ECHA
EUROPEAN CHEMICALS AGENCY
Forum For Exchange Of
Information On Enforcement

FORUM

REF-7 project report on registration duties

Operational phase: January–December 2019

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Disclaimer

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

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Glossary

CLP	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures
COM	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
FORUM	The Forum for Exchange of Information on Enforcement: Network of authorities responsible for the enforcement of the REACH, CLP, PIC and BPR regulations in the EU, Norway, Iceland and Liechtenstein
ICSMS	The internet-supported information and communication system for pan-European market surveillance
MS	Member State
NEA	National enforcement authority
OR	Only representative
PD-NEA	Portal dashboard for national enforcement authorities – the IT system that gives access to data submitted to ECHA to enforcement authorities – PD-NEA was changed to Interact Portal on 25 April 2019
RAPEX	Rapid Exchange of Information System – rapid alert system for dangerous non-food products
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REF	REACH-EN-FORCE, Coordinated Enforcement Project of the Forum
SCC	Strictly controlled condition
SDS	Safety data sheet
SME	Small and medium-sized enterprice
SVHC	Substance of very high concern
WG	Working Group of the Forum

I. Executive summary

The Enforcement Forum's REACH-EN-FORCE 7 project inspected and enforced companies' registration obligations under the REACH Regulation after the last registration deadline of 31 May 2018.

The inspections focused on the compliance of companies with the general obligations to register a substance, as well as on the registration of intermediates.

National enforcement and customs authorities inspected 813 companies in 28 countries in the European Economic Area. In total, registrations for 1 420 chemicals were inspected, of which 952 were for different substances. From the 1 420 checked chemicals, 227 did not need a registration.

Out of the 1 193 substances needing registration, 180 (15 %) did not comply with the registration obligations in the scope of the project and a registration was completely missing for 77 substances (6.5 %).

For the 180 non-compliant substances, measures were taken to bring companies into compliance. The most frequent enforcement measures were written advice and administrative orders. For missing registrations, companies also received fines and in some cases criminal prosecution was started.

This report outlines the project, conclusions and recommendations for companies, the Enforcement Forum, national authorities, European Chemicals Agency and the European Commission.

Content and key findings

The REF-7 project focused on two areas:

Area 1:
Investigate compliance with registration obligations after the last registration deadline for all tonnages, if necessary in cooperation with customs, and a practical check of some parts of the registration dossier. Check basic compliance with obligations in relation to polymers.

Area 2:
Check whether the substances registered as intermediates comply with the obligations for intermediates. This includes checking whether the substances registered as intermediates meet the definition for intermediates and investigating if strictly controlled conditions are applied for substances registered as intermediates.

Participating countries could choose to investigate Area 1, Area 2 or both.

The project included among other things:

- All legal persons with obligations to register one or more chemical (manufacturers, importers and only representatives); downstream users of intermediates;
- Any substance, on its own or in mixtures or in an article with intended release or any type of isolated intermediate (on-site or transported); and
- All sectors of industry and all company sizes (including SMEs).

1. Companies and substances inspected

28 EEA countries[1] reported together on 1 420 inspections of substances. 813 companies were inspected, of which 500 were small and medium-sized enterprises (61.5%). The reported inspections related to a total of 952 different substances.

1 008 (71 %) of the 1 420 substances were classified as hazardous, according to the CLP Regulation. 58 (5.8%) of the 1 008 were also substances of very high concern (SVHCs). In total, 48 different SVHCs were inspected.

Of the 1 420 checked substances, companies registered 824 (58 %) as follows:

- 599 registered purely with the submission of a full registration.
- 212[2] purely with an intermediate registration.
- 13 registered with both full and intermediate registrations.

56 monomers were registered and 11 were missing registration in cases where polymers met the definition of Article 3(5) of REACH.

Companies did not need to register 519 of these 1 420 checked substances. In 292 out of the 519 inspections, the company did not need to register because the registration was already done by a relevant only representative (OR). The remaining 227 of the 519 benefited from another valid criterion for exemption from registration.

There were 226 inspections checking compliance with the obligations for intermediates. Registration as an intermediate was considered to be acceptable by the inspector for 194

[1] AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IS, IT, LI, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK
[2] One substance was additionally checked as an intermediate although its registration as an intermediate was inappropriate.

inspected intermediates and not acceptable for 32[3]. Moreover, 181 reports confirm that the inspected companies applied strictly controlled conditions (SCCs) when managing their intermediates, while 44 reports claim that the inspected company did not apply SCCs[4].

From the 1 420 inspections, there was no duty to register for 227 substances, leaving 1 193 substances which needed registration. 77 from the 1 193 (6.5 %) were missing compulsory registrations.

During the inspection of 62 of the 813 companies, inspectors additionally indicated that for those companies missing compulsory registrations (19 of them were intermediates registrations), but only for part of them (77), did inspectors report under REF-7 project. This suggests that the real non-compliance rate could be higher than the one derived from the filled-in questionnaires.

2. Infringements and enforcement measures

Altogether, 180 of the 1 193 substances were reported to be non-compliant with the obligations checked in the scope of the REF-7 project showing a non-compliance rate for substances of 15 %.

At the time of reporting, the following measures were taken by the enforcement authorities with regard to the 180 non-compliant cases:

- 25 verbal advices;
- 76 written advices;
- 42 administrative orders;
- 17 fines;
- 36 criminal complaints/handing over to public prosecutor's office; and
- 49 other measures.

The follow-up activities had been completed for 1 222 cases and 198 were still ongoing when the inspections finished.

3. Cooperation

During the project, national enforcement authority (NEA) inspectors cooperated with other authorities for 657 inspections, in particular, in 591 cases (90 %) with customs. Information on 33 cases was exchanged with other Member States.

4. Summary of key indicators

The result related to the main indicators are presented in Table 1.

[3] For two inspections, additional explanations were provided by inspectors indicating that the inspector did not observe a non-compliance. This results in 194 compliant cases and 32 non-compliant cases for the 226 inspected intermediates.
[4] The inspector indicated that no non-compliance was observed by the inspector in two cases while no clarity was obtained for one case. This results in 181 compliant cases, 44 non-compliant cases and one case remaining unclear.

Table 1. Main project indicators

No	Indicator	REF-7	REF-3[5]
1	Number of inspections (number of the inspected substances)	1 420	5 746 Phase 1 – 3 065 Phase 2 – 2 681
2	Number of inspected companies	813	1 169 Phase 1 – 528 Phase 2 – 641
3	Number of non-compliant companies	116	Phase 1 – 75 Phase 2 – 76
4	Number of participating countries	28	Phase 1 – 28 Phase 2 – 24
5	Number of the inspections pointing at least one non-compliance	180	Phase 1 – 5 % (153) Phase 2 – 5 % (134)
6	Ratio of non-compliances 1. number of not registered inspected substances/total number of inspected substances that needed registration 2. number of non-compliant companies/total number of inspected companies 3. number of non-compliant substances/total number of inspected substances that needed registration 4. number of non-compliant DIFFERENT substances/total number of inspected DIFFERENT substances	1. 6.5 % (77*100/1 193) 2. 14.3 % (116*100/813) 3. 15 % (180*100/1 193) 4. 16.5% (157*100/952)	1. Phase 1 – 3 % Phase 2 – 3 % 2. Phase 1 – 14 % Phase 2 – 12 % 3. Phase 1 – 5 % Phase 2 – 5 % 4. –
7	Number of different substances inspected	952	Phase 1 – 486 Phase 2 – 494
8	Characterisation of the substances (SVHCs) 1. Number of inspected substances that have a CLP classification 2. Number of inspected substances that have a CLP classification and are an SVHC	1. 1 008 2. 58 out of 1 008 are SVHC	1. – 2. –

[5] REACH-EN-FORCE-3: Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs: Phase 1, Phase 2

II. Project overview

An EU-wide enforcement project on registration obligations was carried out in 2019 to make sure that companies register their substances imported or manufactured especially in quantities of 1-100 tonnes per year. No tonnage band exceeding 1 tonne per year was excluded from the project.

The last REACH registration deadline (for the lowest tonnage band) was 31 May 2018. After this date, all substances produced above one tonne per year needs to have been registered unless they are exempted. The last registration deadline impacted all importers, manufacturers and only representatives of – in particular but not exclusively – "small tonnages". Distributors were not in the scope of REF-7. It was expected that particularly smaller companies involved in the low tonnage bands would be relatively more frequently non-compliant with REACH provisions compared to bigger companies (non-SMEs) with more available operational resources.

The project also aimed to verify that intermediates, manufactured or imported and registered as such, were managed as intermediates under the conditions justifying a simplified registration as an intermediate.

The REF-7 enforcement project invited inspectors to address the quality of registration dossiers (tonnage, production processes, life cycle, uses). This comes on top of ECHA's regular technical completeness and compliance check.

The operational phase of the project ran from January to December 2019. The participating countries were supported by the Forum Working Group "Coordinated enforcement project REACH-EN-FORCE-7".

Legal obligations covered in this project

Table 2 shows the REACH provisions that REF-7 focused on.

Table 2. REACH provisions covered under the REF-7 project

Relevant legal provisions (Articles and Annexes)	Summary
3(5)	Definition of polymer
3(15)	Definition of intermediate
5	No data, no market
6	Obligation to register substances on their own or in mixtures
7(1)	Substance in articles
8	Only representatives
10	Content of the registration dossier
12	Information to be submitted depending on tonnage
17 and 18	Registration of on-site isolated intermediates and registration of transported isolated intermediates
22	Obligation to update the dossier if there is a change of tonnage band
Annexes VI-XI	Information requirements referred to in Article 10

III. Results of the project

The results of this project are derived from the answers of the inspectors to the questions in the questionnaires sent to Forum's working group (see Annex I: copy of the REF-7 questionnaire).

For each inspected substance, one questionnaire was filled-in. In some companies, the inspector just checked one substance, filling-in one questionnaire for that company. In other companies, the inspector could have checked more than one substance, filling-in several questionnaires for the same company.

The choice of inspected companies and substances was up to the participating countries. Only a small percentage of cases (3.5 %) were triggered by information provided by ECHA.

1. Participating countries and number of inspections

28 countries (EU and EEA)[6] participated in the project and sent 1 420 filled-in questionnaires. Each questionnaire related to one inspected substance. There could be several filled-in questionnaires per inspected company, depending on the number of substances inspected in that company. The number of filled-in questionnaires equals the number of inspected substances, not the number of inspected companies. Each participating Member State decided on the number of inspections to be conducted.

The number of reported inspections per country together with the number of companies inspected is presented in Table 3 and Chart 1.

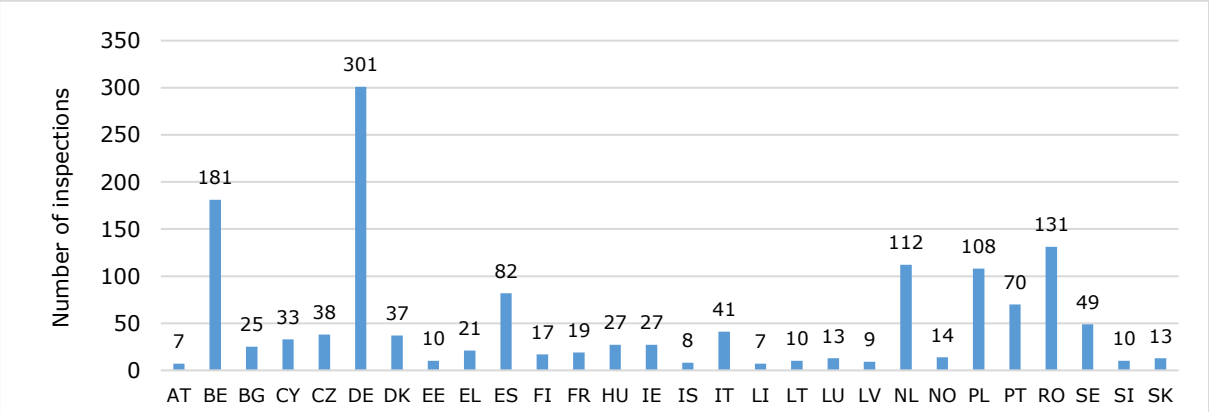
Table 3. Reported inspections per country

No	Country	Number of inspected substances	Number of inspected companies
1	AT	7	5
2	BE	181	59
3	BG	25	25
4	CY	33	19
5	CZ	38	21
6	DE	301	156
7	DK	37	12
8	EE	10	8
9	EL	21	20
10	ES	82	57
11	FI	17	12

[6] AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IS, IT, LI, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK

12	FR	19	12
13	HU	27	20
14	IE	27	16
15	IS	8	8
16	IT	41	31
17	LI	7	5
18	LT	10	10
19	LU	13	11
20	LV	9	9
21	NL	112	54
22	NO	14	8
23	PL	108	90
24	PT	70	46
25	RO	131	55
26	SE	49	21
27	SI	10	10
28	SK	13	13
	SUM	**1 420**	**813**

Chart 1: Number of inspections per country



2. Type of companies and substances inspected

There were 813 companies inspected, and 952 different substances were checked, for a total of 1 420 inspections.

Inspections were executed both on-site and at desktops. They are distributed as follows:

- pure on-site inspections (895);
- pure desktop inspections (334);
- both (191).

2.1. Type of companies inspected

Inspectors indicated in the questionnaires the main NACE[7]-codes of the companies inspected. It resulted in the identification of 165 particular NACE-values. For the sake of general insight, these values were grouped in sets of key economic sectors (see Table 4).

Table 4. Economic sectors addressed during the REF-7 project

	NACE code	Amount of inspected companies
A - Agriculture, forestry and fishing	01.11-3.22	16
B - Mining and quarrying	05.10-9.90	6
C - Manufacturing	10.11-33.20	**518**
D - Electricity, gas, steam and air conditioning supply	35.11-35.30	9
E - Water supply; sewage, waste management and remediation activities	36.00-39.00	3
F - Construction	41.10-43.99	3
G - Wholesale and retail trade; repair of motor vehicles and motorcycles	45.11-47.99	**232**
H - Transportation and storage	49.10-53.20	5
K - Financial and insurance activities	64.11-66.30	1
M - Professional, scientific and technical activities	69.10-75.00	11
N - Administrative and support service activities	77.11-82.99	5
S - Other services activities	94.11-96.09	4
	Grand Total	**813**

This distribution shows that most of the companies addressed have their main economic activities in following sectors:

– Manufacturing (NACE codes 10.1-33.20) – 63.7 %
– Wholesale and retail trade (NACE codes 45.11-47.99) – 28.5 %

[7] NACE (Nomenclature des Activités Économiques dans la Communauté Européenne) is a European industry standard classification system

These sectors can be detailed as shown in Table 5:

Table 5. Detailed distribution of the major economic sectors addressed

NACE	%
46.75 Wholesale of chemical products	13.7
20.59 Manufacture of other chemical products not else classified	8.5
20.14 Manufacture of other organic basic chemicals	7.5
20.13 Manufacture of other inorganic basic chemicals	4.4
20.16 Manufacture of plastics in primary forms	2.5
21.10 Manufacture of basic pharmaceutical products	2.3
20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	2.2
19.20 Manufacture of refined petroleum products	2.1
46.90 Non-specialised wholesale trade	2.1
24.10 Manufacture of basic iron and steel and of ferro-alloys	2.0

Company size

61.5% of the inspected companies (500) were small and medium-sized enterprises (SMEs). Chart 2 presents the overall distribution of the size of the inspected companies and Chart 3 shows the distribution of the size of companies per participating country.

Chart 2. The distribution of the size of the inspected companies

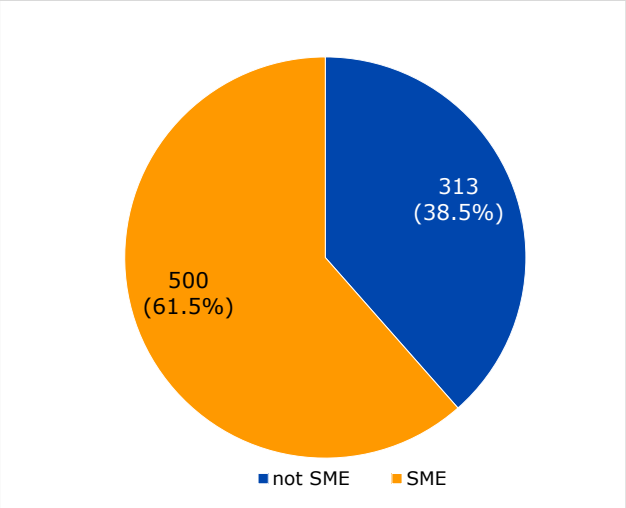
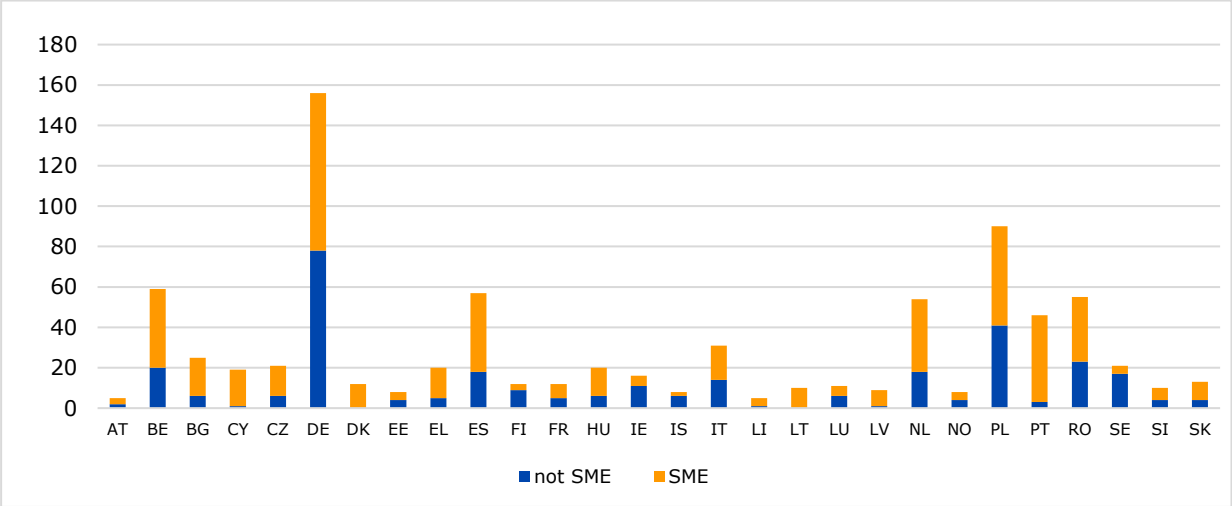


Chart 3. Distribution of the size of the inspected companies per country



Company role

The inspected companies could have five different roles: manufacturer, importer, downstream user, only representative (OR), and importing downstream user[8]. The company could assume all or part of these roles for a particular inspected substance.

The questionnaire asked the inspector to clarify for the inspected company its general situation (see Charts 4 and 5) and its particular situation per inspected substance (see Table 6).

The received questionnaires show that 368 (45.3%) out of 813 inspected companies play more than one role under REACH. 24 companies assume REACH registration obligations as manufacturer, importer and only representative simultaneously. Only 8 (1.0%) inspected companies assume all five type of roles.

Inspected companies playing a unique role under REACH are distributed as follows:

- 139 (17.7%) out of 813 inspected companies play exclusively the role of manufacturer;
- 157 (19.3%) companies play exclusively the role of importer;
- 41 (5.0%) play only the role of downstream user;
- 14 (1.7%) play only the role of only representative;
- and 94 (11.6%) are exclusively importing downstream user.

[8] An importing downstream user (IDU) is a downstream user who is responsible for bringing a substance not exempt from registration into the EU, the registration obligations having been fulfilled by an only representative. If the IDU's import is not "covered" by an OR, the IDU would not be an IDU but an importer with registration obligations.

Chart 4. The general role of the inspected company under REACH observed under REF-7 (each company may assume more than one role)

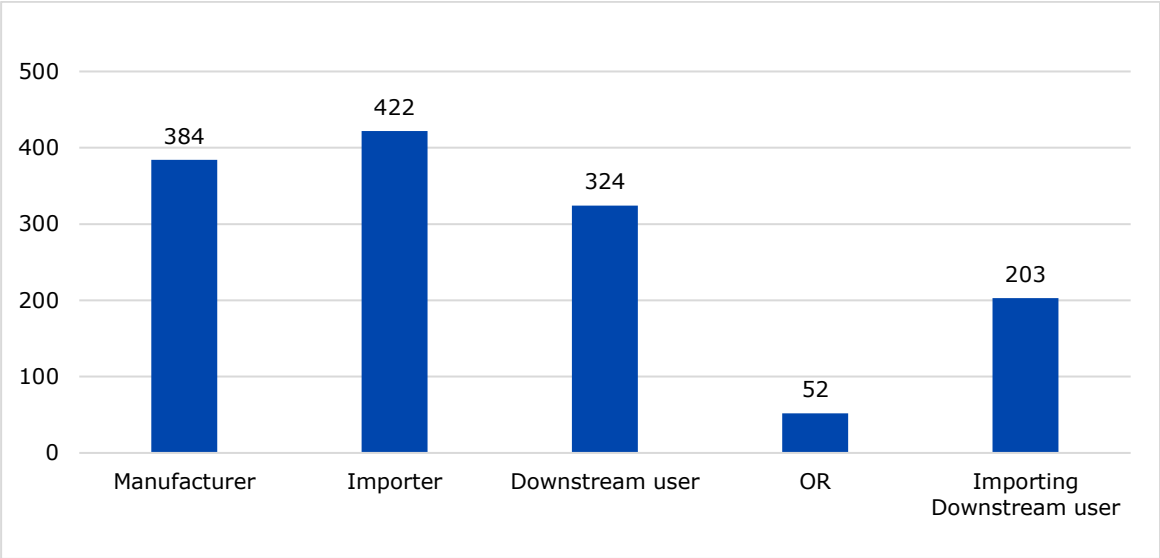
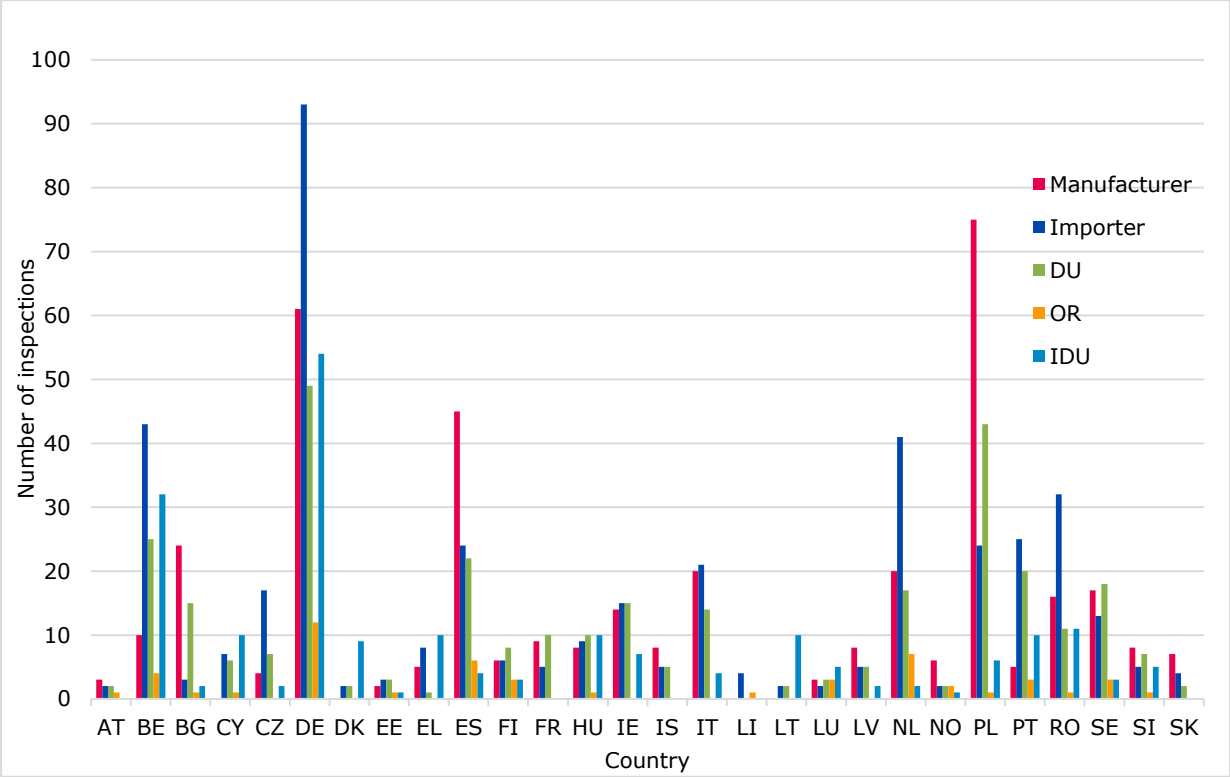


Chart 5. Distribution of the general company roles under REACH, per country[9]



[9] Chart 5 presents the frequency of the roles of the companies addressed per country.

Table 6: For all inspections (1 420), occurrence of company role

Role under REACH	How many companies being ...	% occurence
manufacturer	495	34.9
importer	468	33.0
DU	293	20.6
importing DU	237	16.7
OR	49	3.5

Registration obligations under the REACH Regulation

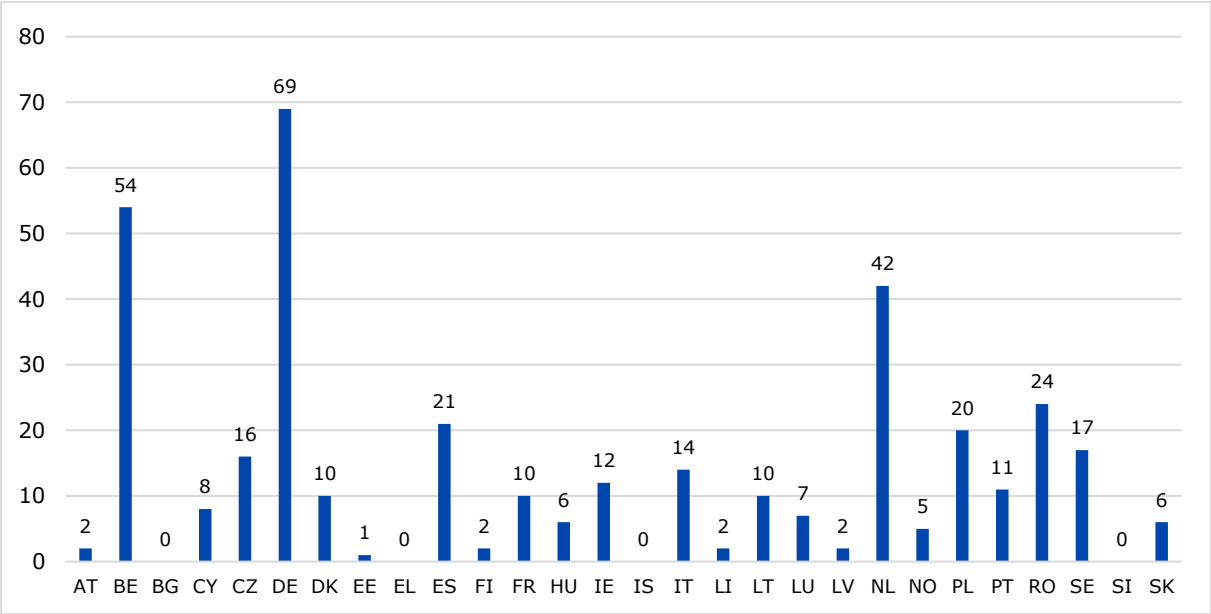
Among the 384 companies that have the general manufacturer role, only 376 manufacturers had REACH registration obligations as they manufactured substances in quantities equal or more than one tonne per year. The kind of manufactured substance was divided into three types: substances as such; substances as a polymer according to Article 3(5) of REACH; substances intended to be used as an intermediate. Companies could manufacture more than one type of substance.

From those 376 companies having manufacturer obligations with REACH registration, about 25.5 % (96) manufactured more than one kind of substance, and only 4.3 % (16) manufactured all three kinds of substances (substances as such, as a polymer and as an intermediates) subject to REACH registration obligations.

For the 527 companies with importer obligations for substances in quantities of one tonne or more per year, 352 are related with substances as such, 201 are related to substances present in mixtures, 46 are related to polymers according to Article 3(5) of REACH, 86 related to substances intended to be used as intermediates.

During 371 (45.6 %) inspections of the companies, inspectors checked more than one substance. Detailed country-specific information is shown on Chart 6.

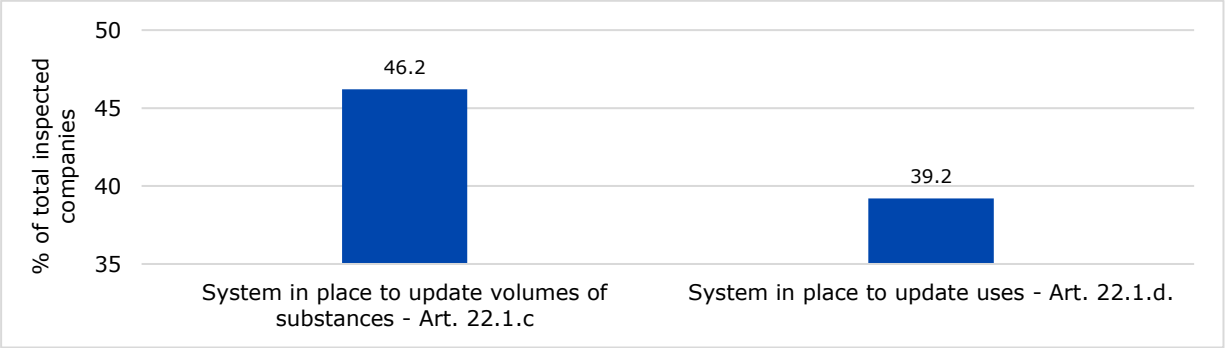
Chart 6. Number of companies per country where inspectors checked more than one substance during inspection



Company system to track update information

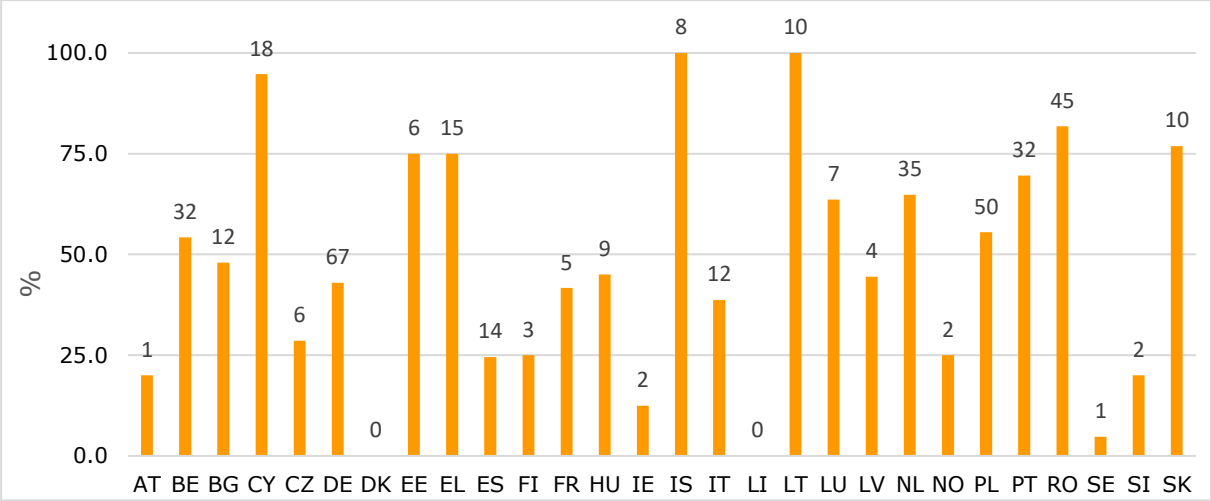
With regard to companies' abilities to update their registration timely under Article 22(1) of REACH, it was observed that less than half of the inspected companies had systems in place to manage follow-up (see Chart 7).

Chart 7. Percentage of companies with systems in place to ensure updates of registration dossiers according to Article 22 of REACH (813 companies inspected)



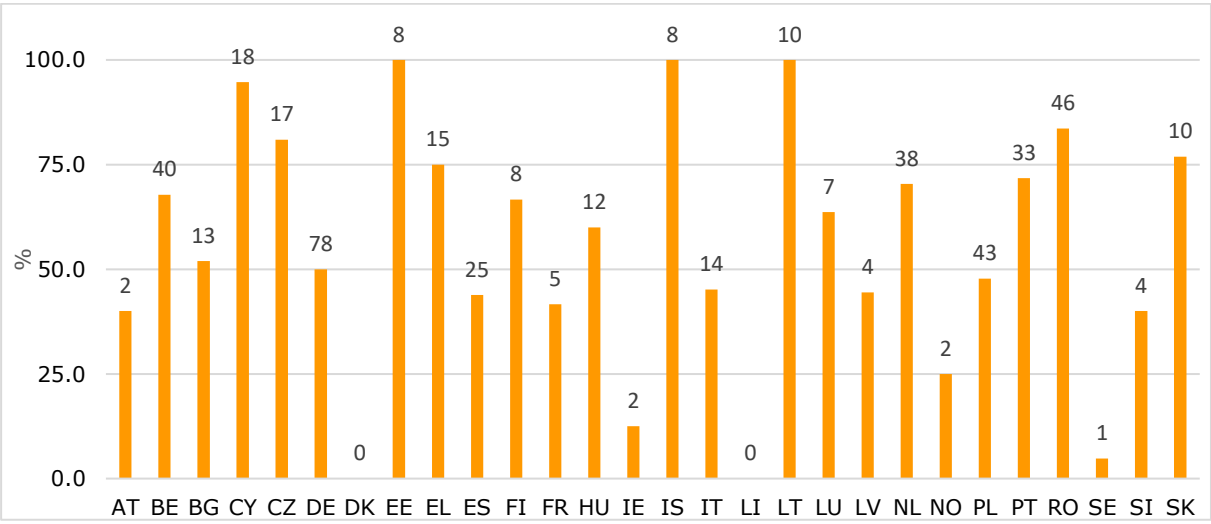
To track their annual manufacturing/importing of substance volumes to be able to implement Article 22(1).c, for 376 inspected companies it was reported that they had a system in place, while for 408 inspected companies it was reported that they had not a system in place (it was not reported for 29 companies). Out of the 376, only 31 % had an automated system (e.g. SAP or another ERP software), where they would immediately get notified upon approaching the limits of their registrations' tonnage bands. The vast majority had either a process of manual tracking with a high likelihood of recognising changes in less than 12 months (36 %) or a once-a-year review of their annual quantities (20 %). Chart 8 shows the percentage of companies per country that do not have systems in place to ensure updates under Article 22(1)c of REACH in companies.

Chart 8. Percentage of companies per country that do not have a system in place to ensure updates under Article 22(1)c (the number of companies that do not have a system in place are above the bars).



In relation to the obligation to update, for adding/removing/changing uses of the registered substance to be able to implement Article 22(1)d, it was found that 319 companies had a system in place to track those changes, while 463 did not (it was not reported for 31 companies). Breaking it down shows that 12 % of respondents have an automated system in place (e.g. SAP or another ERP software). 60 % of those with a system in place are following the potential changes of the uses with manual tracking, finding those changes likely within 12 months. Another 15 % is following up the uses during a yearly review cycle. Chart 9 shows the percentage of companies per country that do not have systems in place to ensure updates under Article 22(1)d of REACH.

Chart 9. Percentage of companies per country that do not have a system in place to ensure that the uses in the registration dossier are updated (Article 22(1)d) (amount of companies that do not have a system in place are above the bars).



From the above findings, it is clear that most of these companies at the time of the inspections were not in a position to keep the deadlines listed in the upcoming Commission Implementing Regulation on dossier updates. This Implementing Regulation clarifies the

deadlines for each trigger point listed in Article 22(1) of REACH. The implementing regulation provides a three-month deadline for most update types, while more complex ones get six, nine or 12 months.

With regard to fulfilling legal obligations on submitting updated registrations, amongst all companies inspected (813) and 1 193 inspected substances not exempted from the duty to register, it was found that 166 updates for the inspected substances related to the Article 22 of REACH Regulation were needed.

125 of the 166 substances of which the registration dossier needed an update, were updated. 30 were not. The update of 11 substances was incomplete. This points to a non-compliance rate for Article 22 of REACH of 18 % (30 of the 166) regarding the substances that needed an update of the registration.

2.2. Substances inspected

During REF-7 inspections, 952 different substances were checked from a total of 1 420 substances.

As already mentioned, the inspections checked if the companies manufactured and/or imported substances in quantities of one tonne or more per calendar year.

376 companies that manufactured substances met this condition, for 282 different substances. Inspectors checked during the inspections the following manufactured substances types:

- 336 substances as such (249 different);
- 28 polymers (27 different); and
- 137 substances intended to be used as an intermediate (127 different).

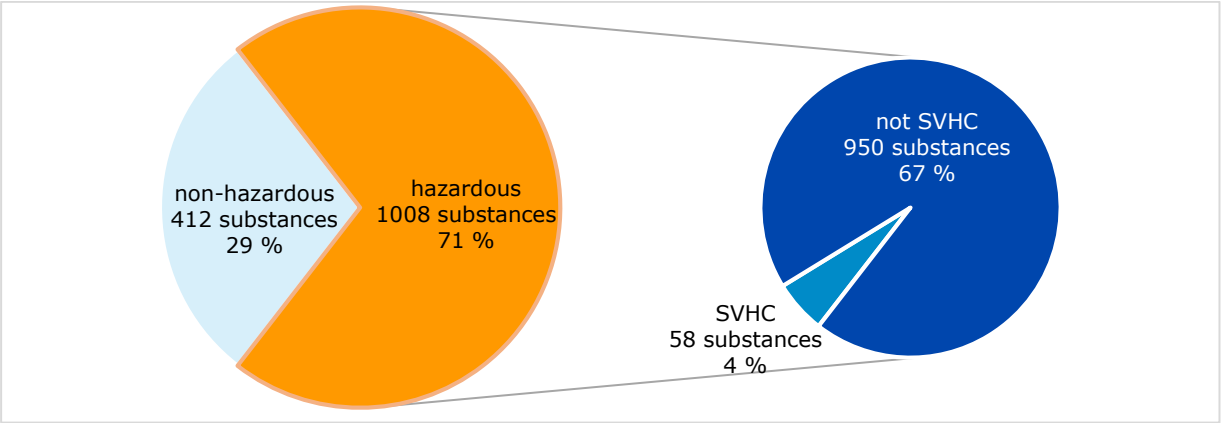
527 companies also imported substances in quantities of 1 tonne or more per calendar year. Inspectors checked during the inspections the following imported substances types:

- 352 substances as such (289 different);
- 201 as substances in a mixture (169 different);
- 46 as a polymer (44 different); and
- 86 substances intended to be used as an intermediate (86 different).

Substance types inspected

1 008 of the 1 420 inspections (71 %) related to substances that are hazardous according to CLP Regulation. 58 of the 1 420 (4.1%) related to SVHCs. In total, 708 different hazardous substances were addressed, among them 46 different SVHCs (see Chart 10). The most often non-compliant substances are indicated in Chapter 3.1.

Chart 10. Substance types inspected



Registration obligations

Inspections revealed that about 58 % (824 out of 1420) of all inspected substances were registered by the inspected companies, most of all (599 substances) were registered purely with the submission of a full registration, 213 were registered purely as intermediates, and 13 substances had both full and intermediate registrations.

The remaining 596 substances were not registered by companies, either because the companies did not need to register them as the registrations were done by a relevant only representative (292) or they were exempt from registration (227), or because there was a failure in the registration obligations (77).

For 245 registrations of substances done by an OR, the notification from the non-EU manufacturer stating that the registration has been done by an OR was available; for 47 it was not.

227 inspected substances were exempted from registration obligations for the following reasons (there were multiple reasons indicated):

- 75 substances were manufactured or imported in quantities below one tonne per year;
- 35 substances were re-imported;
- 30 substances were exempted on Annex IV and V to REACH;
- 21 polymers were compliant with Article 3(5) of REACH;
- 9 were food and feedstuffs;
- 8 were biocides;
- 5 were medicines
- 1 was a recovered substance that was registered before; and
- 57 other reasons (e.g. company is a downstream user and only used the substance, NONS, phase-in substance, article without release of substances (Article 7), PPORD).

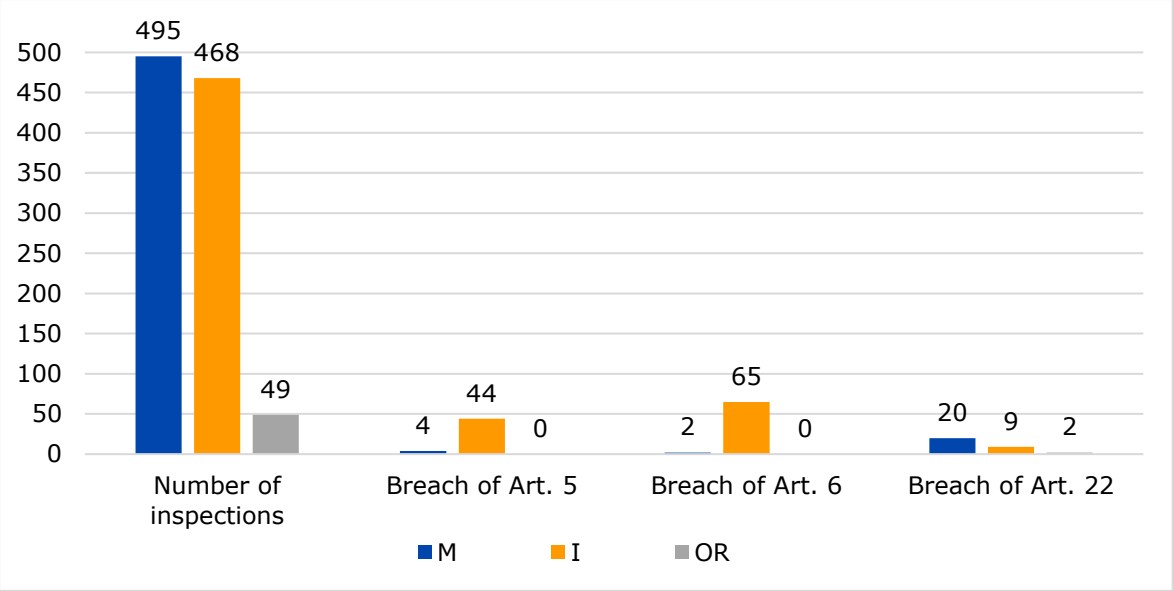
77 inspections reported non-compliance with the duty to register, 75 relating to Article 6 of REACH and two to Article 18 of REACH (more detailed information is available in Chapter 3. Infringements).

Inspections relating to polymers were processed as complying with Article 3(5) of REACH. Those inspections mention 67 monomers being involved. 56 of those monomers were registered and 11 were not. 6 out of those 11 were considered as exempted from

registration because the polymer in question consisted of less than 2 % by weight (w/w) of such monomer substances or other substances in the form of monomeric units and chemically bound substances and the total quantity of such monomer substances or other substances are less than one tonne per year.

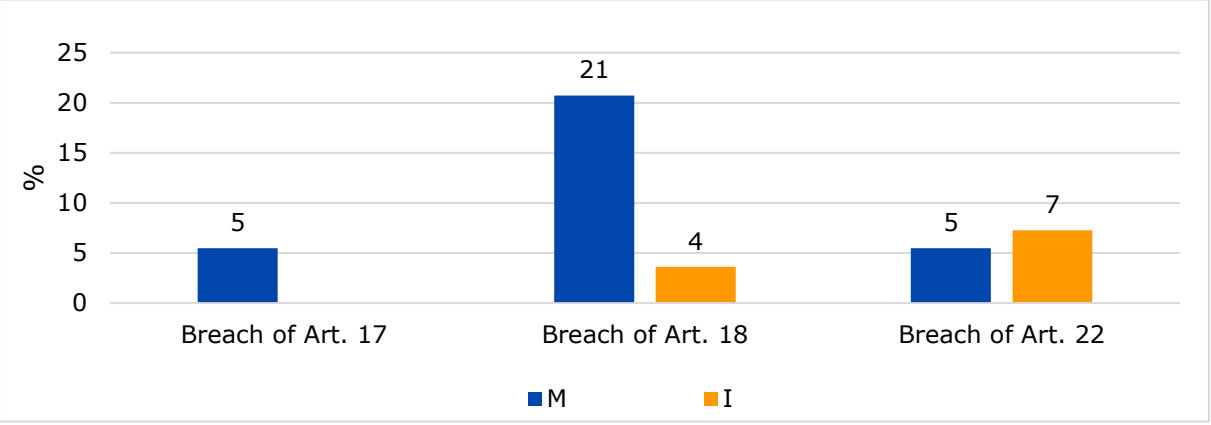
For all inspected substances that needed full registration, Chart 11 shows how many duty-holders of each role (M, I, OR) were inspected, and per key provision (Articles 5, 6, 22) how many non-compliances were observed for each company role.

Chart 11: Full registration – number of violations of key provisions observed per company role



For all inspected substances that needed registration as an intermediate, Chart 12 shows the frequency of detected non-compliances per key provision (Articles 17, 18, 22) per company role (164 manufactured isolated intermediates and 55 imported isolated intermediates were inspected; no violations observed nor shown for those covered by ORs).

Chart 12. Registration as isolated intermediate – frequency of detected violations of key provisions per company role

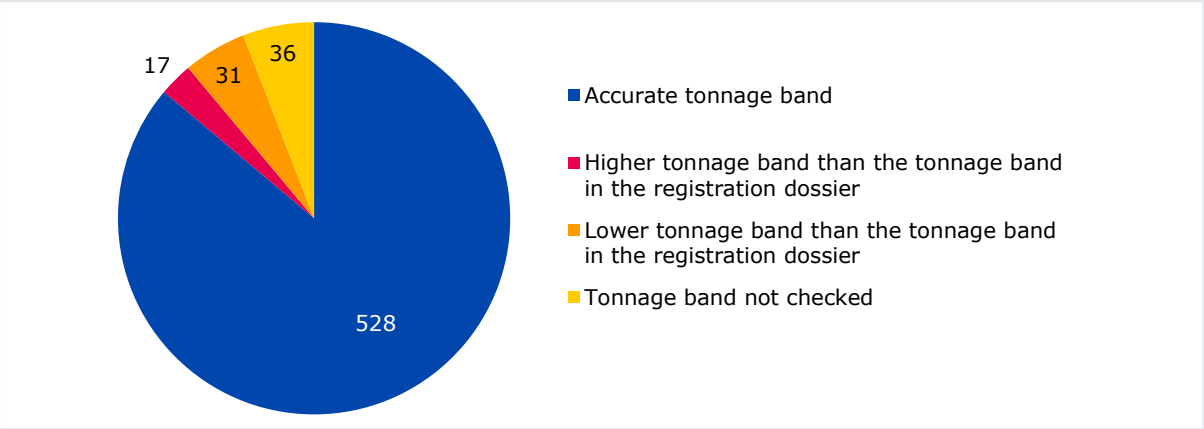


2.3. Practical check of the quality of the dossiers of substances with full registration (area I)

The inspectors did a practical check of the quality of the registration dossiers during the inspections for the 612 substances with a full registration.

The tonnage band in the registration dossier corresponded to the real tonnages of the inspected substance for 528 substances but not for 48 (36 substances not checked). For those 48 cases, in 17 cases the real tonnage was higher than the registered one, in 31 cases it was lower (see Chart 13).

Chart 13. Checks on tonnage bands.



The production processes stated in the registration dossier corresponded to the real processes in the inspected company for 365 inspected substances and not for six others. The situation for 241 other substances was not reported.

The lifecycle of the inspected substance in the registration dossier corresponded to the real lifecycle of the inspected substance in the inspected company for 368 substances and for 22 it did not (222 were not checked).

The uses of the inspected substance in the registration dossier corresponded to the real uses of the inspected substance in the inspected company for 419 substances and for 23 it did not (for 170 were not checked).

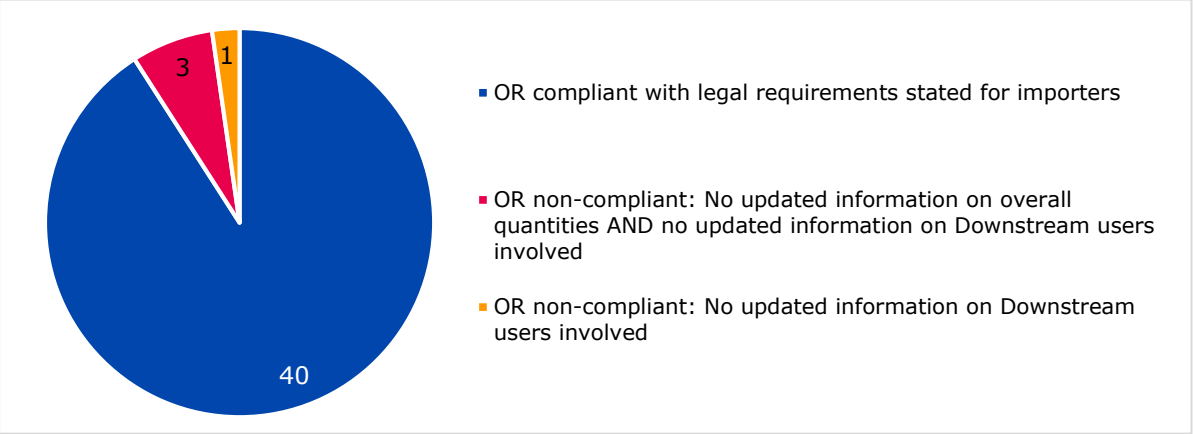
2.4. Inspections of only representatives (ORs)

49 ORs were controlled with regard to the inspected substances. 40 of them complied with legal requirements stated for importers under REACH and four ORs did not (for five ORs, the information was inconclusive) (see Chart 14).

Regarding the four cases where ORs were non-compliant, the following reasons were provided:

- For three, the ORs did not keep updated information available on overall quantities of inspected substances imported per calendar year (2018 and earlier).
- For four, the ORs did not keep updated information available on the downstream users involved.

Chart 14. Only representatives: Checks on legal requirement stated for importer



43 of the 49 ORs had a proof of their appointment as OR for the specific substance, two ORs did not (for one it was not checked and for three ORs no information was received). 35 non-EU companies that had appointed an OR for the imported substance, informed the importing downstream users about this appointment, one non-EU company did not (for 10 cases it was not checked and for three cases no information was received).

2.5. Inspections of substances with intermediate registration (area 2)

226[10] inspections focused on isolated intermediates. 62 of those relate purely to on-site isolated intermediates and 148 purely to transported isolated intermediates, 15 companies were reported to have both on-site and transported intermediates.

141 of the isolated intermediates were used by companies and 85 were not used within the same company.

Life cycle stages of the inspected intermediates

Inspections showed that for 157 inspected intermediates the companies were manufacturers of the intermediate in question.

It is reported that for intermediates manufacturing processes companies had technical *measures for rigorous containment* for 145 inspected intermediates; for the final synthesis process companies had measures for rigorous containment for 105 inspected intermediates and for waste management companies had measures for rigorous containment for 89 inspected intermediates..

Further, for 140 inspected substances the companies had *procedures/practices for ensuring rigorous containment* during manufacturing, while 110 had procedures/practices under the synthesis process and 99 under during waste management.

Use of the intermediate

The 226 inspections report on use processes identified in the inspected companies (no information was provided for one inspection):

- for 179 substances transfer processes (loading/unloading, transfer into vessels);

[10] 225 intermediates were checked. One substance was additionally checked as intermediate although its registration as an intermediate was inappropriate. Result of this one inspection was included in data presented in chapter 2.5.

- for 100 purification processes;
- for 171 sampling and analysis processes; and
- for 179 storage processes.

The 226 inspections checked the control measures in the form of technologies/installations for rigorous containment in the inspected company (no information was provided for two inspections):

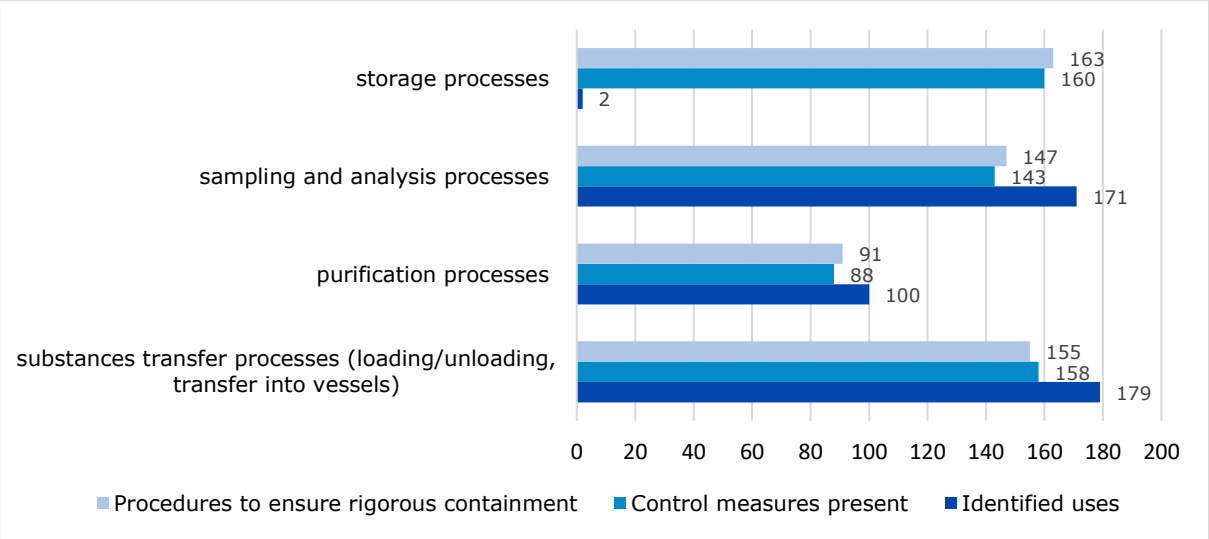
- for 158 substances transfer processes;
- for 88 substances during purification process;
- for 143 substances during sampling; and
- for 160 substances analysis and under storage.

Further, availability of procedures/practices to ensure rigorous containment was reported as following (no information was provided for two inspections):

- for 155 substances transfer process;
- for 91 substances for purification process;
- for 147 substances during sampling and analysis; and
- for 163 substances during storage.

Chart 15 summarises the use of the substance.

Chart 15. Use of the substance.



Control technologies

Moreover, inspections show that there are control technologies used to minimise emissions:

- with regard to controlling eventual residual emissions from rigorous containment:
  - for 157 intermediates there are technical measures in place,
  - for 156 written operational procedures are available;
- with regard to controlling emissions from purification process:
  - for 101 intermediates there are technical measures in place,
  - for 102 written operational procedures are available;
- with regard to controlling emissions during cleaning and maintenance work:
  - for 174 intermediates there are technical measures in place,

- for 174 written operational procedures are available;

- with regard to controlling emissions in case of an accident
  - for 179 intermediates there are technical measures in place,
  - for 181 written operational procedures are available.

Special procedures

During 223 inspections, a check was carried out on whether or not there are special procedures applied/followed before the system is opened, and entered, during cleaning and maintenance work. There were particular process procedures for containment in place for 157 inspected substances, and process procedures for operational system checks for 152 substances. It was observed that specific risk management measures are in place for 172 substances and specific procedures for opening the system for 171 substances.

Training of personnel and measures to minimise exposure to workers

It was reported that the personnel handling the isolate intermediate did not receive relevant training for 29 inspected substances (as a part of complying with strictly controlled condition requirements) and for handling 193 inspected intermediates personnel received it in the following way (no information for four inspected intermediates):

- for 107 through specific training and/or authorisation for this substance;
- for 145 through specific training and/or authorisation for the process; and
- for 152 cases through general training based on other legislative frameworks controlling handling of the substance considered).

It is reported that companies could document that only trained workers are tasked to handle of the substance for 191 inspected intermediates as follows:

- in 119 cases, the supervisor keeps the worker's authorisation sheets with information on the workers authorised to handle the intermediate;
- in 86 cases only one specially trained worker handled the substance; and
- in 83 cases there were other ways of documenting that only trained workers are tasked to handle of the substance.

For 30 inspected intermediates, the companies could not document that only trained workers handled the intermediates.

For 190 inspected intermediates, the companies could document that there was a proper supervision of the implementation of the substance handling procedures and 32 companies could not (no information for four inspected intermediates):

- in 111 cases, substance handler sign-sheets were used, which were controlled by the supervisor;
- in 89 cases, there were records showing written authority by supervisors in implementation of handling procedures; and
- in 86 cases, there were other ways of documenting.

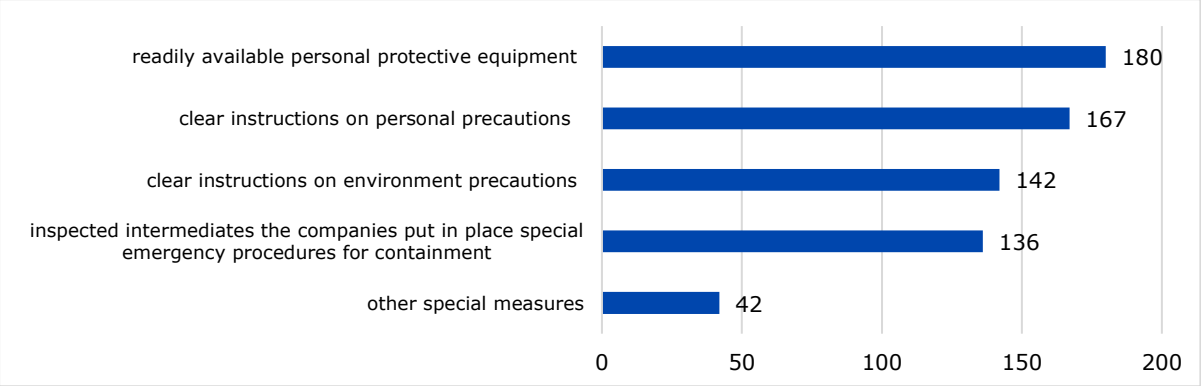
In 195 cases, the personnel handling the substances had access to relevant information on safe handling, as part of complying with strictly controlled condition requirements. Whereas in 27 cases, personnel did not have access to information (no information for four inspected intermediates). In the 195 cases, they had access through the following sources:

- 158 through information in the safety data sheet;
- 65 through information in the form of exposure scenario;

- 167 through written instructions on how to handle the substance; and
- 166 through written instructions on process operation.

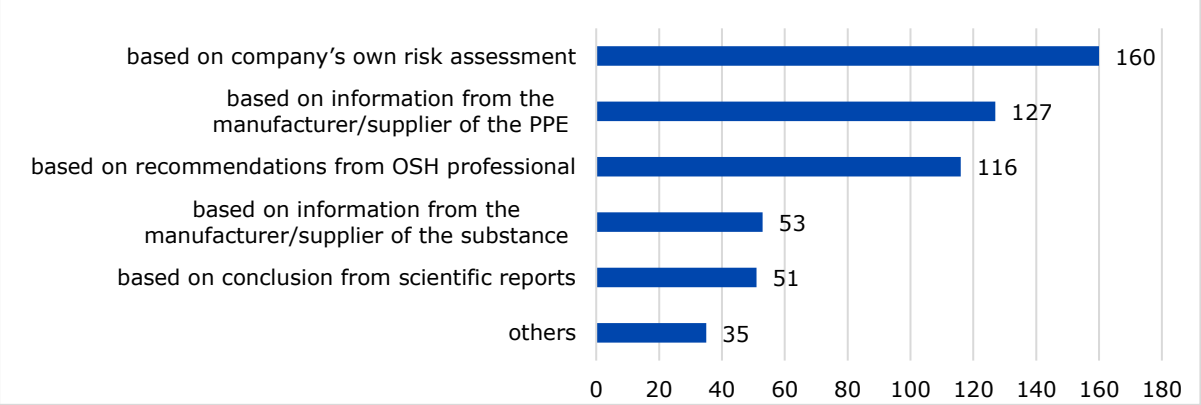
In case of accidental release of the substance, for 196 inspected intermediates there were special measures put in place by the companies to minimise exposure to workers and for 26 inspected intermediates not (no information for four inspected intermediates). For 196, special measures were put in place (see Chart 16).

Chart 16. Special measures put in place in the companies to minimise exposure to workers



The received questionnaires relating to the inspections of 226 isolated intermediates mentioned that for 200 substances the companies could document that the PPE chosen were suitable for protection against exposure to the substance (where the use of PPE may be necessary e.g. during accidental release) and 19 questionnaires mentioned absence of this (no information for seven inspected intermediates). For 200 companies, it was documented in the ways that are presented in Chart 17 (multiple answers were possible).

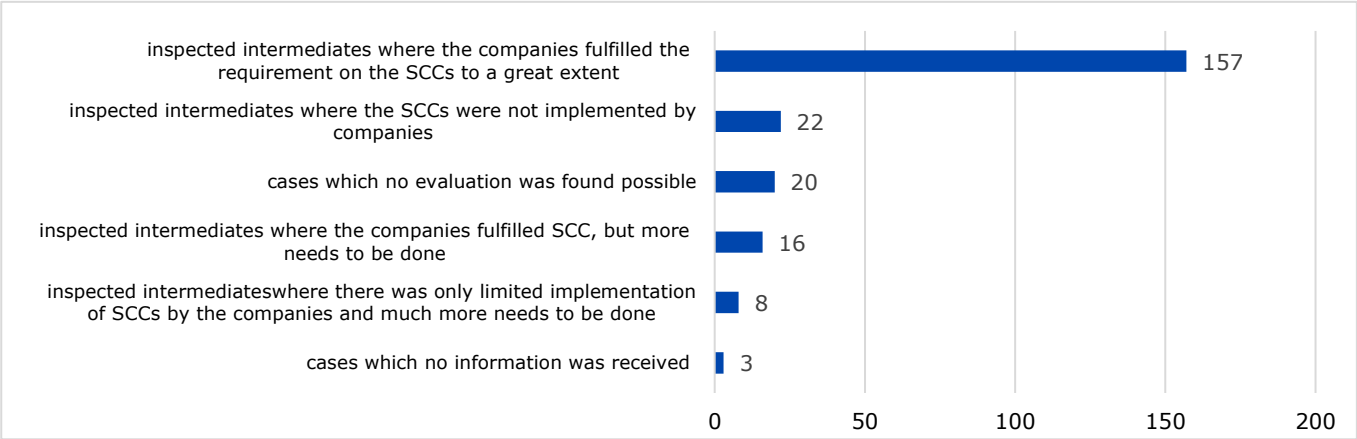
Chart 17. The ways how companies can document that the PPE chosen were suitable for protection against exposure (multiple answer were possible).



Implementation of strictly controlled conditions (SCCs)

Based on the measures put in place in the inspected company for the inspected intermediates, the inspectors evaluated the implementation of SCCs as presented in Chart 18.

Chart 18. Evaluation of the measures put in place for the inspected intermedates



The inspectors evaluated the inspected companies were applying SCCs for 179 inspected intermediates and not in 44 (no information for three inspected intermediates).

In cases where the inspected company was a downstream user (importing DU or not) of the intermediate, the downstream user used the inspected intermediate as an intermediate in 61 cases and in two they did not.

The inspectors considered that the registration of the inspected substance as intermediate was acceptable in 192 inspections and in 32 it was not (no information for two inspected intermediates).

3. Infringements and enforcement measures

3.1. Infringements

In 180 of all 1 193 inspections, there were found at least one non-compliance with REACH obligations. This accounts for a 15 % non-compliance rate.

All non-compliances with REACH provisions in the scope of REF-7 are presented in Table 7 (multiple violations of the REACH articles could be detected for the same substance).

Table 7. Non–compliance with REACH articles (multiple violations for the same substance are possible)

REACH Articles	Number of violations reported for 180 non-compliant substances	% [N=252]
Article 5	53	21.0
Article 6	75	29.8
Article 7	0	0.0
Article 8	18	7.1
Article 12	14	5.6

Article 17	9	3.6
Article 18	39	15.5
Article 22	44	17.5
Sum	252	100%

The inspected substances reported most often as non-compliant with REACH are: paraffin wax (6), ethanol (4) and sodium hydroxide (4).

89 of 180 non-compliances were observed in SMEs and 91 in non-SMEs. Therefore, it could not be generally concluded, that smaller companies would be more frequently non-compliant with REACH provisions than bigger companies.

From 180 inspected substances that were reported as non-compliant, 77 refer to missing valid registrations for inspected substances (see Chart 19).

75 of the 77 inspections where non-compliance with the duty to register was observed, point to non-compliance with Article 6 of REACH. 53 of these 75 inspections also mention non-compliance with Article 5 of REACH.

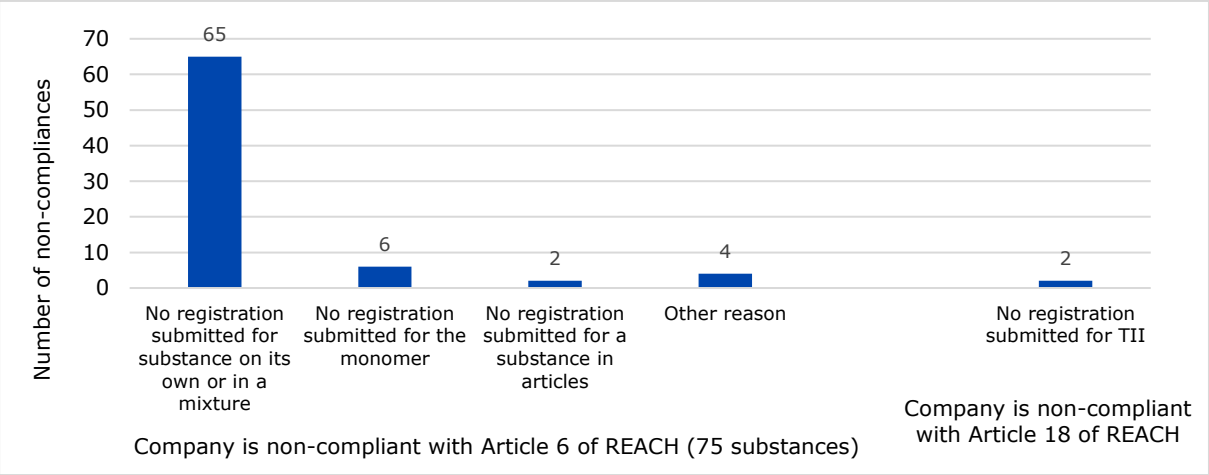
Two of the 77 inspections where non-compliance with the duty to register was observed, point to non-compliance with Article 18 of REACH.

The reasons for non-compliance for the 75 inspected substances with Article 6 of REACH were:

- for 65 inspected substances, the companies have not submitted registration;
- for six inspected substances (monomer substance or any other substances by manufacturer or importer of the polymer), the companies have not submitted the registration for the monomer;
- for two inspected substances, the producer or importer of article has not submitted the registration for a substance in articles; and
- for four inspected substances, there were other ”explanations” given for the missing registrations:
    - the inspected company claimed that a registration was not necessary because the registration of the inspected substance was done by an only representative, but the registration by the OR could not be related to the specific substance imported by the inspected company;
    - the company considered the product to be an article but instead it was a mixture within a container;
    - the company wrongly used the Plant Protection Product derogation of Article 15(1) of REACH; and
    - The registration was revoked by ECHA.

The reason for non-compliance for two inspected substances with Article 18 of REACH was that there was no registration submitted for transported isolated intermediates.

Chart 19. Non-compliances with registration obligations



Regarding the non-compliance with Articles 17 and 18 of REACH there were:

- Nine non-compliances with Article 17 of REACH for on-site isolated intermediates:

  - for three inspected OSIIs, the measures put in place were not enough to concluded that the requirement on strictly controlled conditions was fulfilled and for one, there were only limited measures put in place based on on-site inspection;
  - for six inspected OSIIs, the inspected company was not applying SCCs; and
  - for seven inspected OSIIs, the inspectors assessed (based on their observations) that the registrations were not acceptable.

- 39 non-compliances indicated with Article 18 of REACH for transported isolated intermediates:

  - for 16 inspected TIIs, the measures put in place were not enough to conclude that the requirement on strictly controlled conditions was fulfilled and for seven there were only limited measures put in place based on on-site inspection;
  - for 29 inspected TIIs, the inspected company was not applying SCCs;
  - for 22 inspected TIIs, the inspectors assessed (based on their observations) that the registrations were not acceptable; and
  - 2 TIIs were missing registration.

During 180 inspections, where a non-compliance was detected with the REACH obligations checked in the REF-7 project, measures were imposed (multiple measures could be imposed). These measures were:

- 25 verbal advices;
- 78 written advices;
- 42 administrative orders;
- 17 fines;
- 36 criminal complaints/handing over to public prosecutor's office; and
- 49 other (e.g. company was asked to report the correct tonnage to ECHA, ORs were asked to update information on the registration dossier, fines proceedings have been initiated but the company has very quickly achieved legal compliance).

There were additionally 74 measures imposed during inspections of 67 substances due to non-compliance with other REACH/CLP obligations that were not subject to the REF-7 project.

No measures were imposed during the 1 173 inspections of substances (out of 1 420). This can be understood that the inspector did not initiate corrective action in about 82.6 % of the inspections as the substances were compliant.

Corrective measures were imposed during inspection of 180 substances that were non-compliant with the articles of REACH subject to the REF-7 project and additionally during the above mentioned inspections of 67 substances where non-compliance were found with other REACH/CLP obligations.

3.2. Follow-up actions

The follow-up activities were reported as completed for 1 222 inspections and for 198 they were still ongoing in time when the inspections finished.

3.3. Cooperation

3.3.1. Cooperation with other Member States

Information on 33 cases was shared with other participating countries (through Forum Members (11 cases) or dedicated Focal Points (17 cases) or REF-7 national coordinators (13 cases)).

3.3.2. Cooperation with other authorities

Inspectors cooperated with the other national authorities for or even during 657 inspections. For 591 out of 1 420 inspections (42 %) they cooperated with customs and for 115 with other authorities including:

- regional inspectorates;
- Seveso and OSH inspectorates;
- environment and transport inspectorates;
- waste authorities;
- country administrative board;
- public prosecutor office;
- ECHA; and
- ministries.

3.3.3. Cooperation with industrial sectoral organisations

388 out of 798 inspected companies were affiliated to an industrial sectoral organisation. For 15 companies, this information was not checked.

IV. Conclusions and recommendations

Based on the data received and the analyses that could be conducted on them, the following conclusions and recommendations can be drawn from the project.

1. Conclusions

28 countries participated in Forum's seventh coordinated REACH enforcement project. The project focused on the duty to register substances manufactured or placed on the market in all tonnage bands exceeding one tonne per year. Two similar projects have been conducted (REF-1, REF-3) and the present project can be seen as the last in the trilogy of projects, focusing on the duty to register – each after registration deadlines related to ever smaller tonnage bands impacting obviously a wider set of chemicals. REF-7 came about after the 31 May 2018 registration deadline.

Participants reported inspection findings for 1 420 substances collected in 813 companies dispersed over nearly the whole European Economic Area. As could be expected, a number of substances were investigated repeatedly, albeit at different geographical locations. Data on 952 different substances were obtained, indicating that an eclectic set of investigated substances was available in REF-7.

REACH is not new. Yet this project shows a relatively high degree of non-compliance with the legal *acquis* in the scope of REF-7. From the 1 420 checked substances, there was no duty to register for 227 substances, leaving 1 193 substances which needed registration.

For 180 of the 1 193 inspections executed, almost 15 %, REF-7 relevant non-compliance was reported. For 77 inspections (6.5% of the total number of inspections) registrations were missing for which no exemption could be invoked. It remains unclear if this finding typifies the general situation in the EEA or not. The process of selecting companies for inspection can influence the ultimately observed non-compliance degree in the project, with the process being subjective.

Past enforcement projects show many inspected substances being exempt from registration. 227 of the 1 420 substances did not need to be registered with many exemption opportunities provided in REACH, leaving 1 193 inspected substances with a duty to be registered. Some duty holders proved to be exempt from registration obligations because the registration duty had been fulfilled by an only representative. This was the case for 292 inspected substances. A poignant example are the high-volume hazardous substances considered as polymers according to REACH, consequently exempt from registration.

This project fostered good communication between competent enforcers (environment, health, labour) as well as cooperation between them and customs officers. This interaction is of critical importance when investigating manufacture as well as import in the EEA, considering the widespread distribution of inspection and enforcement competencies (cross-country, international).

All inspectors used the same questionnaire annexed to the inspection manual developed by the Forum. By this the Forum hopes that it contributed to harmonisation of the inspections throughout the EEA.

The inspectors were invited for the first time to evaluate thoroughly and methodically the management of intermediates, whether by registrants or end users. It is well known that

fewer efforts are necessary to draft a registration dossier for an intermediate than for a registration compliant with Article 10 of REACH ("full registration"). But are the registered intermediates used as intermediate? And are all executable measures taken to ensure that introduction of the intermediate into the surroundings is kept minimal at all times? The REF-7 questionnaire guided the inspectors in their verification of the conditions to respect.

Some years ago a study of the quality of registration dossiers[11] claimed that this quality is way below expected standards. This project is innovative too insofar that for the first time inspectors were invited to verify partial content of the registration dossier with observed reality. The reported basic findings do not seem to corroborate this claim.

This report intends to present the inspection findings sent to ECHA Forum's dedicated REF-7 working group. The report copies the questionnaire used by the inspectors, a questionnaire that can be used by stakeholders wishing to perform self-control as part of a quality assurance company policy.

2. Recommendations

2.1. To industry

1. Companies are recommended to regularly verify if they are compliant with the provisions this project focused on. To this aim they can be guided by using the annexed questionnaire.
2. Put more attention on keeping registration dossiers synchronised with actual company operations.
3. Registrants of intermediates ensure that the safety data sheet and information according to Article 32 regarding intermediates makes it explicit that intermediates need to be used under strictly controlled conditions at all times.
4. Recognising that despite the easier registration of intermediates, such entails fulfilment of SCCs at all times by registrants and downstream users.

2.2. To the Forum

1. Develop questionnaires where questions are less exposed to misinterpretations and limited to enforcement of compliance with provisions.
2. Run the testing inspections before the approval of the questionnaire.
3. Design and implement strategies that will improve the quality of reporting of results to ensure evaluation efficiency and certainty in decision-making.

2.3. To the inspectors (REACH, customs)

1. Make checking compliance with registration obligations a point of attention of every inspection. The present manual can be kept as reference material.

2.4. To ECHA

1. Continue allotting resources for Forum WG-operations, in particular, for the development of surveillance tools like inspection manuals.
2. Continue making public information regarding the need for quality registration information.

[11] https://www.bfr.bund.de/en/press_information/2019/18/bfr_research_project_to_enhance_the_quality_of_registration_dossiers_on_chemicals-240986.html

2.5. To the European Commission

1. Continue its efforts to streamline the EU *acquis* on chemicals with a view to legislation that is easy to control and easy to comply with.
2. Continue its efforts to raise awareness among SMEs and support SMEs with registration obligations.

Annexes:

Annex I: Questionnaire

Annex 1: Questionnaire

Forum Project REF-7 **QUESTIONNAIRE** Fill out one questionnaire for each substance per company inspected.	
Section 0 - General Information about the inspection	
0.1.Participating country:	
0.2. Inspector: 0.3. Date of inspection: 0.4. File reference:	This data is only for internal use e.g. in case you need to forward this dossier to other NEAs e.g. for assistance.
0.5 The inspection is: ☐ On-site inspection ☐ Desk-top inspection	
0.6. ECHA case number:	Please mention the ECHA case number when you are addressing an ECHA case (a case provided by ECHA separately e.g. after ECHA manual verification, intermediate screening).

Section 1: General information about the inspected company	
1.0. Company ID code	ID code is a random but unique 5 character code to name the inspected company, like for example "AT001"(for Austria), and is independent from the name for internal use in the NEA. The ID code is used for statistical processing during project evaluation.
1.1. Name of company: 1.2. Name of the contact person: 1.3. Contact person's role:	This data is only for internal use e.g. in the case you need to forward this dossier to other NEAs e.g. for assistance.
1.4. Company's NACE-Code:	
1.5. According to Commission Recommendation 2003/361/EC the company qualifies as[12]: ◯ - SME ◯ - not SME SME: <250 employees and ≤50 million euro annual turnover	

[12] In this project, for ORs it means the size of non-EU company represented by the OR.

1.6. Role(s) of the company under REACH: ☐ Manufacturer ☐ Importer ☐ Downstream user ☐ OR ☐ Importing Downstream user	Company can have more than one role.
1.7. Does the company **manufacture** substances in quantities of 1 tonne or more per calendar year (3 years average 2018 – 2017 – 2016)? ◯ Yes If yes, which of the following apply? ☐ As substances as such how many? ☐ As a polymer according to Article 3.5 of REACH how many? ☐ As a substance intended to be used as an intermediate how many? ◯ No	Art. 3.8 of REACH. 'Substances as such' are the substances manufactured that are, according to the company, no REACH polymers nor intermediates.
1.8. Does the company **import** substances in quantities of 1 tonne or more per calendar year (3 years average 2018 – 2017 – 2016)? ◯ Yes If yes, which of the following apply? ☐ As substances as such how many? ☐ As substances in mixtures how many? ☐ as a polymer how many? ☐ intended to be used as an intermediate how many? ◯ **No**	Art. 3.10 of REACH. Please include here also companies that are ORs.
1.9. **Number of compulsory registrations NOT** submitted by the inspected company to ECHA: Number of missing registrations in total: Number of missing intermediates registrations	Numbers based on the information during the inspection (and checked in PD-NEA). Number for all substances handled by the company. Please insert 0 in case there are no missing registrations.
1.10. Is there more than one substance checked in the company: ◯ Yes If yes, how many ◯ No	

1.11. Does the company have a system in place to ensure updates of the registration dossier according to Article 22 of REACH related to the following update triggers? 1. Volumes of substances - Art. 22.1.c ◯ Yes If yes please provide short description + how long it would take to notice that the tonnage band has increased (optional) ◯ No 2. Uses – Art. 22.1.d ◯ Yes If yes, please provide short description + how long it would take to notice that a new use has occurred (optional) ◯ No	Article 22 of REACH requires updating the registration dossier with relevant new information. This requires a review/tracking and alert system for volumes of substances (alerts for tonnage band increases) and uses (e.g. from new customers and new uses by old customers, incl. the continued use as an intermediate under SCC). If 'Yes' inspectors should verify the system on-site.
1.12. Did the company have to submit updates for the inspected substance triggered by a change of tonnage band or the use of substance? ◯ Yes If yes, did the company submit the update(s) to the Agency? ◯ Yes If yes, what is the time between the trigger and the update of the dossier: ◯ Some yes, some no ◯ No ◯ No	If company had to submit ('yes') but did not submit ('no') then there is a breach of Art. 22 of REACH.

Section 2 - Details of the substance inspected	Choose 1 substance for 1 report.
2.1. Inspected substance in present report: Name: CAS number: EC number	
2.2. Is the substance classified as hazardous according to the CLP Regulation? ◯ Yes If yes, is the substance identified as a SVHC? ◯ Yes ◯ No ◯ No	The substance is identified as a SVHC if it figures on the candidate list of SVHCs or on Annex XIV of REACH.

2.3. Did the company register the inspected substance? ◯ **Yes** ☐ full registration Year of the registration of the substance: ☐ intermediate registration Year of the registration of the substance: ◯ **No** If **not**, ◯ Company is not compliant with Article 6 and/or 7 of REACH The reason of non-compliance: ☐ no registration submitted for substance on its own or in a mixture ☐ no registration submitted for the monomer substance(s) or any other substances(s) by manufacturer or importer of a polymer ☐ no registration submitted for a substance in articles by producer or importer of article ☐ another substance identity was registered ☐ Others ◯ Company is not compliant with Article 17 or 18 of REACH The reason of non-compliance: ☐ no registration submitted for on-site isolated intermediates ☐ no registration submitted for transported isolated intermediates ☐ another substance identity was registered ☐ Others	Full registration: then the substance identity in the registration dossier must be correct. Articles 6.1 and 7 of REACH. Substances on their own, in mixtures and in articles with the intention to be released. Registration as intermediate: then the substance identity in the registration dossier must be correct and the substance is used as an intermediate under SCCs. Articles 17 and 18 of REACH. ECHA's Guidance for identification and naming of substances under REACH and CLP. **If the answer is 'intermediate registration' please fill section 3 of the questionnaire** Art. 6.1. of REACH Art. 6.2. of REACH Art. 7.1. of REACH Art. 17.1. of REACH Art. 18.1. of REACH

◯ **Company does not need to register** The reason why registration is not necessary: ☐ exempted because of Annex IV and V ☐ re-imported ☐ food ☐ medicines ☐ Below 1 tonne/year ☐ Non-isolated intermediates ☐ biocide ☐ food and feeding stuffs ☐ polymer compliant with Art. 3.5 REACH ☐ recovered substances which were registered before ☐ registration done by OR Is there a notification from the non-EU manufacturer stating that the registration has been done by an OR? ☐ Yes ☐ No Others	If there is no registration and no exemption motivating this, there is a breach of Art. 6 of REACH. ECHA's Guidance on waste and recovered substances. **If the company did not register the inspected substance because the company does not need to register it, please mention the reason, skip the questions from 2.6 - 3.18 of the questionnaire.**

2.4. Based on the findings of the inspector the company is: ☐ the manufacturer of the inspected substance ☐ the importer of the inspected substance ☐ the Only Representative for the inspected substance ☐ the Downstream User of the inspected substance ☐ Importing Downstream User of the inspected substance	Art. 3.8, 3.10 and 8.1 of REACH. Report the findings of the inspector's investigation here. The importer covered by an OR is a DU as per Article 8.3 of REACH.
2.5 In case of polymers complying with Art. 3.5 REACH, are the monomers (and the substances which are chemically bound to the polymer) registered? ◯ Yes ◯ No If No, are the monomers exempted from registration because the polymer consists of less than 2% by weight (w/w) of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) and the total quantity of such monomer substance(s) or other substance(s) are less than one tonne per year? ◯ Yes ◯ No ◯ Not checked ◯ Not relevant	Art. 6.3 of REACH. **If there is 'no' registration of the monomer and no exemptions there is a breach of Article 6 of REACH.**

AREA 1 – FULL REGISTRATION

If the inspected company has done a full registration of the inspected substance, please answer questions 2.6. – 2.9 in relation to the practical check (see Annex 6 to the manual).	
2.6. Does the tonnage band in the registration dossier correspond to the real tonnages[13] of the inspected substance? ◯ Yes ◯ No If not, ◯ is higher ◯ is lower ☐ some tonnages are exempted from registration ◯ Not checked	Questions 2.6-2.12 are only relevant if the company registered the inspected substance. Based on Article 10 and the relevant Annexes. A higher level indicates the breach of obligations of Art. 6 or 22 of REACH. See Annex 6 to the manual.
2.7. Do the production processes in the registration dossier correspond to the real processes with the inspected substance in the inspected company? ◯ Yes ◯ No ◯ Not checked	Based on Article 10 and the relevant Annexes. See Annex 6 to the manual.
2.8. Does the life cycle of the inspected substance in the registration dossier correspond to the real life cycle of the inspected substance in the inspected company? ◯ Yes ◯ No ◯ Not checked	Based on Article 10 and the relevant Annexes. See Annex 6 to the manual.
2.9. Do the real uses of the inspected substance in the inspected company correspond to the uses of the inspected substance in the registration dossier? ◯ Yes ◯ No ◯ Not checked	Based on Article 10 and the relevant Annexes. Annex VI point 3.5 includes the obligation to report the (correct) uses. See Annex 6 to the manual. When checking the categories of uses (industrial, professional and consumer) the inspector should check if the real use is also registered e.g. a substance ending up as a consumer product might not have any consumer use in the registration dossier.

[13] Please take into account that some tonnages may be exempted while other tonnages of the same substance need to be registered. Please note also that a company can produce/import the same substance as a substance **and** as an intermediate: in this case, verify the tonnage band for each use.

If the inspected company is an Only Representative (OR) with regard to the inspected substance, please answer questions 2.10-2.12	
2.10. Does the OR comply with legal requirements stated for importers under REACH? ◯ Yes If yes, - overall quantity (tonnes) for the calendar year 2018: - 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 2018 and earlier) ☐ keep available and up-to-date the information on customers the substance is sold to ◯ Not checked	Art. 8.2 of REACH requires complying with the obligations of importers. REACH FAQs for ORs.
2.11. Is there proof of the company's appointment as OR for the specific substance when asked for? ◯ Yes ◯ No ◯ Not checked	Art. 8.1 of REACH. REACH FAQ for ORs.
2.12. Has the non-EU company (manufacturer, formulator) that has appointed the OR for registration of the inspected substance informed the importing downstream users about the appointment of the OR? ◯ Yes ◯ No ◯ Not checked	Art. 8.3 of REACH.

AREA 2- INTERMEDIATES REGISTRATION

Section 3 – Inspection of intermediates	
3.01. Does the company place the inspected substance on the market as an isolated intermediate? ◯ Yes ◯ No	
3.02. Does the company use the inspected substance – previously registered as isolated intermediate? ◯ Yes ◯ No	
1.1. Which type of intermediate is the inspected substance claimed to be? ☐ On-site isolated intermediate ☐ Transported isolated intermediate	Art. 3.15 a-c of REACH.

3.2. 1._Which of the following **life cycle stages** of the substance are identified on the inspected site? ☐ Manufacture of the intermediate ◯ Yes ◯ No ☐ Synthesis process ◯ Yes ◯ No ☐ Waste treatment ◯ Yes ◯ No 2._Which of the following **uses** of the substance are identified on the inspected site? ☐ Substance transfers (Loading/unloading, transfer into vessels) ◯ Yes ◯ No ☐ Purification ◯ Yes ◯ No ☐ Sampling and analysis ◯ Yes ◯ No ☐ Storage ◯ Yes ◯ No	Please answer based on the results of the on-site inspection. Questions 3.2 to 3.13 are necessary to conclude questions 3.14-3.16. 'Synthesis process' - this may apply to the DUs.

3.3. 1._Are there control technologies/installations for rigorous containment of the substance for the relevant **life cycle stages** identified on the inspected site? ☐ Manufacture of the intermediate ◯ Yes ◯ No ◯ Not applicable ☐ Final synthesis process ◯ Yes ◯ No ◯ Not applicable ☐ Waste handling/treatment ◯ Yes ◯ No ◯ Not applicable 2._Are there control technologies/installations for rigorous containment of the substance for the relevant **uses** identified on the inspected site? ☐ Substance transfers (Loading/unloading, transfer into vessels) ◯ Yes ◯ No ◯ Not applicable ☐ Purification ◯ Yes ◯ No ◯ Not applicable ☐ Sampling and analysis ◯ Yes ◯ No ◯ Not applicable ☐ Storage ◯ Yes ◯ No ◯ Not applicable	Art. 18.4 of REACH. See examples in Annex 7 to the manual on what can be considered as rigorous containment. Use of PPE is not considered as a method of rigorous containment. Please choose 'not applicable' in case you selected 'no' in question 3.2.

3.4. 1. Are procedures/practices to ensure rigorous containment/minimisation of emissions applied and maintained for the life cycle **stages** identified on the inspected site? ☐ Manufacture of the intermediate ◯ Yes ◯ No ◯ Not applicable ☐ Final synthesis process ◯ Yes ◯ No ◯ Not applicable ☐ Waste handling/treatment ◯ Yes ◯ No ◯ Not applicable 2. Are procedures/practices to ensure rigorous containment/minimisation of emissions applied and maintained for the **uses** identified on the inspected site? ☐ Substance transfers (Loading/unloading, transfer into vessels) ◯ Yes ◯ No ◯ Not applicable ☐ Purification ◯ Yes ◯ No ◯ Not applicable ☐ Sampling and analysis ◯ Yes ◯ No ◯ Not applicable ☐ Storage ◯ Yes ◯ No ◯ Not applicable	Please choose 'not applicable' in case you selected 'no' in question 3.2.

3.5._Are there control technologies used to minimise emissions, such as/from...? ☐ Eventual residual emissions from rigorous containment ◯ Yes ◯ No ◯ Not applicable ☐ Emissions from purification process ◯ Yes ◯ No ◯ Not applicable ☐ Cleaning and maintenance ◯ Yes ◯ No ◯ Not applicable ☐ In case of accident ◯ Yes ◯ No ◯ Not applicable	

3.6._Are there written operational procedures/instructions followed to minimise emissions, such as/from...? ☐ Eventual residual emissions from rigorous containment ◯ Yes ◯ No ◯ not applicable ☐ Emissions from purification process ◯ Yes ◯ No ◯ Not applicable ☐ Cleaning and maintenance ◯ Yes ◯ No ◯ Not applicable ☐ In case of accident ◯ Yes ◯ No ◯ Not applicable	
3.7._Are there special procedures which are applied/followed before the system is opened, and entered, during cleaning and maintenance work? ☐ Process procedures for containment ◯ Yes ◯ No ☐ Operational procedure system checks ◯ Yes ◯ no ☐ Specific risk management measures ◯ Yes ◯ no ☐ Specific procedures before the system is opened ◯ Yes ◯ no	

3.8._As part of complying with strictly controlled conditions requirements, have the personnel handling the substance received relevant training? ◯ Yes If yes, which of the following apply? ☐ Specific training and/or authorisation for this substance ☐ Specific training and/or authorisation for the process ☐ General training based on other legislative frameworks controlling handling of the substance considered ◯ No	
3.9._Can the company document that only trained workers are tasked to handle of the substance? ◯ Yes If yes, which of the following apply? ☐ Supervisor keeps workers authorisation sheets ☐ Only one designated trained worker handles the substance ☐ Other: ◯ No	
3.10._Can the company document that there is proper supervision of the implementation of the substance handling procedures? ◯ Yes If yes, which of the following apply? ☐ Substance handler sign-sheets are used, and are controlled by the supervisor ☐ Recorded written authority by supervisor ☐ Other: ◯ No	

3.11. As part of complying with strictly controlled conditions requirements, does the personnel handling the substance have access to relevant information? ◯ Yes If yes, which of the following apply? ☐ Information in the form of safety data sheet ☐ Information in the form of exposure scenario ☐ Written instructions on how to handle the substance ☐ Written instructions on process operation ◯ No	
3.12. In case of accidental release of the substance, are there special measures put in place to minimise workers exposures? ◯ Yes If yes, which of the following apply? ☐ There are special emergency procedures for containment ☐ Readily available personal protective equipment ☐ Clear instructions on personal precautions ☐ Clear instructions on environment precautions ☐ Other: ◯ No	
3.13. Where the use of PPE may be necessary e.g. during accidental release, can the company document that the PPE chosen are suitable for protection against exposure to the substance? ◯ Yes If yes, which of the following apply? ☐ Based on conclusion from scientific reports ☐ Based on company's own risk assessment ☐ Based on information from the manufacturer/supplier of the substance ☐ Based on information from the manufacturer/supplier of the PPE ☐ Based on recommendations from OSH professional ☐ Other: ◯ No	

3.14._From the inspector's own on-site assessment in the inspected company, are the measures put in place enough to conclude that the requirement on strictly controlled conditions are fulfilled? ◯ Yes, the requirements are fulfilled to a great extent ◯ Yes, but more needs to be done ◯ Only limited fulfilment. Much more needs to be done ◯ No ◯ Not possible to make such a conclusion	
3.15._In case the inspected substance would be a transported isolated intermediate: 1. Does the manufacturer or importer confirm themselves, that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under SCCs? ◯ Yes ◯ No 2. Does the manufacturer or importer state that they have received confirmation from the user(s) that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under SCCs? ◯ Yes ◯ No	The trustworthiness of the allegations of the manufacturer or importer should be checked. The inspector should ask the duty holder on what their confirmation is based. Whether their customers have attested that they use the intermediate as an intermediate. If so, the inspector can ask for a copy of the customers' declarations. An OR that is importing, is an importer under REACH and must comply with REACH obligations for importers.
3.16._Is the inspected company applying SCCs? ◯ Yes ◯ No	

3.17 In case the inspected company is a DU (importing DU or not) of the intermediate: 1. Does the DU use the intermediate as an intermediate? ◯ Yes ◯ No ◯ Not a relevant question (inspected company is not a DU) 2. Does the DU use the intermediate under SCCs? ◯ Yes ◯ No ◯ Not a relevant question (inspected company is not a DU)	Choose 'not a relevant question' in case the inspected company is not a DU. Answer is necessary for finishing properly the questionnaire.
3.18. Based on your observations, could registration of the inspected substance as intermediate be acceptable? ◯ Yes ◯ No	

Section 4: Summary/Follow up Actions	
4.1._Has non-compliance been observed? ◯ Yes If yes, with which Article of REACH? ☐ Article 5 ☐ Article 6 ☐ Article 7 ☐ Article 8 ☐ Article 12 ☐ Article 17 ☐ Article 18 ☐ Article 22 ◯ No	- Art. 5 – substance is not registered but is manufactured in the Community or placed on the market - Art. 6 – substance is not registered on its own or in mixtures - Art. 7 – substance in articles is not registered - Art. 8 – non-compliance with registration obligations by ORs - Art. 12 – not correct information depending on tonnage submitted - Art. 17 – on-site isolated intermediates were not registered (1) or the required submitted information was not correct (2) or they were not used under SCCs (3) - Art. 18 - transported isolated intermediates were not registered (1) or the required submitted information was not correct (2, 3) or they were not used under SCCs (4) - Art. 22 – registrant did not update their registration with relevant new information
4.2._Measures imposed due to non-compliance with REACH obligations subject to this project ☐ No measures ☐ Verbal advice ☐ Written advice ☐ Administrative order ☐ Fine ☐ Criminal complaint / Handing over to public prosecutor's office ☐ Others:	
4.3._Are the follow-up activities? ◯ completed ◯ ongoing	
Section 5: Cooperation with other Member States	

5.1._Have any cases been forwarded to other Member States?

◯ Yes, to:
- ☐ Focal point
- ☐ Forum Member
- ☐ National coordinator REF-7

◯ No

Section 6: Cooperation with other authorities (e.g. customs authorities, labour inspectorate)

6.1._Has the inspector cooperated with the other authorities during the inspection?

◯ Yes
◯ No

☐ Customs

☐ Others:

Section 7: Cooperation with an industrial sectoral organisations

7.1._Is the inspected company affiliated with an industrial sectoral organization?

◯ Yes
◯ No

Section 8: - Informal comments (not obligatory)

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