



**FINAL REPORT OF THE FIRST COORDINATED REACH ENFORCEMENT PROJECT  
ON REGISTRATION, PRE-REGISTRATION AND SAFETY DATA SHEETS**

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# Forum REACH-EN-FORCE 1 Project Report

## First forum coordinated REACH enforcement project on registration, pre-registration and safety data sheets

### Executive summary

#### 1 Content of the project

At the beginning of 2009 the Forum for Exchange of Information on Enforcement established by the REACH Regulation (EC 1907/2006) agreed to start the first coordinated Forum enforcement project. The scope of this project was to verify the compliance of manufacturers and importers of substances with the REACH obligations on the preregistration, registration and Safety Data Sheets (SDS).

During a first phase, between May 2009 and December 2009, the project was performed in 25 Member States participating and the inspections of almost 1 600 companies were reported in the framework of the project. At the beginning of 2010 the project was extended and during a second phase, between May 2010 and April 2011, almost 800 additional companies were inspected in 19 countries. Overall, the inspections of almost 2 400 companies were reported in 26 Member States in the framework of the project.

This project has been a valid kick-off of one of the main activities of the Forum.

#### 2 Main results and conclusions

A significant number of inspections have been done all over Europe, which has made it possible to undertake consistent reporting and to highlight valid results in a significant number of cases.

Coordination of the project through the Forum (through a Working group), good cooperation between the national enforcement authorities and support from ECHA has been a feature of the project.

Over the whole project, cases of non-compliance with the relevant duties of the REACH regulation were found in 22 % of the companies inspected, some on very basic, though essential, requirements. In particular, the required Safety Data Sheets (SDS) were not available or only partly available in 11% of the companies inspected and 17% of the SDS did not comply with the obligation for the correct language or concerning the necessary headings of the SDS. The quality of the SDS definitely needs to be improved. So does the compliance with registration obligations, since cases of non-compliance were found in 7% of the inspected companies.

These issues will certainly be key areas for inspectors to consider in the following years.

### 3 Main recommendations resulting from this first project

#### To companies:

- There are signals that it is difficult, especially for SMEs, to comply with the registration obligations, mainly due to the lack of resources and information.
- Higher than expected non-compliance was found.
- Companies should prepare to react to improve their registration dossiers and their SDS
- Companies should not wait for controls but anticipate
- Inspectors within each Member State may always inspect the fulfillment of REACH and CLP obligations outside coordinated enforcement projects of the Forum.
- Stakeholder organisations on national and international level should intensify their support and information on the REACH obligations, especially towards SMEs and Only Representatives. Among others, the organisation of webinars and the distribution of leaflets can be useful.
- Communication within companies and within the supply chain should be improved.

#### To enforcement authorities and to the inspectors:

- Enforcement of REACH and CLP is a key issue, contributing to reach the full objectives of these regulations. It will need to be addressed through an increasing number of controls. Inspectors should be prepared for this.
- Good cooperation and information exchange is needed between the national enforcement authorities, Member States competent authorities (when involved in enforcement issues) and ECHA. The cooperation between the national enforcement authorities enforcing REACH and CLP should be further strengthened in order to facilitate the enforcement of companies active in several Member States.

#### To the Forum:

- The Forum, proposing harmonised approaches, coordinating projects and encouraging cooperation between Member States, is a good and efficient incitement for surveillance and enforcement. Continuation of coordinated Forum enforcement projects is recommended.
- The methodology of this first project was well balanced and efficient. It provided a good basis to set up a horizontal methodology for a harmonised elaboration, management, reporting and evaluation of Forum coordinated enforcement projects.
- Coordinated enforcement projects done in the framework of the Forum should be focused on some specific topics and should not try to cover all REACH and CLP obligations in order to enable all inspectors to focus on the same topics and to facilitate the comparison and assessment of results.
- Besides, when doing their “regular” work outside the scope of the coordinated enforcement projects, inspectors also look into other obligations of REACH regulation having flexibility to choose the relevant topics according to their national priorities.
- It is useful to have a common grid to report the follow-up actions after inspection. This allows comparison of enforcement action between participating countries. This grid could be more refined and it would be useful to seek for further suggestions that could help harmonization of enforcement. However, it will not be possible to put the

follow-up actions on a uniform common basis. Indeed, each participating country has its own legal framework and judicial system.

- For the reporting, a unique and standardised IT tool would be very useful. It should be user friendly and simple. It should allow easy and quick access to the raw data reported, which would make it useful for other purposes than reporting to the Forum (e.g. at national level).

## Detailed results of the project

### 1. General overview

93% of the inspections were performed to check both the (pre)registration and provisions of the Safety Data Sheets (SDSs) and 6% of the inspections were limited to the SDS provisions of the project.

The inspected companies play different roles under REACH. One company can play more than one role. The inspectors controlled 1327 manufacturers, 994 importers, 121 only representatives and 1 294 downstream users.

Inspectors have reported production or import of phase-in substances as such or in mixtures in quantities of 1 tonne or more per year respectively in 1 446 (substances) and 696 (mixtures) companies. 330 companies were identified to be a first time manufacturer or importer and therefore able to benefit from a late pre-registration under Article 28(6). 151 companies were not in compliance with the registration obligations for certain substances manufactured or imported. In 61 companies it was found that a number of substances were neither pre-registered nor registered and in 90 companies the content of the pre-registration was incorrect for a certain number of checked substances subject to pre-registration requirements.

The inspectors performing the control of the SDS provisions have reported 1 827 companies keeping the required SDSs for all the substances and mixtures. The required SDSs were not available in 116 companies and only partly available in 128 companies. In total the presence of the required SDSs was checked for 7 106 substances and mixtures: in 1 825 cases the required SDSs were not available. 1 478 companies were found in compliance with the requirements of Article 31(5) regarding the language provisions and Article 31(6) concerning the headings format in the SDS. 432 companies were not in compliance with these provisions. In total 7 049 SDSs were checked and of those 1 174 SDSs were not in compliance with language and/or format provisions.

Non-compliance with the REACH obligations was observed in 530 (22%) of the inspected companies. The non-compliance cases concern infringements to the registration provisions (63), SDS provisions (416) and other defects (126). The prescribed measures undertaken as a result of non-compliance were: blame and shame (5), letter of appeal (132), administrative order (211), fines (18), criminal complaint (6) and others (229). In order to achieve compliance after follow-up actions undertaken by inspectors, the companies initiated some of the following measures during the time of the project: subsequent registration assured (29), subsequent registration carried out (2) and other measures (312). No further measures were taken in 202 cases.

## 2. Coordination of the project

The project was guided by a Working Group of the Forum, which delivered a project manual with guidance and recommendations for inspectors and a questionnaire or checklist with inspection items. For each inspection a questionnaire was completed by the inspector. The Working Group was also responsible for the report of the results of the project.

National coordinators were appointed in each participating country. They were trained in Helsinki. The national coordinators were among others responsible for the training of the inspectors in their countries.

## 3. Participation and number of inspections

In table 1 the 26<sup>1</sup> participating countries and the number of inspections carried out are presented.

**Table 1:** Overview of the number of received questionnaires (during first and follow up project phase of REACH-EN-FORCE-1 : from may 2009 to april 2011)

Country	Questionnaires completed
Austria	20
Belgium	71
Bulgaria	137
Cyprus	39
Denmark	13
Estonia	86
Finland	14
France	35
Germany	407
Greece	95
Hungary	123
Iceland	12
Ireland	47
Italy	19
Latvia	20
Malta	7
Netherlands	85
Norway	20
Poland	557
Portugal	4
Romania	24
Slovakia	87
Slovenia	5
Spain	297
Sweden	40
United Kingdom	116
<b>Total</b>	<b>2 380</b>

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<sup>1</sup> In most countries additional inspections were performed but not included in the report, in particular: Austria (9), Cyprus (4), France (438), Germany (11), Spain (18). In general, in some countries, more inspections on similar subjects were performed outside the scope of this project.

The majority of the inspections (2 220)<sup>2</sup> covered the full scope of the project and 152 inspections were focused just on checking SDSs (about 6%).

#### 4. Type of companies inspected

The types of company, which were inspected, are represented by the NACE<sup>3</sup> code. There is a wide range of codes reported. In table 2 there is an overview of the main NACE indications.

**Table 2 :** Overview of companies represented by NACE codes (during first and follow up project phase of REACH-EN-FORCE-1 : from may 2009 to april 2011)

<b>NACE indication</b>	<b>Number of companies</b>
<b>Manufacturing (C)</b>	<b>1 513</b>
<i>Food products (C10)</i>	29
<i>Manufacture of beverages (C11)</i>	75
<i>Manufacture of coke and refined petroleum products (C19)</i>	43
<i>Manufacture of chemicals and chemical products (C20)</i>	796
<i>Manufacture of basic pharmaceutical products and preparations (C21)</i>	51
<i>Manufacture of rubber and plastic products (C22)</i>	41
<i>Manufacture of other non-metallic mineral products (C23)</i>	151
<i>Manufacture of basic metals (C24)</i>	112
<i>Manufacture of fabricated metal products, except machinery and equipment (C25)</i>	51
<i>Manufacture of computer, electronic and optical products (C26)</i>	23
<i>Other manufacturing (C32)</i>	141
<b>Wholesale and (retail) trade (G)</b>	<b>467</b>
<i>Agents involved in the sale of fuels, ores, metals and industrial chemicals (G46.1.2)</i>	35
<i>Wholesale of computers, computer peripheral equipment and software (G46.5.1)</i>	28
<i>Wholesale of chemical products (G46.7.5)</i>	242
<i>Wholesale others</i>	162
<b>Other activities</b>	<b>198</b>
<b>Not specified</b>	<b>202</b>
<b>Total</b>	<b>2 380</b>

In 2 347 of the completed questionnaires the role of the visited company was reported. The results (multiple responses possible) are given in table 3.

<sup>2</sup> At each result the number of answers or percentage of answers is added to give an indication of the value of the result. Not all questions in each questionnaire were answered.

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

**Table 3 :** Role of the company under REACH (during first and follow up project phase of REACH-EN-FORCE-1 : from may 2009 to april 2011)

Role of the company under REACH	Number of companies
Manufacturer	1 327
Importer	944
Only representative	121
Downstream user	1 294

## 5. Registration obligations

Inspectors have identified production or import of phase-in substances as such or in mixtures in quantities of 1 tonne or more per year respectively in 1 446 and 696 companies (multiple responses possible) inspected.

There is a wide range of number of manufactured or imported phase-in substances as such or in preparations per company reported.

In 847 cases exemptions from the obligation to register were reported. The kind of exemptions is given in table 4 (multiple responses possible). In 1 138 cases no exemptions were reported.

**Table 4 :** Overview of reported exemptions from the obligation to register (during first and follow up project phase of REACH-EN-FORCE-1 : from may 2009 to april 2011)

Exemptions for the obligation to register	Number
Substances less than 1 tonne per year	350
Substances listed in Annex V	231
Polymers	230
Waste	154
Substances listed in Annex IV	121
Special use <sup>4</sup>	114
Non-isolated intermediate products	76
Notified substances (regarded as registered)	76
Substances in transit	15
Due to national regulations in the interest of national defence	4
Radioactive substances	3

<sup>4</sup> "Special use" is understood to mean the exemptions mentioned in the Articles 2 (3,5 6,7), 9 and 15 of the REACH Regulation.



For the transport	2
Not applicable	143

The number of pre-registrations sent to ECHA as given by the companies is 140 069. In this figure there is a wide dispersion of the range in the number of pre-registration per company, as shown in table 5.

**Table 5 :** Range in number of pre-registrations as reported by the companies (during first and follow up project phase of REACH-EN-FORCE-1 : from may 2009 to april 2011)

Range in number of pre-registrations	Number of companies
0	288
1-10	1112
11-100	558
101-1000	177
>1000	23
Not reported	222
<b>Total</b>	<b>2380</b>

124 (6%) of in total 2 059<sup>5</sup> visited companies are only representatives in relation to imported substances. The number of pre-registrations submitted by these only representatives is 19 211.

In 61 cases no pre-registration or registration had been submitted and in 90 cases the content of the pre-registration was incorrect (from a total of 2 176 answers). So, the total number of non-compliances regarding with the registration obligation was 151 (about 7%).

In 330 inspections (2 056 answers) the inspected company is or was a first time manufacturer or importer able to benefit from a late pre-registration under Article 28(6) of the REACH Regulation.

## 6. SDS obligations

In total 1 827 visited companies (out of 2 300 responses) had the required SDS's. For 244 companies (about 11%) the required SDS was not available or only partly available. In the case of 229 inspections no information on this subject was required or this item was indicated as not applicable. In total 7 106 products were checked and of these 1 825 SDS's were not available (about 26%).

<sup>5</sup> The assessment is based on the number of answers to specific questions reported by the inspectors participating in the project. The number of answers to different questions is not necessarily the same as the total number of companies inspected because some questions have been skipped in some cases.

Structures or instruments (e.g. software) which make the preparation of SDSs in accordance with the REACH Regulation possible, were available in 1 459 (66%) companies (2 224 responses). In 468 companies such structures or instruments were not or only partially available.

The inspectors reported that 1 478 companies (64% of 2 293 responses) fulfilled the formal requirements of Articles 31(5) (SDS shall be supplied in an official language of the member state) and 31(6) (SDS shall be dated and contain 16 headings). For 432 (19%) of the companies the prescribed formal requirements for SDSs were not correct. In total 7 049 SDSs were checked and 1 174 (17%) were not correct for these issues.

## 7. Infringements

For the whole project, cases of non-compliance were found in 22 % of the companies covered in the reported inspections. An overview of the measures taken due to non-compliance (multiple responses possible) is given in table 6. By 'others' is, for instance, meant an written advice, a letter with additional information or an announcement that a company gets some time to make sufficient corrections.

**Table 6 :** Overview of the measures due to non-compliance (during first and follow up project phase of REACH-EN-FORCE-1 : from may 2009 to april 2011)

Measure	Number
Administrative order	211
Letter of appeal	132
Fine	18
Public information ("Blame and Shame")	5
Criminal complaint	6
Others	229

When inspectors undertook follow-up actions after inspection (within the timescale of the project), the measures to achieve compliance taken by the company during the time of the project are given in table 7 (multiple responses possible). In the case of 'others', most companies are involved in harmonizing their SDSs with the REACH Regulation.

**Table 7 :** Follow-up actions taken by the company (during first and follow up project phase of REACH-EN-FORCE-1 : from may 2009 to april 2011)

Measure	Number
No measure taken	202
Subsequent registration assured	29
Subsequent registration carried out	2
Others (mostly improvement of SDSs)	312

## Conclusions and Recommendations

The first coordinated Forum enforcement project on registration, pre-registration and provision of SDSs was successful. Interesting conclusions and recommendations can be drawn from it.

It has been a valid kick-off of one of the main activities of the Forum.

### Keys of success of this projet

- A significant number of inspections have been done all over Europe : almost 2 400 companies have been inspected in 26 countries. There has been a wide diversity in the type of companies inspected, which were manufacturers, importers, downstream users and only representatives (from manufacturing in various fields to wholesale and trade). It is interesting to note that the selection of the inspected companies in the Member States has been done according to different criteria and selection methods. This subsidiarity made it possible to adapt to different national realities and contexts.
- On this basis, it has been possible to do a consistent reporting (with well-structured questionnaires and a common reporting process), making it possible to carry out a certain analysis at EU level with results valid in a significant number of cases.
- Coordination of the project through the Forum, good cooperation between the national enforcement authorities and support from ECHA has been an important part of the project.

## Results

- Over the whole project, cases of non-compliance with some of the relevant duties of the REACH regulation were found in 22 % of the companies inspected.
- Non-compliances regarding registration obligations were found in about 7% of the companies inspected: no pre-registration or registration had been submitted or the content of the pre-registration was incorrect.
- In 11% of the companies inspected regarding SDS obligations, the required SDS was not available or only partly available. 17% of the SDS did not comply with the obligation for the correct language or concerning the necessary headings of the SDS<sup>6</sup>.
- Only Representatives were not always in compliance with Article 8 of REACH.
- In some countries, more inspections on issues covered by REACH-EN-FORCE 1 were done, but not reported in the framework of this project.

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<sup>6</sup> The results on the required SDSs must be seen with caution when compared to earlier results, as the scope of the SDS checks in the project was quite limited : previous surveys of the content of SDSs made by the Inspectorates under CLEEN (ECLIPS) projects were much more advanced and detailed. Since under the Forum project only basic and formal requirements of the SDSs were checked, the results of this project cannot be considered as an improvement of compliance for the SDSs in relation to the CLEEN project

## Conclusions

- The percentage of non-compliances concerning very basic, though essential, requirements of the REACH Regulation is considered high.
- The quality of the SDS needs to be improved, as well as the compliance with registration obligations.
- These issues will certainly be key areas for inspectors in the following years.
- The Forum, proposing harmonised approaches, coordinating projects and encouraging cooperation between Member States, is a good and efficient incitement for surveillance and enforcement.
- There are signals that it is difficult, especially for SMEs, to comply with the registration obligations, mainly due to the lack of resources and information.
- The knowledge about REACH in companies varies from “quite good” to “never heard of it before”.
- It was noted that some companies do not have the intention to proceed towards submitting a registration for all the substances they have pre-registered.

## Recommendations

### **To companies :**

- Higher than expected non-compliance was found. As learnt during this project by using the pre-registration information, the data quality of information given by companies is not always sufficient.
- Companies should prepare to react to improve their registration dossiers and their SDSs.
- Companies should not wait for controls but anticipate.
- Inspectors within each Member State may always inspect the fulfillment of REACH and CLP obligations outside coordinated enforcement projects of the Forum.
- Stakeholder organisations on national and international level should intensify their support and information on the REACH obligations, especially towards SMEs and Only Representatives. Among others, the organisation of webinars and the distribution of leaflets can be useful.
- Communication within companies could be improved (for instance between parent company and subsidiary enterprises or between legal department, purchasing department, HSE department), as well as communication within the supply chain.

### **To enforcement authorities and to the inspectors :**

- Enforcement of REACH and CLP is a key issue, contributing to reach the full objectives of these regulations. It will need to be addressed through an increasing number of controls. Inspectors should be prepared for this.
- Good cooperation and information exchange is needed between the national enforcement authorities, Member States competent authorities (when involved in enforcement issues) and ECHA, in particular to check the compliance of the registration of substances.

- The cooperation between the national enforcement authorities enforcing REACH and CLP should be further strengthened in order to facilitate the enforcement of companies active in several Member States.
- The implementation of RIPE should help solve the difficulties resulting from the lack of access to REACH-IT for inspectors.

**To ECHA and to the Member States' competent authorities :**

- Inspectors' access to REACH data is essential (including information about substances identification, impurities, classification & labelling, also from companies located in other Member States). Since the data quality of information given by companies is not always sufficient, searching data bases might then be difficult and this is one reason why inspectors need also information about the results of ECHA verification and compliance checks.

**To the Forum :**

- Continuation of coordinated Forum enforcement projects is recommended. The execution of such projects contributes to the harmonisation of REACH enforcement strategies between the Member States. It also increases the efficiency of enforcement as Member States can share their experiences and the results can be compared. Besides, it helps to put companies throughout Europe on an equal footing regarding enforcement.
- The methodology of this first project was well balanced and efficient (among others : dedicated Working Group of the Forum ; the setting up of a project manual with guidance and recommendations for inspectors and a questionnaire or checklist with inspection items ; a structured reporting tool, which ergonomics can still be improved ; a system of national coordinators appointed and trained).
- Coordinated enforcement projects done in the framework of the Forum should be focused on some specific topics and should not try to cover all REACH and CLP obligations. This makes it possible to focus the attention of all inspectors on similar points, to facilitate the comparison and assessment of results and then to draw valid conclusions at EU level.
- Besides, when doing their "regular" work outside the scope of the coordinated enforcement projects, inspectors also look into other obligations of REACH regulation and for that they have flexibility to choose the relevant topics according to their national priorities.
- It is useful to have a common grid to report the follow-up actions after inspection. This allows comparison of enforcement action between participating countries. This grid could be more refined and it would be useful to seek for further suggestions that could help harmonization of enforcement. However, it will not be possible to put the follow-up actions on a uniform common basis. Indeed, each participating country has its own legal framework and judicial system.
- On the basis of lessons learnt from REACH-EN-FORCE 1, and with the experience that will be gathered through other coordinated enforcement projects, it would be useful to set up a horizontal methodology for a harmonised elaboration, management, reporting and evaluation of Forum coordinated enforcement projects.

- It has been needed to have two operational phases in the project, allowing sufficient time for the inspections to be done (not only for the inspectors to plan and do the inspections, but also when facing a company that needs some time to provide information, to have sufficient time to complete the inspection). The initial period (8 months) has needed to be prolonged. A unique period of one year for performing the inspections and initiating the legal actions under next projects could be considered (reporting and final follow-up of legal actions would fall outside this period of one year) : it would enhance mobilisation of the inspectors (in all the countries, all having different procedures, different rhythms and different deployment strategies), it would allow to put this mobilisation to good use once launched, it would give from the beginning a clear and significant basis for reporting and drawing conclusions. Hence, having one calendar year to carry out the inspections would be a good timeline.
- For the reporting, a unique and standardised IT tool would be very useful. The same tool could be used for all coordinated enforcement projects (avoiding unnecessary trainings as everybody will be familiar with it). It should be userfriendly and simple. It should also be possible for the national coordinators and for the inspectors themselves at local or regional level to have easy and quick access to the raw data they have reported (through an excel file or other similar format). This would help them to answer to other reporting duties (i.e. for national governments or for the Commission).