

Forum REACH-EN-FORCE 3 – Phase 1 Project Report

Inspection and enforcement of compliance with
registration obligations by manufacturers, importers and
only representatives in close cooperation with customs



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1. Executive summary

REACH-EN-FORCE-3 is the third enforcement project of the Forum and encompasses the “Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs”. The focus of the inspection has been on the registration duties of Article 5 and 6 of the REACH Regulation (EC) No 1096/2006 and, in particular, the principle “No data, no market”. The inspection phase in the 28 participating countries lasted between February 2013 and August 2013 with 528 company inspections being carried out, covering an average of 6 substance inspections per manufacturer, importer and only representative (3 065 substances in total).

In a novel and broad approach, all participating countries have utilised data on substances and mixtures from import declarations (typically an annual data set of predefined CN¹ codes from various chapters of TARIC has been in use) to target their inspections of importers and only representatives. This data was gathered through cooperation with customs and in 85% of the participating countries the REACH enforcement authorities used the customs data provided them, while in 15% of countries, the risk assessment for targeting individual duty holders was performed by customs themselves. Companies with mainly an importer role (64%) and small and medium enterprises (67%) have been inspected.

As regards the economic group „manufacture of chemicals“, such companies represent about half of the inspected companies (53%) and are typically large companies. 30% of inspected companies fall into the economic group of retail and are typically small and medium sized enterprises. Based on the average numbers² of manufactured or imported substances per inspected company in the tonnage band above 1 tonne/year, REACH-EN-FORCE-3 inspections checked the compliance of relevant duty holders, with the number of substances manufactured or imported by a company ranging between 22 and 134 depending on the duty holder’s specific use profile. It was found that more than 50% of the companies inspected benefit from exemptions of their registration duty, mainly due to the phase-in status of substances and due to substances listed in Annex IV/V of REACH.

84% of the inspected companies have already filed a registration or a pre-registration while 55% of mostly large companies have already registered a substance (on average 19 registrations per company). 29% of companies have only pre-registered so far.

As a consequence of the enforcement project’s focus, the emphasis during inspections has been on importers (64%) and imported substances (71%). Manufacturers have been targeted in only 29% of the inspections. Inspections at only representatives have been clearly under-represented (7%) during phase 1 of the enforcement project which is also a major reason for the extension of inspection activities into 2014 during phase 2 of the REACH-EN-FORCE-3 project.

A 14% non-compliance rate was identified with respect to the registration duties of inspected companies. A missing registration is the most frequent reason for companies not being in compliance with registration duties. From the 528 companies inspected, 3% have been identified as “free-riders” who have not registered any of their substances requiring registration.

¹ CN: The CN comprises the first 8 digits of the 10-digit TARIC Goods Code, see code in the database TARIC: http://ec.europa.eu/taxation_customs/dds2/taric/

For classification of chemicals in the CN the European Customs Inventory of Chemical Substances ECICS is available: http://ec.europa.eu/taxation_customs/dds2/ecics

² The average number of manufactured or imported substances per inspected company is estimated based on the information given by the inspected companies: the total number of manufactured or imported substances / substances in mixtures for all inspected companies divided by the number of inspected companies.

It was also found that 5% of inspected substances are non-compliant and 3% of the substances lack the required registration. Moreover, within the top 12 substances of highest incident rate, 4 substances have hazardous properties. Missing registrations have also been found for 2 substances from the Substances of Very High Concern (SVHC) Candidate List.

As has been identified already in previous REACH-EN-FORCE projects, non-compliance rates for companies are higher for small and medium sized enterprises (17%) compared to larger companies (6%). When analysing companies holding different (single/multiple) REACH roles, only representatives show the highest non-compliance rate (25%) compared to importers (15%) and manufacturers (7%). The highest rate of non-compliance (43%) is found in the group of only representatives performing this one role only.

A breakdown of non-compliance within an economic sector reveals that in general the “non-classical” chemical business shows higher incident rates (22%), while the “classical” manufacturers and distributors of chemicals are more compliant (11%). However, a more detailed analysis clearly indicates that core chemical manufacturing and distribution businesses (NACE divisions 20 and 46) have non-compliance rates higher than the mean value while, for example, manufacturers of mineral products and metals show better compliance than the average.

In general, the priorities of enforcement authorities have not been limited to using the enforcement method of sanctioning by imposing fines and initiating criminal complaint procedures on identified registration contraventions (11% each). Rather, the focus has been on first hand risk reduction measures. The reactions of enforcement authorities in cases of non-compliant companies have been focused on immediate actions by advising (71% of cases) or ordering remediation (32% of cases) and thus restoring to compliance the respective company and substance. Due to the complex regulatory nature of the cases, a focus of enforcement has also been to act beyond short term administrative measures and to commence in 37% of cases various kinds of follow-up activities.

The overall conclusion of the REACH-EN-FORCE-3 project is that there is a considerable number of non-compliant companies that do not fully observe REACH registration obligations. Moreover, it has been confirmed that importing companies need more attention as they are less compliant than manufacturers. The project has identified only representatives as a group specifically at risk of non-compliance with their registration duties. For this reason the Forum and Member States have decided to extend the enforcement project with further inspections in 2014. Special attention also needs to be drawn to economic sectors not belonging to “classical” manufacturers and distributors of chemicals. However, it must be noted that there is no indication of a systematic breach with the legislation and there is a low number of identified “free-riders” that do not register their substances at all.

REACH-EN-FORCE-3 has proven that REACH enforcement authorities in the 28 participating countries have established a functioning cooperation with customs. This allows enforcement authorities to make use of data from individual customs declarations in their routine inspections of REACH duties. The project design and the actual inspections in the participating countries have been successful in implementing harmonised, focused and balanced enforcement activities with regards to REACH registration duties. Consequently, this has contributed to a non-discriminatory enforcement approach in all Member States while achieving a broad coverage of relevant economic sectors in the market.

Enforcement of REACH registration obligations is – due to the complexity of the rules and the high number of various exemptions – an extremely demanding task for any National Enforcement Authority (NEA). Therefore, the complexity of the rules puts enforceability at stake as resources in NEAs are limited. Investigations targeted towards identifying relevant duty holders consume considerable resources even when starting from prepared data like that from customs declarations. Furthermore, investigations on the registration status of substances at an individual duty holder are highly complex in nature. It is the responsibility of the regulator

to watch out for regulatory simplification in order to ensure better implementation of the registration duty and to reduce the unnecessary burden on duty holders and authorities who implement the REACH regulation.

In cases of non-compliant companies, enforcement authorities have focused their action on first-hand risk reduction measures by advising and ordering remediation. Subsequently, these measures have restored the legality of the substances concerned. However, to ensure non-discriminatory enforcement and a level playing field for the enterprises based in the internal market, it will become more and more important to reprove incorrigible duty holders who persistently breach their substance registration duties with intensified sanctioning (fining, criminal complaints, etc.).

Due to the enforcement project's findings, the main recommendations are as follows:

- The high non-compliance rate for only representatives' needs to be addressed by the industries and industry stakeholders concerned. Only representatives have the highest non-compliance rate, which is twice the average rate for non-compliant companies. Only representatives are often non-compliant not only due to missing registrations, but also due to the breach of Article 8 of REACH regarding the duties of only representatives.
- The high non-compliance rate for importers needs to be addressed by the industries and industry stakeholders concerned. Importers have a non-compliance rate at least twice that of manufacturers. Importers are often not aware and not familiar with their registration obligations under the REACH regulation.
- The high non-compliance rate for actors which are not related to the chemical industry and chemical distribution sectors needs to be addressed by the industries and industry stakeholders concerned. These actors have a non-compliance rate twice that of the chemical industry and distribution sectors. These actors are often not aware and not familiar with their registration obligations under the REACH regulation.

2. Background

2.1 BACKGROUND OF THE PROJECT

The Forum for Exchange of Information on Enforcement (Forum) has up to now conducted two coordinated enforcement projects in the European Economic Area (EEA).

REACH-EN-FORCE 1 (REF-1) focused on obligations for manufacturers and importers of substances on their own or in mixtures with regards to pre-registration and information in the supply chain.

REACH-EN-FORCE 2 (REF-2) focused on the compliance with the legal requirements imposed by REACH and CLP on those downstream users who are formulators of mixtures.

The Forum adopted its third coordinated enforcement project, REACH-EN-FORCE 3 (REF-3) “Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs”, at its tenth meeting in October 2011 (Forum-10). The REF-3 project is the logical continuation of the REF-1 and REF-2 projects and it aims to check compliance with REACH registration obligations of Manufacturers (M), Importers (I) and Only Representatives (ORs). Where necessary, compliance with the relevant registration duties may be enforced. The REF-3 project also endeavours to establish where possible, cooperation between Member States enforcement authorities and Customs Authorities (Customs).

REF-3 focuses, as with REF-1, on the registration obligation of manufacturers and importers. The difference is that REF-1 mainly focused on the transitional regime based on Article 23 and 28 (pre-registration). After the registration deadline of 2010 and 2013 more substances needed to be registered and are subject for an inspection in REF-3. REF-3 also puts emphasis on ORs because a large number of registrations (8 693 unique company registrations which circa 30% are from ORs)³ are submitted by ORs. In addition to non-compliant companies that do not observe their registration obligations, one of the target groups for REF-3 inspections are the 8 693 registrants of full registrations listed in ECHA’s database.

The project was guided by the Forum Working Group (WG) REF-3 project. This WG produced a project manual with guidance and recommendations for inspectors, a questionnaire with inspection items and a reporting tool.

National coordinators were appointed in each participating country and supported by the WG. The national coordinators were primarily responsible for the training of the inspectors in their countries and managing for the WG the reporting of the inspection findings. For the latter purpose, the WG organised a web-conference with all appointed national coordinators to provide them with the information (manual and answers to questions) elaborated by the WG.

For each company inspection, a questionnaire was completed by the inspector and submitted to the national coordinator via an electronic reporting tool. The report for a company inspection can document inspection results of up to 10 substances. This tool was introduced to enhance the preparation and submission of inspection reports, as well as to facilitate data processing and the analysis of project results.

³ Based on statistics from ECHA March 2014. Intermediate registrations have not been in focus of this enforcement project and are excluded from this number.

2.2 LEGISLATIVE BACKGROUND

The REACH Regulation (EC) No. 1907/2006 lays down specific obligations for manufacturers, importers and downstream users of substances on their own, in mixtures and/or 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 manufacturers, importers and ORs should take appropriate measures in order to control and to identify what risks substances pose. If a company is acting as a supplier, they are obliged to provide information on the safe use of the substance to the recipient down the supply chain with a safety data sheet and/or to communicate any necessary risk management information. However, checking these communication obligations in the supply chain is not part of this project.

In order to ensure that any risk posed by substances is assessed appropriately and in order to make the relevant information generally available, manufacturers, importers and ORs are obliged to register their substances. This is the REACH principle of “No data, no market”.

The focus of the REF-3 enforcement project has been the investigation of compliance of manufacturers, importers and only representatives with their REACH duty to register their relevant substances.

The majority of NEAs’ investigations in this project have started with data from customs declarations for imports provided by Customs. As a consequence, the project aims at giving special attention to the registration duty of importers and only representatives.

Any inspection result for importers that actually do not have a registration obligation due to a re-import situation (Art 2(7)(c) of REACH) or due to the presence of an OR (Art 8(3) of REACH) has not been reported. Inspection results for these duty holders will be reported only in phase 2 of the REF-3 project.

The REF-3 project is limited to the obligations stipulated in the REACH Regulation. Obligations imposed by the CLP Regulation are not in the scope of this project.

Table 1: Obligations checked and eventually enforced within the project

Article in REACH	Description	Remark
5	No data, no market	-
6	General obligation to register substances on their own or in mixtures	Investigations and inspections have also covered various exemptions to the registration obligation, e.g. the exemptions defined in Art 2
8	Only representative of a non-Community manufacturer	Inspections have taken place at the importers covered by an OR and at the ORs, however only the results of ORs have been reported
12.2	Information to be submitted depending on tonnage	Art 12(1) is enforced by “Evaluation”, only. Art 12(2) is relevant for NEAs in terms of cross checking the annual tonnages on site and in the dossier
28	Duty to pre-register for phase-in substances	Late pre-registrations have also been covered by the inspections

3. Results of the project

3.1 PARTICIPATION AND NUMBER OF COMPANY INSPECTIONS

The REF-3 project was performed by 28 Member States and inspections of 528 companies were included in the project. Table 2 lists the participating countries and the number of national inspections reported.

During inspections it was observed that some companies only have a role as a downstream user (DU)/ distributor and not, as expected when selecting the companies to be inspected, having manufacturer, importer or OR roles. The NEAs have identified a number of such cases, and these inspections are not included in the scope of this project. Instead, they will be part of the scope of phase 2 of the REF-3 project. For example, in some countries the number of such inspections is up to 80% of the total number of inspections. A frequent reason is the presence of an OR who has taken over the registration obligation.

The varying economic conditions between countries, disparity in the availability of resources and/or the size of the country could 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 other national projects. Therefore, this report does not reflect all the inspections carried out in the Member States for checking compliance with REACH.

Table 2: Participating countries and company inspections included in the project⁴

Country	Number of company inspections included in the project
Austria	17
Belgium	18
Bulgaria	42
Cyprus	10
Czech Republic	17
Denmark	14
Estonia	14
Finland	1
France	19
Germany	73
Greece	27
Hungary	60
Iceland	3
Ireland	20
Italy	37
Latvia	7

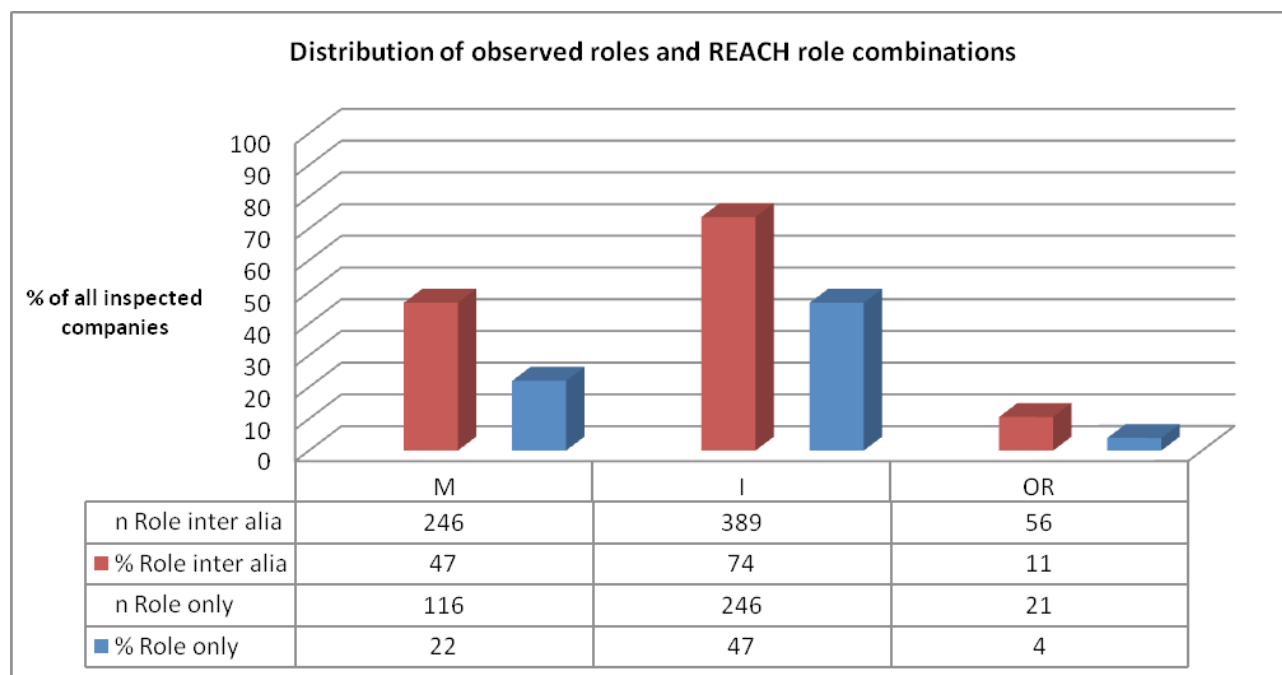
⁴ In some countries the number of inspections not included in the report could be over 100% of the total number of inspections reported for this project.

Liechtenstein	2
Luxembourg	0 ⁵
Lithuania	13
Malta	5
Netherlands	18
Poland	20
Portugal	15
Slovakia	7
Slovenia	8
Spain	27
Sweden	19
United Kingdom	15
Total number	528

3.2 ROLE OF INSPECTED COMPANIES UNDER REACH AND THEIR SIZE

Enterprises may have various roles under REACH. Some assume a variety of roles at the same time. The distribution of REACH roles observed by inspectors for the checked companies (multiple responses possible) is given in Figure 1. 73% (383 from 528) of the inspected companies having REACH duties only have one single role (M, I or OR).

Figure 1: Distribution of company roles (n= 528).



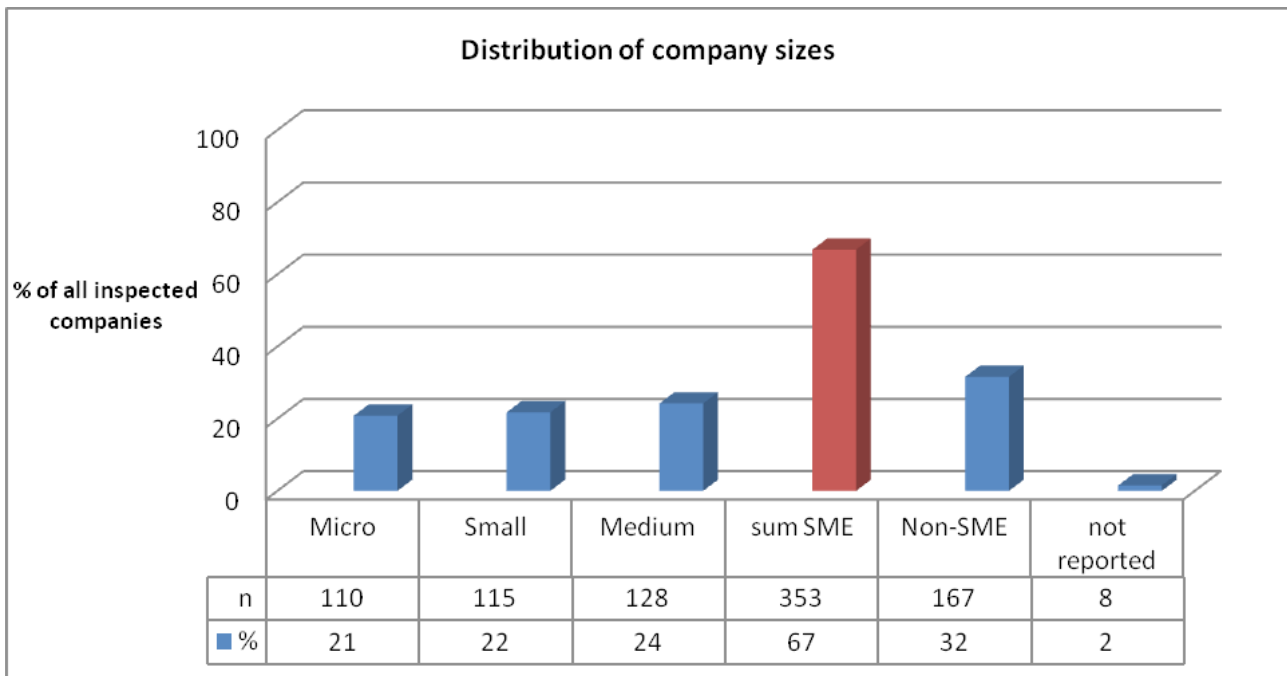
⁵ Inspections not finished by the date of the report

According to the scope of the project, all the inspected companies act as either a manufacturer (M), importer (I) or only representative (OR)⁶. Importers are represented at a higher rate than manufacturers. The proportion of companies acting as ORs are relatively small (11%) and very few of them act solely as ORs (4%). Any companies with an additional role as a DU/distributor have not been considered in the project report.

Companies of all size categories according to the EU standard scale⁷ were included in the inspections. Micro, small and medium-sized companies (SMEs) are represented in relatively equal proportions and make up 67% of the entire sample. One third of the inspected companies (32%) were larger enterprises, not belonging to the SME category.

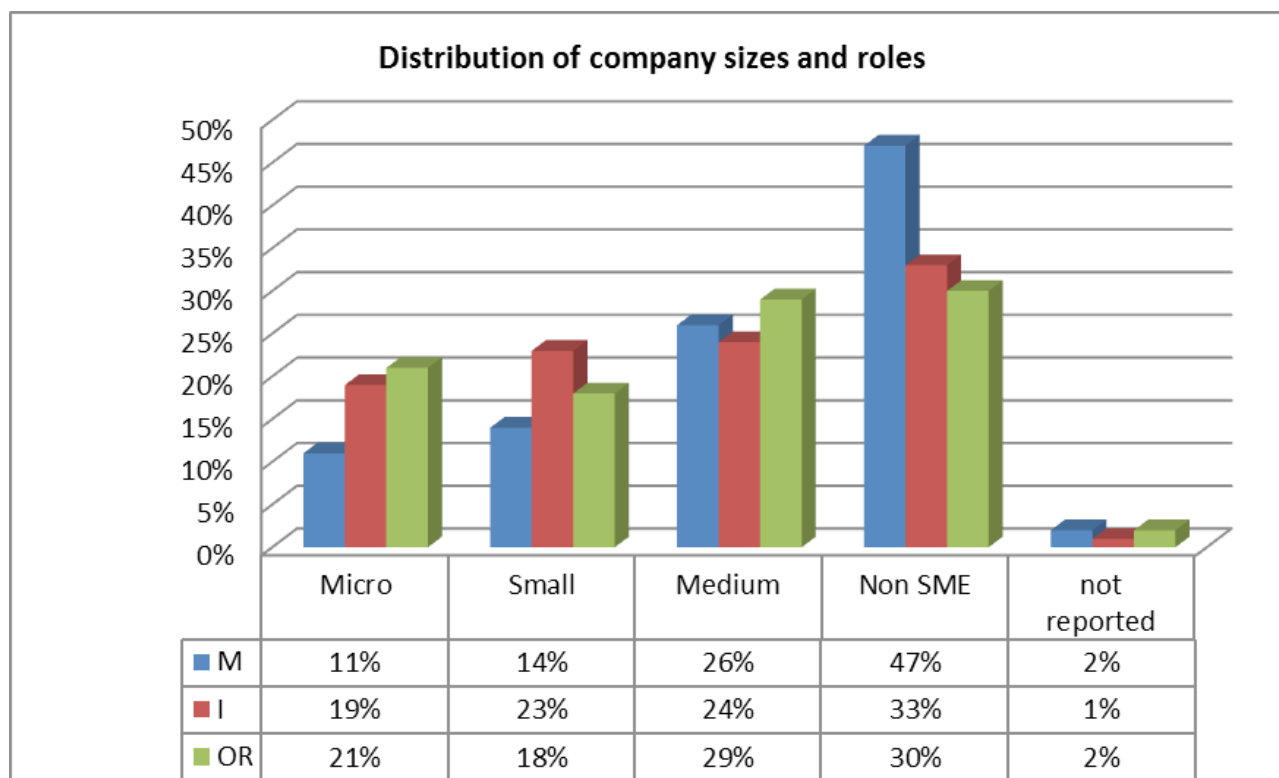
The distribution of company size is illustrated in Figure 2 (see also Figure A1 in Annex 2) and is compared with the roles in Figure 3. The proportion of SME (353) to non-SME companies (167) is 2:1.

Figure 2: Distribution of company sizes (n=528)



⁶ Companies may assume several roles, e.g. a manufacturer can be a manufacturer and having other roles (inter alia) and companies may assume only one role (role only). The group “role only” is part of the group “inter alia”.

⁷ Commission Recommendation 2003/361/EC

Figure 3: Distribution of company sizes and REACH roles of companies (role inter alia)⁸

There is a good balance between the sizes and the roles of the inspected companies and therefore a good basis for further analysis of the received data.

3.3 TYPES OF THE INSPECTED COMPANIES ACCORDING TO THEIR ECONOMIC ACTIVITIES

The range of surveyed economic activities represented by the inspected enterprises was specified in the inspection report by the NACE⁹ code (4 digit NACE classes). In order to present all economic activities that are relevant for the 528 companies inspected, the assigned NACE classes have been grouped into 4 relevant NACE units according to Table 3. The most frequent NACE divisions covered by the inspections are shown in Annex 2, in Figures A2 and A3; in Table A2 an example of NACE divisions and classes relevant in this project are shown.

Table 3: Used NACE divisions combinations in forming the four NACE units

NACE Unit	NACE definitions covered
A (Manufacture of chemicals)	Manufacture of chemicals and chemical and refined petroleum products
B (Wholesale, retail)	Wholesale, retail, transport and storage,
C (Manufacture of non-chemicals)	Manufacture (other than chemicals) and mining, NACE Sections B and C
D (Other)	Construction, energy/water supply, technical activities

⁸ For absolute numbers, see Table A1 in Annex 2.

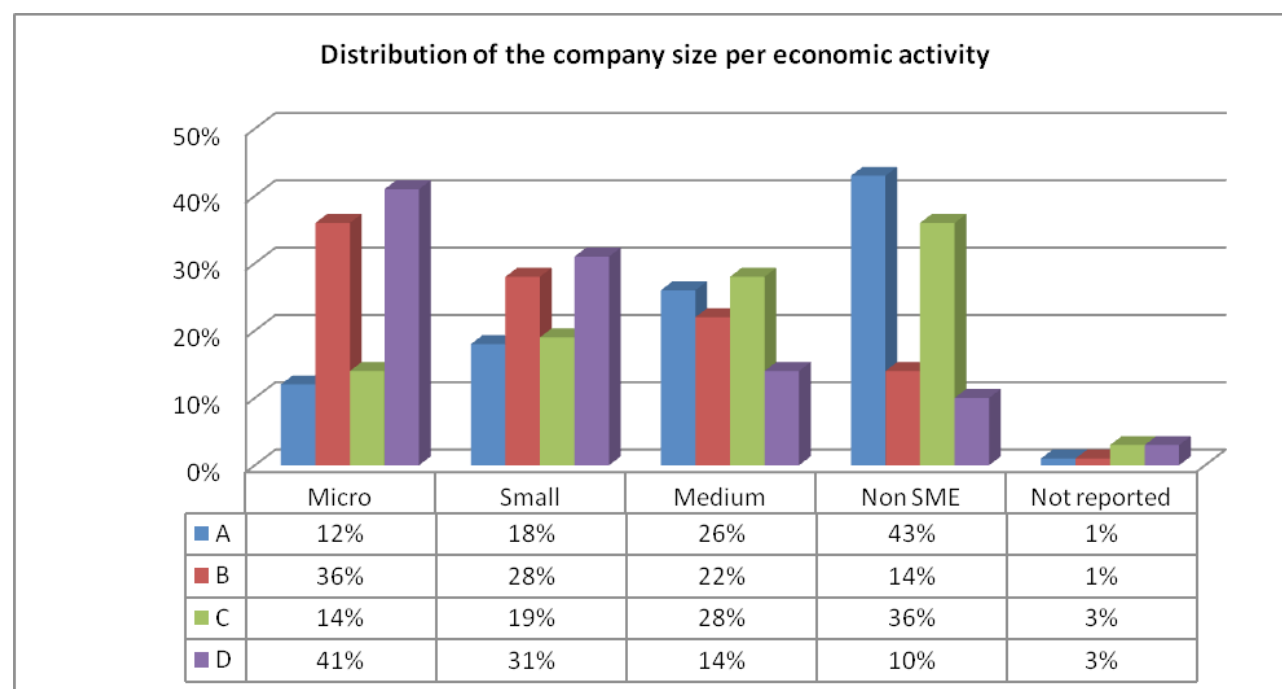
⁹ NACE, the Statistical Classification of Economic Activities in the European Community, is a European industry standard classification system for economic activities, Regulation (EC) No 1893/2006.

More than half of inspected companies (53%) fall into the group “manufacturer of chemicals”. The activities reported for this group include the preparation of paints and varnishes as well as detergents, cleaning and polishing mixtures and manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms. Other sectors with a major share of the number of inspections in the project are wholesale / retail (30%) and manufacture of non-chemicals (11%). While non-SMEs are often manufacturers, the small and micro enterprises which were inspected are often active in wholesale/retail.

Table 4: Main economic activities in the scope of the project grouped into NACE units.

NACE Units	Number of companies	Fraction of total number of inspected companies (%)
A Manufacture of chemicals	281	53
B Wholesale, retail	160	30
C Manufacture of non-chemicals	58	11
D Other	29	6

Figure 4: Distribution of company size for each economic activity - NACE unit¹⁰



¹⁰ For absolute numbers see Table A3 in Annex 2.

3.4 INSPECTED COMPANIES' TOTAL NUMBER OF MANUFACTURED AND IMPORTED¹¹ SUBSTANCES AND MIXTURES

In the inspected companies substances and mixtures are manufactured as well as imported with 38% (200) of the inspected companies doing both. In Table 5, the findings on this issue are reported.

Table 5: Average number of substances and substances in mixtures that an inspected company is manufacturing or importing in amounts of > 1 tonne/year

	Average number manufactured	Average number imported
Mixtures	134	25
Substances	25	22

45% (232) of the inspected companies are manufacturing substances in amounts > 1 tonne/year. The vast majority manufacture substances on their own (91%), while 30% also manufacture substances in mixtures (a company could manufacture both: substances and substances in mixtures). 47% of the manufacturers benefit from at least one substance exempted from the REACH registration duty. On average, 15% of the manufactured substances benefit from registration exemptions.

A considerable amount of inspected companies (76%, 390) are importing substances in amounts > 1 tonne/year, of which the majority import substances on their own (82%), whilst 35% import substances in mixtures (a company could import both: substances and substances in mixtures). 54% of the importers benefit from at least one substance exempted from the REACH registration duty. On average, 35% of the imported substances benefit from registration exemptions.

As can be seen from Table 6, there are two major reasons for substances being exempted from the REACH registration duty. Most exemptions are valid either because of an existing pre-registration for a phase-in substance (Art 28 of the REACH Regulation) or due to the substances being listed in Annex IV or V of the REACH Regulation (Art 2(7)(a) and 2(7)(b) of the REACH Regulation).

As DUs are not considered in REF-3 phase 1, the exemptions for ORs and on Re-import are therefore of reduced incidence.

Table 6: Distribution of different possible exemptions from substance registration relevant for the inspected companies

	Manufacture (N=104)		Import (N=201)	
A. Exemptions for phase-in substances	32	31%	75	37%
B. Exemptions for substances from the scope of REACH	-	-	-	-
B.1 Substances manufactured or imported less than 1 tonne per year	5	5%	5	2%
B.2 Waste	2	2%		
B.3 Polymers	13	12%	7	3%
B.4 Others	6	6%	6	3%

¹¹ For the purpose of this statistics on substances imported by the inspected companies, the substances covered by activities of an OR have been also regarded as "imported substances".

C. Exemptions from registration due to special use	-	-	-	-
C.1 Reimport			4	2%
C.2 Recycling	1	1%		
C.3 Others	9	8%	28	14%
D. Exemptions from registration due to inclusion in Annex IV and V	28	27%	44	22%
E. Others	-	-	-	-
E.1 OR			16	9%
E.2 NONs	2	2%	7	3%
E.3 Others	6	6%	9	5%
Total	104	100%	201	100%

3.5 REGISTRATION 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 if no exemptions are applicable, it is mandatory to submit registrations to ECHA.

Inspections at companies on registration obligations have been undertaken in the first half of 2013 until August 2013. Therefore, not all inspections undertaken during this project could cover a compliance assessment related to the second registration deadline for phase-in substances, which was scheduled for 31 May 2013.

According to information given by the 528 inspected companies, 84% (442 companies) have already filed at least one registration or pre-registration. 55% (289) of the inspected companies have at least one substance already registered and 29% (153) of the inspected companies have so far, only pre-registered. The inspections at 289 registrants cover 3% of all registrants recorded in ECHA's registration database³.

16% (86) of companies hold neither registrations nor pre-registrations for their substances in their role as a manufacturer, importer or OR. Some might not be in compliance with their REACH registration duty (see the average non-compliance rate given in Section 3.7) while others might benefit from additional registration exemptions listed in Table 6 for all of their substances.

The 442 registrants and pre-registrants have filed a total of 54 658 pre-registrations and 5 370 registrations, making an average of 19 registrations per registrant for the 298 companies that registered substance(s)¹².

Table 7 lists the average number of registrations and pre-registrations per company sorted by size, role or economic sector.

¹² The minimum number of registrations per company is 1, the maximum number of registrations per company is 1 239.

Table 7: Average number of registrations and pre-registrations per company

Type of duty holder	Average number of registrations per company	Average number of pre-registrations per company
Company size		
Micro	18	173
Small	3	61
Medium	7	91
non-SME	31	166
Company role (inter alia)		
M	22	111
I	21	116
OR	40	402
NACE unit A-D		
A	21	114
B	11	100
C	3	10
D	36	630

The table indicates that on average, non-SME companies are more active in filing registrations than SMEs. Also, companies with the role of an OR are the most active registrants (and pre-registrants). For the result of NACE unit D (“other”) it has to be highlighted that the number of company inspections is low (see Table 4) and only relatively few registrations were observed.

3.6 RESULTS OF THE COMPANY INSPECTIONS

In the first phase of inspections for project REF-3, a total of 3065 substances were reported as being checked for compliance in relation to their registration obligations. The general assessment of non-compliance rates for inspected substances in Section 3.7 will be based on these 3065 substances.

The breakdown of uses gives evidence that a majority of the 3065 substances actually examined in this enforcement project are imported substances (71%) and the majority of companies (64%) have the role of an importer for their inspected substances. Manufacturers have been targeted in only 29% of the inspections. Inspections at ORs have been clearly under-represented (7%) during the first phase of the enforcement project, which is also a major reason for extending inspection activities into 2014 (phase 2 of the REACH-EN-FORCE-3 project).

For a subset of 755 inspected substances more details on investigation findings have been documented. On average, investigation results for 2 such substances have been documented per company. 3% (23) of the 755 documented substances have covered 16 different substances from the 151 entries of the actual SVHC Candidate List published on the web page of ECHA¹³.

32% (242) of the 755 documented substance inspections in the enforcement project have covered 145 different substances from the 4485 Annex VI entries for harmonised classification and labelling of the CLP Regulation in the version of the third amendment to the technical progress.

¹³ List status on 8 March 2014.

The figures also reveal that the possibility to identify ORs based on customs data for import consignments of chemicals is limited, as ORs are not consignees or suppliers. Compared to the breakdown of roles for all 8 693 registrants of full registrations recorded at ECHA3 (46% manufacturer role, 34% importer role, 30% OR role), the ORs are clearly under-represented in the inspection results of this enforcement project.

However, the shortcomings during the first phase of the project will be better dealt with during phase 2 of the project in 2014. It is expected that by the end of the enforcement project more of the 2983 ORs recorded in ECHA's data base will be addressed by the inspections.

Taking into account the 32 621 full substance registrations filed at ECHA3, the number of inspected substances (3 065) are in an order of magnitude of 10% of all existing relevant substance registrations.

In looking at all registration dossiers filed at ECHA3, 85% of the registration dossiers were submitted from large companies. Therefore, the sample of inspected companies in the enforcement project does not reflect the proportion of SMEs who have filed a registration dossier with ECHA. The reason for this is that the enforcement project has aimed at a more balanced sample of companies of all sizes for the inspection.

3.7 NON-COMPLIANCE ISSUES AND MEASURES TAKEN

Considering all the duties following from a company's registration obligations, 75 of the 528 inspected companies are non-compliant for at least one substance. From these, 56 companies failed to register at least one substance.

The inspected companies did not comply with the registration duties for 143 substances including 92 substances with a missing registration.

Table 8: Non-compliance rates of inspected companies and inspected substances

Non-compliance rate	(%)
Inspected companies	14%
Inspected companies with missing substance registrations	11%
Inspected companies with all substance registrations missing ("free riders")	3%
Inspected substances	5%
Inspected substances with a missing registration	3%

When a company was not in compliance, on average 2 non-compliant substances were reported.

Within the group of companies missing their obligatory registration for more than one substance, 14 inspected companies (3%) were reported to have all the required substance registrations missing ("free-riders"). The worst case investigated showed 10 non-compliant substances out of 10 substances checked.

The highest number of non-compliant substances identified in a single company has been 13 (out of 188 checked substances).

An analysis of the number of non-compliant companies and the participating countries where these non-compliant companies were located, shows that non-compliant companies are found in a range of different countries:

- non-compliant companies have been observed in 19 participating countries;
- the number of non-compliant companies in each participating country varies from 0 to 13.

Due to the high number of different substances investigated during the inspections (486 different substance identities) the incidence of non-compliance for each of the inspected substances does not exceed 4. The incidence of non-compliance for a substance does not fully correlate with the frequency of inspections focused on the substance.

In two inspections on SVHC the required registration was missing (9% of all 23 inspections on SVHC). 28 inspections on substances with harmonised classification have identified non-compliance due to registration duties (12% of all 242 inspections on substances with harmonised classification).

Inspections for both SVHCs and substances with harmonised classification indicate a higher non-compliance rate for these two sub-groups of substances compared to the average non-compliance of all substances inspected.

Moreover, within the top 12 substances of highest incident rate, 4 substances have hazardous properties.

The distribution of non-compliant companies and substances for which the registration obligations are not fulfilled are analysed in the following Sections in terms of company size, the role of the companies and the economic sectors affected. Moreover, the reasons for the non-compliance and the measures taken have been investigated.

3.7.1 Company size

The inspected companies and non-compliant companies could be classified based on the size of the company in micro, small, medium-sized enterprises (SME) and non-SME companies.

SMEs show a higher non-compliance rate compared to non-SMEs which is evident when looking at the set of all non-compliant companies (the vast majority of which are SME) as well as when analysing the number of non-compliant companies among inspected companies of a certain size, i.e. there is a much higher number -in absolute terms- of non-compliant companies when looking at SMEs compared to non-SMEs (see Table 9).

Compared to non-SMEs, there is again a much higher number (in absolute terms) of SMEs where non-compliant substances were detected during inspections. However, when looking only at non-compliant companies, relatively more non-compliant substances were detected for non-SMEs than for SMEs (see Table 10).

Table 9: Company size and non-compliant companies (n=71)

Company size	Distribution of inspected companies (N=528)	Distribution for non-compliant companies (N=71)	Proportion of non-compliant companies within each company size group ¹⁴
Micro	21%	28%	18% (20/110)
Small	22%	30%	18% (21/115)
Medium	25%	28%	16% (20/128)
Non-SME	32%	14%	6% (10/167)
Total	100%	100%	(71/515)

¹⁴ Not considering the “not reported” data.

Table 10: Company size and percentage of non-compliant substances of the controlled substances

Company size			
Micro	Small	Medium	non-SME
9% non-compliance	8% non-compliance	5% non-compliance	2% non-compliance
2 non-compliant substances per non-compliant company (353 SME companies)			3 non-compliant substances per non-compliant company (167 non-SME companies)

3.7.2 Role of the non-compliant companies

How frequently a non-compliant company is found also depends on the role of a company. In addition, differences appear between companies having only one role and companies having multiple roles (e.g. between a “manufacturer only” and a “manufacturer inter alia”).

The rate of non-compliance is higher in cases where the role of importer and OR is the single role, compared to companies having multiple roles. Companies with single roles tend to be less compliant than the companies having several roles.

The rate of non-compliance for importers is higher compared to that of manufacturers. The highest non-compliance rate is found for the role of the OR, especially if the OR is the only role.

The same trend can be observed for the related non-compliant substances. If the OR is the single role, the non-compliance rate for substances is 22 % (see Table 11).

Table 11: Non-compliance distribution for the different roles of duty holders

Role	Non-compliant companies (N=143)	Non-compliant substances of companies with the role (N=75)
Manufacturer only	8 %	2 %
Manufacturer inter alia	7 %	1 %
Importer only	18 %	7 %
Importer inter alia	15 %	5 %
OR only	43 %	22 %
OR Inter alia	25 %	8 %

3.7.3 Economic sectors of non-compliant companies

The companies belonging to the NACE units of manufacturers of chemicals and wholesale/trade (NACE unit A and B) show the highest incidence of non-compliance in terms of total number of non-compliant companies. The sectors to be regarded as non-typical for chemical activities (NACE unit C and D) show the highest non-compliance rate within the NACE unit (see Table 12).

Table 12: Non-compliant companies of inspected companies within NACE unit

	A	B	C	D	Total
Non-compliance rate within the NACE unit	11%	14%	22%	28%	
Number of non-compliant companies/ number inspected companies	32/281	22/160	13/58	8/29	75/528

Some of the economic sectors are typical of the chemical industry like the “Manufacture of chemicals and chemical products” (NACE 20). This sector shows a non-compliance rate of 15% and is similar to wholesale (NACE 46). For further details see Table 13. For other economic sectors, see Table A4 in Annex 2.

Table 13: Non-compliance distribution of inspected companies within selected economic activities / NACE Division (n=75)

NACE Division		Number of non-compliant companies/ number inspected companies	Rate of non-compliant companies
20	Manufacture of chemicals and chemical products	27/181	15%
23	Manufacture of other non-metallic mineral products	2/32	6%
24	Manufacture of basic metals	1/26	4%
46	Wholesale trade, except of motor vehicles and motorcycles	19/145	13%

3.7.4 Reasons for non-compliance and observations

Non-compliance of registration duties has different causes. In most cases of non-compliance, companies have not submitted the required registrations for their substances. About one quarter of the non-compliant substances originating from an OR did not fulfil the required specific registration duties of an OR according to Article 8 of REACH (see Table 14).

Table 14: Distribution of the reasons of non-compliance for inspected companies and checked substances (multiple responses are possible)

Reason for non-compliance	Companies (N=75)*	Substances (N=143)*
Substance identity	5 (7%)	17 (12%)
Missing registration	56 (76%)	92 (64%)
Wrong tonnage band	2 (4 %)	6 (4%)
Not all REACH obligations according to the applicable role M/I/OR	7 (9 %)	16 (11%)
Criteria and/or obligation of an OR not fulfilled, missing evidence for appointment of an OR	15 (20%)	37 (26%)

* see section 3.7

A more detailed investigation of a company's obligation to file a registration dossier for substances has been carried out for a reduced sample of 51115 substances. This detailed investigation has also focused on the possibility of making use of phase-in options for the registration at the time of the inspections (including also some inspections that have been undertaken prior to the registration deadline 31 May 2013) or other existing exemptions from registration obligations. In total, 58% (298) of the 511 substances investigated for such detail have not been registered.

The prevailing reason for substances not being registered at the time of inspection is due to companies using one of the various registration exemptions (49%, 253/511):

- 21% (107) of the substances inspected were not registered at the time of the inspection because the company intends to register by 31.05.2018
- 2% (11) of the substances inspected had not been registered at the time of the inspection (before 31.5.2013) because the company intended to register by 31.05.2013
- 26% (135) of the substances were not registered because the company were making use of existing registration exemptions.

Only 9 % (45) of the substances thus investigated were missing the required registration and are cases of non-compliance.

An investigation that gives more detail on companies using the various existing exemptions from the registration obligation can be found in the report of the Forum enforcement project REF-116.

39 ORs have been specifically addressed by inspectors for their compliance with the OR duties defined in Article 8 of REACH. 35% (15) of them have been proven to be non-compliant for a total of 37 substances. The 39 inspected ORs have been reported to cover between 1 and 60 importing downstream users and annual tonnage bands from 1 up to >1000 ton/year. Of the 37 registrations lacking compliance with OR duties, almost 50% (18) cover substances with hazardous properties.

3.7.5 Non-compliance and measures taken

During the first operational phase of REF-3, 75 companies have been identified as being non-compliant regarding their registration obligations.

In reaction to contraventions, inspectors imposed various measures in order to correct non-compliance by providing verbal or written advice and issuing administrative orders, but also by imposing sanctions such as fines and criminal complaints.

Due to the first operational phase being short, not all inspectors could conclude the investigations completely. Therefore, follow up activities were still on-going or no measures had been taken and these would follow henceforth.

A high percentage of corrective measures taken to correct non-compliant companies took the form of written and verbal advice. Imposing measures are not always advisable as companies are obliged by law to comply in any case on their own initiative without an authority's order. Altogether, the percentage of applied sanctions against an offender in the form of a fine or criminal complaint is low. It is important to note, that national situations and legal action against offenders specific to each particular situation of non-compliance might vary among the participating countries.

¹⁵ When asked to clarify the actual registration obligation in more detail for one selected substance per inspected company, inspectors have reported back details for 511 substances.

¹⁶ See report: http://echa.europa.eu/documents/10162/13577/forum_ref-1_consolidated_report.pdf

Different approaches may exist in any one Member State. It seems that in terms of sanctioning missing substance registrations, rather soft measures are taken by NEAs in cases where companies do not comply with registration obligations.

During the first operational phase, results of 6 inspections obtained in a Member State have been forwarded to the other Member States where these companies are located. 4 cases related to potentially non-compliant companies and 2 other cases, have been forwarded. For this purpose different communication channels have been used (Table 15).

Table 15: Communication channels used to forward information on inspections to other MS (for one case multiple choice is possible)

Used communication channels	Number
To National Enforcement Authority	1
To National Competent Authority	2
To Forum Member	2
To National REF-3 Coordinator	1
To NEA Contact Point / Focal Point in RIPE	2
Feedback from the other Member State approached is already available	0

The limited use of opportunities for liaising with authorities in other Member States might have been due to difficulties in using the REACH information portal for inspectors (RIPE). Communication via RIPE has been implemented only during the operational phase of the enforcement project.

4. Overall conclusions

The REACH-EN-FORCE-3 project has shown that in the year 2013 there were a considerable number of non-compliant companies not observing REACH registration obligations. In 75 of the 528 inspected companies non-compliance was detected. This needs to be considered as a very high non-compliance rate taking into account the many years since the entry into force of REACH. It has also been seen that more attention needs to be given to importing companies as they are less compliant than manufacturers. Furthermore, the project has identified only representatives as a specific group at risk of non-compliance with their registration duties. For this reason also, an extension of the project with further inspections in 2014 has been agreed on by the Forum and Member States, at the Forum-16 meeting.

In future, special attention also needs to be drawn to economic sectors not belonging to the “classical” manufacturers and distributors of chemicals. Again it has been confirmed that SMEs have more problems in ensuring their compliance compared to larger enterprises. However, there is no indication of a systematic breach with the legislation and the numbers of identified “free-riders” that do not register their substances at all, are low.

Due to the high number of detailed investigations performed during the inspections of 528 duty holders as well as the substantial amount of data obtained, a realistic picture of the level of compliance of manufacturers, importers and only representatives can be formed.

REACH-EN-FORCE-3 has proven that REACH enforcement authorities in the 28 participating countries have established a functioning cooperation with customs which allows for making use of data from individual customs declarations in routine inspections of REACH duties. The project design and the actual inspections in the participating countries have been successful in implementing well-distributed, harmonised and focused inspections and enforcement activities. Subsequently, this has contributed to a non-discriminatory enforcement approach in all Member States while achieving a broad coverage of relevant economic sectors in the internal market.

Although import declarations do not necessarily and not always directly indicate the actual REACH duty holder, the customs declarations are both an efficient and effective tool to start with in case of REACH control activities focused on importers and ORs.

Enforcement of REACH registration obligations is – due to the complexity of the rules and the high number of various exemptions – an extremely demanding task for any NEA. Eventually the complexity of the rules puts enforceability at stake as resources in NEAs are limited. Investigations targeted at identifying relevant duty holders consume considerable resources in NEAs even when starting from prepared data like customs declarations. In addition, investigations of individual duty holders concerning the registration status of their substances are highly complex in nature. In such situations, efficient tools like data access in RIPE are of utmost importance. However, the regulator has to be on the look-out for regulatory simplification in order to ensure better implementation of a registrant’s registration duty and to reduce the unnecessary burden on duty holders and the authorities who have roles within REACH.

In cases when companies are found to be non-compliant, enforcement authorities have focused their action on first hand risk reduction measures by advising and ordering remediation. Subsequently, these measures have restored to legality the substances concerned. A focus of enforcement has also been to act beyond short-term administrative measures and to start follow-up activities of various kinds. It can be seen therefore that the priorities for enforcement authorities have not been limited to sanctioning and initiating criminal complaint procedures. Despite this more ‘soft’ approach, in order to ensure non-discriminatory enforcement and a level playing field for the enterprises in the internal market it will become more and more important to reprove incorrigible duty holders who persistently breach their substance registration duties with intensified sanctioning (fining, criminal complaints, etc.).

5. Recommendations

- The high non-compliance rate for only representatives' needs to be addressed by the industries and industry stakeholders concerned. Only representatives have the highest non-compliance rate; twice the average rate for non-compliant companies. Often, only representatives are non-compliant not only because of missing registrations, but also due to the breach of Article 8 of REACH relating to the duties of only representatives.
- The high non-compliance rate for importers needs to be addressed by the industries and industry stakeholders concerned. Importers have a non-compliance rate at least twice the non-compliance rate of manufacturers. Importers are often not aware and not familiar with their registration obligations under REACH.
- The high non-compliance rate for SMEs needs to be addressed by the industries and industry stakeholders concerned. SMEs have a non-compliance rate which is twice the non-compliance rate of non-SMEs.
- The high non-compliance rate for actors which are not related to the chemical industry and distribution sectors needs to be addressed by the industries and industry stakeholders concerned. These actors have a non-compliance rate that is twice the non-compliance rate of the chemical industry and distribution sectors. These actors are often not aware and not familiar with their obligations for REACH registration.
- Enhanced non-compliance rates for the classical chemical industry sector (NACE Division 20) needs to be addressed by the industries and industry stakeholders concerned. In contrast to what would be expected, the classical chemical industry sector is not the economic sector that is most aware of their REACH registration duties. However, this sector does not have the lowest non-compliance rate compared to the other economic sectors concerned.

6. Annexes

6.1 ANNEX 1: LIST OF THE RELEVANT COMMUNITY LEGAL ACTS

- 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.
- 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.
- Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code
- Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (TARIC)
- Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises

6.2 ANNEX 2: SUPPLEMENTARY FIGURES AND TABLES

Figure A1: Distribution of the company sizes

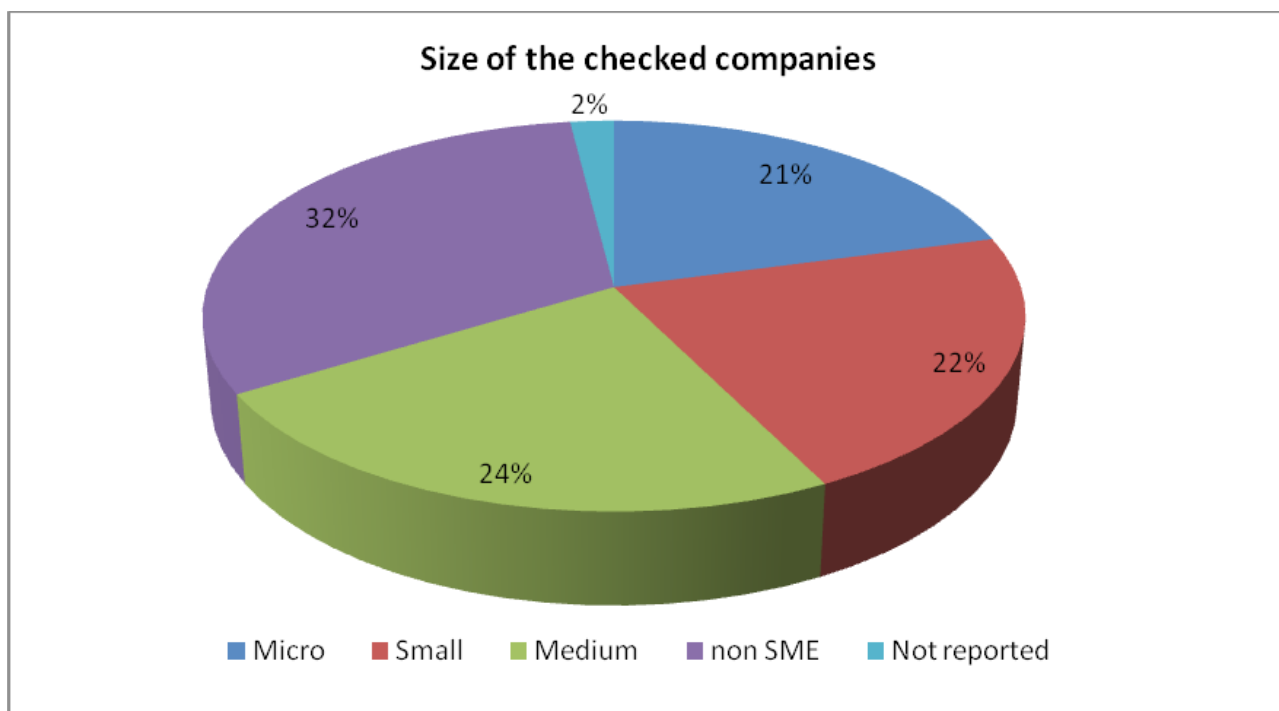


Table A1: Distribution of company sizes and role (n=528).

Role inter alia	Micro	Small	Medium	Non-SME	Not reported
M	28	34	64	116	4
I	73	90	94	128	4
OR	12	10	16	17	1

Figure A2: Range of a selection of surveyed economic sectors represented by the inspected enterprises specified by the NACE code

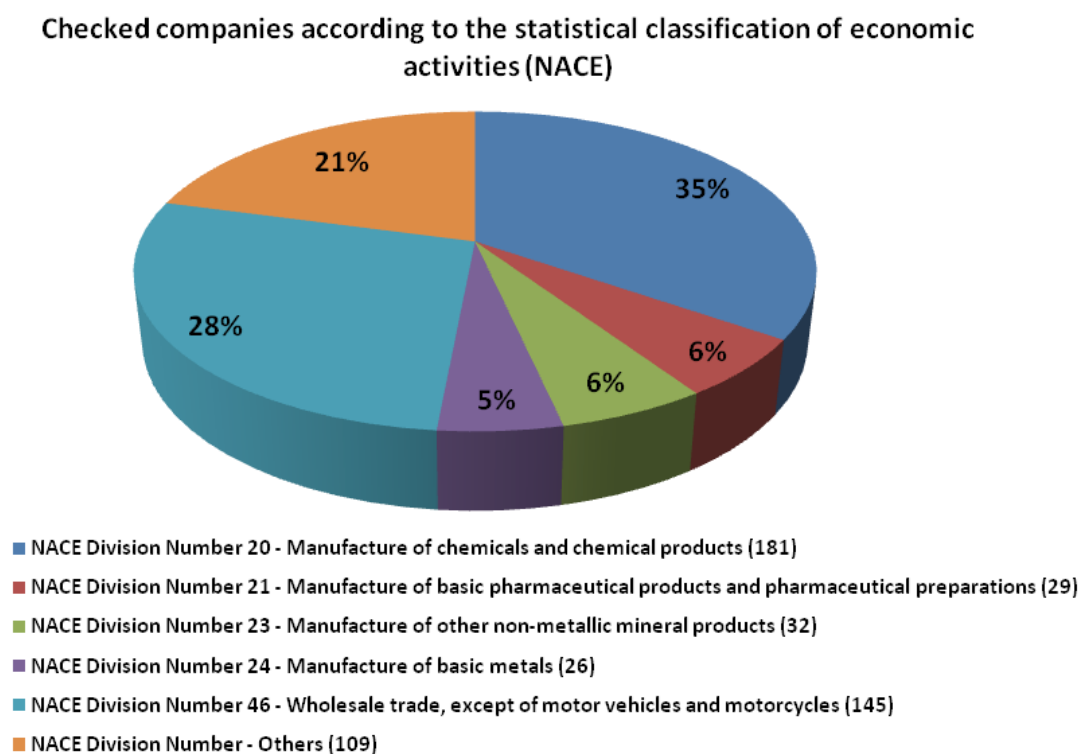


Figure A3: Range of surveyed economic sectors represented by the inspected enterprises specified by the NACE Division

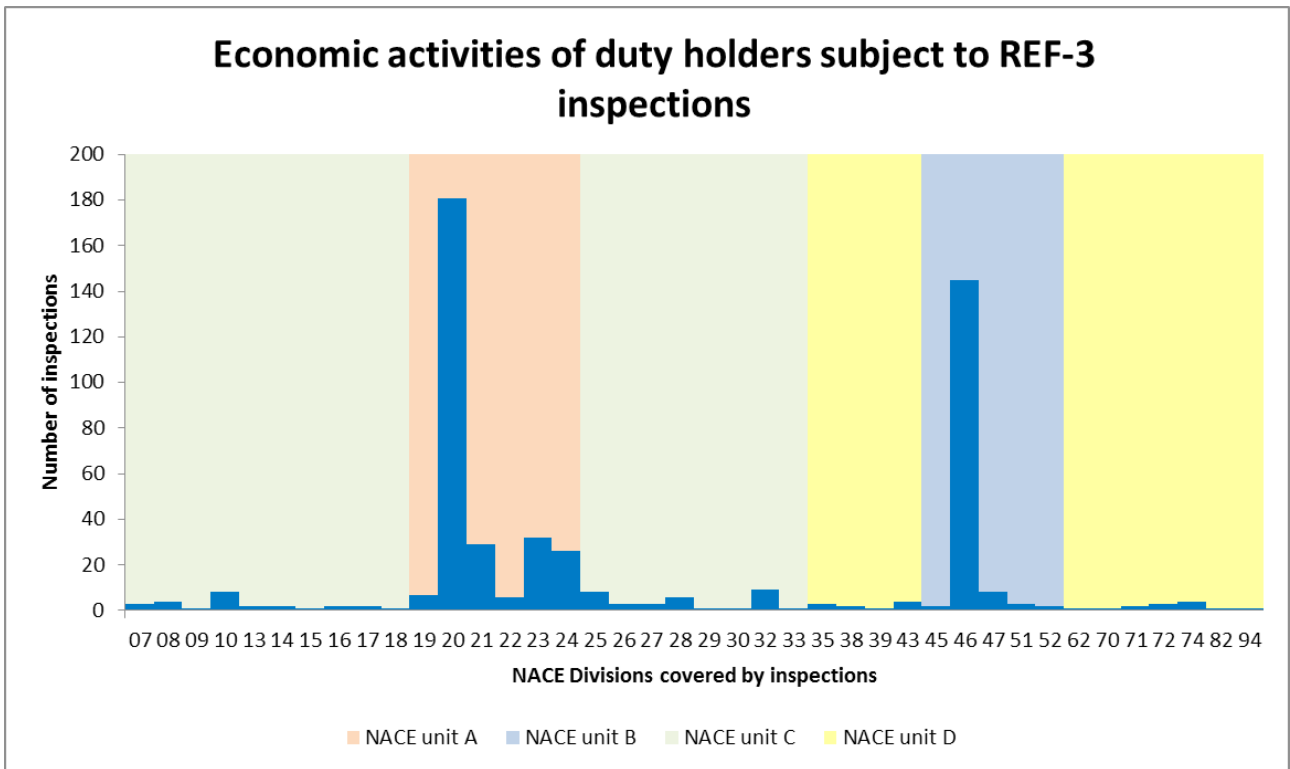


Table A2: Economic sectors most often covered by company inspections

NACE unit	Most important NACE Sections covered during inspections in REF-3	Number of company inspections
A	C 20 Manufacture of chemicals and chemical products	181
A	C 20.11 Manufacture of industrial gases	8
A	C 20.13 Manufacture of other inorganic basic chemicals	33
A	C 20.14 Manufacture of other organic basic chemicals	48
A	C 20.15 Manufacture of fertilisers and nitrogen compounds	12
A	C 20.16 Manufacture of plastics in primary forms	12
A	C 20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	8
A	C 20.59 Manufacture of other chemical products n.e.c.	25
A	C 21 Manufacture of basic pharmaceutical products and pharmaceutical preparations	29
A	C 21.10 Manufacture of basic pharmaceutical products	15
A	C 21.20 Manufacture of pharmaceutical preparations	11
A	C 23 Manufacture of other non-metallic mineral products	32
A	C 23.52 Manufacture of lime and plaster	16
A	C 24 Manufacture of basic metals	26
A	C 24.10 Manufacture of basic iron and steel and of ferro-alloys	7
A	C 24.42 Aluminium production	6
A	C 24.43 Lead, zinc and tin production	6
B	G 46 Wholesale trade (except of motor vehicles and motorcycles)	145
B	G 46.12 Agents involved in the sale of fuels, ores, metals and industrial chemicals	14
B	G 46.75 Wholesale of chemical products	84
B	G 46.90 Non-specialised wholesale trade	7

Table A3: Distribution of company sizes and economic sectors (n=528)

NACE-groups	Company size				
	Micro	Small	Medium	Not SME	Not reported
A	33	51	73	121	3
B	57	44	35	22	2
C	8	11	16	21	2
D	12	9	4	3	1

Table A4: All NACE Divisions covered by REF-3 inspections and assignment of NACE units, inspections and non-compliances per NACE Division

NACE Divisions	NACE unit A - D	Number of company inspections	Number of non-compliant companies
07	C	3	-
08	C	4	-
09	C	1	1
10	C	8	1
13	C	2	1
14	C	2	1
15	C	1	-
16	C	2	-
17	C	2	1
18	C	1	-
19	A	7	-
20	A	181	27
21	A	29	-
22	A	6	2
23	A	32	2
24	A	26	1
25	C	8	3
26	C	3	1
27	C	3	-
28	C	6	1
29	C	1	-
30	C	1	-
32	C	9	3
33	C	1	-
35	D	3	1
38	D	2	-
39	D	1	-
43	D	4	1
45	B	2	1
46	B	145	19
47	B	8	1
51	B	3	1
52	B	2	-
62	D	1	1
70	D	1	-
71	D	2	-
72	D	3	-
74	D	4	4
82	D	1	-
94	D	1	1

6.3 ANNEX 3: GLOSSARY

CMR	a substance or mixture which is carcinogenic, mutagenic or toxic to reproduction
CN	Combined nomenclature
DU	Downstream user
I	Importer
M	Manufacturer
NACE:	Nomenclature of Economic Activities - Nomenclature des Activités Économiques dans la Communauté Européenne
NEAs	National Enforcement Authorities
OR	Only representative
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REF	REACH-EN-FORCE, Coordinated Enforcement Project of the Forum
SME	Small and Medium Sized Enterprises
SVHC	Substance of very high concern
WG	Working Group of the Forum

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