

**FORUM**  
**Substances in Articles**  
**Pilot project report**

**Harmonised Enforcement Project**

Version 1.0

A large, abstract white graphic consisting of several overlapping, curved shapes that resemble stylized petals or segments of a circle, set against a dark blue background.

## Disclaimer

This publication is solely intended for information purposes and does not necessarily represent the official opinion of the European Chemicals Agency. The European Chemicals Agency is not responsible for the use that may be made of the information contained in this document.

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

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## FORUM PILOT PROJECT SUBSTANCES IN ARTICLES PROJECT REPORT

### Harmonised Enforcement Pilot Project on Substances in Articles

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## European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

Visiting address: Annankatu 18, Helsinki, Finland

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## 1. Summary

### 1.1 Content of the project

The Forum carried out a pilot project to control substances of very high concern (SVHCs) on the Candidate List<sup>1</sup> (CL substances) in articles sold on the European market ("Substances in Articles"- called SiA). This enforcement project focused on the notification and communication obligations regarding CL substances in articles under Articles 7(2) and 33 of the REACH Regulation<sup>2</sup>.

The operational phase took place from October 2017 until December 2018. In total, 15 Member States participated and 405 companies were inspected and 682 articles checked. The project targeted consumer articles (i.e. clothing, footwear and home textiles), electronic products, interior articles and plastic and rubber articles.

### 1.2 Legal obligations

The Candidate List (CL) is a list of substances of very high concern which are "candidates" for inclusion in Annex XIV, the authorization list in REACH and may be subject to restrictions. The CL is established by Article 59(1) of REACH Regulation.

According to Article 33, substances which are on the CL are allowed in articles, but companies must inform professional customers about the presence of those substances no later than on the supply of the articles and provide sufficient information to allow the safe use of articles. If a consumer asks, they have to be informed within 45 days, free of charge. Article 7.2 states the circumstances where these substances have to be notified to the European Chemicals Agency (ECHA).

### 1.3 Key findings

From the 682 articles inspected, 84 (12 %) contained CL substances in concentration above 0,1 % w/w. Determining whether the article in question contains a CL substance poses challenges. The project targeted a few CL substances. Phthalates (mostly DEHP) were found the most (in 51 out of 84 articles) followed by SCCP (short chain chlorinated paraffins), ADCA (azodicarbonamide) and lead. Phthalates and SCCP were found in soft plastic materials. ADCA was found in foamed material such as in yoga mats and the softer inside lining of a hockey helmet.

Out of these CL substance-containing articles, the non-compliant articles and the deficiencies in the information flow through the supply chain is described below. Also included in this report are recommendations for different stakeholders – see chapter 3.2 Recommendations.

#### 1.3.1 Article 7(2)

The notification obligation did not apply in most inspected cases, and where it did, the company complied with the obligation. There was no non-compliance found.

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<sup>1</sup> <https://echa.europa.eu/candidate-list-table>

<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

### 1.3.2 Article 33

If an article contains a substance on the CL above a concentration of 0,1 % w/w, the information regarding this substance must be passed on to all company customers. The information must be given to consumers upon request within 45 days, independently of whether the article was purchased or not. 89 % and 56 % of the inspected articles that contained CL substances above 0,1 % w/w, were found non-compliant with the requirements of Article 33(1) and Article 33 (2) respectively. So when CL substances are found in concentrations above 0,1 % w/w, it is also likely that the companies do not fulfil the communication obligations and therefore non-compliance occurs.

For most of the articles where information obligation existed, the project found deficiencies on the information on the presence of the CL substance throughout the supply chain. In 73 % of the cases, the inspected company did not give the information to their customer and in 86 % of the cases the inspected company had not received the information from their supplier of the articles. This shows that there is a big gap in communication throughout the supply chain and many of the suppliers are outside of the EU.

Therefore, the companies that buy the products must actively ask their suppliers for the information on the presence of CL substances, thus ensuring the flow of information in the supply chain.

## 2. Detailed results of the project

### 2.1 General overview

At Forum-22 plenary meeting, the Forum decided to initiate a Forum pilot project on Substances in Articles that would focus on enforcement of Articles 7(2) and 33 of the REACH Regulation. The manual was drafted during 2017 by a dedicated Forum Working Group (WG). Inspections were carried out during 2017 – 2018 and coordinated at national level. Reporting and evaluation of national feedback took place in 2019.

The notification and communication obligations regarding CL substances in articles (SiA) under Articles 7(2) and 33 of REACH have not been widely enforced throughout the EU before this pilot project, despite the suspected high rate of non-compliance with the SiA-related REACH obligations (e.g. results from enforcement activities in some MSs, low number of SiA notifications received by ECHA under Article 7(2), NGO and authorities' reports). This situation could hinder one of the objectives of REACH, namely ensuring safe use of chemicals in produced and imported articles, in particular in articles to be used by consumers. In addition, it also appeared necessary to raise awareness regarding the legal developments on the matter (e.g. Court case C-106/14).

The legal requirements related to the scope of this pilot project were the Articles 7(2) and 33 of the REACH Regulation. The main objective of this project was to check compliance with Articles 7(2) and 33(1) of the REACH Regulation by all types of suppliers of articles (including e-commerce) with a main focus on producers and importers of articles. In this project, the enforcement of obligations to communicate information to consumers (Article 33(2)) was optional. This pilot enforcement project contributes to get a better estimation of the actual level of compliance with these REACH obligations and identify the reasons for non-compliance and possible corrective actions (e.g. support to duty holders). The project should also allow gathering experience and establishing enforcement methods for checking these obligations in a larger scale (e.g. other duty holders and groups of articles), in the future.

Consequently, the main aims of the pilot project were:

- enforcing Articles 7(2), 33(1) and optionally 33(2) of the REACH Regulation by checking compliance of all types of suppliers of articles with their obligations, but focusing more on producers and importers of articles;
- contributing to raise awareness and understanding of the legal obligations and to raise the level of compliance amongst duty holders;
- getting a better picture of the actual level of compliance within suppliers of articles;
- identifying the reasons for non-compliance, in order to prepare possible supporting actions (e.g. support to duty holders) by ECHA, the Commission and Competent Authorities of Member States (MSCAs);
- gathering experience and establishing enforcement methods for checking these obligations on a larger scale in the future.

The basis for inspections was documentation checking with the possibility to complement it with chemical analysis. The details about the target duty holders, groups of articles, and on the CL substances that could be tested by chemical analysis as well as the proposed procedure were included in the manual.

## 2.2 Coordination of the project

The project was prepared by a Working Group (WG) of the Forum steered by the Forum. A national coordinator (NC) was nominated to the project by each participating country. The WG developed the project manual and prepared and delivered the training for NCs. The WG organised a webinar and a WebEx for NCs during the operational phase. NCs organised training for inspectors at national level before the inspections started and reported proceedings of the project before every Forum meeting during the operational phase. NCs reported the results of the inspections to the WG by using the reporting tools prepared for the project by ECHA Secretariat. The WG analysed the reported data, evaluated the results and prepared the project report. The project report has been consulted with the Forum and approved by the Forum.

## 2.3 Participation and number of inspections

15 Member States participated in the operational phase of the pilot project, with a total of 405 companies inspected and 682 articles checked.

Table 1 details the number of companies inspected and the number of articles checked by each participating country.

**Table 1: Participating countries, number of companies inspected and number of articles checked**

Member State	No. of companies	No. of articles	Member State	No. of companies	No. of articles
Austria (AT)	4	11	Italy (IT)	47	57
Belgium (BE)	29	45	Lithuania (LT)	5	5
Czech Republic (CZ)	21	79	Luxembourg (LU)	6	31
Estonia (EE)	12	20	Latvia (LV)	6	6
Finland (FI)	44	45	Norway (NO)	23	20
Germany (DE)	48	64	Sweden (SE)	75	209
Greece (EL)	33	40	Slovenia (SI)	10	10
Hungary (HU)	41	41			
			<b>TOTAL:</b>	<b>405</b>	<b>682</b>

## 2.4 Type of companies inspected, type of articles targeted and procedures in place at company level

### 2.4.1 Types of companies inspected

#### 2.4.1.1 Description of the sample of companies covered by the pilot project

In terms of the NACE classification, the majority of the inspected companies within the scope of the project belonged to two types of business sectors:

- 128 companies (32 % of all companies) fall into the category 'manufacturing' (NACE codes 10.00-33.99):
  - from which companies dedicated to the manufacture of rubber and plastic products, electric and electronic equipment were the most representative (more than 50 % of those belonging to this sector);
- 256 companies (64 % of all companies) of companies inspected fall into the category 'Wholesale and retail trade' (NACE codes 45.00 – 47.99):
  - from which more than 52 % are retailers. Table 2 provides further details on the type of business sector of the inspected companies.

**Table 2 - NACE codes: main business sectors of the companies inspected**

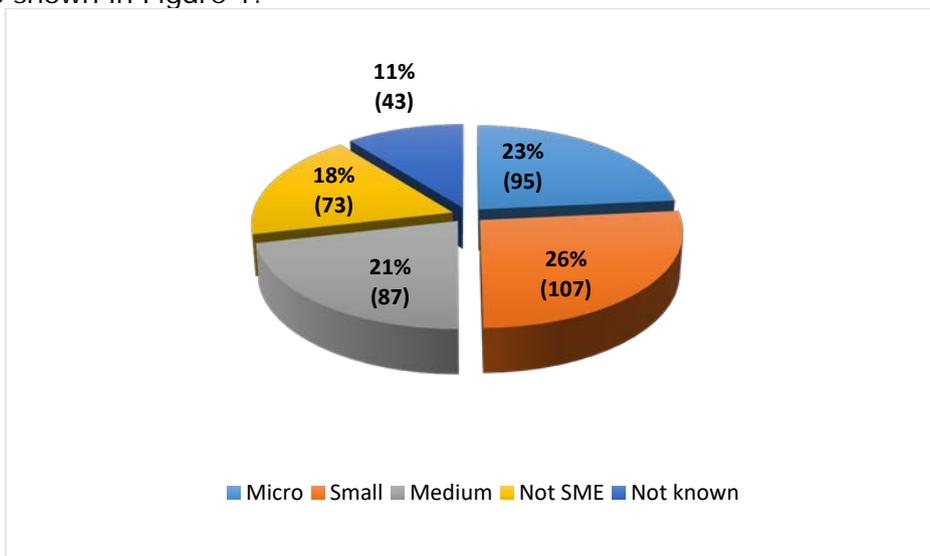
NACE Classification		No. of companies	%
<b>10.00-33.99</b>	<b>MANUFACTURING</b>	130	32
22.00	Manufacture of rubber and plastic products	45	35
26.00	Manufacture of computer, electronic and optical products; Manufacture of electrical equipment	21	16
27.00	Manufacture of machinery and equipment NEC;	14	11
28.00	Manufacture of motor vehicles, trailers and semi-trailers; Manufacture of other transport equipment		
29.00	Manufacture of paper and paper products; Printing and reproduction of recorded media	13	12
30.00	Manufacture of textiles; Manufacture of wearing apparel	10	8
17.00	Manufacture of furniture	4	3
18.00	Manufacture of furniture	4	3
14.00	Manufacture of furniture	4	3
31.00	Manufacture of furniture	4	3
-	Other	21	16
<b>45.00-47.99</b>	<b>WHOLESALE AND RETAIL TRADE; REPAIR OF MOTOR VEHICLES AND MOTORCYCLES</b>	256	63
45.00	Wholesale and retail trade and repair of motor vehicles and motorcycles	9	4
46.00	Wholesale trade, except of motor vehicles and motorcycles <i>(Wholesale of household goods)</i>	113 (61)	44
47.00	Retail trade, except of motor vehicles and motorcycles <i>(Retail sale of information and communication equipment, other household equipment (incl. textiles, carpets and floor coverings, and furniture), and cultural and recreation goods (incl. sporting equipment and games and toys)</i>	134 (68)	52
-	OTHER	19	5
<b>TOTAL:</b>		<b>405</b>	<b>100</b>

Many companies inspected have several roles under REACH (suppliers of articles, producers of articles (including assemblers) and importers of articles). Table 3 shows the number of the REACH roles for the 405 companies inspected.

**Table 3 – REACH roles of the companies inspected**

Role	No. of companies
<b>Supplier of articles</b>	320
• Supplier in the supply chain (B-to-B)	189
• Supplier to the consumer (B-to-C)	203
<b>Article producer (including assemblers)</b>	131
<b>Article importer</b>	161
<b>Only Representative (appointed by non EU producer of an article)</b>	0

Although companies of all category sizes according to the EU<sup>3</sup> standard scale were included in the inspections (N=405), at least 70 % are micro, small and medium-sized companies (SMEs) as shown in Figure 1.



**Figure 1 – Rates of inspected company sizes determined according to Commission Recommendation 2003/361/EC**

#### 2.4.1.2 Analysis of the voluntary audits undertaken in the companies to give an overview of the implemented management structures to fulfil the relevant legal duties

The management systems in companies have also been assessed as a voluntary audit was a part of the inspection according to the project methodology. The management system is not a requirement under REACH. However, since there was the possibility to conduct voluntary audits of the inspected companies, it was helpful to have an overview of the management structures that companies have chosen to implement to fulfil the relevant SiA duties.

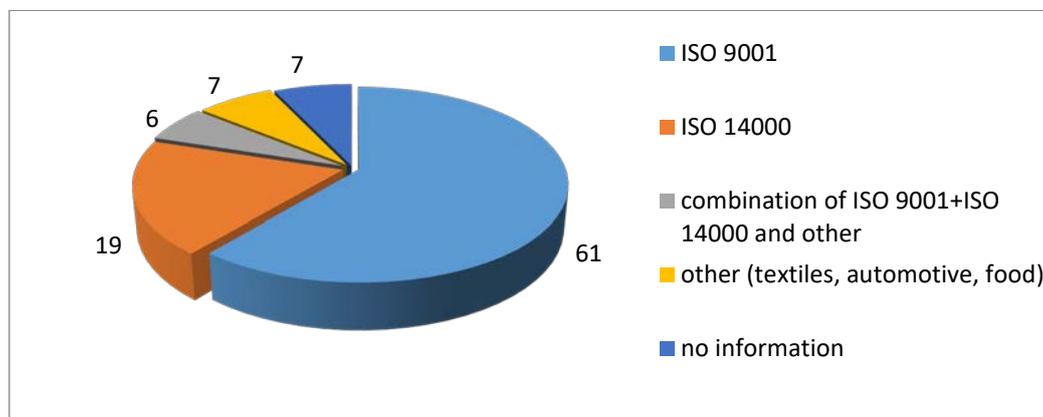
##### 2.4.1.2.1 Analysis of general approach of Companies to comply with chemical legislations

Out of the 405 inspected companies, for 202 companies (about 50 %) an audit of National Enforcement Authorities (NEA) was undertaken and in 100 cases management systems were implemented.

Out of the 202 audited companies, only 50 % have a management system. Significantly more than half of these enterprises with management systems (61 %) use ISO 9000, a widely spread quality management system. ISO 14000, an environmental management system, is used by 19 % of these companies. The others are using various individual systems.

<sup>3</sup> Commission Recommendation 2003/361/EC

Figure 2 shows in detail the kind of management systems implemented by the cited 100 companies.

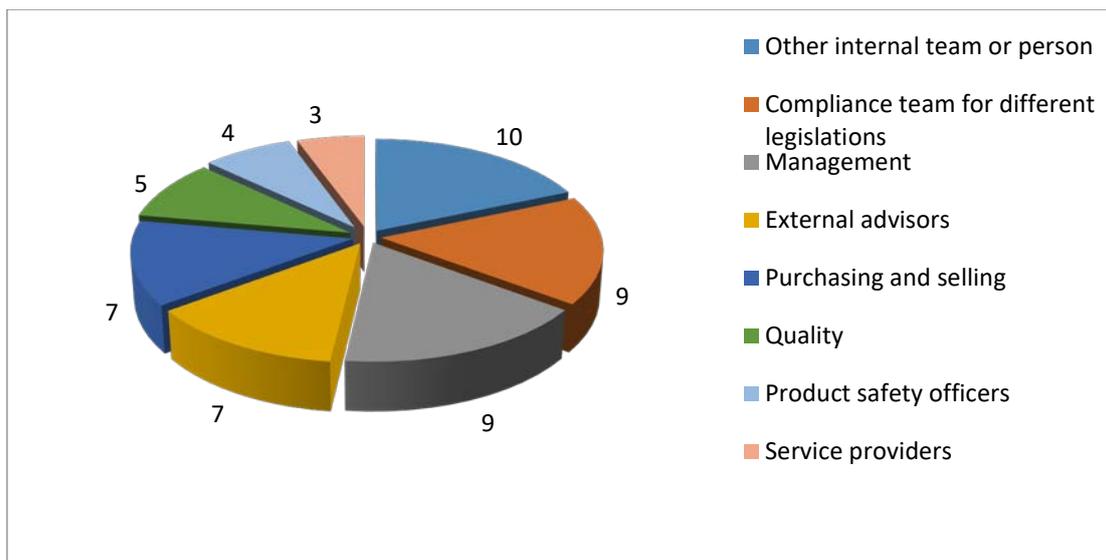


**Figure 2 – Management systems implemented in a sample of 100 audited companies**

73 % of the total number of audited companies have a team or a responsible person in charge of the compliance with chemical legislation. This applies in total to 146 companies. Table 4 shows the distribution of responsibility roles on different figures either internally in the company or by external consultants. EHS Officers, REACH/CLP officers and *ad hoc* teams appeared to be the most common figures. A detailed view of the other roles is provided in Figure 3 which explores the role “others” listed in Table 4.

**Table 4 – Responsibility roles for the compliance with chemical legislation**

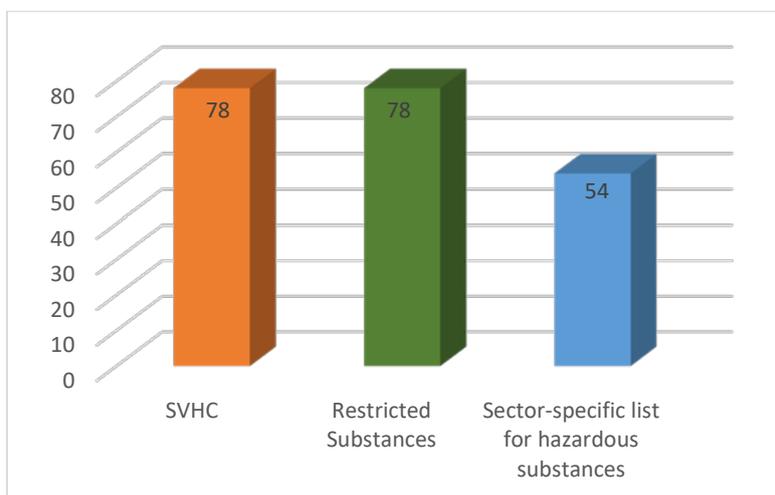
Role	No.
EHS Officer	65
REACH/CLP officer	32
Ad hoc teams	27
Others	55



**Figure 3 – Distribution of other roles of persons/teams in charge of chemical legislation**

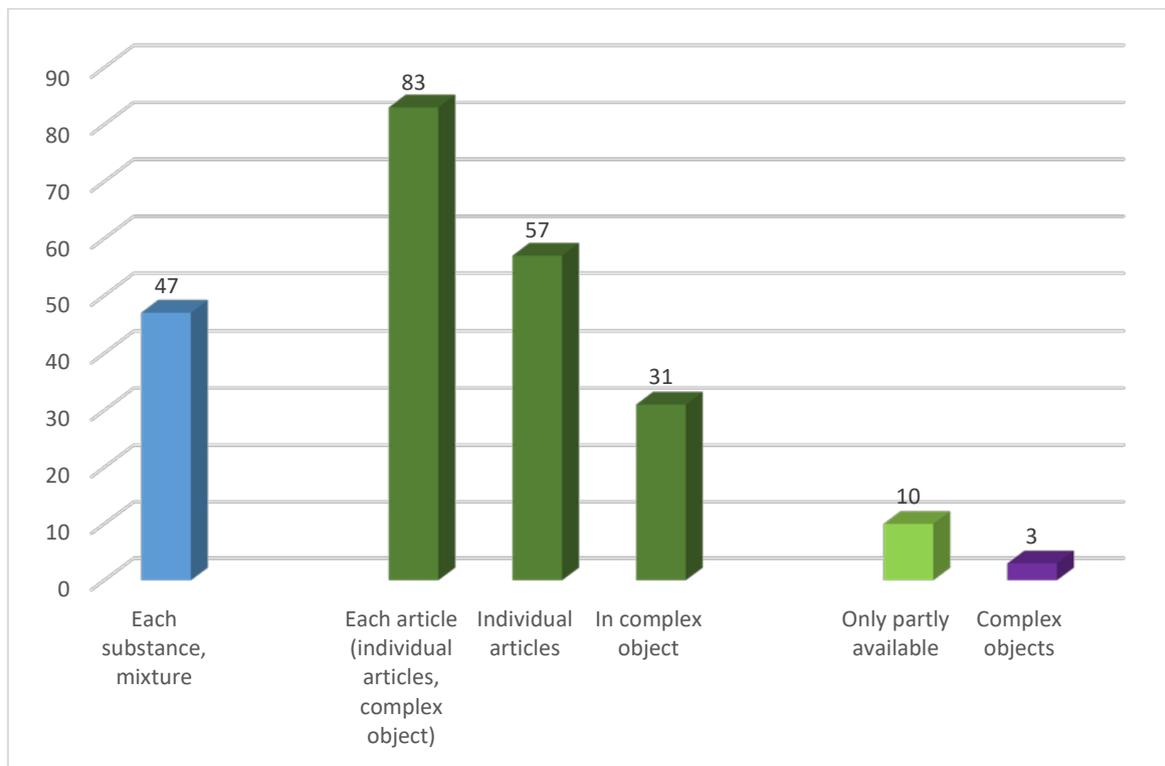
60 % of the total number of audited companies have information on hazardous substances as such, in mixtures and articles handled in the company. This applies in total to 120 companies.

The details on the scope of such information are reported in Figure 4. The focus is broadly comparable to both regulated substances and specific lists of hazardous or undesirable substances. These specific lists are developed by the companies themselves or are part of the delivery terms of the customers.



**Figure 4 – Scope of information on hazardous substances available at company level**

The level of information available in the analysed sample of 120 companies is reported in Figure 5. This figure shows that about 2/3 of the companies have the necessary information on each article (individual and complex articles).



**Figure 5 – Level of information on hazardous substances available at company level**

In case of “only partial information available”, the companies have reported different explanations (e.g. difficulty in obtaining data from the supplier, focus only on specific substances, focus on risk assessment of materials).

Out of the 202 audited companies, 21 companies have other type of information source (e.g. manufacturer / supplier, other company sites, test reports are available / requested, SDS).

#### **2.4.1.2.2 Analysis of the knowledge and procedures, etc. in connection to SiA obligations**

Overall, the proportion of audited companies having knowledge of the actual list of CL substances was 72 %, corresponding to 144 companies. The number of companies with information available on CL substances in their articles was 171 (85 %).

In Figure 6, the details of information source in such cases are reported. Most companies rely on the information provided by the supplier. However, many companies also actively ask their suppliers for additional information and another smaller part of the companies carries out its own chemical analysis.

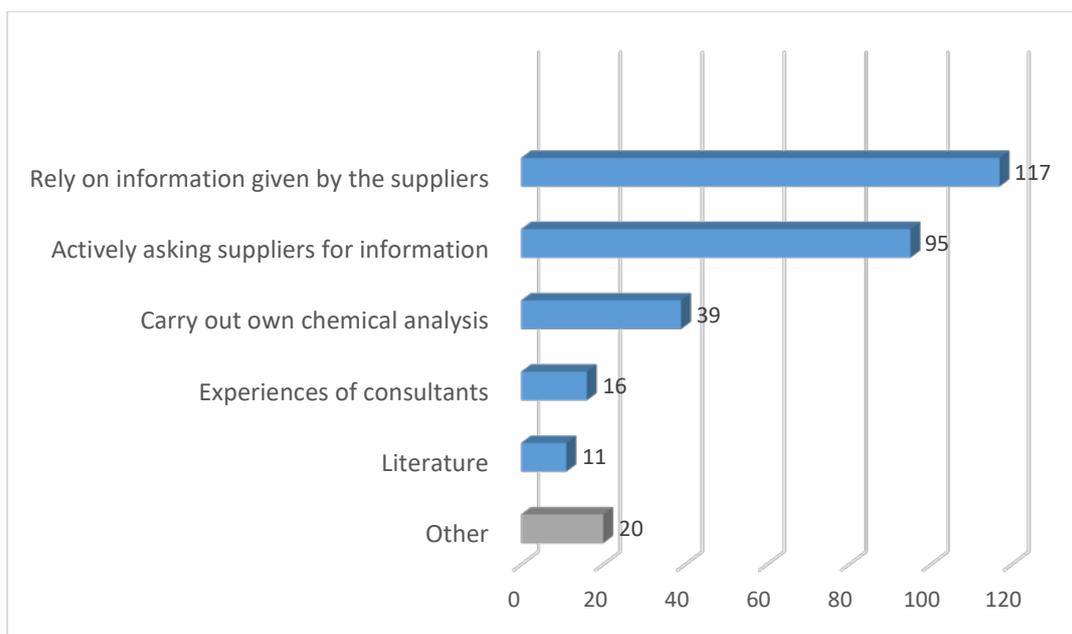


Figure 6 – Source of information on CL substances in articles

#### 2.4.1.2.3 Analysis of the cooperation and experience with suppliers

57 % of the audited companies reported to have an assessment scheme for suppliers. This applies in total to 117 companies. Figure 7 shows the resulting main assessment schemes for suppliers available in those companies.

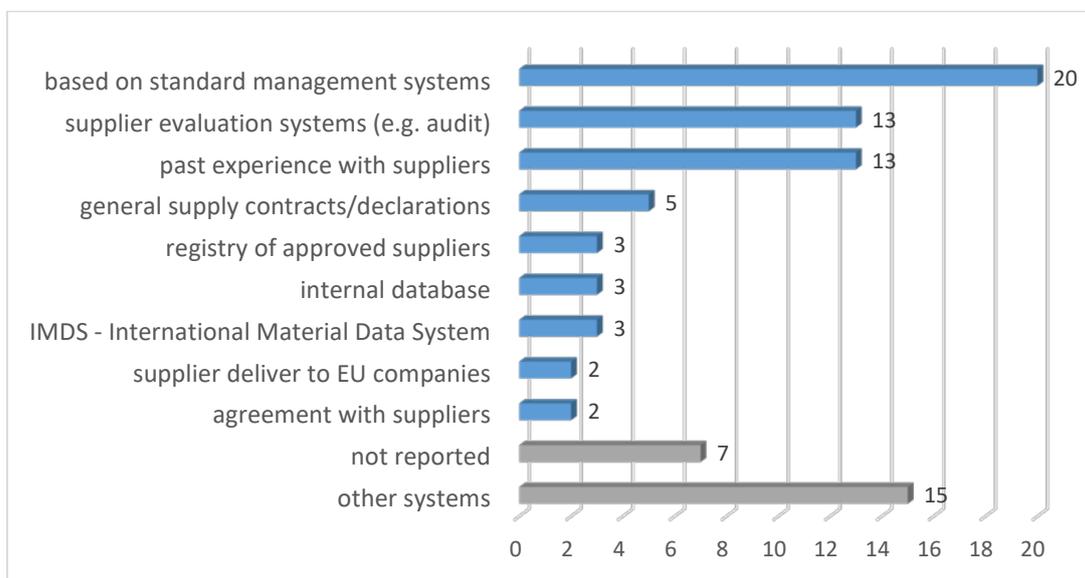


Figure 7 – Main assessment schemes for suppliers

It has to be noted that out of the 117 companies having an assessment scheme for suppliers, only 56 companies reported that relevant information on CL substances is included in such scheme. In total only 31 companies have downgraded or rejected a supplier because of weak information on CL substances.

In terms of cooperation and experience with suppliers, the proportion of audited companies having ever received information from suppliers about the presence in the articles of CL substances in concentrations above 0.1 % w/w and/or information on the related safe use was 18 %, corresponding to 36 companies.

## 2.4.2 Types of articles inspected

### 2.4.2.1 Analysis of the specific articles and their most relevant CL substance

The 682 articles inspected in this project belonged to four main groups as summarised in Table 5 below, 40 % of them being components of complex objects<sup>4</sup>. The Table also shows the number of articles in each group which contain CL substances in a concentration above 0,1 % w/w.

**Table 5 – Types and figures for inspected articles**

	No. of checked articles (%)	No. of articles with CL substance(s) above 0.1 % w/w (%)
<b>1. Consumer articles: consumer clothing and footwear, and home textiles</b>	133 (20)	17 (13)
<b>2. Electric/electronic products: wires and cables and electric/electronic accessories</b>	72 (11)	17 (24)
<b>3. Building, interior articles: plastic or textile floorings, wall coverings and plastic furniture</b>	71 (10)	2 (3)
<b>4. Other: other plastic and rubber articles.</b>	406 (60)	48 (12)
<b>TOTAL:</b>	<b>682 (100)</b>	<b>84 (12)</b>

From the 682 articles inspected, 84 contained CL substances in a concentration above 0.1 % w/w. The distribution of the CL substances present in these 84 articles is given in Table 6. In the sample of articles inspected, only the CL substances checked are reported in Table 6. Some articles contained more than one CL substance. Not all of the CL Substances considered in the project were found in the sample of articles inspected.

<sup>4</sup> See definition in subchapter 2.4 of the *Guidance on requirements for substances in articles*

**Table 6 – Distribution of CL substances present in the inspected articles**

CL substances	No. of articles	Notes
<b>Phthalates</b>	51	- Bis(2-ethylhexyl) phthalate (DEHP) is the most representative (present in 36)
<b>Short-chain chloroparaffins (SCCP)</b>	12	
<b>Diazeno-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)</b>	12	
<b>Lead</b>	11	
<b>Cadmium</b>	1	
<b>Bisphenol A</b>	1	
<b>Brominated flame retardants (DecaBDE, HBCDD)</b>	1	
<b>Aprotic polar solvents (DMF/DMAC)</b>	0	
<b>Perfluorinated substances</b>	0	
<b>Phenolic benzotriazoles</b>	0	
<b>Phosphorous flame retardants (TCEP, TXP)</b>	0	

#### 2.4.2.2 Analysis of the methodology for getting the information on the concentration of CL substance

The 682 articles inspected in this project were checked for the content of CL substances. In Table 7, the different sources for obtaining the content of CL substances are listed. In 78 % of the cases the information came from chemical analysis. Most of the chemical analysis was done by the inspecting authority (69 %). In five cases, the chemical analysis was done both by the supplier of the inspected company as well as the inspecting authority.

In five other cases, the chemical analysis was done by the inspected company as well by the supplier of the inspected company. In 24 cases, the entity responsible for the chemical analysis was not specified. Out of the 84 articles which contained CL substances in a concentration above 0,1 % w/w, 81 of them were checked by chemical analysis. 78 out of the 81 articles were checked by the inspecting authority. For 42 articles out of the 84 articles that contained CL substances, the results of the chemical analyses where not in line with the information given by the company. In 9 % of the cases the information was given by the inspected company or by its supplier (12 %). In eight cases the information was provided by other sources.

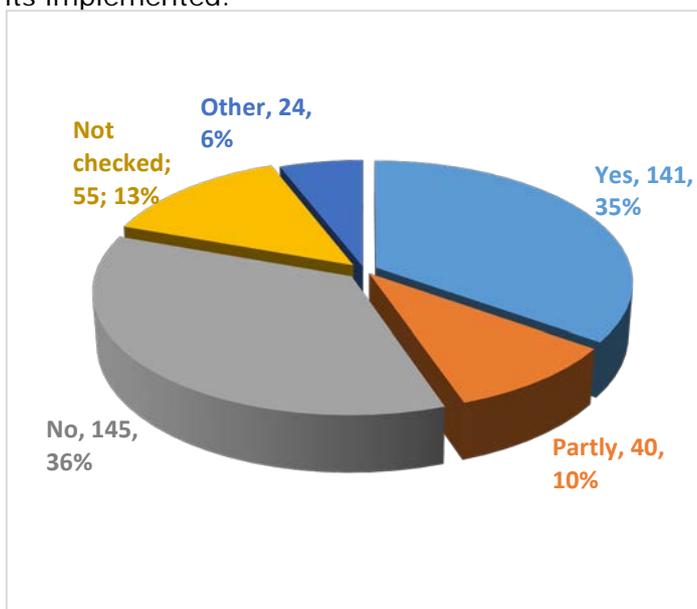
**Table 7 – Sources of information to obtain the content of CL-substances**

Source of information	No. of articles (%)	Notes
<b>Chemical analysis</b>	529 (78)	mostly by the inspecting authority
- <b>By the inspected company</b>	19 (3)	
- <b>By a supplier of the inspected company</b>	23 (3)	
- <b>By the inspecting authority</b>	473 (69)	
<b>Information given by the inspected company</b>	63 (9)	
<b>Information given by the supplier of the inspected company</b>	82 (12)	
<b>Other sources</b>	8 (1)	

### 2.4.3 Procedures in place at company level

The project collected information on procedures and management tools used to fulfil the information requirements according to Article 33 and Article 7(2). As already described in chapter 2.4.1.2.1, only about 50 % of the investigated companies have a general management system.

Figure 8 shows the number and percentage of companies with procedures to meet the requirements of Articles 33 and 7 (2). 35 % of companies have such a specific management system; 36 % have no system implemented. 10 % of the companies have systems only partly in place; 13 % were not checked and 6 % of the companies have other measurements implemented.



**Figure 8 – Procedures implemented to fulfil the information requirements of Article 33 and/or Article 7(2) (Number; %)**

Companies with the option "other" usually stated that this question was not relevant for

them or that their products do not contain CL substances or that there is no need for specific procedures.

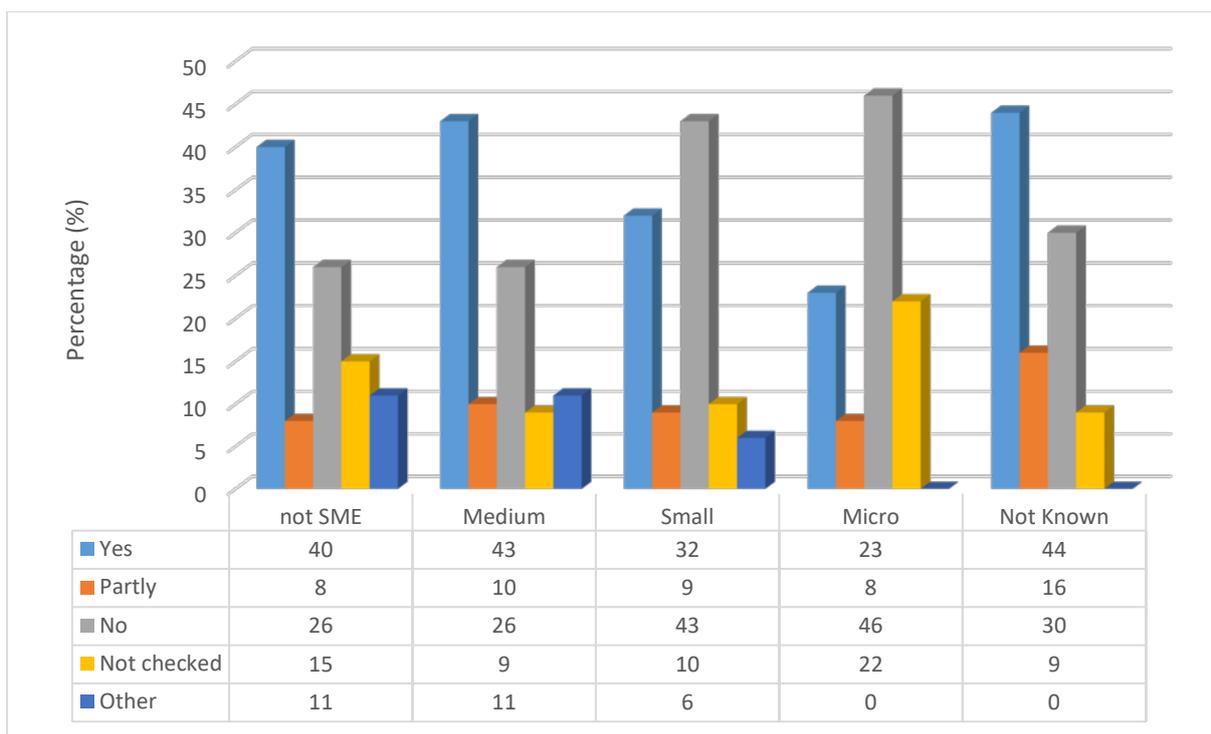
The most commonly used systems for monitoring and complying with legal requirements are declarations of conformity and product declarations. This is information provided by the supplier. Also very common are specifications for substance restrictions by the company. These include lists of restricted substances as well as the complete ban of CL substances in articles. Details are shown in Table 8.

**Table 8: Specification of General Procedures used to fulfil the requirements**  
(Absolute numbers)

Procedures	Counts
Declarations of compliance with Art 33 / Art 7(2)	61
A praxis not to sell articles that contain CL substances	58
Third party certification	41
Other	41
Restricted substances list (with CL substance)	38
Bill of materials/articles specifying CL substances	33
Product declarations related to Art 33 / Art 7(2)	33
IT platform/database	12

Only a few companies claim to carry out their own laboratory analyses. Some companies also use the information from the SDS to comply with the legal requirements.

When taking the size of the company into consideration, this reveals a quite clear connection between the size of the company and the implementation of procedures. Around 50 % of medium and non-SME companies have at least partially implemented such procedures, while only 30-40 % of small and micro companies have such tools in place. Detail are shown in Table 9.



**Table 9: Percentage of Procedures to fulfil information requirements vs. company size**

When selling products containing more than 0.1 % w/w CL substances, the company is required to provide the necessary information for safe handling to customers. In each case the substance name must be stated.

Subsequently, the companies were asked if additional procedures or information on the CL substances were provided to customers. More than half (54 %) of all surveyed companies did not provide any further information or procedures. Only 16 % of the companies have additional voluntary general procedures implemented.

**Table 10: Number of companies with additional voluntary general procedure implemented**

Add. Procedures	Count	Percentage
Yes	66	16 %
No	219	54 %
Not checked	120	29 %
<b>Grand Total</b>	<b>405</b>	

Most of these companies provide additional information via the labels, pictograms or user manuals. Some companies use their website to communicate information in both directions, towards the consumer and the supplier. Overall, nine companies give additional information for safe handling. One company provides a mobile app with additional information.

**Table 11: Additional Procedures to inform about CL Substances**

Additional Procedures in Place	Count
Information on labels	26
Other	24
Information in accompanying documentation (e.g. in instruction for product use)	17
Labelling pictograms	11
Providing information to (databases of) Article 33(2) Phone Apps	1
In instructions for safe use	9

The last question of this section asked about the implementation of the European Court of Justice's (the Court) decision on the definition of products. According to that decision, in the case of complex objects the reference value for calculating the concentration of a CL substance is the individual product. Only around 50 % of the companies surveyed stated that they had implemented the decision. The other companies have not yet integrated this decision into their process. This does not necessarily mean that these companies do not act in accordance with the law. The Court decision only has a direct impact on information and notification obligations if the products are complex and CL substances are present in small components.

**Table 12: Implementation of the new interpretation of an article**

Implementation of Court decision	Count
Yes	69
No	63
Not checked	273
<b>Grand Total</b>	<b>405</b>

## 2.5 Infringements

The following results of the enforcement project are related to the inspected articles and companies.

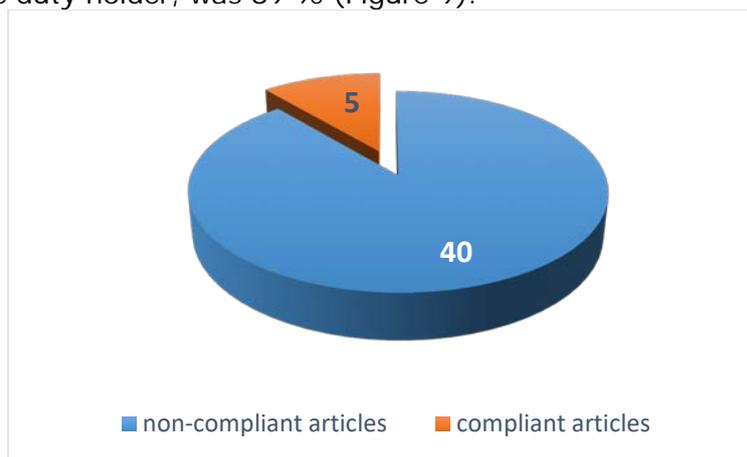
### 2.5.1 Article 33(1)

#### Summarised observations on non-compliance

From the total amount of 682 inspected articles, fulfilling the two following conditions:

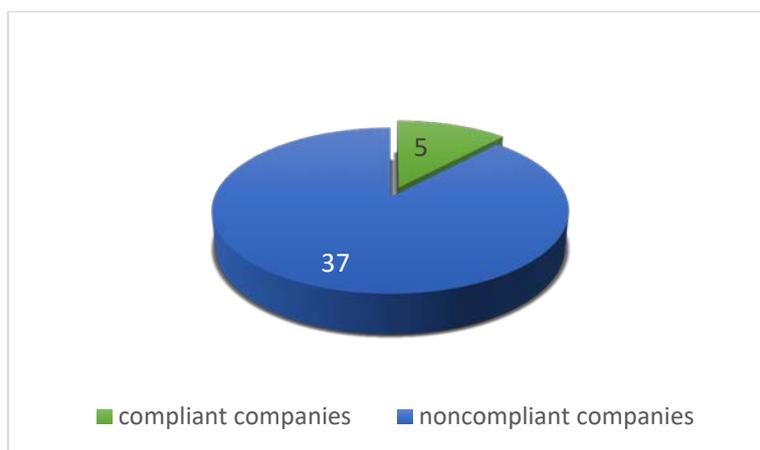
- the concentration of CL substances is above 0.1 % w/w;
- the inspected company has the role of a B-to-B supplier (business to business supplier);

the obligation, according to Article 33(1) of REACH, exists for only 45 articles. From these 45 articles the information obligation was fulfilled in five cases and was not fulfilled in 40 cases. Therefore, the non-compliance rate concerning the articles with information obligation for the duty holder, was 89 % (Figure 9).



**Figure 9 – Compliant and non-compliant articles related to Article 33(1) of REACH**

From the total amount of 405 inspected companies the obligation according to Article 33(1) of REACH was considered to exist in only 42 cases. From these 42 companies the information obligation was fulfilled in five cases and was not fulfilled in 37 cases. Therefore, the non-compliance rate concerning the companies with information obligation for the duty holder, was 88 % (Figure 10).



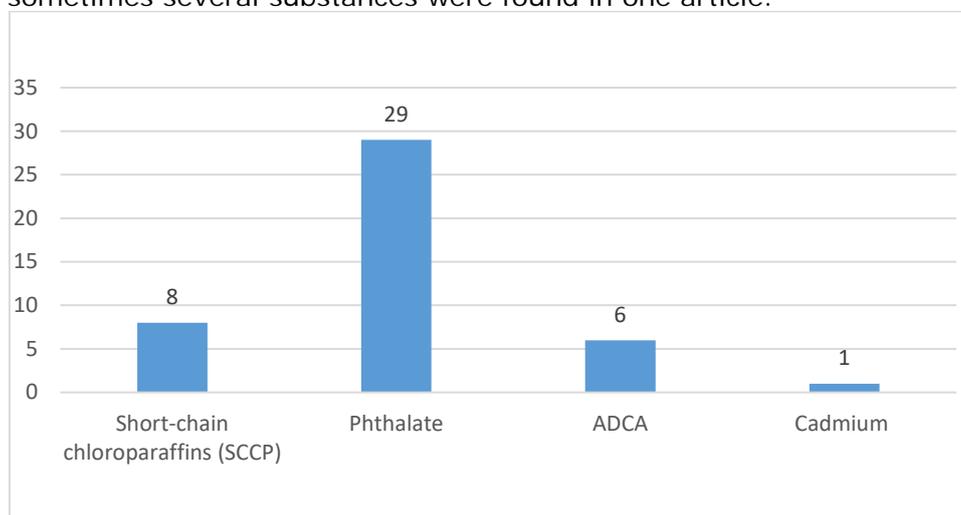
**Figure 10 – Compliant and non-compliant companies related to the information obligations according to Article 33(1) of REACH**

CL-substances in non-compliant articles

The following CL substances were identified in concentrations above 0,1 % w/w in the 40 articles for which the communication duty under Article 33(1) of REACH was not fulfilled (Figure 11):

- different phthalates in 29 cases;
- SCCP in eight cases;
- ADCA in six cases;
- cadmium in one case.

To note: sometimes several substances were found in one article.



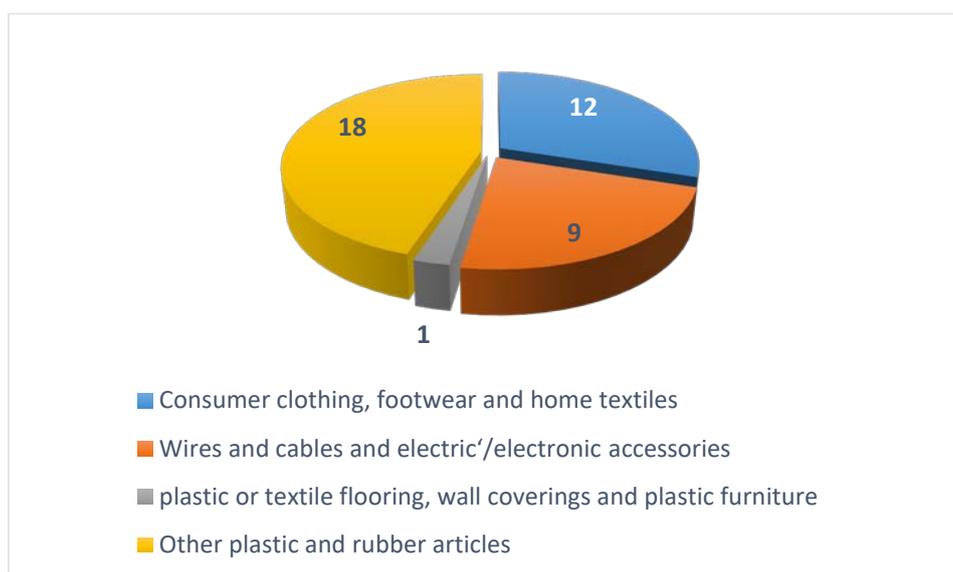
**Figure 11 –Number of non-compliant articles according to Article 33(1) of REACH and relevant substances identified**

## Data source and non-compliance

In all cases of non-compliance according to Article 33(1) of REACH, the non-compliance is identified from data obtained by chemical analysis. 95 % of these analysis were performed by the Authority.

### Sector and non-compliances

Within the non-compliant articles, the sector where the most non-compliance was found was in the group of “other plastic and rubber articles”, with 18 cases of non-compliance. These were followed by 12 cases in the group of consumer clothing, footwear and home textiles, nine cases in the group of wires and cables and electric / electronic accessories and one article in the group of plastic or textile flooring, wall coverings and plastic furniture (Figure 12).



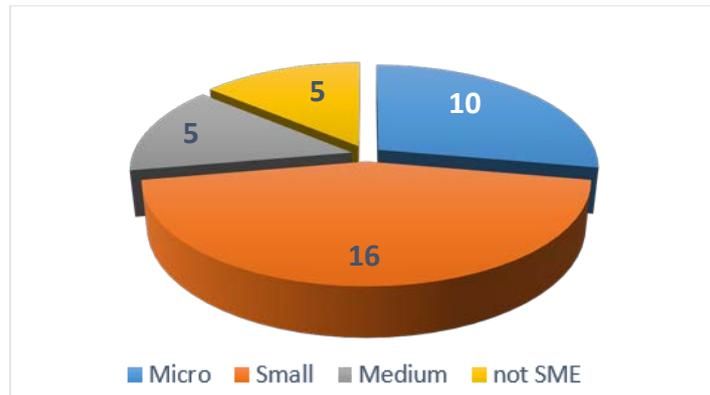
**Figure 12 – Types of non-compliant articles related to Article 33(1) of REACH**

### Non-compliance and Complex object

The non-compliance according to Article 33(1) was found mostly in components of a complex object, specifically in 25 articles. The other 15 cases of non-compliance were found in single or “stand alone” articles, i.e. the article is not a component in a complex object.

### Non-compliance and company size or role of the company

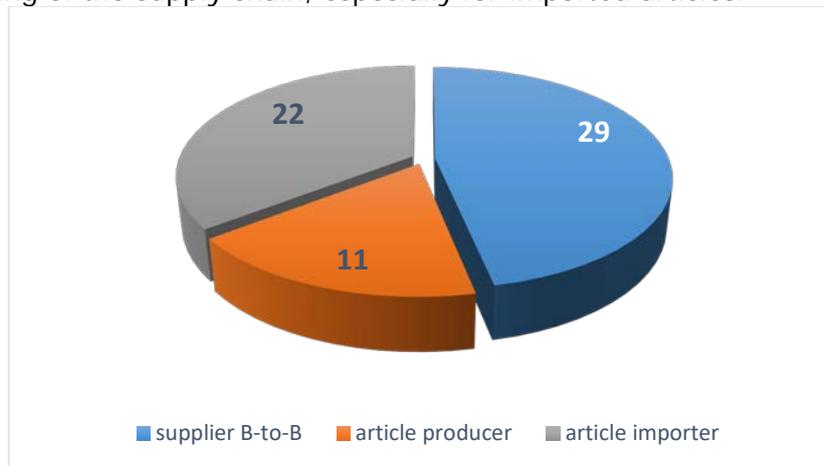
Regarding the size of the non-compliant companies, the conclusion was that five were not SME companies, implying that 86 % non-compliant companies are SME companies (Figure 13).



**Figure 13 – Company size and non-compliant companies related to the information obligation according to Article 33(1) of REACH**

A company can have multiple roles in the supply chain (i.e. an article producer can be an article importer and a supplier B-to-B). The companies with the role of a B-to-B supplier (i.e. the company is a supplier in the supply chain and the recipient is also a company) were most often non-compliant (Figure 14).

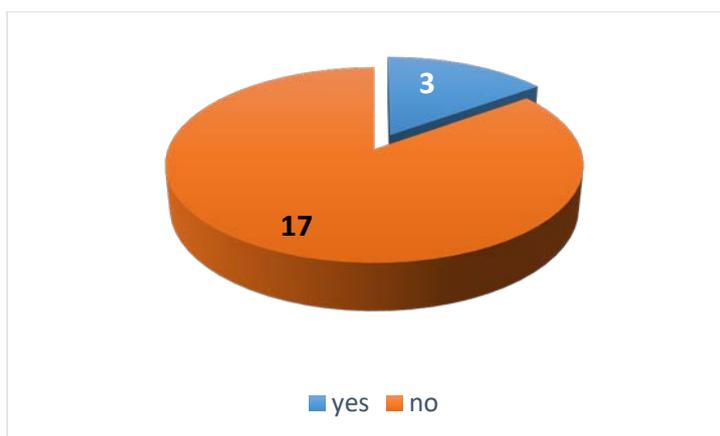
Importers were also more often non-compliant compared to article producer (Figure 14). The results show that the lack of information and the non-compliances could already start at the beginning of the supply chain, especially for imported articles.



**Figure 14 – Role of non-compliant companies related to the information obligations according to Article 33(1) of REACH**

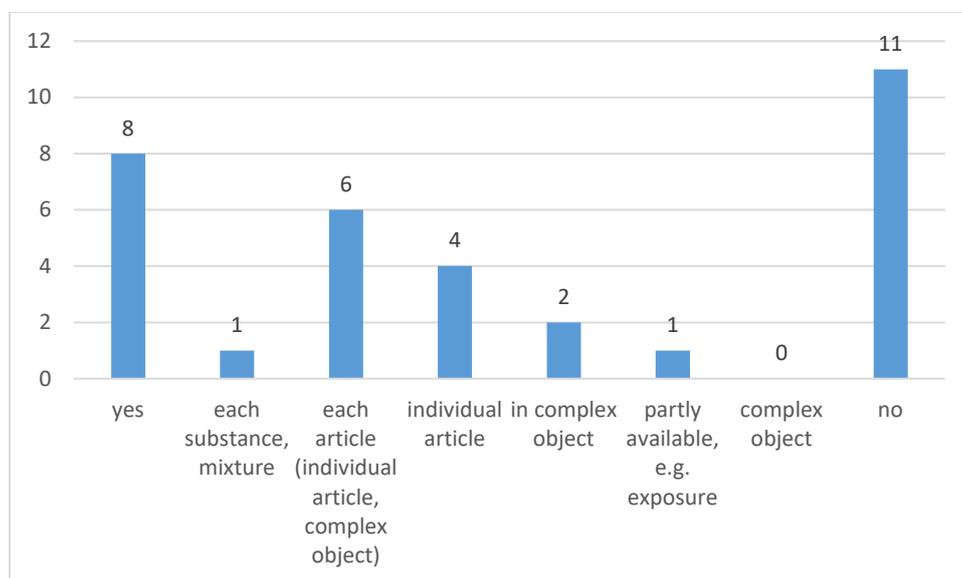
#### Non-compliance and management system

Management systems help the companies to fulfil their legal duties. Most of the non-compliant companies had no management system implemented (85 %) whereas only three of the non-compliant companies had management system implemented (Figure 15). An overview of the management systems of all companies can be found in chapter 2.4.1.2.1 Figure 2.



**Figure 15 – Relationship between the implementation of a management system and the non-compliance in relation to the information obligations according to Article 33(1) of REACH**

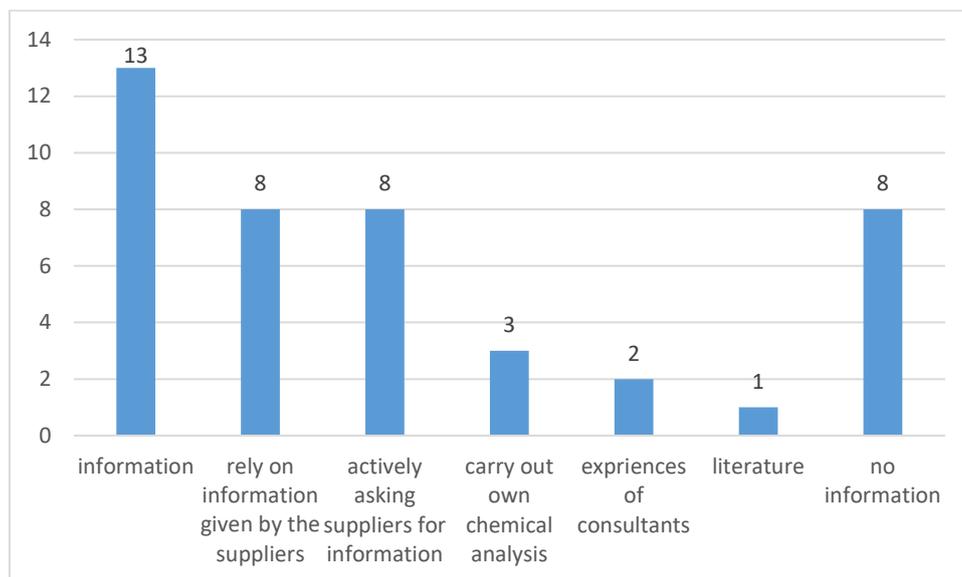
The availability of information on hazardous substances as such, in a mixture or in an article handled in the company is one important aspect of a management system. The inspections revealed that in eight non-compliant companies, this information was available on different levels (for each substance or mixture, each article as an individual article or articles within complex objects) (Figure 16). However, in 11 non-compliant companies no information on hazardous substances was available (Figure 16). An overview of the level of information in all companies can be found in chapter 2.4.1.2.2 Figure 5.



**Figure 16 – Relationship between the availability of information on hazardous substances in the company and the levels of the availability of the information in companies not complying with the information obligations according to Article 33(1) of REACH**

Within the non-compliant companies, the source of information revealing the presence of CL substances in concentrations above 0,1 % w/w in their articles varied. Eight companies did not have information and 13 companies had information. Companies with information mostly relied on information given by their suppliers, some asking suppliers actively for

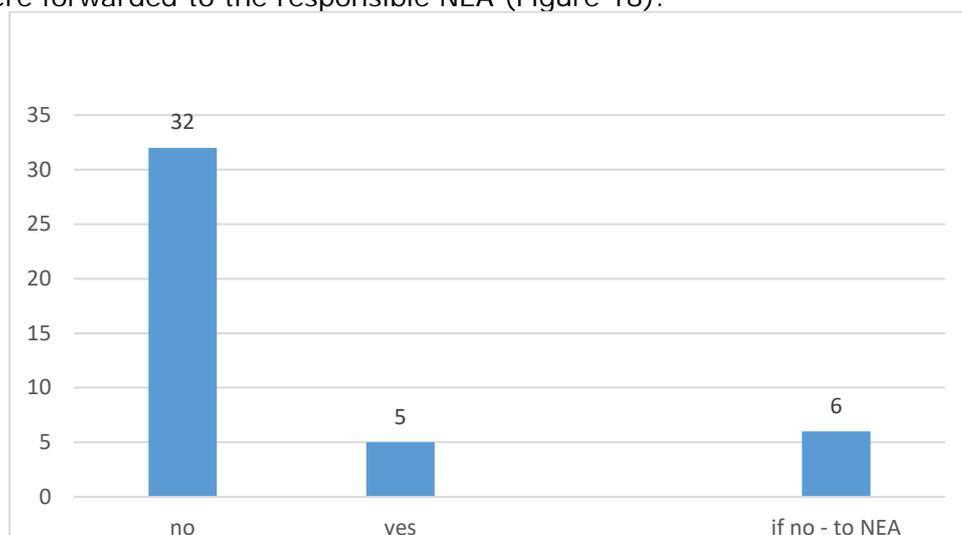
information, some used the experiences of consultants and some obtained the information from literature sources. Only a few carried out their own chemical analysis (Figure 17). An overview of the source of information of all companies can be found in chapter 2.4.1.2.2 Figure 6.



**Figure 17 – Relationship between the availability of information and the source of information on CL substances in companies not complying with the information obligations according to Article 33(1) of REACH**

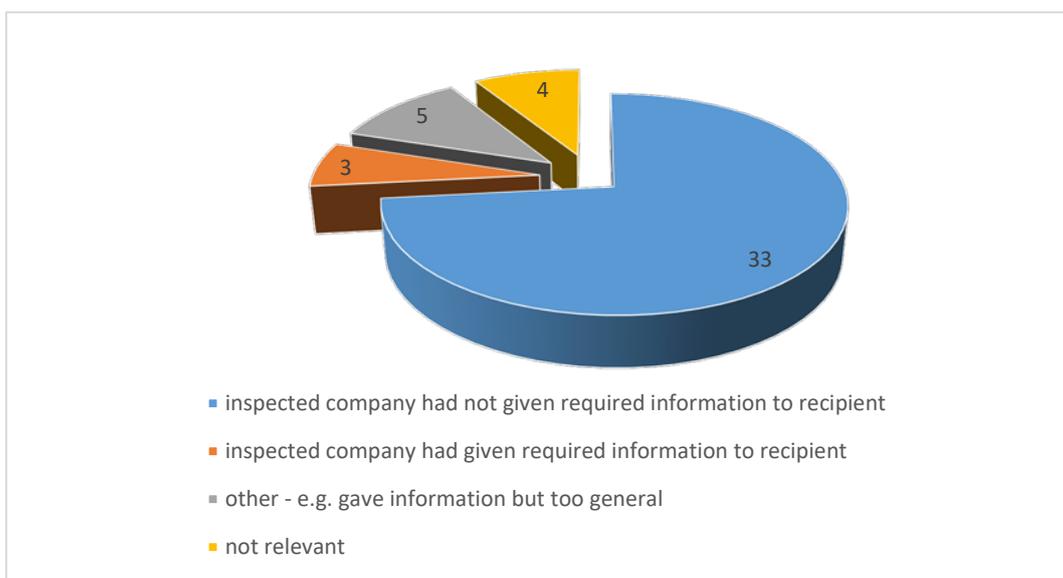
Information in the supply chain and non-compliance

According to Article 33(1) the recipient of an article must be informed by its supplier with the required information. The inspections found 32 articles for which the obligation existed but the inspected company had not received the relevant information from their supplier. Therefore, the supplier of the inspected company was non-compliant. Only six of these cases were forwarded to the responsible NEA (Figure 18).



**Figure 18 – Occurrence of articles with information duties according to Article 33(1) of REACH for which the inspected company was/was not informed by its supplier with relevant information and cases sent to NEAs**

The information obligation according to Article 33(1) was related to 45 non-compliant articles. In 33 cases the inspected companies did not inform the recipient of the CL substances included in the articles they supplied. This means that in 73 % of the inspected non-compliant articles, the recipient did not receive the relevant information from the inspected supplier. The inspected supplier informed the recipient according to Article 33(1) for only three articles (Figure 19). The information obligation according to Article 33(1) was related to 45 non-compliant articles. In 33 cases of them the inspected companies did not inform the recipient of the CL substances included in the articles their supplied. This means that in 73 % of the inspected non-compliant articles the recipient did not receive the relevant information from the inspected supplier. The inspected supplier informed the recipient according to Article 33(1) only for 3 articles (Figure 19).



**Figure 19 – Required information given/not given according to Article 33(1) of REACH for the inspected articles from the inspected suppliers to the recipient**

### **Summary: Article 33(1)**

The results show a high non-compliance rate of 89 % for the articles with information obligations according to Article 33(1) and also a high non-compliance rate of 88 % for the duty holder with this information obligation according to Article 33(1). One very relevant reason for this high non-compliance rate is that the information flow in the supply chain is not working. This is clear from the high non-compliance rate related to the information duties within the supply chain, i.e. in 86 % of the cases with information obligations, the inspected company was the party which had not received the relevant information from its supplier; and in 73 % of the articles with information duties, the inspected company did not inform the recipient of the article.

### **2.5.2 Article 33(2)**

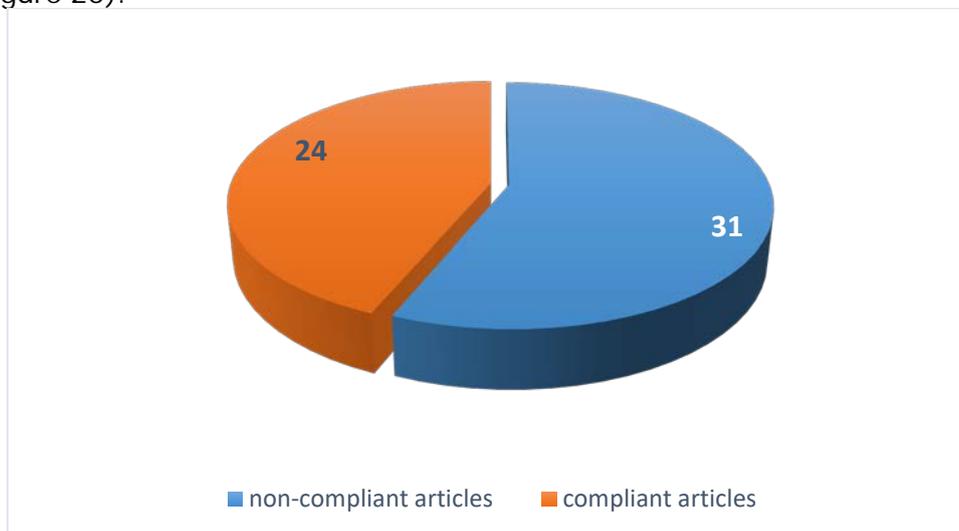
#### Summary of the non-compliance observations

From the total amount of 682 inspected articles and considering the two following conditions:

- the concentration of the CL substances is above 0,1 % w/w;

- and the articles were supplied to a consumer by the inspected supplier;

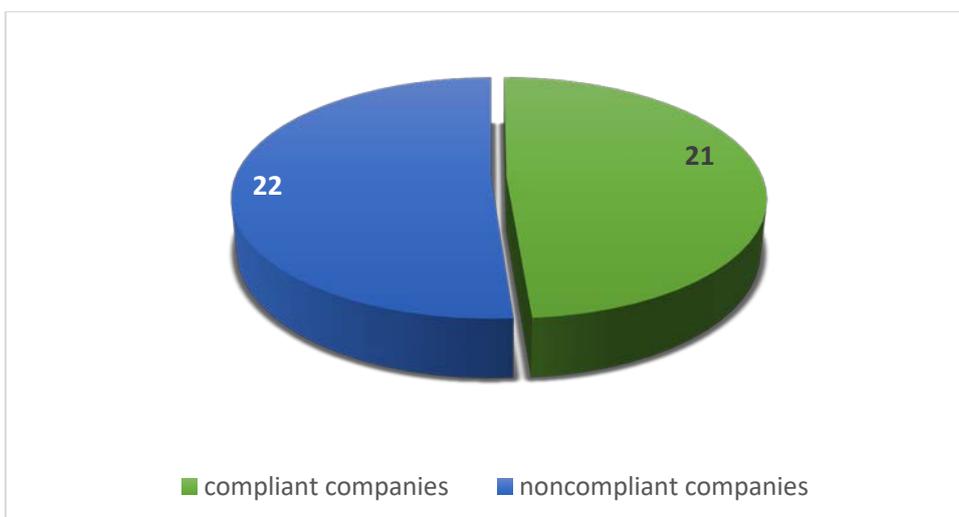
the obligation, according to Article 33(2) of REACH, exists for only 55 articles. From these 55 articles the information obligation was fulfilled in 24 cases and was not fulfilled in 31 cases (Figure 20).



**Figure 20 –Compliant and non-compliant articles according to Article 33(2) of REACH**

The results show a non-compliance rate of 56 % for the articles with information obligations for the consumer according to Article 33(2). In case of an information obligation according to Article 33(2), the relevant information was not available in 83 % of the cases.

From the total amount of 405 inspected companies, results show that in 43 companies, information obligations according to Article 33(2) REACH exist, as the concentration of CL substances is above 0.1 % w/w and the articles were supplied to a consumer. 21 companies fulfilled the information obligation and 22 companies had not fulfilled the information obligations according to Article 33(2) (Figure 21). The non-compliant rate with information obligations for the duty holder was 51 %.

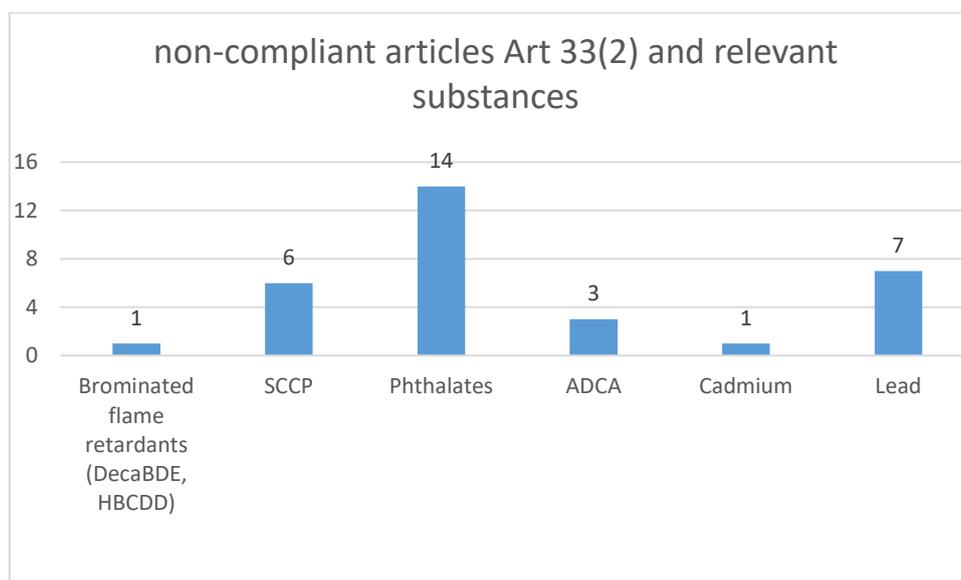


**Figure 21 –Compliant and non-compliant companies related to the information obligations according to Article 33(2) of REACH**

### CL-substances in non-compliant articles

The following CL substances were identified in concentrations above 0,1 % w/w in the 40 articles for which the communication duty under Article 33(2) of REACH was not fulfilled (Figure 22):

- different phthalates in 14 cases;
- SCCP in six cases;
- ADCA in three cases;
- cadmium in one case;
- brominated flame retardants in one case;
- lead in seven cases.



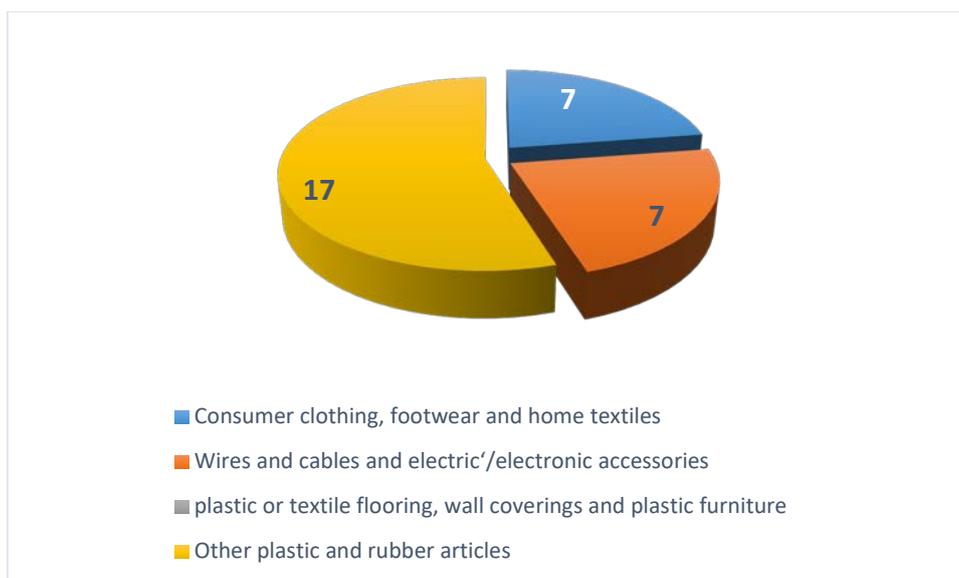
**Figure 22 – Number of non-compliant articles according to Article 33(2) of REACH and relevant substances identified**

### Data source and non-compliance

In nearly all non-compliance cases according to Article 33(2) of REACH, the data source on which the NEAs decided on the non-compliance, was results from a laboratory. In only one case was the information on the article given by the inspected company.

### Sector and non-compliances

Within the non-compliant articles according to Article 33(2), the sector where the most non-compliance was found in the group of “other plastic and rubber articles”, with 17 cases of non-compliance. These were followed by seven cases in the group of “consumer clothing, footwear and home textiles” and seven cases in the group of “wires and cables and electric / electronic accessories”.



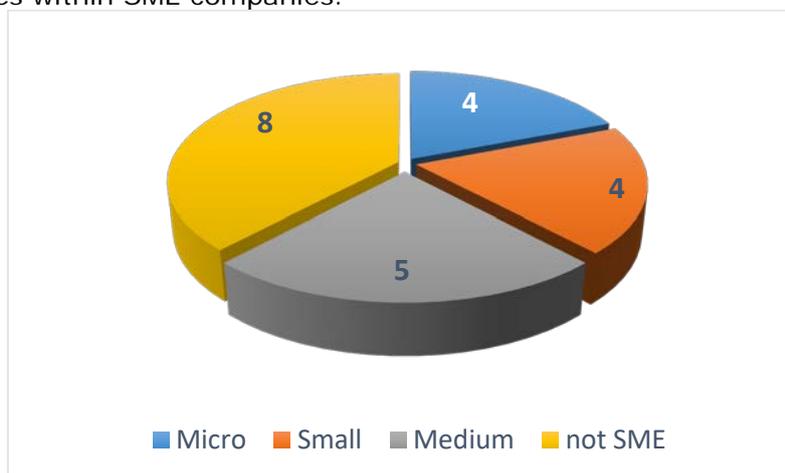
**Figure 23 – Types of non-compliant articles related to Article 33(2) of REACH**

Non-compliance and complex object

The non-compliance according to Article 33(2) was found in 15 cases in components of a complex object. In 16 cases the non-compliance according to Article 33(2) was found in single or “stand alone” articles.

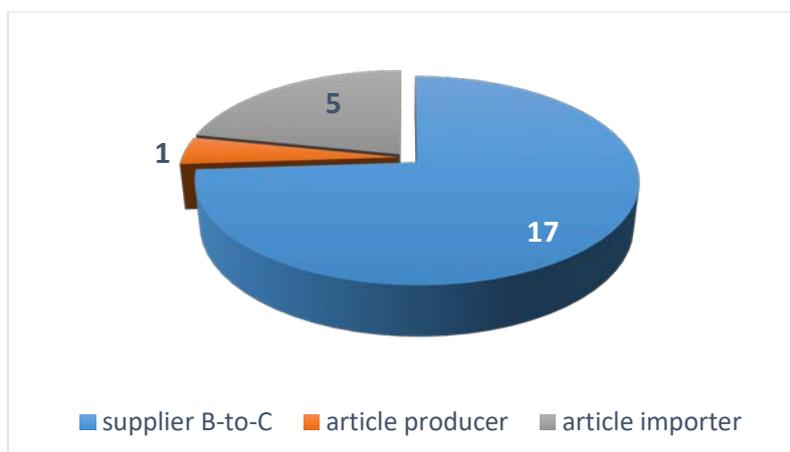
Non-compliance and company size and role of the company

Regarding the size of the non-compliant companies according to Article 33(2), the conclusion was that only eight were not SME companies, which implies more than 50 % non-compliances within SME companies.



**Figure 24 – Company size and non-compliant companies related to the information obligation according to Article 33(2) of REACH**

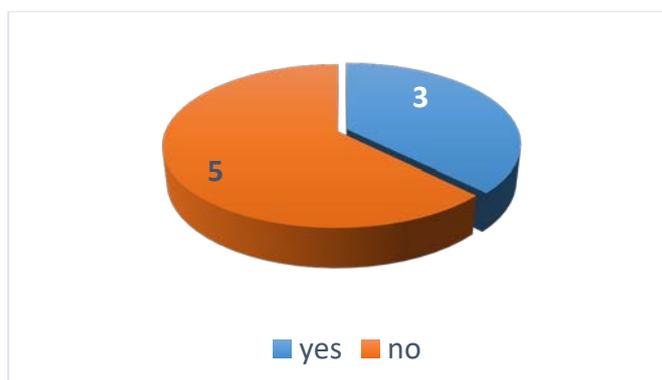
A company can have multiple roles in the supply chain. Regarding the role, the companies with the role of a B-to-C supplier (i.e. the company is a supplier and the recipient is a consumer) were most often non-compliant.



**Figure 25 – Role of non-compliant companies related to the information obligations according to Article 33(2) of REACH**

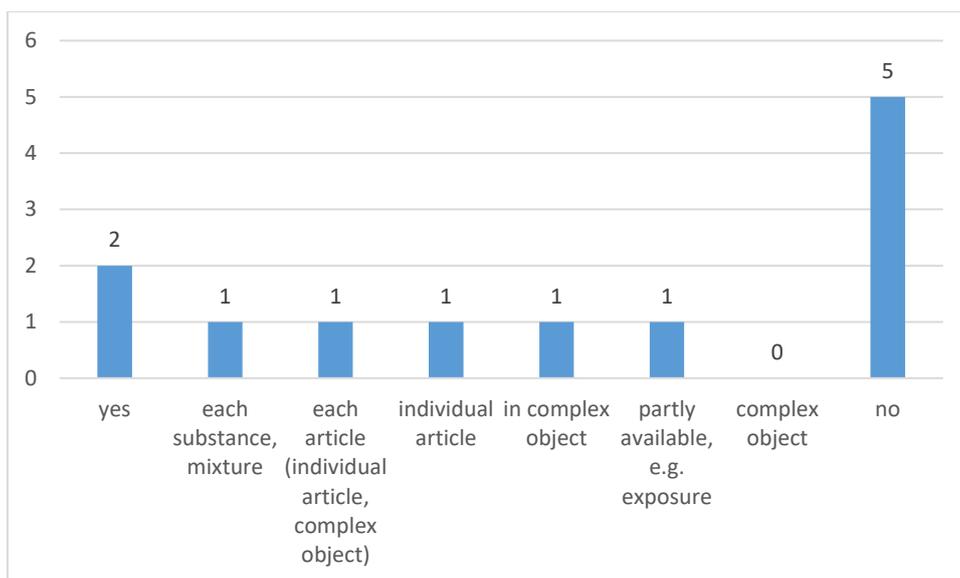
Non-compliance and management system

Management systems help companies fulfil their legal duties. Most of the non-compliant companies had no management system implemented, whereas only three of the non-compliant companies had a management system implemented (Figure 26).



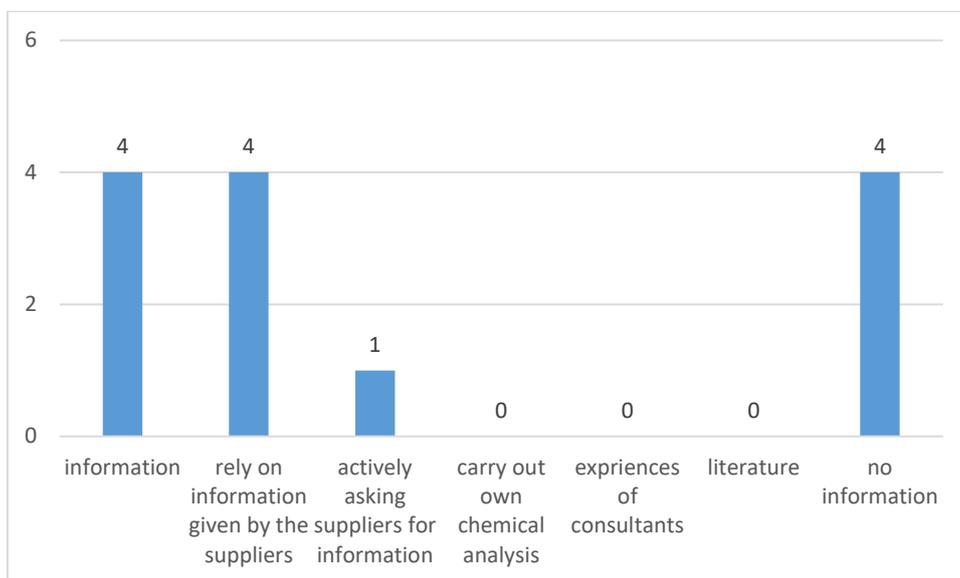
**Figure 26 – Relationship between the implementation of a management system and the non-compliance in relation to the information obligations according to Article 33(2) of REACH**

The availability of information on hazardous substances as such, in a mixture or in an article handled in the company is one important aspect of a management system. The inspections revealed that in two non-compliant companies, this information was available on different levels (for each substance or mixture, each article as an individual article or articles within complex objects) (Figure 27). However, in five non-compliant companies no information on hazardous substances was available (Figure 27).



**Figure 27 – Relationship between the availability of information on hazardous substances in the company and the levels of the availability of the information in companies not complying with the information obligations according to Article 33(2) of REACH**

Within the non-compliant companies according to Article 33(2), the source of information on the CL substances present in their articles varied. Four companies had no information. Four had information and they mostly relied on information given by suppliers, some even asking suppliers actively for information (Figure 28).

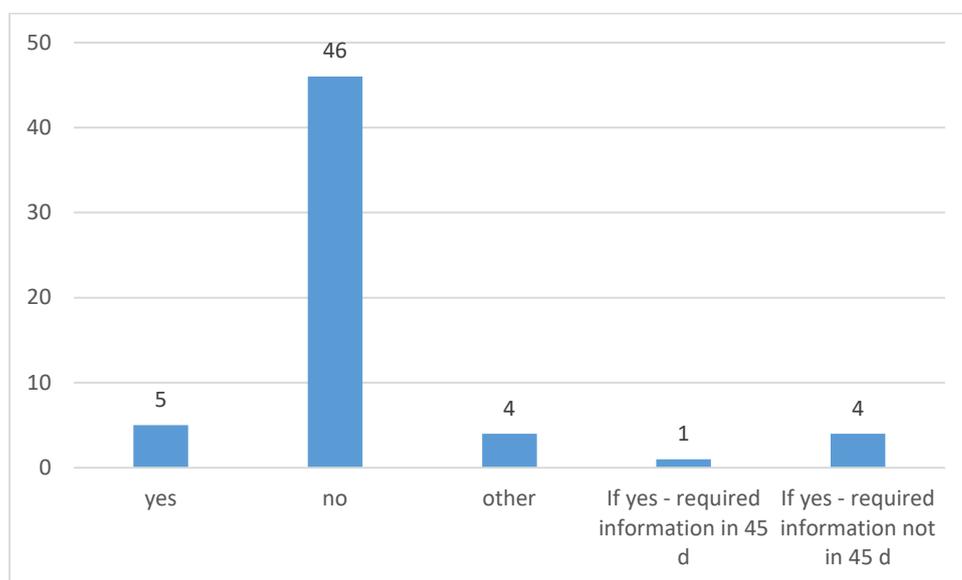


**Figure 28 – Relationship between the availability of information and the source of information on CL substances in companies not complying with the information obligations according to Article 33(2) of REACH**

Consumer request

On request by a consumer, any supplier of an article containing a CL substance in a concentration above 0.1 % w/w shall provide the consumer with sufficient information available to the supplier, to allow the safe use of the article including, as a minimum, the name of that substance. Information obligations according to Article 33(2) are related to a consumer request. For 46 articles, no consumer requested the information according to Article 33(2). For five articles, consumers requested the information according to Article 33(2). For four articles, consumers requested the information according to Article 33(2). For four of the articles, the information was not provided in 45 days (Figure 29).

The results show that the decision related to non-compliance of Article 33(2) was taken by the NEAs also when no consumer requested the information according to Article 33(2). Based on the available results the WG would summarize that NEA probably decided that information obligation according to Article 33(2) was not fulfilled when the article was supplied to a consumer and the inspected company was not able to provide the correct information to NEA. In case of a consumer request, the inspected company would also not have provided the consumer with the correct information.



**Figure 29 – Requested information from consumers to suppliers. Required information provided to consumers according to Article 33(2) of REACH**

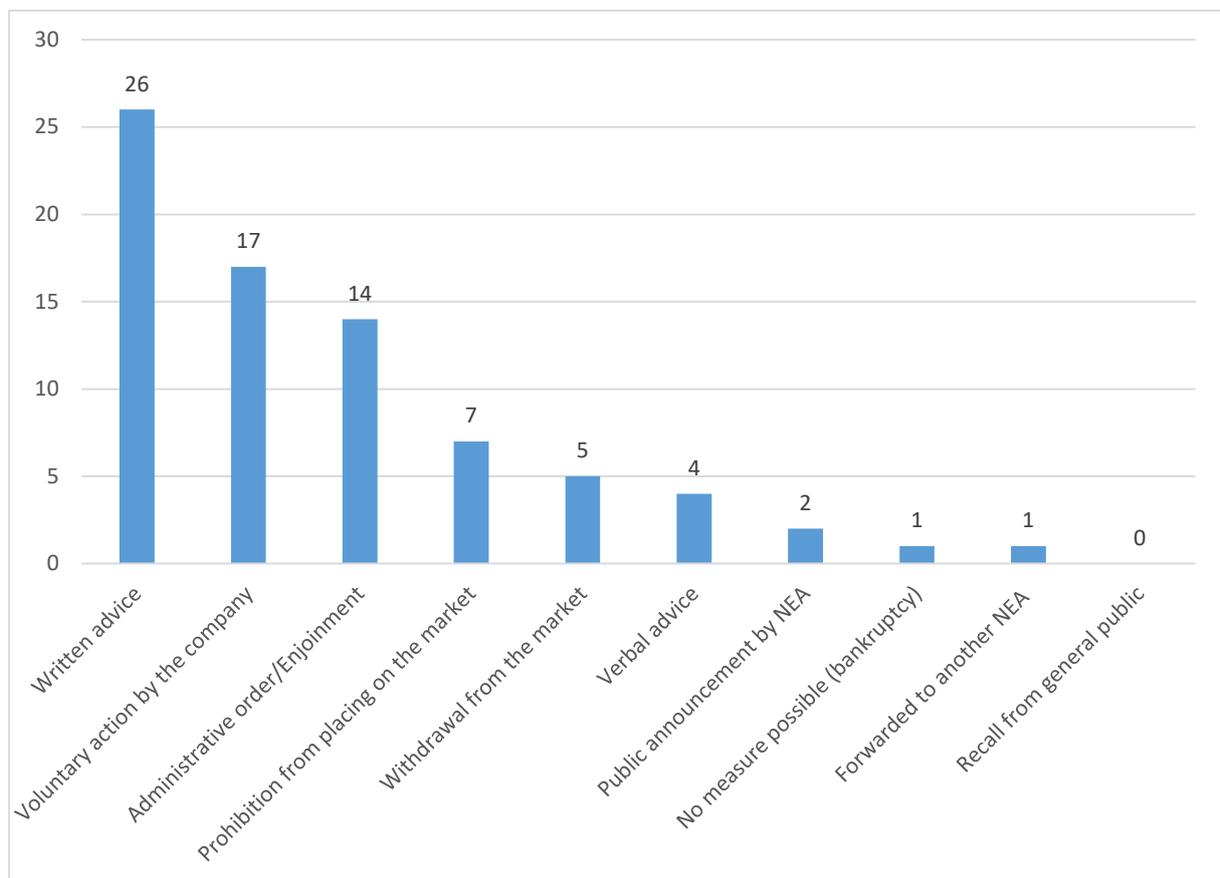
**Summary: Article 33(2)**

The results show a high non-compliance rate of 56 % for the articles with information obligations according to Article 33(2) and also a high non-compliance rate of 51 % for the duty holder with this information obligations according to Article 33(2). Related to the articles with information obligations according to Article 33(2), it is noted that only a few consumers requested information.

### 2.5.3 Legal actions

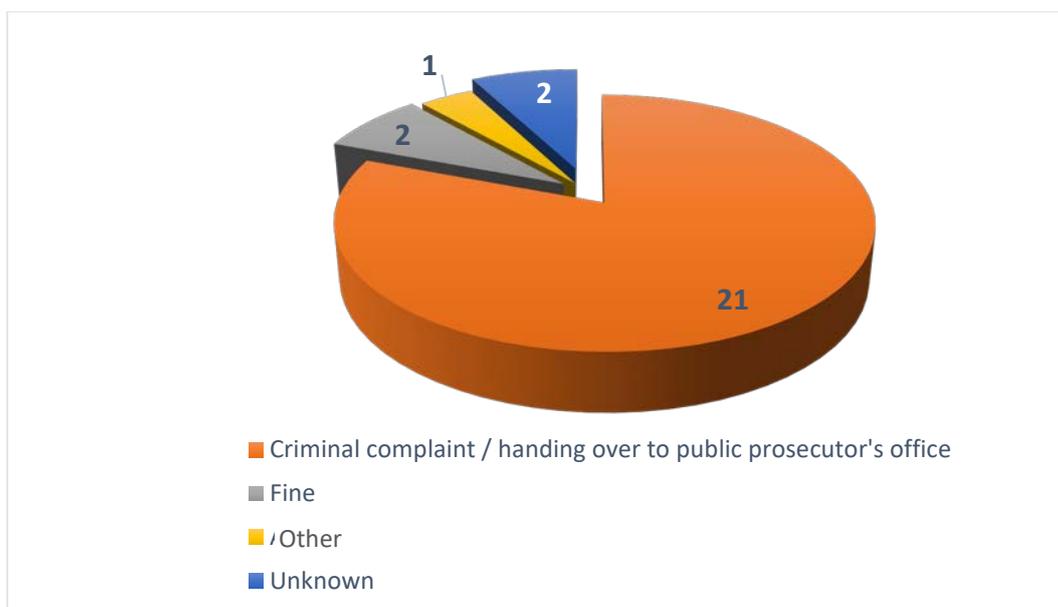
Legal actions were initiated against the non-compliant company for 45 cases and 13 cases were still on-going after the project was completed at national level. The enforcement measures used by NEAs were (see Figure 30):

- written advice was the most used enforcement measure with 26 cases following the administrative order (or injunction) with 14 cases by the NEA;
- voluntary action by the company, meaning withdrawal from the market (including sales stops), were made for 16 cases and in one instance, a company voluntarily recalled product(s) from its customers;
- in seven cases non-compliant products were prohibited from being placed on the market and in five cases products were withdrawn from the market;
- verbal advice was used in four cases;
- public announcement by the enforcement authority i.e. “Name and Shame” in two cases; no articles had to be recalled from consumers;
- in one case no enforcement measure against the company was possible because of the bankruptcy of the company; and
- one case was forwarded to another enforcement authority.



**Figure 30 –Enforcement measures and other actions for non-compliant cases related to SiA duties** (please note that several measures could be relevant in one case)

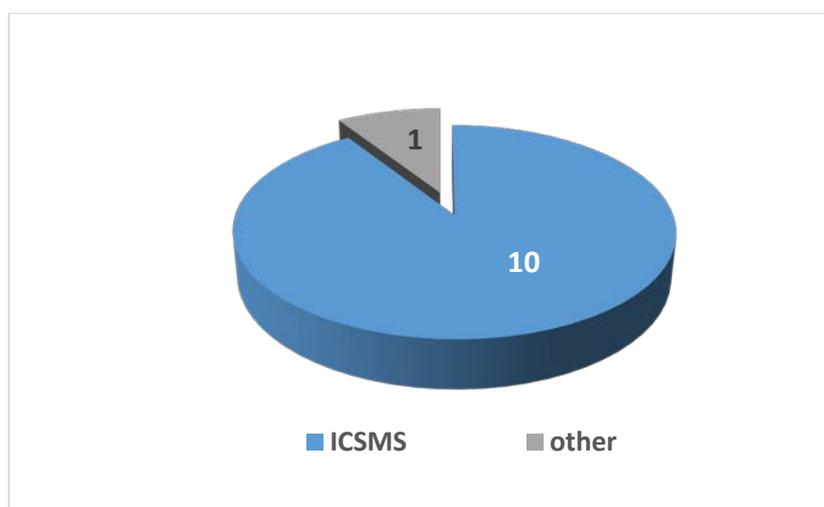
Regarding sanctions, a criminal complaint and/or handing over to NEA public prosecutor's offices was a result in 21 cases and fines were given for two cases. For two cases, the sanctions were still unknown at the end of the project (See figure 3).



**Figure 31 – Sanctions for non-compliant cases related to SiA duties** (please note that several measures could be relevant in one case)

#### 2.5.4 Communication between Member States

Participants of the project were asked if they used ICSMS, RAPEX or PD-NEA<sup>5</sup> to communicate information on their detected non-compliant cases. Altogether 11 non-compliant cases were communicated to other MSs, 10 via ICSMS and one by some other mechanism not reported (Figure 32). Also, many *compliant* cases were communicated to other MSs by ICSMS.



**Figure 32 – Communication mechanism for cases of non-compliance with SiA duties**

<sup>5</sup> ICSMS: Information and Communication System on Market Surveillance; RAPEX: Rapid Alert System for Non-Food Consumer Products ; PD-NEA: Portal Dashboard for National Enforcement Authorities

## 3. Conclusions and Recommendations

### 3.1 Conclusions

15 Member States participated in the operational phase of the pilot project, with a total of 405 companies inspected and 682 articles checked.

Out of the 682 articles inspected, 84 contained CL substances in a concentration above 0.1 % w/w. Phthalates (mostly DEHP) were found in most (51 articles), followed by SCCP, ADCA and lead. Phthalates and SCCP were found in soft plastic materials especially PVC. ADCA was found in foamed material such as in yoga mats and hockey helmets. Out of the 84 products which contained CL substances in concentration above 0,1 % w/w, 81 were checked by chemical analysis, and out of these cases, 78 (96 %) were checked by the authorities. This indicates that it is important for NEAs to carry out their own chemical analysis when enforcing these obligations.

57 out of 201 (28 %) companies do not have knowledge about the CL and 50 % of the 202 audited companies do not have a general management system. The most commonly used systems for monitoring and complying with legal requirements are declarations of conformity<sup>6</sup> and product declarations. This is information provided by the supplier. Also very common are specifications for substances (which restrict the presence of certain substances in articles) adopted by companies towards their suppliers who are given a “black list for substances”. These include lists of restricted substances as well as the complete ban of CL substances in articles. Only few companies claim to carry out their own laboratory analyses. Some companies also use the information from the safety data sheet to comply with legal requirements.

Taking the size of the company into consideration reveals a quite clear connection between the size of the company and the implementation of procedures. Around 50 % of medium and non-SME companies have at least partially implemented such procedures, while only 30-40 % of small and micro companies have such tools in place.

#### 3.1.1 Article 7

The notification obligation did not apply in most inspected cases, and where it did, the company complied with it. There was no non-compliance found. The checks of the compliance with the notification obligation rely on the information provided by the companies and therefore companies should organise their records well and show clearly that they follow the ECHA’s Guidance on requirements for substances in articles.

#### 3.1.2 Article 33

The selection of articles focused on high risk products or materials. 12 % of articles contained CL substances in a concentration above 0,1 % w/w. Determining whether the article in question contains a CL substance poses challenges. The project targeted only a few CL substances.

The information provided under Article 33(1) shall enable safe handling of the article and shall contain the name of the substance of very high concern. 89 % and 56 % of the inspected articles that contained CL substances above 0,1 % w/w, were found non-compliant with the requirements of Article 33(1) and Article 33(2) respectively. So when

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<sup>6</sup> Note that legal obligations for EU Declaration of conformity (DoC) only exists for CE labelling directives such as Toys and RoHS directive. There is no legal obligation for DoC for REACH.

CL substances are found, it is likely that also non-compliance occurs.

Even though it is allowed to sell articles that contain CL substances, some companies state that they do not want to sell articles that contain CL substances (58 companies).

One aspect of this project was to investigate if the information flow is working in the supply chain. The finding was that for most of the articles (86 %) where there was an information duty, the inspected company had not been informed by its supplier about the presence of CL substances. This shows that companies need to set demands on their suppliers to ensure that information flows through the supply chain. For high risk materials, it is also advisable for suppliers and recipients of articles to do chemical analysis from time to time. In a long supply chain, raw material suppliers may change, and it might be difficult to secure the information flow. In 73 % of the non-compliant articles, the recipient had not received the relevant information from the inspected supplier. For only three articles, the inspected supplier informed the recipient according to Article 33(1).

For the non-compliant companies, 86 % were either micro or SME companies. This indicates that smaller companies are less aware of their obligation regarding CL substances. For the companies that were audited, none of the non-compliant SME and micro-sized companies had implemented a management system (ISO 9001, ISO 14000, EMAS, etc.). Only about 20 % of the non-compliant micro and SME companies had implemented a general procedure to fulfil the information obligation of Article 33 and Article 7(2). Examples of procedures were restricted substance list, declaration of compliance, third party certification and a practise not to sell articles that contain CL substances.

According to Article 33(1) the recipient of an article has to be informed by its supplier with the required information. In 86 % of articles where information obligations existed, the inspected company had not been informed by their supplier with the required information. In 73 % of the non-compliant articles the recipient had not received the relevant information from the inspected supplier. This shows that there is a big gap in the communication trough the supply chain.

## 3.2 Recommendations

The following recommendations are a result of the experiences gained in this project.

### 3.2.1 Recommendations to industry

- The results show that the information through the supply chain can improve significantly. The improvement needs to come twofold:
  - duty holders need to observe their communication duties on CL substances in articles;
  - in addition, they have to take action and shall set clear demands on their suppliers about CL substances and do random chemical analysis.
- Choose suppliers wisely, consider what to demand or ask for, and what to pay particular attention to.
- The requirements of Article 33 and 7 (2) impose high demands on companies. On the one hand, these are only information obligations that have to be provided by the supplier. On the other hand, the practice has shown that these information obligations of suppliers are often not met. In addition, important information about CL substances sometimes disappears along multi-level supply chains or never existed in the supply chain.

As a rule, the company cannot rely on receiving the required information without

its own activity. Each company should therefore define a procedure to obtain the required information. This procedure can be integrated into the general management system. This can be, for example, the quality management system. However, independent procedures are also possible, such as contractual agreements with the suppliers. Many companies rely on the information provided by their suppliers. However, conducting their own chemical analysis may appear necessary from time to time.

- The results show that the information through the supply chain can improve significantly. A way to do this is to:
  - strengthen the communication with suppliers;
  - set clear demands the suppliers about CL substances; and
  - do random chemical analysis.
- The results show that in almost all the cases only the name of the candidate list substance was communicated in the supply chain. However, there are cases where more information on safe handling should be provided.
- Article 33(2) states that the information about the CL substance should be given when a consumer request it. Some companies also use additional voluntary measures by providing additional information via the labels, pictograms or user manuals. Another way is to use the company's website to communicate information.
- Adopting quality management system and/or an alternative means of ensuring traceability through IT systems or tools could help in improving compliance.
- Companies must better organise their records and show more clearly how they take their decisions in line with the recommendations in ECHA's Guidance on requirements for substances in articles.<sup>7</sup>

### 3.2.2 Recommendation to ECHA / COM / National helpdesks

- As all results show that companies have low level of knowledge about their SiA-related obligations, the first and most important suggestion to ECHA, COM, and National helpdesks would be to organise a comprehensive awareness-raising campaign on SiA duties, including timing and how to follow up of the regularly updated CL list.
- It is proposed to ECHA, potentially in cooperation with COM and MSs, to develop a methodology to better target relevant articles for SiA duties and to provide additional practical guidance (further to those already present in the pilot project manual) about the proper selection of types of substances to be looked for in certain types of articles.
- It is also recommended that ECHA develop more guidance on what specific information is to be provided in the supply chain beyond the name of the substance(s) and in what cases such information is needed.
- It is possible to get surveillance grants from the DG for Internal Market, Industry, Entrepreneurship and SMEs for the analyses of products. However, the administration of the application is quite complicated and hinders Member States to apply. A suggestion would be to simplify the administrative requirements linked to the application and ECHA / Forum Secretariat to support MSs using these grants.

### 3.2.3 Recommendations to National Enforcement Authorities (NEAs)

- Finding non-compliance requires first of all the identification of CL substances in concentrations above 0,1 % w/w. The identification of these substances in the articles reveals high degrees of non-compliance with SiA communication duties. More targeted inspections are needed with more targeted article choices. Attention has to be paid to the likelihood of presence of the substance in the article, due to

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<sup>7</sup> <https://echa.europa.eu/guidance-documents/guidance-on-reach>

the function of the CL substance. In this respect, guidance has already been provided by the pilot project manual.

- Although companies can have multiple roles, in general, inspectors reported higher degrees of compliance amongst producers of articles and lower degrees of compliance amongst the importers. Therefore, more checks on importers should be promoted, in cooperation with customs whenever possible. The benefit would to address the problem of lack of information and where it frequently originates from in the supply chain – although it is more difficult to identify importers. When importers do not have information or do not inform the next company in the supply chain, the non-compliance is repeated through the whole supply chain.
- Non-compliance is best stated when the presence of a CL substance is examined in the lab. As laboratory testing is often necessary for such a direction of inspection, resources need to be allocated already at the planning stage.
- According to the report, there are Member States where the NEAs identify higher rates of non-compliant articles. It would be very useful to share practices between Member States on targeting articles.
- Reduction of costs and better organisation of tasks can be achieved by combining SiA duties with other duties for the same article (e.g. with Reach-restrictions, POPs). In terms of analysis of articles, the methodology used does not differ.
- For the same reasons as above, it is also suggested that joint inspections with other national authorities such as customs or other market surveillance authorities are conducted.

#### **3.2.4 Recommendations to Forum**

- Perform a REACH-EN-FORCE (REF) project which includes SiA duties (at least article 33). A combination of SiA duties with other legal requirements applicable to substances in articles could be considered (e.g. REACH Restrictions, POPs), as indicated above.

### 3.3 Annex I – Project questionnaire

## PILOT PROJECT QUESTIONNAIRE

### Section 1: General Information

No	Question	Remarks
0	Company <input type="text"/> Address <input type="text"/> Contact person <input type="text"/> Organisation number <input type="text"/> Telephone <input type="text"/> E-mail contact person <input type="text"/>	This data will be deleted by NC - this data are only for internal use e.g. in case you need to forward the questionnaire to other NEAs for assistance

No	Question	Remarks
1	Participating country <input type="text"/>	
2	Inspection date <input type="text"/> Present NEA <input type="text"/> Person in charge (NEA) <input type="text"/> Phone <input type="text"/> E-Mail <input type="text"/>	This data will be deleted by NC - this data are only for internal use e.g. in case you need to forward the questionnaire to other NEAs for assistance
3	File Reference <input type="text"/>	The file reference needs to match the file reference in section 4 for the articles inspected and reported in the company. The format can be alphanumerical.

## Section 2: Company information (company related) – obligatory

4	NACE-Code of company: <input type="text"/>	source for NACE codes, see Annex 5.
5	<p>Role of the Company under REACH</p> <p><input type="checkbox"/> supplier of an article</p> <p style="padding-left: 20px;"><input type="checkbox"/> Supplier in the supply chain (B-to-B)</p> <p style="padding-left: 20px;"><input type="checkbox"/> Supplier to the consumer (B-to-C)</p> <p><input type="checkbox"/> article producer (including assemblers)</p> <p><input type="checkbox"/> article importer</p> <p><input type="checkbox"/> Only Representative (appointed by non EU producer of an article)</p>	<p>see REACH Art 3 (33)</p> <p>see REACH Art 3 (4)<sup>8</sup> see REACH Art 3 (11) and Art 3(10) see REACH Art 8, an Only Representative needs to be appointed by a non EU producer of an article</p> <p>In case of the role of a distributor (including a retailer, see REACH Art 3(14)) please tick either “supplier in the supply chain(B-to-B)” or “Supplier to the consumer (B-to-C)” or both, whatever is applicable</p> <p>“B-to-B”: business to business, a supplier provides an article to another company</p> <p>“B-to-C”: business to consumer, a supplier provides an article to a consumer</p>
6	<p>Definition of the company according to Commission Recommendation 2003/361/EC</p> <p><input type="checkbox"/> Micro      <input type="checkbox"/> Small      <input type="checkbox"/> Medium</p> <p><input type="checkbox"/> Not SME    <input type="checkbox"/> Not known</p> <p>Micro: &lt;10 employees and ≤2 million euro annual turnover Small: &lt;50 employees and ≤10 million euro annual turnover Medium: &lt;250 employees and ≤50 million euro annual turnover</p>	

<sup>8</sup> See the description of the role of an assembler in the Scenario 1 and 2 described in Table 3 of Section 3.2.2 and in footnote 13 in Section 2.4. of the Guidance on requirements for substances in Articles, Version 4, ECHA June 2017, <https://echa.europa.eu/guidance-documents/guidance-on-reach?panel=guidance-on-requirements-for-substances-in-articles#guidance-on-requirements-for-substances-in-articles>

## Section 3: Company audit and inspection (company related)

Section 3a – voluntary

Section 3b - obligatory

Section 3 a) Company audit (company related) (voluntary section to give an overview of the implemented management structures to fulfil the relevant legal duties)

### Scope of the audit

7	Has this section been covered by the inspector? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, go to section 3b	
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### Company's general approach to comply with chemical legislations

8	Is a management system implemented? <input type="checkbox"/> Yes  If yes, which kind, please specify : <input type="text"/> (Drop down: ISO 9001 ISO 14000 EMAS Free text)  <input type="checkbox"/> No	management systems like ISO 9001, ISO 14000, EMAS, etc. certified for the company can be relevant
9	Is a team or a responsible person in charge for compliance with chemical legislation? <input type="checkbox"/> Yes If yes <input type="checkbox"/> EHS Officer <input type="checkbox"/> REACH / CLP Officer <input type="checkbox"/> Ad-hoc Teams <input type="checkbox"/> Others, please specify <input type="text"/> <input type="checkbox"/> No	EHS officer: environment, health safety officer  Others: please specify whether a consultant, service provider, etc.
10	Is information on hazardous substances as such, in substances, in mixtures and articles handled in the company available <input type="checkbox"/> Yes If yes, what is the scope <input type="checkbox"/> CL Substances (SVHC in Candidate List) <input type="checkbox"/> Restricted Substances (e.g. Annex XVII of REACH) <input type="checkbox"/> Own definition of company list or sector-specific list for hazardous substances  If yes on which level is information available in the company	Substances can be present in substances (e.g. in UVCB (Unknown or Variable composition, Complex reaction products or Biological materials) or multiconstituent

	<input type="checkbox"/> Each substance, mixture <input type="checkbox"/> Each article (individual articles, complex object) <ul style="list-style-type: none"> <li><input type="checkbox"/> individual articles</li> <li><input type="checkbox"/> in complex object</li> </ul> <input type="checkbox"/> Only partly available, please specify (e.g. only focusing on exposure / risk assessment) <input type="text"/> <input type="checkbox"/> Complex objects (see note in the column) <input type="checkbox"/> No <input type="checkbox"/> Other, please specify <input type="text"/>	substances), in mixtures or in articles  “complex object” in the Guidance: refers to any object made up of more than one article, like coffee machines or cars.  Please note that information only on the level of complex object is not allowed unless it is a substance or a mixture used to join two articles (e.g. solder, glue)
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**Knowledge and procedures, etc. in connection to SiA obligations**

11	Does the company have knowledge of the actual list of candidate substances? <input type="checkbox"/> Yes <input type="checkbox"/> No	Knowledge of the company could also be not in-house knowledge but the knowledge from a consultant Examples how the company get actual information on new CL substances: - Periodical views of ECHA home page - Newsletter e.g. Chamber of commerce, sector organisations - External consultant
12	How does the company get information on CL substances in their articles? <input type="checkbox"/> Information: <ul style="list-style-type: none"> <li><input type="checkbox"/> Rely on information given by the suppliers</li> <li><input type="checkbox"/> Actively asking suppliers for information</li> <li><input type="checkbox"/> Carry out own chemical analysis</li> <li><input type="checkbox"/> Experiences of consultants</li> <li><input type="checkbox"/> Literature</li> <li><input type="checkbox"/> Other, please specify: <input type="text"/></li> </ul> <input type="checkbox"/> No information <input type="checkbox"/> Not relevant	Producer of articles need to consult the Safety Data Sheets of the raw materials (substances, mixtures) for the presence of a CL substance)

**Cooperation and experiences with suppliers**

13	<p>Has the company ever received information that an article they have been supplied with contains substances on the Candidate List in concentrations above 0.1 % and/ or information on the related safe use?</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> Partly  <input type="checkbox"/> Not relevant  <input type="checkbox"/> Other <input type="text"/></p>	
14	<p>Does the company have an assessment scheme for suppliers?</p> <p><input type="checkbox"/> Yes          If yes, could the scheme be named/described?  <input type="text"/></p> <p>If yes, is the relevant information (for SiA) on CL substance included in the assessment scheme</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p> <p><input type="checkbox"/> No</p>	<p>Examples for assessment criteria:</p> <ul style="list-style-type: none"> <li>• REACH-awareness of the supplier</li> <li>• results of previous supplier audits</li> <li>• likelihood of restricted substances being present in supplied articles / materials</li> <li>• experience with the supplier in the past</li> </ul> <p>The most popular scheme is the EN 50581 used under the RoHS Directive</p>
15	<p>Did the company ever downgrade/ reject a supplier because of weak information on SVHC?</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p>	

**3 b) Company inspection (company related) - obligatory**

16	<p>Number of articles subject to the SiA duties in the company (not each batch or each individual product)</p> <p><input type="text"/></p> <p><input type="checkbox"/> Not known</p>	<p>The answer is only based on the information of the inspected company. Please provide rough estimates for the number of articles.</p>
17	<p>Number of articles checked by the inspector</p> <p><input type="text"/></p>	<p>Recommended range: 1 - 10, for each of the articles inspected Section 4 of the Questionnaire should be filled separately (for each reported article).</p>

18	<p>Is there a general procedure implemented to fulfil the information requirements of Article 33 and/or Article 7(2)?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partly <input type="checkbox"/> Not checked <input type="checkbox"/> Other: Free text box <input type="text"/></p> <p>If Yes/partly, please specify:</p> <p><input type="checkbox"/> Bill of materials/articles specifying CL substances <input type="checkbox"/> Declarations of compliance with Art 33 / Art 7(2) <input type="checkbox"/> Restricted substances list (with CL substance) <input type="checkbox"/> Third party certification <input type="checkbox"/> IT platform/database <input type="checkbox"/> Product declarations related to Art 33 / Art 7(2) <input type="checkbox"/> A praxis not to sell articles that contain Candidate list substances <input type="checkbox"/> Other, please specify: <input type="text"/></p>	<p>Please note that the procedure(s) need to cover Art 33(1) and Art33(2) as well as Art 7(2), where relevant</p> <p>Third party certification: Service provided by third parties assessing products against certain criteria, including the content of hazardous substances (e.g. Bluesign®, OEKO-TEX®, BASTA). Often this service also includes a labelling scheme for approved products.</p> <p>IT platform/database: An IT platform/database into which actors at different stages of the supply chain may enter, manage and extract information on composition of mixtures, semi-finished and finished articles they produce or use. The system supports the sharing/transfer of information or declarations throughout the supply chain which allow to track the relevant composition of materials/articles used to produce a product. Examples: IMDS, BOMcheck, Octopus, CDX, ChemSherpa.</p> <p>For more information on the</p>
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		<p>tools mentioned in the list please refer to the Commission study available at: <a href="https://publications.europa.eu/en/publication-detail/-/publication/58f951af-809b-11e7-b5c6-01aa75ed71a1/language-en/format-PDF">https://publications.europa.eu/en/publication-detail/-/publication/58f951af-809b-11e7-b5c6-01aa75ed71a1/language-en/format-PDF</a></p>
19	<p>Is there in addition a voluntary general procedure implemented to fulfil the specific information requirements of Article 33(2) for consumers?</p> <p><input type="checkbox"/> Yes:</p> <p>If yes please specify:</p> <p><input type="checkbox"/> Information on labels</p> <p><input type="checkbox"/> Labelling pictograms</p> <p><input type="checkbox"/> Providing information to (databases of) Article 33(2) Phone Apps</p> <p><input type="checkbox"/> In instructions for safe use</p> <p><input type="checkbox"/> Information in accompanying documentation (e.g. in instruction for product use)</p> <p><input type="checkbox"/> Other. Please specify: <input type="text"/></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not checked</p>	<p>The general procedures are most often aiming at providing the consumer pro-actively with the required information without the need for an explicit consumer request.</p> <p>Existing Labelling pictograms, e.g. "Phthalate free"</p> <p>Phone Apps: e.g. ToxFox</p> <p>For more information on the tools mentioned in the list please refer to the Commission study available at: <a href="https://publications.europa.eu/en/publication-detail/-/publication/58f951af-809b-11e7-b5c6-01aa75ed71a1/language-en/format-PDF">https://publications.europa.eu/en/publication-detail/-/publication/58f951af-809b-11e7-b5c6-01aa75ed71a1/language-en/format-PDF</a></p>
20	<p>Does the company implement the new interpretation of an article (Court decision, Guidance, Version 4) and the related procedures / structures?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not checked</p>	<p>For background information on "complex objects" see in Section 2.4 in the Guidance</p>

## Section 4 - Enforcement of CL substances in selected articles (article related) - obligatory

Questions about specific articles and their most relevant CL substance, etc. to be filled in for each article

3	File Reference <input type="text"/>	The file reference needs to match the file reference in section 1.
21	EAN / GTIN No. <input type="text"/>	This data will be deleted by NC - this data are only for internal use
22	Internal identifier (sample no.) <input type="text"/>	e.g. in case you need to forward the questionnaire to other NEAs for assistance
23	Type of article <input type="text"/>  Select one of the 4 categories within the scope of the project <input type="checkbox"/> 1 Consumer clothing, footwear and home textiles <input type="checkbox"/> 2 Wires and cables and electric'/electronic accessories <input type="checkbox"/> 3 Plastic or textile flooring, wall coverings and plastic furniture <input type="checkbox"/> 4 Other plastic and rubber articles  Is the inspected article a component of a complex object? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other: <input type="text"/>	For the scope, see in Section 4.2.1 of the Manual
24	Is the concentration of the selected CL substance above (>) 0,1 %: <input type="checkbox"/> Yes If yes <input type="checkbox"/> Brominated flame retardants (DecaBDE, HBCDD) <input type="checkbox"/> Phosphorous flame retardants (TCEP, TXP) <input type="checkbox"/> Short-chain chloroparaffins (SCCP) <input type="checkbox"/> Phthalates <input type="checkbox"/> Aprotic polar solvents (DMF/DMAC) <input type="checkbox"/> Perfluorinated substances <input type="checkbox"/> Phenolic benzotriazoles <input type="checkbox"/> Other: free text  Please indicate which substance by providing the CAS number or any other identifier when CAS number does not exist: <input type="text"/>  <input type="checkbox"/> No	Please indicate the most relevant from those CL substances for which the inspected article has been checked for  For a list of relevant CL substances, see Annex 9 of the Manual

	<input type="checkbox"/> Other <input type="text"/>	
25	<p>On what kind of information is the answer in question 24 ((previous answer) based?</p> <p><input type="checkbox"/> on information from chemical analysis in a laboratory</p> <p style="padding-left: 20px;"><input type="checkbox"/> by the inspected company</p> <p style="padding-left: 20px;"><input type="checkbox"/> by a supplier of the inspected company</p> <p style="padding-left: 20px;"><input type="checkbox"/> by the inspecting authority</p> <p><input type="checkbox"/> only on the information of the inspected company</p> <p><input type="checkbox"/> on the information of the supplier of the inspected company</p> <p><input type="checkbox"/> other: <input type="text"/></p>	

<b>I. Obligation to notify CL substances in articles according to Article 7 (2) REACH (article producer, importer)</b>		
26	<p>Has the company (in its role of the article producer or importer) notified the selected CL substance for the inspected article according to article 7(2)</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not checked</p> <p><input type="checkbox"/> Not relevant</p>	<p>Art 7(2) requires a notification for a CL substance in all articles of the company in which the CL substance is present (above 0,1 % in each article and above 1 tonne) in total)</p> <p>If yes go to question 30. If no go to questions 27 and 28. Depending on the best approach taken by the inspector, he/she can start either by checking question 27 or question 28.</p> <p>Not relevant: e.g. the producer is an "assembler" of a complex object (mechanically assembling of articles)</p>
27	<p>If no in the above question (question 26): - does the following apply (if it applies please tick the box)?</p> <p><input type="checkbox"/> (a) the date of production or of import of the inspected article is after the date of inclusion of the SVHC into the Candidate List</p>	<p>The preconditions for notification are fulfilled in case all three boxes (a), (b) and (c) are checked</p>

	<p><input type="checkbox"/> (b) the concentration of the selected CL substance is &gt; 0,1 % in the produced / imported articles</p> <p><input type="checkbox"/> (c) the total amount of the selected CL substance, which is present (&gt;0,1 %) in the inspected and all other articles produced or imported by the inspected company, exceeds the limit of 1 t / year</p> <p><input type="checkbox"/> (d) no check for the preconditions was required (see Question 28, lines a,b and c)</p>	<p>Note on option (b): according to the investigations in questions 23 and 24</p> <p>Note on option (d): to be ticked following the conclusion reached in question 28, if the inspector starts with that question (see note under question 26)</p>
28	<p>In case the selected CL substance has not been notified for the inspected article(s) by the company, do the following exemptions from the notification obligation apply for the inspected article(s) (if it applies please tick the box)?</p> <p><input type="checkbox"/> (a) Exposure to humans or the environment is demonstrated to be excluded during normal or reasonably foreseeable conditions of use of the inspected article, including disposal.</p> <p><input type="checkbox"/> (b) Substance is already registered for that use in the inspected article</p>	<p>For the inspection methodology see the remark under Question 27. An exemption applies if at least one box (a), (b) or (c) is ticked.</p> <p>Art 7(3)</p> <p>As it needs to be ensured that the CL substance does not come into contact with humans or the environment, there is almost never a reason for an exemption based on Art 7(3)</p> <p>Art 7(6)</p> <p>At a producer (not assembler): the use of the CL substance in the inspected article should be mentioned in the</p>

	<p><input type="checkbox"/> (c) Six months after the date of inclusion of the SVHC in the Candidate List have not yet passed in accordance with Article 7(7) REACH</p> <p><input type="checkbox"/> (d) no check for the exemptions was required (see Question 27, lines a, b and c)</p>	<p>SDS (and in the CSR) of the registration of the supplier of the CL substance</p> <p>At an importer: as a minimum the SDS or the CSR of the CL substance needs to be available for the importer and they need to cover the use of the CL substance in the inspected article</p> <p>Art 7(7)</p> <p>Note on option (d): to be ticked following the conclusion reached in question 27, if the inspector starts with that question (see note under question 26)</p>
29	<p>In case the company had notified the selected CL substance for the inspected article is the mandatory information consistent with the inspected article:</p> <p>(a) Is the annual tonnage band for the CL substance notified to ECHA consistent with the data for relevant articles produced / imported in the calendar year 2016</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not checked</p> <p>(b) Is the brief general description of the identified uses of the CL substance in the article (e.g. technical function) provided in the notification consistent with the inspected article?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not checked</p> <p>(c) Is the brief description of the uses of the article provided</p>	<p>Please consider for Question 28(c) for the inspected article:</p> <ul style="list-style-type: none"> <li>- "Article Category" according to guidance R12</li> <li>- overall description of the article</li> <li>- user groups</li> <li>- reasonably foreseeable uses / misuses</li> </ul> <p>Note for (a): Article 7.4.f. of</p>

	<p>in the notification consistent with the inspected article (article service life)?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not checked</p>	<p>REACH</p> <p>Note for (b) and (c): Article 7.4.e. of REACH</p>
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<b>II. Communication obligation according to Article 33 REACH</b>		
30	<p>Had the inspected company given the required information on CL substance to the recipient of the article according to article 33 (1) REACH (B-to-B)</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not relevant</p> <p><input type="checkbox"/> Other</p>	<p>This question is related to the communication between the inspected company and its commercial customers/ the recipients.</p>
31	<p>Has any consumer requested the information according to article 33 (2)</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Other <input type="text"/></p> <p>If yes – had the required information on CL substance been provided to the consumer within the 45 days?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not relevant</p> <p><input type="checkbox"/> other <input type="text"/></p> <p>If no - is the relevant information already available in the inspected company?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not relevant</p> <p><input type="checkbox"/> other <input type="text"/></p>	<p>This question is related to the communication between the inspected company and its customers/ the recipients (consumers).</p> <p>Note: Article 36 documentation duties apply for the inspected company immediately</p> <p>In case no information is already available in the inspected company the company shall be asked by the inspector to make the information available from its suppliers in order to become compliant with Article 36</p> <p>In case the upstream supplier of the inspected company had not</p>

		<p>provided the article 33 (1) information to the inspected company, the upstream supplier had potentially not fulfilled his duties according to Article 33 (1).</p>
<p>32</p>	<p>In case of a communication obligation according to Article 33 (1) or Article 33 (2) exists what kind of information is / would be provided?</p> <p><input type="checkbox"/> Information exists. Please specify:</p> <p><input type="checkbox"/> Name of the CL substance</p> <p><input type="checkbox"/> Specific article within a complex object containing CL substances</p> <p style="padding-left: 20px;"><input type="checkbox"/> recipients are ONLY informed on CL substance at the level of the complex object (not in-line with the Court Decision)</p> <p style="padding-left: 20px;"><input type="checkbox"/> recipients are informed on CL substances at the level of an article (in-line with the Court Decision)</p> <p><input type="checkbox"/> Information to allow safe use of the article (e.g. on operational conditions / risk management measures for all life cycle stages of the article, on user groups, information that goes beyond the name of the CL substance)</p> <p style="padding-left: 20px;"><input type="checkbox"/> Give the text of the information: <input style="width: 150px; height: 15px;" type="text"/></p> <p><input type="checkbox"/> Concentration of CL substance (not mandatory to be provided by the company))</p> <p><input type="checkbox"/> No information exists</p> <p><input type="checkbox"/> Not checked</p> <p><input type="checkbox"/> Not relevant</p> <p><input type="checkbox"/> Other, please specify: <input style="width: 150px; height: 15px;" type="text"/></p>	<p>Guidance cases</p> <p>The decision of the Court emphasises the requirement to provide information for each article within a complex object. According to the interpretation of the guidance the communication obligation could only be given ALSO on the level of a complex object in addition to the communication obligation at the level of an article. (see Guidance page 50ff)</p> <p>This information is not mandatory but helpful for further assessment (e.g. risk assessment, exposure)</p>
<p>33</p>	<p>Did the NEA carry out own chemical analytics?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>If yes, were the results in line with the information given by the company?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	<p>See also Question 24</p>

	<input type="checkbox"/> Not applicable <input type="checkbox"/> Other	
34	<p>Had the inspected company as a recipient of the article been informed by its supplier with the required information (according to Article 33 (1)?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No if no <input type="checkbox"/> information of potential non-compliance of the upstream supplier is forwarded to the inspector of the supplier of the inspected company  <input type="checkbox"/> Other	<p>This question is related to the communication between the inspected company and its upstream suppliers. In case the supplier of the inspected company had not provided the article 33 (1) information to the inspected company, the supplier had potentially not fulfilled his duties of article 33 (1).</p>
35	<p>All in all, had the inspected company fulfilled the communication obligations according article 33 (1) REACH ?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No obligation according to article 33(1)	
36	<p>All in all, had the inspected company fulfilled the communication obligations according to article 33 (2) REACH ?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No obligation according to article 33(2)	

## Section 5 Summary / action (company related)

37	<p>Has non-compliance with REACH obligations of the inspected company related to the communication duties or notification duties been detected?</p> <p><input type="checkbox"/> Yes</p> <p>If yes:</p> <p><input type="checkbox"/> communication obligations of Article 33 (1)</p> <p><input type="checkbox"/> communication obligations of Article 33 (2)</p> <p><input type="checkbox"/> notification obligations of Article 7 (2). Please specify the number of articles for which the obligation was not fulfilled : <input type="text"/></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not relevant</p>	
38	<p>Legal action was initiated against the offender:</p> <p><input type="checkbox"/> Yes</p> <p>If Yes, please specify:</p> <p>Type of legal action initiated against the offender</p> <p>A) Enforcement measures (multiple responses are possible):</p> <p><input type="checkbox"/> Verbal advice</p> <p><input type="checkbox"/> Written advice</p> <p><input type="checkbox"/> Administrative order / Enjoinment</p> <p><input type="checkbox"/> Prohibition from placing on the market of the non-compliant product</p> <p><input type="checkbox"/> Withdrawal from the market of the non-compliant product</p> <p><input type="checkbox"/> Recall from the general public</p> <p><input type="checkbox"/> Voluntary action by the company to remedy the situation</p> <p><input type="checkbox"/> Public announcement by the Enforcement Authorities "Name and shame"</p> <p><input type="checkbox"/> Other. Please specify: <input type="text"/></p> <p>B) Sanctions (multiple responses are possible):</p> <p><input type="checkbox"/> Fine</p> <p><input type="checkbox"/> Criminal complaint / handing over to public prosecutor's office</p> <p><input type="checkbox"/> Other. Please specify: <input type="text"/></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Follow up activities still on-going</p>	
39	<p>This case has been forwarded to other Member States</p> <p><input type="checkbox"/> Yes</p>	

	<p>Yes. If Yes, please specify:</p> <ul style="list-style-type: none"><li><input type="checkbox"/> PD-NEA</li><li><input type="checkbox"/> ICSMS</li><li><input type="checkbox"/> Informal (e.g. e-mail)</li><li><input type="checkbox"/> Other. Please specify: <input type="text"/></li></ul> <p><input type="checkbox"/> No</p>	
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