

Working Committee of the Federal Government
and the States on Chemical Safety (BLAC)

Results 2010/2011

concerning the continuation of the
1st REACH Enforcement Project at national level
within the framework of

REACH-EN-FORCE 1

as of: March 2011

Contents

1	Introduction	5
2	Objectives and Procedure	5
3	Results of the Enforcement in Germany.....	5
3.1	Phase-in Substances and Exemptions from the Obligation to Register	8
3.2	Non-phase-in substances.....	9
3.3	Substances in articles	9
3.4	Safety Data Sheets	10
3.5	Measures taken by the Authorities	11
4	Conclusion.....	12

1 Introduction

REACH-EN-FORCE-1 is the first Europe-wide enforcement project for inspecting compliance with the provisions of the EU chemicals regulation REACH (EC) 1907/2006. The project was implemented in 2009. The results of the enforcement at national level were submitted to the Conference of Environment Ministers¹ and published by BLAC. The report has been published in addition in an English-language version.

At European level a total of 23 Member States plus Iceland and Norway participated in the project. Numerous federal states were involved.

At the FORUM-6 meeting the Member States resolved to continue the project REACH-EN-FORCE-1 (REF-1). Germany was also involved in the continuation of REF-1.

The results at a national level are summarised below and compared with the European results.

2 Objectives and Procedure

The continuation of REF-1 was implemented in the period 01/2010 – 03/2011. There were no changes to the objectives and procedure as compared to the first project phase.

3 Results of the Enforcement in Germany

A total of seven German federal states were involved on the national level in the continuation of the REACH-EN-FORCE-1 project and of these two were involved for the first time. A total of twelve states were involved in the Europe-wide REACH Enforcement Project in the period 2009 to 2011.

In the period under review a total of 161 inspections were conducted in Germany and were documented separately statistically as REACH-EN-FORCE-1 inspections (Table 1). In at least one federal state a further 22 companies were inspected, but the results were not incorporated additionally into the REF-1 statistics.

Results of the inspection of compliance with REACH provisions, e.g. information obligations pursuant to Article 33 or restrictions on placing on the market pursuant to Annex XVII of the REACH Regulation, are also not considered since they were either only aimed at individual aspects of REF-1 or lay outside the project's focal concern.

¹ Conference of the Environment Ministers: Circulation Resolution 18/2010

State	Number of companies inspected 2010/2011	Number of companies inspected 2009
BW	83	61
BY		60
HB	4	
HE	(22)	10
HH		10
NI		33
NW	48	73
SH		4
SL	5	
SN	6	6
ST	6	3
TH	9	19
Total	161 (183)	279

Table 1: Overview of the federal states' involvement in the REACH Enforcement Project REACH-EN-FORCE-1
Figures in brackets: results not documented separately in statistical terms.

Table 2 shows the distribution of sectors on the basis of the NACE Codes. Although on a European level there were no specifications with respect to sectors to be concentrated on, it was mainly manufacturers and trading companies in the chemical industry who were inspected. On a national level, however, more companies from other sectors, such as companies from the metals and waste domains, were inspected in 2010 as compared to 2009.

NACE	Description	D, 2010/2011 [%]	D, 2009 [%] ²	EU, 2009 ³ [%]
10/11/ 19.2	Manufacture of food products and animal feed / beverages / petroleum products	7	7	6
20	Manufacture of basic chemicals / chemical products	32	51	35
21	Manufacture of basic pharmaceutical products and pharmaceutical preparations	2	2	2
22	Manufacture of rubber and plastic products	4	0	0
23	Manufacture of other non-metallic mineral products (glass and ceramic), processing of non-metallic mineral products	1	1	6
24	Manufacture of basic metals	6	3	4

² BLAC: Joint Report of the Federal States, Results of the 1st REACH Enforcement Project on a national level within the framework of REACH-EN-FORCE 1, 2010

German version:

http://www.blac.de/servlet/is/2146/Bericht_REACH_EN_FORCE_1.pdf?command=downloadContent&filename=Bericht_REACH_EN_FORCE_1.pdf

English version:

http://www.blac.de/servlet/is/2146/Report_REACH_EN_FORCE_1_results_german_2010_03_end.pdf?command=downloadContent&filename=Report_REACH_EN_FORCE_1_results_german_2010_03_end.pdf

³ ECHA / Forum for Exchange of Information on Enforcement: 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, Helsinki, 2010

http://echa.europa.eu/doc/about/organisation/forum/ref-1_project_report_conclusions.pdf

NACE	Description	D, 2010/2011 [%]	D, 2009 [%] ²	EU, 2009 ³ [%]
25	Manufacture of fabricated metal products	11	3	2
26	Manufacture of computer, electronic and optical products	1	1	1
	Manufacture of other goods	4	6	6
38	Waste collection, treatment and disposal activities; materials recovery	4	0	0
	Wholesale and retail trade	24	13	20
	Other activities	3	5	7
	not specified	2	8	11

Table 2: Overview of the distribution of sectors of the companies inspected within the framework of REACH-EN-FORCE-1

If one takes as a basis the definition for manufacturers and importers within the meaning of the REACH Regulation, which is geared to the status in relation to the chemical itself, one obtains a somewhat different picture (Table 3): The proportion of the manufacturers and importers inspected in the project period 2010/2011 is about 30 to 40 per cent; the proportion of only representatives is about 10 per cent⁴. Approximately 80 per cent of the companies inspected are downstream users according to the REACH definition, of which about 2/3 are at the same time both manufacturers or importers and downstream users. This means that most of the companies have, on the one hand, the obligation to collect substance information within the context of the registration and submit it as a dossier to the European Chemicals Agency (ECHA). On the other, they profit from the improved availability of toxicological and eco-toxicological data.

Role of companies under REACH ⁴	Number D, 2010/2011	Number D, 2009	Number EU, 2009
Manufacturer	48	127	878
Importer	59	133	666
Only representative	15	25	83
Downstream user	125	201	858

Table 3: Status of the companies inspected within the meaning of the REACH Regulation. About 2/3 of the downstream users (DU) inspected in 2009 and 2010/2011 are at the same time manufacturers or importers

Within the framework of the company inspection, questions were also put in 145 companies concerning the presence of management systems.

⁴ Multiple responses possible because companies may, for example, be simultaneously manufacturers and importers within the meaning of the REACH Regulation.

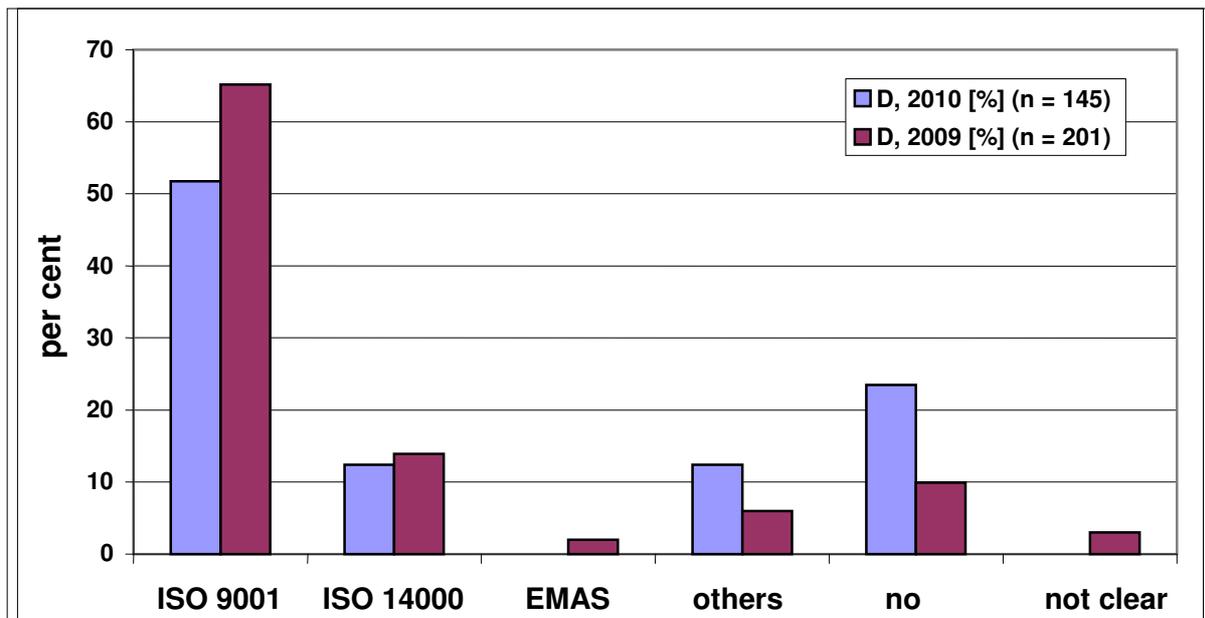


Figure 1: Overview of the implementation of management systems in the companies inspected within the context of REACH-EN-FORCE-1

The companies inspected predominantly have a management system, preferable according to ISO 9001 or ISO 14000. The differences between 2009 and 2010/2011 are presumably due to the fact that in the period under review it tended to be small and medium-sized companies that were inspected.

3.1 Phase-in Substances and Exemptions from the Obligation to Register

Of the 161 (279)⁵ companies inspected, 70 (152)⁵ companies produce or import phase-in substances on their own and 31 (94)⁵ companies produce or import substances in preparations (mixtures)⁶. In all, of the companies inspected about 4600 (11,000)⁵ produce or import substances on their own or in preparations (mixtures) in quantities of one tonne or more per year, of which over 350 (2000)⁵ produce or import substances of a single company.

In a European comparison companies based in Germany profit twice as frequently from exemptions from the obligation to register (Table 4). The most relevant exemption is the quantity threshold of one tonne/year, followed by the exemption for polymers and waste or for special substances listed in Annex V of the REACH Regulation. It is striking that the characteristic figure "number of exemptions in relation to the number of companies inspected" has remained almost unchanged as compared to the action in 2009.

⁵ Figure in brackets: Results 2009

⁶ Multiple responses possible

	Number 2010/2011 in D	Exemptions / Companies 2010/2011 in D	Number 2009 in D	Exemptions / Companies 2009 in D	Number 2009 in EU	Exemptions / Companies 2009 in EU
Substances in quantities < 1 tonne/year	58	0.36	64	0.23	231	0.15
Polymers	36	0.22	61	0.22	160	0.1
Waste	19	0.12	44	0.16	122	0.08
Exemptions pursuant to Annex V	29	0.18	39	0.14	166	0.1
non-isolated intermediates	4	0.02	24	0.09	64	0.04
Exemption due to special use	11	0.07	23	0.08	84	0.05
Exemptions pursuant to Annex IV	13	0.08	21	0.08	88	0.06
Notified Substances (substances deemed to be registered)	5	0.03	19	0.07	56	0.04
Substances in transit	0	0.00	5	0.02	13	0.01
Radioactive substances	0	0.00	1	0	3	0
For transport	0	0.00	1	0	2	0
National defence	0	0.00	0	0	2	0
	175	1.09	302	1.08	991	0.62

Table 4: Overview of the number of exemptions from the obligation to register in relation to the number of companies inspected (D, 2010/2011: 161 companies; D, 2009: 279 companies; EU, 2009: 1589 companies)

3.2 Non-phase-in substances

Of the companies inspected only 4 (18)⁵ manufacture or import non-phase-in substances on their own or in preparations in quantities. In view of the tonnage threshold of one tonne/year and on the basis of special uses (foodstuffs, pharmaceutical products) the obligation to register only applies to one of the companies inspected.

3.3 Substances in articles

A total of 9 (27)⁵ substances (phase-in and non phase-in) in articles intended to be released are manufactured or imported in quantities of one tonne or more per year.

Of the companies inspected 2 (1)⁵ manufacture or import 2 (3)⁵ substances of concern such as carcinogenic substances in articles containing more than 0.1 per cent and in a total quantity of 1 tonne or more per year. With the inclusion of these substances of concern in the candidate list for chemicals subject to authorisation there arises directly the obligation to provide commercial purchasers, without the need for a request, and consumers within 45 days on request with sufficient information for safe use of the product, and at least the name

of the substance. Compliance with this obligation was not verified within the framework of this first REACH Enforcement Project however.

3.4 Safety Data Sheets

The availability of safety data sheets in the companies was subject to a random check (a maximum of 5-10 safety data sheets per company). As compared to the same period in the previous year the quota of companies who did not have the required safety data sheets or only partly had them fell from 6 per cent in the 2009 period to 5 per cent in the period 2010/2011. For the inspection at a European level the required safety data sheets were lacking wholly or in part in 11 per cent of the companies in 2009.

The inspection of safety data sheets was only conducted with reference to formal criteria with respect to the requirements that the safety data sheet must be available in German, the date drawn up and revision be indicated and the specified headings be included. It is not rated as a deficiency if the headings 2 (possible risks) and 3 (composition / information on ingredients) were not in accordance with the specifications of the REACH Regulation, but with the safety data sheet directive which went of force in 2007.

	D, 2010/2011	D, 2009	EU, 2009
Number of safety data sheets inspected	865	745	5338
Number safety data sheets with deficiencies	61	75	808
% deficiencies	7	10	15

Table 5: Overview of the number of safety data sheets (SDS) chosen at random and inspected according to formal criteria (language, date, headings) and the number of objections

As compared to 2009 there is evidence of an improvement and hence a reduction in the objections rate from 10 to 7 per cent. This rate is, however, still remarkable since the companies inspected predominantly have structures at their disposal, and especially computer programs to draw up safety data sheets – and on a European comparison to a much greater extent.

Comparisons with earlier inspections^{7,8}, where the quality and correct nature as well as the completeness of the content of safety data sheets were checked, suggest that an inspection which is not only purely formal will continue to result in substantially greater objection rates. For example, there was a safety data sheet for a rust converter where only water was given as a hazardous component under heading 3. Related follow-up errors, such as details of protective measures or waste disposal, are a necessary consequence in this case. But

⁷ Annual Report of the Gewerbeaufsicht (Labour Inspectorate) Baden-Württemberg, 2006/2007
<http://www.gaa.baden-wuerttemberg.de/servlet/is/17475/>

⁸ Chemicals Legislation European Enforcement Network“ (CLEEN): European Classification and Labelling Inspections of Preparations including Safety Data Sheets“ (ECLIPS), 2004
<http://www.cleen-europe.eu>
http://www.cleen-europe.eu/projects/ECLIPS_Final_report.pdf

formally the safety data sheet was up to date according to REACH; there were even indications of an identified use.

97 (95)⁵ of the companies inspected assign knowledgeable personnel to draw up safety data sheets in accordance with the requirements of the REACH Regulation. 86 (82)⁵ per cent of the knowledgeable personnel also have the opportunity to attend courses of training and refresher courses.

One company refused workers access to the safety data sheets, which is contrary to the specifications of Article 35 of the REACH Regulation.

In the spot check of the pre-suppliers' safety data sheets it was found that more than 30 per cent of these were lacking or deficient. Despite this high objections rate this still represents an improvement in the situation as compared to 2009 (around 40 per cent) in the companies.

3.5 Measures taken by the Authorities

In the project period 2010/2011 cases of non-compliance with the provisions of the REACH Regulation which were the subject of this enforcement project were found in a total of 13 of the companies inspected (8 per cent). In 2009 the rate was 20 per cent on a national level and 24 per cent on a European level.

With 2 (3)⁵ of the companies inspected the cases of non-compliance concerned the obligation to register. One of the companies dispensed immediately with any further imports. A second company had wrongly assumed that the obligations to register had been fulfilled by an appointed only representative.

With 7 (44)⁵ companies cases of non-compliance with the provisions regarding safety data sheets and 4 (10) infringements of other obligations under REACH were found which were checked within the framework of REACH-EN-FORCE-1. Further cases of non-compliance with other REACH provisions concerned, for example, provisions of Annex XVII relating to restrictions of placing on the market or obligations to provide information pursuant to Article 35.

Number of measures	D, 2010 (161 companies)	D, 2009 (279 companies)	EU, 2009 (1589 companies)
Blame and shame	0	0	3
Letter of appeal	24	31	96
Administrative order	1	3	169
Fines	0	0	12
Criminal complaint	0	1	3
Others	4	13	121

Table 6: Overview of the measures taken by the authorities concerning non-compliance with the REACH obligations which were the subject of the REACH-EN-FORCE-1 project, on a national level and in a European comparison.

4 Conclusion

As in 2009, in the project phase 2010/2011 only very few major cases of non-compliance with the obligation to register were ascertained and in all a high level of compliance with the statutory provisions can be assumed. It is probable that the early provision of information to the companies by the authorities and associations, improved communication between authorities and companies, and inspections prior to pre-registration contributed to this.

In all there is still a highly heterogeneous picture of the state of knowledge in the companies concerning the provisions of the REACH Regulation.

Below some examples of the authorities' experience are summarised in order to sensitise further companies and associations to these questions:

1. REACH has to date been given too little attention by a number of companies:
For example one company inspected only concerned itself with a possible obligation to register when the enforcement authority intended to inspect the import quantities. Up to this point the quantities of the substances in the imported mixtures in the company had not been known.
2. REACH was sometimes used too little as an opportunity to solve known problems, concerning for example the provisions on and the quality of safety data sheets.
3. The in-company networking of the purchasing, production, environment, and occupational safety and health domains is in need of improvement in some companies. On the national level, as on the European level, companies were inspected which received no information or only inadequate information on the parent companies' REACH activities, even though these activities affected them directly as subsidiaries.
4. Lack of clarity was established in some cases in relation to the identity of the substances, even though the substance identity is geared to the "old" EINECS rules and an ECHA guidance document is available. The rules documented in the guidance document have sometimes been insufficiently considered. In addition not all companies are aware of the fact that only phase-in substances, but no non-phase-in substances, could be pre-registered.
5. Some companies have problems not only with "new" statutory chemical provisions, but also with "old" ones. Restrictions concerning placing on the market, which for many years were a component of national regulations and were only "incorporated" in Annex XVII of the REACH Regulation or have long become provisions on safety data sheets and are not always observed.
6. The assumption that companies partly trust too much in technical and/or organisational instruments is reinforced by the current results. Although most companies have corporate management systems and computer programs for creating safety data sheets, it is repeatedly found that the hazard and risk communication within the companies and in the supply chain is in need of improvement. From the authorities' point of view it has to date been incomprehensible how a safety data sheet can be drawn up for a rust converter without anyone in the company noticing that the declarations of hazardous components are incorrect and only water is indicated.

With a view to the supply chain and sectors less closely associated with chemicals functioning communication channels are becoming more important in addition since they are

an absolute prerequisite for compliance with the obligations under REACH. It is therefore essential to have an improved internal networking of the purchasing, production, environmental protection, and occupational safety and health domains and the REACH officers on the one hand, as well as improved communication within the supply chain on the other. It is intended that the awareness of this be reinforced by the second Europe-wide REACH-EN-FORCE-2 Enforcement Project, which is being conducted in 2011 and is concerned with the obligations on the part of downstream users and communication in the supply chain.

As was already the case in the first phase in 2009, the inspectors have again thoroughly prepared for their REACH enforcement functions by the continuous training courses conducted within the authorities. Many also benefited from the fact that they had prior experience within the framework of the first REACH-EN-FORCE-1 project phase. But it cannot be discounted that in individual cases difficulties arose because of changes in personnel or reorganization by the authorities, meaning that inspectors were sometimes assigned to REACH enforcement at short notice and only had a brief induction period.

Furthermore the structured inspection with reference to the questionnaire used throughout Europe and the standardised result documentation have also proven valuable; only this makes quantitative and qualitative analyses and comparisons possible in the European context. In this way it was demonstrated, for example, that with respect to the enforcement intensity there was neither a north-south nor an east-west divergence and the enforcement authorities successfully work for a comparable implementation.

An important function is performed here by the Forum for Exchange of Information on Enforcement at European level and the planned exchange of inspectors between the different European states.

It is becoming increasingly urgent that the authorities finally obtain simple and prompt access – as far as possible across Member States – to data of pre-registration and registration at ECHA. The availability of this information is the indispensable basis for efficient enforcement. Initial indications suggest that the quality of the registration dossiers, and especially those on toxicological and classification-relevant information, is not always adequate and so the enforcement authorities will have to face new challenges. The experience already accumulated by the enforcement authorities when handling the pre-registration data would also appear to be confirmed by the dossiers themselves. Typographical errors or input errors by the companies make searches in the databases and datasets themselves more difficult. This means that the enforcement authorities need not only the dossier information, but also the results of the completeness check and the quality checks of the content.

Without access to data and in view of the large number of companies and chemicals as well as of notifications for the future harmonized classification and labelling under the CLP Regulation, the situation must be reduced to the simple principle "no data – no enforcement".