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Forum For Exchange Of
Information On Enforcement

Forum REACH-EN-FORCE 3 – Final Report

Including the data reporting for project phase 2

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

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Forum REACH-EN-FORCE 3 – Final Report
Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs

Report for the overall project including the data reporting for phase 2 of the project

Reference: ECHA-15-R-19-EN

Cat. number: ED-04-15-818-EN-N

ISBN: 978-92-9247-649-6

DOI: 10.2823/31087

Date: December 2015

Language: English: EN

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1.Executive summary for the overall project

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 was 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 project with inspection activities during three years was divided into two phases. Phase 1 was executed in 28 Member States in 2013 and the results of this project phase were reported in June 2014[1]. The inspections in the 24 participating countries during phase 2 lasted from February to November 2014, with 641 company inspections being carried out, covering an average of four substance inspections per manufacturer, importer or only representative (2 681 substances in total). Combining the figures of phase 1 and phase 2 of the project, a total of 1 169 companies and 5 746 substances were inspected[2].

In a novel and broad approach, all participating countries, in both project phases, used data on substances and mixtures from import declarations to target their inspections of importers and only representatives (typically an annual data set of predefined CN[3] codes from various chapters of TARIC has been in use).

This data was gathered through cooperation with customs and during the two project phases it has been the data basis for both, the REACH enforcement authorities and customs for the risk assessment targeting individual duty holders. In 7 % of countries, the risk assessment for targeting individual duty holders was performed by customs themselves.

Consequently, when focusing on the roles of the inspected companies that are relevant for their registration duties (manufacturers, importers and only representatives) the most relevant role of the companies is the importer role (71 %). Most inspected companies were small and medium-sized enterprises (70 %).

With regard to the economic group "manufacture of chemicals", such companies represent about half of the inspected companies (47 %) and are typically medium or large companies. 34 % of inspected companies fell into the economic group of retail and are typically small and medium-sized enterprises.

REACH-EN-FORCE-3 inspections checked the compliance of relevant duty holders responsible for substance registrations, with the number of substances manufactured or imported by a

[1] For the report, see: http://echa.europa.eu/documents/10162/13577/forum_report_ref3_en.pdf
[2] The summary section and sections 2 (Background), 4 (Overall project findings) and 5 (Conclusions and recommendations) of this report focus on the combined findings from both phases of the project, while Section 3 (Results of the second phase) provides a focus on findings only from project phase 2.
[3] CN: The CN comprises the first eight 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

company ranging between 22 and 134, depending on the duty holder's specific use profile[4].

It was found that 48 % of the manufacturers and 67 % of the importers inspected benefit from exemptions from registration duties. The manufacturers benefit from exemptions mainly due to the phase-in status of substances, substances being listed in annexes IV or V to REACH or substances being polymers. Importers benefit mainly from the exemptions due to the nomination of an Only Representative (OR).

71 % of the inspected companies had already filed a registration or a pre-registration while large companies were more active in filing registrations than SMEs (on average, 22 registrations per non-SME company). 27 % of inspected companies had only pre-registered at the time of inspection.

As a consequence of the enforcement project's focus, the emphasis during inspections was on importer roles (71 %) – including importers covered by an OR ("importing DUs"[5]) - and on imported substances (86 %). Manufactured substances were targeted in only 14 % of the inspections.

Considering the high number of imports of substances into the EU market, and considering that 30 % of the registrants are ORs[6], inspections at ORs were under-represented.

A 13 % non-compliance rate was identified with respect to the registration duties of inspected companies. A missing registration was the most frequent reason for companies not being in compliance with registration duties. From the 1 169 companies inspected, 2 % were identified as "free-riders" who had not registered any of their substances requiring registration.

It was also found that 5 % of inspected substances were, to a varying extent, non-compliant with registration duties (please see reasons in Table 14) and 3 % of the substances lack the required registration.

As has been identified already in previous REACH-EN-FORCE projects[7], non-compliance rates for companies were higher for SMEs (sum of micro, small and medium) compared to larger companies.

When analysing companies holding different (single/multiple) REACH roles, the group of ORs - especially when investigated in more detail for their specific duties according to Article 8 of REACH - showed the highest proportion of non-compliant companies within the role (34 %) compared to importers (15 %) and manufacturers (6 %).

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[4] The average number of manufactured or imported substances per inspected company in the tonnage bands above one tonne per year 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.

[5] In this report, the term "importing DU" means a downstream user (DU) physically introducing substances (substances in mixtures) into the customs territory of the Community without having formal duties of a REACH-importer for the registration of the imported substances. An importing DU for a substance can be related to an appointed OR or to a re-import situation.

[6] Based on the statistics from ECHA June 2015.

[7] REACH-EN-FORCE 1 and REACH-EN-FORCE 2, for the reports see: http://echa.europa.eu/about-us/who-we-are/enforcement-forum

The companies belonging to the NACE units of manufacturers of chemicals and wholesale/trade show the highest non-compliance rates and also the highest incidence of non-compliance in terms of the absolute number of non-compliant companies.

In general, the priorities of enforcement authorities were not limited to using the enforcement method of sanctioning by imposing fines (10 %) and initiating criminal complaint procedures on identified registration contraventions (7 %). Rather, the focus was on first hand risk reduction measures. The reactions of enforcement authorities in cases of non-compliant companies was focused on immediate actions by advising (69 % of cases) or ordering remediation (23 % of cases) and restoring the respective company and substance to compliance. Due to the complex regulatory nature of the cases, a focus of enforcement was also to act beyond short-term administrative measures and to commence various kinds of follow-up activities in 41 % of cases.

The overall conclusion of the REACH-EN-FORCE-3 project was that there is a considerable number of non-compliant companies that do not fully observe REACH registration obligations. Moreover, it was confirmed that importing companies need more attention as they are less compliant than manufacturers.

Ultimately, the project identified ORs as a group specifically at risk of non-compliance with their registration duties (34%). Detailed investigations during phase 2 of the project revealed that there was also non-compliance in the information chain and most often cases with inconsistent information at the importing DUs covered by an OR and at the related OR have been found.

Consistency checks for the information at importing DUs and at ORs turned out to be an important enforcement approach in order to draw a conclusion on the functioning of REACH related to Article 8 on OR duties. Such investigations need a specific knowledge base to inspect the specific registration obligations linked to ORs.

Special attention also needs to be drawn to economic sectors belonging to “classical” manufacturers and wholesale of chemicals.

However, it must be noted that there is no indication of a systematic breach with the legislation by a specific economic group 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 all the 28 participating countries have at a minimum a functioning cooperation with customs. This cooperation allows enforcement authorities also in the future 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 enforce-

ment 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. This situation is severely aggravated once the compliance of ORs is investigated. 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 unnecessary burden on duty holders and authorities who implement the REACH regulation.

For 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 hold incorrigible duty holders who persistently breach their substance registration duties accountable also through intensified sanctioning (fining, criminal complaints, etc.).

Based on the enforcement project's findings, the main recommendations are as follows:

- The high non-compliance rate for ORs needs to be addressed by the industries and industry stakeholders concerned. Only representatives have the highest non-compliance rate. Often, ORs are non-compliant not so much due to missing registrations, but due to breaching 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 are often not aware and not familiar with their registration obligations under the REACH Regulation.

- Importing DUs need to be advised to cooperate directly with their ORs and to make sure that their ORs are fully complying with their duties under Article 8. This is important for the importing DU so they do not end up in a situation where their imports of substances become affected once it turns out that required registrations of the ORs are missing, not valid or not applicable to them.

- The high non-compliance rate (34 % and more) also for companies which are related to the chemical industry and chemical distribution sectors needs to be addressed by the industries and industry stakeholders concerned.

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 the obligations for manufacturers and importers of substances on their own or in mixtures with regard to pre-registration and information in the supply chain.

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

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 ORs in close cooperation with customs", at its 10th meeting in October 2011 (Forum-10).

The REF-3 project is the logical continuation of the REF-1 and REF-2 projects. The REF-3 project aimed to check compliance with REACH registration obligations of manufacturers, importers and only representatives (ORs). Where necessary, compliance with the relevant registration duties may be enforced. The REF-3 project also endeavoured to establish where possible, cooperation between Member State enforcement authorities and customs authorities (customs).

REF-3 focused, 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 deadlines of 2010 and 2013, more substances needed to be registered and were then subject for an inspection in REF-3.

REF-3 also put emphasis on ORs because a large number of registrants are ORs (30 % of the total number of registrants[6]). In addition to non-compliant companies that do not observe registration obligations, one of the target groups for REF-3 inspections was the 10 620 unique registrants of full registrations listed in ECHA's database.

The project was divided into two phases. Phase 1 was executed in 2013 and reported in June 2014[1]. The execution of the first phase of the REF-3 project in the Member States revealed the following general findings with respect to investigations on registration obligations for imported substances:

- data from customs declarations provided by customs authorities proved a good source for further investigations on REACH registration obligations for the imported substances/substances in mixtures;
- a number of customs declarations led inspectors to importers with no direct REACH registration obligations due to the fact that an OR had been established ("importing DUs[5]");

- a number of customs declarations led to cases with no REACH registration obligations because of the of re-import exemption.

These findings were specifically addressed during the inspection phase 2 for the REF-3 project in 2014.

The first phase of REF-3 revealed that a number of companies, identified in the data from customs declarations, import substances while the non-EU manufacturers have appointed an OR for these imports. Phase 2 of REF-3 was used to investigate the situation found at these importers: they have the obligations of a DU (importing DUs).

Phase 2 of the REF-3 project provided an additional focus on imports for which the REACH duty holder has no registration obligation as there is an OR established or as there is a re-import situation (duty holders are becoming importing DUs, see also Article 8 (3) of REACH).

As an added value, phase 2 of the REF-3 project has, for the first time, recorded and collected inspection and enforcement information at importing DUs. In 104 cases, phase 2 of the project linked inspections at importing DUs with related follow-up inspections at the ORs to investigate the compliance of REACH actors in the context of an established OR (chain-investigations). For this phase, a specific information exchange mechanism between Member States was established.

Besides the manufacturers, importers and ORs, in the second phase of REF-3 the importing DUs were also inspected to clarify their relationship with ORs and the re-import exemption situation. Although originally not included in the scope of REF-3, findings from inspections of DUs, either from phase 1 of REF-3 or from the forthcoming phase 2 of REF-3, were reported during the reporting phase of the second phase of REF-3.

In addition, inspectors focused attention on those actors being consignees in customs declarations, which according to the criteria in the ECHA Guidance on Registration (Version 2.0, chapter 2.1.2.3), are not to be regarded as REACH importers while another EU-based actor in the supply chain is the REACH importer. NEAs undertook all efforts, including cooperation between Member States, to investigate the case at different actors along the supply chain up to an identified REACH importer (i.e. the company that ordered the physical import of the substance from outside the EU).

The second phase of the project was also guided by the Forum Working Group (WG) REF-3 project[8]. This WG produced a project manual with guidance and recommendations for inspectors, a questionnaire[9] 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 training the inspectors in their countries and for managing the reporting of the inspection findings to the WG. 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.

[8] see Annex 5 of this report
[9] see Annex 3 of this report

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

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 in articles.

The regulation should make sure 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 to control and identify what risks substances pose.

If the mentioned companies are acting as suppliers, they have to provide the information on safe use of the substance to the recipient down the supply chain with a safety data sheet and/or communicate necessary information. However, checking these communication obligations in the supply chain was not part of this project.

To ensure that any risk posed by substances is assessed appropriately and 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 was to investigate the compliance of manufacturers, importers and only representatives with their REACH duty to register their relevant substances.

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

Any inspection result for importers that actually did not have a registration obligation due to a re-import situation (Article 2(7)(c) of REACH) or due to the presence of an OR (Article 8(3) of REACH) were reported only in the second phase of the REF-3 project.

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

Table 1: Obligations checked and eventually enforced within the project

Article in REACH	Description	Remark
5[10]	No data, no market	-
6	General obligation to register substances on their own or in preparations	Investigations and inspections also covered various exemptions to the registration obligation, e.g. the exemptions defined in Article 2
8	Only representative of a non-Community manufacturer	Inspections took place at the importers covered by an OR and at the ORs. However, only the results of ORs were reported
12.2	Information to be submitted depending on tonnage	Article 12(1) was enforced by "Evaluation", only. Article 12(2) is relevant for NEAs for cross checking the annual tonnages on site and in the dossier
28	Duty to pre-register for phase-in substances	Late pre-registrations were also covered by the inspections

2.3 Participation and number of company inspections

The REF-3 project was performed by 28 Member States and inspections of 1 169 companies were included in the project (both phases). 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/distributor and not as a manufacturer, importer or OR as was expected during the company selection.

The NEAs identified a number of such cases and these inspections were not included in phase 1 of the project. However, they were part of the scope of phase 2 of the REF-3 project. For example, in some countries the number of such inspections was up to 80 % of the total number of inspections. A frequent reason was the presence of an OR who took over the registration obligation.

Varying economic conditions, disparity in the availability of resources and/or the size of the country could provide an explanation as to the difference in numbers of enforcement actions performed within the scope of this project by the participating countries.

Moreover, additional inspections were 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.

[10] In relation to Articles 5 and 6, there are specific provisions for phase-in substances as mentioned in Article 23.

Table 2: Participating countries and company inspections included in the project.

Country	Number of company inspections included in phase 1	Number of company inspections included in phase 2	Number of company inspections included in the total project
Austria	17	47	64
Belgium	18	40	58
Bulgaria	42	29	71
Cyprus	10	8	18
Czech Republic	17	19	36
Denmark	14	10	24
Estonia	14	7	21
Finland	1	6	7
France	19	9	28
Germany	73	106	179
Greece	27	26	53
Hungary	60	111	171
Iceland	3	0	3
Ireland	20	7	27
Italy	37	45	82
Latvia	7	20	27
Liechtenstein	2	5	7
Lithuania	13	18	31
Luxembourg	0	7	7
Malta	5	0	5
Netherlands	18	45	63
Poland	20	0	20
Portugal	15	15	30
Slovakia	7	1	8
Slovenia	8	9	17
Spain	27	35	62
Sweden	19	0	19
United Kingdom	15	16	31
Total number	**528**	**641**	**1 169**

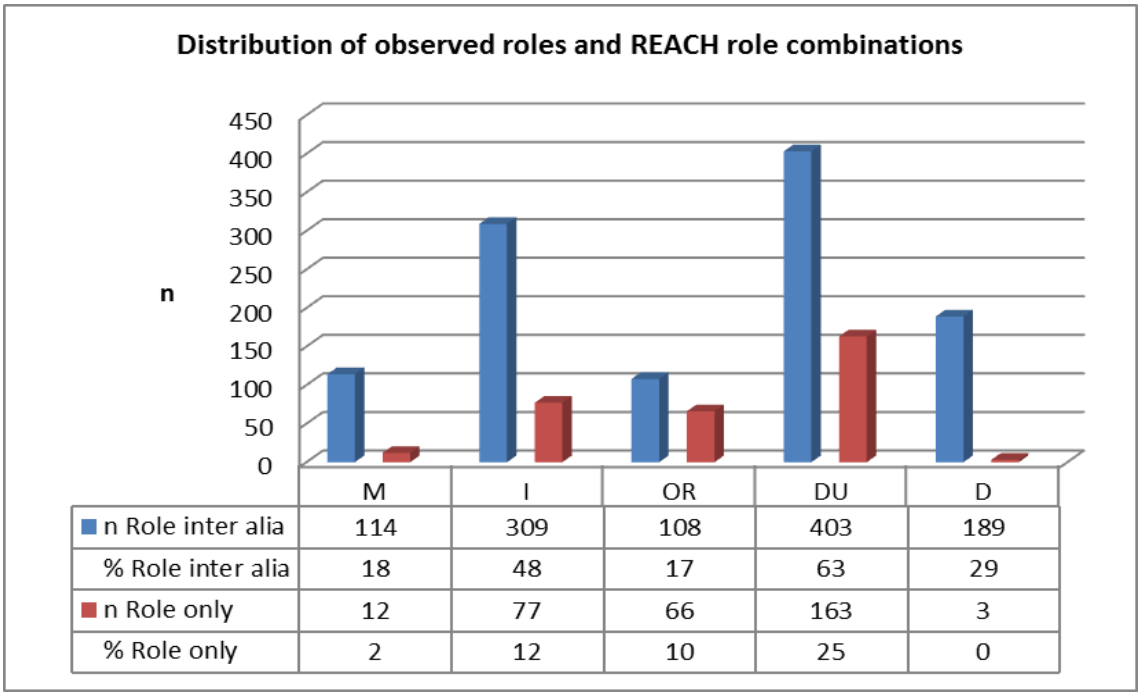
3.Results of the second phase of the project

In Section 3, results of the inspections in phase 2 of the project (inspections for 2014) are reported in a structure that is comparable to the project report already published for phase 1.

For a presentation of major results summarising the findings of the overall project (i.e. combined results of phases 1 and 2 of the project) see Section 4.

3.1 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. Half (321 from 641) of the inspected companies with REACH duties only have a single role (manufacturer (M), importer (I), only representative (OR), downstream user (DU) or distributor (D)).



	M	I	OR	DU	D
n Role inter alia	114	309	108	403	189
% Role inter alia	18	48	17	63	29
n Role only	12	77	66	163	3
% Role only	2	12	10	25	0

Figure 1: Distribution of company roles (n=641).

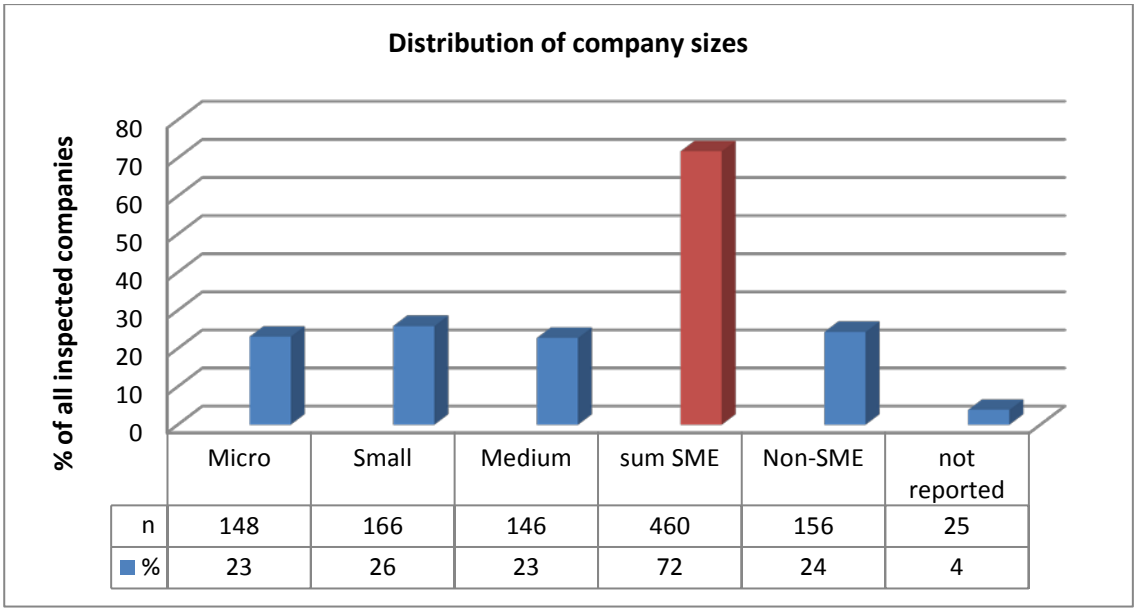
Although initially the scope of the project was to inspect companies that act as either a manufacturer (M), importer (I) or only representative (OR), downstream users (DU) with appointed ORs were also included in the second phase of the project.

The M, I and OR groups[11] represent two-thirds of the inspected companies. Importers are represented at a higher rate than manufacturers. The proportion of companies acting as ORs are relatively small (17 %) and more than a half of them act solely as ORs (10 %).

Companies of all size categories according to the EU standard scale[12] were included in the inspections and are represented in relatively equal proportions. Micro, small and medium-sized companies (SMEs) make up 72 % of the entire sample. 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 (460) to non-SME companies (156) is 3:1.

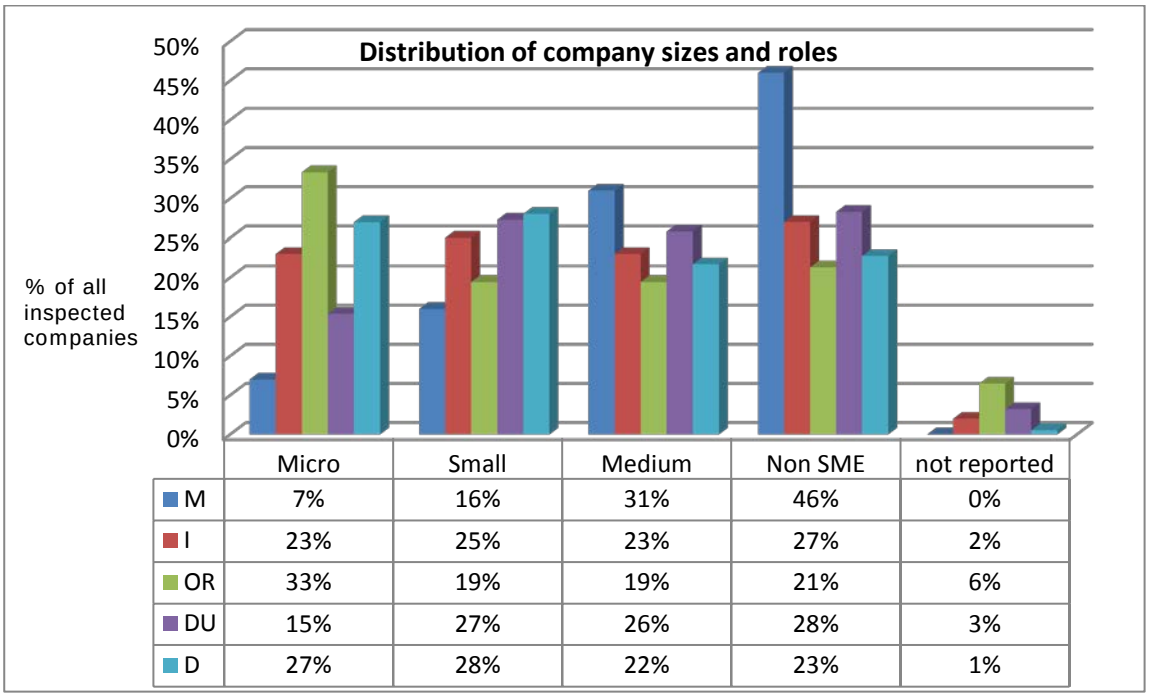
[11] Companies may assume several roles, e.g. a manufacturer can be a manufacturer and having other roles (*inter alia*) and companies may assume only one role (role only). The group "role only" is part of the group "*inter alia*".

[12] Commission Recommendation 2003/361/EC.



	Micro	Small	Medium	sum SME	Non-SME	not reported
n	148	166	146	460	156	25
%	23	26	23	72	24	4

Figure 2: Distribution of company sizes (n=641)



	Micro	Small	Medium	Non SME	not reported
M	7%	16%	31%	46%	0%
I	23%	25%	23%	27%	2%
OR	33%	19%	19%	21%	6%
DU	15%	27%	26%	28%	3%
D	27%	28%	22%	23%	1%

Figure 3: Distribution of company sizes and REACH roles of companies (role *inter alia*)[13]

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.

[13] For absolute numbers, see Table A1 in Annex 2.

3.2 Types of 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 NACE[14] code (four-digit NACE classes). To present all economic activities that are relevant for the 641 companies inspected, the assigned NACE classes were grouped into four 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 units	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

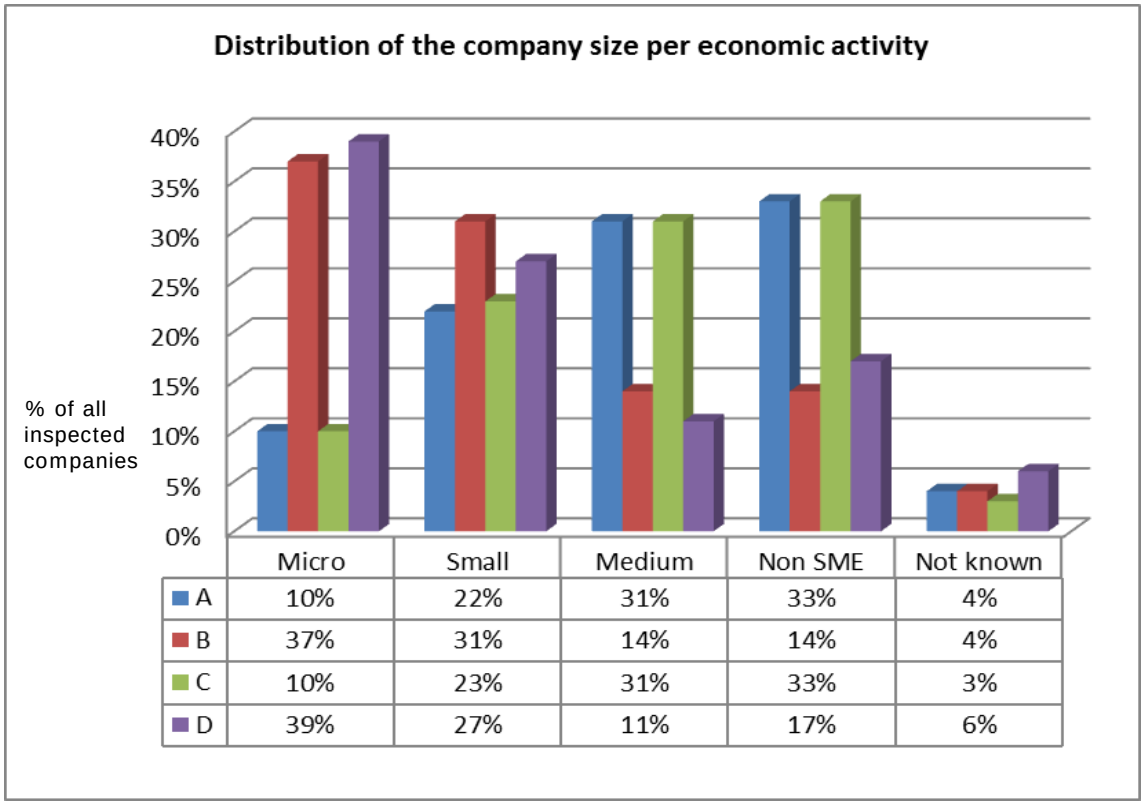
Two-fifths of the inspected companies (40 %) fall into the group “manufacturer of chemicals”. The activities reported for this group include preparing paints and varnishes as well as detergents, cleaning and polishing mixtures and manufacturing basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms.

Other sectors with a major share of the number of inspections in the project are wholesale/retail (36 %) and manufacture of non-chemicals (13 %). 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	254	40
B Wholesale, retail	234	36
C Manufacture of non-chemicals	81	13
D Other	70	11
Not reported	2	0

14 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.



	Micro	Small	Medium	Non SME	Not known
A	10%	22%	31%	33%	4%
B	37%	31%	14%	14%	4%
C	10%	23%	31%	33%	3%
D	39%	27%	11%	17%	6%

Figure 4: Distribution of company size for each economic activity - NACE unit[15]

3.3 Inspected companies' total number of manufactured and imported[16] substances and mixtures

For the inspected companies where substances and mixtures are manufactured and/or imported, 10 % (63) of the inspected companies are 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 manufactures or imports in amounts > 1 tonne/year

	Average number manufactured	Average number imported
Mixtures	37	40
Substances	36	37

[15] For absolute numbers see Table A3 in Annex 2.

[16] For the purpose of these statistics on substances imported by the inspected companies, the substances covered by activities of an OR have also been regarded as "imported substances".

22 % (138) of the inspected companies are manufacturing substances in amounts > 1 tonne/year. The majority manufacture substances on their own (68 %), whilst 24 % import substances in mixtures (a company could import both: substances and substances in mixtures). 43 % of the manufacturers benefit from at least one substance exempted from the REACH registration duty. On average, 22 % of the manufactured substances benefit from registration exemptions.

A considerable amount of inspected companies (80 %, 515) are importing substances in amounts > 1 tonne/year, of which the majority import substances on their own (82 %), whilst 36 % import substances in mixtures (a company could import both: substances and substances in mixtures). 72 % 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 were three major reasons for manufactured substances being exempted from the REACH registration duty. Most exemptions were valid either because of an existing pre-registration for a phase-in substance (Article 28 of the REACH Regulation), it is a polymer or due to the substances being listed in Annexes IV or V of the REACH Regulation (Articles 2(7)(a) and 2(7)(b) of the REACH Regulation). For imported substances, the most common exception was due to the appointment of an OR.

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

	Manufacture (N=60)		**Import (N=576)**	
A. Exemptions for phase-in substances	18	30 %	55	10 %
B. Exemptions for substances from the scope of REACH	-	-	-	-
B.1 Substances manufactured or imported less than 1 tonne per year	1	1 %	39	7 %
B.2 Waste	1	1 %	-	-
B.3 Polymers	16	27 %	14	2 %
B.4 Others	5	9 %	5	1 %
C. Exemptions from registration due to special use	-	-	-	-
C.1 Reimport		-	26	4 %
C.2 Recycling	1	1 %	0	0 %
C.3 Others	6	10 %	122	21 %
D. Exemptions from registration due to inclusion in Annexes IV and V	12	20 %	50	9 %
E. Others	-	-	-	-
E.1 OR	-	-	262	45 %
E.2 NONs	0	0 %	0	0 %
E.3 Others	0	0 %	3	1 %
TOTAL	**60**	**100 %**	**576**	**100%**

3.4 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.

According to information given by the 641 inspected companies, 60 % (383 companies) already filed at least one registration or pre-registration. 35 % (226) of the inspected companies have at least one substance already registered and 25 % (158) of the inspected companies have so far, only pre-registered.

20 % (127) of companies held 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 383 registrants and pre-registrants filed a total of 110 151 pre-registrations and 6 124 registrations, making an average of 27 registrations per registrant for the 226 companies that registered substance(s)[17].

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

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	8	141
Small	8	233
Medium	6	71
non-SME	14	192
Company role (inter alia)		
M	18	227
I	10	163
OR	47	798
DU	6	102
D	3	70
NACE units A-D		
A	10	143
B	2	51
C	1	7
D	43	878

[17] The minimum number of registrations per company is one, the maximum number of registrations per company is 750.

The table indicates that on average, non-SME companies were more active in filing registrations than SMEs. Also, companies with the role of an OR were the most active registrants (and pre-registrants). For the result of NACE unit D ("other"), it has to be highlighted that this group of companies tends to cover highly specialised actors which can explain their prominent registration activities under REACH.

3.5 Results of the company inspections

In the second phase of inspections for project REF-3, a total of 2 681 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 2 681 substances.

The breakdown of uses gives evidence that the majority of the 2 681 substances actually examined are imported substances (99 %) and the majority of companies (76 %) have the role of an importer for the inspected substances.

Manufactured substances were targeted in only 1 % of the inspections. Substance inspections at ORs were clearly under-represented (15 %) during the second phase of the enforcement project, but considerably increased compared to the first phase of the enforcement project during 2013 (7 %). This enhanced focus on ORs is mainly due to the 104 combined investigations undertaken both at ORs and the related importing DUs covered by these ORs (see Section 3.6).

For a subset of 749 inspected substances, more details on investigation findings have been documented. Statistically, investigation results for 1.2 substances have been documented per company.

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 10 620 unique registrants of full registrations recorded at ECHA[6] (45 % manufacturer role, 34 % importer role, 30 % OR role), the ORs are clearly under-represented in the inspection results of this enforcement project (17%).

However, the shortcomings during the first phase of the project were dealt with during the second phase of the project in 2014. By the end of the enforcement project, more of the ORs recorded in ECHA's database were addressed by the inspections.

Taking into account the 35 399 full substance registrations filed at ECHA[18], the number of inspected substances (2 681) is in an order of magnitude of 8 % of all existing relevant substance registrations.

[18] Unique registrations with potentially the same company doing several registrations, based on statistics from ECHA June 2015.

3.6 Results on the cross-border investigations

When importers were inspected during REF-3, a number of importers declared to be downstream users (importing DUs) as an OR had been nominated.

Initially, circa 630 investigations at the importing DU were carried out. Based on the information given by the importer during the second phase of the REF-3 project, 104 ORs were controlled and at 33 controlled OR/companies, at least one non-compliance was identified. This results in 32 % of the controlled ORs being non-compliant.

Having regard to the responsibilities of the ORs stipulated in Articles 5 and 8 of REACH, which are not observed by 32 % of the ORs, up to 32 % of the cases targeting an OR could eventually result in non-compliance with registration duties at the level of the importing DU.

Once investigating the information chain (importing DUs, ORs, non-EU manufacturers), the distribution of identified inconsistencies is as follows:

- Company is not the OR: 23 %
- OR does not know the importer/DU: 21 %
- OR does not exist: 10 %
- ORs with a lack of sufficient background in the practical handling of the substance: 8 %
- ORs do not keep available and up-to-date information on overall quantities of the inspected imported substance per calendar year: 6 %
- OR did not register/pre-register the substance: 5 %
- CAS number incorrect: 3 %
- The OR cannot provide an appointment letter of the non-EU manufacturer: 2 %
- The OR does not know the non EU-manufacturer: 2 %

When the OR was investigated in more detail (cross border investigations/supply chain investigation) for the OR specific duties, the number of non-compliant ORs as well as the number of non-compliant substances rose by a factor of circa two for the non-compliant ORs (see Table 11)[19]. This leads to an overall non-compliance rate of 32 % for ORs investigated in detail with regards to their specific OR duties.

Once the compliance of ORs is investigated, enforcement of REACH registration obligations is an extremely demanding task for any NEA especially due to the generic nature of the provisions of Article 8, which do not define the duties and the functioning of the information chain in a comprehensive form for duty holders and enforcement authorities.

Having a look at the findings of the cross border investigations, it is apparent that communication and cooperation between the importing DUs and their ORs is not efficient in many cases and also it was clear that a number of ORs are not fully compliant with their duties under Article 8. Such cooperation and communication is important to make sure that the importing DUs do not end up in a situation where imports of substances become affected once it turns out that required registrations of the ORs are missing, not valid or not applicable to them. There-

[19] Number of non-compliant ORs changed from 16 to 33, number of non-compliant substances from 29 to 67.

fore, based on these findings during Phase 2 of the REF-3 project, the ECHA Forum's Working Group REF-3 compiled specific advice on the requirements of Article 8 of REACH, which are relevant when inspecting ORs. This advice, which is in Annex 4, aims to provide assistance to inspectors and is based on clarifications made available in June 2014 in relevant ECHA Guidance documents, Question and Answers, FAQs and discussions in the network of helpdesks.

3.7 Non-compliance issues and measures taken

Considering all the duties following from a company's registration obligations, 76 of the 641 inspected companies during phase 2 were non-compliant for at least one substance. From these, 51 companies failed to register at least one substance.

The inspected companies did not comply with the registration duties for 122 substances including 75 substances with a missing registration.

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

Non-compliance rate	(%)
Inspected companies	12 %
Inspected companies with missing substance registrations	9 %
Inspected companies with all substance registrations missing ("free riders")	2 %
Inspected substances	5 %
Inspected substances with a missing registration	3 %

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

Within the group of companies missing their obligatory registration for more than one substance, 15 inspected companies (2 %) were reported to have all the required substance registrations missing ("free-riders"). The worst case investigated showed seven non-compliant substances out of seven substances checked.

The highest number of non-compliant substances identified in a single company was 13.

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 were observed in 18 participating countries;
- the number of non-compliant companies in each participating country varied from 0 to 36.

Due to the high number of different substances investigated during the inspections (494 different substance identities), the incidence of non-compliance for each of the inspected substances does not exceed six. The incidence of non-compliance for a substance does not fully correlate with the frequency of inspections focused on the substance.

The distribution of non-compliant companies and substances for which the registration obliga-

tions 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 can be classified based on the size of the company in micro, small, medium-sized enterprises (SME) and non-SME companies.

SMEs (sum of micro, small and medium) show a higher non-compliance rate compared to non-SMEs as well as when analysing the number of non-compliant companies among companies of a certain size group, 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 also a much higher number of non-compliant substances for SMEs compared to non-SMEs. 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=72)

Company size	Distribution of inspected companies (N=641)	Distribution of non-compliance rates for companies (N=72)	Proportion of non-compliant companies within each company size group[20]
Micro	23 %	36 %	18 % (26/148)
Small	26 %	24 %	10 % (17/166)
Medium	23 %	19 %	10 % (14/146)
Non-SME	24 %	21 %	10 % (15/156)
Total	**100 %**	**100 %**	**(72/616)**

Table 10: Percentage of non-compliant substances for different company size groups

Company size			
Micro	**Small**	**Medium**	**non-SME**
7 % non-compliance	4 % non-compliance	3 % non-compliance	4 % non-compliance
Statistically 1.2 non-compliant substances per non-compliant company (460 SME companies)			Statistically 1.7 non-compliant substances per non-compliant company (156 non-SME companies)

[20] Not considering the "not reported" data.

3.7.2 Role of the non-compliant companies

The role of a company appeared to influence the rate of non-compliance. In addition, differences appear between companies with only one role and companies with 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 with multiple roles. From the results, it can be considered that companies with single roles tended to be less compliant than the companies with several roles.

The rate of non-compliance for importers and ORs was higher compared to that of manufacturers. For OR specific non-compliance analysis see Section 3.6.

The same trend can be observed for the related non-compliant substances. If the importer or OR has a single role, the non-compliance rate for substances is 9 % and 7 % respectively (see Table 11).

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

Role	Proportion of non-compliant companies within each role (N=76)	Proportion of non-compliant substances of companies within each role (N=122)
Manufacturer only	6 %	3 %
Manufacturer inter alia	4 %	1 %
Importer only	20 %	9 %
Importer inter alia	15 %	5 %
OR only	20 %	7 %
OR Inter alia	15 %	4 %

3.7.3 Economic sectors of non-compliant companies

The companies belonging to the NACE units of manufacturers of chemicals and wholesale/retail (NACE units A and B) showed the highest incidence of non-compliance in terms of total number of non-compliant companies. The sectors wholesale/trade and others (NACE units B and D) showed the highest non-compliance rate within the NACE units (see Table 12).

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

	A	B	C	D	Total
Non-compliance rate within the NACE units	7 %	16 %	10 %	16 %	
Number of non-compliant companies/ number inspected companies	19/254	38/234	8/81	11/70	76/639

Some of the economic sectors are typical of the chemical industry like the "Manufacture of chemicals and chemical products" (NACE 20). This sector showed a non-compliance rate of 8 % and was lower compared to wholesale (NACE 46). For further details see Table 13.

Table 13: Non-compliance distribution of inspected companies within selected economic activities / NACE division (n=76)

NACE division		Number of non-compliant companies/ number inspected companies	Proportion of non-compliant companies within each NACE division
20	Manufacture of chemicals and chemical products	14/167	8 %
23	Manufacture of other non-metallic mineral products	2/19	10 %
24	Manufacture of basic metals	2/16	12 %
46	Wholesale trade, except of motor vehicles and motorcycles	23/206	14 %

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.

When asking the inspectors to report on selected reasons of non-compliance, the findings as given in Table 14 can be obtained. For example, 37 % 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=76)*	Substances (N=122)*
(1) Substance identity	5 (7 %)	6 (5 %)
(2) Missing registration	53 (70 %)	76 (62%)
(3) Wrong tonnage band	1 (1 %)	1 (1 %)
(4) Not all REACH obligations according to the applicable role M/I/OR	10 (13 %)	14 (11 %)
(5) Criteria and/or obligation of an OR not fulfilled, missing evidence for appointment of an OR	25 (35 %)	45 (37 %)

* See Section 3.7

A more detailed investigation of a company's obligation to file a registration dossier for substances was carried out for a reduced sample of 627[21] substances. This detailed investigation also focused on the possibility of making use of phase-in options for the registration at the time of the inspections (also including some inspections that have been undertaken before the registration deadline on 31 May 2018) or other existing exemptions from registration obligations. In total, 74 % (463) of the 627 substances investigated for such detail were not regis-

[21] When asked to clarify the actual registration obligation in more detail for one selected substance per inspected company, inspectors have reported back details for 627 substances.

tered.

The prevailing reason for substances not being registered at the time of inspection is due to companies using one of the various registration exemptions (67 %, 418/627):

- 9 % (57) of the substances inspected were not registered at the time of the inspection because the company intends to register by 31 May 2018
- 58 % (361) of the substances were not registered because the company was making use of existing registration exemptions (8 % re-import, 31 % nomination of an OR, 19 % other exemptions).

Only 7 % (43) of the substances from this reduced sample were missing the required registration and are cases of non-compliance.

The report from the Forum enforcement project REF-1[22] provides more detail on companies using the various existing exemptions from the registration obligation.

3.7.5 Non-compliance and measures taken

Overall, 641 companies were assessed by inspectors for their compliance and for different reasons of non-compliance regarding their registration obligations.

The rates of non-compliance identified by the inspectors in the course of their investigations on compliance levels as listed in Table 15 correlate well with the relevant part of the statistical data on non-compliance provided in Table 14[23].

Table 15: Identified non-compliances and rates of non-compliance of inspected companies

Non-compliances	(%)
(1) Substance subject to registration (e.g. substance identity)[24]	37 %
(2) Registration status of the inspected substance	30 %
(3) Specific duties of an Only Representative	17 %
(4) Other	16 %
(5) Role of the company under REACH	13 %
(6) Registrant identity	7 %
(7) Substance quantities per calendar year	4 %
(8) Registration number	2 %
(9) Information provided in the registration dossier	1 %

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

[23] see the sum of entries (1) and (2) of Table 14 and the sum of entries (1) and (2) of Table 15; entry 3 of Table 14 and entry 7 of Table 15; entry 4 of Table 14 and entry 5 of Table 15; entry 5 of Table 14 and entry 3 of Table 15 (a comparison is also available in Table A4 in Annex 2).

[24] This non-compliance can be related to either inconsistencies in the substance identity or to a missing registration for the substance.

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

In some cases, the inspections could not be concluded during the operational phase. Therefore, follow up activities were still on-going or no measures had been taken and these would follow.

A high percentage of corrective measures taken to correct non-compliant companies took the form of written and verbal advice. Administrative orders imposing corrective measures are often not necessary as most companies immediately fulfil the legal requirements advised by the enforcement authorities on their own initiative.

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.

Different enforcement schemes and approaches exist in every Member State and each case was dealt with individually e.g. where it was determined that the breach was not intentional, inspectors initially issued advice on corrective measures to bring the company into compliance. This situation might indicate that in general the inspectorates do not assess identified contraventions as being intentional or systematic breaches.

For 92 inspection cases with substances found to be non-compliant with registration duties in general, inspectors have taken the following actions: issuing administrative orders in 17 % of the cases, undertaking follow-up activities for 43 % of cases and taking other measures in 12 % of cases (see Figure 5).

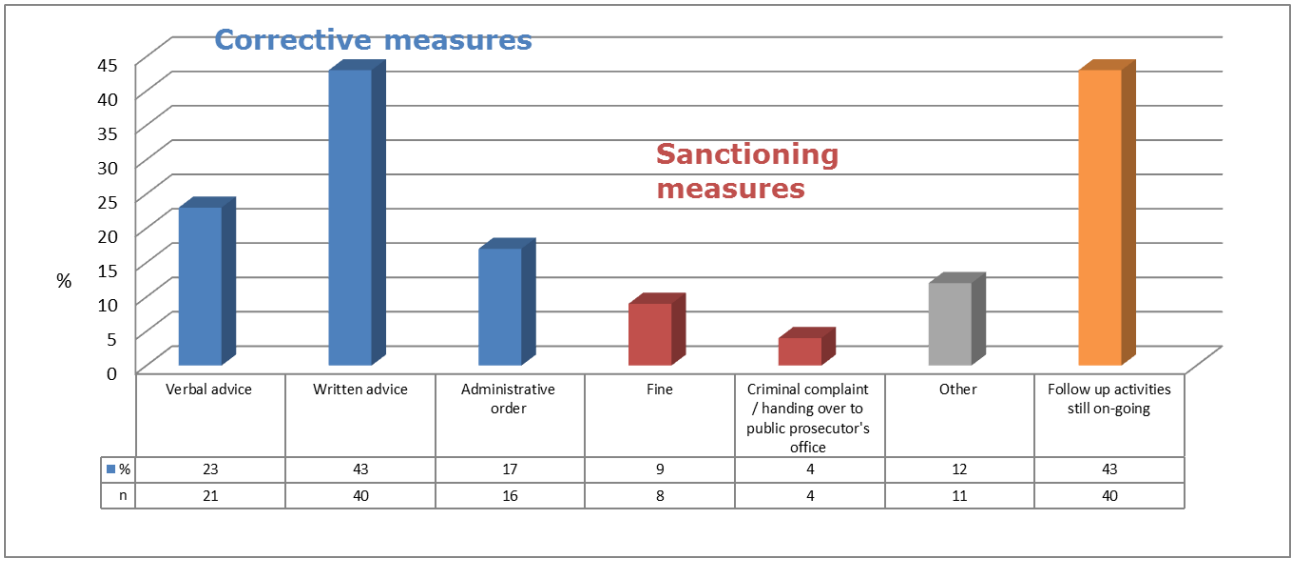


Figure 5: Non-compliance and measures taken by enforcement authorities (N=92)

Specifically, in the 52 inspection cases with substances found to be not registered at all although they should have been, inspectors imposed the following measures: 27% administrative orders, 58% allowed time to bring the substance into compliances in 33 % other measures.

4.Overall project findings (phases 1 and 2)

4.1 Observations on non-compliances

Inspected samples of duty holders in phases 1 and 2 of the project do not differ to a relevant extent with regard to the distribution of roles, size and economic activities. The only difference is that in phase 2, the importing DUs and re-importers had also been inspected. This can be seen in Sections 3.1 and 3.2 of this report.

As the data between phase 1 and phase 2 of the project are comparable, it was not felt necessary to also report overall project figures for those results which are provided in Sections 3.1 to 3.5, which are for phase 2 only. Nevertheless, a selection of data describing the overall project is provided in the Summary Section of this report.

Consequently, in Section 4.1, only the aggregated data from phase 1 and phase 2 of the project focusing on non-compliance rates are presented.

4.1.1 Non-compliance issues and measures taken

Considering all the duties that follow a company's registration obligations, 151 of the 1 169 inspected companies are non-compliant for at least one substance. From these, 107 companies failed to register at least one substance.

The inspected companies did not comply with the registration duties for 265 substances including 167 substances with a missing registration.

Table 16: Non-compliance rates of inspected companies and inspected substances

Non-compliance Rate	(%)
Inspected companies	13 %
Inspected companies with missing substance registrations	9 %
Inspected companies with all substance registrations missing ("free riders")	2 %
Inspected substances	5 %
Inspected substances with a missing registration	3 %

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

Within the group of companies missing their obligatory registration for more than one substance, 29 inspected companies (2 %) 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 was 13.

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 21 participating countries;
- the number of non-compliant companies in each participating country varies from 0 to 36.

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.

4.1.2 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 (sum of micro, small and medium) show a higher non-compliance rate compared to non-SMEs as well as when analysing the number of non-compliant companies among companies of a certain size group, 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 17).

Table 17: Non-compliance distribution for the different company sizes of duty holder (n=143)

Company size	Distribution of inspected companies (N=1 169)	Distribution of non-compliance rates for companies (non-compliance rate) (N=143)	Proportion of non-compliant companies within each company size group[25]
Micro	22 %	32 %	18 %
Small	24 %	27 %	14 %
Medium	23 %	24 %	12 %
Non-SME	28 %	17 %	8 %
Total	**100 %**	**100 %**	**-**

4.1.3 Role of the non-compliant companies

How frequently a non-compliant company is found also depends on the role of a company.

The rate of non-compliance for importers and especially for ORs is higher compared to that of manufacturers.

The same trend can be observed for the related non-compliant substances. If the importer or OR has the single role, the non-compliance rate for substances is 8 % and 11 % respectively (see Table 18).

[25] Not considering the "not reported" data.

Table 18: Non-compliance distribution for the different roles of duty holders

Role	Distribution of non-compliant rates for companies (N=151)	Proportion of non-compliant companies within the role (N=151)	Proportion of non-compliant substances of companies within the role (N=265)
Manufacturer only	8 %	7 %	2 %
Manufacturer inter alia	15 %	6 %	1 %
Importer only	60 %	19 %	8 %
Importer inter alia	69 %	15 %	5 %
OR only	28 %	34 %	11 %

4.1.4 Economic sectors of non-compliant companies

The companies belonging to the NACE units of manufacturers of chemicals and wholesale/retail (NACE units A and B) show the highest incidence of non-compliance in terms of absolute number of non-compliant companies and the highest non-compliance rates. The sectors to be regarded as non-typical for chemical activities (NACE units C and D) show a high proportion of non-compliant companies within the NACE units (see Table 19).

Table 19: Non-compliant companies for economic sectors

	Distribution of non-compliant rates for companies (N=151)	Proportion of non-compliant companies within the NACE unit
A	34 %	10 %
B	40 %	15 %
C	14 %	15 %
D	12 %	19 %
Total	**100 %**	**-**

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 proportion of non-compliant companies within the NACE unit of 12 % and is identical to wholesale (NACE 46). For further details see Table 20.

Table 20: Non-compliance distribution for selected economic activities / NACE Division (n=151)

NACE Division		Distribution for non-compliant companies (non-compliance rate) (N=151)	Proportion of non-compliant companies within the NACE unit
20	Manufacture of chemicals and chemical products	27 %	12 % (41/197)
23	Manufacture of other non-metallic mineral products	3 %	8 % (4/51)
24	Manufacture of basic metals	2 %	7 % (3/42)
46	Wholesale trade, except of motor vehicles and motorcycles	28 %	12 % (42/351)

4.1.5 Observations on non-compliance

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 1 138[26] 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 (also including some inspections that have been undertaken before the registration deadline of 31 May 2013) or other existing exemptions from registration obligations. In total, 67 % (761) of the 1 138 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 (59 %, 671/1138):

- 15 % (175) of the substances inspected were not registered at the time of the inspection because the company intends to register at a later deadline (2013 and/or 2018)
- 44 % (496) of the substances were not registered because the company was making use of existing registration exemptions.

Only 8 % (88) of the substances from this reduced sample were missing the required registration and are cases of non-compliance.

4.1.6 Non-compliance and measures taken

Overall, 1 169 companies were assessed by inspectors for compliance regarding their registration obligations.

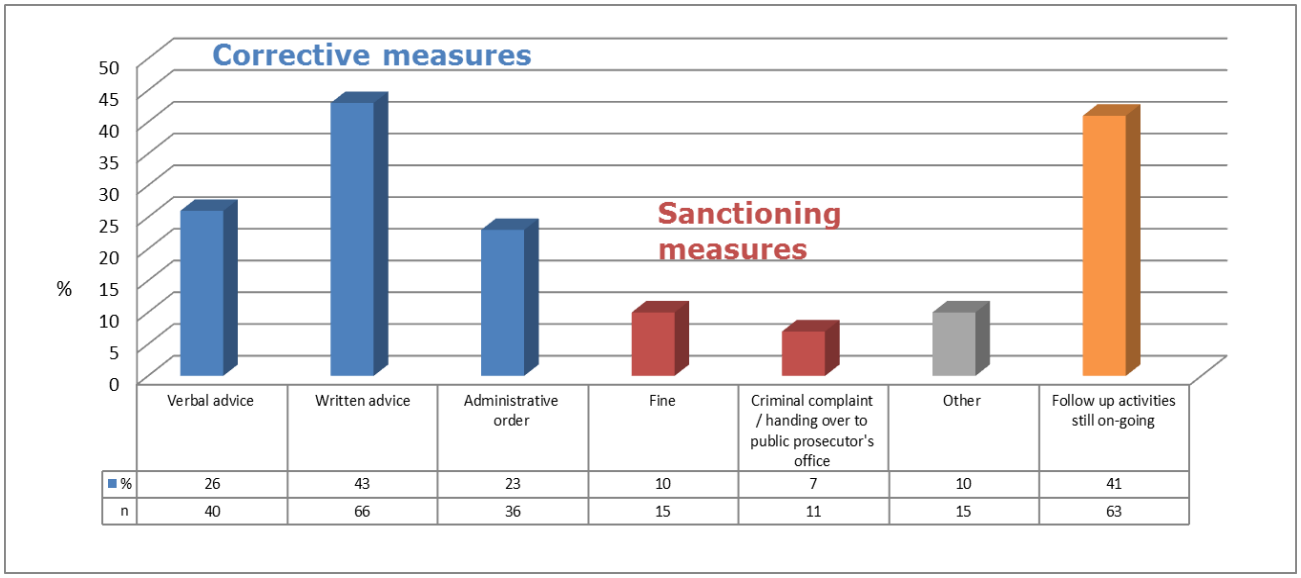
In reaction to contraventions, inspectors imposed various measures to correct non-compliance by providing verbal or written advice and issuing administrative orders. Inspectors also imposed sanctions such as fines and criminal complaints.

Due to the complex inspection cases, not all inspectors could conclude the investigations completely during the operational phase. Therefore, follow-up activities were still on-going or no measures had been taken (decided) so far but they would follow.

A high percentage of corrective measures taken to correct non-compliant companies took the form of written and verbal advice. Altogether, the percentage of applied sanctions against an offender in the form of a fine or criminal complaint is low. National situations and legal action against offenders specific to each particular situation of non-compliance might vary among the participating countries.

Different enforcement schemes and approaches exist in every Member State. Administrative orders imposing corrective measures are often not necessary as most companies immediately fulfil the legal requirements advised by the enforcement authorities on their own initiative. This situation might indicate that in general the inspectorates do not assess identified contraventions as being intentional or systematic breaches.

[26] When asked to clarify the actual registration obligation in more detail for one selected substance per inspected company, inspectors have reported back details for 1 138 substances in phases 1 and 2.



	Verbal advice	Written advice	Administrative order	Fine	Criminal complaint / handing over to public prosecutor's office	Other	Follow up activities still on-going
%	26	43	23	10	7	10	41
n	40	66	36	15	11	15	63

Figure 6: Non-compliance and measures taken by enforcement authorities (overall project) (N=155)

4.2 Cooperation with customs in this project

4.2.1 Information received from customs

All the 28 countries which comprehensively participated in the project reported that information has been received from customs. 21 countries received information on substances/mixtures based only on pre-identified CN codes. Only one country received information based only on pre-identified companies and six countries received information on substances/mixtures based on pre-identified CN codes and on pre-identified importers. The results are reported in Table 21.

In 75 % of cases, the chosen approach targeted the import of specific substances into the EEA, 4 % of the cases focused on data on specific companies importing substances into the EEA and in 21 % of cases a combination of both approaches was used (see Figure 7).

Table 21: Participating countries and details of information received from customs

Country	Info received based on pre-identified CN only	Info received based on pre-identified importers only	Info received based on pre-identified both CN and importers
Austria	✓		
Belgium	✓		
Bulgaria	✓		
Cyprus	✓		
Czech Republic	✓		
Denmark			✓
Finland	✓		
France		✓	
Estonia			✓
Germany			✓
Greece			✓
Hungary	✓		
Iceland	✓		
Ireland	✓		
Italy	✓		
Latvia	✓		
Liechtenstein	✓		
Lithuania			✓
Luxembourg	✓		
Malta	✓		
Netherlands			✓
Poland	✓		
Portugal	✓		
Slovakia	✓		
Slovenia	✓		
Spain	✓		
Sweden	✓		
United Kingdom	✓		
Total	***21***	***1***	***6***

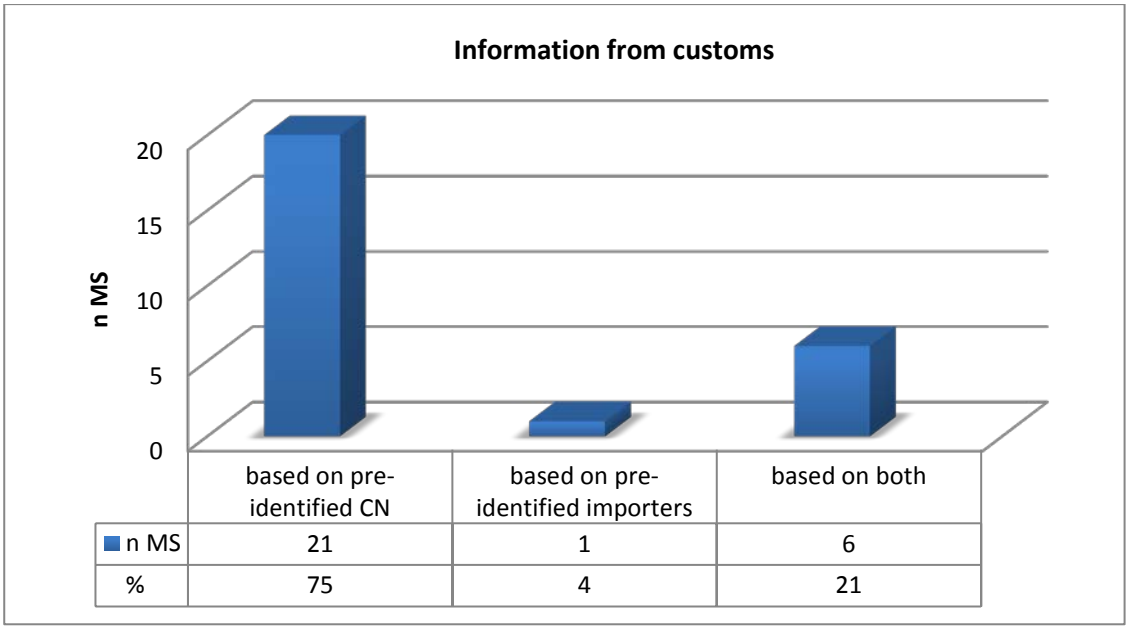


Figure 7: Proportion of approaches taken in requesting information from customs

4.2.2 Substance-related information received from customs

The 27 countries which pre-selected substances or substances in mixtures when requesting information from customs had the following choice set: 22 substances recommended by the Forum WG "Cooperation with Customs", or the substances designated by all CN codes from relevant chapters of the TARIC, or the substances of the Candidate List, or substances from Annex XVII or other.

The results show that substance-related information received from customs is in 19 cases about all predefined CN codes from the selected chapters of TARIC and in 13 cases about the minimum list of substances (proposed by the Forum WG "Cooperation with Customs"). Only one case is reported for Annex XVII substances and in five cases other substances have been chosen.

The distribution of substance-related information is reported in Figure 8.

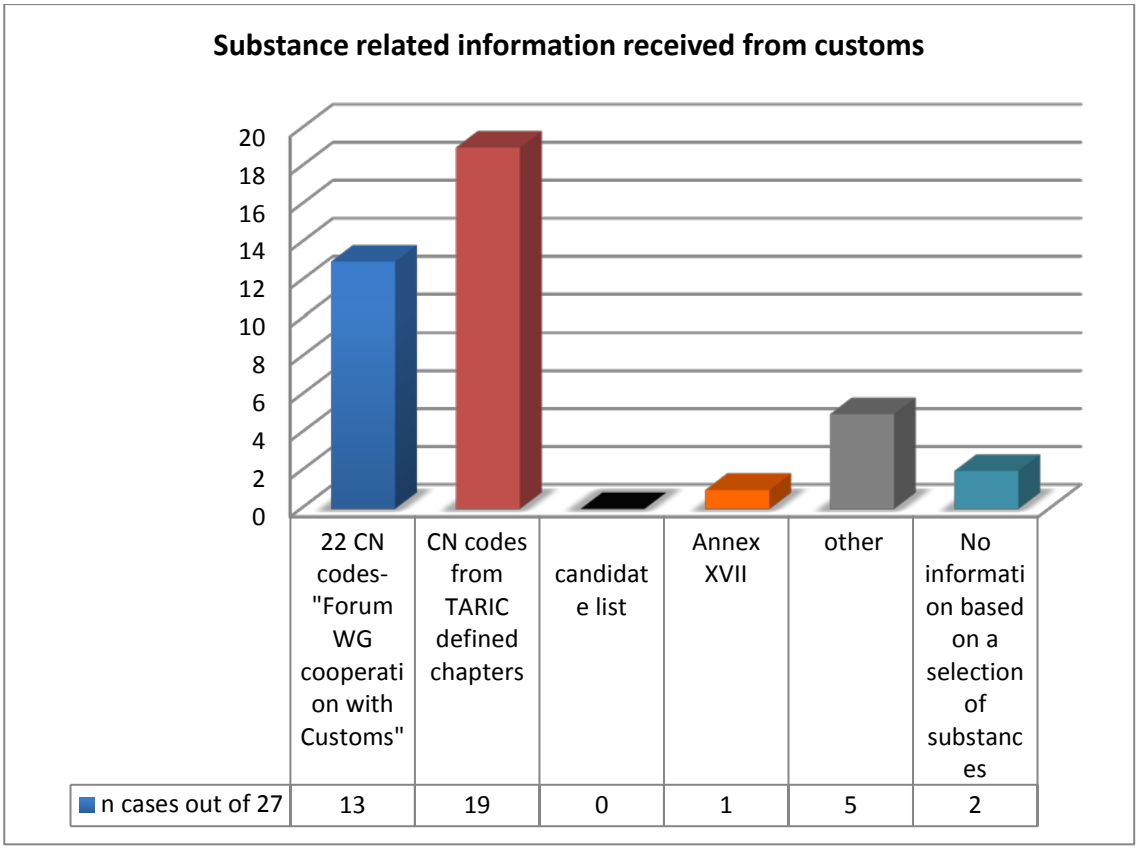


Figure 8: Details of substance-related information received from customs

4.2.3 Selection method of the inspected importers

28 participating countries selected the importers for the inspection based on information received from customs. The identified targets result from a risk assessment carried out by customs in only two countries while in 13 countries such risk assessment has been carried out by others (in a Member State both approaches could be in place in parallel).

In 14 countries the selection of importers is not related to information based on a company selection. In Figure 9, the details of the selection of importers for the inspection per participating country are reported.

Figure 9: Selection method of importers (inspection targets)

Information received for REF-3 from customs authorities related to declarations about substances to be released for free circulation. In 10 countries, the quantities concerned are at least one tonne per record or year. In four countries, they are less than one tonne per record or year. In 13 countries no tonnage threshold has been selected while in one country no information on quantities are available. The results are reported in Figure 10.

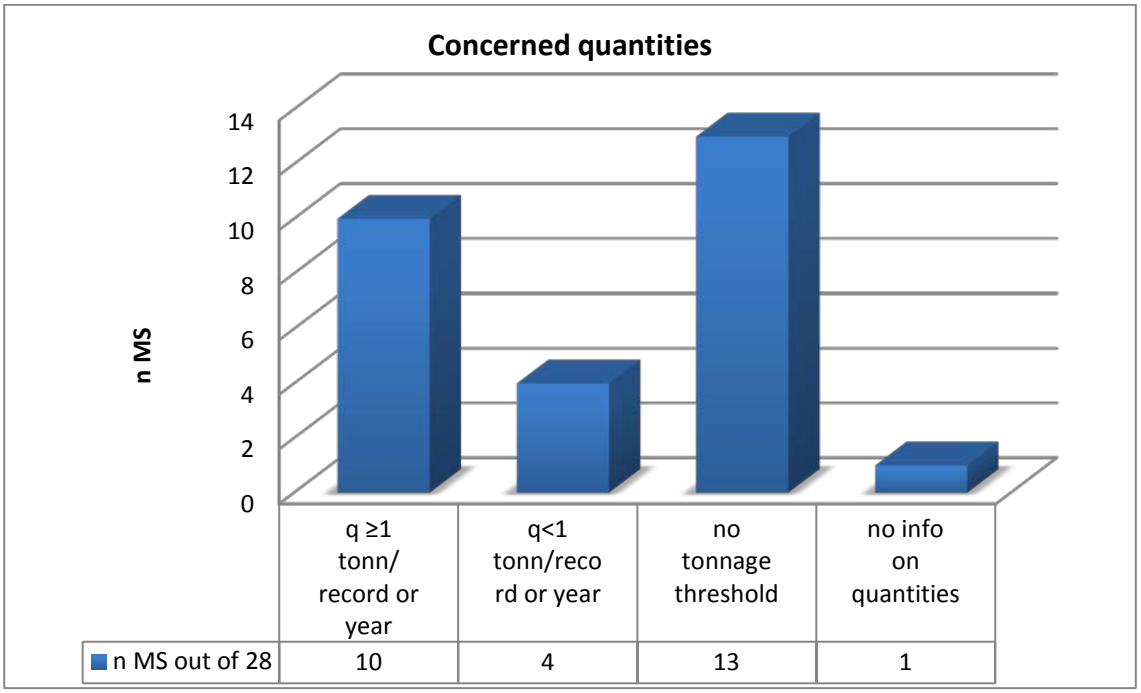


Figure 10: Imported quantities related to information received from customs

4.2.4 Period of the received information

The received information from customs is related to a period of time of at least one year in 71 % of cases, as reported in Figure 11. This allows for the immediate assessment of the import quantities provided in the customs data for overrunning annual tonnage limits related to registration deadlines in REACH.

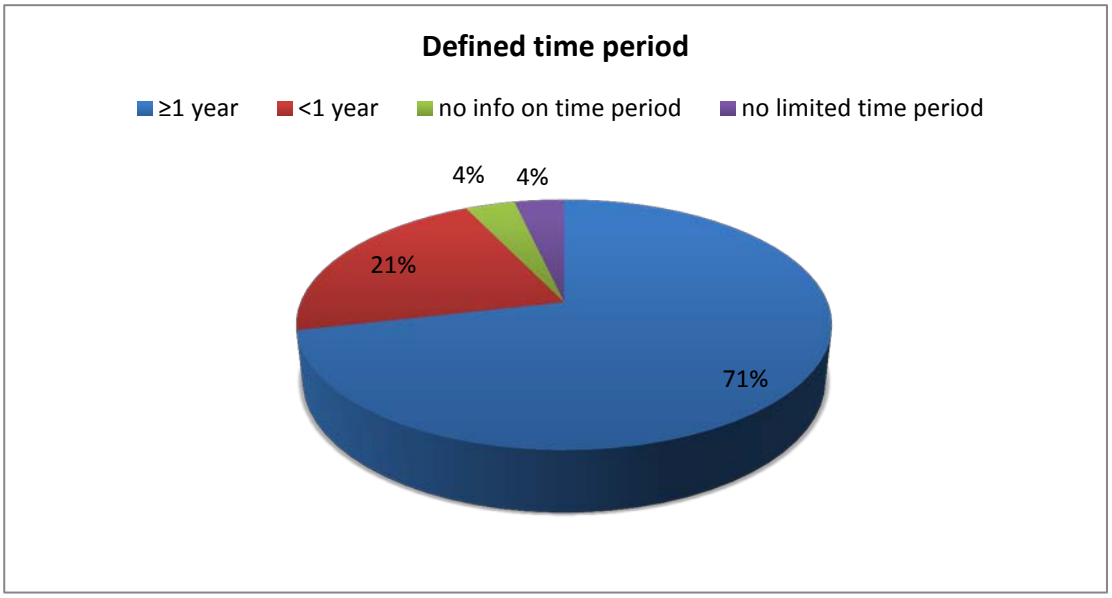


Figure 11: Selected timeframe for receiving information from customs

4.2.5 Part of customs organisation that sends the information

Information for REF-3 from customs was received in the vast majority of cases from central customs while in three countries the cooperation with both central and local customs is reported.

The results are shown in Figure 12.

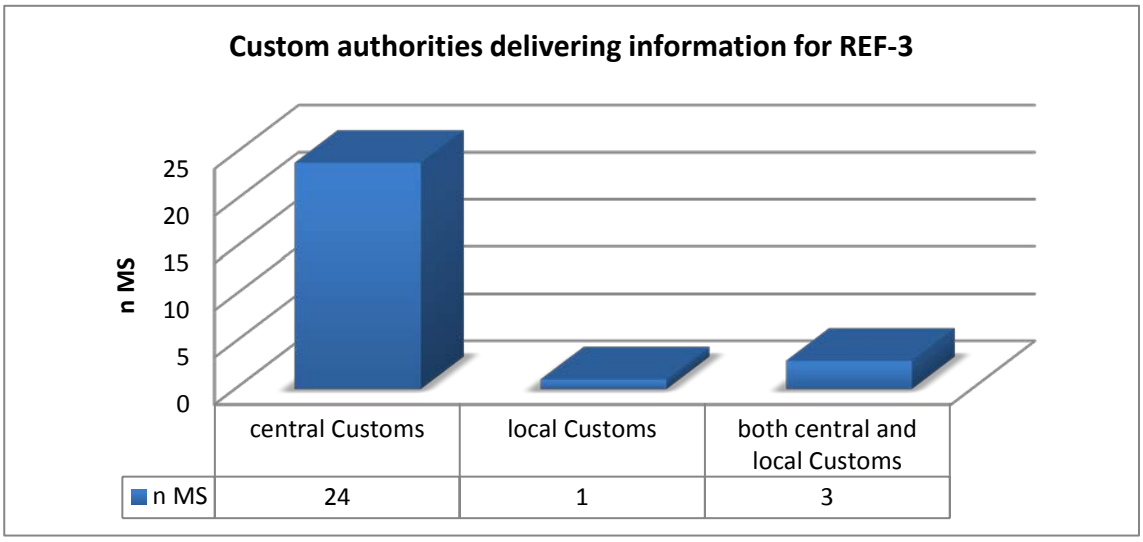


Figure 12: Customs departments involved

Information for REF-3 from customs was received through different channels. Most often encrypted "email only" is used (in 64 % of cases) while communication through other channels also occurs in a few cases (21 %). Details of the ways of receiving information from customs are reported in Figure 13.

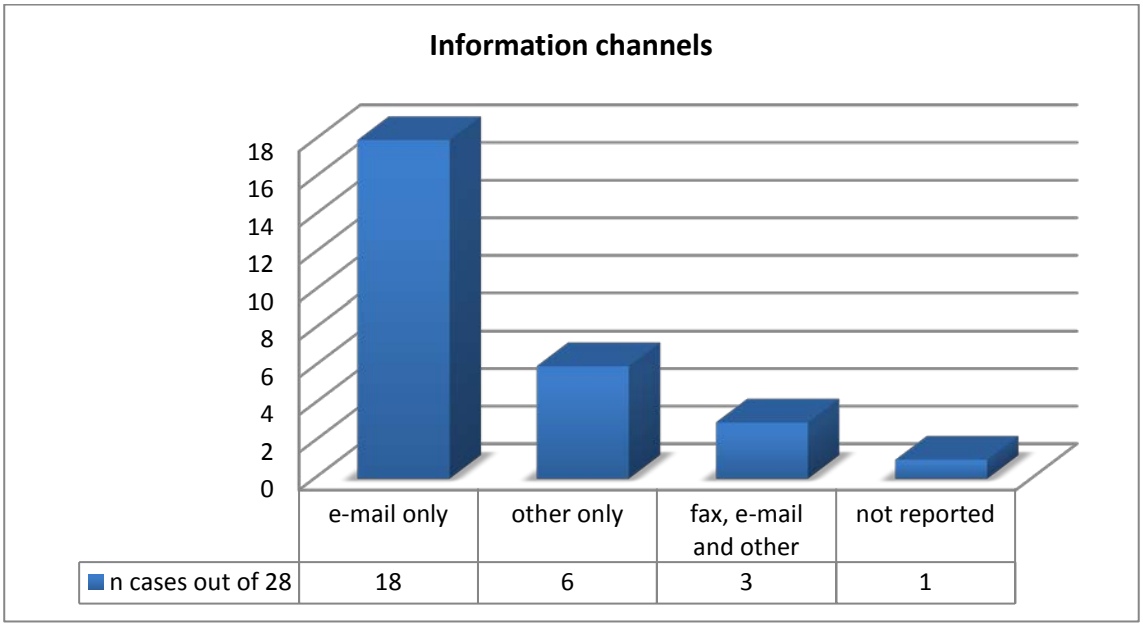
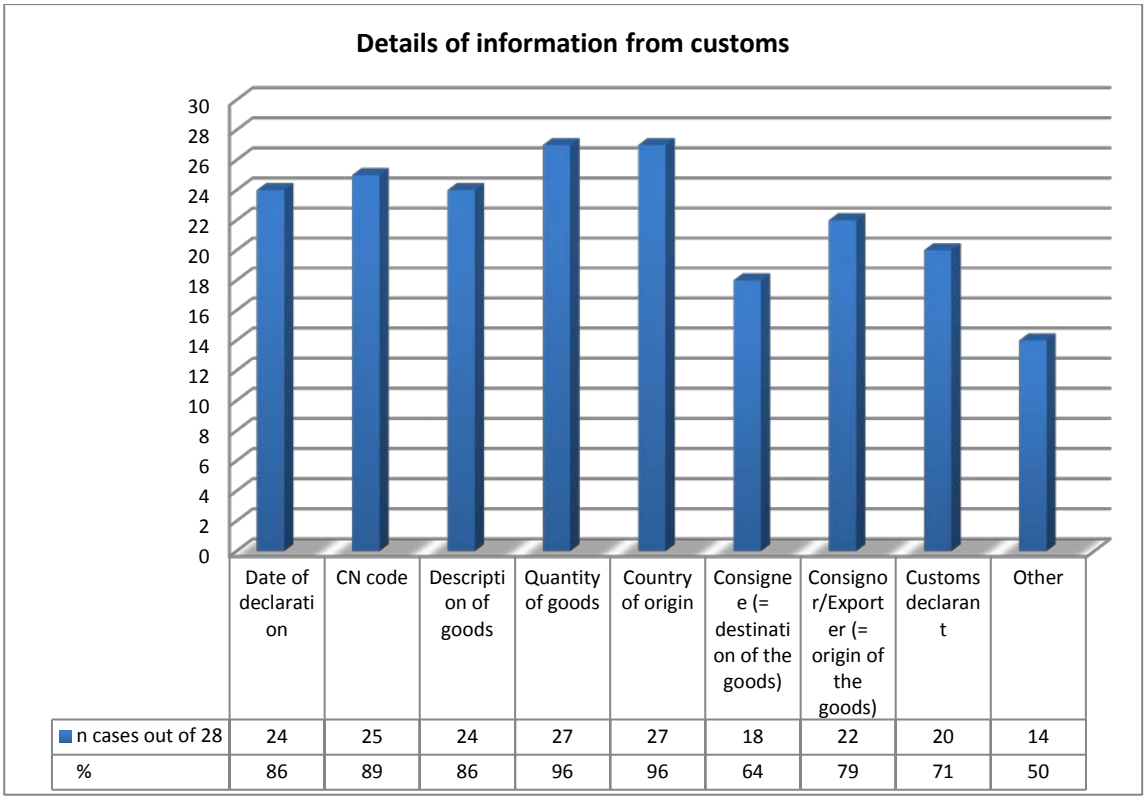


Figure 13: Ways of receiving information from Customs

The reported details of the information for REF-3 received from customs with regard to release for free circulation show that in 86% of the countries the date of declaration has been made available to the inspectors. 96 % of the countries received information on the quantity and country of origin, while respectively in 89 % and 86% of cases information on CN codes and a description of goods is also provided from customs. While 79 % of the countries received information on the exporter's identity, the destination of the goods was known (consignee) in only 64 % of cases. In 71 % of cases, the exporter's and custom declarant's details were revealed. For a complete picture of the information details, see Figure 14.



	Date of declaration	CN code	Description of goods	Quantity of goods	Country of origin	Consignee (= destination of the goods)	Consignor/Exporter (= origin of the goods)	Customs declarant	Other
n cases out of 28	24	25	24	27	27	18	22	20	14
%	86	89	86	96	96	64	79	71	50

Figure 14: Details of information received from customs

5.Conclusions and recommendations

The REACH-EN-FORCE-3 project has shown that in 2013 and 2014, 13 % of inspected companies did not observe REACH registration obligations.

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. 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.

It has also been seen that more attention needs to be given to importing companies.

Ultimately, the project has identified only representatives as a group specifically at risk of non-compliance with their registration duties. Detailed investigations during phase 2 of the project have revealed that the ORs were not compliant in 32 % of the cases.

Once investigating the information chain (importing DUs, ORs, non-EU manufacturers) inconsistencies were identified as inspectors observed that information at the importing DU covered by an OR was not consistent with the information available at the relevant OR.

Consistency checks for the information at importing DUs and at ORs turned out to be an important enforcement approach to draw conclusions on the functioning of REACH related to Article 8 on OR duties. Such investigations need a specific knowledge base to inspect the specific registration obligations linked to ORs.

In future, enduring and special attention needs to be drawn to these groups of duty holders at risk of non-compliance.

REACH-EN-FORCE-3 has proven that REACH enforcement authorities in the 28 participating countries have at a minimum a functioning cooperation with customs which also in the future will allow data to be used from individual customs declarations in routine inspections of REACH duties.

The enforcement design and the inspections based on customs information enable targeted inspections for special companies with a risk of non-compliance and therefore the number of non-compliant companies is higher compared to previous enforcement projects.

Based on the enforcement project’s findings, the lessons learnt and the recommendations are as follows:

1. To national enforcement authorities:

1.1. Especially in light of the REACH registration deadline in 2018, include a check of compliance with registration obligations in the national routine inspection methodology.

1.2. Include routine use of customs data/information for checks related to importers (and the related ORs) in the national inspection methodology for checks on registration obligations.

1.3. All Member States to provide input into a shared database of inspection results from importing DUs and corresponding ORs. This database should be made accessible to and should be filled in by all NEAs (e.g. in Portal Dashboard NEA).

1.4. In addition to inspectors taking strict enforcement measures only, the Member States shall offer and support an option for inspectors focusing on importing DUs to ask, on a voluntary basis, additional information directly from the OR company while collecting evidence, even when the OR is located in a different Member State.

Forum could also support this approach by compiling and providing a common letter template.

1.5. Create a sustainable cooperation platform at national level between NEAs and customs (e.g. common working group, contact points, seminar) where such platform does not already exist.

1.6 Inspections covering OR-specific duties should focus on the functioning of the communication and interaction between ORs and the importing DUs. It is important for the customer list to be complete and that the correct annual tonnage/quantities are recorded for each substance which the OR is responsible for.

2. To the Forum:

2.1. Create and maintain a database (e.g. in Portal Dashboard-NEA) of the inspection results of importing DUs and corresponding ORs in different Member States in cooperation with the NEAs.

2.2. Develop a cross-border pilot exercise about understanding and potentially filling an important data gap due to missing customs information from other Member States: inspections at the importer A located in Member State 1 based on the customs information (import declarations for importer A) available at and provided by Member State 2. National regulations and other EU regulations (e.g. Market Surveillance Regulation) must be considered.

2.3. Organise a seminar/workshop in collaboration with DG TAXUD (and possibly the PARCS Project Group) to exchange new information between NEAs and customs in the context of REACH (e.g. re-import, importing DUs, ORs): on how to use customs data and understand customs' procedures, on how to work in inspection teams NEA/customs, on a need for development of a customs guideline on REACH registration obligations of importers within PARCS, etc. As all 28 participating countries have established a functioning basic cooperation with customs, the NEAs become more experienced. These experiences of different approaches of REF-3 should be integrated.

2.4. Future WGs: test the questionnaire before the start of the operational phase.

2.5. Future WGs: organise a webinar/meeting with NCs during or at the beginning of the reporting phase to clarify how to perform a quality check on the national data and prepare a paper defining criteria on quality checking.

3. To Commission:

3.1 The regulator should re-visit Article 8 as it has proven to be difficult to be consistently implemented and enforced in its current form: define an explicit duty for a documented contact/exchange of information between the importing DU and the OR, which means:

- explicitly defining the duty for an importing DU to keep a documentation for the relevant substance(s) with annual tonnages confirmed by the OR(s) (e.g. keeping confirmation documents from the related ORs); and
- stipulate that only an importing DU keeping such documentation is released from the registration duties of an importer;
- define a new duty for the OR to send the information on covering the registration duties for the importing DU for a specific substance and the information about the related annual quantities of the substance imported according to its lists (i.e. the

tonnages covered by the OR) to the importing DU.

3.2 Clarify the conditions for relying on the REACH provisions exempting re-import from the registration obligation (regarding the practical feasibility for the inspection context).

3.3 Create a single database for all REACH-relevant import declarations to enable better targeting of inspections. Currently, the data is maintained per Member State by the national customs authorities so it is difficult to trace all imports covered by a single duty holder (OR) if they are administered by customs authorities in several countries. As a possible initial step, develop a firm legal basis for an exchange of relevant data from import declarations of identified duty holders between authorities (enforcement, customs) in different Member States.

3.4 Change the data requirements and make it mandatory for ORs to submit information on covered importers in their registration file. This would be helpful for the ORs and importing DUs and related inspections. It would allow ECHA to check the presence of this information in the registration file during the completeness check.

4. To ECHA:

4.1 Review the Guidance documents emphasising the OR duties and the consistent functioning of the information chain along the line OR - importing DU requiring communication by ORs as well as by the importing DUs.

5. To industries and industry stakeholders

5.1 The high non-compliance rate for only representatives needs to be addressed by the industries and industry stakeholders concerned. In this project, only representatives have the highest non-compliance rate. Often, only representatives were non-compliant not so much due to missing registrations, but due to breaching of Article 8 of REACH relating to the duties of only representatives.

5.2 Importing DUs need to be advised to cooperate directly with ORs and to make sure that their ORs are fully complying with their duties under Article 8. This is important for the importing DU so they do not end up in situations where their imports of substances become affected once it turns out that required registrations of the ORs are missing, not valid or not applicable to them.

5.3 The high non-compliance rate for importers needs to be addressed by the industries and industry stakeholders concerned. Importers are often not aware and not familiar with their registration obligations under the REACH Regulation.

5.4 The high non-compliance rate for SMEs/micro-sized enterprises needs to be addressed by the industries and industry stakeholders concerned.

5.5 The high non-compliance rate for companies which are related to the chemical industry and chemical distribution sectors needs to be addressed by the industries and industry stakeholders concerned.

6. Annexes

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 Recommendation2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises

Annex 2: Supplementary figures and tables

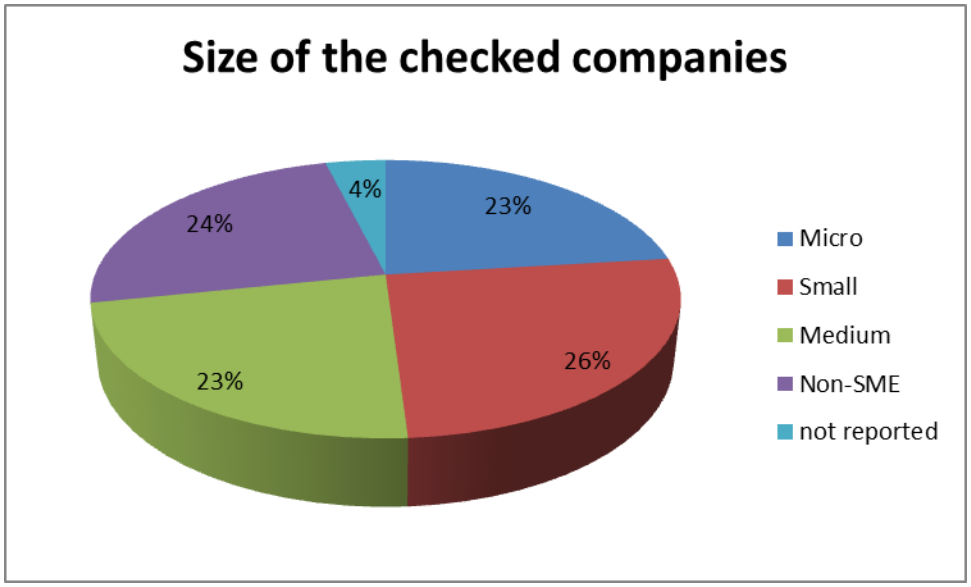


Figure A1: Distribution of the company sizes

Table A1: Distribution of company sizes and role (n=641).

Role inter alia	Micro	Small	Medium	Non-SME	Not reported
M	8	18	35	53	0
I	71	78	69	84	7
OR	36	21	21	23	7
DU	62	110	104	114	13
D	51	53	41	43	1

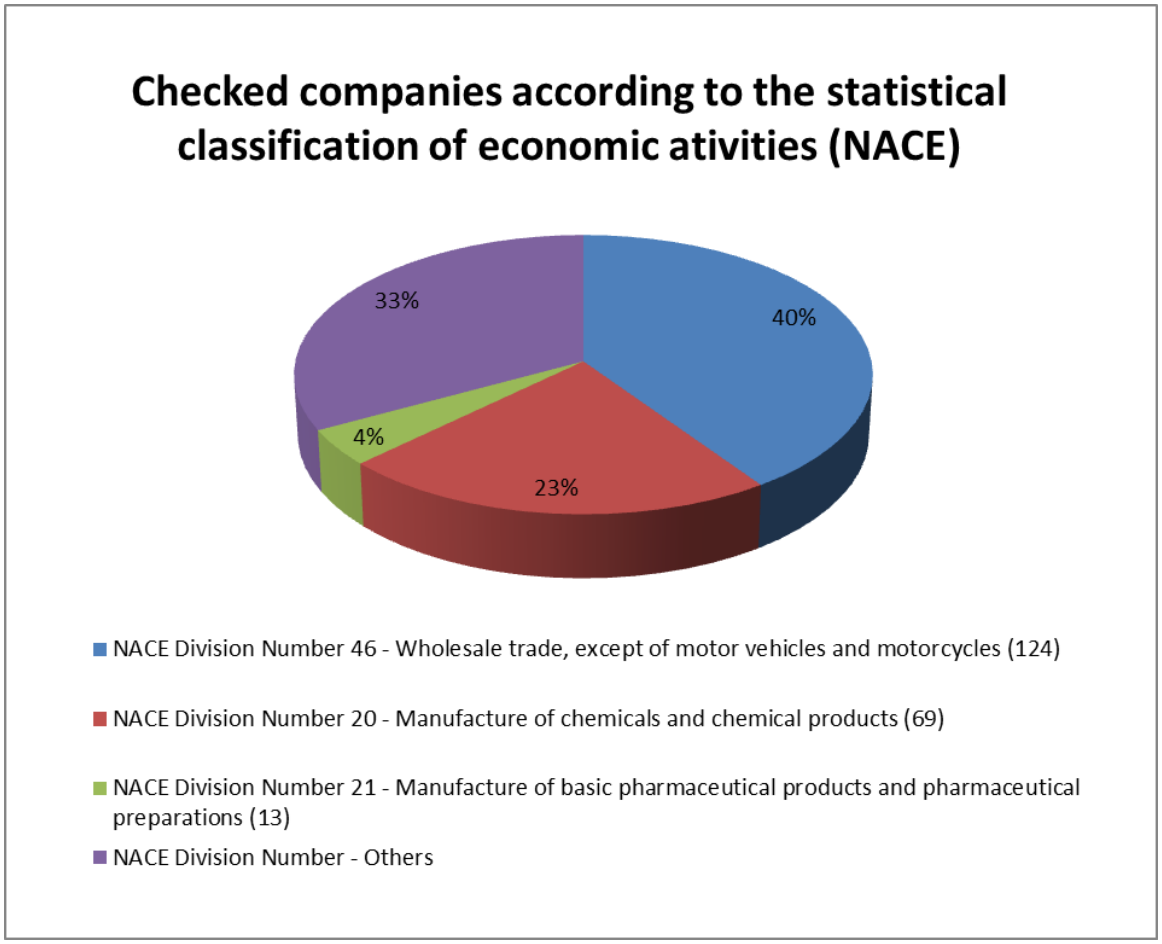


Figure A2: Range of a selection of surveyed economic sectors represented by the inspected enterprises specified by the NACE code

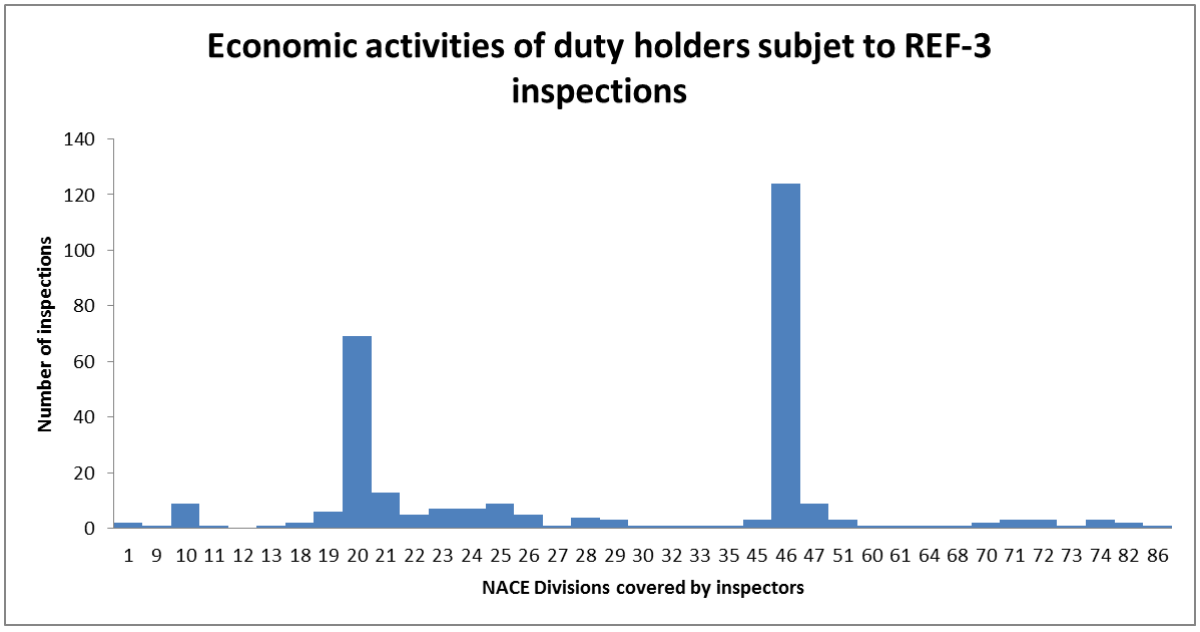


Figure A3: Range of surveyed economic sectors represented by the inspected enterprises specified by the NACE Division

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*		*171*
A	C 20.12	Manufacture of dyes and pigments	12
A	C 20.13	Manufacture of other inorganic basic Chemicals	13
A	C 20.14	Manufacture of other organic basic chemicals	24
A	C 20.15	Manufacture of fertilisers and nitrogen Compounds	11
A	C 20.16	Manufacture of plastics in primary forms	17
A	C 20.30	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	28
A	C 20.59	Manufacture of other chemical products n.e.c.	26
A	*C 22 Manufacture of rubber and plastic products*		*26*
A	*C 23 Manufacture of other non-metallic mineral products*		*29*
A	*C 24 Manufacture of basic metals*		*17*
B	*C 46 Wholesale trade (except of motor vehicles and motorcycles)*		*207*
B	G 46.12	Agents involved in the sale of fuels, ores, metals and industrial chemicals	16
B	G 46.75	Wholesale of chemical products	118
B	G 46.90	Non-specialised wholesale trade	15

Table A3: Distribution of company sizes and economic sectors (n=641)

	Company size				
NACE-groups	Micro	Small	Medium	Not SME	Not report-ed
A	27	55	79	83	10
B	87	73	34	33	9
C	8	19	25	27	2
D	27	19	8	12	4

Table A4: Correlation between reasons and rates of non-compliance (data from Table 14 and 15)

Reason for non-compliance (Table 14)	Identified non-compliance (Table 15)
Substance identity + Missing registration (67%)	Substance subject to registration (e.g. sub-stance identity) + Registration status of the inspected substance (67%)
Wrong tonnage band (1%)	Substance quantities per calendar year (4%)
Not all REACH obligations according to the applicable role M/I/OR (13%)	Role of the company under REACH (13%)
Criteria and/or obligation of an OR not ful-filled, missing evidence for appointment of an OR (35%)	Specific duties of an Only Representative (17%)

Annex 3: Questionnaires

Questionnaires used on the Forum project REACH-EN-FORCE 3 (Phase 1 and 2)

Questionnaire used in Phase 1 of the project:

QUESTIONNAIRE PART A (One (1) questionnaire per inspected company)	
0. Section – General Information about the inspection (questions 0.2 to 0.5 will not be recorded)	
0.1.Participating country:	
0.2. Authority: 0.3. Person in Charge: Telephone: Fax: E-mail: 0.4. Date of inspection: 0.5. File reference:	Only for internal use – do not submit data

I. Section – General information about the inspected company (questions 1.1. to 1.3. will not be recorded)	
1.1. Name of company: 1.2. Name of the contact person: 1.3. Contact person's qualification:	Only for internal use – do not submit data
1.4. Company's NACE-Code(s):	Source for NACE Code (see in Annex 3)
2. According to Commission Recommendation 2003/361/EC the company qualifies as: (☐) Micro (☐) Small (☐) Medium (☐) not SME (☐) unknown 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	
3. Roles of the company under REACH: ☐ Manufacturer ☐ Importer (company not covered by an OR) ☐ Only Representative (OR) ☐ Downstream User (e g: formulator, importer covered by an OR, end-user) ☐ Distributor	Note: Art 3.9 of REACH Art 3.11 of REACH Art 8.1 of REACH Art 3.13 of REACH Art 3.14 of REACH

II. Section - Compliance with registration duties by the company	
4. Does the company manufacture (phase-in or non-phase-in) substances in quantities of 1 tonne or more per year? ☐ As substances as such how many? ☐ As substances in mixtures how many? ☐ No ☐ Is for any substance manufactured no / actually no registration required? how many ? why?	Note: Art 3.8 of REACH Please give here the exemption that is the most relevant in the situation of the company. For exemptions, see in Annex 3. For low tonnage phase-in substances before the deadlines 2013 or 2018 there might be at the time of the inspection no registration required.

5. Does the company import (phase-in or non-phase-in) substances in quantities of 1 tonne or more per year? ☐ As substances as such how many? ☐ As substances in mixtures how many? ☐ No ☐ Is for any substance imported no / actually no registration required? how many? why?	Note: Art 3.10 of REACH Include here also companies that are ORs. Please give here the exemption that is the most relevant in the situation of the company. For exemptions, see in Annex 3. For low tonnage phase-in substances before the deadlines 2013 or 2018 there might be at the time of the inspection no registration required.
6. Total number of pre-registrations/ registrations submitted by the inspected company to ECHA: Number of pre-registrations Number of registrations	Numbers based on the information of the RIPE portal

7. Total number of substances checked at the company for compliance with the registration obligations:
Total number of substances checked:
Total number of substances for which incompliance with registration obligations according to Section III (entry 9 to 13) of this questionnaire has been identified:

Listing of substances
and summary of major reasons for incompliance with registration obligations:

**) Please indicate for each substance listed as reasons 1-3 the most severe incompliance identified on basis of Section III (entry 9 to 13) of this questionnaire.*
Please note that for any substance listed in the following table the questions 9 to 13 should be documented by the REACH inspector and where required should only be passed on enquiry in case of national summaries

Substance name	CAS number	EINECS number	CN code	Up to three major reasons for incompliance with registration obligation		
				Reason 1 *)	Reason 2 *)	Reason 3 *)
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						

III. Section - Compliance with registration duties for the selected substance	
REMARK At least one substance is checked per inspected company. Several substances can be inspected per company, but only the investigation for one substance should be reported in full detail in this Section III. As REF-3 is focused on non-compliance, ➔ if NO non-compliance was detected with regard to any of the investigated substances, findings on an arbitrary investigated substance is to be reported. It should be explicitly reported in the questionnaire that no non-compliance was detected (in question 7 of Section II) ➔ if non-compliance was detected with regard to one or more of the investigated substances, full details of the findings are to be reported on this substance of all investigated substances that is judged by the inspector to be related to the most serious offence. ➔ in addition to this one substance reported in Section III: for any substance listed in the table of question 7, the questions 9 to 13 should be documented by the REACH inspector and, where required, should only be passed on enquiry in case of national summaries.	
8. Inspected substance: Name: CAS number:	
9. Did the company register the inspected substance? (☐) Yes If yes, is the identity of the substance in the registration dossier identical to the inspected substance? ☐ Yes ☐ No (☐) No If not, (☐) Company intends to register by 01.06.2013 (☐) Company intends to register by 01.06.2018 (☐) Company does not need to register (☐) Company does not observe registration obligation (☐) Not reported	Note: Art 6.1 of REACH Art 23 of REACH for exemptions, see in Annex 3
10. The inspected substance is: (☐) manufactured as a substance on its own (☐) manufactured as a substance in a mixture (☐) imported as substance on its own (☐) imported as a substance in a mixture (☐) Not reported	Note: Art 3.8 and 3.10 of REACH
11. Does the tonnage band in the registration dossier comprise the real tonnages of the inspected substance for 2011 and for 2012? (☐) Yes (☐) No (☐) Not reported	Note: Question 11 is only relevant once the answer to question 9 is “Yes”
12. Based on the findings of the inspector: is the company the legal entity responsible for: (☐) the manufacture of the inspected substance? (☐) the import of the inspected substance? (☐) as Only Representative of the inspected substance? (☐) Not reported	Note: Art 3.8, 3.10 and Art 8.1 of REACH Report here the findings of the inspector’s investigation
13. Based on the role the inspected company is actually taking: is the inspected company acting as: (☐) the manufacturer of the inspected substance? (☐) the importer of the inspected substance? (☐) the Only Representative of the inspected substance? (☐) Not reported	Note: Art 3.8, 3.10 and Art 8.1 of REACH Describe here - in contrast to question 12 - the situation as it is found on-site
If the company with regard to the selected substance is an Only Representative (OR) questions 14-16 shall be filled	

14. Does the company comply with Article 8.2 REACH? (☐) Yes If yes, - overall quantity (tonnes) for the calendar year 2012: - total number of customers covered by the OR: (☐) No If not, with regard to the inspected substance, the OR does not ☐ have sufficient background in the practical handling of the substance ☐ have the information related to the substance ☐ keep available and up-to-date the information on overall quantities of the inspected substance imported per calendar year (year 2012 and earlier) ☐ keep available and up-to-date the information on customers the substance is sold to (☐) Not reported	Note: Art 8.2 of REACH REACH FAQ 4.3 and 4.7
15. Is there material evidence proving the company's appointment as only representative for the specific substance when asked for? (☐) Yes (☐) No (☐) Not reported	Note: Art 8.1 of REACH REACH FAQ 4.4
16. Has the non-EEA company (manufacturer, formulator) that has appointed the only representative for registration of the inspected substance informed the importing downstream users about the appointment of the only representative? (☐) Yes (☐) No (☐) Not reported	Note: Art 8.3 of REACH

IV. Section – Summary / action (company related)
17. Has non-compliance with REACH obligations of the inspected company related to the registration (and / or OR duties) been detected? (☐) Yes If yes, ☐ Substance subject to registration (e.g. substance identity) ☐ Role of the company under REACH ☐ Registration status of the inspected substance ☐ Registration number ☐ Registrant identity ☐ Substance quantities per calendar year ☐ Information provided in the registration dossier ☐ Specific duties of an Only Representative ☐ Other: (☐) No
18. Was legal action initiated against the offender? (☐) Yes If yes, ☐ Verbal advice ☐ Written advice ☐ Administrative order ☐ Order ☐ Enjoinment ☐ Fine ☐ Criminal complaint / handing over to public prosecutor's office ☐ Other: ☐ Follow up activities still on-going (☐) No

19. In case a substance or a substance in a mixture (manufactured or imported by the inspected company) is found not to be registered, though it should have been, were measures imposed by the inspector?
(☐) Yes
If yes,
☐ Order / Enjoinment
☐ Allowed time for bringing the substance in compliance
☐ Other measures
(☐) No

20. Have any cases been forwarded to other Member States?
(☐) Yes
If yes,
☐ National Enforcement Authority
☐ National Competent Authority
☐ Forum Member
☐ National REF-3 Coordinator
☐ NEA Contact Point / Focal Point in RIPE
☐ Feedback from the other Member State approached is already available
(☐) No

QUESTIONNAIRE PART B
(One (1) questionnaire per participating EEA/EU-country filled by the National Coordinator)

Role of Customs:
- Customs act as a supplier of information (go to **Part B**)
- No role for customs authorities : **DO NOT FILL** IN QUESTIONNAIRE PART B

1. Information for REF-3 from Customs received:
☐ on substances/mixtures based on pre-identified CN codes
☐ on pre-identified importers

2. Substance related information for REF-3 from Customs received is:
☐ about the minimum list of substances proposed by the Forum WG “Cooperation with Customs” (22 CN codes)
(☐) all 22 CN codes
(☐) not all 22 CN codes
excluded CN codes:
☐ about all CN codes:

☐ about:
☐ candidate list
☐ Annex XVII of REACH
☐ other
☐ No information based on a selection of substances

3. The selection of importers for the inspection is based on information received from customs:
☐ a list of companies following a custom’s risk assessment
☐ a list of companies following a risk assessment by others
other:
☐ No information based on a company selection

4. Information for REF-3 from customs received concerns declarations about substances to be released for free circulation:
☐ in quantities of at least 1 tonne per record or year
☐ in quantities less than 1 tonne per record or year

5. Information for REF-3 from customs received relates to a defined time period of:
☐ at least 1 year
☐ less than 1 year
time period = days

6. Information for REF-3 from customs was received:
- ☐ from central customs administration
- ☐ from local customs administrations

7. Information for REF-3 from customs was received:
- ☐ via fax
- ☐ via e-mail
- ☐ other

8. Included in the information for REF-3 received from customs was:
- ☐ Date of the declaration
- ☐ CN code
- ☐ Description of goods
- ☐ Quantity of goods
- ☐ Country of origin
- ☐ Consignor/Exporter (= origin of the goods)
- ☐ Consignee (= destination of the goods)
- ☐ Customs declarant
- ☐ Other

which type of other information was received?

Questionnaire used in Phase 2 of the project:

REF-3 Phase 2 - QUESTIONNAIRE PART A (One (1) questionnaire per inspected company)	
0. Section – General Information about the inspection (questions 0.2 to 0.5 will not be recorded)	
0.1.Participating country:	
0.2. Authority: 0.3. Person in Charge: Telephone: Fax: E-mail: 0.4. Date of inspection: 0.5. File reference:	For internal use – do not submit data

I. Section – General information about the inspected company (questions 1.1. to 1.3. will not be recorded)	
1.1. Name of company: 1.2. Name of the contact person: 1.3. Contact person's qualification:	Only for internal use – do not submit data
1.4. Company's NACE-Code(s):	Source for NACE Code (see in Annex 3 of the Manual)
2. According to Commission Recommendation 2003/361/EC the company qualifies as: (☐) Micro (☐) Small (☐) Medium (☐) not SME (☐) unknown 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	
3. Roles of the company under REACH: ☐ Manufacturer ☐ Importer (company not covered by an OR) ☐ Only Representative (OR) ☐ Downstream User (e g: formulator, importer covered by an OR, end-user) ☐ Distributor	Note: Art 3.9 of REACH Art 3.11 of REACH Art 8.1 of REACH Art 3.13 of REACH Art 3.14 of REACH

II. Section - Compliance with registration duties by the company	
4. Does the company manufacture (phase-in or non-phase-in) substances in quantities of 1 tonne or more per year? ☐ As substances as such how many? ☐ As substances in mixtures how many? ☐ No ☐ Are there any substances manufactured which do not require registration If so, how many? Provide brief reason why registration is not required	Note: Art 3.8 of REACH Please give here the exemption that is the most relevant in the situation of the company. For exemptions, see in Annex 3 of the Manual. For low tonnage phase-in substances before the deadline in 2018 there might be at the time of the inspection no registration required.

5. Does the company import (phase-in or non-phase-in) substances in quantities of 1 tonne or more per year? ☐ As substances on their own how many? ☐ As substances in mixtures how many? ☐ No ☐ Are there any substances imported which do not require registration If so, how many due to an appointment of an OR? how many due to an exemption of re-import? how many due to other reasons? brief specification of the other reasons	Note: Art 3.10 of REACH includes imports by DU in context of an OR and of re-import Include here also companies that are ORs. Please give here the exemption that is the most relevant in the situation of the company. For exemptions, see in Annex 3 of the Manual. For low tonnage phase-in substances before the deadline in 2018 there might be at the time of the inspection no registration required.
6. Total number of pre-registrations/ registrations submitted by the inspected company to ECHA: Number of pre-registrations Number of registrations	Numbers based on the information of the RIPE portal

7. Total number of substances checked at the company for compliance with the registration obligations:
Total number of substances checked:
Total number of substances for which incompliance with registration obligations according to Section III (entry 9 to 13) of this questionnaire has been identified:

Listing of substances
and summary of major reasons for incompliance with registration obligations:

**) Please indicate for each substance listed as reasons 1-3 the most severe incompliance identified on basis of Section III (entry 9 to 13) of this questionnaire.*
Please note that for any substance listed in the following table the questions 9 to 13 should be documented by the REACH inspector and where required should only be passed on enquiry in case of national summaries

Substance name	CAS number	EINECS number	CN code	Up to three major reasons for incompliance with registration obligation		
				Reason 1 *)	Reason 2 *)	Reason 3 *)
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						

III. Section - Compliance with registration duties for the selected substance	
REMARK At least one substance is checked per inspected company. Several substances can be inspected per company, but only the investigation for one substance should be reported in full detail in this Section III. As REF-3 is focused on non-compliance, ➔ if NO non-compliance was detected with regard to any of the investigated substances, findings on an arbitrary investigated substance is to be reported. It should be explicitly reported in the questionnaire that no non-compliance was detected (in question 7 of Section II) ➔ if non-compliance was detected with regard to one or more of the investigated substances, full details of the findings are to be reported on this substance of all investigated substances that is judged by the inspector to be related to the most serious offence. ➔ in addition to this one substance reported in Section III: for any substance listed in the table of question 7, the questions 9 to 13 should be documented by the REACH inspector and, where required, should only be passed on enquiry in case of national summaries.	
8. Inspected substance: Name: CAS number:	
9. Did the company register the inspected substance? (☐) Yes If yes, is the identity of the substance in the registration dossier identical to the inspected substance? ☐ Yes ☐ No (☐) No If not, (☐) Company intends to register by 01.06.2018 (☐) Company does not need to register (☐) Company does not need to register -exemption of re-import (☐) Company does not need to register - an OR is appointed (☐) Company does not need to register - other reason (☐) Company does not observe registration obligation (☐) Not reported	Note: Art 6.1 of REACH Art 23 of REACH for exemptions, see in Annex 3 of the Manual
10. The inspected substance is: (☐) manufactured as a substance on its own (☐) manufactured as a substance in a mixture (☐) imported as substance on its own (☐) imported as a substance in a mixture (☐) Not reported	Note: Art 3.8 and 3.10 of REACH Art 3.10 of REACH includes imports by DU in context of an OR and of re-import
11. Does the tonnage band in the registration dossier comprise the real tonnages per year of the inspected substance? (☐) Yes (☐) No (☐) Not reported	Note: Question 11 is only relevant once the answer to question 9 is “Yes”
12. Based on the findings of the inspector: is the company the legal entity responsible for: (☐) the manufacture of the inspected substance? (☐) the import of the inspected substance? (☐) as Only Representative of the inspected substance? (☐) Not reported	Note: Art 3.8, 3.10 and Art 8.1 of REACH Art 3.10 of REACH includes imports by DU in context of an OR and of re-import Report here the findings of the inspector’s investigation
13. Based on the role the inspected company is actually taking: is the inspected company acting as: (☐) the manufacturer of the inspected substance? (☐) the importer of the inspected substance? (☐) the Only Representative of the inspected substance? (☐) Not reported	Note: Art 3.8, 3.10 and Art 8.1 of REACH Art 3.10 (and Art 3.11) of REACH includes imports by DU in context of an OR and of re-import Describe here - in contrast to question 12 - the situation as it is found on-site

If the company with regard to the selected substance is an Only Representative (OR) questions 14-16 shall be filled	
(☐) The following assessment includes results received from inspected importing DUs 14. Does the company comply with Article 8.2 REACH? (☐) Yes If yes, - overall quantity (tonnes) for calendar year : - total number of customers covered by the OR: (☐) No If not, with regard to the inspected substance, the OR does not ☐ have sufficient background in the practical handling of the substance ☐ have the information related to the substance ☐ keep available and up-to-date the information on overall quantities of the inspected substance imported per calendar year ☐ keep available and up-to-date the information on customers the substance is sold to (☐) Not reported	Note: Art 8.2 of REACH REACH FAQ 4.3 and 4.7
15. Is there material evidence proving the company's appointment as only representative for the specific substance when asked for? (☐) Yes (☐) No (☐) Not reported	Note: Art 8.1 of REACH REACH FAQ 4.4
16. Has the non-EEA company (manufacturer, formulator) that has appointed the only representative for registration of the inspected substance informed the importing downstream users about the appointment of the only representative? (☐) Yes (☐) No (☐) Not reported (☐) The assessment includes results received from inspected importing DUs	Note: Art 8.3 of REACH

IV. Section – Summary / action (company related)
17. Has non-compliance with REACH obligations of the inspected company related to the registration (and / or OR duties) been detected? (☐) Yes If yes, ☐ Substance subject to registration (e.g. substance identity) ☐ Role of the company under REACH ☐ Registration status of the inspected substance ☐ Registration number ☐ Registrant identity ☐ Substance quantities per calendar year ☐ Information provided in the registration dossier ☐ Specific duties of an Only Representative ☐ Other: (☐) No

18. Was legal action initiated against the offender?
(☐) Yes
If yes,
☐ Verbal advice
☐ Written advice
☐ Administrative order
☐ Order
☐ Enjoinment
☐ Fine
☐ Criminal complaint / handing over to public prosecutor's office
☐ Other:
☐ Follow up activities still on-going
(☐) No

19. In case a substance or a substance in a mixture (manufactured or imported by the inspected company) is found not to be registered, though it should have been, were measures imposed by the inspector?
(☐) Yes
If yes,
☐ Order / Enjoinment
☐ Allowed time for bringing the substance in compliance
☐ Other measures
(☐) No

20. Have any cases bilaterally been forwarded to other Member States?
(☐) Yes
If yes,
☐ National Enforcement Authority
☐ National Competent Authority
☐ Forum Member
☐ National REF-3 Coordinator
☐ NEA Contact Point / Focal Point in RIPE
☐ Feedback from the other Member State approached is already available
(☐) No

REF-3 Phase 2 - QUESTIONNAIRE PART B
(One (1) questionnaire per participating EEA/EU-country filled by the National Coordinator)

Role of Customs:
- Customs act as a supplier of information (go to **Part B**)
- No role for customs authorities : **DO NOT FILL** IN QUESTIONNAIRE PART B

1. Information for REF-3 from Customs received:
☐ on substances/mixtures based on pre-identified CN codes
☐ on pre-identified importers

2. Substance related information for REF-3 from Customs received is:
☐ about the minimum list of substances proposed by the Forum WG “Cooperation with Customs” (22 CN codes)
(☐) all 22 CN codes
(☐) not all 22 CN codes
excluded CN codes:
☐ about all CN codes:

☐ about:
☐ candidate list
☐ Annex XVII of REACH
☐ other
☐ No information based on a selection of substances

3. The selection of importers for the inspection is based on information received from customs:
☐ a list of companies following a custom's risk assessment
☐ a list of companies following a risk assessment by others
other:
☐ No information based on a company selection

4. Information for REF-3 from customs received concerns declarations about substances to be released for free circulation:
☐ in quantities of at least 1 tonne per record or year
☐ in quantities less than 1 tonne per record or year

5. Information for REF-3 from customs received relates to a defined time period of:
☐ at least 1 year
☐ less than 1 year
time period = days

6. Information for REF-3 from customs was received:
☐ from central customs administration
☐ from local customs administrations

7. Information for REF-3 from customs was received:
☐ via fax
☐ via e-mail
☐ other

8. Included in the information for REF-3 received from customs was:
☐ Date of the declaration
☐ CN code
☐ Description of goods
☐ Quantity of goods
☐ Country of origin
☐ Consignor/Exporter (= origin of the goods)
☐ Consignee (= destination of the goods)
☐ Customs declarant
☐ Other
which type of other information was received?

Annex 4: Considerations on the requirements of Article 8 of REACH

The Working Group REF-3 prepared a document on the requirements of Article 8 of REACH that are relevant when inspecting only representatives. Please note that this document aimed to compile the status of clarifications on Article 8 of REACH that were accessible to the WG REF-3 and to Forum.

It is a service tool in the context of the REF-3 enforcement project and the intention is to provide assistance in situations the inspectors consider formal action. The document has been consulted with the WG REF-3 and with Forum but the content cannot be regarded as a final conclusion of the Forum.

Inspections in the interrelation between only representatives and "importing downstream users"

Where a substance or a substance in a mixture was imported, the importer had the obligation to pre-register according to Article 28 or register the substance according to Article 5 of REACH.

According to Article 8 of REACH, an exemption of a registration for an importer is given if an only representative (OR) is appointed. This will relieve the EU importers within the same supply chain from their registration obligations and they will be regarded as downstream users (DUs).

For substances that have been registered (pre-registered) successfully by an OR according to Article 8(3) of REACH, importers for such imported substances are to be regarded as DUs ("importing DUs"). Therefore, "importing DUs" are only exempted from the registration duty if the conditions of Article 8 of REACH for ORs are fulfilled.

The following conditions must be established for the importer to benefit from the registration exemption of an imported substance/substance in a mixture within an OR constellation (see also ECHA Guidance on Registration V.2.0, Section 2.1.2.5):

a) appointment of the OR by a natural or legal person established outside the Union who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article;
b) the OR shall have a sufficient background in the practical handling of substances and the information related to them[27];
c) the OR shall keep available and up-to-date information on quantities imported and on customers sold to[1];
d) the OR shall keep available and up-to-date information on the supply of the latest update of the safety data sheet referred to in Article 31[1];
e) the only representative fulfil the obligations on importers,;
f) the OR has successfully pre-registered or registered the imported substance in the proper tonnage band; and
g) the non-EU manufacturer shall inform the importer(s) within the same supply chain of the appointment of the OR.

In the ECHA Guidance on Registration, there is some further detail on the kind and form of evidence or proof necessary to show that the basic conditions of Article 8 are met.
However, one can also conclude that there are a variety of possibilities from which an OR and

[27] The OR is responsible to establish these conditions to fulfil the obligations stated in Article 8 of REACH.

"importing DU" can choose to provide evidence and proof for meeting the conditions of Article 8 of REACH.

Any surveillance targeted to the OR and to "importing DU" implies the specific situation and the lawfulness of the status as an "importing DU" depends on the duties fulfilled by the OR. However, the duties fulfilled by the OR could only be checked by the NEA of the OR.

Table 1 shall help in the identification of any necessary documentation / information / evidence / proof that needs to be available at the OR or the "importing DU" to benefit from Article 8 of REACH.

Table 1: Documentation of the conditions to be fulfilled to use and benefit from the provisions of Article 8[28]

Legal requirement	Comment	Possible examples for documentation / information / evidence / proof
Inspection at the OR[29]		
OR established in the Union Article 8 (1) Only representative is a natural or legal person established in the Union	The OR is a natural or legal person established in the Union not e.g. a post box. The criteria for "being established in the Union" needs to be clarified based on the national legislation relevant for operation of businesses and for establishing legal entities.	A proof if the company is established in the Member State could be if there is e.g. an entry in the commercial register.
Non-EU entity appointing the OR Article 8 (1) Appointment of the OR by a natural or legal person established outside the Union who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article	According to Article 8(1), only non-EU manufacturers, formulators or article producers can appoint an OR. Non-EU distributors cannot appoint ORs. NEAs can then attempt to verify whether it is the non-EU entity that has manufactured the imported substance, formulated the imported mixture or produced the imported article.	NEAs can attempt to verify the role of the non-EU entity appointing the OR based on: - the name of the non-EU company; - documents and other evidence available at the OR; - documents and other evidence from other sources (e.g. internet); and - a direct request at the non-EU company.
Appointment document for the OR	An OR must be able to inform NEAs which non-EU manufacturer, formulator or article	NEAs can check if a document/appointment letter is available at the OR and then

[28] Used literature: text from HelpEX, Forum (practical issues), Guidance on registration (ECHA) and BAUA inquiry.

[29] In most of the inspections of ORs, where non-compliance is found at the OR, it will be the "importing DU" that will be left with an import in breach of Article 5, who may have acted in good faith assuming all was in place up the supply chain. This should be considered in the inspections at the ORs and at the "importing DU"s.
In such cases, a suitable inspection approach can be: if the "importing DU" can prove he relied on the OR, then a warning should be given to the "importing DU" not to import anymore unless legal obligations are fulfilled (be it by the OR or by the "importing DU").

	producer it is representing. Every OR must have a document/appointment letter that they must make available to the NEA on request. The document/appointment letter indicates the non-EU entity that has appointed the OR. This letter must be made available to the NEAs of the Member State where the OR is established on request and can be checked by the NEA.	attempt to verify the appointment letter (substance ID, appointing non-EU entity, REACH role of non-EU entity). There is no specified format of the document in the REACH Regulation text, but to provide the required evidence, the appointing non-EU entity and the substance ID need to be present. To require a documentation giving evidence on the REACH role of the non-EU entity seems not to be covered by REACH. If the OR is established in another EU Member State, any complaint or request for clarification should be transferred to the NEAs of the Member States where the OR was established as it is their competence to enforce the compliance of the OR with REACH.
Background of an OR Article 8(2) The OR shall have a sufficient background in the practical handling of substances and the information related to them	An OR having experience of an importer for substances/mixtures /articles can be regarded to have sufficient background. The OR may be supported by the expertise provided from outside the EEA and this is acceptable as far as the performance of the OR is in compliance with the relevant articles of REACH.	A proof for the sufficient background could be a certificate or the obvious practical experience of the OR.
Information on quantities and customers Article 8(2) The OR shall keep available and up-to-date information on quantities imported and customers sold to	The OR will need to maintain up-to-date and exact documentation on the imported quantities and the customers sold the substances covered by its registration. Up-to-date: For tonnages at least on an annual basis, comparable to the timeliness needs for an importer.	The OR has to keep available and up-to-date: - information of the quantities imported, - information on the EU customers (importers) sold to. This available and up-to-date documentation needs to be presented to enforcement authorities on request.

	Quantities imported: detailed quantities per importer. Customers: all importers that intend to benefit from the registration of the OR. In their records on tonnages, ORs should be advised to record zero tonnage where there is a year with no imports for a particular substance and importer rather than providing no info (which can be interpreted as missing the documentation obligation).	
Article 8(2) The OR shall keep available and up-to-date information on the supply of the latest update of the safety data sheet referred to in Article 31	According to Article 8(2), the OR has "to keep available and up-to-date information on the latest update of the SDS". Three different situations can be further distinguished[30]: - OR does not act as an actual supplier in the supply chain: the OR is responsible for providing the importer (= "importing DU") with all the necessary information (Article 31) so that the importer is able to compile its own SDS for further recipients down the supply chain. - Supply of the SDS when the OR also acts as an actual supplier of substance: OR has to provide SDS and also has to be indicated in it (section 1.3 of the SDS) for the substance they supply to their recipients, according to Article 31 (1). - Substances in mixtures: OR does not have the responsibility to provide an SDS for	The documentation that can be expected to be provided by an OR for a substance is specified in the two relevant scenarios described in the advice given by the European Commission service[5]: At least an OR has to provide the "importing DU" with all the necessary information to enable the "importing DU" to compile its own SDS. In any SDSs which an OR has to provide, section 1.3 has to identify the OR. However, in the constellation of an OR, the actual supply chain is from the non-EU entity to the "importing DU". The legal text and the ECHA Guidance can be interpreted regarding the OR implicitly as an actor of the supply chain having a duty to provide the SDS to the recipients of the substance actually supplied by the non-EU entity (i.e. the "importing DU").

[30] Advice given by the European Commission service.

	a mixture. However, to facilitate the compilation of the SDS of the imported mixture, the OR should provide the importer at least with all the necessary information (Article 31) regarding its registered substance.	In respect to the duties of an importer assigned to the OR according to Article 8(1) and 8(2), irrespective of the flow of goods, the OR is also the responsible entity in the EU for all supply-related duties of an importer under REACH. In this interpretation based on these importer's duties assigned to an OR, an OR can be expected to provide an SDS to the recipients of the substance actually supplied by the non-EU entity (i.e the "importing DU").
Article 8 (1) The OR fulfils the obligations of importers under this Title	The OR is responsible for the registration. The OR can represent one or several non-EU manufacturers and must submit a separate registration for each non-EU company it represents. The tonnage of the substance to be registered in each registration is the total of the tonnages of the substance covered by the contractual agreements with the OR and the specific non-EU manufacturer represented by them. It is expected that an OR will receive the information on substances from its non-EU supplier(s), but the particular relations between the OR and any actors outside the Union, with respect to exchange of information, are up to the involved parties and are not regulated by REACH.	If the import is > 1 tonne/year: Proof of a registration by the OR: - Registration number for the registered substance - Registration in the tonnage band suitable for the imported tonnage per year The OR also needs to have the information on the imported tonnages available and up-to date.
Inspection in the company of the "importing DU"		
Article 8 (3) The non-EU manufacturer shall inform the importer(s) within the same supply chain of the appointment	Every "importing DU" must have a document in which the non-EU manufacturer confirms that an OR is appointed. The format is not regulated.	Document (format not regulated) as a proof of the non-EU manufacturer informing about an appointed OR for the relevant substance

	The non-EU manufacturer could pass the information in any format and also a non-EU trade company could pass the information to the "importing DU".	
	As the name of the OR is not mentioned in Article 8 (3) it can be regarded not mandatory for the non-EU manufacturer to communicate the name of the OR to the "importing DU". Consequently, and in worst-case situations, the name of the OR could not be available at the "importing DU"[31].	For the NEA, it is not possible to detect the connection between non-EU manufacturer and OR based on the information in REACH-IT/ RIPE. Also, the importer needs to know the name of the non-EU entity, not the name of the OR. To identify the OR in the supply chain of an "importing DU", the inspector could: - ask the "importing DU" to verify the information by the non-EU manufacturer, - contact actors up the supply chain and the non-EU manufacturer to verify the name of the OR (in cases where the non-EU manufacturer does not inform the importer about the name of the appointed OR). To use the SDS as an information basis to identify the OR is not always possible, but presence of a complete registration number in the SDS can help (See above).
	The appointment of an OR by the 'non EU manufacturer' creates the need for importers to keep exact documentation on which imported quantities of the substance are covered by the OR registration and which quantities imported through another supply chain are not.	At the "importing DU", documentation is required to identify which imported quantities of the substance are covered by the OR registration and which imported quantities are not.

[31] Despite not being an obligation of Article 8(3), inspectors should always convey the advice to the ORs to send a letter to the "importing DUs" to inform them of the presence of the OR, including who the OR is and the substance and the covered uses in question. Complementary to this, the ECHA Guidance on Registration recommends for "importing DUs" to obtain confirmation in writing from the OR that the imported tonnage and use is covered by the registration submitted by the OR.

	For the import of mixtures, the importers will also need to know what quantity of the substance in a mixture is covered by an OR registration, as they would otherwise be subject to a registration requirement themself.	
	REACH does not distinguish between direct and indirect imports into the EU. “Importers within the same supply chain" means that it is not necessary that the non-EU manufacturer directly exports the substance to the EU but a supply chain outside the EU may follow before the substance is imported into the EU. Importer(s) within the same supply chain of the appointment of the OR according to Article 8(3) of the REACH Regulation are regarded as downstream users.	Documentation that the importer is in the supply chain of the non-EU company that has appointed the OR.

Specific constellations

The situation in the context of the OR and “importing DU” implies the specific situation and the lawfulness of the status as an “importing DU” depends on the duties fulfilled by the OR. NEAs can face several specific constellations.

The status and the compliance of an “importing DU” in the context of an appointed OR depends on the duties fulfilled for pre-registration and registration by the OR. This compliance can only be checked by the NEAs responsible for the OR. In any particular case, the specific constellation needs to be considered and also the knowledge the OR and the importer had or should have had about their specific interrelationship.

Table 2: Possible constellations between OR/”importing DUs” and related compliance or non-compliance

Importer /”importing DU” has imported substance > 1 tonne and ….	**Compliance/ non-compliance by the OR**	**Compliance/ non-compliance by the importer/”importing DU”**
(1) OR failed to pre-register/ register and importers are informed about an OR. Also, the OR is informed about the importer and the OR is also appointed by the non-EU manufacturer	No incompliance with Article 5. Currently, there is no final decision if a non-compliance of Article 8(1) is existent. On the basis of Article 8(1), the OR is obliged to fulfil the obligations on importers under Title II of REACH, which includes the registra-	Instead of being an “importing DU”, the company is the importer that is obliged to register. If there is no applicable registration, a non-compliance of Article 5 is existent (if applicable, as a negligent act).

	tion of substances. However, the OR did not import. (However, a private law contract between the non-EU manufacturer and the OR was not fulfilled.)	
(2) OR pre-registered/ registered and covered the importing company (also the tonnage), "importing DU" is not informed by the non-EU manufacturer that an OR is available	Valid pre-registration/ registration of the OR, compliance with ArtICLE 8 (2).	Attempted contravention of Article 5 Non-compliance of Article 36 (the importer and also the DU shall make the information available upon request to any competent authority. This also includes the documentation of the status of the company and the reason why the company did not register the substance).
(3) OR pre-registered/registered and not covered the importing company (also the tonnage), as the non-EU manufacturer had not informed both the OR of the existence of the importer and also the importer of the appointment and the existence of an OR	Valid pre-registration/ registration of the OR, but not applicable to the "importing DU".	Non-compliance of Article 5 as the pre-registration/registration is not applicable to the "importing DU".
(4) OR pre-registered/registered and not covered the importing company. The non-EU manufacturer had informed the importer of the appointment of the OR, the importer had no indication the imports were not covered by the OR	Valid pre-registration/registration of the OR, but not applicable to the "importing DU". Non-compliance of Article 8(2) in case the non-EU manufacturer had informed the OR	Non-compliance of Article 5 (if applicable, as a negligent act)
(5) OR pre-registered/registered, the non-EU company appointed the OR is not a manufacturer nor a formulator, OR knows the importer, non-EU company had informed the importer of the appointment of the OR	No valid pre-registration/registration (as the appointing non-EU company is not the manufacturer or the formulator) Non-compliance with Article 8(1)	Non-compliance with Article 5 as the non-valid pre-registration/registration of the OR is not applicable to the "importing DU"[6].
(6) OR pre-registered/registered, total tonnage of several "importing DUs" are not covered by the tonnage the OR declared in the registration dossier and	Valid pre-registration/registration of the OR. Non-compliance with Article 8(2).	Compliance with Article 5 depends on the total tonnage of this importer being covered by the tonnage band of the OR

had available in the documentation. Non-EU company had informed the importer of the appointment of the OR	Non-compliance with Article 12 if the registration is not in the correct tonnage band	

Annex 5: Forum Working Group REACH-EN-FORCE 3

Forum Working Group[32]
Work Package A.1
"Coordinated enforcement project REACH-EN-FORCE-3"
(Mandate adopted at Forum-22)

Composition:

Chair:

Forum Members

- Jos VAN DEN BERG (NL)
- Eugen ANWANDER (AT)
- Pablo SÁNCHEZ PEÑA (ES)
- Maria Letizia POLCI (IT Alternate)

Invited Experts

- Alfred EBNET (DE) (customs)
- Paivi SIMPANEN (FI) (customs)
- Panagiotis GIMNAOU (CY)
- Ruta Birute DAUKSIENE (LT) (customs)
- Sibylle WURSTHORN (DE)

Commission

Objective:

- conceive and manage the third major Forum enforcement project

Mandate:

- Prepare a document identifying and proposing priority of possible subjects for third Forum enforcement project, considering the project prioritisation criteria
- Subject proposals shall include an aspect where the procedure of cooperation with customs could be tested
- After the subject is approved by the Forum, develop the project manual (guidance document, checklist, planning, recommendations) for the execution of the third Forum enforcement project
- Prepare and deliver the training for project national coordinators
- Management of the Operational phase
- Management the Reporting phase: Follow-up operational phase, collect the results and draft project evaluation

Timeline:

First phase

- Subject proposals and prioritisation: 1 September 2010
- Approval of the REF-3 subject : Forum-10
- Project manual: Q3 2012 (written procedure)
- Prepare and deliver the training for project national coordinators:Q4 2012 – Q1 2013

[32] Since Forum-18, the Working Group Chair position is vacant and formally the activities of the group of Forum Members and the experts related to REF-3 are organised in a *Task force*. However, for simplicity, the terminology "working group" is pertained.

- Operational phase: 01 February 2013 – 31 August 2013
- Reporting phase (National Coordinators): 01 September - 31 October 2013
- Evaluation phase: 01 November – 31 December 2013
- Draft report of phase 1 with the WG recommendations: Forum 17
- Adoption REF-3 phase 1 report: After Forum-17 (written procedure)

Timeline for the prolonged REF-3 (sequel project):

Second phase:

- Inform National Coordinators: after F-15
- Adjusted scope and update supportive documents (Addendum): scope was adopted at Forum-16. Addendum to be adopted after Forum-16 via written procedure
- Inform National Coordinators about new documents: Q4 2013- January 2014
- Second Operational phase: 01 February 2014– 30 November 2014
- Second Reporting phase (National Coordinators): 01 December - 31 January 2015
- Evaluation phase: 01 February – 31 May 2015
- Draft report for REF-3 with the WG recommendations: June 2015 (Forum 21)
- Final consolidated report: adoption after Forum-22 via written procedure

Annex 6: Glossary

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 and REACH Regulation: 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

WG: Working Group of the Forum

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