

Forum REACH-EN-FORCE 2 Project Report

Obligation of downstream users -
formulators of mixtures



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Table of Contents

1. EXECUTIVE SUMMARY	4
2. BACKGROUND.....	6
2.1 Background of the project	6
2.2 Legislative background.....	6
3. RESULTS OF THE PROJECT	7
3.1 General overview.....	7
3.2 Participation and number of inspections.....	8
3.3 Role of the companies under REACH and their size	9
3.4 Types of the inspected companies according to their economic activities	11
3.5 Total number of checked substances, mixtures and SDSs	11
3.6 Registration and notification obligations	12
3.7 Details regarding information obligations in the supply chain (Title IV of the REACH Regulation)	14
3.8 Details regarding the quality of the information in the SDSs (Annex II of the REACH Regulation)	15
3.9 Details regarding downstream user obligations (Title V of the REACH Regulation)	17
3.10 Non-compliance issues and measures taken.....	20
4. OVERALL CONCLUSIONS.....	24
5. RECOMMENDATIONS.....	25
5.1 Recommendations to the Forum	25
5.2 Recommendations to ECHA.....	26
5.3 Recommendations to enforcement authorities and inspectors.....	27
5.4 Recommendations to industry	27
Annexes:	
1. List of the relevant Community legal acts	
2. Questionnaire on the Forum project REACH-EN-FORCE 2	
3. Supplementary diagrams	

1. Executive summary

The REACH-EN-FORCE-2 project was adopted by the Forum at its sixth meeting in December 2009. After an analysis of 11 concepts for enforcement projects by the mandated Working Group, the decision was taken by the Forum to initiate a project with the focus of checking the compliance of downstream users with essential requirements provided by the REACH and CLP regulations, titled "Obligations of downstream users – formulators of mixtures".

The project was carried out by 29 Member States¹ with the inspection phase lasting from May 2011 until March 2012 correspondent to the decision of the Forum. The survey addressed the conduct of companies with regard to the registration (REACH) and notification (CLP) of substances and concerning their duties of providing information down the supply chain and implementing risk reduction measures on site. Particular attention was paid to the quality and management of the downstream users' own safety data sheets (SDSs).

Inspections of 1 181 enterprises of four size categories were reported with checks on approximately 6 900 substances, 4 500 mixtures and the evaluation of 4 500 SDSs. Although the majority of the visited companies were downstream users, more than 50% were also active in additional roles, e.g. as manufacturers, importers, only representatives.

Inspectors reported that two thirds of the surveyed enterprises (67%) violated provisions of the chemicals legislation to various extents of concern. Non-compliance included registration and notification contraventions, failing to sufficiently provide information on hazardous chemicals downstream and deficient implementation of risk management measures. In particular, major relevant findings of non-compliance have been:

- 269 enterprises acting as manufacturers, importers or only representatives were proven by inspectors to actually be required to (pre-)register substances, of which 8% failed to fulfil their legal obligations. More than 50% of this non-compliant group were non-SME companies (57%).
- For 57% of formulators already using registered substances in their mixtures, inspectors verified that the identified uses for the mixtures matched the identified uses in the registration of the substances.
- 275 enterprises acting as manufacturers, importers or only representatives were proven by inspectors to actually be required to notify their substances to the classification and labelling inventory at ECHA, of which 15% failed to fulfil this legal obligation.
- The required SDSs have been available on site in 97% of 1 118 inspected companies signalling a somewhat improved compliance compared to the previous REF-1 project (87%). Such a slight improvement in compliance has also been observed for 86% of the companies with regard to the national language and formats used for the SDSs.
- 52% of the checked SDSs have shown defects in the information of various types and to various extents within the sections of the SDSs that have been investigated.
- The correspondence of the information in the SDSs and on the label for substances or mixtures is deficient for 24% of the inspected companies.

¹ Member States should be understood as EEA countries meaning the 26 EU Member States, Iceland, Liechtenstein and Norway.

However, with regard to the formats used and the availability of SDSs, improvements were observed in comparison to the results of the earlier REF-1 project.

The detailed report describes the compliance status of the sample companies and gives a comparison by size category and by REACH role. In addition, the reaction of the enforcement authorities to detected offenses, in terms of measures imposed is analysed.

Based on the project results, conclusions are drawn and recommendations are given, addressed to the Forum, ECHA, enforcement authorities and industry.

The main recommendations are as follows:

- Industry should focus on further knowledge-building within companies concerning REACH and CLP. Awareness and knowledge on REACH among smaller downstream user companies is sometimes very low or even non-existent. This is a matter of concern and should be monitored.
- The ECHA website is a very useful source of information for companies who want to gain deeper knowledge of the REACH and CLP regulations. Companies can also clarify whether they have any obligations under the regulation by consulting their national helpdesks or the competent authorities.
- The Electronic Information Exchange System (EIES) could be a useful communication tool to help resolve specific cases and matters of concern identified through REACH and/or CLP inspection activities that relate to the compliance of duty holders based in other Member States.
- Further strengthening of cooperation between authorities enforcing REACH and CLP in different Member States should be encouraged.
- Training on exposure scenarios, extended SDSs, assessment of identified uses and compliance with risk management measures in SDSs/ESs for inspectors should be considered as a topic for future 'Train the Trainers' events.

The objective of the REACH-EN-FORCE 2 project was to contribute to the ultimate goal of the Forum: coordination and harmonisation of REACH and CLP enforcement in the Member States.

2. Background

2.1 Background of the project

The first coordinated enforcement project, REACH-EN-FORCE-1, focused on pre-registration and information in the supply chain, obligations of manufacturers and importers of substances on their own or in mixtures. The REACH-EN-FORCE-2 project went further down the supply chain to focus on the next group of REACH duty holders – the downstream users who formulate mixtures. ECHA supported the project by preparing a fact sheet on safety data sheets and exposure scenarios. Great efforts were undertaken to carefully design and balance the methodology of the project.

The project was guided by a Working Group which delivered a project manual with guidance and recommendations for inspectors, a questionnaire with inspection items and a new reporting tool.

National coordinators were appointed in each participating country and trained by the Working Group in ECHA. The national coordinators were primarily responsible for the training of the inspectors in their countries. For the latter purpose, they were provided with model presentations and case studies elaborated by the Working Group.

For each inspection undertaken during the operational phase of the project, a questionnaire was completed by the inspector.

An electronic reporting tool was introduced to enhance preparation and submission of inspection reports and to facilitate data processing and the analysis of project results. The tool served as a prototype for reporting procedures in future projects.

2.2 Legislative background

REACH Regulation

The REACH Regulation lays down specific duties and obligations for manufacturers, importers and downstream users of substances on their own, in mixtures and in articles. The regulation should ensure that substances placed on the market are used in such a way that human health and the environment are not adversely affected and that recommended measures to control the risks are taken. The regulation contains both general and detailed provisions on how downstream users have to take appropriate measures to control and identify risks. As a formulator of mixtures, the downstream user is acting as a supplier who is also covered by the obligations to provide the recipient down the supply chain with a safety data sheet and/or to communicate necessary information.

The REACH-EN-FORCE 2 project focused on enforcing the following articles of the REACH Regulation:

- Article 5 - No data, no market
- Article 6 – General obligation to register substances on their own or in mixtures (only if the downstream user is also a manufacturer or importer of substances)
- Article 31 - Requirements for safety data sheets (SDSs) (including Annex II – SDS)
- Article 32 – Information when SDSs are not needed
- Article 35 – Access of information to workers

- Article 36 – Archiving
- Article 37(5) - Duty for downstream users to apply appropriate measures to adequately control risks identified in an SDS supplied to them, their own chemical safety assessment, or any information supplied
- Article 37(6) - This provision concerns downstream users not preparing chemical safety reports according to Article 37(4c), who are obliged to consider the use(s) of the substance and to identify and apply any appropriate risk management measures.

Article 37(5) is very important as it obliges the downstream users to actually implement the measures indicated in the SDS. However, according to Article 39(1) of REACH, the downstream users had 12 months to implement the measures after they received the registration number communicated to them in the SDS. This means that during the operational phase of this project the provision was unlikely to be effective in operation, as the downstream users – at the very earliest – received registration numbers in the SDSs in early 2011.

The duty to implement the risk management measures from the SDS is not new and, in any case, workplace safety must be ensured. Therefore, as far as it was within their competence, inspectors enforced the implementation of risk management measures identified in the SDS under other appropriate legislation, such as national implementations of directives 89/391/EEC and 98/24/EC. Inspectors promoted knowledge amongst the duty holders on Articles 37(5) and 37(6) of REACH and enforced, where possible, the provisions of relevant national workplace safety and environmental legislation.

CLP Regulation

The REACH-EN-FORCE 2 project focused on enforcing the following articles of the CLP Regulation, where applicable:

- Article 40 - obligation to notify ECHA (only if the downstream user is also a manufacturer or importer of substances).
- Article 49 – there is a duty for suppliers to collect and maintain information as required by CLP for at least 10 years after the substance or the mixture was last supplied by that supplier.

3. Results of the project

3.1 General overview

The subsequently presented results are based on the reports of 1 181 inspections conducted throughout Europe over a period of 11 months during 2011/2012.

The campaign was supervised by the "National Coordinators" of the participating countries and coordinated by the Forum's project Working Group.

The new reporting tool, developed and introduced by the Working Group, improved the quality, submission and processing of reports, enhanced data interpretation and enabled a detailed extraction of results.

The results of the REF-2 project are presented in the executive summary as well as in chapters three and four. The legal provisions that were checked during the REF-2 project will certainly be key areas for inspectors to consider in the following years.

3.2 Participation and number of inspections

The project was performed by 29 Member States and inspections of 1 181 companies were conducted. Table 1 lists the 29 participating countries and the number of inspections carried out.

It is noteworthy to state that the varying economic conditions between countries, disparity in the availability of resources and/or the size of the country provide an explanation as to why certain countries have performed more enforcement actions within the scope of this project than others.

Moreover, additional inspections have been carried out on the REACH Regulation within the scope of national projects and may not have been reported in this REF project.

Table 1: Participating countries and reported inspections

Country	Number of submitted inspection reports
Austria	20
Belgium	41
Bulgaria	31
Cyprus	13
Czech Republic	17
Denmark	20
Estonia	20
Finland	14
France	97
Germany	228
Greece	41
Hungary	22
Iceland	5
Ireland	22
Italy	43
Latvia	24
Liechtenstein	3
Lithuania	26
Malta	7
Netherlands	48
Norway	24
Poland	90
Portugal	43
Romania	10
Slovakia	39
Slovenia	9
Spain	161
Sweden	43
United Kingdom	20
Total	1 181

3.3 Role of the companies under REACH and their size

Enterprises may have various roles under REACH. The project shows that companies usually undertake more than one of these roles in the supply chain. The proportion of functions and their occurring combinations are listed in Table 2.

Table 2: Rates of observed roles and REACH role combinations. Functions named do not exclude others unless otherwise stated.

Company roles under REACH and occurring role combinations	% (n = 1181)	Number of companies
Downstream user (DU)	95	1121
Downstream user DU (single role)	42	497
Distributor (DI)	40	469
Manufacturer (M)	18	216
Importer (I)	16	193
Only representative (OR)	2	27
Manufacturer or importer or OR (MIOR)	28	328
Manufacturer, not importer	11	130
Importer, not manufacturer	9	109
Manufacturer and importer	7	83
OR, neither manufacturer nor importer	<1	3
OR and importer	<2	23
OR and importer, not manufacturer	1	9
OR and manufacturer, not importer	<1	1
OR and distributor	1	14

Almost all the inspected enterprises are downstream users (95%) of which more than half execute multiple roles (56%). More than one quarter of the sample companies (28%) act as either a manufacturer (M), importer (I), only representative (OR) or have combinations of these functions (MIOR). Manufacturers are represented at a slightly higher rate than importers. The proportion of companies acting as ORs is relatively small (2%) and very few of them act solely as ORs (< 1%) but mostly in combination with the importer function (8 out of 10 companies) and less often combined with manufacturer or distributor activities (5 out of 10 companies).

The distribution of REACH roles observed by inspectors for the checked companies (multiple responses possible) is given in Figure 1 (see Diagram 1 in Annex 3).

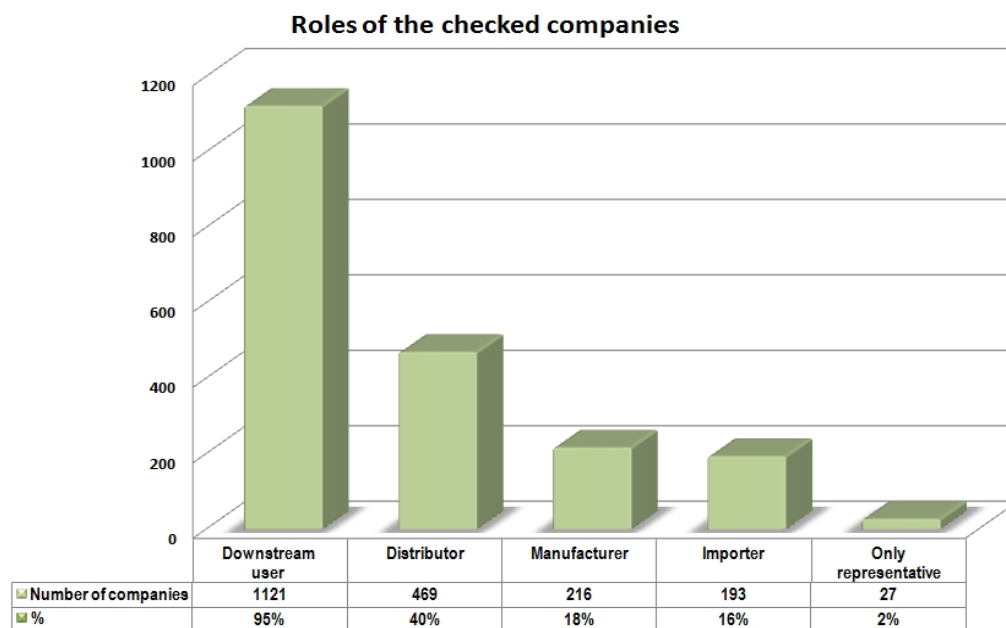


Figure 1: Proportion of company roles (n= 1 181).

Companies of all size categories according to the EU² standard scale were included in the inspections (Table 3). Micro, small and medium-sized companies (SMEs) are represented in relatively equal proportions and make up 86% of the entire sample. Larger enterprises, not belonging to the SME category, form a smaller group of inspected companies (14%).

The distribution of the company sizes is given in Table 3 (see Diagram 2 in Annex 3). The selection of companies of the various sizes for inspection and the resulting size group ratio might have been influenced by such factors as the economically and geographically determined unequal presence and structure of certain business types and sectors in the participating countries. The proportion of SMEs (1 014) to non-SMEs (160) companies is 6:1.

Table 3: Rates of company sizes determined according to Commission Recommendation 2003/361/EC.

Company size category	% (n = 1181)	Number of companies
Micro	28	330
Small	32	379
Medium	26	305
sum SME	86	1 014
Non-SME	14	160
Not known	<1	7

² Commission Recommendation 2003/361/EC

3.4 Types of the inspected companies according to their economic activities

The range of surveyed business sectors represented by the inspected enterprises is specified by the NACE³ code in Table 4 (see Diagram 3 in Annex 3). In terms of the NACE system, the vast majority of enterprises (74%) fall into the category “manufacturer of chemicals and chemical products” (NACE Code 20)⁴. The activities reported for this group include the preparation of paints and varnishes as well as detergents, cleaning and polishing mixtures. Other sectors with a relevant share of inspections in the project are the pharmaceutical industry, metal and mineral industry and wholesale traders.

Table 4: Main business sectors in the scope of the project.

NACE identifier	Number of companies	Proportion of companies
Manufacture of chemicals and chemical products (NACE Code 20)	870	74%
Manufacture of basic pharmaceutical products and pharmaceutical preparations (NACE Code 21)	19	2%
Manufacture of other non-metallic mineral products (NACE Code 23)	44	4%
Manufacture of basic metals (NACE code 24)	61	5%
Wholesale trade, except of motor vehicles and motorcycles (NACE code 46)	64	5%
Others	123	10%

3.5 Total number of checked substances, mixtures and SDSs

Nearly all companies were subject to examination of their SDSs concerning availability and quality (94%). If checks were not performed, it was mostly due to the lack of legal obligations for the companies to provide SDSs. The number of assessed mixtures, substances and corresponding SDSs are given in Table 5. Although in total more substances than mixtures were checked, the figures show that inspectors put stronger emphasis on assessing the quality of SDSs of mixtures than of substances.

Table 5: Number of checked substances, mixtures and related SDSs.

Checked	Number checked	SDS checked	Percentage
Mixtures	4 484	3 542	79%
Substances	6 907	954	14%

3 NACE, the Statistical Classification of Economic Activities in the European Community, is a European industry standard classification system for economic activities.

4 The definitions of “manufacturer” according to the NACE code Regulation (EC) No 1893/2006 and the REACH Regulation are not equivalent.

3.6 Registration and notification obligations

According to Article 5 of the REACH Regulation, substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market at one tonne or more per year unless they have been registered. If companies not only formulate mixtures, but also manufacture or import substances as such or in mixtures in quantities of one tonne or more annually, and no exemptions are applicable, submitting (pre-)registrations to ECHA is mandatory. 328 enterprises in the survey were determined to be potential (pre-)registrants due to their manufacturing, importing and OR activities (MIOR). Of these enterprises, 269 were proven by inspectors to actually be required to (pre-)register substances, of which 8% failed to fulfil their legal obligations. More than half of this non-compliant group were non-SME companies (Table 6; see Diagram 4 in Annex 3).

A more detailed activity analysis shows:

- in 153 cases companies manufactured/ imported substances as such,
- in 69 cases companies manufactured/ imported substances in mixtures,
- in 96 cases companies manufactured/ imported both substances as such and substances in mixtures.

Table 6: Registration duties and compliance. Comparison of MIOR-companies by size categories.

Size	Number comps.	M-I-OR	Registration duties			Registration offences		
			Cases	%	%	Cases	%	%
				of MIOR in size category	of duty group		of obliged MIOR in size category	of offense group
Micro	330	29	18	62	7	2	11	10
Small	379	76	56	74	21	3	5	14
Medium	305	116	98	84	36	4	4	19
Non-SME	160	107	97	91	36	12	12	57
		MIOR group	duty group	of MIOR group	of all comps	offense group	of duty group	of MIOR group
Overall	1 181	328	269	82	23	21	8	6

Another aspect investigated in the inspections was the (pre-)registration status of substances used in mixtures produced by formulators. Generally inspectors came across two types of formulators: those additionally importing and/or manufacturing substances and those solely having the downstream user function. A check of compliance with the legal requirement to use only substances in line with (pre-)registration provisions when formulating mixtures was made during 88% of all inspections (1 037 companies).

Inspectors found that more than two thirds of the companies (69%) had a fully (pre-)registered range of substances while the others were using partially or fully (5%) non-pre-registered substances. Examinations revealed that exemptions applied in more than half of the detected cases (53%) of not pre-registered/not registered substances. In almost half of the cases (49%), no information was available from the supplier.

Assessment of the legal awareness in the supply chain showed that a great majority of the checked companies (72%) initially knew the (pre-)registration status of the substances they used. Moreover, figures indicate, that the degree of knowledge

progressively increases with the growing size of the companies. However, a significant portion of formulators (28%) were unaware of the (pre-)registration status of the substance they use, a fact that highlights the need for intensified information efforts addressed towards downstream users. The rates of formulators using not (pre-) registered substances and awareness of status among companies of the different size groups and their level of compliance are given in Figure 2.

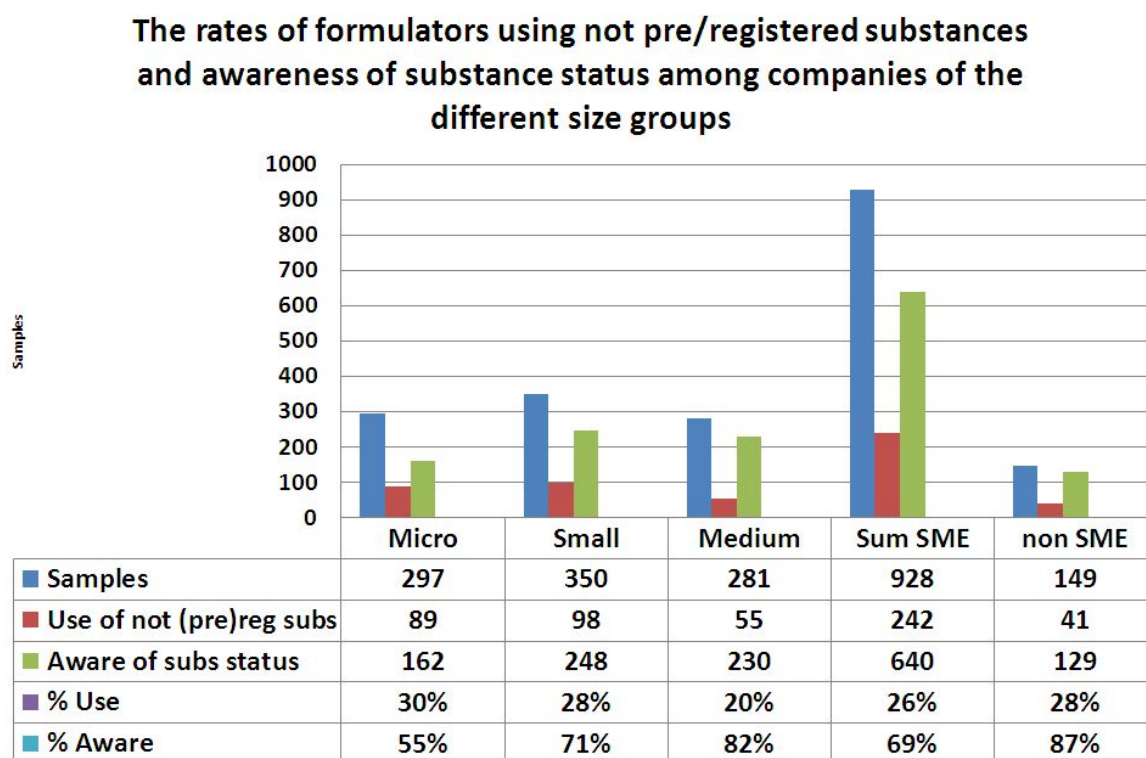


Figure 2: The rates of formulators using not (pre-)registered substances and their awareness of the substance status. Comparison by company size (n = 1 077).

For registered substances used by formulators in mixtures, the issue of identified uses was also enforced. Inspectors checked whether the uses identified for the formulator's mixture match the identified uses included in the registration of the substance. Figures indicate that in more than half of the cases (57%), identified uses for formulated mixtures were relevant with those identified uses for registered substances.

Among the companies acting as manufacturers, importers or only representatives (MIOR), the large majority (85%) had the obligation to notify substances to the classification and labelling inventory at ECHA as per the requirement laid down by Article 40 of the CLP Regulation (EC) No. 1272/2008. Inspections showed that 15% of these 275 enterprises did not fulfil this legal duty. Non-SME enterprises make up 14% of this non-compliant group, while the proportions of smaller companies range from 19% up to 40% (Table 7; see Diagram 5 in Annex 3).

Table 7: Notification duties and compliance. Comparison of MIOR-companies by size categories.

Size	Number comps.	M-I-OR	Notification duties			Notification offences		
			Cases	%	%	Cases	%	%
				of MIOR in size category	of duty group		of obliged MIOR in size category	of offense group
Micro	330	29	21	72	8	8	38	19
Small	379	76	58	76	21	17	29	40
Medium	305	116	93	80	34	11	12	26
Non SME	160	107	103	96	37	6	6	14
		MIOR group	duty group	of MIOR group	of all comps	offense group	of duty group	of MIOR group
Over all	1 181	328	275	85	23	42	15	13

3.7 Details regarding information obligations in the supply chain (Title IV of the REACH Regulation)

Almost all companies inspected (97%) had the required SDSs available on site. This fact signals improved compliance in comparison to the REF-1 project where the availability rate of SDSs reached only 87%. However, although SDSs were available in the inspected company, the quality of the SDSs was frequently insufficient as defects of various types and to various extents occurred in the checked sections. In total, every second SDS (52%) was reported to be defective by inspectors (Figure 3).

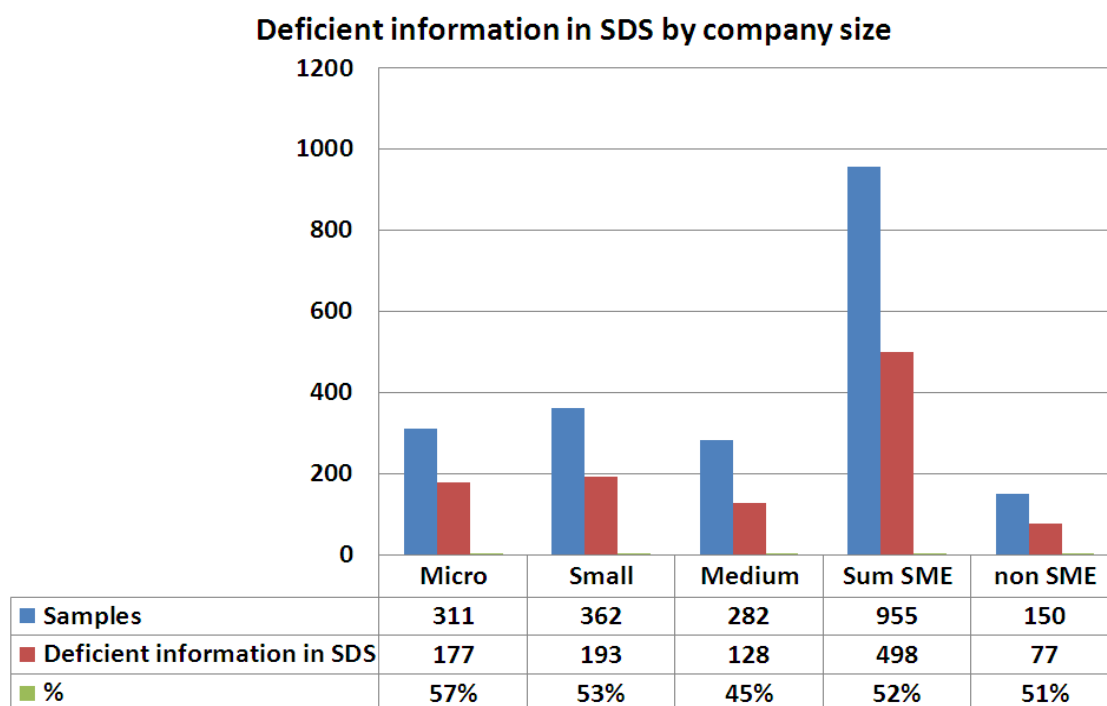


Figure 3: Deficient information in SDS by company size (n=1 105).

Among the non-compliant group, enterprises of all sizes were found. Deficient SDSs occurred at nearly the same rate in all size groups. Thus, size does not seem to influence the quality and reliability of the companies' SDSs.

According to the judgement of inspectors, more than two thirds of the companies (68%) have sufficient competence and structures within the company to prepare SDSs. However, it is an important finding that every fifth company (19%) has outsourced the elaboration/preparation of their SDSs to external contractors. This fact is unsurprising due to the increased information obligations under REACH (see Diagram 6 in Annex 3).

The large majority of companies (78%) that were checked for the issue (n=1 101) had the necessary systems for distributing SDSs to their customers/recipients fully in place. Sufficient structures were completely missing in only a small number of cases (6%). However, this subject should still be followed up since shortcomings in SDS provision may disrupt the information flow in the entire supply chain. A very small group of companies (2%) appeared to have no legal requirements to provide SDSs and, accordingly, had no structures for the purpose in place (see Diagram 7 in Annex 3).

Companies distribute SDSs by several means to their recipients/customers: on paper, electronically, via links to websites, through commissioned external contractors and others. The main method of provision is in paper form (69%); however, this often occurs in combination with an electronic distribution of the SDSs (54%). The proportions of SDS provision channels used are given in Diagram 8 in Annex 3.

One in every three companies (35%) inspected on this issue (n=938) had obligations to provide sufficient information about substances and/or mixtures placed on the market for which an SDS is not required (Article 32 of REACH). Concerning this aspect, inspectors found nearly all companies to be compliant (95%). An overview of reported obligations for companies is given in Diagram 9 in Annex 3. Diagram 10 in Annex 3 shows the compliance rates among companies of different sizes.

One of the crucial provisions of REACH (Article 36) and CLP (Article 49) is to keep an archive of all required information available over a period of at least 10 years.

From the entirety of the sample (1 018), four out of five companies (80%) were found to have adequate structures/instruments in place to enable archiving and fulfilling the information duties in line with the REACH and CLP regulations (see Diagrams 11 and 12 in Annex 3).

The results also indicate that companies with good systems and structures (i.e. established management system) are more likely to fulfil the existing information duties along the supply chain.

3.8 Details regarding the quality of the information in the SDSs (Annex II of the REACH Regulation)

Almost all conducted inspections during the campaign included an SDS assessment (94%). Inspectors omitted checks mostly due to the fact that an obligation to provide an SDS did not exist for the company (4%). (Table 8).

Table 8: Performed SDS checks (n=1 112).

Type of SDS check	Number	% of total inspections
full check	1 009	85%
partial check	103	9%
no check since company had no obligation to provide SDS	42	4%
no for other reasons	27	2%

According to the provisions of REACH Article 31 (5) and (6), SDSs have to be available in the national language and contain 16 mandatory sections. Of the 1 104 companies checked for this issue, 86% were fully compliant, 9% partially compliant and 5% entirely non-compliant (see Diagram 13 in Annex 3). In comparison to the compliance rate of 81% determined during the REACH-EN-FORCE-1 project, the results indicate an improved situation.

The content of SDSs was assessed with regard to sections 1, 2, 3, 8 and 15 and defects of various types and extent were found. Deficiency rates for the individual sections range from 11% to 18% (Table 9).

Table 9: SDS quality assessment (Annex II REACH). Compliance rate by selected headings. Number of inspections with SDS checks = 1 112 (= 94% of conducted inspections).

SDS heading	assessed number of SDSs	total deficient	
		number determined	%
SDS heading 1 - identification subs/mix, company	4 205	474	11
SDS heading 2 - hazard identification	4 313	552	13
SDS heading 3 - information on composition, ingredients	4 143	574	14
SDS heading 8 - exposure controls, personal protection	3 760	671	18
SDS heading 15 - regulatory information	4 063	483	12

During the course of the SDS evaluation, the question was posed whether or not companies were using the new format according to Regulation (EU) No 453/2010 when preparing their SDSs for substances. This question was addressed during more than half of all SDS-inspections (561 cases). It was found that in 52% of the checks, companies already had the SDSs prepared in compliance with the new format. In 9% of the cases, the SDSs were partially available in the new format. In 4% of the cases, the new format was not used despite being required (see Diagram 14 in Annex 3).

The number of SDSs evaluated for correspondence of Section 15 (S15) or Section 2 (S2) of the SDS with the label was 938 and in 222 cases (24%) inspectors detected deficiencies (see Diagram 15 in Annex 3).

During the inspections, Section 3 of the SDS was also checked in 965 cases and inspectors evaluated the verification of correspondence between information in the SDS and composition. In 88% (846) of the reported cases, companies did verify correspondence between information and composition whereas in 12% (119) of the reported cases they did not. Detailed information on the rates of verification of correspondence between information in the SDS and composition by company size is given in Figure 4.

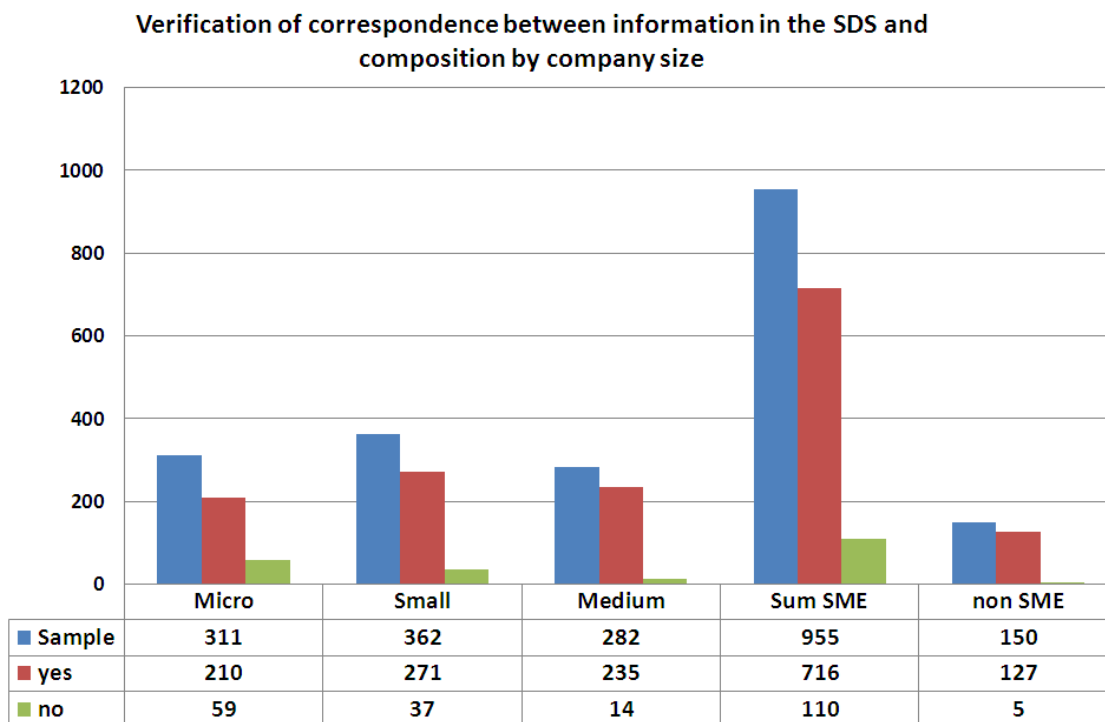


Figure 4: Rates of verification of correspondence between information in the SDS and composition by company size.

3.9 Details regarding downstream user obligations (Title V of the REACH Regulation)

One of the enforcement issues dealt with was the obligations for the manufacturing and formulating companies to ensure that the workers have access to relevant information from SDSs/exposure scenarios. Since the tasks regarding occupational health are often the responsibility of the occupational authorities, the inspections were carried out in cooperation with OHS. Due to the fact that in some cases joint inspection could not be performed with inspectors from occupational authorities on the production site, the number of inspected companies was 757. The outcome of this is that 64% of all inspections performed included downstream user obligation checks. Detailed information on answers to the checklist with regard to checks on downstream user obligations are given in Figure 5.

DU obligation checks performed on the production site

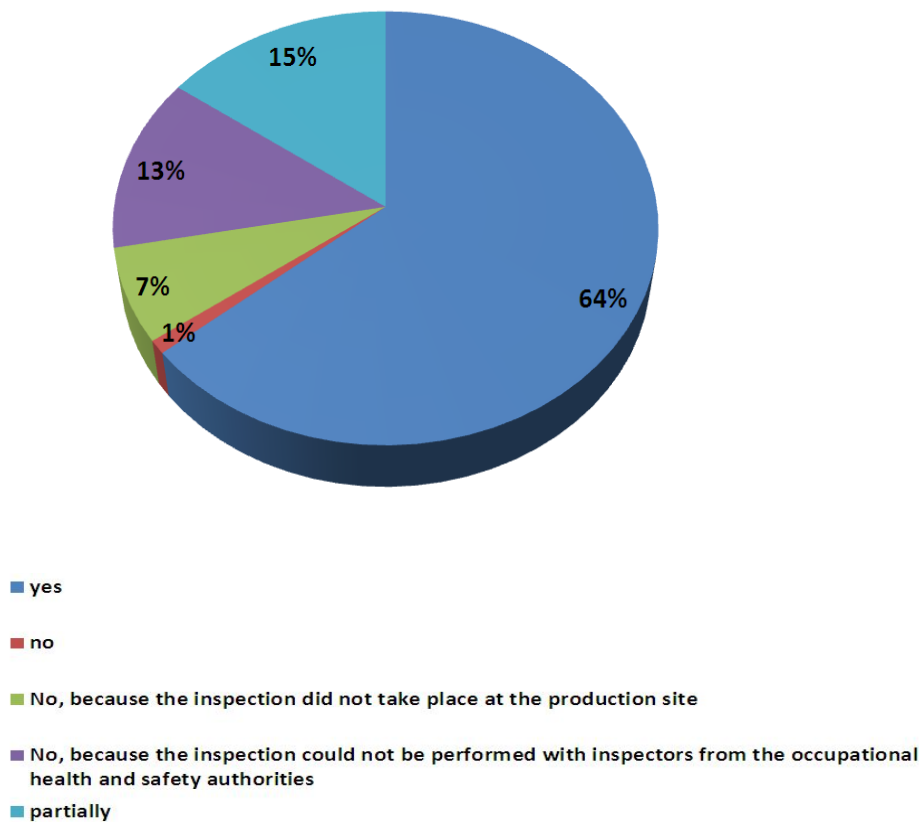


Figure 5: Proportion of downstream users obligations checked at the production site.

Relevant information from SDSs/exposure scenarios accessible for the workers.

The findings show that formally - in 855 cases (93% of the checked group, n=932) the workers have access to relevant information, but with more in depth examination about workers' access in practice - the rate was significantly lower - 713 cases (79%) (see Diagrams 16 and 17 in Annex 3).

Compliance with measures recommended in SDSs/exposure scenarios.

Another aspect is whether the companies comply with the risk management measures (RMMs) recommended in the SDS/exposure scenarios. For about 69% of 664 checked companies, the implementation of RMMs was confirmed. In every fifth case, no exposure scenario was required at the time of inspection (Figure 6).

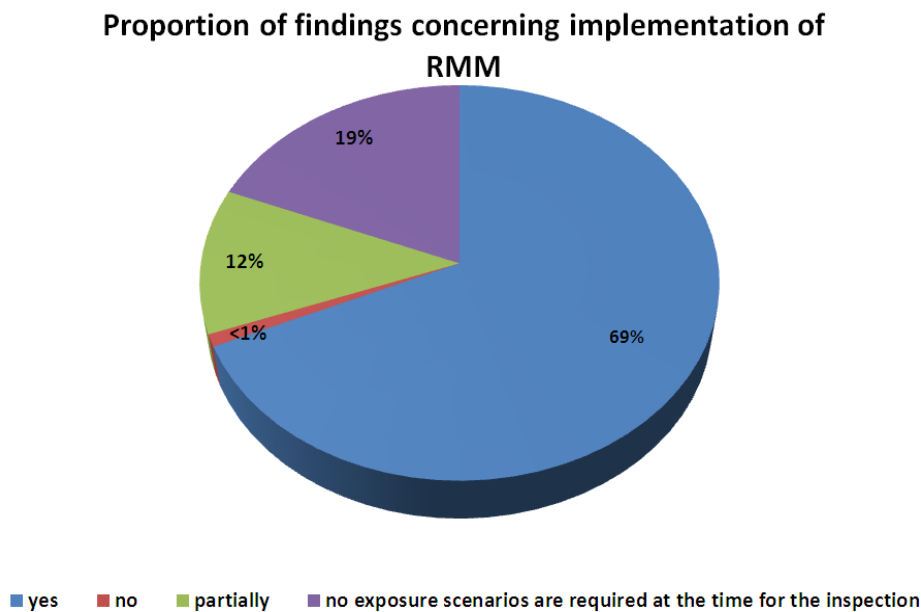


Figure 6: Proportion of findings concerning implementation of RMMs.

Figure 7 demonstrates the implementation of RMMs in companies by size groups. The implementation of RMMs differs between SME and non-SME companies. RMMs were implemented in 379 SMEs, which is 48% of all SME enterprises (551), where the issue was investigated. Implementation of RMMs in non-SME companies was confirmed in 78 cases, which is 57% of all non-SME enterprises (113), where the issue was investigated.

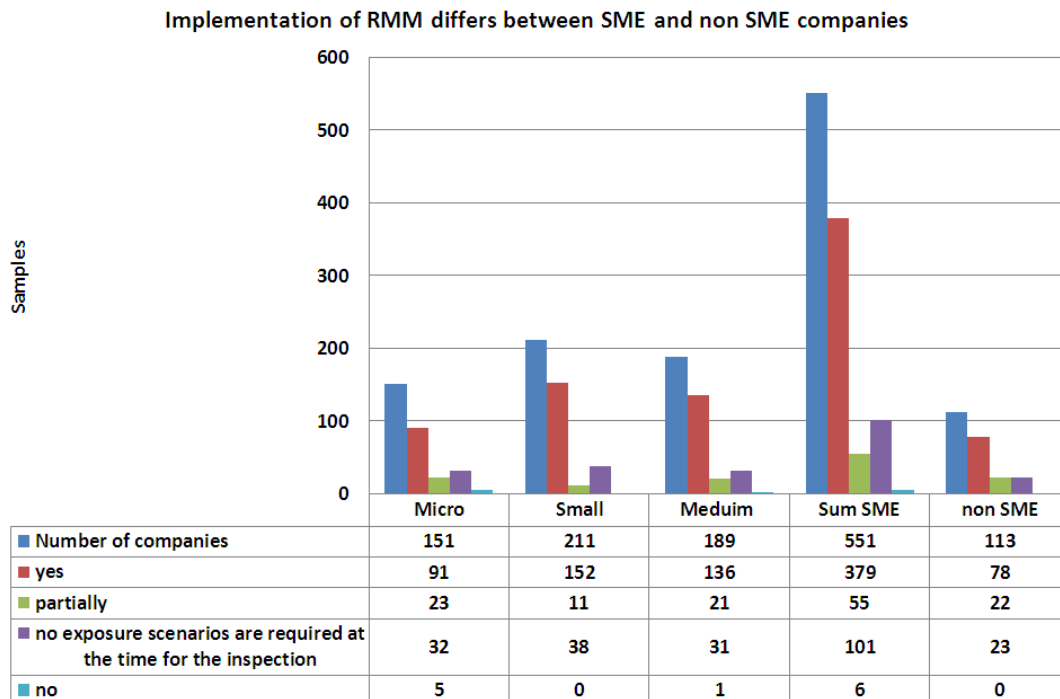


Figure 7: Implementation of RMMs in companies by size.

Considerations: It may be too early to expect that identified uses and RMMs should be implemented at the time the inspections were performed due to the transitional period given in REACH.

3.10 Non-compliance issues and measures taken

Inspectors reported that two thirds of surveyed enterprises (67%) violated provisions of the relevant chemicals legislation to various extents.

As demonstrated in the previous chapters of this report, non-compliance included for example:

- not fulfilling the obligation to register and/or notify substances according to the REACH/CLP Regulation,
- using unregistered substances when formulating mixtures,
- not meeting the information obligation concerning products that contain dangerous substances, e.g. lacking required SDS entirely or submitting SDS with deficient information,
- failing to adequately inform workers about risks,
- missing a sufficient archiving infrastructure.

The comparison by size shows the highest rate of infringements in the group of micro-sized enterprises (73%), while the lowest rate occurred in medium-sized enterprises, nevertheless indicating non-compliance at more than every second company in this group (55%).

Not all infringement types occur with the same frequency. SDSs with deficient information were reported for more than half of the companies checked (52%, n=1 112). Quality problems were observed in the companies of all size categories at very similar rates.

The second most frequent problem for companies turned out to be the collection and long-term storage of information on the manufactured, imported and used substances and mixtures. In every fifth case (20%), companies showed insufficiencies in fulfilling these duties in line with the provisions of REACH Article 36 and CLP Article 49.

Violation of provisions related to registration (REACH) and notification (CLP) requirements were less frequent. The use of unregistered substances in mixtures by formulators was observed at a relatively low percentage (13%) within the total inspected sample and companies that failed to submit mandatory notifications to the C&L inventory occurred at approximately the same rate (15%). Although only a portion (~ 30%) of all companies were inspected concerning the latter issue, available data suggested better compliance with increasing company size.

Certain violations appear to be typical for companies of particular size classes. By tendency, smaller companies exhibit increased rates of problems related to managing information and providing good quality information on the properties of chemicals downstream. Micro-sized companies were found to have the highest proportions of missing SDSs (50%). On the other hand, larger companies appear to have increased compliance problems related to the issue of registration and notification of substances. As the results show, significantly more than half of all cases of registration contraventions (57%) were detected in the group of non-SME companies.

The rates of violations detected in SME and non-SME companies are shown in Table 10.

Table 10: Violation types and rates in SME and non-SME companies.

Type of violation	Number cases	Cases SME	%	Cases non SME	%
Failure to register	21	9	<1	12	8
Using unregistered substances in mixtures	131	106	12	23	16
Failure to notify to C&L inventory	42	36	20	6	6
Required SDS missing	56	52	5	4	3
Deficient information in SDS	580	498	52	77	51
Information obligations acc. Art. 32 REACH not met	18	16	2	2	2
No access to relevant information for workers	91	83	11	8	6
insufficient archiving infrastructure/ instruments	205	185	21	18	14
Other shortcomings	179	154	15	25	16
Violations overall	789	678	67	104	65

% is calculated as a total number of cases checked in this issue per size category

In reaction to contraventions, inspectors imposed various measures such as: verbal or written advice, administrative orders, orders, enjoiments, fines, criminal complaints and others. Written advice was given in every second case (51%). Verbal advice was chosen less often (43%), e.g. in cases of misdemeanours such as a single shortcoming in one SDS section or in the label. If more severe offenses comprising of several deficiencies were detected, more formal measures such as orders, administrative orders, enjoiments, fines and criminal complaints were taken. Follow-up activities were reported for one third of the inspections (34%). A quantitative overview of measures imposed by authorities due to offenses identified is given in Figure 8.

Types of measures imposed by authorities on non-compliant companies

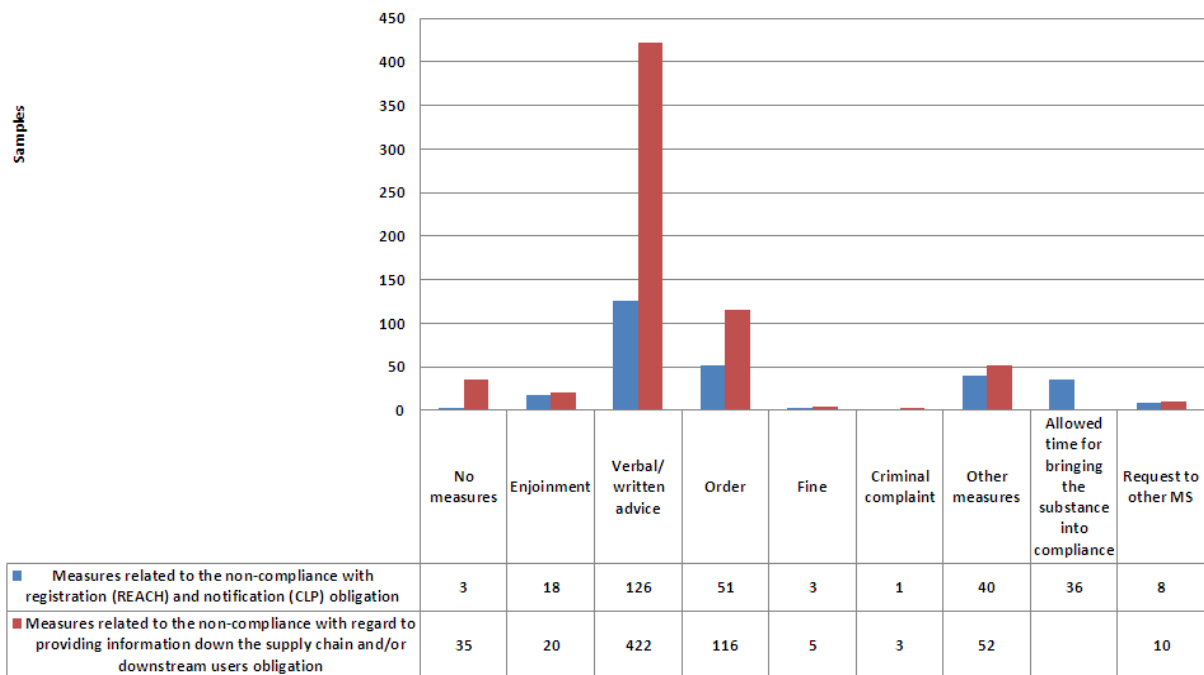


Figure 8: Types of measures imposed by authorities on non-compliant companies. Quantitative overview (n=789).

Table 11 gives a more detailed picture of the reaction of the enforcement authorities to occurring offenses. The obtained project reports partly link single infringement types directly with particular measures that were reactively imposed by the authorities. This applies to the failure to register, the use of unregistered substances and the failure to make C&L notifications.

In addition a bulk analysis for the aforementioned three types of offenses was made. This assessment links the accumulated number of non-compliant companies with the total array of measures reported for this sub-sample of inspections (166 cases). The results show that authorities generally impose measures and sanctions moderately as the most frequent reactions are advice (76%), orders (31%), other measures (24%) and allowing time to establish compliance (22%). In contrast, fines were rarely being imposed.

For all other frequently detected offenses in companies, a direct link to specific measures cannot be established, due to the design of the inspection report that was used. Nevertheless, available data from 623 inspections allowed a summarised correlation of measures taken and found violations of duties with regard to providing information down the supply chain and/or implementing risk reduction measures on site.

Table 11: Measures imposed by authorities in reaction to detected violations of REACH and/or CLP provisions.

Infringement category	n	No measures		Allowed time for bringing the substance into compliance		Enjoinments		Other measures		Advice (verbal, written)		Fines		Orders		Criminal complaints		Request to other MS	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
non-compliance over all	789	38	5	47	6	38	5	92	12	548	69	8	1	167	21	4	1	18	2
Failure to comply with obligations related to the registration (REACH) and notification (CLP) of substances: (itemised and accumulated cases)																			
– failure to register	21			5	24	2	10	14	67	21	100	0	0	5	24	0	0	4	19
– using unregistered substances in mixtures ¹	131	3	2	34	26	11	8	29	22	69	53	1	1	19	15	1	1	3	2
– failure to notify to C&L inventory ²	32	2	6	1	3	4	13	1	3	19	59	2	6	12	38		0	1	3
non-compliance pertains to (and/or):																			
– registration, notification and/or use of non-registered subs ³	166	3	2	36	22	18	11	40	24	126	76	3	2	51	31	1	1	8	5
Failure to carry out duties with regard to providing information down the supply chain and/or implementing risk reduction measures on site: (accumulated cases)																			
– required SDSs missing – deficient information in SDS – information obligations acc. Art 32 REACH not met – no access to relevant information for workers – insufficient archiving infrastructure/instruments – other defects	623	35	6			20	3	52	8	422	68	5	1	116	19	3	0	10	2

n: sample size #: cases reported

% s.i.c.: percentage of the total number of cases in the infringement category

1: imposed "enjoinment", "advice" and "orders" cumulated over all offenses where measures not explicitly linked to a certain offense

2: includes only MIOR-companies with no further offense related to the (pre-)registration status of managed substances (n = 42 for all detected violations of notification rules)

3: accumulated cases

4. Overall conclusions

The REF-2 project has demonstrated the existence and effective operation of a system of official controls throughout the EU Member States pursuant to Article 125 of REACH. The participation of 29 Member States shows that the Member State authorities have a high level of interest in the enforcement and implementation of the provisions of the REACH and CLP regulations.

Being the second common campaign initiated and coordinated by the Forum, the project served to further advance a harmonised enforcement approach within the Member States zone.

Essential requirements provided by the REACH and CLP regulations have been covered (downstream user obligations, SDS management, CLP notification, (pre-)registration of substances).

The large number of inspections carried out (1 181) and the substantial amount of data obtained on the issues covered, constitute a representative sample that allows a realistic portrayal of the level of compliance amongst downstream user companies in relation to the legal provisions.

On the whole, the project results show that a significant number of downstream users still appear to be insufficiently aware of their obligations, as two thirds of the inspected enterprises were failing to comply with REACH/CLP provisions. To a certain extent, core principles of REACH/CLP were violated, as obliged companies both unlawfully manufactured/imported substances or missed notifying substances to the C&L inventory. Thus, companies have to significantly increase their efforts to respect the applicable chemicals legislation.

There are indications that certain types of infringement are associated with the size of companies. Problems related to information management and providing good quality information on the properties of chemicals downstream seem to be typical for smaller companies, whereas larger companies exhibit compliance problems related to the issue of registration and notification of substances. However, SDSs of insufficient quality were found in every second company, regardless of size.

Clearly, industry must step up their stewardship of SDSs to establish compliance in this area of responsibility. The issue will also have to be subject to intensified monitoring by the authorities in the future.

In reaction to contraventions, inspectors have taken various measures, e.g. verbal or written advice, administrative orders, injunctions, fines, criminal complaints and others. Nevertheless, according to the reports, authorities generally impose measures and sanctions moderately and proportionally, often with companies being given time to establish compliance as well as rarely imposing fines.

The project is a successful continuation of a main activity of the Forum. It promotes the establishment of a level playing field, due to the harmonised approach followed in the Member States and cooperation between Member States (cross-border administrative assistance) as well as providing important lessons and conclusions for future projects.

5. Recommendations

Recommendations are based on the experience of the members of the Working Group as well as on the results of the project and the feedback in the questionnaire from the national coordinators.

5.1 Recommendations to the Forum

Coordination

- Continued coordination of enforcement projects is highly recommended as it contributes to the harmonisation of REACH and CLP enforcement strategies throughout the Member States.
- Organisation of a general information campaign for duty holders before the next enforcement project would be highly recommended.
- A project newsletter could be issued during the next project. A newsletter for inspectors would inform them on the work done, might lead to a deeper involvement in the project, and make them aware of the European scale.
- Promotion of exchange of inspectors, i.e. within the frame of REACH-EN-FORCE projects should be considered.
- Joint inspections by occupational health and chemical inspectors should be encouraged, where appropriate.

Future Projects

- Future projects might be elaborated on the basis of major public health, occupational health and environmental risks and a general estimation of the likelihood of non-compliance.
- Pilot projects would be beneficial to the success of subsequent coordinated enforcement projects.
- Manuals could benefit from more clarity through being more concise, containing less legislative information, and having visual aids such as flowcharts or diagrams. All questions in questionnaires should offer standardised answering options that provide the basis for the project's data collection and are subject to analysis and extraction of the results by the project steering group. Free text responses have proven to be helpful for reporting purposes on a national level but are unsuitable for general statistics. Thus, the free text responses should not be collected by the project steering group of the Forum.
- Awareness raising campaigns addressed to industry should focus on the supplier's obligation to provide SDSs and labels in the appropriate national languages.
- Recommended topics for future REACH-EN-FORCE projects: inspections on the content of SDSs, classification of mixtures, projects pertaining to the control of restrictions/articles/extended SDSs/exposure scenarios.
- Working Groups, responsible for future enforcement projects, may assist enforcers with strategic advice on how to select companies for the survey.

Exchange of information

- National coordinators should establish a communication channel with inspectors participating in the project in order to provide them with information and explanatory material concerning the project and to organise their training throughout the entirety of the project.
- Exchange of information with the Exchange Network on Exposure Scenarios (ENES) regarding extended SDS obligations would be recommended. Articles 37(5) and (6) obligations were checked within the REACH-EN-FORCE-2 project. Nevertheless, during the operational phase of the project, in early 2011, formulators in many cases did not receive an exposure scenario attached to the SDS. Additionally, according to Article 39 downstream users shall be required to

comply with the requirements of Article 37 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet. Therefore within the REACH-EN-FORCE-2 project, inspectors raised the awareness of companies on these obligations.

- Creation of a helpline for inspectors might be worth considering, with the purpose of helping to resolve specific cases, including additional expertise to assist in the identification and classification of substances and mixtures. The Electronic Information Exchange System (EIES) (until further notice RIPE is the interim messaging tool for fulfilling the purpose of EIES) might be a good way to stimulate communication and discussion. However, the helpline was recommended by inspectors involved in the project.
- Efforts should be made to ensure, as far as is reasonably practicable, that enforcing authorities cooperate and exchange information with:
 - a) enforcing authorities or competent authorities in other Member States,
 - b) the European Chemicals Agency.
- Matters of concern identified through REACH and/or CLP inspection activities that relate to the compliance of duty holders based in other Member States should be communicated to the national coordinator who will then inform the NEA focal point/Forum Member and request further contacts with NEA focal points/Forum Members in other Member States.

Reporting Tool

- A uniform data entry tool for reporting was used to aid the REF-2 project and proved to be beneficial for obtaining standardised reports. Adopting and optimising the method of building standard data entry templates for future enforcement projects would contribute to reducing reporting efforts for the Member States as well as the Forum and facilitate increased project efficiency.
- The reporting tool should be elaborated in parallel with the manual and questionnaire and a separate training or webinar for national coordinators should be organised.
- Questionnaires and manuals should be provided in national languages.

Training

- Case studies proved to be very useful at the training for REF-2 national coordinators and also in trainings at national level. The development of these cases by the Forum WG was highly appreciated. Continuation of this service by future REF WGs is highly recommended.
- Training of inspectors in regards to exposure scenarios, extended SDSs, assessment of identified use and compliance with risk management measures in SDSs/exposure scenarios should be considered as a topic for future 'Train the Trainers' events.

5.2 Recommendations to ECHA

- Compliance promotion would be recommended i.e. actions for providing education and building expert and administrative/managerial capacity, addressed both to companies and to enforcers.
- ECHA and especially industry are encouraged to continue providing support to companies in SDS matters upon request.
- The continuation of the 'Train the Trainers' event is highly recommended. Webinars for inspectors on the regional level would also be worth considering.
- ECHA and the MSCAs might consider an improvement of communication in terms of interlinks with NEAs. An initiative to provide more in-depth information about legal obligations of suppliers of extended SDSs would be beneficial.

5.3 Recommendations to enforcement authorities and inspectors

- An increasing number of Forum initiatives, coordinated actions and pilot projects will facilitate attainment of the objectives of REACH and CLP.
- Enforcement authorities in Member States should arrange their budgetary plans, and their human and financial resources in a way that enables and encourages active participation of national inspectors in the above mentioned initiatives and Forum projects. Member States should ensure that appropriate resources are available for REACH and CLP inspections and that inspectors have suitable qualifications.
- Good cooperation and information exchange is needed between the enforcement authorities on a national level.
- The cooperation between authorities enforcing REACH and CLP in different Member States should be further strengthened, in order to facilitate the enforcement of companies active in several Member States.
- Training of regional inspectors by the national coordinator within Forum projects is quite often realised as a two-level training – NCs train inspectors at a regional or at a provincial level. Those persons are then responsible for training colleagues at a local level. Situations might occur in which not every inspector on the local level involved in the project is well trained, due to administrative burdens and budgetary constraints. For future projects it would be advisable to organise broader training for bigger groups of inspector on the national level, including those from local levels. It would be helpful to let them directly discuss the content of the project with the NCs, not only via phone and email, but also during the realisation of the project.
- The inspection reports should be properly recorded in writing and kept in an accessible and retrievable format to enable re-use and re-analysis of data even after the conclusion of the operational phase.
- Continuous education and training is required for the involved inspectors due to the broad range of obligations that need to be checked, and due to the regular updating and revision of EU and national legislation.
- Inspectors performing inspection activities should proceed exactly with the directions set in the project manual.
- The role of the company under REACH should be precisely defined. It is noteworthy to state that in the case of projects devoted particularly to a specific part of the supply chain (REF-2: downstream users, formulators of mixtures), inspectors should make sure that the inspected company is representing a suitable target group.
- The size of the company according to Commission Recommendation 2003/361/EC should be carefully checked by inspectors.
- Training of inspectors with regard to exposure scenarios, extended SDSs, assessment of identified use and compliance with risk management measures in SDSs/exposure scenarios should be considered as a topic of possible training on the national level, maybe in cooperation with the national helpdesks.

5.4 Recommendations to industry

- Awareness and knowledge on REACH among smaller downstream user companies is sometimes very low or even non-existent. This is a matter of concern and should be monitored. Industry should focus on further knowledge-building within companies concerning REACH and CLP.
- A common issue found within the REACH-EN-FORCE-2 project was poor quality of safety data sheets. There is a common difficulty in getting good quality SDSs from suppliers; obtaining SDSs in the national language also seems to be problematic. Therefore, companies should pay more attention to the communication within the supply chain.
- Stakeholder organisations on a national and international level should intensify their support and information provision on the REACH and CLP obligations, especially towards downstream users and SMEs, i.e. with the support of helpdesks or HelpNet.
- ECHA and industry are invited to provide further guidance to companies.

- Companies are encouraged to gain deeper knowledge through periodic consultation of the ECHA website and clarify their doubts regarding REACH and CLP obligations with helpdesks, ECHA or the competent authorities.
- Companies should consider the implementation of document management systems.

Industry is invited to keep track and further raise awareness on SDSs and extended SDSs as being central risk management tools with a view to disseminating good practices within the supply chain (SDS-stewardship).

Annex 1

List of the relevant Community legal acts

Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Council Directive 79/831/EEC of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste.

Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

Regulation (EC) No 1893/2006 of the European Parliament and of the Council of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains Text with EEA relevance.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Annex 2

Questionnaire on the Forum project REACH-EN-FORCE 2 2010/2011

Forum project on the enforcement of the obligations of downstream users - formulators of mixtures in 2010/2011

Questionnaire No.

1. Section – General Information (questions 1.2 to 2.5 will not be on the web portal)	
1.1. Participating country:	
1.2. Authority: Person in-charge: Telephone: Fax: E-Mail:	Only for internal use – do not submit data
1.3. Date of inspection:	
1.4. File reference:	

2. Section - Information about the Monitored Company	
- Name of company: Street: Postal code, place: Telephone: Fax: E-Mail:	only for internal use – do not submit data
- Workplace-number:	only relevant for internal use if other documentation systems exists
- Name of the contact person:	only for internal use – do not submit data
- Function of the contact person:	only for internal use – do not submit data
- Other discussion participants: Name: Function: Name: Function:	only for internal use – do not submit data
- Remarks	
- NACE-Code of company:	
- Role of the company under REACH (multiple responses possible, since companies can have many parallel roles) <input type="checkbox"/> Downstream User (E g: formulator, end user) <input type="checkbox"/> Distributor <input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input type="checkbox"/> Only Representative	
Remarks:	
- Definition of the company according to Commission Recommendation 2003/361/EC <input type="checkbox"/> Micro <input type="checkbox"/> Small <input type="checkbox"/> Medium <input type="checkbox"/> Not SME <input type="checkbox"/> Not known Micro: <10 employees and ≤2 million euro annual turnover Small: <50 employees and ≤10 million euro annual turnover Medium: <250 employees and ≤50 million euro annual turnover	

<p>- Total number of checked mixtures, formulated and placed on the market, by the inspected company:</p> <p>- Total number of checked SDSs of mixtures, formulated and placed on the market by the inspected company:</p>	
<p>a) Total number of checked substances (on their own or in a mixture) that are manufactured, imported or used in mixtures by the inspected company:</p> <p>b) Total number of checked SDSs for substances (Only substances manufactured or imported) and placed on the market by the inspected company: Note: Do not include the SDSs checked in section 5</p> <p>c) <input type="checkbox"/> No substances are manufactured or imported by the inspected company.</p>	
<p>3. Section – Company within the Scope of the REACH / CLP Regulation: Registration / Notification</p>	
<p><u>Subsection A</u> - Company’s general obligation to register and notify</p> <p>Has this section been checked at the inspected company?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially</p>	
<p>3.1. Does the company manufacture / import substances as such or in mixtures?</p> <p><input type="checkbox"/> Yes, substances as such <input type="checkbox"/> Yes, substances in mixtures <input type="checkbox"/> No</p> <p>Remarks:</p>	<p>Note: Only import from non-EEA States (specifically, physical introduction into the customs territory of the community) are considered as Import</p>
<p>3.2. If the company manufactures/imports substances as such or in mixtures in quantities of 1 tonne or more per year, have the required pre/registrations been submitted to ECHA?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially _____ of the _____ required pre/registrations have been submitted to ECHA.</p>	<p>Note: REACH, Article 6, paragraph 1: The obligation to register substances as such or in a mixture from 1 tonne/year (if no exemption applies)</p> <p>For further guidance see enclosure.</p>

<p>3.3. If the company manufactures/imports substances as such or in mixtures, have the required C&L notification(s) been submitted to the inventory at ECHA?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> Yes, given in the REACH registration</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Partially _____ of the _____ required notifications have been submitted to ECHA.</p>	<p>Note: Classification and labelling inventory, Article 39-42 in the CLP regulation. There is no tonnage threshold for notification of C&L under CLP as it is in REACH. For further guidance see enclosure.</p>
<p><u>Subsection B</u> – Registration status of substances used in checked mixtures Has this section been checked at the inspected company?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Partially</p>	
<p>3.4. Are the substances, used in formulation of the mixtures, pre-registered/registered?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Partially _____ substances of _____ checked are not pre registered/registered</p> <p><input type="checkbox"/> The inspected company could not get this information from the supplier.</p> <p><input type="checkbox"/> The inspected company did not know about this requirement and doesn't know if the substances used are pre-registered/registered.</p> <p><i>If the substances used are not pre-registered/registered, why?</i></p> <p><input type="checkbox"/> The substances are exempted from registration</p> <p><input type="checkbox"/> Other</p> <p>Remarks:</p>	<p>Note: Exemptions from registration. Article 2, para 1, 2, 3, 5, 6, 7 Article 9 Article 15 para 1,2 Exemption from registration due to special use is only valid if the substance is used exclusively for the mentioned purposes. Re-imports are exempted from registration under certain conditions. Substances resulting from recovery processes are exempted from registration under certain conditions</p>
<p>3.5. Has the company ensured that all substances they receive have been pre-registered/registered?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p>	<p>Note: When a downstream user does not have the knowledge of the registration number of the substance(s) he uses, he has to ask for it from his supplier (<i>upstream</i> the supply chain).</p>

<p>3.6. In case of registered substances, are the uses identified for the formulator's mixture matching the intended uses included in the registration of the substances?</p> <p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not checked <input type="checkbox"/> Not applicable </p>	
<p>4. Section - Details regarding Information Obligations in the Supply Chain (Title IV REACH Regulation)</p> <p>This section refers to information in the supply chain with regard to substances (manufactured or imported) / mixtures formulated and placed on the market by the inspected company.</p> <p>Has this section been checked at the inspected company?</p> <p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially </p>	
<p>4.1. Does the company have the <i>required</i> Safety Data Sheets (SDSs) for the <i>checked</i> substances / mixtures it formulates and places on the market?</p> <p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially (please give numbers under "Remarks") <input type="checkbox"/> Not checked </p> <p>Remarks: _____ of _____ checked substances/ mixtures do not have the required SDSs.</p>	<p>Note:</p> <p>"Partially" means that not all required SDS are available.</p>
<p>4.2. Does the company have structures/instruments, which make the preparation of SDSs in accordance with the REACH Regulation possible?</p> <p> <input type="checkbox"/> Yes, within the company <input type="checkbox"/> Yes, the company has commissioned external contractors to prepare SDSs. </p> <p> <input type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Not required <input type="checkbox"/> Not checked </p> <p>Remarks:</p>	<p>Note:</p> <p>If the company has internal structures and instruments in place (e.g. software, expert staff) which make a preparation in conformity with REACH possible, answer "Yes, within the company"</p> <p>If the company does not compile the SDSs itself and has contracted the task to external experts instead, respond "Yes, the company has commissioned contractors..."</p> <p>Mark the "Partially" box, if for example structures/ instruments are under construction.</p>

<p>4.3. Does the company have structures/instruments, which makes the distribution of SDSs in accordance with the REACH Regulation possible?</p> <p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Not required <input type="checkbox"/> Not checked </p>	<p>Note: Article 31.8 and 31.9 E.g.: Does the company have files and/or software available which includes all former recipients to whom it has supplied the substance or mixture. Mark the “Partially” box, if for example structures/ instruments are under construction. </p>
<p>4.4. How does the company provide their customers with SDSs?</p> <p> <input type="checkbox"/> On paper <input type="checkbox"/> Electronically (pdf attached) <input type="checkbox"/> Link to a website where SDSs are located <input type="checkbox"/> Other <input type="checkbox"/> Through commissioned external contractors. <input type="checkbox"/> Not required (since there are no requirements for SDSs for the substances / mixtures placed on the market) <input type="checkbox"/> Not checked </p>	<p>Note: According to Article 31.8 a safety data sheet shall be provided free of charge on paper or electronically. Note: Single answer option! E.g. If the company has commissioned external contractors no other option should be crossed. </p>
<p>4.5. Does the company fulfil the requirements in Article 32 for substances on their own or in mixtures, which the company places on the market and for which a SDS is not required?</p> <p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially (please give numbers under “Remarks”) <input type="checkbox"/> Not required <input type="checkbox"/> Not checked </p> <p>Remarks: _____ of _____ checked substances/mixtures are not ok</p>	<p>Note: Article 32 <i>Duty to communicate information about:</i> Registration number Authorisation Restriction Risk management measures <i>This information is only required if at least one of the three options (authorisation, restriction, RMM’s) is fulfilled.</i> </p>
<p>4.6. Does the company have structures/instruments to keep all the required information available, for carrying out its duties under the REACH Regulation, over the minimum period of 10 years after the last manufacture, import, supply or use of a substance or mixture?</p> <p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Not checked </p>	<p>Note: Article 36 in the REACH regulation. Mark the “Partially” box, if for example structures/ instruments are under construction. </p>

5. Section – Obligations under Title V – Downstream Users

This section can only be checked if the inspection takes place at the production site. **Some companies have subcontracted the production which means that the real production takes place at another company.**

Since the tasks regarding/with respect to the occupational health often are the responsibility for the occupational authorities, the inspections might have to be carried out in cooperation with them.

Has this section been checked at the inspected company?

- Yes
- No, because the inspection did not take place at the production site.
- No, because the inspection could not be performed with inspectors from the occupational health and safety authorities
- Partially

5.1. **Do the workers at the inspected company have access to the relevant information from the SDSs/exposure scenarios etc. provided in accordance with Articles 31 and 32 for substances and mixtures they use or may be exposed to in the course of their work?**

- Yes
- No
- Partially
- Not checked

Is this information accessible in real practice?

- Yes
- No
- Partially
- Not checked

Note:
Article 35
 It is preferable to have the information from SDSs /exposure scenarios etc. available in paper format (numerically/alphabetically etc so that workers know how to retrieve them) or electronically, for example on the company's computer. It is not advisable for workers to have to look through suppliers websites or CDs for the info they require in an emergency

It is appropriate for the inspector to check that real access is possible.

5.2. **Does the company comply with the measures recommended in the SDSs/exposure scenarios?**

- Yes
- No
- Partially
- No exposure scenarios are required at the time for the inspection.
- Not checked

Note:
Article 37.5 and 37.6
 Inspectors should enforce the implementation of risk managements measures identified in the SDS under appropriate legislation such as national implementations of directives (89/391/EEC and 98/24/EC).

6. Section - Details regarding the quality of the information in the SDSs
(Annex II REACH Regulation)

Note: The project only includes checking of the SDSs of substances (manufactured or imported) / mixtures formulated and placed on the market by the inspected company.

If the inspected company manufacture or import substances / formulate mixtures which do not contain hazardous substances and thus has no obligation to provide SDSs, use answering option No 3 below and then continue to Section 7.

Has this section been checked at the inspected company?

- Yes
- No
- No, because the company has no obligation to provide SDSs
- Partially

According to the Commission Regulation (EU) No 453/2010, potentially, there will be up to 3 “Valid” formats of SDSs on the market during the operational phase of this project.

[Current Annex II, 1st new Annex II, second new Annex II].

6.1. Do the checked SDSs prepared by the inspected company fulfil the requirements of Article 31 paragraph 5 and 6?

- Yes
- No
- Partially (please give numbers under “Remarks“)
- Not checked

Remarks: _____ SDS(s) _____ of checked SDS(s) are not correct
(e.g. SDS under revision)

Note:
“Partially” should be crossed if SDSs are not available in an official language of the Member State or contains no date or obligatory headings are missing (Article 31 paragraph 5 and 6)
“No” should be crossed if more than one obligation given in Article 31 paragraph and 6 are not fulfilled.

<p>6.2. Are the checked SDSs prepared by the inspected company compiled in the new format according to Regulation (EU) No 453/2010?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No (though they should have been)</p> <p><input type="checkbox"/> Partially (please give numbers under "Remarks")</p> <p><input type="checkbox"/> Not required (since the mixtures were provided to any recipient at least once before the 1st December 2010)</p> <p><input type="checkbox"/> Not checked</p> <p>Remarks: _____ substance(s) / mixture(s) SDSs of SDSs checked are not compiled in the new format even though they should be.</p>	<p>Note: Article 2.6 in EU 453/2010: Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, for substances which are placed on the market before 1 December 2010 and which are not required to be relabelled and repackaged in accordance with Article 61(4) of Regulation (EC) No 1272/2008, the safety data sheet need not be replaced with a safety data sheet complying with Annex I to this Regulation before 1 December 2012.</p> <p>Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, for mixtures which are placed on the market before 1 June 2015 and which are not required to be relabelled and repackaged in accordance with Article 61(4) of Regulation (EC) No 1272/2008, the safety data sheet need not be replaced with a safety data sheet complying with Annex II to this Regulation before 1 June 2017.</p> <p>Article 2.7 in EU 453/2010: Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, safety data sheets for mixtures provided to any recipient at least once before 1 December 2010 may continue to be used and need not comply with Annex I to this Regulation until 30 November 2012.</p>
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<p>6.3. Does the information in the checked SDSs fulfil the requirements of the REACH regulation with amendments regarding:</p> <p>a) Heading / Section 1, Identification of the substance/mixture and of the company undertaking?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially (please give numbers under "Remarks") <input type="checkbox"/> Not checked</p> <p>Remarks: _____ SDS(s) of _____ checked SDS(s) are not complete or are incorrect</p> <p>b) Heading / Section 2, Hazard identification?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially (please give numbers under "Remarks") <input type="checkbox"/> Not checked</p> <p>Remarks: _____ SDS(s) of _____ checked SDS(s) are not complete or are incorrect</p> <p>c) Heading / Section 3, Composition/information on ingredients?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially (please give numbers under "Remarks") <input type="checkbox"/> Not checked</p> <p>Remarks: _____ SDS(s) of _____ checked SDS(s) are not complete or are incorrect</p>	<p>Note: For guidance on questions 6.4 a – 6.4e, see enclosure.</p>
<p>d) Heading / Section 8, Exposure controls/personal protection?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially (please give numbers under "Remarks") <input type="checkbox"/> Not checked</p> <p>Remarks: _____ SDS(s) of _____ checked SDS(s) are not complete.</p> <p>e) Heading / Section 15, Regulatory information?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially (give numbers under "Remarks") <input type="checkbox"/> Not checked</p> <p>Remarks: _____ SDS(s) of _____ checked SDS(s) are not complete or are incorrect</p>	

<p>6.4. Does the information on the label correspond to the information in Heading / Section 15, or in Heading / Section 2 for SDSs compiled according to Regulation (EU) 453/2010?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Partially (please give numbers under "Remarks") <input type="checkbox"/> Not checked</p> <p>Remarks: For _____ SDS(s) of _____ checked SDS(s) the information on the label does not correspond to the information in the SDS.</p>	<p>Note: In SDSs compiled in the new format according to Regulation (EU) No 453/2010 this information shall be placed in heading 2.</p>
<p>6.5. Does the company have management procedures to ensure that composition of substances / mixtures are in compliance with the information given in SDSs, e.g. heading 3?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not checked</p>	<p>Note: E.g.: Does the company have procedures to update the SDSs when changes in the composition of a product have been accomplished.</p>
<p>7. Section – Summary / Follow-up Action</p>	
<p>7.1. Has non-compliance with REACH / CLP obligations subject to this project been determined? (multiple responses possible)</p> <p>OBSERVE! Only the inspected company's non-compliance with REACH obligations shall be filled out! E.g.: If supplier's SDSs are found to be non-compliant, this information should <u>NOT</u> be filled out here!</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, with regard to</p> <ul style="list-style-type: none"> <input type="checkbox"/> Obligations to register, in case they also have an importer/manufacture role (violation against Article 5) <input type="checkbox"/> Using substances in their formulations that are not registered, although they should be <input type="checkbox"/> Obligation to notify to classification and labelling inventory <input type="checkbox"/> Preparation of SDS <input type="checkbox"/> Information when SDS is not required <input type="checkbox"/> Information to workers <input type="checkbox"/> Obligation to keep information <input type="checkbox"/> Information in the SDSs <input type="checkbox"/> Other defects: <p>Remarks:</p>	

7.2. Measures imposed due to non-compliance with REACH obligations subject to this project? (multiple responses possible)

- No measures
- Verbal advice
- Written advice

- Administrative order
 - Order
 - Enjoinment
- Fine
- Criminal complaint / Handing over to public prosecutor's office
- Others

- Follow up activities finished or Follow up activities still on going

Remarks:

7.3. With reference to question 3.2:

In case a substance (manufactures or imported by the inspected company) is found not to be registered though, it should have been, which measures where imposed by the inspector?

- Enjoinment
- Allowed time for bringing the substance in compliance
- Other measures

7.4. With reference to question 3.4:

In case a substance (used in mixtures by the inspected company) is found not to be registered though, it should have been, which measures where imposed by the inspector?

- Enjoinment
- Allowed time for bringing the substance in compliance
- Other measures

7.5. Have any cases been forwarded to other Member States?

- No
- Yes, to:
 - National Competent Authority
 - Forum Member
 - National coordinator

Enclosure to the Annex 2:

Item no. 6.3 a)-e)

Item no. 6.3

Some of the requirements in Annex II to the REACH regulation, with amendments, have been chosen to be checked within the frame of the project. To include all headings / sections in Annex II would not have been possible.

The chosen checkpoints are given beside the question in the questionnaire but also in this enclosure.

You find all requirements for the compilation of SDSs according to the REACH regulation with amendments:

here **(for the former format)**: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20090220:EN:PDF>

and here **(the new format)** : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:133:FULL:EN:PDF>

6.3 a)

Heading / Section 1

Identification of the substance/mixture and of the company/undertaking

Requirements to control:

- The name of the substance /mixture
- Use(s) of the substance/mixture
- Company identification: The person responsible for placing the substance or mixture on the market within the community (EU). Give the full address and telephone number of this person as well as the e-mail address of the competent person responsible for the SDS
- Emergency telephone

6.3 b)

Heading / Section 2

Hazards identification

Requirements to control:

- Classification of the substance/mixture
- Description of the most important adverse physicochemical, human health and environmental effects and symptoms

Note:

In SDSs compiled in the new format according to (EU) No 453/2010 also control the requirements for information about the label elements.

6.3 c)

Heading / Section 3

Composition/information on ingredients

Requirements to control:

- Substances with concentration range
- Classification of the substances
- Name and registration number of the substances

Note:

In SDSs compiled in the new format according to (EU) No 453/2010 control the requirements that the substances are classified according to Directive 67/548/EEC, including indication of danger, symbol letter(s) and R phrases, as well as according to Regulation (EC) No 1272/2008, including the hazard class(es), category code(s) and the hazard statements.

6.3 d)

Heading / Section 8

Exposure controls/personal protection

Requirements to control:

- Exposure limit values
 - Occupational exposure controls (respiratory/hand/ eye and skin protection)
- CEN standards are required for all PPE (Personal Protection Equipment) listed and for gloves breakthrough time and type of material are required.

6.3 e)

Heading / Section 15

Regulatory information

Requirements to control:

- Relevant Community safety, health and environmental provisions.
- National laws of the relevant Member States which implement these provisions.
- If the substance or mixture covered by the SDS is the subject of specific provisions (such as authorisations or restrictions) these provisions shall be mentioned.

Note:

For SDSs compiled according to the "old" format given before 1st of December 2010 control the requirement:

That the health, safety and environmental information shown on the label according to Directives 67/548/EEC and 1999/45/EC is given in this heading.

Annex 3

Supplementary diagrams

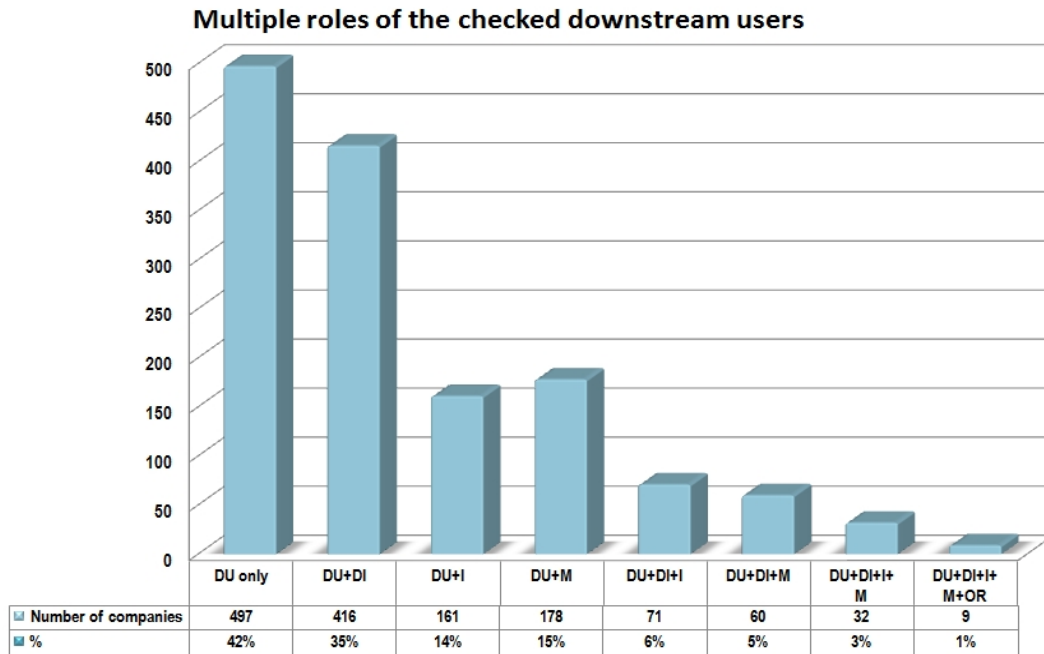


Diagram 1: Proportions of multiple roles of checked downstream user companies (n=1 121).

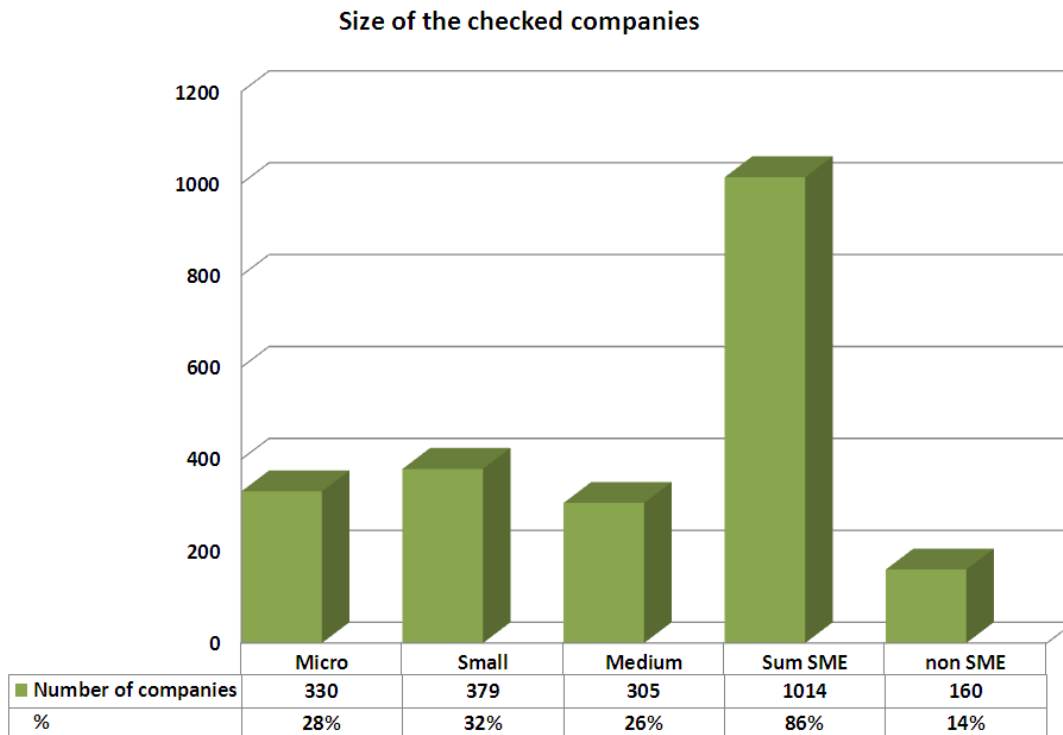


Diagram 2: Proportion of companies according to their size (n=1 174).

Checked companies according to the statistical classification of economic activities (NACE)

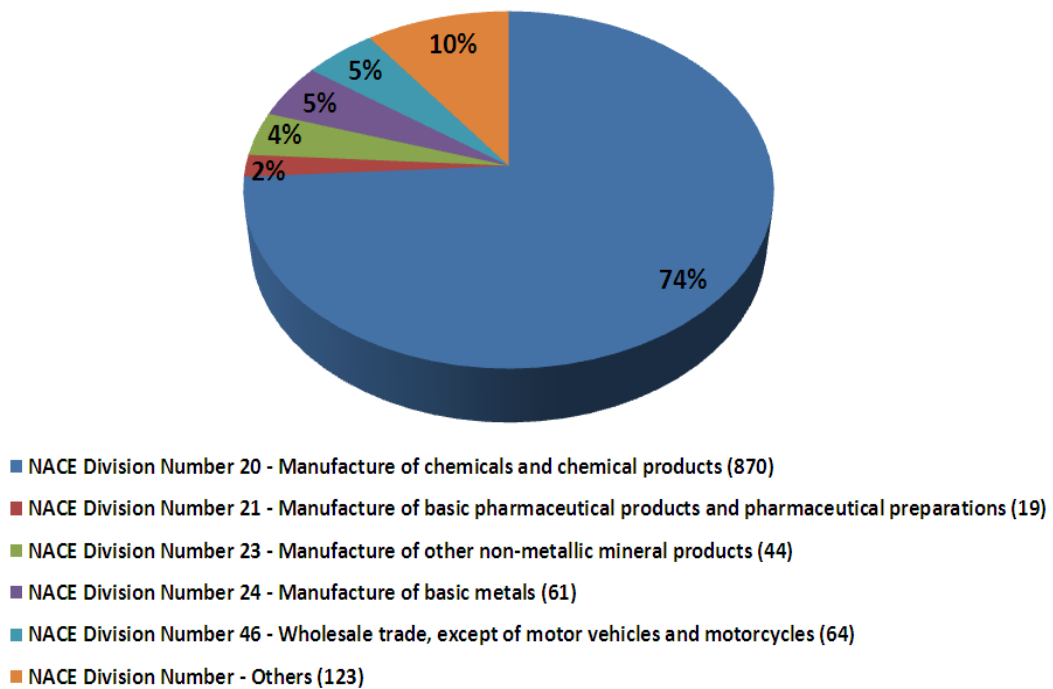


Diagram 3: Proportion of companies according to the statistical classification of economic activities (NACE) (n = 1 181).

Registration duties and compliance by company size

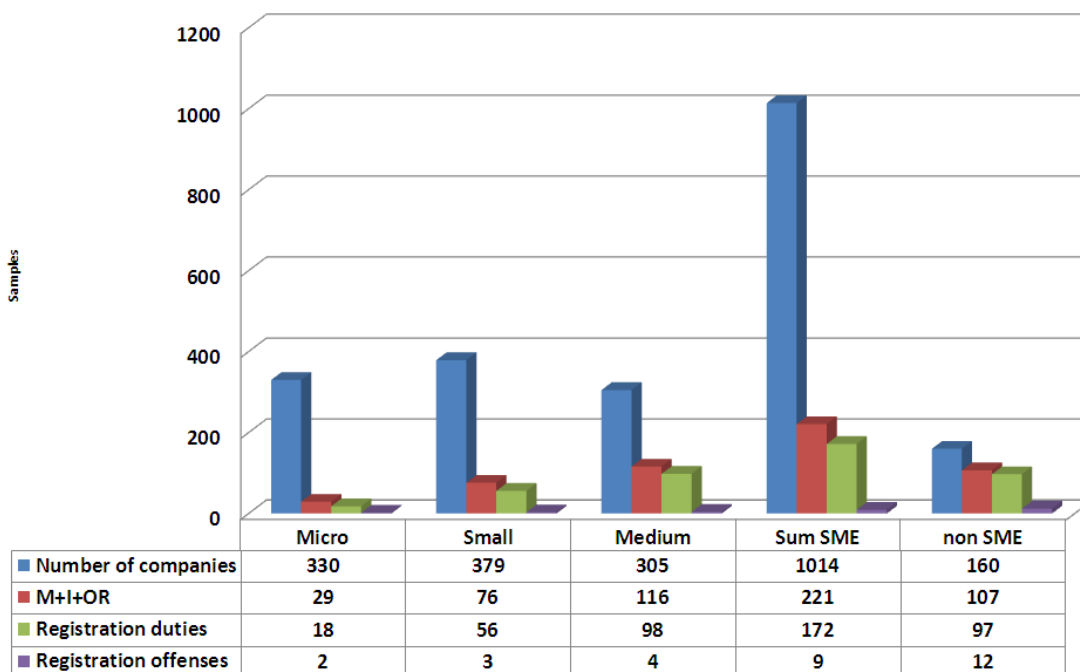


Diagram 4: Registration duties and compliance by company size (obliged companies).

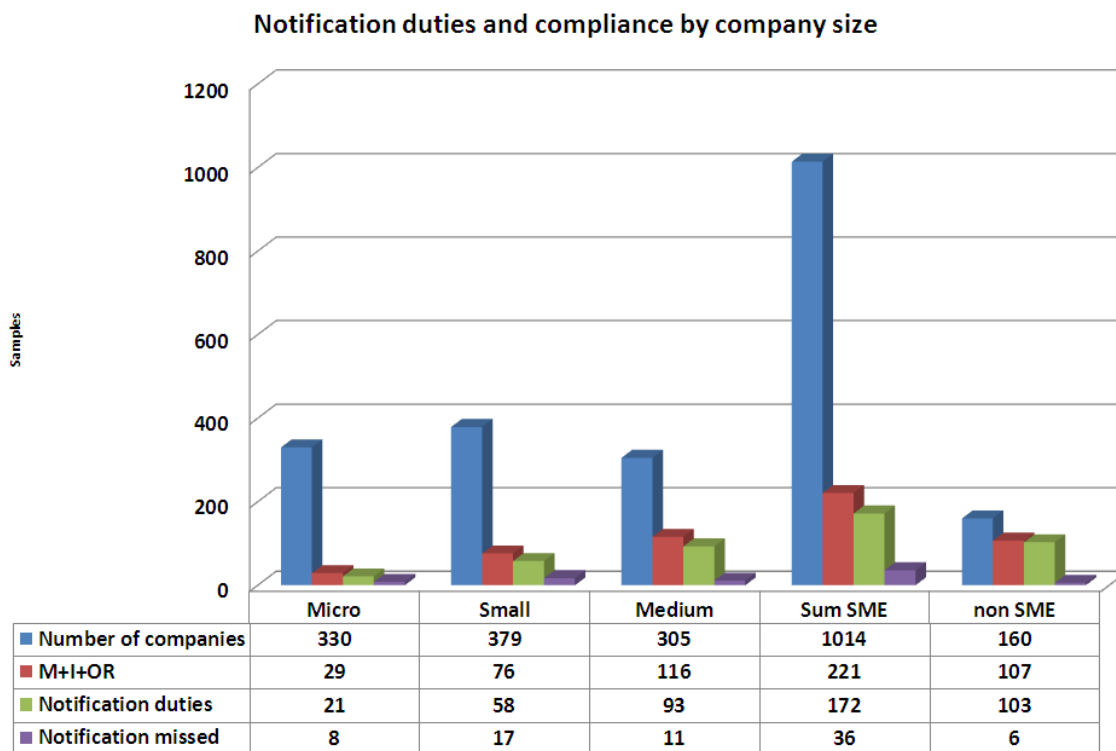


Diagram 5: Notification duties and compliance by company size (obliged companies).

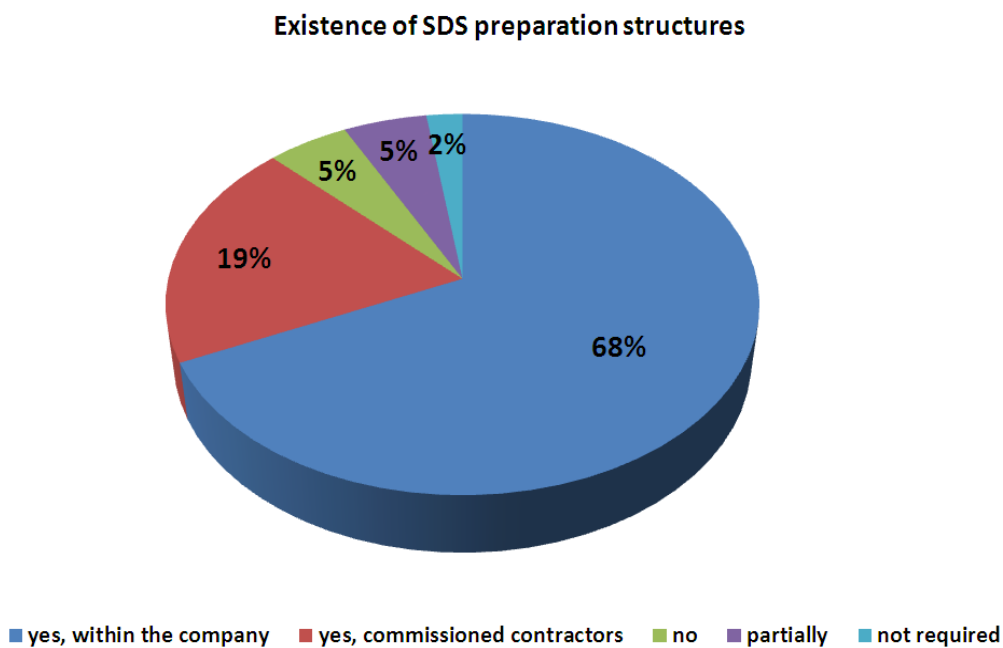


Diagram 6: SDS preparation structures in companies.

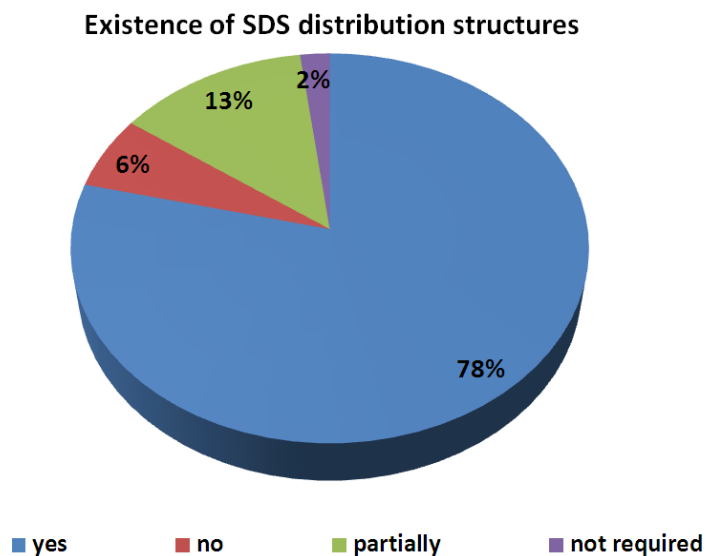


Diagram 7: Existence of structures for SDSs distribution (n = 1101).

Dominant means of SDS provision. Comparison of companies by size categories.

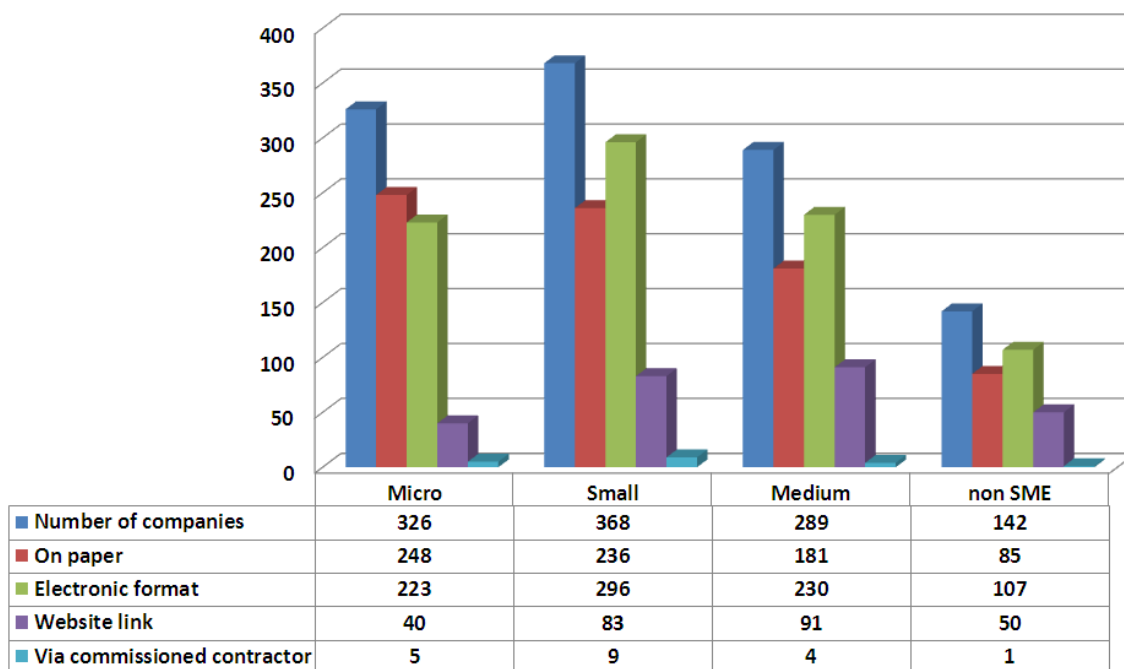
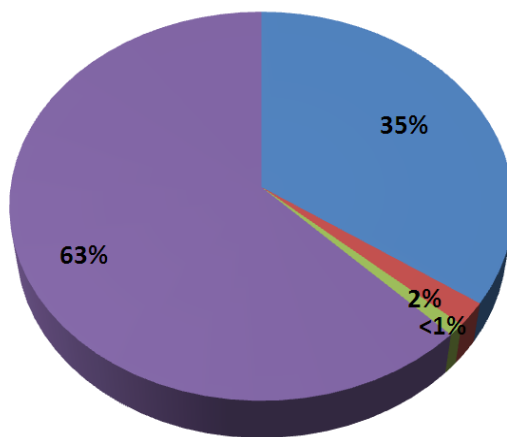


Diagram 8: Means of SDS provision. Comparison of companies by size.

Information provision obligation in accordance with Art.32 of REACH



■ yes ■ no ■ partially ■ not required

Diagram 9: Information requirements provided by Article 32 of REACH (n = 938).

Non compliances with regard to obligation of the art.32 of REACH by company size

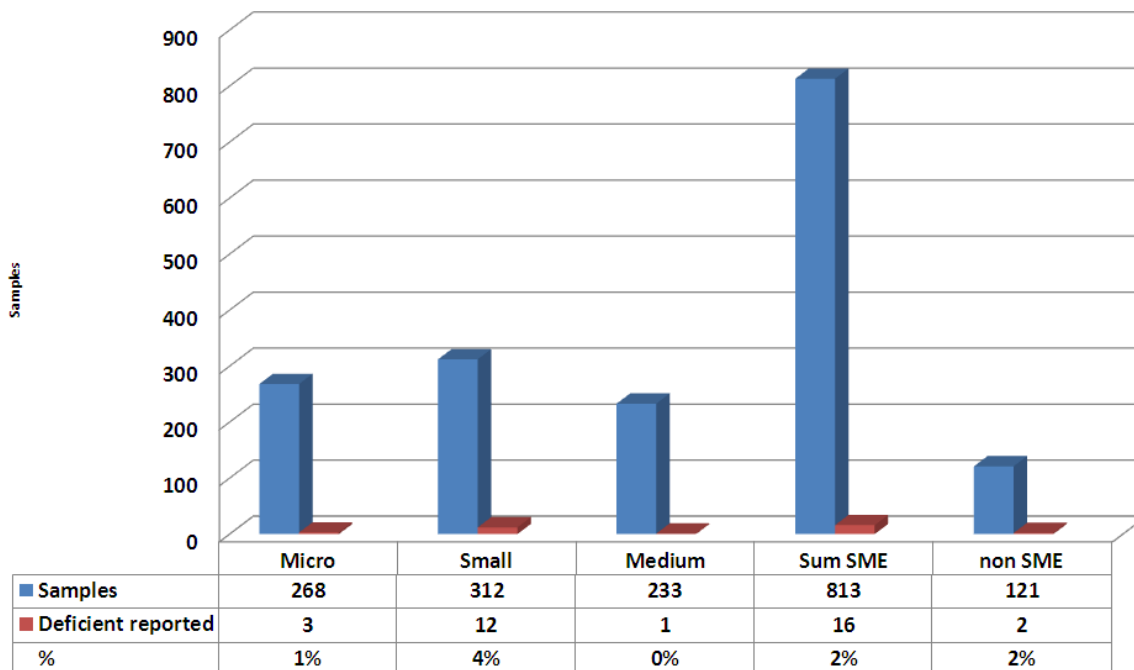


Diagram 10: Compliance with requirements provided by Article 32, REACH. Comparison of companies by size.

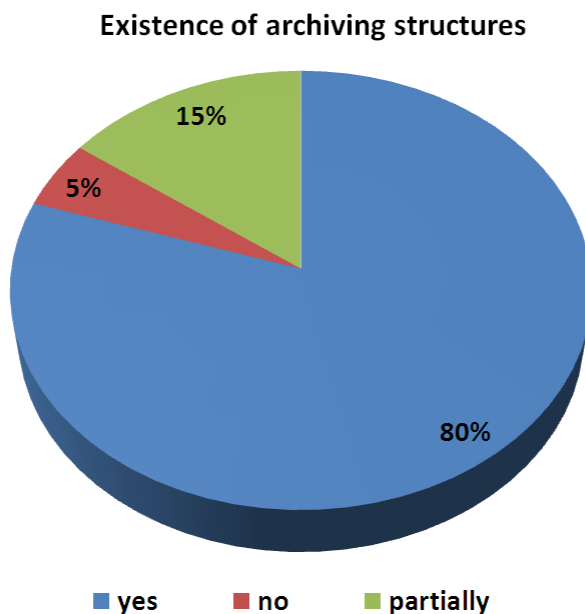


Diagram 11: Compliance with obligation to archive (n = 1018).

Compliance with the requirement to keep and archive information in regard to the size of the companies

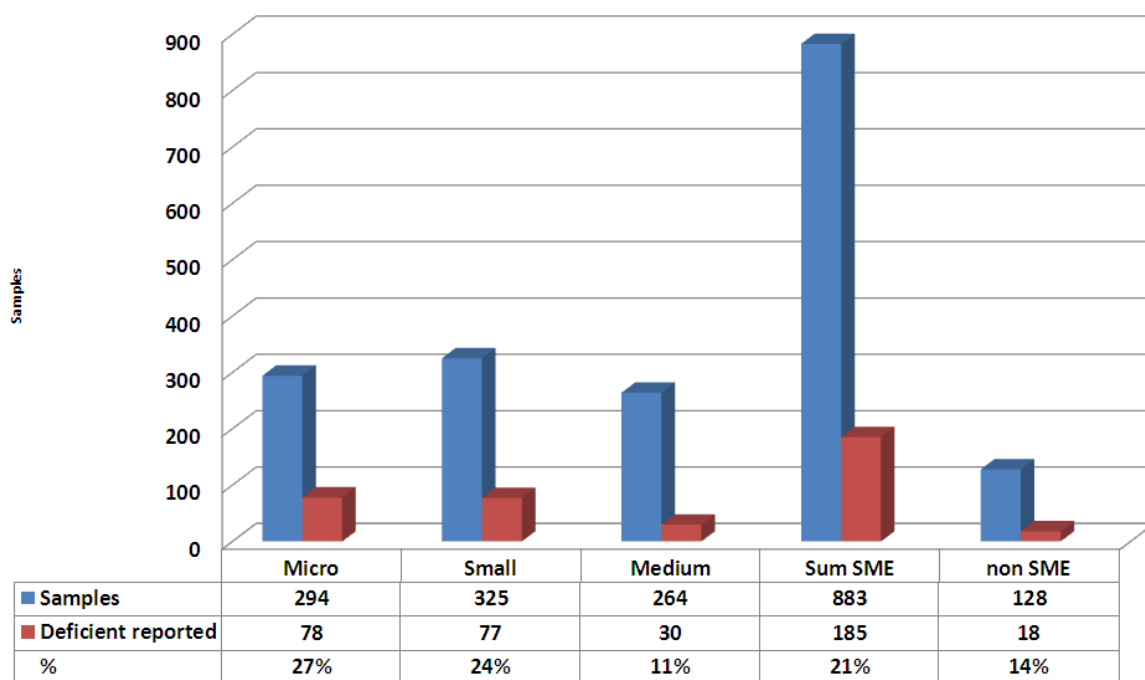


Diagram 12: Compliance with REACH (Article 36) and CLP (Article 49) among companies of different sizes.

SDS comply with REACH article 31.5 and 31.6

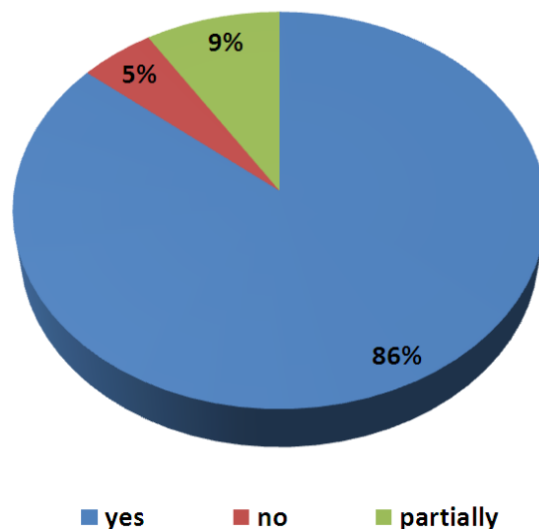


Diagram 13: Proportion of SDS compliant with REACH articles 31.5 and 31.6 (n=1104).

New format of SDS for substances in the checked companies

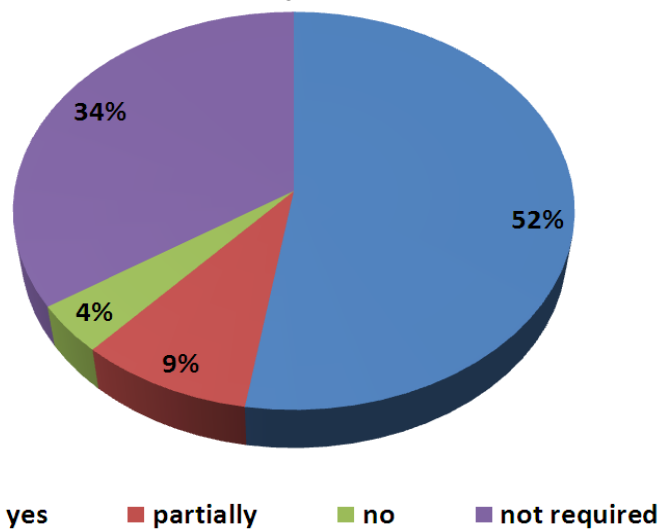


Diagram 14: Presence of SDS for substances in the new format acc. Regulation (EU) No 453/2010. Sample size = 561 (52% of conducted SDS-inspections).

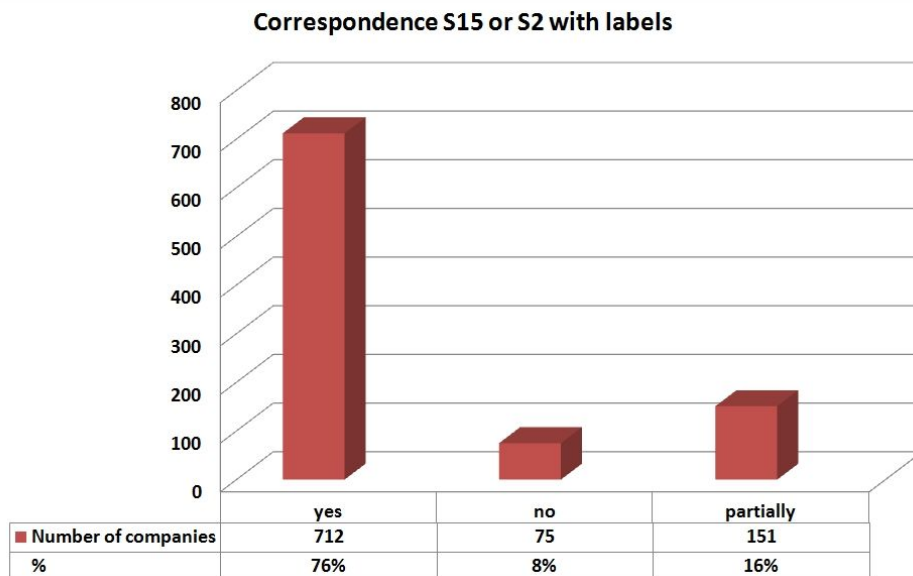


Diagram 15: Proportion of inspections where inspectors evaluated correspondence of Section 15 or Section 2 of SDS with the label.

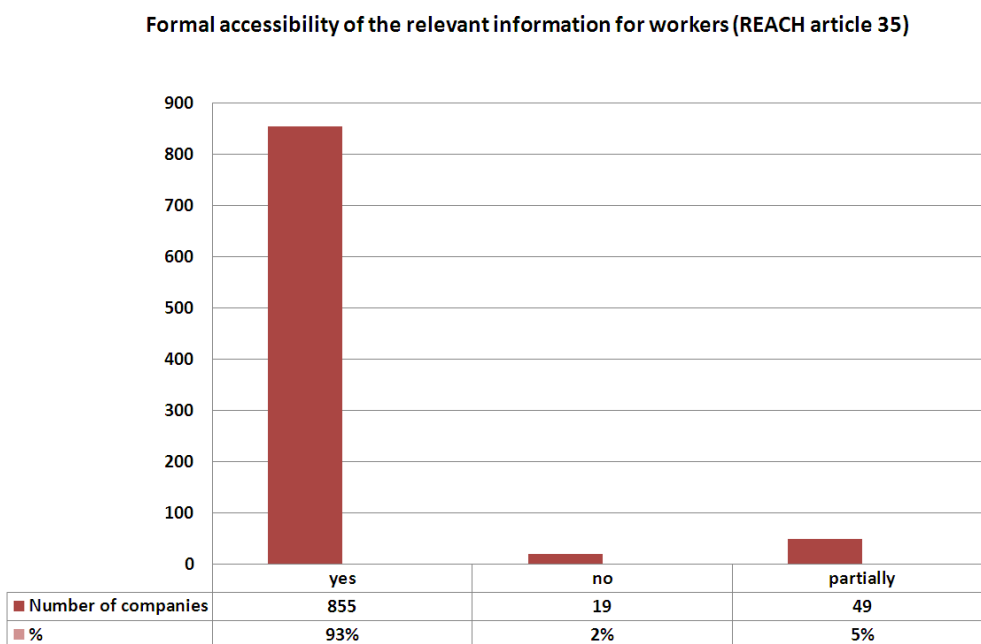


Diagram 16: Proportion of formal accessibility of relevant information (REACH article 35) to workers (n = 923).

Accessibility of relevant information for workers (REACH article 35) in practice

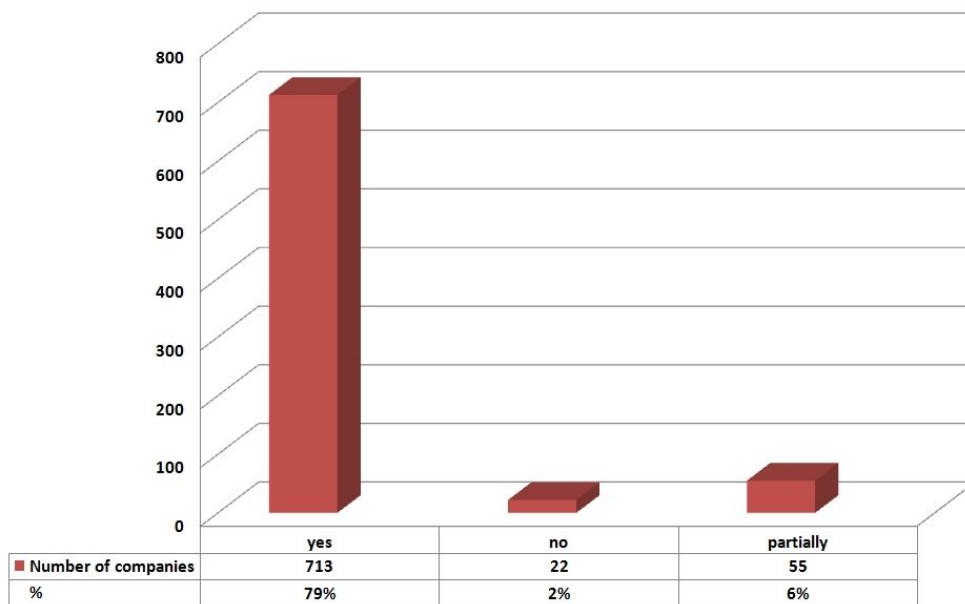


Diagram 17: Proportion of accessibility of relevant information (REACH article 35) to workers in practice.