Final Report on the Research Project

REACH Implementation Support (RIS)

Implementation support for successful risk management within the framework of REACH

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Contents

1 Summary

The objective of the RIS project was to ascertain the specific support needs of companies for implementation of REACH, relating, in particular, to difficulties in communications and co-operation within the product chain. In a subsequent step, it was to be established in which way and by which organizations (e.g. industry associations, public authorities) these needs could be met. Possible interfaces between REACH and existing legislation on installations and the environment had also to be examined and illustrated with the help of case studies. A further project objective was to support (regional) environmental authorities in their preparations for changes initiated by REACH.

A particular feature of the project was that participating companies and industry associations took over a substantial part of the work.[1] This way it was ensured from the beginning that the points of view of those companies and industries targeted by REACH flowed directly into the project. The knowledge gained by the researchers involved formed the basis for recommendations on preparing companies, industries and industrial associations for implementation of REACH.

The RIS project is divided into four operating phases:

- Specific implementation support for individual companies and associations in preparation for REACH were the subject of Work Package 1.
- In Work Package 2, substance assessment for the environment – greatly reduced compared with the requirements of REACH – was carried out on the basis of exemplary substances, and conflicts and synergies with existing sectoral environmental law were demonstrated.
- A start was made within the scope of Work Package 3 on the development of an industry-specific Internet platform, and a glossary as well as a description of REACH requirements was prepared.
- In Work Package 4, representatives of responsible authorities discussed monitoring requirements in connection to REACH and explored the possible use of data generated by REACH within the context of their existing monitoring duties.

2 Project methodology

On the basis of specific terms of reference, support needs for implementation of REACH were identified and discussed with companies and industrial associations. Here, it was not so

[1] The project was carried out by a working group comprising Society for Institutional Analysis (sofia, Darmstadt), Ökopol (Hamburg) and Öko-Institut (Freiburg) in co-operation with the Surface Engineering Association (ZVO as umbrella organization of the surface engineering industry), the North-west German Textile and Clothing Industry Association, the German Textile Finishing Industry Association (TVI), the Textile and Fashion Association, and the TEGEWA Association, as well as different companies from the electroplating and textile industries. The project lasted twelve months (December 2005 to November 2006). The implementation supports evolved during the project are documented on the Internet at www.reach-helpdesk.info, at the same time providing information on existing online services ("a guide to reach-helpdesks").

much a matter of providing extensive documentation or information; the aim was rather to initiate learning processes, to define problems and to jointly develop solution concepts. The project therefore included a large number of workshops and telephone conferences as well as brief interviews and E-mail communications between all participants. The measures drawn up and tested in this project are to be found in German on the project Website: www.reach-helpdesk.info.

3 Specific implementation support for individual companies and industry associations

In Work Package 1, the type and scope of necessary implementation processes for REACH should be identified and estimated regarding chemical substances and co-operation in the galvanic supply chain. At the same time, the main emphasis was on the identification of possible substance-related risks as well as gaps in the knowledge of stakeholders concerning the identity of substances, substance properties and present conditions of use according to the current legal situation.

The determination of this "actual status" in the industry in comparison with the "planned status" under REACH shows needs and gaps in implementation (variance analysis), which have to be closed by stakeholders within a company and at industry level within the framework of REACH, as well as the costs to be expected in this connection. In addition, the 'individual plant' and 'electroplating industry as a whole' levels were considered.

3.1 Industry analysis and inventory of chemical substances used

Initially, the project team compiled general industry information, information on the central industry association (ZVO) as well as data on the market and stakeholders. The networking of specialized associations under the umbrella of the Surface Engineering Association (ZVO) was also described. Information for the industry analysis was obtained through

- the evaluation of documents,
- personal interviews with companies (in their REACH-role as chemical manufacturers, formulators and downstream users).
- a survey of association representatives,
- a survey of those having an expert knowledge of the industry, such as representatives of competent authorities and the trade association and
- discussion of the results with stakeholders in a workshop.

Industry association survey

Since an inventory of chemical substances currently used in the industry[2] was not available, the ZVO conducted a survey of its member companies at the formulator level concerning the substances they supplied (substance portfolio). The information provided by the companies covered the name, CAS number and annual quantity of substances used. This data was depersonalized and aggregated to ensure confidentiality.

[2] The "TEGEWA catalogue" provides the chemicals inventory in the textile production chain.

Guide for initial in-company effect analysis

REACH tasks and obligations are role-specific. In order to help companies to identify their concern a guidance paper and a check list were prepared to identify shortcomings concerning the chemical substances used, technical processes and organizational structure. The check list is role-specific (registrant, formulator or downstream user) and shows why a company should compile certain information and carry out operational steps. With this decision-making support, companies can prioritize their REACH-tasks selectively and efficiently.

3.2 Evaluation of safety data sheets

The aim of this work package was to assess the state of knowledge concerning the properties of substances used in galvanic plating. The project team prepared a check list to analyze safety data sheets (SDS), in which currently-required information on substances and preparations was evaluated as well as information additionally required under REACH. The project team analyzed 20 SDSs for single substances and preparations. It was examined whether the minimum data set of the VCI (Chemical Industry Association) was available and whether information from IUCLID was shown in the SDS. In addition, a comparison was made with data required in safety data sheets under REACH (for substances manufactured or imported in quantities > 1 tonne / year). Where available, technical annexes to safety data sheets were checked for additional information.

The evaluation showed that formal demands on SDSs are largely met. Data on the "identified use" of a substance or preparation, as required in future under REACH, was included only in a few SDSs. The function of substances/preparations was stated only in one case.

The detected shortcomings in safety data sheets primarily concerned the following points:

- Information on risk management measures was generally expressed, and standard texts (standard EDP phrases) were often tailored to the particular substance or preparation. In part, inconsistent statements were made (employee protection / unintended release).
- The safety data sheets showed errors not only with regard to information on first aid, but also to R and S numbers as well as classification in (German) water hazard classes.

The SDSs demonstrated information gaps concerning physical/chemical properties as well as toxicology and ecotoxicology. Available information – for example in IUCLID – was partly neither used nor listed.

Analysis of technical data sheets showed that these include detailed information on application and process conditions and also, in part, on disposal. They can therefore be regarded as an important source of information on conditions of use as well as for the drawing up of exposure scenarios and recommended risk management measures.

4 Substance assessment for the environment

In Work Package 2, the implications of REACH for requirements under sectoral environmental law are described in concrete terms. On the basis of a cursory examination of nine exemplary substances, and the identification of corresponding requirements in existing legislation on water, installations and waste, overlapping and/or conflicts with existing legislation are pointed out. In a subsequent step, respective information and assessment requirements for risk communications under REACH are described in detail.

4.1 Cursory examination of chemical substances

The project team prepared a guidance paper, which describes the individual steps of cursory examination of substance and provides "substance examiners" with specific instructions. The guidance paper does not comprise REACH-conform instructions for the assessment of environmental risks, but rather practical support. Project participants elaborated and proved basic procedures and basic information as well as co-operation requirements in practice. As further support, an explanation of waiving[3] and the calculation of PNECs was prepared.

For the assessment of heavy metals and cyanide a great deal of information on substance properties and, occasionally, concluded risk assessments is already available. Participants mainly used existing safety data sheets and the GESTIS[4] database as sources of information. In rare cases other databases were also used, or there was contact with manufacturers. With the help of the guidance, all companies calculated a predicted no effect concentration (PNEC) for surface waters on the basis of available information.

The best data were available for chromic compounds. On the basis of cursory risk assessment of substances as well as EU risk assessments, the project team deduced conditions of use for an exposure assessment. The example of chromium provided the main questions for the potential general exposure scenario (water pathway only), which was discussed during a workshop with company representatives. The conditions of application for chromatization were abstracted and on this basis a potential general environmental exposure scenario for other relevant metal compounds in surface coating was developed. As expected, substance examination of other metals indicated parallels.

During the course of cursory examination of substances a number of participating companies dealt for the first time in concrete terms with the life cycle of single substances. They acquired a better understanding not only of the principle of safety assessment under REACH, but also of the information demands of their customers.

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3 This explanation is concerned, however, only with how waiving possibilities under REACH are to be understood. No detailed information was provided, since an EU-wide interpretation of the criteria is not yet available.

4 GESTIS: Gefahrstoffinformationssystem): information system on hazardous substances of the employers' liability insurance association. http://www.gefahrstoff-info.de/gdl_gestis/gdl_gestis.htm.

4.2 Legal classification of exemplary substances and industrial practice

The inquiry into the legal classification of exemplary substances pursued three purposes. At first it was a matter of precisely defining the interfaces between the new requirements in REACH and existing sectoral environmental legislation. In accordance with the general project approach, the required information had to be supplied by the companies participating in the project, and only selective supplementary research on legal classification was carried out by the project team. The results of the inquiry flowed into the description of the interface situation (see in this connection the overviews and the evaluation of interfaces).

Beyond that, the survey of the legal situation in sectoral environmental law also makes an indirect contribution to the examination of exposure. Here, three constellations have to be distinguished:

a) It could be that the emission limit values in sectoral Regulations (and the implementing decree) already guarantee that emissions fall short of PNEC values. These emission limit values generally pose no technical problems for registrants or downstream users.

b) In other cases, it might be that the emission-permits (water, air) are regularly based on more stringent values, e.g due to technological progress. The registrant could then reflect this situation in the development of the exposure scenario on these values, provided he disposes of corresponding information.

c) In industrial practice it is often the case that actual emissions remain well below limit values laid down in legislation or emission-permits. In such a case it would be advantageous to reflect the reduced values in the development of the exposure scenario.

Finally, the survey serves familiarization with conventional channels of information and communications in the industry and thus makes a contribution towards RIS Work Package 3.

As a result it has to be emphasized that regulations in sectoral environmental law seldom contain specifications related to individual substances. Heavy metals have an exceptional character due to their well known hazardous properties. Industrial practice mainly concerns with chemicals in preparations, and is used to the task of controlling application processes related to them. On the other hand, REACH initially pursues – just as existing chemicals law – a single-substance approach. In the formulator role both perspectives meet. Up to now the formulator has obviously solved the resulting linkage problem in an additive-mechanistic manner: Single-substance requirements are accumulated – provided irrelevance thresholds do not take effect – in safety data sheets. This will presumably not change fundamentally under REACH, at any rate so long as the great complexity continues to exist, due to the variety of single-substance components. One should bear this problem in mind when called upon to judge the efficiency of the REACH regulation.

Many substances used in galvanic plating are already regulated in detail and – so far as substances examined within the scope of the RIS project are concerned (for example,

chromic compounds[5], nickel) – no serious additional requirements are to be expected under REACH. The varied regulative approach has to be borne in mind, however: Individual requirements in the Annexes to the German Waste Water Regulation include provisions on the pollutant content of process water "before mixing". By contrast, exposure assessment under REACH examines the immission concentration in recipient water bodies and seeks to ensure levels below PNEC.

With regard to organic substances, it is unclear whether more stringent or weaker provisions on emission control will be triggered off by REACH. These substances are generally not subject to substance-specific emission limit values, but rather – if at all – to cumulated sum-parameters. Furthermore, organic substances are frequently contained in preparations for galvanic plating in concentrations that fall short of relevance thresholds. So they do neither require an assessment of substance safety nor an exposure scenario[6] However the question persists whether and in which way PNECs that are derived under REACH will find their way into the enforcement of sectoral environmental legislation.

5 Information, communication and co-operation (IC&C)

The aim of work on elements of IC&C[7] was to "define possible programmatical and organizational structures" of support proposals concerning implementation of REACH. Such proposals should be modular with regard to both its contents and its form of communication. While some support proposals – whether for all REACH addressees or industry-related – can be offered on the Internet, with others direct communication will be necessary.

This Work Package was concerned with identifying, from a bottom-up perspective, relevant obstacles to implementation of REACH, which require particular attention within the scope of an industry's IC&C activities. The obstacles indicated were regarded by practitioners and consultants as typical difficulties. Proposals for avoiding or overcoming them are therefore also applicable in other industries. The technical nature of the IC&C platform makes obstacles more transparent and eases both the exchange of information on further typical difficulties and the shared acquisition of knowledge.

6 Activities at a regional, Laender and federal level

Work Package 4 deals with links between substance related information generated within the REACH mechanisms on the one hand and the enforcement of environmental legislation in the fields of waste, immission control and water on the other. The activities in can be divided into two phases:

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5 Chromic compounds are candidates for authorization, and from that point of view more stringent requirements could arise. It can be expected, however, that due to its indisputable societal benefits the use of chrome in galvanic plating will not necessarily be covered by authorization procedures, or, alternatively, that existing risk management measures will suffice to secure authorization.

6 Irrespective of this, restrictions on use might arise (as under existing EC chemicals law), which would naturally have an effect on water and installations law.

7 Information, communication and co-operation.

1. Discussions with the environment department of the Regional Council[8] in Darmstadt on the practical implications on regional enforcement bodies,
2. Discussions with government representatives at the federal and *Laender* levels on the governance options.

The discussions were conducted in the form of workshops.

Both in waste and water legislation, additional substance-related information with regard to hazardous properties is regarded as supportive of enforcement. In a slightly graded manner this applies also for immission control regulations, including installation safety (enforcement of the Seveso II Directive and the 12 th Federal Immission Control Decree (BImSchV)). With regard to the discharge of pollutants into water bodies, it appeared that in this enforcement area a (single-) substance-related approach was hardly enforceable. The Waste Water Regulation in compliance with Article 7a of the Federal Water Act (WHG) introduced cumulated and effect parameters for waste water, particularly from the chemicals industry, and for a few individual substances of very high concern, which are applied in authorization decisions.

With regard to emission-related requirements (Article 7a WHG), authority representatives pointed out that substances, for which according to the REACH Regulation a water-body-related PNEC is required, should be documented in the waste water register.[9] This way, the authorities could more easily ascertain the possible source water pollution comes from. With immission-related requirements (Article 6 WHG), aquatic PNECs could also be helpful. On this basis, the authorities could specify – where applicable – their environmental quality objectives. There is a need for clarification how consistency could be achieved between environmental quality standards according to water law and PNEC values.

With regard to legislation on industrial installations (IPPC Directive / Federal Immission Control Act (BImSchG)), information gained within the framework of REACH could above all contribute to fulfilling dynamic operator's obligations (basic obligations according to Article 5 (1) BImSchG)[10] and to putting the indeterminate legal terms used in the act into quantified provisions. The effects of REACH on the enforcement of immission control legislation can be made clear with the following exemplary points:[11]

- Determining the PNEC in REACH has an indicative effect for the immission-side exposure threshold = noxiousness threshold.
- In the case of substance- releases during plant operation, the necessity of emission-limiting measures has to be examined. A relevant reference point could be included in exposure scenarios.
- Permission-documents could be supplemented with data on PNEC values and thereby support responsible authorities in their decision-making.

8 Regierungspräsidium.
9 So a proposal for amendment of the Waste Water Regulation and the corresponding annexes.
10 Dynamic obligations of manufacturers and importers of chemical substances relate to Article 22 REACH.
11 See also the contributions at the workshop on 11 October 2006 in Berlin, Annex 32 to the German version of the project report.

As far as substances in installations are concerned ("input perspective"), it would have to be assumed that – in accordance with the principle of the "uniformity of the legal system" – substances whose use is restricted according to Title VIII REACH, or which are not authorized for the application practised in the installation, should also be restricted permissible under immission control law.

Furthermore, the legal position with regard to small installations not subject to permitting according to Article 22 ff. BImSchG[12] needs to be clarified.

7 Activities in the textile product chain

The pilot projects that have been carried out up to now with the participation of industry associations have shown that in-company and industry-wide communications are of great importance. The aim of the complementary "Textile Product Chain" project was to develop specific implementation support for risk management in companies of the textile-finishing sector. Work focused on examining if the use of substances and preparations were covered by the description of safe use in the safety data sheet of the supplier.[13] This examination was carried out in respect of two preparations. The manufacturers of the preparations prepared extended safety data sheets in accordance with REACH,[14] and the finishers checked these for comprehensibility and practicability.

On the basis of exemplary processing, a number of useful components for effective communication of safe use in the textile production chain could be identified, for example:

- The overview of relevant uses in Chapter 1 of the safety data sheet based on tables of use- and exposure-categories.
- Valid substance- and preparation-related data in the safety data sheet (PNECs, data on behaviour in the environment – degradation and dispersion – with the naming of tests).
- A standardized description of typical application situations, similar to the exposure scenario from RIP 3.5.1 (quantitative assumptions on input quantity, recipient water-body situation, typical risk management measures and expected share of losses).
- Uniformly structured risk assessment for standard application on the basis of comprehensible estimation (use of excel file, table with input data).
- Naming of determined permissible input quantity under standard conditions.
- Uniformly structured examination of in-plant application by the textile finisher (for example, with the use of the same excel instrument).
- Standardized communications with the manufacturer / formulator in the case of critical applications. Here in particular, is a need for further trials.

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12 This applies particularly for the EC level, since there are no regulations functionally equivalent to Article 22 ff. BImSchG for installations that do not fall under the IPPC Directive.

13 In contrast to the galvanic plating chain, industry-specific surveys were not carried out for the textile product chain (Work Package 1) due to the lack of time. For the same reason, Work Package 3 (information and communications platform) was developed in the project with the galvanic plating chain, but not with the textile product chain. Here, results for the textile chain were commented on.

14 The extended safety data sheets prepared in the textile project served as internal training material and proved to be very useful. They were not checked for complete compliance with REACH.

For work in the textile project, use was made of both the standard exposure scenario for textiles (from the report of results on phase 1 of RIP 3.1.5) and the model of use- and exposure-categories of the Chemical Industry Association (VCI). Adjustment and supplementation of both approaches were necessary for practical work in the project.

The large number of existing means of communication and information reflected the importance that the exchange of information has in the textile product chain for a long time. Some of these information processes can be attributed to the particular consumer proximity of clothing (labelling on health safety) and cannot be directly applied to other industries. However, what is applicable, is, the principle of communicating preparation-related data by means of the safety data sheet, and on the other hand, the requesting of specific information in a standardized manner through the use of special supplements. The system of product classification, as developed in the catalogue of textile auxiliaries for the textile industry (now available as an online information system at: www.thk-online.com), might be useful in many industrial sectors.

8 Conclusions

The cooperation with companies has clearly shown that plant employees suffer not infrequently from a lack of basic knowledge on the REACH mechanism and its implementation in existing business routines.

Cooperation can only be successful if the respective partners are convinced beforehand that they will each benefit as a result of their efforts, and if they share a common goal. Such "co-operation honesty" is difficult to achieve from outside the group or by legislation.

Stakeholders expect that a great degree of standardization will be laid down and IT tools will be made available for implementation of REACH. New standard phrases are necessary in order to convey the flow of information on substance properties and applications up and down the supply chain. Not only the importance but also the limitations of IT tools became clear during the project. The reduction of complexity stays a challenge for manufacturers / importers and formulators. The task of deducing and describing application conditions and risk management measures, in particular, can only be performed at reasonable costs in a standardized manner.

Industry-wide communication structures exist both in galvanic plating and textile production as a result of the long-standing involvement of the industry associations in environmental protection. But routine processes have not yet been established for the passing on of information "up the supply chain". There is still a great need for agreement regarding a common "REACH language" on substance-related risks.

Important information on the safe handling of hazardous substances is often available at different sections in companies, but information exchange is neither technically nor organizationally integrated. Product safety and customer services departments are generally linked to support the introduction of new products or to solve process control problems for customers (chance management). But the resultant knowledge on customer application

conditions is rarely made available for industrial safety and environmental protection assessment (risk management).

As far as the range of substances is concerned, data maintenance is carried out in companies not only in the purchasing department, but also in the other departments as product safety (In case of small and medium sized enterprises, often no specific departments exist). Varied database structures exist in the different departments. This makes it technically difficult to run simple inquiries into quantities per year, origin, classification and use. However, such an overview is an important prerequisite under REACH, and for an efficient implementation of the REACH requirements.

All in all, it has become clear that co-operation both within a company and between companies is essential for the implementation of REACH. However, co-operation requires time and also readiness to involve in the appropriate processes. Technical guidance and support as well as a REACH Internet platform for industry associations could save both money and time. It would also be useful to publicize typical obstacles, in order to avoid mistakes wherever possible.

In future, additional information on substance properties and safe use conditions has to be prepared and communicated up and down the supply chain. Such information has to be structured and processed at reasonable costs. The involvement of industry associations in the promotion and structuring of co-operation assignments and objectives within the respective industry seems absolutely essential.

In future the safety data sheet and the exposure scenario will assume greater importance in the sale of chemical products. New, varied routines will have to be established in companies that ensure the capacity to fulfil their substance stewardship under REACH. In particular standard tools have to be developed that support self-responsibility for decision, communication and action[15].

During the project, a considerable need for clarification has been identified concerning the degree of control that should be exercised in future by the authorities and the precise tasks that will remain the responsibility of companies. It became clear, however, that control under REACH could not be exercised through the mere perusal of checklists.

[15] The implication has also to be clarified when in future the SDS/ES for electrolytes to be inserted into an acid solution states: "not to be brought into contact with acid".