



## **Results of the Forum coordinated REACH enforcement project on registration, pre-registration and safety data sheets**

**Project Report of the REACH-EN-FORCE-1 project**

*Sections 1, 2 and 3 adopted by the Forum for Exchange of Information on Enforcement in May 2010*

*Section 4 adopted by the Forum for Exchange for Information on Enforcement in August 2010*

### **1. Summary**

#### **1.1. Participation and number of inspections**

In the period May – December 2009 almost 1,600 companies were inspected in 25 Members States of the Economic European Area<sup>1</sup> (EEA) participating in the project. 93% of the inspections were performed to check both the (pre)registration and provisions of the Safety Data Sheets (SDSs) and 7% of the inspections were limited to the SDS provisions of the project.

#### **1.2. Type of companies visited**

The inspected companies play different roles under REACH. One company can play more roles. The inspectors controlled 878 manufacturers, 666 importers, 83 only representatives and 858 downstream users.

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<sup>1</sup> The European Economic Area is an agreement between the European Union and Norway, Iceland and Liechtenstein. It allows these three countries to participate in the EU's single market without joining the EU. This agreement was established on 1 January 1994.

### 1.3. Registration obligations

Inspectors performing the project in its entirety 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 974 and 493 companies. 244 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). 119 companies were not in compliance with the registration obligations for certain substances manufactured or imported. In 38 companies it was found that a number of substances were neither pre-registered nor registered and in 81 companies the content of the pre-registration was incorrect for a certain number of checked substances subject to preregistration requirements.

### 1.4. SDS obligations

The inspectors performing the control of the SDS provisions have reported 1,204 companies keeping the required SDSs for all the substances and preparations. In 84 companies the required SDSs were not available and they were only partly available in 93 companies. In total the presence of the required SDSs was checked for 5,137 substances and preparations and in 1,446 cases the required SDSs were not available. 985 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. 313 companies were not in compliance with these provisions. In total 5,338 SDSs were checked and of those 808 SDSs were not in compliance with language and/or format provisions.

### 1.5. Infringements

Non-compliance with the REACH obligations was observed in 378 (24 %) of the inspected companies. The non-compliance cases concern infringements to the registration provisions (38), SDS provisions (293) and other defects (108). The prescribed measures undertaken as a result of non-compliance were: blame and shame (3), letter of appeal (96), administrative order (169), fines (12), criminal complaint (3) and others (121). 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 (20), subsequent registration carried out (1) and other measures (215). No further measures were taken in 141 cases.

## 2. Introduction

At the end of 2008 the Forum for Exchange of Information on Enforcement of the REACH Regulation EC 1907/2006 decided to start a 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 (pre-)registration and Safety Data Sheets (SDSs). The project was executed in 25 countries in the Economic European Area in the period May – December 2009 and guided by a Working Group, 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.

In the participating countries national coordinators were appointed who were trained in Helsinki in April 2009. The national coordinators were among others responsible for the training of the inspectors in their countries.

In this report the results of the project are presented without conclusions and recommendations. These latter items have been presented during the Forum meeting in May 2010.

## 3. Results of the project

### 3.1. Participation and number of inspections

In table 1 the 25 participating countries and the number of inspections carried out are presented.

**Table 1:** Overview of the number of received questionnaires

Country	Questionnaires completed	Country	Questionnaires completed
Austria	20	Latvia	14
Belgium	59	Malta	3
Bulgaria	137	The Netherlands	34
Cyprus	29	Norway	15
Denmark	13	Poland	268
Estonia	75	Portugal	2
Finland	14	Romania	19
France	14	Slovakia	59
Germany	257	Slovenia	5
Greece	28	Spain	220
Hungary	123	Sweden	40
Iceland	11	United Kingdom	99
Ireland	31	<b>Total</b>	<b>1589</b>

The majority of the inspections (1,474)<sup>2</sup> covered the full scope of the project and 107 inspections were focused just on checking SDSs (about 7%).

### 3.2. Type of companies visited

The type of company, which was inspected, is 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

<b>NACE indication</b>	<b>Number of companies</b>	
<b>Manufacturing (C)</b>		<b>993</b>
Food products (C10)	23	
Distilling, rectifying and blending of spirits (C11.0.1)	40	
Manufacture of refined petroleum products (C19.2)	25	
Manufacture of chemicals and chemical products (C20)	556	
Manufacture of basic pharmaceutical products and preparations (C21)	32	
Manufacture of other non-metallic mineral products (C23)	102	
Manufacture of basic metals (C24)	68	
Manufacture of fabricated metal products, except machinery and equipment (C25)	29	
Manufacture of computer, electronic and optical products (C26)	21	
Other manufacturing (C32)	97	
<b>Wholesale and (retail) trade (G)</b>		<b>310</b>
Wholesale of computers, computer peripheral equipment and software (G46.5.1)	28	
Wholesale of chemical products (G46.7.5)	149	
Wholesale others	133	
<b>Other activities</b>		<b>108</b>
<b>Not specified</b>		<b>178</b>
<b>Total</b>		<b>1589</b>

In 1,573 of the completed questionnaires the role of the visited company was reported. The results (multiple responses possible) are given in table 3.

**Table 3:** Role of the company under REACH

<b>Role of the company under REACH</b>	<b>Number of companies</b>
Manufacturer	878
Importer	666
Only Representative	83
Downstream User	858

<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.

### 3.3. Registration obligations

Inspectors performing the project in its entirety 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 974 and 493 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 609 cases exemptions from the obligation to register were reported. The kind of exemptions is given in table 4 (multiple responses possible). In 816 cases no exemptions were reported.

**Table 4:** Overview of reported exemptions from the obligation to register

Exemptions for the obligation to register	Number
Substances less than 1 tonne per year	231
Waste	122
Non-isolated intermediate products	64
Radioactive substances	3
Polymers	160
Substances in transit	13
Due to national regulations in the interest of national defence	2
For the transport	2
Notified substances (substances regarded as registered substances)	56
Special use <sup>4</sup>	84
Substances listed in Annex IV	88
Substances listed in Annex V	166
Not applicable	94

The number of pre-registrations sent to ECHA as given by the companies is 105,054<sup>5</sup>. In this figure there is a wide dispersion of the range of the number of pre-registration per company as given in table 5. In this table the ranges in the numbers of pre-registrations by the different inspected companies are given.

**Table 5:** Range in number of pre-registrations as reported by the companies

Range in number of pre-registrations	Number of companies
0	190
1-10	740
11-100	379
101-1000	131
>1000	19
Not reported	130

<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.

<sup>5</sup> The number of pre-registrations submitted by the inspected companies at ECHA is 111,116. The cause of this difference comparing to the number as given by the companies is unknown.

83 (6%) of in total 1,403<sup>6</sup> visited companies are only representatives in relation to imported substances. The number of pre-registrations submitted by these only representatives is 15,645.

In 38 cases no pre-registration or registration had been submitted and in 81 cases the content of the pre-registration was incorrect (from a total of 1,449 answers). So, the total number of non-compliances regarding with the registration obligation was 119 (about 8%).

In 244 inspections (1,459 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.

### **3.4. SDS obligations**

In total 1,204 visited companies (out of 1,543 responses) had the required SDS's. For 177 companies (about 11%) the required SDS was not available or only partly available. In the case of 162 inspections no information on this subject was required or this item was indicated as not applicable. In total 5,137 products were checked and of these 1,446 SDS's were not available.

Structures or instruments (e.g. software) which make the preparation of SDSs in accordance with the REACH Regulation possible, were available in 1,008 (65%) companies. In 333 companies such structures or instruments were not or only partially available.

The inspectors reported that 985 companies (from 1,546 responses) fulfilled the 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 313 (20%) of the companies the prescribed requirements for SDSs were not correct. In total 5,338 SDSs were checked and 808 SDSs were not correct for these issues.

### **3.5. Infringements**

For the whole project, cases of non-compliance were found in 24% of the companies covered in the sample. 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.

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<sup>6</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.

**Table 6:** Overview of the measures due to non-compliance

Measure	Number
Blame and shame	3
Letter of appeal	96
Administrative order	169
Fine	12
Criminal complaint	3
Others	121

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

Measure	Number
No measure taken	141
Subsequent registration assured	20
Subsequent registration carried out	1
Others	215

## 4. Conclusions and Recommendations of the project

### Results and conclusions

The first coordinated Forum enforcement project on (pre-)registration of phase-in substances and provisions of SDSs, was successful due to good cooperation between the national enforcement authorities and support from ECHA. This project has provided an important contribution to a harmonized REACH enforcement (between the Member States) in the EU.

### Factual background

- 25 Member States of the EEA participated
- The participating inspectors inspected almost 1,600 companies.
- The inspected companies in the Member States, which were manufacturers, importers, downstream users and only representatives, were selected on the basis of different criteria and selection methods.

## Results

- Non compliance regarding the (pre-)registration obligations was found in 8% of the inspected companies. Eleven % of the required SDSs was non compliant with obligation to have a SDS and 20% did not comply with the obligation for the right language and the necessary headings in the SDS.
- Only representatives were not always in compliance with Article 8 of REACH.

## Conclusions

- The results on the required SDSs must be seen with caution, 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 the REACH-EN-Force-1 project checked only the basic and formal requirements of the SDSs, its results cannot be considered as an improvement of compliance for the SDSs.
- Companies don't have the intention to proceed in a registration for all the pre-registered substances. There are also signals that it is unlikely that especially SMEs will be able to comply with the registration obligations, mainly due to the lack of material resources and information.

## Recommendations

- Continuation of coordinated Forum enforcement projects is recommended. The execution of such projects contributes to the harmonization of REACH enforcement as well as further harmonization of the national enforcement and sanction strategies in REACH enforcement between the Member States.
- The cooperation between the NEAs enforcing REACH and CLP should be further strengthen in order to facilitate the enforcement of companies active in many MS. Good cooperation and information exchange will be needed between the national enforcement authorities (NEAs), Member States competent authorities (MSCAs) and ECHA to check the compliance of the registration of substances.
- Stakeholder organisations on national and international level should intensify their support and information on the REACH obligations towards (especially) SMEs and ORs.