

Testing of selected elements of the REACH procedures¹

in practice

by authorities and companies

in North Rhine-Westphalia (Germany)

sponsored by the Government of North Rhine-Westphalia

Summary project report

December 22, 2003

¹ As proposed by DG ENV and ENT in May 2003 and modified in September 2003.

FOREWORD

The proposed new EU Chemicals Policy will affect all sectors of industry that are involved in the production, import and use of chemicals. Since the publication in February 2001 of the White Paper relating to the strategy of a future Chemicals Policy, North Rhine-Westphalia has played an active part in the discussions in that regard.

As the Regional Government of North Rhine-Westphalia we welcomed the goals of the new EU Chemicals Policy. In our capacity as the Government of one of Europe's major chemical regions, it is our wish to make a contribution of our own towards a practicable system that is aimed at protecting human health and the environment while safeguarding the competitiveness and innovative ability of the chemical industry.

Given this background, the Regional Government of North Rhine-Westphalia decided to put the practicality of certain key elements of the REACH System (**R**egistration, **E**valuation, **A**uthorization and **R**estriction of **C**hemicals) to the test in the form of a simulation.

The German Chemical Industry Association (VCI), other business associations, the Chemical Industrial Union (IGBE), environmental and consumer associations, as well as German Federal authorities, gave active support to this initiative.

The objective of the exercise was to assess the practicality, from the point of view of companies and authorities, of the draft Regulation from the European Commission, to evaluate proposed improvements and to propose new solutions.

The focus of the simulation was not to test the entire draft Regulation, but to analyze the practicability of selected processes, of requirements relating to the evaluation of substances and of communication processes connected with the registration of chemicals and the creation of more detailed safety data sheets.

At this point, we would like to express our thanks to all involved. As a result of their outstanding commitment, a series of proposed improvements to the REACH system were developed during the course of the simulation and these have been included in the present report.

The results and recommendations of the simulation will now be put forward as a key component of proposals by the North Rhine-Westphalia region during the remainder of the legislative process at national and EU level.

It is our hope that as a result, the REACH system will be much more practical in its approach and will therefore be easier to implement for all concerned.

On behalf of the Regional Government



Bärbel Höhn



Harald Schartau

1. Background to the simulation

On October 29, 2003, the European Commission published its draft regulation relating to the **Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)** and submitted it for consultation to the European Council and the European Parliament. Earlier, in May 2003, the European Commission had published a Consultation Document² on the Internet, in order that all interested parties were able to submit their opinions during the course of a 6-week consultation process.

The Consultation Document contained the joint proposal of the Directorate General (DG) Environment and the DG Enterprise for a regulation implementing the Commission's strategy for a future Chemicals Policy, set out in the White Paper published in Spring 2001.

The proposed new EU Chemicals Policy will affect all sectors of industry that are involved in the manufacture, import and use of chemicals. Since the publication of the White Paper, North Rhine-Westphalia has therefore played an active part in the debate. The government of North Rhine-Westphalia welcomed the overall objectives of the new EU Chemicals Policy. The workability of the system, however, is regarded as a touchstone when it comes to maintaining a balanced relation between the protection of human health and the environment on the one hand and the safeguarding of the competitiveness and innovative capacity of the chemical industry on the other.

This was the reason why the government of North Rhine-Westphalia decided to test certain key elements of the REACH system (as proposed in May 2003 and modified in September 2003³) in practice.

The German Chemical Industry Association (VCI) and other industry associations actively supported this idea.

The regional government of North Rhine-Westphalia assigned the implementation of this test run to a working party (ARGE) consisting of four consultancy companies, OEKOPOL GmbH, IKU GmbH, GWU GmbH and Oeko-Institut e.V.

² (<http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm>)

³ In September 2003 a new draft proposal by the two Directorates General was announced. This version was used as the basis for the simulation.

2. Aims of the simulation

The aim of the study was to test the workability of the draft REACH regulation for companies and authorities and, where applicable, to evaluate proposals already made to improve it and, also where applicable, to work out new proposals for improvement.

The focus of the simulation was not to test the entire regulation, but to analyze the practicability of selected processes, evaluation requirements and communication processes connected with the registration of substances and the generation of more detailed safety data sheets.

The procedure and the results are therefore fundamentally different from previous *Impact Assessments* published by the EU, which focused primarily on issues relating to the costs of generating substance data.

The utility of the REACH system with regard to the environment, health, innovation and competition was not examined as part of the simulation.

The results and recommendations of the simulation will be put forward as proposals by the North Rhine-Westphalian government at National and EU level for the legislative process.

3. Who were the “Simulators”?

The practicability of the REACH system was tested in the following supply chains.

- Chemical finishing of textiles (textile chain = TEX)
- Spray painting in vehicle repair (paint chain = LACK)
- Manufacture of foamed plastics (plastics chain = KU)
- Electroplating of surfaces (electroplating chain = GAL)

Substance manufacturers, manufacturers of preparations, industrial and commercial users of preparations and (import) traders took part. Although the majority of these companies are based in North Rhine-Westphalia, companies from other regions of Germany also participated.

Other participants in the simulation who only took part in specific value-added chains included German Federal authorities, who, in the context of REACH, are required to check registration dossiers and evaluate registered substances and also have to inspect proposals for animal testing. Regional authorities, who will be responsible for enforcing the REACH regulation and will also act as consultants for REACH, also took part in the simulation. Environmental and consumer associations made up another important group of participants.

4. How the simulation was carried out

All “simulators” took part on a voluntary basis and common project parameters were agreed. A representative from one of the participating companies was selected to head each of the four groups involved in the project. The heads of the groups were responsible for ensuring productive co-operation between those involved in the individual chains and effective communication with the project management team and specialist consultants.

A Steering Committee supported the simulation by providing recommendations, commenting on intermediate results and discussing overall results. The relevant NRW ministries, and business delegates from the relevant associations, the responsible Federal authorities, associations active in the field of occupational and environmental safety and consumer protection and the IG BCE⁴ all formed part of the Steering Committee.

The simulation process, which ran from July to December 2003, comprised several stages and practical testing was carried out in the supply chains between September and November 2003.

Step 1 – Basics: Four managed, chain-specific inaugural meetings were held in which those taking part in the process developed a joint understanding of the material requirements of the REACH regulation. The results of these inaugural meetings were recorded and can be viewed at <http://www.europa.nrw.de/themen/chemikalienpolitik/index.html>

Step 2 – Investigation of tasks defined in chains: The participants in the four supply chains spent a period of approximately six weeks working on the agreed tasks and recorded their experiences.

Step 3 – Formulation of overall results within the context of chaired closing meetings for the four supply chains (documentation can be accessed at <http://www.europa.nrw.de/themen/chemikalienpolitik/index.html>

and drafting of a result report for each chain (report can be accessed at <http://www.europa.nrw.de/themen/chemikalienpolitik/index.html>

Step 4 - Individual issues: In parallel with the simulation process, specific issues were investigated in greater detail in the context of workshops, meetings or question and answer sessions. The documentation can be accessed at <http://www.europa.nrw.de/themen/chemikalienpolitik/index.html>

⁴ IG BCE = Mining, Chemical and Energy Industrial Unions

Step 5 - Evaluation and summary of project results

- Technically relevant outcomes relating to the workability of the REACH requirements simulated and possible solutions as worked out in the chains and as viewed from the point of view of those involved in the project.
- Results according to topic: Substances in imported products (textile sector), registration of low-volume substances (textiles and paint), the effects of REACH on the import trade in clothing, registration of substances in the import trade (substances for chemical processing), transparency and confidentiality, interfaces between REACH and substance-related regulations in relation to occupational health and the protection of consumers and of the environment.
- Retrospective analysis of methodology and outlook from the point of view of the Project Group (ARGE).

5. Results of the simulation

5.1 Preliminary note as to the evaluation method

In accordance with the aims and objectives, the simulation concentrated on selected problem areas of the implementation of the draft regulation and not on an overall assessment of the possible benefits of the new system.

The discoveries made during the simulation were evaluated jointly in the four chains. Views shared by participants were recorded separately from areas of disagreement. The participants in the simulation process proposed solutions for many of the problems identified whilst implementing the REACH requirements that were being tested. These concerned

- the tailoring and content of the REACH regulation itself, or
- the need to develop implementation tools to be available before the regulation comes into force or
- the development of new forms of co-operation between the parties involved or
- the clarification of outstanding issues.

5.2 Common description of problem and proposed solution

Many substance manufacturers, importers and almost all users are facing new types of qualitative and quantitative requirements, such as the generation of a registration dossier and a Chemical Safety Assessment (CSA), including exposure estimates with regard to the users (with particular reference to environmental or consumer-related risks).

It is the shared view of all those involved that:

The implementation of the requirements examined during the simulation during the course of the next few years in particular will give rise to a considerable increase in the numbers of personnel required.

- The registration of phase-in substances (and new substances)⁵ will pose problems to companies (and official bodies)⁶.

⁵ Phase-in substances are substances that were registered as existing in the EU in 1981 and have been produced or used within the EU during the past 15 years. These substances will be incorporated into the REACH system by 2017, in accordance with specific procedural regulations. “New substances” are substances that are to be introduced to the market for the first time or substances that have not been used or produced for the past 15 years and are therefore treated as new substances (non-phase-in substances).

⁶ The expense per substance for the evaluation of existing chemicals (until now by the authorities) will probably be lower under the REACH system than it was before. By incorporating a large number of substances into the system (estimates lie at around 30,000 in the course of 11 years) the workload will increase during that same period. Under the REACH system, data recording and the evaluation of substances is mainly carried out by the commercial parties involved. Under the REACH system, the authorities will play a different role to the one they currently play, an example of this being the scrutiny of test proposals in the registration dossiers.

- Certain companies in particular could find themselves overstretched as a result of specific requirements of REACH, increasing costs in terms of time, personnel and money. It has become clear that the majority of these companies are currently unable to carry out a product evaluation to the level of detail and scope specified by REACH. Many small and medium-sized companies that make use of chemicals – particularly those at the end of the supply chain – would be significantly overstretched without simplifications in the legal text and without support from external bodies (state authorities, industry associations, service providers, suppliers). This would, for example, apply to:
 - small and medium-sized enterprises that are required to register a large number of different substances (substance manufacturers, importers);
 - small and medium-sized enterprises, who as users or importers of substances or preparations are required to produce their own CSA/CSR when the safety data sheet of the relevant supplier does not fulfil the specific requirements.
- These tasks would have to be outsourced to testing institutes and external consultants, incurring corresponding costs. In this regard, companies fear that problems would also arise with regard to the protection of know-how.
- The requirements of REACH may lead to a restriction in the range of substances manufactured, imported and/or used. In addition, it will not be possible to offset entirely against price the effects on costs in individual sectors where chemical products are produced using a large number and wide variety of separate substances in low volumes (concentration of registration requirements) and which compete globally with these products (textiles). This would give rise to a high element of commercial risk. On the other hand, the BUND⁷ believes that an opportunity will arise that will enable manufacturers to gain customer loyalty as a result of the enhanced quality of goods that will arise as a result of REACH. The possible consequences for innovation and ability to compete were not quantified in the context of the simulation.

All participants **shared the view** that inefficient or impractical processes identified during the simulation can be avoided or reduced by means of the following measures:

- Clarifying the precise requirements of the draft regulation and clarification in the text of the regulation, where necessary.

⁷ BUND = Friends of the Earth, Germany

- Modifications to requirements in the regulation, particularly in relation to:
 - simplified procedures for assessing exposure and communicating exposure scenarios⁸ or categories⁹ within the supply chains, and
 - the possibility of using the exposure assessment in order to adjust the extent of testing required to the possible risks
 - reducing GLP requirements¹⁰ in relation to new tests to be carried out, if other quality assurance systems (such as EN 17025, for example) are in force
- How REACH is applied in practice, in particular clear, pragmatic rules for acknowledging data that are already available and evaluating existing studies and in terms of the approval of analogous conclusions and substance group analyses.
- Provision of simple EU guidelines, in addition to other aids and implementation tools before the system is introduced, in particular:
 - the development of standard exposure scenarios and exposure categories for the various supply chains, in collaboration with substance manufacturers, manufacturers of preparations and users of substances.

It should be decided on a case-by-case basis whether the specifications or detailed explanation of the requirements are contained in the text of the regulation itself, in the Annexes included with the regulation or in EU guidelines.¹¹

⁸ An *exposure scenario* is a concept from Annex 1 of the REACH regulation: An exposure scenario is understood to constitute a set of information (statistics, investigations, assumptions) that describes

- how the substance is manufactured (in the case of substances manufactured in the EU) and/or
- how it will be used during the course of its life cycle (example: Processing into paints, application with the paint [including disposal of overspray and cleanser residues], useful life of paint, removal of paint, disposal of old paint)
- which measures are used by manufacturers or importers to limit risk and which risk-reducing measures the manufacturer or importer recommends to end-users.
- Exposure scenarios may be stipulated that are, as necessary, either broad or narrow in their scope.

⁹ The term “exposure category” does not form part of the draft REACH regulation. For the purposes of this project report, it is used as follows: Exposure categories combine types of exposure pathways (skin, inhaled air, mouth, wastewater), frequencies of exposure, levels of exposure and sets of measures to be taken as groups of “comparable exposure”. Particular applications may then be routinely assigned to a particular exposure category, without a) either having to carry out a detailed exposure assessment and b) without any requirement to notify any application-related data with regard to the product chain. The requisite number and level of detail of the exposure categories for the practical implementation of the REACH system has not been clarified.

¹⁰ GLP= Good Laboratory Practice

5.3 Problems and proposals for improved workability

The following proposals to improve the workability of the program were produced during the simulation.¹²

1. Development of simple and more specific means of communication and analysis of exposure in the supply chains (exposure scenarios and/or exposure categories).
2. Development of tools and procedures in order to prevent the need for industrial and commercial users of preparations to produce their own CSAs excessively frequently. Application categories that are sufficiently broadly defined and exposure scenarios and categories, including user-specific protection measures in the safety data sheet, can make a contribution in this regard.
3. Revision and simplification of TGD methodology¹³ for quantitative exposure assessment (and risk assessment) to improve workability for participants in supply chains.
4. Compilation of clear and pragmatic rules in order to reduce the effort involved in the generation of substance data: recognition of existing test data; evaluation of studies; implementation of group assessments; limitation of GLP requirements (with regards to tests upon vertebrates for example) if other quality assurance systems (such as EN 17025 for example) are in force.
5. Creation of format templates and standards for all documents which have to be submitted to the authorities or are used for communication in the supply chains (safety data sheet, exposure scenarios and categories, Chemical Safety Report).
6. Joint development by the authorities of simple rules with regard to the level of detail and structure of registration documentation, in conjunction with the commercial parties involved.
7. Determination of test requirements based upon the estimated likelihood of exposure (expressed by means of exposure categories), in order to adjust the data required to the risks likely to occur in the case of low-volume substances.
8. Possibility for supplying required test data at a later date, should volume thresholds be exceeded in cases where a market requirement for increased volumes of a substance could not have been foreseen (markets with innovation cycles that are short or are dictated by trends).

¹¹ Guidelines can be developed with the direct involvement of commercial entities involved, trades unions and the environmental and consumer associations. They may include the specific framework requirements of the regulations with regard to practical work in individual supply chains.

¹² These are numbered in accordance with the sections of the project report.

¹³ TGD = Technical Guidance Document, method of risk assessment (existing chemicals, new substances and biocides) as agreed by the relevant authorities of the EU Member States, the European Commission and the Scientific Committee of the EU, in accordance with a Guideline.

9. Cut-off criteria for evaluating the use of substances in products (not preparations) indicating the concentration levels and/or application conditions in excess of which the use of a substance in a product no longer has to be taken into account in the Chemical Safety Report of a manufacturer (or importer).
10. The opinions of the various parties involved as to the scope of substance and preparation-related information and access to this information were exchanged with regard to the textile chain and in the form of a thematic workshop.
 - All parties involved were of the unanimous opinion that the safety data sheet (SDS) should be as brief as possible, but should be clear and precise and contain all of the information that the user may require.
 - It was not possible to achieve consensus with regard to other proposals: a) the safety data sheet as a suitable vehicle in which to publish substance and formulation information; b) the communication of quantitative details of formulations of preparations within each chain; c) production and public access to information about the cumulative market volumes of substances and emissions throughout the life cycle.
11. The ongoing obligation to inform in accordance with the current version of Article 30 should be modified so that it does not give rise to a scenario where the user of a preparation is able to request the qualitative breakdown of the recipe from his/her supplier via the registration numbers.
12. The registration of substances classified as hazardous in the central EU database and the publication of this classification may lead to the existence of a number of different classifications for one single substance. It has been suggested that a central EU clearing center be set up to deal with such cases.
13. Information materials, advice and support, training and helpdesks are required in the periods both before and during the introduction of the REACH system, because the current expertise and personnel resources of many small and medium-sized enterprises will not be sufficient to cope with the system.
14. The following issues remained outstanding with regard to the supply chains:
 - How will risk assessments be carried out for preparations?
 - How does a manufacturer of a semi-finished product inform customers about the area of application (the exposure scenario) of the additives (s)he has used (no provision for a safety data sheet)?
 - How are harmful reaction products of reactive components to be taken into account in the Chemical Safety Report?
 - What will be the effect of the differing requirements expected of European product manufacturers in comparison with competitors outside Europe?

5.4 Specific issues

Specific issue 1: Those active in the market believe that it is almost impossible to identify the textile processing materials in imported textile products or semi-finished goods in the manner proposed in the REACH regulation.

Specific issue 2: The particular risks that apply to the companies involved were established during the course of a special survey relating to low volume substances in the textile sectors and part of the paints sector. Proposals for changes to the draft regulation (see also topics 1,2,7), to the necessary implementation tools and measures on a company level will then be made on this basis.

Specific issue 3: The implementation of REACH in the EU will give rise to additional expenses in the textile processing sector. This could have a negative effect on the competitive position of Europe's textile industry on a global world level. The simulation did not set out to quantify these particular effects.

Specific issue 4: One specific area relating to the chemical raw material import trade was examined during the simulation, but not, however, the full range of issues relating to imports. Using a substance from the textiles chain, the REACH system requirements to be met by a trading company importing intermediates (more exacting requirements as a closed system cannot be documented) were compared with those to be met by a processing company which imports its intermediates directly (less exacting requirements as closed system is assumed). An alternative to the discrepancy in requirements made of these two commercial players could not be identified.

Specific issue 5: A workshop was held on the subject of the transparency and confidentiality of information in the context of REACH to discuss the possibilities and limitations of publishing information. Environmental and consumer associations were able to reach agreement with the commercial participants in some areas (general three-way classification of information in accordance with Article 116 of REACH). In other areas, however, (length of the application process for access to information) no agreement was reached. In addition, the environmental and consumer associations pointed out that as it is a substance-related system, it is possible that REACH may reach its limits where it is a matter of improving the provision of information to the public about preparations and products. In this regard, other tools would be required, over and above the REACH system.

Specific issue 6: The REACH requirements and procedures reveal several intersections with numerous substance-related regulations governing consumer protection, employee protection and the protection of the environment. Examples demonstrated anticipated areas of friction, in the context of which the commercial participants and authorities have very different approaches to dealing with potential areas of conflict. With regard to this issue, there is a need for dialog between federal and regional authorities, and in the political arena.

6. Retrospective analysis of methodology and outlook from the point of view of the Project Group (ARGE)

- With hindsight, the **point in time** at which the regional government decided to take the initiative and bring all parties concerned to the table was very appropriate. Sufficient time still remains for improvements to be made to the current draft regulation or for the specific development of implementation tools.
- The simulation has provided concrete evidence of where and why REACH may cause problems. Yet, at the same time, those who participated in the simulation developed proposed solutions for avoiding or at least minimizing **implementation problems**.
- By “thinking through practically” the requirements and processes in the context of the simulation led to a list of **well-founded proposals** for improvement. These proposals concern modifications to the regulation itself, implementation tools required and guidelines which will need to be available before the REACH system is launched, in addition to the necessity for training.
- The selection of the supply chains was **suitable** for a sufficiently **representative** portrayal of the effect mechanisms in the context of REACH registration and the potential areas of difficulty in implementation. **Large companies and SMEs** who manufacture substances, formulate preparations or use preparations in the industrial manufacture of products were represented in the simulation group. Issues of employee protection, consumer protection and environmental protection were also addressed.
- In addition, the simulation facilitated the **development of new networks** to ease co-operation between those active on the market as well as dialog between authorities and companies in the implementation of new requirements. This also includes the acceptance of responsibility by companies.
- Another benefit can be derived from the fact that those involved in the intense debate of a future regulation in the context of a simulation project can **learn** about the viewpoints of the parties involved. This is also a good way by means of which these parties may prepare for their own responsibilities that will be incumbent upon them once the system is implemented.
- The benefits (or opportunities) provided by the REACH system and the possible quantitative and commercial effects were not examined as part of the simulation.

The simulation in North Rhine-Westphalia was limited due to its **focus on a national level**. Problems due to language barriers, different cultural backgrounds and variances between existing regulatory systems with regard to substances could not be identified.

It is advisable that simulation-type projects be carried out on a European level, in parallel to the regulatory process. In this way, it would be possible to review other elements within REACH, such as the pre-registration, the formation of consortia, the detailed evaluation processes and the authorization and restriction of substances, in addition to problems relating to imports.

In addition, the network of parties created by the simulation project in North Rhine-Westphalia should use the experiences it has gained to develop the proposed implementation tools.