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FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT

**Coordinated Forum REACH enforcement project on
registration, pre-registration and safety data sheets
(REF-1 project)**

**Facts Report
Prolongation phase
May 2010 – April 2011**

Adopted by Forum on 21 November 2011

1. Summary

In the meeting of May 2010 (Forum-7), the Forum for Exchange of Information on Enforcement of the REACH Regulation EC 1907/2006 decided to prolong the first coordinated Forum enforcement project. During the period from May 2009 to December 2009, a first project was carried out with 25 Member States participating with almost 1,600 companies being inspected. During the period from May 2010 to April 2011, almost 800 companies were inspected in 19 countries of the Economic European Area¹ (EEA) participating in the project. 94% 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 also play different roles. The inspectors inspected 449 manufacturers, 278 importers, 38 only representatives and 436 downstream users.

Inspectors who took part in the project for its entirety have reported the production or import of phase-in substances as such or in mixtures in quantities of one tonne or more per year respectively in 472 (substances) and 203 (mixtures) companies. 86 companies were identified as being a first time manufacturer or importer and therefore able to benefit from a late pre-registration under Article 28(6). 32 companies were not in compliance with the registration obligations for certain substances manufactured or imported. In 23 companies, it was found that a number of substances were neither pre-registered nor registered and in nine companies the content of the pre-registration was incorrect for a certain number of checked substances subject to pre-registration requirements.

The inspectors who performed the control of the SDS provisions reported 623 companies keeping the required SDSs for all the substances and mixtures. In 32 companies the required SDSs were not available and they were only partly available in 35 companies (in 67 companies, no information was required). In total, the presence of the required SDSs was checked for 1,969 substances and mixtures, in 379 cases the required SDSs were unavailable. 493 companies were found to be in compliance with the formal requirements of Article 31(5) regarding the language provisions and Article 31(6) concerning the headings format in the SDS. 119 companies were not in compliance with these provisions. In total, 1,711 SDSs were checked and of those, 366 SDSs were not in compliance with language and/or format provisions.

Altogether non-compliance with the REACH obligations was observed in 152 (20%) of the inspected companies. The non-compliance cases concern infringements to the registration provisions (25), SDS provisions (123) and other defects (18). The prescribed measures undertaken as a result of non-compliance were: blame and shame (2), letters of appeal (36), administrative orders (42), fines (6), criminal complaints (3) and others (108) (multiple responses possible). 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 (9), subsequent registration carried out (1) and other measures (97). No further measures were taken in 61 cases.

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

2. Introduction

At the beginning of 2010, the Forum for Exchange of Information on Enforcement of the REACH Regulation EC 1907/2006 decided to prolong the first coordinated Forum enforcement project. During the period from May to December 2009 a first project was performed with 25 Member States participating and almost 1600 companies being inspected. 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 follow-up project was executed in 19 countries in the Economic European Area during the period from May 2010 to April 2011 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 at the start of the project in April 2009. The national coordinators were, among other things, 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 will be made public after consultation of the Forum in October 2011.

3. Results of the project

3.1. Participation and number of inspections

In Table 1, the 19² participating countries and the number of inspections carried out are presented.

Country	Questionnaires completed	Country	Questionnaires completed
Belgium	12	Malta	4
Cyprus	10	The Netherlands	51
Estonia	11	Norway	5
France	21	Poland	289
Germany	150	Portugal	2
Greece	67	Romania	5
Iceland	1	Slovakia	28
Ireland	16	Spain	77
Italy	19	United Kingdom	17
Latvia	6	Total	791

Table 1: Overview of the number of received questionnaires

The majority of the inspections (746)³ covered the full scope of the project and 45 inspections were focused on only checking SDSs (about 6%).

² Additional inspections were performed in Austria (9), Cyprus (4), Germany (11) and Spain (18) but not included in the report. In general, in some countries more inspections on similar subjects were performed outside the scope of this project, among others in France (176).

³ 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.

3.2. Types of companies visited

The type of company which was inspected, is represented by the NACE⁴ code. There is a wide range of codes reported. In Table 2, there is an overview of the main NACE indications.

NACE indication	Number of companies	
Manufacturing (C)		520
Manufacture of beverages (C11)	35	
Manufacture of coke and refined petroleum products (C19)	18	
Manufacture of chemicals and chemical products (C20)	240	
Manufacture of basic pharmaceutical products and preparations (C21)	19	
Manufacture of rubber and plastic products (C22)	22	
Manufacture of other non-metallic mineral products (C23)	49	
Manufacture of basic metals (C24)	44	
Manufacture of fabricated metal products, except machinery and equipment (C25)	22	
Other manufacturing	71	
Wholesale and (retail) trade (G)		157
Agents involved in the sale of fuels, ores, metals and industrial chemicals (G46.1.2)	16	
Wholesale of chemical products (G46.7.5)	93	
Wholesale others	48	
Other activities		90
Not specified		24
Total		791

Table 2: Overview of companies represented by NACE codes

In 774 of the completed questionnaires, the role of the visited company was reported. The results (multiple responses possible) are given in Table 3.

Role of the company under REACH	Number of companies
Manufacturer	449
Importer	278
Only Representative	38
Downstream User	436

Table 3: Role of the company under REACH

⁴ 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 who took part in the project for its entirety have identified the production or import of phase-in substances as such or in mixtures in quantities of one tonne or more per year respectively in 472 (substances) and 203 companies (mixtures) (multiple responses possible) inspected.

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

In 238 cases, exemptions from the obligation to register were reported. The kind of exemptions are given in Table 4 (multiple responses possible). In 322 cases, no exemptions were reported.

Exemptions for the obligation to register	Number
Substances less than one tonne per year	119
Waste	32
Non-isolated intermediate products	12
Polymers	70
Substances in transit	2
Due to national regulations in the interest of national defence	2
Notified substances (substances regarded as registered substances)	20
Special use ⁵	30
Substances listed in Annex IV	33
Substances listed in Annex V	65
Not applicable	49

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

The number of pre-registrations sent to ECHA, as given by the companies, is 35,015⁶. In this figure, there is a wide dispersion in the range of the number of pre-registrations 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.

Range in number of pre-registrations	Number of companies
0	98
1-10	372
11-100	179
101-1000	46
>1000	4
Not reported	92

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

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

⁶ The number of pre-registrations submitted by the inspected companies at ECHA is 19,406. The cause of this difference comparing to the number as given by the companies is unknown.

41 (6% of in total 656 responses) of the visited companies are Only Representatives (ORs) in relation to imported substances. The number of pre-registrations submitted by these ORs is 3,566.

In 23 cases, no pre-registration or registration had been submitted, and in nine cases the content of the pre-registration was incorrect (from a total of 727 answers). Therefore, the total number of non-compliances regarding the registration obligation was 32 (about 4%).

In 86 inspections (from a total of 597 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, 623 of the visited companies (from a total of 757 responses) had the required SDSs. For 67 companies (about 9%) the required SDS was not available or only partly available. In the case of 67 inspections, no information on this subject was required or this item was indicated as not applicable. In total, 1,969 products were checked and of these, 379 SDSs were not correct.

Structures or instruments (e.g. software) which make the preparation of SDSs in accordance with the REACH Regulation possible, were available in 451 (66%) companies (683 responses). In 135 companies such structures or instruments were not or only partially available.

The inspectors reported that 493 companies (from a total of 747 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 119 (16%) of the companies, the prescribed requirements for SDSs were not correct. In total 1,711 SDSs were checked and 366 SDSs were incorrect due to these issues.

3.5. Infringements

For the whole project, cases of non-compliance were found in 20% 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. The label 'others' is used, for instance, to mean a written advice, a letter with additional information or an announcement that a company gets some time to make sufficient corrections.

Measure	Number
Blame and shame	2
Letter of appeal	36
Administrative order	42
Fine	6
Criminal compliant	3
Others	108

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

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 harmonising their SDSs with the REACH Regulation.

Measure	Number
No measure taken	61
Subsequent registration assured	9
Subsequent registration carried out	1
Others	97

Table 7: Follow-up actions taken by the company

3.6. Comparison with the results of the project during the period from May to December 2009

The results in the prolongation of the project are comparable with the results of the same project during 2009. The total number of inspections carried out in the prolongation is about half the amount of inspections in the first project. The percentage of non-compliance in the prolongation is slightly less (20%) than in the project in 2009 (24%).