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**Testing the REACH procedures<sup>1</sup> in practice  
by authorities and companies  
in North Rhine-Westphalia (Germany)**

Sponsored by the Government of  
North Rhine-Westphalia

**Public Information**

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<sup>1</sup> As proposed by DG ENV and ENT in May 2003 and modified in September 2003.

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## **Background and Objectives of the Project**

In May 2003 the EU Commission published a Consultation Document concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).<sup>2</sup>

This document contains the joint proposal of the Directorate General (DG) Environment and DG Enterprise for a regulation implementing the Commissions "Strategy for a future Chemicals Policy" published in spring 2001 (White Paper).

North Rhine-Westphalia is one of the leading regions for the production of chemicals in Europe. The proposed new EU Chemicals policy will have impacts on all companies manufacturing, importing and using chemicals. Since the publication of the White Paper North Rhine-Westphalia has therefore actively participated in the discussion. The government of North Rhine-Westphalia has welcomed the overall objectives of the new EU Chemicals policy. However, the workability of the system has been seen as a cornerstone in order to secure a well-balanced relation between protecting human health and the environment on the one hand and safeguarding the competitiveness and innovative capacity of the chemical industry on the other hand.

This is 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<sup>3</sup> in September 2003) in practice.

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

The Government of North Rhine-Westphalia launched a tender for contracting an independent consultant to facilitate such test. The successful tenderer OEKOPOL formed a consortium of consultants providing a broad background of many years experience at international level, in mediation processes and of industry and NGO consultation.

The objective of the project is to

- test the workability of the proposed system and identify chances, barriers and open questions in the REACH proposal, seen from the perspective of companies and competent authorities expected to implement the system and
- on this basis develop recommendations for improving the workability of the REACH system and its implementation.

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

<sup>3</sup> In September, a new draft proposal by the two Directorates General was submitted for Commission Interservice Consultation. The relevant changes are explained in footnotes.

The outcome of the process and the recommendations will provide arguments for the legislative process at national and EU level, as appropriate.

The implementation of the REACH system will be tested in four value chains in order to cover the main issues of the proposal. These supply chains are formed by companies mainly located in North Rhine-Westphalia.

## Background

### Political Objectives

The EU Commission sets out seven specific objectives for the development of a new EU chemicals policy:

- protection of human health and the environment against risks related to the production, use and disposal of chemicals
- strengthening the competitiveness of the European chemical industry
- prevention of fragmentation of the internal market due to different national standards on chemicals safety and risk communication
- increased transparency, e.g. on the properties of chemicals existing in the market and the exposure to man and the environment
- integration with international efforts at UN and OECD level, like the Globally Harmonised System (GHS) related to hazard classification and labelling of chemicals and the implementation of the Stockholm Convention on Persistent Organic Pollutants (POP)
- promotion of non-animal testing, for example by defining information requirements which can be met without vertebrate testing or sharing existing data
- conformity with international obligations of the EU under the World Trade Organisation (WTO), related for example to unjustified and/or unfair barriers to the marketing of chemicals

### Main elements of the proposed system

A central element of the new system is the duty of all companies to manufacture, import or use chemical substances in a way that human health (workers and consumers) and the environment are not adversely affected (*Duty of Care*). The system is organized along the value chains down to the final products:

- import and production of single chemical substances

- the production of chemical products, like for example paints or textile dyes (composition of single substances = *preparations*),
- the industrial use of chemicals in manufacture of industrial goods, like for example textiles or cars (*articles*) and the professional (non-industrial) use of preparations, for example wall paints.

## Registration and Evaluation

Within 11 years after entering into force of the regulation (2006), substances manufactured or imported in amounts > 1t/a shall be registered at EU level (new Central EU Agency) based on a set of obligatory information. The phase-in-process will take place in a step-wise manner starting with the substances of a high production volume (> 1000 t/a) and priority substances classified as carcinogenic, mutagenic or toxic to reproduction.

If certain types of information concerning a registered substance are not available, the registrant shall make testing proposals which will be evaluated by the competent authorities within a certain time frame (standard evaluation). In addition to that, the competent authorities may select certain registration dossiers for deeper evaluation (priority evaluation).

The manufacturers are requested to carry out a Chemicals Safety Assessment (CSA) for their products, covering the entire life-cycle of the substances, thus taking into account the manufacturing in the own company, the generic uses of the direct customers and other uses further down the supply chain. The conclusion of the CSA and the subsequent risk management advice have to be compiled in a Chemicals Safety Report (CSR)<sup>4</sup>. The CSR has to include also the relevant information on which such conclusions were based, like e.g. the characterisation of the chemicals' intrinsic properties, the acceptable level of exposure based on (eco)toxicological considerations, and the assumptions related to the conditions of use and the level of exposure. The relevant information in the CSR is forwarded to the down stream user via the Safety Data Sheet (SDS)<sup>5</sup>.

The industrial users or other (non-industrial) professional users of chemicals are obliged to compare their specific use with the use defined in the SDS they received from the supplier<sup>6</sup>. If the user applies the chemical in a way not foreseen by the supplier, he can proceed in various ways:

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<sup>4</sup> New proposal: applies only if volume is 10 t/a or higher; exposure assessment and risk characterisation in the CSR only required for dangerous substances. The CSR is the written documentation of the CSA.

<sup>5</sup> New proposal: replaces the CSR as information transport mechanisms;

<sup>6</sup> New proposal: evaluating the type of use instead of a full down-stream-user risk assessment;

- inform the supplier and ask to include his use the SDS
- adjust his own type of use to the use foreseen by the supplier
- search for a supplier who covers the specific type of use in his Safety Data Sheet
- carry out a *down stream user* chemicals safety assessment under his own responsibility and notify the “unidentified use” to the Central EU Agency

## Authorisation and Restriction

In addition to these registration, evaluation and information mechanisms, REACH includes two instruments to restrict the use of the most hazardous substances by regulatory means. An authorisation will be needed in future for the continued use of substances of very high concern like e.g. mutagenic substances. Restrictions on marketing and use may be imposed on those substances where a risk assessment by the authorities identifies unacceptable risks, taking account of socio-economic factors. Both these elements are not addressed in the framework of the current project.

## Who are the Players

The simulation will be carried out in four value chains. These are

- the chemical finishing of textiles
- the spray painting in repair work of cars
- manufacture of foamed plastic
- electroplating

The authorities directly involved in the evaluation of registration dossiers and testing proposals or in the enforcement work at local level take also part in the simulation.

Each simulation-group focuses the work on a few substances or preparations and certain aspects of the REACH system aiming to derive representative information on some major questions related to REACH. The supply chains basically consist of at least three companies:

- The manufacturer of a chemical preparation for industrial or professional use.
- The producer(s) of one or two compounds in these preparations.
- The industrial or professional user of the preparation.

	Chemical finishing of textile	Spray painting of cars in repair work	Manufacture of foamed plastic	Electroplating
Supplier of intermediates	Intermediates	Solvents Intermediates	to be determined	to be determined
Key substance producer	Producer of optical brightener	Producer of a small quantity substance	To be determined	Surfactant
Other substances of interest	Surfactant	additives, Solvents	additives, foamer, pigments	No
Trader	No	No	No	Yes
Importer	Yes	No	Yes	Yes
Formulator of preparation	Producer of textile finishing product	Producer of paint	Producer of compound (including additives)	Producers of electroplating chemicals
User	Textile finisher	Paint shop	Foam Producer	Electroplater
User			Producer of foamed packaging	
Central EU Agency National CA* Local Authorities	To be clarified BAuA* (+ BfR**) case by case	To be clarified BAuA Case by case	To be clarified UBA** case by case	To be clarified UBA case by case
Target product	Corsetry containing optical brightener	Paint layer on repaired car	Packaging	Plated metal parts
* German Competent Authority: Federal Agency for Occupational Safety and Health (BAuA); ** Federal Institute for Risk Assessment (BfR) and Federal Environment Agency (UBA)				

Other relevant actors in the supply chain have also joined the working groups. Representatives of the German Competent Authority and related Federal Agencies take part in all four groups.

A Steering Group provides advice on the procedures and the issues to be addressed, comments on intermediate results in the different supply chains and is expected to discuss and agree on the documentation of the outcome. It consists of representatives of the involved ministries of North Rhine-Westphalia, industry, the Competent Authority on chemicals, Federal Agencies and NGOs (environment and consumer).

## Rules of the Game

All players act on the basis of a voluntary commitment. During the working process a three-step-approach will be taken:

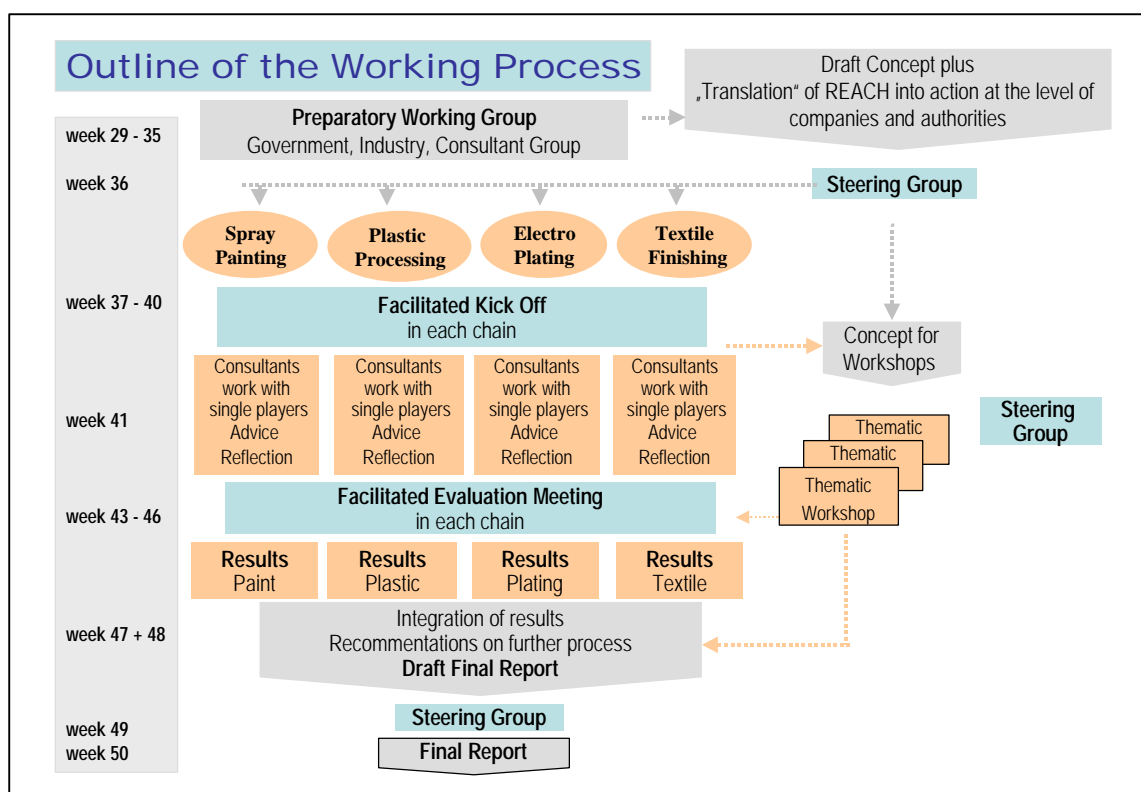
- 1) Developing a common understanding of the factual requirements laid down in the REACH proposal
- 2) Identification of challenges and barriers, and evaluation of efforts needed to meet the requirements

- 3) Working out recommendations how to achieve more practicability and efficiency in the REACH system, based on the experience gained during the simulation

All stakeholders in the project will seek to agree on common recommendations. Where no common view can be found, the different opinions will be documented in a transparent way.

## Time Frame and Organisation

The work has been started after endorsement of the concept by the Steering Group on 3. September 2003. The simulation in the four supply chains will be carried out in different meetings between September and November. In these meetings, selected tasks related to REACH will be discussed, partly carried out and partly “thought through”. The results and conclusions will be published by the end of the year.





## **Procedures and requirements to be tested**

### **Registration**

The registration process and the main requirements related to it will be worked through for one substance in all four supply chains. This also includes an evaluation of certain parts of the registration dossier by the competent authority.

### **Registration of low volume substances**

The selected substances in each of the supply chains are high volume chemicals. In order to include the specific issue of “low volume substances”, a separate information gathering and evaluation process will be carried out in the textile and/or the paint chain.

### **Registration of imported substances**

The selected substances in each of the supply chains are produced in Germany or in the EU. In order to include the specific issue of registration related to imported chemicals by traders, a separate information gathering and evaluation process will be carried out in one of the chains.

### **Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR)**

For at least one substance in each chain a CSA/CSR will be done. Based on the CSA the relevant information will be compiled in a Safety Data Sheet (SDS).

In two chains (spray painting and polymer processing), the requirements related to the CSR (or SDS) for preparations and the evaluation of the SDS at the level of a professional user, which are of particular interest, will be assessed.

### **Communication with suppliers and customers**

How to receive the SDS from the supplier and how to communicate back any questions and possible problems related to the coverage of the use will be part of the interaction among the players.

### **Communication with authorities**

Usually the completeness check is the first action by EU authorities after receiving the dossier. This step will be theoretically discussed during the simulation. The dossier will then be evaluated by the German CA and the Federal Agencies. This may include dossier evaluation (test proposals or compliance of dossier) or substance evaluation.

## **Issues to be discussed in workshops**

Some issues in REACH have been identified as relevant horizontal issues. These will be discussed in workshops taking place in parallel to the supply chain groups.

### **Public information, transparency and business secrets**

The overall objectives of the new chemicals policy is to increase transparency related to the risks of chemicals and to enhance the chemical industry's competitiveness and to promote innovation. These objectives may sometimes be in conflict with each other. In addition, publicly available information and confidential business information are one of the issues discussed among stakeholders. It was therefore considered useful to carry out a multi-stakeholder workshop on this issue in the framework of the current project.

### **REACH requirements and existing down-stream legislation related to chemicals**

The CSA under REACH will lead to conclusions related to acceptable exposure levels. These assessments carried out under the "duty of care" may overlap or be in conflict with requirements laid down in other legislation concerning chemicals, in particular the legislation on occupational health and safety, consumer protection, the protection of the environment or the legislation on food and consumer goods and the legislation on construction material.

So far there is no guidance how to handle this overlap and possible conflicts. In order to illustrate and discuss the issue in more detail, it was decided to carry out a corresponding workshop in the framework of the current project. This workshop will also address the **import of articles**.

## Annex: Project Partners

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### Trade and Industry Partners

German Chemical Industry Association (VCI)

German Association of Plastic Manufacturers (VKE)

German Association of Paint Manufacturers (VDL)

Federation Surface Technology (ZVO)

German Association of Textile Manufacturers

German Association textile-, leather-processing chemicals and surfactants (TEGEWA)

German Association of Chemical Traders (VCH)

### Federal Agencies

Federal Agency for Occupational Health and Safety (BAuA)

Federal Environment Agency (UBA)

Federal Institute for Risk Assessment (BfR)