

**Bund/Länder-Arbeitsgemeinschaft
Chemikaliensicherheit**

**Federal/Federal State Working Committee
Chemical Safety**

Joint report of the Federal States

**Results of the first REACH
enforcement project on the
national level
(REACH-EN-FORCE-1)
in Germany**

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Created by: BLAC experts under the direction of the MAGS NRW (Ministry of Labour, Health, and Social Affairs of North Rhine-Westphalia)

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Contents

1. Introduction.....	4
2. Objectives and procedure.....	5
3. Results of enforcement in Germany	6
3.1 Comparison of findings with the pre-registration data	7
3.2 Non-phase-in substances and notified substances	8
3.3 Substances in articles	8
3.4 Safety data sheets.....	8
3.5 Qualitative results	9
3.6 Measures by the authorities.....	10
3.7 Results as seen by the authorities.....	11
4. Conclusion	13
5. Annex.....	14
Statistical results	14
5.1 Federal State participation	14
5.2 Overview of sectors.....	15
5.3 Status as defined under the REACH Regulation.....	16
5.4 Exemptions from the obligation to register	16

1. Introduction

The EU chemicals regulation REACH (EC 1907/2006) presents a set of standardised requirements that companies and authorities throughout Europe must observe when handling chemicals. The core elements of REACH are registration, evaluation, and authorisation procedures for chemicals. REACH is also based on the precautionary principle, which stipulates that companies are responsible for the safe handling of chemicals. This gives rise to new tasks and obligations for both companies and authorities. Also new for the authorities is examining compliance to the REACH requirements, although many of these enforcement tasks are in principle the same as the chemical legislation applying to date. Some do however require new channels of communication like access to the registration data at the European Chemicals Agency ECHA, and all add considerably to their total number.¹

For the purpose of standardising the protection of the environment and human health, especially of workers, and of preventing distortion of competition, efforts must be directed towards a standard procedure that the enforcement authorities can apply throughout the nation and Europe. In order to realise these objectives the BLAC took the initiative early and passed a concept for enforcing compliance to the REACH provisions.

Developed on the national level, this enforcement concept could be introduced successfully to the European level and provided the basis of the enforcement project REACH-EN-FORCE-1² passed by the Forum³ for the EU level. It deals with the examination of the registration requirements following the pre-registration phase, and selected aspects of the safety data sheets.

At the 25th BLAC session, the Federal States were requested to participate in the European enforcement project according to their means. NW (North Rhine-Westphalia) accepted the national coordination.

The following reports on the objectives, procedures, and findings of REACH-EN-FORCE-1 in Germany.

¹ Bundesrat publication 8/08

² http://echa.europa.eu/doc/press/pr_08_56_Forum_project_20081208.pdf
http://echa.europa.eu/doc/press/pr_09_05_enforcement_project_Forum%2020090430.pdf
http://echa.europa.eu/doc/press/newsletter/echa_newsletter_2009_12_18.pdf

³ Under Article 75 of the REACH Regulations, forum for the exchange of information and for the coordination of the network operated by the authorities of the Member States responsible for implementing the REACH Regulations.

2. Objectives and procedure

The first pan-European REACH enforcement project serves to implement Article 5 (“No data, no market”) of the REACH Regulation and focuses on the inspection of safety data sheets, manufacturers, and importers for their compliance to the pre-registration and registration of phase-in substances as such and in preparations (mixtures). This inspection may also extend to non-phase-in substances, substances in articles, and the communication within the supply chain.

The objectives of the project are in particular:

- to improve the knowledge companies have of the REACH Regulation and its observance overall in the form of:
 - enforcement and advice and
 - exchange of knowledge and experience, and therefore
- to enhance the protection of the environment and human health as defined by the REACH Regulation and to prevent distortion of competition,
- to set up institutional capacities for enforcement authorities and to train inspectors, and
- to promote the interinstitutional cooperation of national authorities on the enforcement of chemical legislation.

The inspection takes the form of tours through the production facilities. Compliance to provisions of the REACH Regulation is examined by spot checks, i.e. the objective is not to inspect all of the substances at a company, but only a number of examples, including their safety data sheets.

No decision was made concerning the choice of industrial sectors for inspections in this project.

As a means to support the enforcement authorities, a project manual was drawn up and a standardised questionnaire provided in electronic form for documenting the findings. This questionnaire contains in addition references to legal sources and further explanations and is divided into two sections: an obligatory section focusing on phase-in substances and a voluntary section for non-phase-in substances and articles.

The operative phase of the project was scheduled for the period from April to December 2009, and was extended to the end of 2010 following a resolution passed by the Forum at the end of 2009.

There are 25 Member States and Norway participating on the European level.

3. Results of enforcement in Germany

The results of enforcement in Germany were forwarded in early 2010 to the ECHA, which submitted the overall findings to the Forum that spring.

The following depictions of findings and analyses are based on the inspections conducted by the authorities in Germany from February 2009 to February 2010.

A total of 279 production facilities in 10 federal states were inspected as part of the REACH-EN-FORCE-1 project (Table 1). In 2010, a number of Federal States will be continuing the enforcement project or making this the focus of enforcement for the first time.

The majority of inspections were conducted at chemicals manufacturers and traders according to the economic classifications (Table 2). The choice of production facility was also influenced by its size. In some cases, the pre-registration details of companies that operate plants requiring official authorisation under the Federal Immission Control Act BImSchG (chemical products, surface treatment) were compared with that information. There were also inspections of companies when there were indications that they manufacture or import non-phase-in substances.

About 75% of the inspected companies fall under the economic classification of “manufacturer”, and about half of these are “manufacturers” of chemicals, crop protectants, paints, cleaning agents, and fibres. The proportion of trading companies is just under 15% (Table 2).

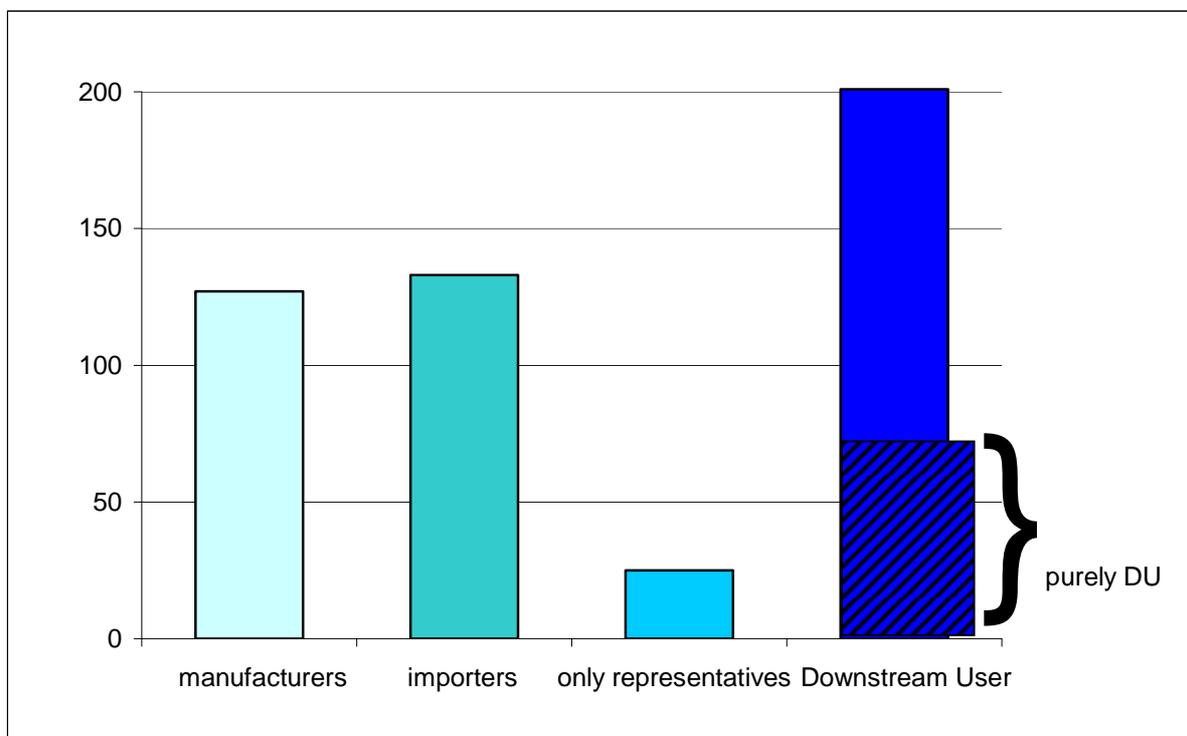


Figure 1: Status of inspected companies as defined in the REACH Regulation: about two thirds of the Downstream Users (DUs) are also manufacturer and importer

When, however, the definition of manufacturer and importer is taken from the REACH Regulation, which defines the status based on the chemical itself, the picture is slightly

different (Figure 1, Table 3): the proportion of manufacturers and importers is about 50% each, and the only representatives about 10%.⁴ About 80% of the inspected companies are Downstream Users according to the REACH definition, of which about two thirds are both manufacturer or importer and Downstream User.

The inspection of production facilities at 201 companies also enquired into the availability of a management system. Only 26 production facilities do not operate or operate only to a certain extent an in-house quality assurance system. The majority of the inspected companies operate environmental or quality management systems. Of the production facilities, 131 operate a quality assurance or quality management system certificated under ISO 9001. An environmental management system under ISO 14000 was implemented at 28 production facilities, and 4 production facilities are EMAS certificated. Twelve further companies operate other quality assurance systems.

3.1 Comparison of findings with the pre-registration data

Of the 279 inspected companies, 152 produce or import phase-in substances as such, and 94 produce or import these substances in preparations.⁵ The inspected companies manufacture or import a total of about 11,000 substances as such or in preparations in quantities of 1 tonne or more per year, of which over 2000 of these substances are manufactured or imported by a single company.

The ECHA processed a total of 2.75 million pre-registrations, of which almost 700,000 came from about 8000 companies in Germany.

In purely statistical terms, an inspection was conducted at about 3% of all companies in Germany that had pre-registered their chemicals.

According to a semiquantitative estimate, companies tended to pre-register considerably more chemicals than they manufacture or import. Some Downstream Users pre-registered substances, although they are neither manufacturer nor importer.

This trend towards “precautionary” pre-registration is in line with the recommendations issued by authorities and associations, and will lead to considerably fewer actual registrations than can be expected from the number of pre-registrations.

About 23% (64) of the inspected companies may claim exemptions from the obligation to register (Table 4) by referring to the tonnage threshold. These are followed by exemptions for polymers at 22% (61) and waste at about 16% (44).⁶

⁴ Multiple entries possible because companies can be e.g. both manufacturer and importer under the REACH Regulation.

⁵ Multiple entries possible

⁶ Multiple entries possible

3.2 Non-phase-in substances and notified substances

Of the inspected companies, 18 manufacture or import 292 non-phase-in substances as such or in preparations in quantities of 1 tonne or more per year.

Of the inspected companies, 15 submitted a total of 235 notifications of new substances as defined by Directive 67/548/EEC, of which 152 were submitted by the one company. Moreover, a registration dossier was submitted to the ECHA for a total of 8 non-phase-in substances in quantities of 1 tonne or more per year.

3.3 Substances in articles

A total of 27 (phase-in and non-phase-in) substances in articles released under reasonably foreseeable conditions of use are manufactured or imported by the inspected companies in quantities of 1 tonne or more per year.

One of the inspected companies manufactures or imports 3 substances of very high concern, e.g. carcinogens, in concentrations of more than 0.1% of the articles for a total quantity of 1 tonne or more per year. Entering these substances of very high concern on the candidate list for inclusion in the authorisation procedure immediately gives rise to the obligation to provide commercial buyers, on request or not, and consumers within 45 days of their request, with adequate information on how to use the article safely, specifying at least the name of the substance. Compliance to this obligation was, however, not examined during this first REACH enforcement project.

3.4 Safety data sheets

Safety data sheets are a key instrument within the value adding chain for communicating information on the risks involved in handling hazardous chemicals. They therefore provide a basis for the safe handling of chemicals. It is therefore highly important that the safety data sheets contain all of the relevant information and that this information is correct.

Employees have a legal right to consult safety data sheets for the chemicals they use or are exposed to during their work.

In view of the great significance of safety data sheets and the experience gained to date from the enforcement,⁷ showing that a very high percentage of safety data sheets are deficient in quality (incomplete, incorrect, inconsistent), the enforcement focused particularly on this instrument for communicating risks. However, because this was the first enforcement project for the REACH Regulation, there was no detailed inspection of the contents, but a formal examination of the requirements: that the safety data sheet must be provided in German, that it bears the date it was created and its revision status, and that it contains the stipulated

⁷ Project (2004) of the Chemical Legislation European Enforcement Network (CLEEN) for European Classification and Labelling Inspections of Preparations, including Safety Data Sheets (ECLIPS): 69% of the safety data sheets contain errors.

sections. It was not seen to be a deficiency when sections 2 (possible risks) and 3 (composition and details on constituents) do not comply with the specifications in the REACH Regulation, but still follow the old safety data sheet guideline (invalid since 2007) and have remained unchanged since the REACH Regulation came into force.

Nevertheless, 15 of the 265 companies do not have or have only some of the requisite safety data sheets. At 14 other companies a safety data sheet was not required.

Of the 745 safety data sheets inspected in total, 10% (75) were unavailable in German, did not bear the date, or presented an incorrect section title. In view of the fact that 82% of the inspected companies have access to structures, in particular computer programs, for generating safety data sheets, and that the companies in Germany generally utilise software for generating safety data sheets, this a remarkable development, and the findings are unacceptable. It must be feared that the information on safety data sheets that requires expert wording on how chemicals are handled safely will be deficient in quality to a far greater extent.

Notwithstanding this, 160 of the inspected companies employed expert personnel. Of these companies, most of them (131) also provide advanced training. The deficiencies in quality must therefore be assumed to lie in the corporate structure. This assumption is further strengthened by the findings of additional inspections on safety data sheets provided to the inspected companies by their suppliers. At about 40% of all these companies, supplier's safety data sheets were either absent or contained errors. One encouraging point, though, is that the employee's legal right to access safety data sheets is observed at all inspected companies.

3.5 Qualitative results

The inspections at the companies ascertained various problems, in particular in connection with the identification of chemicals.

The following presents a number of examples experienced by the authorities and is intended to promote greater awareness at companies and associations for these issues.

1. Registration of non-phase-in substances

The inspection at companies ascertained on more than one occasion that these had erroneously used the ELINCS for their pre-registrations. These companies were unaware of the definition for phase-in substances and the fact that only these could be pre-registered.

2. Lack of clarity on the identification of a substance

Although the term "identification" was adopted from the old EINECS list, it was not always clear at the inspected companies which substance was meant.

For example, a substance for registration was subjected to a number of pre-registrations with different CAS numbers for the categories "substance", "reaction mass", and "UVCB substance".⁸ Vice versa, several substances were pre-registered together as a reaction

⁸ Substances of unknown or variable composition

mass or UVCB substance, when the individual constituents should have been pre-registered. In some cases the hydrates were pre-registered instead of the anhydrous forms, although the hydrates are not EINECS substances. There were similar experiences with polymers, when companies submitted pre-registrations for monomers other than those actually used.

In a number of cases, REACH enforcement also ascertained violations to other provisions of chemical legislation. Although handling toxic and highly toxic chemicals, a number of production facilities were not authorised to do so under § 2 Para. 1 of the Chemical Prohibition Law ChemVerbotsV, or the authorities were not notified as stipulated under § 2 Para. 6 of the same. Also ascertained at companies were incomplete knowledge of and violations to the regulations under the EU Biocide Directive. Other violations affected the authorisation requirements under the Federal Immission Control Act BImSchG and waste legislation. However, violations to other provisions under the chemical legislation were not the subject of statistical investigation by this REACH enforcement project.

In a number of cases the inspections failed to come to a conclusion because contacts at the companies were unavailable or there were differing details in the commercial register.

3.6 Measures by the authorities

A total of 3 inspected companies were found to have failed in their obligation to register, 44 companies to have violated the safety data sheet requirements, and 10 to have failed other REACH obligations.

Orders and interdicts were issued to all three of the companies failing in their obligation to register, and criminal proceedings instituted in addition against one company.

With respect to absent or incorrect safety data sheets, the authorities in many cases issued information to the companies, together with the obligation to rectify the situation.

3.7 Results as seen by the authorities

Overall it was shown that, owing to the advanced training conducted primarily at the authorities themselves, the inspectors were very well prepared for this new enforcement task. In isolated cases there were difficulties following personnel changes and restructuring at the authorities, with the consequence that inspectors were sometimes deployed for REACH enforcement at short notice and only after a brief time of familiarisation.

The structured inspection based on the EU wide questionnaire provides excellent support for the authorities and has proved its merit. This standardised method of documenting the findings has first made it possible to conduct quantitative and qualitative analyses and comparisons in the European context.

In individual cases questions should be worded more precisely if misunderstandings and queries are to be avoided. In addition a number of questions should be expanded with more options so that detailed insights and findings do not have to be worded as additional comments.

A further finding of this first REACH enforcement project as seen by the authorities is that enforcement cannot achieve any efficiency whatsoever unless there is easy and uncomplicated access to the pre-registration and ECHA registration data. If this is not the case, targeted enforcement is impossible or at best extremely difficult owing to the large number of companies and their chemicals. This “easy and uncomplicated access” means that the data are readily available to all inspectors at all times. These data must be provided in a software environment in the German language. This applies in particular to the REACH Information Portal for Enforcement (RIPE) that is presently being developed on the European level. In view of the importance of imports by companies in other Member States, e.g. via domestic airports, the ECHA should be urged with greater emphasis to allow the authorities in all Member States to access the pre-registration and registration data of companies in other Member States. When restrictions should be relevant owing to security concerns, simple data access should be set up via the “responsible authorities” (in Germany the Federal Institute for Occupational Safety and Health BAuA).

Data access by authorities between the Member States can also be in the interests of companies operating throughout Europe: the inspection of a company in Germany with an additional head office in another Member State required conference calls to the second head office because pre-registration documents were unavailable in Germany.

At present the experience of authorities responsible for REACH enforcement has been gained primarily from handling pre-registrations. In this respect, it could be shown that the simple use of data is not possible in all cases. For example, the records cannot always be filtered according to location (e.g. as a result of typing mistakes in place names or alternative spellings). Moreover, because the ECHA has not forwarded the tonnage band to the authorities of the Member States, it is not possible to target the selection of companies manufacturing or importing chemicals on a large scale.

A number of companies, submitted their pre-registrations with differing identification (ID) numbers (over 40), but all bearing the same company identification. The reasons for this,

however, could not as yet be ascertained in every case. Some of them are accidental multiple notifications, and some, in the case of only representatives, intentional.

The data must therefore be edited and search facilities provided.

4. Conclusion

Owing to the small number of companies seriously failing in their obligation to register, good compliance to the legal regulations may be assumed overall. There may possibly have been a larger number of companies failing in their obligation to register under REACH, were it not for the early issue of information, improved communication between the authorities and companies, and inspections in the runup to pre-registration.

It is a cause for concern, though, that – even on the chemicals sector – the safety data sheets exhibit considerable deficiencies in quality, although the inspections affected formal specifications and not the quality of the contents. Moreover, communication problems were ascertained not only within the supply chain, but also in-house, and their cause presumably lies in the corporate structure. One company first learned from the authorities of the valid pre-registrations submitted by its parent. In-house, it appears that available information is not reaching all of the relevant actors, although fully functional communication channels are indispensable for compliance to the REACH obligations. This problem may possibly be counteracted with improved internal networking between the purchasing, production, environmental, and work safety divisions and the REACH officer.

The second European enforcement project REACH-EN-FORCE-2, at present in preparation for its launch in 2011, will be focusing on adherence to the obligations of Downstream Users and the communication along the supply chain to the object.⁹ In view of the findings to date, it would appear appropriate to pay more attention to the inspection of in-house information and control mechanisms for future enforcement projects.

⁹ http://echa.europa.eu/doc/press/na_09_34_Forum_20091214.pdf

5. Annex

Statistical results

5.1 Federal State participation

State	Number of inspected production facilities	Obligatory section only REACH-EN-FORCE-1	Obligatory and voluntary section REACH-EN-FORCE-1
Baden-Wuerttemberg	61		61
Bavaria	60	60	
Hesse	10		10
Free and Hanseatic City of Hamburg	10	10	
Lower Saxony	33		33
North Rhine-Westphalia	73	15	58
Schleswig-Holstein	4		4
Saxony-Anhalt	3		3
Thuringia	19	3	16
Saxony	6		6
Total	279	88	191

Table 1: Overview of Federal States participating in the REACH enforcement project

5.2 Overview of sectors

NACE code	Name	Number
1.*	Crop and animal production, hunting and related service activities	20
20.1.*	Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	58
20.2.*	Manufacture of pesticides and other agrochemical products	5
20.3.*	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	17
20.4.*	Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	17
20.5.*	Manufacture of other chemical products	41
20.6.*	Manufacture of man-made fibres	4
21.*	Manufacture of basic pharmaceutical products and pharmaceutical preparations	5
22.*	Manufacture of rubber and plastic products	7
23.*	Manufacture of other non-metallic mineral products	4
24.*	Manufacture of basic metals	7
25.*	Manufacture of fabricated metal products, except machinery and equipment	9
26.*	Manufacture of computer, electronic and optical products	2
27.*	Manufacture of electrical equipment	3
28.*	Manufacture of machinery and equipment n.e.c.	1
30.*	Manufacture of other transport equipment	11
43.*	Specialised construction activities	1
46.*	Wholesale trade, except motor vehicles and motorcycles	37
47.*	Retail trade, except motor vehicles and motorcycles	4
58.*	Publishing activities	1
74.*	Other professional, scientific and technical activities	2
8.*	Other mining and quarrying	1
	No details	22
Sum		279

Table 2: Overview of inspected companies according to economic sector

5.3 Status as defined under the REACH Regulation

Among the inspected companies there were 71 production facilities that were Downstream Users or traders, and not manufacturers or importers as defined under REACH.

Company status under REACH	Number	Percent
manufacturer	127	46
importer	133	48
only representative	25	9
Downstream User	201	72

Table 3: Status as defined under the REACH Regulation (multiple entries possible)

5.4 Exemptions from the obligation to register

Exemptions from the obligation to register	Number
substances in quantities < 1 tonne per year	64
waste	44
non-isolated intermediates	24
radioactive substances	1
polymers	61
substances in transit	5
national defence	0
transport	1
notified substances	19
exemptions on the grounds of special use	23
exemptions in accordance with Annex IV	21
exemptions in accordance with Annex V	39

Table 4: Overview of exemptions from the obligation to register submitted by the inspected companies (multiple entries possible)