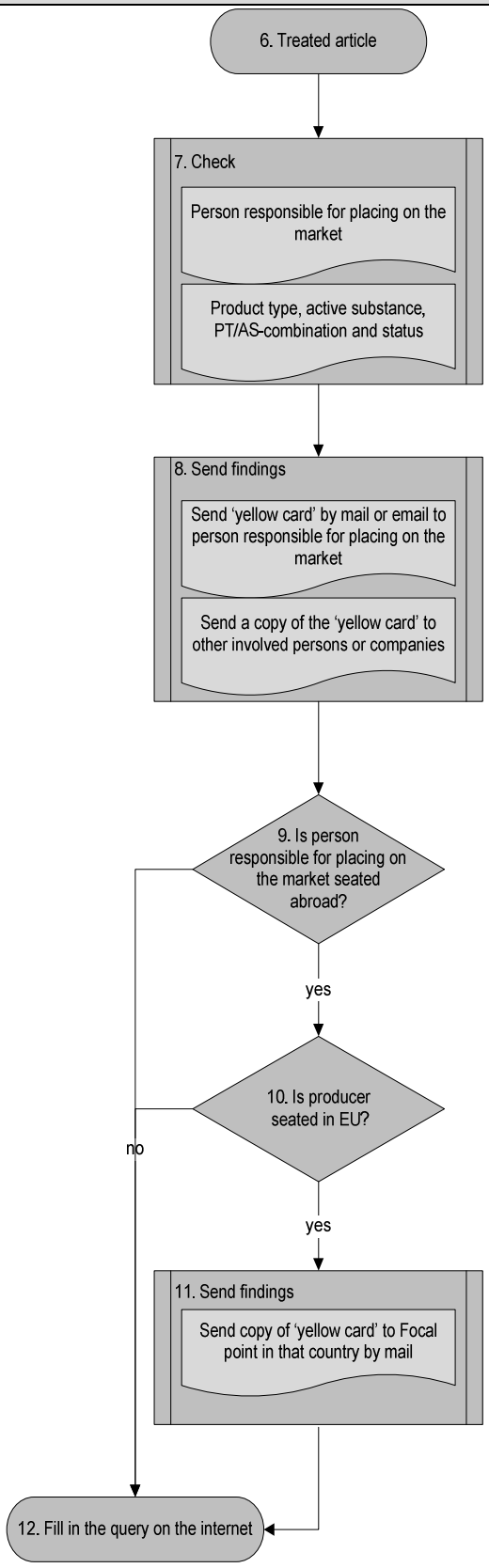
8. Instructions

The project is quite simple. If a treated article is found certain action is taken in regard to the person responsible for placing the treated article on the market and the project management is informed. The project management will publish all notifications received on the restricted area of the CLEEN-website so inspection authorities have access to all the information generated.



Member States can decide their own follow-up action in regard to the person placing treated articles on the market in accordance with their national strategies.

Work scheme	Explanation
	It's important to take good notice of the 'Note for guidance on treated articles' (www.echa.eu) **1/2**.A treated article can be found on the market as a result of on-site inspection or as result of an internet survey, or reactively in the course of other work. We are only interested in articles **with** a (primary or secondary) biocidal claim. This claim may be on the label or in other promotion or marketing material. 2/3. Other substances, mixtures or articles known or expected to have been treated with, or intentionally incorporate, one or more biocidal products (but without any claim) do not have to meet the labeling obligations***** and are of no interest in this project. It may be useful to verify whether the marketing or promotion materials used by downstream retailers of such articles are in compliance. 3. If there is no claim that refers to a biocidal function, the BPR doesn't apply as far as it concerns labelling*****. Of course such articles can only been treated with approved active substances and the customer must be provided with information within 45 days. (See note) 4. According to the guidance document primary function can be considered a 'function of first rank, importance or value compared to other functions.' (See note for guidance Q13 - Q15) 5. When the treated article has a primary biocidal function it is considered a biocidal product. So it cannot be made available on the market unless it is authorized. If no authorization is granted the product can't be marketed, unless transitional measures apply. 6. When there is no primary biocidal function, the product is considered a treated article. ***Note**: It is possible that no biocidal claim is made, but that there still are labelling obligations. This will be. the case when the conditions associated with the approval of the active substance set out specific labelling requirements.

Work scheme	Explanation
	6. When it is certain that the treated article is not a biocidal product the following steps can be undertaken. 7. Figure out who is responsible for the placing on the market (defined as first placing on the market). Furthermore a short inquiry is necessary on the active substances present and the intention of their presence. Currently only a few PT/AS-combinations are approved, so the inspector may consider it is not necessary to check whether the combination found is valid. The person responsible for the placing the treated article on the market is responsible for ensuring that, subject to the transitional measures, the appropriate PT/AS combination is approved. 8. When the information mentioned above is obtained, an email or a letter is sent to the person responsible for placing the treated article on the market and, if relevant, to other persons known in relation to the case. Its key message is: if you think that a treated article is involved, some action is needed in order to keep it on the market after September 1, 2016. A leaflet or link to a web site can provide more information. Taking action with respect to labelling requirements might be an additional option. 9/10/11. If the person responsible for placing the treated article on the EU-market is not seated in your country, but somewhere else in the EU, you should also send an e-mail to the CLEEN focal point of the relevant-country. The expectation is that in most cases the identified responsible person is also the producer or importer of the treated article. The project's questionnaire should then be filled in (online). 12. All activities end by filling in the questionnaire on the internet. [? Follow up?]

9. *Reporting to the project management*

In this CLEEN project we use the Swiss internet tool to collect all project findings. Every participating MS or inspector will be provided with a log-in code. With this code he/she will have access to a short internet-based questionnaire with the following or similar (draft) questions. In Annex 2 a hard copy of this questionnaire is given. As you can see, most of the questions are easy to answer. Full responses are requested, though the tool can still be used when not all answers are known.

Based on the information submitted via the internet tool an interim and final report will be made. It is important that all findings are reported. However, who uses the tool to submit the information is up to the participating MS. In most MS the internet tool will be supplementary to any national databases. When a file is completed it is send to a central database. Automatically a PDF-file is made for the inspector and can be stored in a national database.

10. *Use of the online tool*

Every MS has a national coordinator (see paragraph 5). Each coordinator will receive an e-mail with a password (called token) which allows them to log on www.cheminspect.ch/admin (e-mail will be sent from nadine.grisel@bag.admin.ch or heribert.buergy@bag.admin.ch).

On this interface, the coordinator can:

1) Create personal token for inspectors that are going to use the questionnaire of EuroBiocides III
2) Translate the questionnaire in the language of the country

Coordinators and inspectors will receive a document with specific information.

Every inspector that is authorised to use the internet tool can always reach his/her own files again. The project management will periodically give insight in all reported treated articles.

11. *Questions*

If questions or doubts arise please inform the project management:

- margareta.daho@kemi.se
- Dorrit Skals: dsk@mst.dk
-

The following text can be used for an information leaflet for the industry or trade-organisations. It can also be used for information on the internet.

Annex 1: Background information "Treated Articles"

==========

European rules and a level playing field

Various European directives and regulations are in force in order to protect human health, animal health and the environment against toxic substances and to establish a level playing field on the European market. One of these regulations concerns the making available on the market and use of biocidal products. The placing on the market of articles treated with biocides is also regulated in the so called Biocidal Products Regulation, which came into force on September 1st, 2013 (Regulation 528/2012/EU).

This regulation dictates that biocides should only be made available or placed on the market after an evaluation of their risks and national or EU authorization. The user of biocidal products is also obliged to comply with the user instructions set out as authorization conditions. Articles that have been treated with a biocide do not need authorization. However, subject to transitional measures, they can only be placed on the market (defined as first placed on the market) when the active (biocidal) substance(s) in that particular treated article has (have) been evaluated for that specific purpose. For both biocides and treated articles labelling requirements apply. The labelling obligation applies to treated articles from 1st September 2013. This note focuses on treated articles only.

What is a treated article?

The Biocidal Products Regulation (BPR) defines treated articles as follows:

Treated article: any substance, mixture or article which has been treated with or intentionally incorporates one or more biocidal products;

This definition contains a reference to "biocide" or “biocidal product”:

Biocides: any substance or mixture which, 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.

It is crucial to understand that according to these definitions a substance or mixture can also be a treated article. Furthermore, it is also important to know that the definition of a biocidal product indicates that:

A treated article that has a primary biocidal function shall be considered a biocidal product.

Exceptions

There are two exceptions:

1. Articles that are biocidal products must comply with other BPR-obligations, and

2. Articles where the sole biocidal treatment was the fumigation or disinfection of premises or containers used for storage or transport and where no residues of the biocidal product are expected to remain from such a treatment.

Obligations

The Regulation makes clear that where necessary to protect human health, animal health or the environment, a treated article should always be accompanied with instructions, including precautions. Furthermore, at a consumers request any supplier of a treated article has to provide information about the biocidal treatment of the treated article within 45 days.

Type of treated article There are three types of treated articles:	Active substance (AS) requirements	Labelling requirements
A. Treated article without any claim or reference regarding to biocidal properties (e.g. paint or ink containing in-can preservatives)	AS must be approved or in review program. If not, an application for approval must be submitted before 1 September 2016	No labelling requirements (unless conditions associated with the approval of AS set out specific labelling requirements or other legislation applies)
B. Treated article with claim regarding biocidal properties or claim arising from treatment with a biocidal product. (e.g. tent cloth incorporating an insect repellent)	As above.	Labelling is required as specified in art 58(3) BPR, unless equivalent provisions are required in other EU legislation
C. Treated article with primary biocidal function (e.g. disinfecting detergent)	Article is a biocide and authorization is necessary before making available on the market.	Labelling is required as part of authorization (see also art 22. BPR) (No labelling requirements cording to Art 58(3) BPR)

In case of a treated article without biocidal claim (A) the situation may arise that during the assessment of the active substance it is determined that specific labelling is necessary because of the active substance it was treated with or incorporates. Additional labelling requirements are then required.

In addition, the labelling obligations applicable to a treated article depend on the extent of the biocidal properties of the treated article as claimed on the label or in any promotional material (e.g.

in advertisements or on the Internet). The regulation states that where biocidal properties are claimed information must be given on the label. When the promotion or claim is such that the biocidal function is primary the treated article is considered to be a biocide product (C) and an authorization for the biocidal product must be obtained before it can be placed on the market or used as a biocide.

Labelling requirements

Where a treated article has a biocidal claim or otherwise refers to the biocidal properties of the active substance with which it is treated (B and C), the person placing the product on the market for the first time has to provide certain information on the label of the treated article. The required information is:

◊ A statement that the treated article incorporates biocidal products;
◊ the biocidal property of the treated article;
◊ the name of the active substance(s);
◊ if present, the name of each biocidal (nano-) substance followed by the word 'nano' in brackets;
◊ any relevant instructions for use.

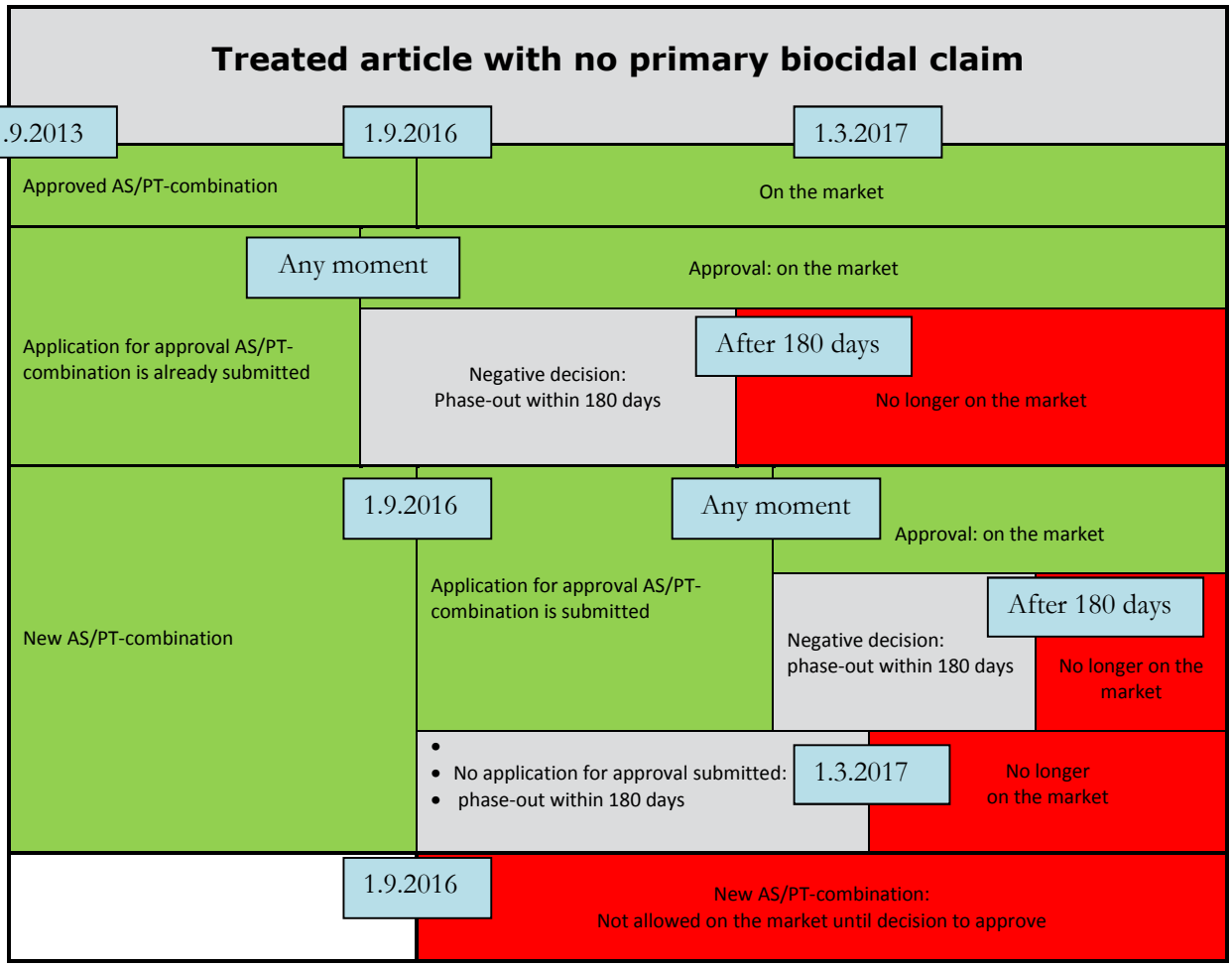
These labelling obligations do not apply where other EU requirements provide equivalent information.

Transitional provisions

The Biocidal Products Regulation came into force on September 1, 2013. For labelling obligations (as described above) no transitional arrangement applies. Treated articles have to comply with the labeling requirements from September 1, 2013. However, there are transitional measures for the active substance(s) in the biocidal products with which the article is treated. Three situations are possible:

1. The active substance(s) has (have) been assessed and approved for use in the product type of the treated article: the treated article can remain on the market (+ labeling requirements, see above)
2. The active substance(s) is (are) in the review program and a dossier(s) has (have) been submitted for approval but has (have) not yet been assessed for this application: the treated article can remain on the market until a decision is published; if the decision is negative: the article has a phase-out period of six months (+ labeling requirements see above).
3. The active substance(s) is (are) not in the review program: the treated article can remain on the market provided a dossier for approval of the active substance is submitted before September 1, 2016. If no dossier is submitted by this date, the treated article must be removed from the market before February 28, 2017. When the assessment leads to a negative decision the treated article also has a phase-out period of 180 days from the date of this decision.

Treated articles can't be placed on the market from March 1, 2017 on if the active substance is not approved for the relevant PT and no dossier has been submitted before this date. This is shown schematically in following figure:



Borderline cases

The BPR requirements concerning the making available on the market of treated articles are new. This fact along with the complexity of the matter causes a lot of borderline cases. The project provides participating MSs with some insight into these borderline cases and gives an opportunity to reach a joint view.

More information:

In the "Note for guidance on treated articles" (web reference), the Commission and EU Member States set out detailed questions and answers on treated articles. This guidance document is available on the website of the European Chemicals Agency (www.echa.eu) together with an increasing amount of information on the requirements in BPR for biocides and treated articles.

More information about treated articles and biocides can also be found on: ….<fill in the website with information about biocides in your country> ……

Annex 2: Questionnaire (online on *Cheminspect*)

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At the start of the project, inspectors will be granted personalized access to the online questionnaire by their national coordinators or focal points. The tool is kindly being hosted by the Federal Office of Public Health FOPH, Switzerland.

Questions with * are mandatory

PART 1: MANAGEMENT AND BASIS INFORMATION (MGI)
[MGI01]: Date of inspection/sampling*:
[MGI02]: Name of the product in native language:
[MGI03]: Where has the product been found [retailer, company, web address ...]? Name or web address: Central address (headquarters) of the economic operator: ZIP code / City:
[MGI04]: Reporting country:* *Rem.: Enter two letters country code: e.g. DE, DK, IE, SE, NL*
[MGI05]: Reporting inspectorate*: *Rem.: Enter reporting inspectorate*
[MGI06]: Responsible inspector: *Rem.: First name, last name*
[MGI07]: Responsible economic operator / company putting the product on the European market: Name of the economic operator (responsible person): Central address (headquarters) of the economic operator: ZIP code / City: *Rem.: If available!*
[MGI08]: Contact person [Economic operator]: Name: eMail address of the contact person / company:

[MGI09]: Name of the product in English:*

Name of the product in English:

Description of the product in English,
if the name doesn't indicate that
(sock, refrigerator, table-cloth, paint...):

Rem.: When "Name of the product" is sufficient type "-" in the field "Description of the product ...".

[MGI10]: Available on the market since:

☐ Before the 1st of September 2013

☐ After the 1st of September 2013

☐ Not known

[MGI11] First made available on the market in which EU-country?

Rem.: Enter full name or two letters country code: e.g. DE, DK, IE, SE, NL

PART 2: QUESTIONS ACCORDING TO ARTICLE 58 BPR (A58)

[A5801] Type of claim [Check the product]?*

☐ A. Treated article without any claim or reference regarding to biocidal properties
(NO labelling requirements according to Art. 58 (3) BPR, only AS/PT-combination relevancy)

☐ B. Treated article with claim regarding to biocidal properties
(labelling requirements according to Art. 58 (3) BPR)

☐ C. Treated article with primary biocidal function
(->Biocide; authorization required, NO labelling requirements according to Art. 58 (3) BPR but normal biocidal labelling required)

Rem.: Aim of the question: define if Art. 58 BPR applies to the article:
Only treated articles with claim regarding to biocidal properties are subjected to labelling requirements according to Art. 58 (3) BPR.

Comment:

[A5801a] Application submitted to which authority?

Name:

Address:

Country:

Rem.: Only answer this question if the following conditions are met:
*Answer was: **C. Treated article with primary biocidal function** (-> Biocide; authorization required, NO labelling requirements according to Art. 58 (3) BPR but normal biocidal labelling required)*

[A5802] Write the claim (translated in English):*

[A5803] Does the product have a label (*Art. 58 (3) BPR*):*

*Please choose **only one** of the following:*

☐ Yes

☐ No

☐ Not known/Unsure or uncertain (If not known, please explain in comment field)

Comments:

[A5804] Does the label indicate that the treated article incorporates biocidal products (*in point a of Art. 58 (3) BPR*)?*

*Please choose **only one** of the following:*

☐ Yes

☐ No

☐ Not known/Unsure or uncertain (If not known, please explain in comment field)

☐ Not relevant

Comments:

[A5805] Where substantiated, does the label indicate the biocidal property attributed to the treated article (*in point b of Art. 58 (3) BPR*)?

*Please choose **only one** of the following:*

☐ Yes

☐ No

☐ Not known/Unsure or uncertain (If not known, please explain in comment field)

☐ Not relevant

Comments:

[A5806] Does the label indicate (all) the active substances contained in the biocidal products (*in point c of Art. 58 (3) BPR)*?

*Please choose **only one** of the following:*

☐ Yes

☐ No

☐ Not known/Unsure or uncertain (If not known, please explain in comment field)

☐ Not relevant

Rem.: Cross comparison with SDS or product information.

Comments:

[A5807] What is/are the name(s) (in English) or CAS/EC-number(s) of the active substance(s) on the label?*

Active substance n°1 on the label: Name and/or CAS/EC n°:

Active substance n°2 on the label: Name and/or CAS/EC n°:

Active substance n°3 on the label: Name and/or CAS/EC n°:

Active substance n°4 on the label: Name and/or CAS/EC n°:

Active substance n°5 on the label: Name and/or CAS/EC n°:

Rem.: Chemical analyses are not necessary (information on label and SDS).

[A5808] Does the label indicate the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets (*in point d of Art. 58 (3) BPR*)?

*Please choose **only one** of the following:*

☐ Yes

☐ No

☐ Not relevant

Comments:

[A5809] Does the label indicate instruction of use, including any precautions to be taken because of the biocidal products with which the treated article was treated or which it incorporates (*in point e of art. 58 (3) BPR)*?*

*Please choose **only one** of the following:*

☐ Yes

☐ No

☐ Not relevant

Comments:

[A5810] Does the label indicate the address of the person responsible for the placing on the market?

*Please choose **only one** of the following:*

☐ Yes (if yes, give the address in the comment field)

☐ No

☐ Not relevant

Comments:

[A5811] Is the labelling clearly visible and easily legible (***Art. 58 (6) BPR)***?*

Please choose only one of the following:

☐ Yes

☐ No

☐ Cannot be evaluated

☐ Not relevant

Comments:

[A5812] Is the labelling (also) in the official language or languages of the Member State (*Art. 58 (6)*)?

*Please choose **only one** of the following:*

☐ Yes

☐ No

☐ Not relevant

Comments:

[A5813] Product-type (defined in annex V of BRP)?*

Enter product-type "1 to 22"]:

Enter product-type "1 to 22"]:

Enter product-type "1 to 22"]:

Rem.: one or more product types possible

http://echa.europa.eu/regulations/biocidal-products-regulation/product-types

PART 3: GENERAL COMMENTS (GCO)
[GCO01] Is the product correctly on the market?* *Please choose **only one** of the following:* ☐ Yes ☐ No -> Yellow card [Reasons in comment field, if not made clear above] ☐ No and removed from the market [Reasons in comment field] ☐ Other action [Describe in comment field] Comments:
[GCO02] General comments:

Separate documents

ANNEX 3: Internet tool CHEMINSPECT documentation for <<Coordinator>>

ANNEX 4: Internet tool CHEMINSPECT documentation for <<Inspector>>