The REACH Project

A Survey of Companies in Baden-Württemberg

Baden-Württemberg
MINISTERIUM FÜR UMWELT UND VERKEHR

LfU

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The Baden-Württemberg REACH Project

Assessment of the Impact of the new European Chemical Policy on Production, Innovation and Competitiveness in Baden-Württemberg

- A Survey of Companies in the Chemicals Industry -

October 2004

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1. Summary

The proposal of the European Commission on 29.10.2003 - in respect of a Directive for the "Registration, Evaluation and Authorisation of Chemicals (REACH)[1]" - has been forwarded to the European Parliament and EU's Council of Ministers, awaiting a decision.

This proposal has been criticised by various parties, representing opposite standpoints, and ways in which it could be improved have been suggested.

The government of Baden-Württemberg recognizes the necessity for changes in the chemicals policy in Europe and therefore supports the aims of REACH. However, it views the effects of the current proposal as being insufficiently thought-out– especially its impact on small and medium-sized enterprises (SMEs). The government of Baden-Württemberg has therefore initiated a study to investigate the possible impact of the implementation of the proposal and discuss the outcome. Various bodies were involved in the design of the study, including the Verband der Chemischen Industrie, (VCI) [Association of the German Chemical Industry], Landesverband Baden-Württemberg [Baden-Württemberg Association] and the Industrie- und Handelskammertag Baden-Württemberg (BWIHK) [Chamber of Industry and Commerce for Baden-Württemberg], as well as the Ministerium für Umwelt und Verkehr Baden-Württemberg (UVM) [Ministry for the Environment and Transport of Baden-Württemberg]. The project was co-ordinated and implemented by the Landesanstalt für Umweltschutz Baden-Württemberg (LfU) [Baden-Württemberg Institute for Environmental Protection].

This study focuses on the possible effects of the implementation of the REACH proposal on trade and industry companies in Baden-Württemberg. Any possible impact on the protection of the environment, employee health and general health were not investigated.

A total of 18 companies in Baden-Württemberg from different sectors were interviewed both in writing and face-to-face. The consequences of the REACH proposal feared by the companies were illustrated using concrete examples. The Landesanstalt für Umweltschutz carried out plausibility checks on the data, in so far as possible.

The most important of the effects of the REACH proposal and the major criticisms are given below:

- The registration procedure is too complex and bureaucratic. It is too challenging for SMEs in particular.
- The withdrawal of substances from the market, the costs associated with registration and the commitment of human resources for registration all impede innovation.
- Imported products will be preferred over products manufactured in the EU. Non-EU manufacturers have advantages over those in the EU and can circumvent the requirements of the REACH proposals.
- The time-consuming registration process will cause considerable problems for sectors with short innovation cycles since they need to respond quickly to short-term market requirements.
- The cost of data capture for substance properties and exposure for the registration dossier are too high.

[1] Internet: http://europa.eu.int/eur-lex/de/com/pdf/2003/com2003_0644de.html

- Equal treatment of companies within the scope of the REACH proposal is not sufficiently ensured. A national evaluation of the dossier and differences in the implementation of REACH within the EU Member States could be a disadvantage for some companies.
- It is not possible to use all existing data, because the criteria for the recognition of data already provided have not been established to a satisfactory degree.
- The data that has to be provided is too comprehensive and, in part, unnecessary since the exposure situation, in particular, has not been sufficiently taken into consideration.
- Substances may no longer be available, either because of the high registration costs, or because they are prohibited. Entire product lines may be removed from the market or their production switched elsewhere.
- Substance data that is already available must be recognised.
- Overlaps with other regulations governing substances increase the work involved and make an overview more difficult for companies.
- The cartel legislation and know-how protection are impediments to substance registration through consortia.

Overall, the companies fear a weakening of the position of Europe as an industrial site and a negative impact on their competitiveness compared to companies from outside Europe. The medium-sized enterprises that are typical for Baden-Württemberg have specialised in innovative, high-quality products, often produced in small quantities and many varieties. They have to react quickly and flexibly to market requirements and are therefore considerably affected by the requirements of the REACH proposal. 67 % of the companies surveyed expected increased costs and reduced profits and believe that the financial costs will be too high. In addition, 39 % of those surveyed believe that there will be a reduction in the variety of products as a result of some substances no longer being available. The current discussion of REACH has led to considerable uncertainty for many companies – who have cut back on investment to a great extent.
The proposed procedure is regarded as a substantial hindrance to investment. They regard a revision of the REACH proposal – to simplify it and reduce associated costs – as absolutely essential.

The criticism of its complexity and the expected difficulties in the implementation of the proposal, the increased costs and the possible disadvantages in terms of international competitiveness, is understandable. For know-how protection and cartel legislation reasons, 61% of the companies surveyed saw no way in which costs could be reduced through the formation of consortia. 17 % saw only limited possibilities for the setting-up of consortia. However, 78 % of those surveyed saw ways in which costs could be reduced and in which the registration procedure could be simplified, and some of them made detailed proposals.

The information provided by the companies was used to derive recommendations that the Landesanstalt für Umweltschutz believes the European Commission should consider and investigate. The most important of these are:

- **Simplification and cost reduction through the use of the model "One substance – one registration"**

  An institution – independent of any country or companies – under the guidance of the EU handles registration centrally, so that identical substances only have to be registered once. All substances from all companies must be notified, with production quantities, within a specified time frame. The institution ensures that the confidentiality of the corporate data is maintained. The necessary studies would be initiated after sifting through existing data. The institution will decide on the cost allocation between different companies that produce the same substance. This approach goes beyond the proposal of Hungary/the UK[2]. The special requirements of SMEs must, however, be taken into consideration in both models.

- **Reduction of the registration work through a basic chemical database**

  The registration of substances, in conjunction with the VCI basic chemical database, could serve as a first step in the implementation of registration and would involve the participants in a positive way. However, it must be clarified whether the (eco) toxicological investigations using this database are sufficient for a fundamental toxicological assessment of a substance.

  With higher production/import quantities, and with corresponding exposure situations, an appropriate expansion of the VCI basic data record following a decision by the central chemical agency, would be necessary. In such cases, application-specific exposure scenarios could also be taken into consideration.

- **Simplification of exposure assessment**

  Simplification of the exposure assessment is necessary – possible through a collation of groups of exposure scenarios or exposure categories. The definition of usage should be widened and the grouping of similar applications into groups of exposure scenarios should be simplified. The proposal to use exposure categories (Model of VCI / Ökoinstitut Freiburg)[3] should be investigated by the European Commission.

  A simplification of the exposure assessment should take the following points into consideration:

  - The reporting of uses of the chemicals for manufacturing must be simplified / summarized without revealing the specific application.
  - Possible exposures must be typified in summary form. The summary of exposure situations (whether they are to be designated as exposure scenario or exposure category) is to be provided for similar substances / substance groups.

[2] One Substance – One Registration: a joint proposal from Hungary and UK (Non-paper of the EU, 2004)
[3] Endbericht zum Projekt "Produktkette Chemikalienpolitik": Anforderungen, Erfahrungen und Perspektiven für den Informationsfluss in der Produktkette, Ökoinstitut e.V. Freiburg (2002). [Final Report on the project "Product Chain Chemicals Policies – Requirements, experience and perspectives for information flow in the product chain, Freiburg Ecological Institute, 2002]

- **Further development of the Safety Data Sheet instead of system change**

  The forwarding of information within the product chain should be ensured through a uniform Safety Data Sheet, a method of identifying hazards now widely adopted. The uniform implementation of the SDS throughout the EU – and its further development in qualitative terms - should be driven forwards with corresponding safety evaluation and not endangered through a novel complex Chemical Safety Report (CSR).

- **Harmonisation of legal aspects within the EU and on an international level**

  The envisaged European Chemical Policy must be accompanied by efforts to harmonise the legal framework on an international level, to prevent disadvantages for global environmental and health protection and the economy of European countries. Duplicate regulations within the EU should be removed.

- **Measures to implement the REACH proposal uniformly throughout Europe**

  The dossier should be evaluated by a chemicals agency on a European level rather than a national one to ensure equal treatment. Implementation should be safeguarded through reviews of the execution by the national administrations and a regular evaluation at the EU level, similarly to the Equipment and Product Safety Act. The decisions on matters that require interpretation should be made at a European level.

- **Creation of a level playing field for domestic and imported products**

  Article 6 should be revised and accompanied by international harmonisation of legal requirements to ensure that imported finished products are not favoured over EU products that have been manufactured under the REACH.

- **Cost reduction through recognition of appropriate existing data on physicochemical and toxicological characteristics**

  To avoid unnecessary new and costly studies, Article 12 and Annex IX should be supplemented in respect of the recognition of existing substance data so that the quality criteria for such recognition are specified explicitly.

- **Review of the necessity for registration of certain substances and simplification of registration through group registration**

  It should be investigated to what extent substances that are covered by other legislation, or which have a low danger potential, can be excluded from the registration process, and whether group registration is possible for similar substances. Examples here are pigments, process chemicals, sintering materials, metals and alloys, naturally-occurring substances, ores and concentrates (enriched ores).

➢ **Support for the registration work**

Irrespective of the essential need for revision and simplification of the REACH proposal, it is considered important for SMEs to be given competent advice in the registration process and assistance where necessary.

2. The Project

On 29.10.2003 the EU Commission forwarded a draft proposal for a new chemicals policy "Registration, Evaluation and Authorisation of Chemicals (REACH)[4]" to the European Parliament and the EU's Council of Ministers for adoption under the co-decision procedure.

This proposal represents the interim culmination of a process that has lasted more than 30 years, with the aim of incrementally extending the statutory controls of chemical substances and transferring that control to a regulatory framework that covers all of the EU. This proposal is based on an assessment by the EU that data available for the 100,000 or so chemicals currently on the market in Europe is insufficient to allow the primary goal of sustainable development. The attempts to date to use the existing statutory instruments to obtain this required information have failed for various reasons. Of the 30,000 existing substances that are produced in quantities > 1 t/a, 140 have been classified as priority substances. A risk assessment has only been provided for approx. 30 existing substances over the last 10 years.

The REACH proposal document was drafted following the development of a strategy for a future chemicals policy, a preliminary draft of the proposal and an Internet-based consultation process, in which approximately 6,000 opinions were expressed.

The aims that are to be met by the REACH system were specified in the White Paper of the European Commission "Strategy for a future Chemicals Policy" (KOM(2001)88):

- The protection of human health and the environment
- Maintenance and enhancement of competitiveness of the EU chemicals industry
- Prevention of fragmentation of the internal market
- Increased transparency
- Integration with international efforts
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO

The chemical industry is the 3rd largest industrial sector in Europe – employing approx. 1.7 million employees directly and with a further 3 million jobs dependent on it. The industry expressed considerable criticism in response to the first draft. It doubts whether the proposal can be implemented and fears that the costs associated with registration will put the European chemical industry at a disadvantage compared to its competitors elsewhere in the world. Although the present draft contains numerous changes as a result of the consultation process, criticism and desires for change have still been expressed from interested parties on various sides.

[4] Internet: http://europa.eu.int/eur-lex/de/com/pdf/2003/com2003_0644de.html

Baden-Württemberg has approximately 100,000 employees in the chemical industry – it ranks No. 3 in Germany. Here too, fears have been expressed that the REACH system cannot be implemented in the proposed form and is a threat to the chemical industry. Approx. 500 companies in the chemical industry achieve a turnover of €25 billion, 50 % of which is for exports throughout the world. 90 % of these companies are medium sized enterprises that are typical for Baden-Württemberg, each with less than 500 employees. The REACH system will not only have an impact on the chemical industry, but also on all branches of the processing sector in which chemicals or preparations are used. Baden-Württemberg has a wide variety of companies that, in many cases, occupy a niche market. These companies in particular are very concerned that it will be almost impossible for them to meet the requirements of the REACH proposal and that their survival is threatened by the costs.

To date, the possible impact of the REACH system has only been investigated in a few special sectors along selected value addition chains. It is therefore desirable to investigate the possible effects of the REACH system on a wide number of small and medium sized enterprises (SMEs) across a broad range of manufacturing sectors and to make recommendations on how the REACH system could be improved.

The Ministerium für Umwelt und Verkehr Baden-Württemberg decided that further investigation of the impact of the REACH proposal was warranted and commissioned the study documented herein. The Landtag of Baden-Württemberg, issued a statement on 11.03.2004, in which its members declared: "The Landesregierung is requested, before conclusion of the legal process, to investigate the impact of the REACH system on the SMEs in Baden-Württemberg and to work towards integration of the data derived in the process into the final regulations.“

The Ministerium für Umwelt und Verkehr entrusted project management to the Landesanstalt für Umweltschutz, together with the Verband der Chemischen Industrie (VCI), the Landesverband Baden-Württemberg and the Industrie- und Handelskammertag Baden-Württemberg (BWIHK). The aims of the project were

- to establish the actual amount of work involved in the registration of substances under the REACH system, using actual products, and to compare this to the procedure in place at present
- to establish the possible impact of the implementation of the REACH proposal from the perspective of the companies
- to investigate aspects of the proposal that have not been considered to date, and
- to draft recommendations to simplify and improve the REACH system from the assessments of the companies.

The activities of 18 different manufacturing companies were considered in the Baden-Württemberg REACH project. These companies were put forward by the Verband der Chemischen Industrie, the Landesverband Baden-Württemberg and the Industrie- und Handelskammertag Baden-Württemberg. Questions were asked about very varied aspects of the REACH proposal using a comprehensive questionnaire developed by the Landesanstalt für Umweltschutz. The plausibility of the data provided by the companies was investigated by the LfU, in so far as possible, and an interview conducted with each company.

The study will therefore provide a basis for further discussion and an improvement of the REACH proposal before political decisions are made.

A report on the progress made is scheduled for 14.10.2004, and a political debate on that report in the European Council is scheduled for 20.12.2004. The first reading of the REACH proposal within the European Parliament is not likely to take place before the end of 2004. The European Commission and the Council of Ministers are expected to publish their joint standpoint in the second half of 2005.

3. The participating companies

A total of 18 companies participated in the Baden-Württemberg REACH project, drawn from a variety of sectors. The companies varied in size from a company with just 10 employees up to a global company with over 360,000 employees. They included classical manufacturers of chemical raw materials, through manufacturers of preparations, to users. The sectors represented included the automotive industry, the chemical industry and the metal and plastics industries. The companies have a combined turnover of €130 billion and a total workforce in Germany of more than 96,000.

The Landesanstalt für Umweltschutz would like to extend its thanks to all the companies involved for their commitment and constructive comments.

The 18 companies are manufacturers, processors, users or importers of chemicals and between them manufacture more than 100,000 items for sale, including more than 3,000 substances, 15,000 preparations and 83,000 products. In addition, some 91,000 substances and 3,000 preparations are imported from outside of the EU. All of the companies in the survey compete with other companies around the world.

The majority of these products will be affected directly by the registration process or by the reporting of uses under the REACH system. Of the 18 companies, 14 expect that they will have to register their products as the manufacturer or importer and 13 expect that they will have to draft substance safety reports as users. It can be seen from the figures for the manufactured substances, preparations and products that the companies will face a considerable burden in having to establish which REACH requirements will apply to them in each individual case.

The companies are listed below in sequence, commencing with the company with the lowest number of employees (in Baden-Württemberg).

Sector	Company	Activities	Product
Electroplating	International Plating Technologies GmbH (IPT)	Exporter and downstream user	Al Clean
Metal processing industry	Silit - Werke GmbH & Co.KG	Manufacturer, importer, exporter and downstream user	Enamel frits
Chemicals	Brüggemann Chemical KG	Manufacturer, importer, exporter and downstream user	Brüggolit
Chemicals / pharmaceuticals	IG Sprühtechnik GmbH & Co. KG	Manufacturer, importer, exporter and downstream user	HL-Ketten-Haftspray
Chemicals	Sigma-Aldrich Produk-tions GmbH	Manufacturer, importer, exporter	Guanidine thiocyanate
Metal / plastic processing	BLANCO GmbH + Co KG	Manufacturer, importer, exporter and downstream user	Silgranit sinks
Metal processing	NEOPERL GmbH	Manufacturer and downstream user	Perlator® aerators
Precious metal processing	Wieland Dental + Tech-nik GmbH & Co. KG	Manufacturer, exporter and downstream user	Gold
Fluid technology	ARGO-HYTOS GmbH	Downstream user	Filters for hydraulic oils
Printing inks and creative inks	Marabuwerke GmbH & Co KG	Manufacturer, importer, exporter and downstream user	Marastar SR
Textile industry	Gütermann AG	Downstream user	Sewing thread
Chemicals	Rheinchemie Rheinau GmbH	Manufacturer, importer, exporter and downstream user	Additin RC 9200
Manufacture of textile auxiliaries	CHT R. Beitlich GmbH	Manufacturer, importer, exporter and downstream user	Tubingal CPJ
Chemicals	Ciba Spezialitätenche-mie Lampertheim GmbH	Manufacturer, importer, exporter and downstream user	Ciba® Cromophtal® Gelb 2RLTS
Plastics	Konrad Hornschuch AG	Manufacturer, importer, exporter and downstream user	tp-print
Metal processing (fittings for the building industry)	Gretsch-Unitas GmbH	Importer, exporter and downstream user	Window and door fittings
Sealing and adhesive substances industrial users	Sika Deutschland GmbH	Manufacturer, importer, exporter and downstream user	Special adhesive for repair glazings
Automotive industry	DaimlerChrysler AG	importer, exporter and downstream user	Automotive repair glazings

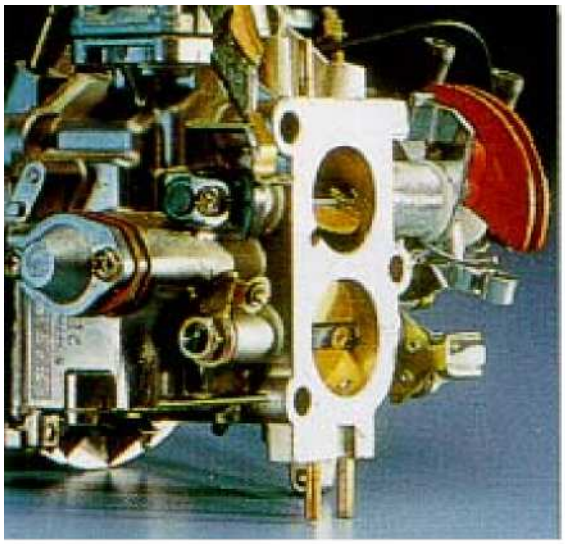
4. Impact of the REACH proposal – Case studies

The 18 companies are profiled in the following pages, with the focus on a typical product from each company[5]. The product is taken as an example to show the expected impact of the REACH proposal of 23.10.2003. In addition, each company was given the opportunity of specifying additional problems they anticipate under the REACH system and asked to provide solutions.

The data presented is the result of written responses and face-to-face interviews carried out by employees of the Landesanstalt für Umweltschutz. They represent the views of the companies.

[5] The term "Product" may be defined as a substance, a preparation or an object depending on how it is viewed from a chemical law perspective. To assist comprehension, the product manufactured by the companies is named and then explained in the following description whether it is a substance, preparation or product.

The Product: "Al Clean"



Al Clean is an alkaline preparation developed by IPT that is an irritant if in contact with the eyes (Xi). It is used to prepare surfaces that are to be electroplated in quantities between 10 and 100 tonnes annually. The surface treatment is used to remove grease and film rust and prevent corrosion of the surface of high-performance engines (including Formula 1 engines). Combined with subsequent electroplating of the surfaces of the cylinders of aluminium engines, it dramatically improves the properties of the inner surfaces of the cylinders. Its use allows modern high-performance engines to attain piston speeds of up to 40 m/s, compared to a maximum value of 20 m/s for uncoated engine blocks.

The Company: IPT GmbH

IPT GmbH is a specialist company in the field of surface engineering with a workforce of 10. It develops innovative solutions to problems in the field of electroplating. This SME offers a range of services, extending from the design and delivery of processes and preparations (basic chemicals) through to equipment for the electroplating of surfaces. Equipment is manufactured and preparations formulated to meet the requirements of the customer via sub-contractors that have to demonstrate that quality assurance requirements are met. A total of over 720 preparations are available for this.
IPT GmbH must be able to react flexibly to the wishes of customers and bring its products to market quickly. Its financial success is primarily based on its special expertise in the formulation and use of special preparations for the electroplating of surfaces to meet the needs of its customers.

The problems from the perspective of the company:

- The company is concerned that the present constituents of the product will be classified differently or no longer registered because of the low volume of their use and therefore no longer be available. The consequence of this would be time delays and a time-consuming search for substitutes. These could endanger the existence of enterprises that need to respond to customer demands with a rapid access to market – especially as the users of electroplating surface treatment (engine developers) generally have to go through a laborious approval process.
- The costs of substance safety evaluation by the downstream user (small and medium sized enterprises, in most cases with special applications) would be substantial given that there are 720 preparations (costs too high). Alternatively, the costs would have to be passed on to those buying their products.

- The strength of the company lies in its expertise within the electroplating sector – it has decided not to apply for patent protection to avoid disclosure of its trade secrets. This advantage could be lost in the course of product registration under REACH (downstream usage) and thus allow other companies to use the technology, threatening the survival of IPT.
- The company uses contract manufacturers for the manufacture of special preparations – a common approach for the electroplating sector. The delineation of responsibilities in a contract-awarder – contractor relationship is not clear to the company for REACH registration.
- The company fears that the costs associated with use-related registration would be disproportionate and lead to an unacceptable time loss for innovations (changes to the formulation). The company states that the total costs for the registration of the substances in question in the preparations would rise from a current 47 working days to 250 working days and the costs for drafting of the Chemical Safety Reports (CSR) is estimated at 170 working days.
- The suppliers of basic chemicals in general at present refuse to issue a statement on accepting responsibility for use-related registration, so that downstream users are unable to assess the situation.
- The company has expressed an urgent desire for clear regulations and feasible solutions for SMEs as these are not generally global players and do not have the resources to switch production to other countries.

Solutions proposed by the company:

The company is a downstream user in the classical sense and awards the manufacture of special preparations to sub-contractors and sells the overall concept. The responsibilities and cost distribution for the manufacture of preparations (within the sense of REACH) is governed by private law (contract-awarder : contractor relationship) for contract manufacture.
The time delay for the use-related registration of chemical substances and the problems of finding substitutes if special chemicals are no longer available appear to be particularly critical here. The requirements for the notification of all special uses downstream (in this case niche uses requiring specialist knowledge) substantially exceeds the capabilities of SMEs.
To protect its know-how, a downstream user will not be prepared to disclose details of its niche use to the manufacturer of the basic chemicals. The manufacturer of basic chemicals will only include a special use in the registration is this is financially viable – the number of special uses is therefore likely to be drastically limited.

- The requirements that downstream users have to meet must be simplified or presented in summary form (without disclosing the special use).
- The registration of downstream uses (if not covered by the substance manufacturer) is too onerous for SMEs in terms of the substance data required and the cost – especially where there are a wide variety of substances in special preparations. The national registration authorities should provide advice on the registration process and take on the administrative workload.
- The workload required under the REACH system and the costs need to be reduced to ensure that the starting materials continue to be available.

The Product: Enamel frits

The enamel frit is an existing substance without danger label that comprises quartz, borax, feldspar and approx. 60 other raw materials that is melted at over 1200 ºC in a rotary-kiln furnace and then quenched in water. Water, clay and colouring are added to this enamel frit material, it is ground and applied to steel pots that are fired at approx. 880 ºC. This yields enamelled pots and pans that have corrosion-resistant surfaces with substantial colour stability and resistance to high temperatures. Enamelled pots that do not leak any nickel into their contents are particularly used by people with an allergy to nickel.

The Company: Silit-Werke GmbH & Co. KG

This medium-sized enterprise has approximately 230 employees, of which around 110 are based in Baden-Württemberg, in the manufacture of enamelled cookware. The company currently has 57 different enamel formulations used to provide different surface qualities and colour shades for a range of approx. 500 different saucepans and frying pans. The company produces a total of 10 - 100 t/a of enamel frit (of which 15 enamel frit formulations lie in the range 1 – 10 t/a). These formulations are resistant to chromic acid as a result of the process used and are used exclusively for enamel production on site. The company relies to a considerable degree on being able to react flexibly to the wishes of customers and on innovations in surface enamelling. There is very considerable competition in the market for cookware that is durable (particularly from the Far East). Cost increases cannot therefore be passed on to customers.

The problems from the perspective of the company:

- On the basis of data available at present (communication of the Bundesanstalt für Arbeitsschutz and Arbeitsmedizin [Federal Office for Occupational Health and Medicine]) this company will have to register 15 enamel frit formulations (manufactured in the range 1 – 10 t/a). Furthermore, an additional demanding approval procedure will be required for the additives (several metal oxides) for this downstream use. Such a procedure would overstretch the capabilities of this a company.
- The magnitude of the possible interpretations of REACH is evident in this case. Although such enamel frits are entered in the register of existing substances as a single substance, in the view of the German registration authorities, 15 substances would have to be registered.
- The company additionally fears that registration of the enamel frit formulations would bring a greater administrative burden and markedly increased costs. These costs could not be passed on in the current highly competitive market for durable cookware.

- The restrictions that result from the use of the above substances will have a substantial adverse impact on the ability of the company to be innovative and the speed of innovation in the development of enamel frits.
- The company cannot disclose the special enamel frit formulations to the manufacturers of the raw materials for them to carry out registration for this downstream usage because of the need to maintain confidentiality. The development, manufacture and usage of enamel frit formulations that are resistant to chromic acid gives the company a major advantage over its competitors. It has not applied for any patents to date to avoid disclosing the data.
- It will be very easy to import enamelled cookware from countries outside of the EU that do not have any registration requirements for enamel formulations since they do not as a rule release substances provided that they are used correctly. The sintering process used with enamelled products rules out any dangers for human health or the environment. The company therefore views a registration of the enamel frit as unnecessary and bureaucratic, impacting adversely on competitiveness.
- The company does not see any need for further regulations as the existing national ones (e.g., those governing emissions, wastewater, solid waste, occupational health and food and utilitarian objects) are sufficient.

Solutions proposed by the company:

Enamel frit is considered to be an existing substance in the EINECS database of the EU, placed on the market before 1981 (EINECS No.: 266-047-6). The example given here only illustrates the use of enamel frits for cookware – but they are also used for the enamelling of bathtubs, ovens, the housings of washing machines and road signs. It should therefore be remembered that very large quantities of such vitreous enamel are manufactured and used within the EU.

- Its high resistance to corrosion and its low solubility in water mean that it is necessary to investigate whether such substances can be excluded from the registration requirement in general since the sintering process causes any substances that could be hazardous to health to be fixed in all enamel frit formulations.
- Since a large number of enamel frit formulations are used in practice, it needs to be clarified whether all enamel frit formulations are to be considered as a group of substances or a single substance. All enamel frit formulations fall under a single EINECS number at present.
- It must be ensured that REACH is implemented uniformly within the EU.

The Product: "Brüggolit"

The product selected for this company is the substance sodium formaldehyde sulphoxylate (SFS), used as a reducing agent in many industrial applications. Once it has been used, its presence can no longer be demonstrated, i.e., it is a process chemical. Brüggolit is produced in quantities in excess of 1000 t/a. SFS is also produced by manufacturers outside of Europe, but in some cases has various contaminants (zinc, iron, sodium sulphite, sodium hydroxymethane sulphonate and sodium sulphate). Brüggolit is used in many applications – such as the manufacture of high-value textiles by the discharge printing process (ties, curtains, upholstery covers etc.), for the polymerisation of adhesives, tyres and plastic profiles, through to usage in dispersion paints, toothpaste and infusion solutions.

The Company: Brüggemann Chemical KG

The company is a medium-sized enterprise in the chemical industry, manufacturing basic, industrial and speciality chemicals, founded in 1868, with approx. 140 employees. These speciality chemicals (including additives and catalysts) are developed, manufactured and marketed in close co-operation with members of the rubber, textile, paper and plastics industries. The company produces a number of substances, some of them in high annual quantities (3 substances > 1000 t/a, 10 substances between 100 and 1,000 t/a and 2 substances between 10 and 100 t/a) and would have a registration obligation under the REACH system. The number of preparations manufactured with the substances is just under 100. It generally takes approximately 2 months to change a formulation – the ability to react quickly to the changing needs of customers is a major factor in the speciality chemicals sector.

The problems from the perspective of the company:

- The company makes it clear that the REACH system would bring about a distortion of competition to the detriment of medium-sized enterprises that produce chemicals on a large scale in Germany (especially substances > 1,000 tonnes/annum). Asiatic producers would still be able to export such chemicals to the EU in quantities > 1000 t/a via distributors (currently approx. 60), with each distributor handling up to 1000 t/a. Since the distributors would bear responsibility for registration in those cases, the complex registration obligations would initially be circumvented (transition period of 6 years / reduced data volume). Following preparation of the required REACH registration dossier for chemicals manufactured in such large volumes by domestic producers (transition period 3 years), the competitors from abroad could then use the data made available (possibly without incurring any costs) resulting in a subvention of direct competitors from outside the EU. It is necessary to avoid distortion of competition through uniform time frames and fair cost allocation between all suppliers.

- A complex registration process for such reducing agents (process chemicals) is not meaningful since the substance is fully reacted during the process and is not present in the product. The manufactured products cannot have any impact on the user / environment through such process chemicals. A reduced testing programme (relative to the manufacturing process) would therefore be sufficient here. A risk-based evaluation approach for process chemicals (occupational health) is regarded as appropriate here.
- A further problem with chemicals of different origin, manufactured both inside and outside of the EU, is their quality at the time of sale. SFS produced cheaply in the Far East contains markedly higher concentrations of heavy metal impurities such as zinc, possibly giving them other (eco)toxicological properties. Testing of individual substances without an exact specification basis appears questionable.
- Co-operation with competitors to jointly prepare registration documentation (especially with competitors from outside the EU) is regarded as “impossible”. Quite aside from the need to protect confidential know-how, this would violate national/European antitrust legislation.
- Since there are presently preparations on an international level to introduce “globally harmonized systems for the classification and labelling of chemicals” (GHS), the implementation of the REACH system within the EU must take this into consideration. The REACH system is regarded as counter-productive and would be an excessive burden on SMEs if this is not taken into consideration.
- The company believes that test data obtained in the past, of sufficient quality as shown by general usage in the field, or by a comparable quality management system (with or without GLP), is generally possible.
- The risk-related approach of downstream use (not a quantity-related approach) by taking into consideration exposure categories with a wide range of applications (industrial, trade, private usage) as far as possible is regarded as practicable. On the basis of practical experience to date, sector-specific and narrowly-defined exposure scenarios for the registration of downstream applications, will fail.

Solutions proposed by the company:

The company, as a manufacturer of chemicals, has experience in the registration of new substances and is in a position to reliably estimate the testing and registration work that will be required.

- All of the afore-mentioned problems for manufacturers of chemicals within the EU have a background that is very close to reality with financial consequences in EU Member States and should be appropriately taken into consideration in the ongoing REACH discussions.
- Products from the “low-level states“ must not be favoured by the REACH system.

The Product: "HL-Ketten-Haftfett" spray

The product "Hochleistungs-Haftfett" spray, provided in 500 ml spray cans, is used as a long-lasting lubricant in the automotive and allied industries. Its uses include the lubrication of gearboxes, worm gears, ball bearings, hinges, door locks, bicycle chains, cables etc. It can be used in the temperature range –30 °C to 110 °C and retains its action up to a temperature of 250 °C. It is labelled as highly-flammable, an irritant and a danger to the environment. It has a total of 14 constituents. The work involved for registration was investigated for the constituent Additin RC. This lubricant additive is purchased in quantities of between 1 and 10 t/a from EU Member States and is used in a total of 85 products manufactured by the company. Given the small quantities and associated costs, it is assumed that the supplier will not register the additive.

The Company: IG Sprühtechnik GmbH & Co. KG (IGS®)

The company, located in Wehr, Baden, with 150 employees, fills cans on behalf of other companies. Within the sense of REACH it is a manufacturer, formulator, importer and downstream user. Products are developed in its own laboratories, manufactured in modern facilities and packed into compressed gas packages. It is also filled in liquid form into bottles, cans, drums etc. It is filled in paste form into tubes and similar packaging forms. The products are delivered exclusively in the packaging of the company awarding the contract. IGS® has more than 2000 of its own formulations and is either a sole holder of medicinal product authorizations and patents or is involved in them.
The spectrum of products is very comprehensive and embraces the areas of cosmetics, household goods, the automotive industry, engineering, human and veterinary medicine, medical technology, sport and the office. The company has specialized in the manufacture of small batch sizes. It has 5 modern aerosol filling lines that can handle batch sizes between 1,000 doses and approx. 100,000 doses.

The problems from the perspective of the company:

- The company fears that the substance Additin RC – chosen here by way of example – will no longer be supplied because of the high costs of registration for the manufacturer. The costs of registration, inclusive of exposure scenarios for 85 uses, if data on the DNEL and PNEC are already available, is estimated by the company to be €120,000. If it is necessary to determine the DNEL and PNEC, then according to VCI figures, additional costs of €250,000 will be incurred. The total costs would therefore be €370,000. A substitute would have to be found with associated high development costs. If no substitute of equivalent value could be found, then the product HL-Ketten-Haftfett spray would have to be re-formulated and extensively tested, as would 84 further preparations. This would bring the danger of loosing the product if no equivalent product could be found. The company believes that there will be a loss in turnover, a reduction in quality and a loss of special applications and thus jobs.

- The uses of the starting materials are not generally disclosed to the company's suppliers for confidentiality reasons. They are therefore also not able to register the use. Suppliers will not register the use in aerosol form (flammable, pressurized) for product liability reasons, or will only do so unwillingly.
- The company believes that the specification of the area of use alone represents a disclosure of know-how. Laborious investigations are needed to establish the uses. Other manufacturers could save themselves the development work and offer comparable products at a lower price.
- The strength of the company lies in its rapid and flexible reaction to the needs of customers. The complex and bureaucratic REACH procedure will bring about a loss of flexibility and innovation potential.
- As a SME, the company believes that the administrative burden for REACH and associated costs will be too high.
- The REACH proposal in its present form is not very suitable for protection of human health and the environment. The fear is that production will be switched to other countries with a lower level of protection.

Solutions proposed by the company:

IGS® is a typical highly-specialised medium-sized enterprise with a very comprehensive product range. It develops its products in-house and reacts rapidly and flexibly to the needs of customers. The main impacts of REACH will be the non-availability of starting materials, the administrative burden of registration, including the uses of numerous downstream users and a disclosure of know-how.
The following measures would improve the situation:

- The Company proposes that the exposure categories in the VCI proposal be adopted and the VCI database used. The Safety Data Sheet used to date as a central information resource is considered to be fully adequate.
- Exposure categories and/or groups of exposure scenarios should be used for risk assessment.
- "One substance – one registration". All substances from all companies should be registered with an institution that is independent of countries and companies. This institution would then decide on the cost allocation between different companies that produce the same substance. This needs to be carried out under the control of the EU because of the confidentiality of corporate data.
- Any overlaps of the REACH system with other regulations (including those covering occupational health / transport law) are to be eliminated.

The Product: Guanidine thiocyanate

The product guanidine thiocyanate is a substance imported from Switzerland in quantities of 1 – 10 tonnes per annum. It is used, *inter alia*, in the manufacture of flameproofing agents, as a modifier and auxiliary agent for formaldehyde resins, melamine resins and phenolic resins. It is also used in the manufacture of medicinal products, crop protection agents, dyes and explosives. The importer, Sigma-Aldrich, is not generally informed of the details of its use.

The Company: Sigma-Aldrich Produktions GmbH

Sigma-Aldrich has 4 sites in Germany with a total of 600 employees. Its Steinheim site has 150 employees. Its headquarters are in the USA. Sigma-Aldrich is a leading company in the field of fine and laboratory chemicals for special applications such as research and development. Its customers need to receive their goods and associated documentation within very short time frames.
Sigma-Aldrich is an importer, manufacturer and distributor. Fine / laboratory chemicals are manufactured on a laboratory scale in Steinheim. It has a global distribution centre for chemicals in Schnelldorf. It typically produces chemicals in 30-litre flasks and now has a pilot plant with vessels of up to 100-litre capacity. Chemicals that are manufactured, bought-in or imported are filled into new containers and sold. The typical package form for sale is a 250-ml bottle, but substances are often packaged in quantities of 15 – 20 g. The company imports approximately 85,000 substances and manufactures 2,500 substances. 450 of these substances fall into the class 1 – 10 t/a and 25 into the 10 – 100 t/a class.

The problems from the perspective of the company:

- The product is imported from Switzerland and the costs for preparation of the registration dossier are estimated at approx. €61,000. Consideration is being given to reducing the imported volume to below 1 t/a through organisational measures. It would also be possible to export the product from outside the EU. Germany would then loose its importance as a distribution centre for exports.
  The product is used primarily for research and development purposes – the supplier has no information on the exact purposes. The company believes that importer and manufacturer should be exempt from the registration obligation where a product is used for R & D.
- The company recommends that exposure categories be used for fine / laboratory chemicals below 10 t/a as these products are used in a large number of the same applications (group formation).
- The company believes that plausible and meaningful laboratory data, including that presented in the literature, be recognised even if the data is not derived from GLP laboratories.
- A registration obligation, with very high costs, may be required for up to 300 substances. The company is considering whether to stop the manufacture and

import of these substances. This would have very severe negative consequences for research and development, and for diagnostics.

- The company has investigated the feasibility of reducing registration costs through the formation of consortia – but in the experience of the company this is not possible because of antitrust legislation.

Solutions proposed by the company:

Sigma-Aldrich Produktions GmbH is an importer, manufacturer and exporter of a large number of fine and laboratory chemicals and thus a hub for the movement of chemicals within Europe. It handles close to 90,000 substances, of which 480 are imported / manufactured in quantities over 1 t/a, for which registration is mandatory. The company could reduce its administrative burden and the associated costs through the use of organisational measures to reduce the volume imported to below 1 tonne/annum, by ceasing to import and manufacture products and by switching trade activities to outside the EU. However, this would have a negative impact on its operations in Germany / Baden-Württemberg. The following measures would improve the situation:

- Substances used for research and development purposes should be exempted from the registration obligation for manufacturers and importers.
- Existing substance data, of demonstrated quality, should be recognised. This is not stated explicitly in Section 12 of the REACH proposal.
- Approval of practicable exposure categories and a simplified formation of group exposure scenarios for fine / laboratory chemicals for similar substances with the same type of uses.
- The inclination of companies to switch production to other countries and/or to relocate chemical distribution centres can only be countered by a massive reduction in the costs and bureaucracy associated with the REACH system.

The Product: Silgranit sinks

The selected product is a sink manufactured from polymethyl methacrylate (PMMA) under the brand name “Silgranit“. Such PMMA sinks have a very hard and scratch-resistant surface and are currently manufactured in 63 shapes and 12 different colours. Its main constituents are a brittle filler (approx. 70% colour-coated quartz sand) and PMMA (20 - 30%). For process engineering and quality reasons the sinks have a further 50 or so constituents. The reaction catalyst “Laurox“ (dilauroyl peroxide), present in a quantity < 1% by weight, is of decisive importance for the rapid and complete curing of the PMMA sinks. It is used in quantities in the range 10 – 100 t/a and it would have to be registered as a downstream use.

The Company: BLANCO GmbH + Co. KG

The company is a medium-sized enterprise founded in 1925 with its headquarters in Baden-Württemberg. It is a member of the EGO Group and is engaged in the kitchen technology, catering systems and medical systems fields. BLANCO is a leading company in the processing of stainless steel and high-performance plastics and has a total of 6 production sites (4 in Germany and 1 in Tchechnia and 1 in Canada). It has approx. 1400 employees in Germany and some 300 in the other sites. Its product range includes stainless steel and composite kitchen sinks, surgical instruments and cabinets for medical usage, through to system solutions for commercial kitchens in hotels and hospitals. It has DIN EN ISO 9001 certification for all sites. The EMAS certification it had gained for one production site in Germany was discontinued because it had no relevance to other countries and has been replaced by DIN EN ISO 14001 certification.
The manufacture of the PMMA sinks is concentrated in Sinsheim, with approx. 180 employees and in Canada. Canada will not be subject to the requirements of REACH, nor will sinks imported from Canada. It generally takes 1 month to 3 years to change formulations and new innovations take 3 – 5 years. Each change to the formulation requires considerable R & D work and an application has to be made for approval under food regulations.

The problems from the perspective of the company:

- The investigation of whether the company will be affected by REACH is, of itself, very time consuming and difficult.
- The company fears that the reaction catalyst Laurox will not be registered by the manufacturer for this downstream use, or that the costs of registration will be passed on. This would make the manufacturing process more expensive. A similar situation is feared for the colour-coated quartz sand used in large quantities.

- The notification of a downstream use is regarded as too onerous for a medium-sized enterprise in the metal sector because of the scope of the draft REACH proposal. Only specialists in the field of REACH can hope to understand its requirements.
- The benefit of providing a detailed exposure scenario for downstream uses is questionable, since, for example, the reaction catalyst can be used for polymerisations in general. A more practicable risk-oriented approach, using wide-ranging exposure categories, is required. The work required for exposure scenarios with a high degree of detail (reaction catalysts for the PMMA-mediated polymerisation of sink components) is considered unjustified and impracticable.
- The formation of consortia envisaged in the REACH draft for the processing of registration documentation is not practical for downstream users as the need to safeguard know-how (especially for data on the composition of the PMMA mix) is of decisive importance for the competitiveness of the company. Such consortia would also breach the national and international anti-trust laws.
- There is an urgent need to harmonise all the regulations governing substances in Germany / Europe. The legal requirements must be streamlined upon implementation of the REACH proposal. This will be a major challenge for European and national authorities. In addition, the national registration authorities or the European Chemicals Agency will have to maintain central databases that are available to users to track the status of substance registration and provide substance-related data.

Solutions proposed by the company:

It has become clear that a downstream user from the metal sector feels over-burdened by the work required under the REACH system to register a downstream use. This applies for all downstream users. The desire for a central agency to provide assistance for the REACH procedure and information on the current status of registrations / substance-related data is understandable and should be regarded as a major factor in achieving the desired acceptance of the REACH system In addition, a downstream user cannot be expected to disclose its uses in detail (especially through the formation of consortia).

- ➢ It is necessary to harmonise all of the regulations governing chemical substances in Germany and the other EU Member States.
- ➢ The registration of downstream uses must be simplified or allowed in summary form (without giving details of special applications). The scope of testing required must be reduced.
- ➢ A risk-oriented approach, taking into consideration wide-ranging exposure categories, for the registration of downstream uses would be far more acceptable to companies in this sector and would be more likely to be realised.

The Product: PERLATOR® aerator

Flow controllers are used at the discharge points of sanitary fittings (shower sprayheads) to shape the water jet and bring about a uniform water stream without splashes.
An aerated system saves water and energy costs. PERLATOR® is a trademark of the NEOPERL Group and is the first industrially-produced flow controller in Europe. The so-called mouthpieces, i.e., the brass parts that secure the flow controller to the unit, are chrome-plated in a fully-automatic process. The company produces approximately 100 million of these items per year in its electroplating plant Müllheim. This plant produces approx. 60 – 70 tonnes of sludge per annum, sent for recycling in approx. 10 container loads. The anticipated impact of REACH on the fate of the waste products from the electroplating plant is considered here.

The Company: NEOPERL GmbH

The NEOPERL Group has its main production site in Müllheim and is the leading manufacturer in the world of neutral components for the valves industry with over 1200 customers in the valve producing industry, extending from South America to Japan. Its customers in Germany include manufacturers such as Grohe, Hansa, Ideal Standard, Kludi and Hansgrohe, but also dealers in spare parts and companies supplying the construction market.
The company is a leading innovator in water control technology. Its special line of low-budget products has allowed it to compete with companies in countries such as India and China.
Its core competence lies in research and development into products to meet the internationally varied requirements and standards in the sanitary fittings sector and in the automated assembly, with integrated controls, of all products to meet the relevant standards.
Under the REACH system, the company is not only a manufacturer of products, but also a manufacturer of waste for re-usage.

The problems from the perspective of the company:

- The electroplate sludge that is produced as waste contains an average of 18 % nickel and is sent for recycling. Under the REACH system, substances in waste have to be registered similarly to preparations and products since they are not excluded under Section 5. The waste contains a total of 7 metals that are produced in quantities greater than 1 t/a and must therefore be registered. The company believes it will be adversely affected by the considerable additional work for the registration under the REACH system and the resultant higher costs for the disposal of the electroplating sludge. This will threaten its ability to supply products at low cost in a sector in which the cost-to-performance ratio is very important. As a medium-sized enterprise

in the processing industry it also sees itself over-burdened and unable to meets its data-providing and registration obligations under the REACH system.

- The recycling of the waste will be made more difficult and even impossible through the obligation to register the constituents of the waste. The recycling of the waste required by German legislation is at risk, as is the continued existence of the operators of the recycling plant.
- If the electroplating process becomes too expensive in Germany then it may be relocated to the site of the company in China. Finished products that do not fall under the REACH system would then be imported into the EU.
- A further problematic area for the company is that of substitute substances. The company uses 10 – 12 organic pigments that are permitted for use with drinking water globally. This is already a considerable restriction. The variety of colours has enabled the product to be differentiated from other products – some of which are otherwise very similar. It further prevents end users from incorrectly assembling the product. The number of colours available to choose from would be reduced if pigments were no longer available under the requirements of the REACH system. The approval process for substitute substances for use with drinking water is very time consuming and costly.

Solutions proposed by the company:

NEOPERL GmbH has presented the consequences of the REACH system with respect to a known product using waste as a subject. Under the REACH system, substances contained in waste are not exempt from the registration requirements. The company has shown that not only will there be an impact on costs as a result of the additional work, putting the company at a disadvantage compared to its competitors, but the recycling required for environmental reasons under waste legislation will be at risk.

- It should be investigated whether waste under Section 5 of the REACH proposal can be exempted from the registration obligation, especially if it falls under other regulations.
- It is necessary to remove competing legal requirements.
- The REACH system in its present form will give companies outside of the EU very considerable advantages over their competitors in the EU, especially with regard to the import of finished products. The requirements of REACH therefore have to be less bureaucratic, time-consuming and costly.

The Product: Gold

Gold is one of the rarest substances (chemical elements) on the planet. It is present at a concentration of approximately 4 mg per tonne (4 ppb) of the earth's crust. It has fascinated mankind from very early times – gold objects are known from 4,000 years B.C. Gold that is 99.9% by weight pure is available on the market in powder form, as wire, film or bars, in gold-containing alloys or preparations. The main customers for fine gold or alloys are the jewellery industry and dental technology. Compounds, electrolytes or preparations containing gold are used by companies engaged in surface technology, catalyst manufacture and parts of the chemical industry. The company Wieland obtains all of its gold from secondary raw materials (separated ore). Pure gold is manufactured by 40 – 50 other companies within the EU.

The Company: Wieland Dental + Technik GmbH & Co. KG

The company was founded in 1871, and its plant in Baden-Württemberg now employs more than 250 staff. It is a medium-sized enterprise manufacturing products and offering services in the field of dental and precious metal technology. It is one of the leading companies in this field in Europe, offering products manufactured from gold, silver, platinum, palladium and rhodium, and associated services. In addition to dental alloys from precious metals, the product range includes high-purity precious metals, alloys, metal compounds and electrolytes for surface applications. A total of approximately 100 tonnes of precious metals are processed annually, with around 1,000 products (50 substances, 800 preparations/alloys and 100 products) manufactured and marketed annually.

The precious metals are recovered from waste using the latest separation technology. The separating plant uses materials such as production residues or old gold or waste that requires special monitoring from plants engaged in surface technology (electroplating baths or ion exchangers). The company uses processes developed in-house, and in part patented, to manufacture its products rapidly and competitively. The company meets statutory requirements for quality/environmental management and has DIN EN ISO 9001 and 14001 certification as required by the Medicinal Products Directive and as a specialist disposal facility.

The problems from the perspective of the company:

- Waste that is treated in waste treatment plant is exempted from the requirements of the REACH system, as laid down in the non-paper (including addendum) drafted by the EU Commission. Waste that is to be recycled in other recycling plant is not exempt from the requirements of the REACH system.
- With substances such as gold - that can be used for many different purposes – the procedure under the REACH system is too onerous for a medium-sized enterprise in terms of its financial and human resources.

- Medicinal products (such as dental alloys) and waste (secondary raw materials) are already sufficiently covered at a European level by the Medicinal Products Directive 93/42/EC and Waste Directive 75/442/EWC. The REACH system would merely be a duplication of these requirements and as such must be avoided.
- Since the import of natural substances, ores and concentrates with dangerous constituents is subject to the requirements of the REACH system, it is feared that global streams of raw materials will bypass the EU and end up in other countries that have lower standards in terms of occupational safety, environmental impact and health protection. It should also be remembered that other substances present in natural materials and ores can be hazardous to health (e.g., lead, cadmium, asbestos) and may even require approval for use.
- The definition of intermediate products in the draft document does not cover intermediates in metal recovery. As a result, intermediates in the metal industry will be subject to the requirements of the REACH system.
- There are concerns that alloys will be considered to be preparations and classified correspondingly. This, however, would not always be justified by the actual potential hazards of metallic alloys.

Solutions proposed by the company:

- The REACH system must not impact adversely on the recycling economy – an economy that is beneficial and desirable politically. Recovery of raw materials from waste for re-usage should therefore remain outside of the scope of the REACH system.
- Naturally-occurring substances, ores and concentrates used to extract metals should in general be excluded from the requirements of the REACH system.
- Exposure categories should be created to simplify the registration process.
- Substances/products that are already sufficiently regulated within the EU (medicinal products and waste) should be excluded from the REACH system (to avoid duplication of regulations).
- For the implementation of a “New Chemical Policy“ within the EU, it is important that no latitude be allowed for interpretation in the implementation and enforcement of the REACH system. This means equal treatment of companies in all EU Member States in which the REACH system applies.
- The definition of intermediate products should be adapted to the requirements for metal recovery, so that the relaxations for intermediates apply here too. Alloys should be defined as “special“ preparations. To reduce the work involved, alloys should generally be regarded as a usage within the evaluation of metals.
- The proposal “One Substance – one Registration“ appears to be a desirable one. A European central authority for registrations should take responsibility for overseeing data on metals and basic materials for which comprehensive information is already available, and it should offer potential users of the substance and registration information a database facility.

The Product: Filters for hydraulic oils

The company ARGO-HYTOS GmbH manufactures complete filter systems and in the process must clean and de-grease metal parts to allow filter bellows to be joined to metal sealing disks. Perchloroethylene – an existing chemical under the REACH system – is used for cleaning purposes. Special stabilizers are added to it by the manufacturer. The perchloroethylene is used in a closed system and at the present time is a substance for which no other substitute is available.
ARGO-HYTOS GmbH purchases this preparation on a small scale (< 10 t/a) from a large producer. Approximately 20,000 tonnes of perchloroethylene are manufactured annually in Germany.

The Company: ARGO-HYTOS GmbH

ARGO-HYTOS has a total of 750 employees, of whom approximately 330 are employed in its site in Baden-Württemberg. Its range of products includes filter systems that are used in hydraulics and lubrication systems, as well as gearboxes. It also manufactures products for fluid management (oil service equipment, de-watering systems), sensors and measurement systems (oil diagnostics equipment) and control technology for hydraulic systems. Production is divided between Baden-Württemberg and Tchechnia. ARGO-HYTOS GmbH sells most of its products in Germany.

The problems from the perspective of the company:

- The company fears that perchloroethylene – a cleaning and degreasing agent that is essential for its production process – will become more expensive as a result of the requirement that it be registered by the manufacturer. Cessation of perchloroethylene production is not a fear because of the size of the market. The company also buys numerous other chemical substances for its production processes, and some of them are indispensable. If these substances were no longer available, or if their price were to increase too much, then this would cause considerable problems. The competitors of the company outside of the EU that export finished products into the EU would have an advantage.
- The situation would become particularly critical if the basic substances used for filter materials, such as glass fibre materials – a cause for concern because of the possible harmful effect of their fibres - were to be removed from the market or only be available at markedly higher prices because of the requirements of the REACH system.
- In addition, the company expressed concern that it will be affected by obligations (e.g., documentation) under the REACH system that it cannot foresee at present and which will generate additional costs.
- The company does not believe that the benefits of the REACH system for the environment in any way justify the additional burden on the companies. The safety standards are already high.

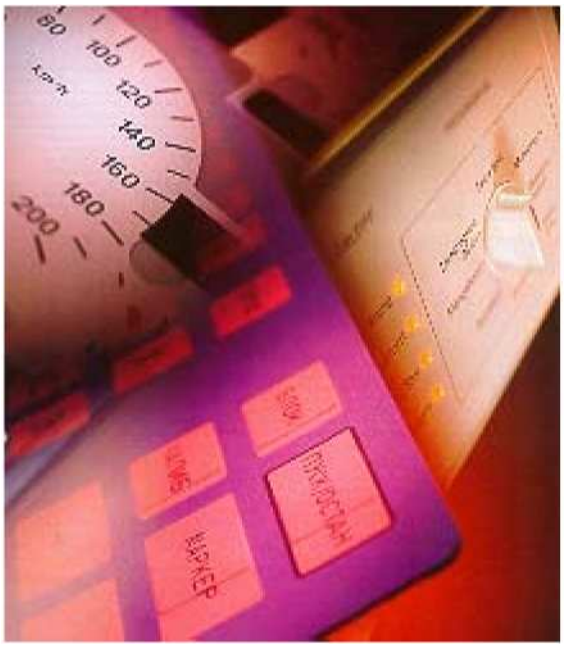
Solutions proposed by the company:

The company generally purchases standard agents for its production process and does not modify them itself. No notifications to the manufacturer would be necessary. The products are used in standard ways known to the manufacturers so that no additional documentation or changes to Chemical Safety Reports are to be expected that would have to be passed on to the manufacturer.
A company that sources substances or preparations from a supplier in small quantities, or purchases special substances or preparations, will have the following problems: It is dependent on its suppliers and is not able to predict their future manufacturing policies. It must reckon on price increases as a result of the registration process. This will bring considerable uncertainty for its continued existence and the further development of its own product range.
The company regards one of the consequences of the REACH system – the intensification of the search for substitute substances by manufacturers of substances that are particularly hazardous – as a positive aspect. The company proposes that an institution, such as the European Chemical Agency, makes a list of substitute substances available that are safer or more suitable for defined uses. Users simply do not have the financial resources and capabilities in terms of subject knowledge to conduct such searches for substitutes.

- Drafting of a positive list of substitute substances for defined applications.
- A risk-oriented approach for the evaluation of substance applications is regarded as feasible and judicious.
- The use of wide-ranging exposure categories will significantly reduce the administration workload for the registration process.

The Product: "Marastar SR"

Marastar SR is a screen printing ink that is available in 55 standard colours. It is suitable for printing on substrates such as keyboard films, automotive applications, valves, scales, signs, vehicle lettering etc. A total of 44 different constituents are used in the production of the inks, approximately 13 for a single colour shade. An obligation to carry out registration is anticipated for around 36 of the constituents. The benzotriazole derivative with the CAS No. 127519-17-19, used in Marastar SR, was selected to assess the implications of the REACH system. The substance is purchased in quantities of between 1 and 10 t/a and used as a light-protecting agent in 80 preparations. It is classified as a hazardous substance. It is assumed that the manufacturer is not prepared to carry out registration for financial reasons.



The Company: Marabuwerke GmbH & Co. KG

Marabu is a medium-sized family-owned enterprise with a total of 450 employees and a long tradition. Its main site is in Tamm near Ludwigsburg (335 employees). It has subsidiaries in Europe, Asia and North and South America. It manufactures printing inks – for screen printing, pad printing and digital printing. It also produces inks for artistic / creative uses – known as creative inks. Printing inks account for 70% of its production and creative inks for 30%. The strength of the company lies in its ability to react rapidly to the needs of its customers. Its activities are aligned with the very varied requirements of different market segments, from development through to marketing.
A total of 100 different types of ink are produced In Tamm, each of them in a comprehensive range of colours. Some 10,000 mixing formulations are stored in a database. Special inks are manufactured in its contract ink centre in quantities of 0.2 kg upwards. The company stores 850 different substances and preparations in its raw materials warehouse and the majority of these would be directly affected by the REACH system.

The problems from the perspective of the company:

- The problem of finding substitutes: The substance selected by way of example here may no longer be supplied because of the high registration costs. Light-protecting agents from other manufacturers that have been tested to date delivered unsatisfactory results. If a satisfactory substitute can be found then the formulations for 80 preparations that contain the light-protecting agent will have to be changed – involving considerable expense. The Company assumes that 20 - 40 % of the substances it uses (around 850) will not be registered because of the cost and will therefore no longer be available. This would mean the re-formulation of 2800 standard products and 300 different inks manufactured on behalf of other companies per annum. The workload for this is estimated at a minimum of 1,000 working days – for which the company does not have the personnel resources.

To meet this requirement it would have to transfer all of its personnel resources from new product development. For this medium sized enterprise the work required to comply with the requirements of the REACH system is simply beyond its means. The re-formulated products would have to be re-certificated by its customers. In the automotive industry this takes at least 4 – 6 months, for disposable syringes it takes 1 – 2 years. This time loss is a further disadvantage to the company that its competitors outside of the EU do not have. Customers are now making concrete plans to switch to competing products or transfer their production processes to other countries. The company fears that there will also be job losses amongst its customers.

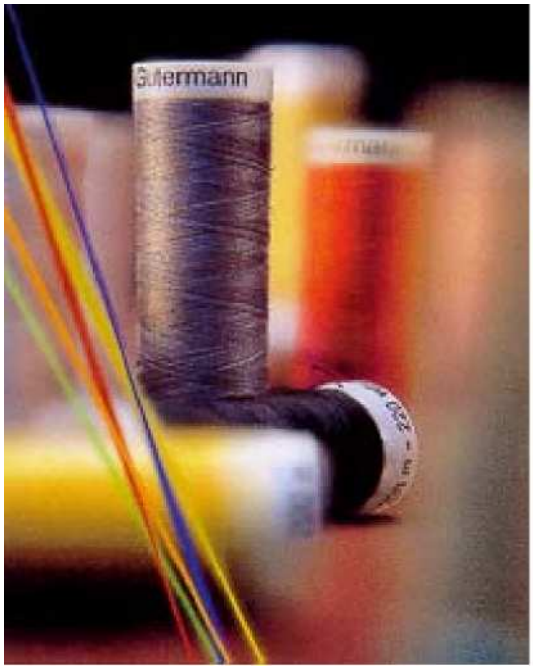
- The company is concerned about the disclosure of know-how through notification of the "intended use". Alone the statement that the use is for "screen printing inks" could be a problem. The company recommends that wide-ranging uses be stated, such as use in the area of "inks / coatings".
- The company fears that the costs incurred under the REACH system will give its competitors outside of the EU an advantage.
- The company makes the general point that the REACH system is too comprehensive, too complex, too bureaucratic and too onerous.

Solutions proposed by the company:

Marabuwerke GmbH & Co. KG is a medium-sized company that manufactures a large number of high quality products, some of them in small quantities. It has to be able to respond quickly to the needs of its customers. This competitive advantage will be put at risk by the REACH system as 20 - 40 % of the substances it uses may not be available because of the high costs of the registration procedure. The likely disclosure of confidential information will also impact adversely on the company – its competitors outside of the EU will have lower costs. The following measures would benefit the company:

- Use of exposure categories for risk assessment.
- Investigation of the possibility of restricting data requirements for the registration, taking the exposure upon correct handling of the substances into consideration.
- Limiting values for concentrations of substances in preparations should be specified that are appropriate for the risk. If the concentration is below a given limit then they can be neglected.
- A centralised and uniform evaluation at a European level by the Chemicals Agency, rather than a decentralised evaluation at a national level, to ensure uniform implementation within the EU.
- Greater protection of confidential data.
- Removal of duplication of regulations.

The product: Sewing thread



The production of polyester sewing thread involves the use of up to 160 different auxiliaries and textile dyes to achieve a high resistance to fading / colourfastness. The textile dye chosen here – "Dianix Gelb E-3G" – is a special quinaphthalone dispersion dye that has no hazard classification under German legislation. This substance is used in 40% of the sewing thread products in quantities in the range 1 – 10 tonnes per annum and is thus subject to registration under the REACH system. A comparable textile dye is manufactured by 5 companies within the EU and approx. 50 manufacturers outside of the EU. The dyes are used by more than 20,000 companies worldwide.

The Company: Gütermann AG

Gütermann AG, founded in 1864, is a leading manufacturer in the field of sewing thread production, with over 500 employees at its headquarters in Baden-Württemberg. It has further production facilities in Spain and Mexico and its products are marketed by 12 subsidiaries and 85 agencies around the world. The company employs a total of approximately 1300 personnel.
The company is a downstream user of textile chemicals in the manufacture of sewing thread for clothing and technical uses. A total of approx. 25,000 different sewing threads, primarily polyester-based, are manufactured in different strengths, colours and qualities. These sewing threads are used by consumers and manufacturers – in the shoe, leather and clothing sectors, as well as in the manufacture of textiles for the automotive, marine and aerospace industries. The company is a leading manufacturer thanks to the wide variety of its high quality products, the consistency of their quality and the outstanding colour range, available at all times. Threads in special colours can be produced within 48 hours. The company is highly dependent on its ability to react flexibly to the needs of its customers and the short time to market. The textile industry has had intense competition for some years – in particular from countries with lower wages – and any increases in its costs would be unacceptable.

The problems from the perspective of the company:

- The company is concerned that the REACH system will markedly increase the costs of the chemicals that it purchases for its dying operations, e.g., "Gelb E-3G", and in particular the special chemicals required in small quantities. These chemicals are only produced and used in small quantities and their manufacturers do not allow fixed prices. The removal of such substances from the market would impact on approx. 10,000 types of sewing thread (40% of 25,000 sewing thread products) and would result in disproportionately high development costs for substitute formulations of equivalent quality for the production of sewing threads. The additional costs would run to

several million euros for the sector as a whole.

- The REACH system would impact considerably on the innovation of dye suppliers, markedly restricting the variety of dyes available and the quality of those dyes. This would subsequently have an adverse affect on the competitiveness of manufacturers of thread and textiles in Germany, given the speed at which fashion changes. Administrative costs will be passed on to the users, with knock-on effects.
- The REACH system must not be the impetus for further relocation of production to non-EU countries. The concern is that sewing thread that is produced under less occupational health, environmental impact and general health protection regulations that are less stringent, will be imported into the EU as finished textile products of similar quality. The domestic production of sewing thread could be transferred to countries outside of the EU to reduce costs – the logistics for this are in place.
- The company does not want any increase in its administrative workload. Harmonization of the legal requirements would make the collection of data easier and reduce the administrative burden for protection of the environment.

Solutions proposed by the company:

The company is a downstream user of textile dyes and uses various auxiliaries for the production of sewing threads. The quantities it uses only exceed 1 tonne per annum in a few isolated cases. It assumes that manufacturers of these textile dyes would have to register them under the REACH system and for production quantities in the range 1 – 10 tonnes per annum this would lead to cost increases for downstream users. The actual cost increases for such textile dyes cannot be reliably quantified at the present time. The possible restriction in the variety of dyes available and the conceivable time delays as a result of the registration process for domestic manufacturers of sewing thread and textiles could present problems, given the speed of colour changes in the fashion industry from season to season.

- A simplified retroactive registration procedure would allow innovation to be retained in a sector such as this, with its need to be able to respond rapidly to customer requirements and the ephemeral nature of the products in the fashion industry.
- The implementation of the REACH system should be accompanied by efforts to harmonise requirements and the legal framework should be rationalised. A practicable protection of the health of consumers, the employees in the workplace and of the environment should be the focus of the system (and not the administration).

The product: Additin RC 9200

Additin RC 9200 is a special additive used in the manufacture of hydraulic oils. Addition of the additive to a base oil, to a concentration of less than 1%, yields hydraulic oils that satisfy the highest quality requirements in the hydraulic oil sector. RC 9200 is a product at the top end of the market, produced in quantities in the range 100 to 1000 t/a.
Additin RC 9200 is a preparation with 12 constituents. The company manufactures 4 of these constituents itself - comprising a total of 5 substances (4 active substances and the flux oil). A total of 15 raw materials (all substances within the meaning of the REACH system) are required for the manufacture of these 4 constituents. The other 8 constituents that the company purchases are estimated to each comprise 2 substances on average. RC 9200 is thus a preparation comprising 21 substances within the meaning of the REACH system. The main component is Additin RC 3080, an agent to protect against abrasion, manufactured by Rheinchemie. This is classified as a hazardous substance.

The company: Rheinchemie Rheinau GmbH

The company is a medium-sized subsidiary of Bayer AG and develops and manufactures special chemicals used as additives in the rubber, mineral oil and polyurethane / plastics industries. The company headquarters are in Mannheim, with approximately 530 employees, out of a total of 1100 employees. It has further production site in Trenton and Chardon in the US, Toyohashy in Japan and Qingdao in China.
Mannheim exports some 50% of its output to more than 100 countries. Around 4,000 products are produced in Mannheim, in the form of approx. 23,000 t/a of its own products and the same quantity of products for sale.
Continuous innovation is required in all 3 fields of activity. The company has numerous competitors both in Germany and abroad, keen to fill any gap in the market. Rheinchemie aims to set itself apart from its competitors not just through the excellence of its products, but also through a correspondingly high level of service.

The problems from the perspective of the company:

- The costs of registration of Additin RC 3080, manufactured in quantities in the range 100 to 1000 t/a, are estimated by the company to be approx. €1 million, because of the complex studies required to establish toxicity and ecotoxicity. Further constituents of the product would also have to be registered. It is questionable whether the suppliers of the products the company purchases would be willing to register the substances. Since some of those suppliers are small ones, the company assumes that these substances would no longer be available. It would be necessary to carry out in-depth investigations of possible substitutes and there is no guarantee that a suitable substitute could be found. Innovation and product

development would be blocked by this since all efforts would have to be directed towards maintaining the status quo.

- The company cannot yet estimate the overall costs it would incur under the REACH system as it would first be necessary to clarify whether substance groups with a common EINECS number can be registered together or whether each individual substance in, for instance, a homologous range of hydrocarbons, would have to be registered separately. The company proposes that the decision on the interpretation of what constitutes a substance be made by a central body at the EU level and not on a national level to ensure that it is implemented uniformly throughout the Member States.
- The company believes that the formation of consortia to reduce the registration costs would be difficult because of antitrust laws.
- Chemical Substance Assessments (CSAs) and Chemical Substance Reports (CSRs) would have to be prepared for 10,000 customers with 50,000 uses (for all products) and further downstream users – a very high workload. The company proposes that exposure categories be used.
- After conducting its own research, the company believes that it has inadequate personnel resources for the studies required under the REACH system, in particular it has too few toxicologists. SMEs in general consider the work required to be too onerous.

Solutions proposed by the company:

Rheinchemie Rheinau, as a medium sized enterprise, develops and manufactures special chemicals in a highly competitive market. Innovations are sought all the time. The work involved in the registration of 4,000 products cannot be quantified exactly as yet because clarification is required for important questions such as how a substance is to be defined and the work necessary for the registration of downstream uses. The following measures would help the situation:

- "One substance – one registration". A single substance is assigned a registration number. All substances from all enterprises would then have to be notified to the EU Commission or to an institution that is independent of any country or company within a specified period of time. That institution would then decide on the allocation of costs between the different companies that produce the same substance. This should be carried out under the auspices of the EU in view of the confidentiality of the data.
- Aspects open to interpretation, such as the grouping together of similar substances to form substance groups, should be handled at an EU level rather than a national one to ensure uniform implementation.
- Introduction of exposure categories.

The product: Tubingal CPJ

Tubingal CPJ is a preparation typical of those used in the textile treatment sector. It is used to improve the surface properties, the ease of processing and life of materials. The preparation improves the outcome of sewing and imparts a pleasing and smooth quality to the material, e.g., jeans. It protects the dye used for the jeans from degradation through ozone or nitrogen oxides. The preparation has 25 different constituents, some of which were developed by the company and therefore have to be registered under the REACH system. The quantities produced are in the range 10 to 100 t/a.

The company: CHT R. Beitlich GmbH

CHT R. Beitlich GmbH was founded in Tübingen in 1953 and develops, produces and markets products for the textile finishing industry. The company has approximately 20 subsidiaries and a total workforce of 1450. It has 2 production sites in Germany and other sites around the world, including Turkey, China, the USA and India. Tübingen houses the competence centre for research and development and applications for the entire company, with 650 personnel. The strength of the company lies in its development of new preparations for the textile industry. It manufactures approx. 1200 preparations and 300 substances. Its close ties with German production facilities are important for assessing its new products. The innovation cycle time for the market is approx. 12 months and the development of new formulations takes between 2 and 12 months.

The problems from the perspective of the company:

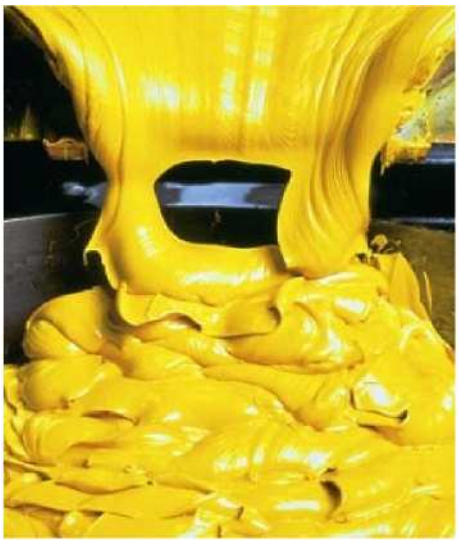
- CHT, as a manufacturer of substances and preparations, and as an importer, user and exporter, is subject to registration obligations under the REACH system, as well as the obligations of a formulator that has to pass on the downstream uses of its customers to the manufacturers of the substances it purchases. For the product considered here this could mean that the company must pass on information on the 4 constituents it manufactures itself. In an extreme case, as a downstream user, it would also have to pass on information on the uses for the 21 substances it buys to the 21 manufacturers. In view of the wide range of uses and the need to protect company know-how, the notification of all uses and the drafting of exposure scenarios are hardly possible. The manufacturer is also not aware of all of the uses. The product could, in principle, be used for leather finishing, in laundries, and in the paper / cosmetics / construction and plastics industries. In view of their need to safeguard company information the downstream users are not likely to be co-operative in the creation of exposure scenarios.
- Tubingal CPJ would have to register 4 substances and the data available for a further 21 constituents would have to be reviewed and supplemented as necessary. The cost of registering a new substance is estimated at between €42,000 and €92,000. If these costs are passed on to customers then the price of the product would have to be increased by more than 100%, or the product withdrawn from sale. The problem would be the same for a further 330 products manufactured in small volumes (< 10 tonnes per annum).

- A further consideration is that the laboratory data to date have been derived in accordance with ISO 9001-14000, but not in accordance with the Good Laboratory Practice (GLP) requirements necessary under the REACH system. GLP testing would increase the costs of the tests by around 150 – 200%. The company estimates that if the VCI data available for the class 10 to 100 tonnes was recognized then 80% of the costs of testing could be saved. The VCI data for the substances to be registered is virtually complete.
- On a global scale, the products would no longer be as competitive because of the disclosure of know-how through the registration process. The formation of consortia for data exchange and cost reduction is hardly possible for these reasons. The registration required under the REACH system would delay the introduction of products onto the market by approx. 12 – 15 months.
- The company expects considerable price increases as a result of the registration process because of the large number of preparations and substances it produces (approximately 1500!). These costs would have to be passed on to the users. This in turn would increase the pressure on the German textile industry to switch production to outside the EU. This transfer of production would also mean that R & D would eventually also have to be transferred. A further consequence of the transfer of production is that products would be manufactured in countries that have lower wage structures, but also have less stringent environmental protection requirements. The products could then be imported, generally without difficulty, into the EU. The company fears that these imported textiles (e.g., T-shirts) would have higher levels of harmful substances, as tests in the past have shown, putting the unaware European consumer at risk. It is doubtful whether the REACH system would sufficiently cover the import of such articles. Manufacturers within the EU would be put at a disadvantage compared to competitors outside the EU.
- With the import of approximately 200 raw substances and preparations there is the risk that the supplier, wishing to protect its company know-how, will have little interest in a complete disclosure of the formulation and will not divulge the information if the quantity imported into the EU is low compared with the volume manufactured outside of the EU. The outcome would be that the products manufactured with these raw materials/preparations would no longer be available.

Solutions proposed by the company:

- The situation would be improved considerably through a broad definition of the term “use”, together with a grouping of typical exposure scenarios to form exposure categories.
- Additional costs could be avoided through the recognition of existing data if specified quality criteria are satisfied. This is not explicitly provided for in Section 12 of the proposal.
- It should be investigated under which conditions the data of the VCI is adequate to meet the requirements of a CSR.
- It must be ensured under Section 6 that finished products imported into the EU do not have advantages over products manufactured within the EU that have to meet the requirements of the REACH system.
- The implementation of the REACH system must be uniform throughout the EU, through the work of the Chemicals Agency, with regular evaluation of the implementation.

The product: "Ciba® CROMOPHTAL® Gelb 2RLTS"



The product is a yellow colour pigment that is used to dye plastics and in printing inks. The company Konrad Hornschuch AG, also participating in the survey, uses the pigment to colour PVC window sections for external use. Ciba CROMOPHTAL Gelb 2RLTS comprises 90% pure organic pigment and 10% resin, added to increase dispersion properties. The colour pigment is imported from Switzerland in quantities in the range 100 to 1000 tonnes per annum.

The company: CIBA Spezialitätenchemie Lampertheim GmbH

Ciba-Spezialitätenchemie is a company with global operations and around 19,000 personnel divided between more than 60 production sites. It manufactures speciality chemicals that improve the performance, appearance and quality of finished products. In Lampertheim, 820 personnel are engaged in the production of additives for plastics, coatings and lubricants such as stabilisers to protect against light/UV radiation and processing stabilizers (approx. 50 different substances and more than 250 preparations). Lampertheim is also home to the marketing headquarters that provides customers in Germany and Austria with approx. 1000 substances and 1500 preparations, imported from different production facilities of the Group. The company manufactures a large number of products, in different mixes and preparations, in small volumes. The strength of the company lies in its ability to react flexibly and quickly to special customer requirements and providing innovative products with customized qualities. It generally takes around 3 months to develop new formulations for specific customer requirements in terms of performance and uses. Short innovation cycles are a major factor in determining how competitive a manufacturer of speciality chemicals is, and the ability to react flexibly to customer needs is a decisive factor for the success of the company.

The problems from the perspective of the company:

- The high costs of registration – estimated at up to €800,000 inclusive of the complex studies necessary on reproductive toxicity etc. – are not regarded as justifiable. The company comments as follows on the form: The risk associated with the product is not taken adequately into consideration in the data capture. It is meaningless to push hundreds of pigments – generally insoluble in water and chemically inert – through the same test program, using innumerable experimental animals and spending millions of euros in the process, with no increase in our knowledge base".
- The work involved in the drafting of the CSA / CSR is excessive because of the high number of substances in the speciality chemicals sector and the different exposure scenarios for the downstream users. Approximately 70% of the

substances are classified as hazardous. Since they often have similar characteristics, group exposure scenarios could be used. The costs for the drafting of the CSA / CSR would then be reduced to around €3,000 per substance. If exposure scenarios are required for each substance then the costs would increase to up to €50,000 per substance.

- A factor that increases the costs associated with new products is that in the experience of the company, existing test data is not recognised for new substance approvals in cases where newer methods of establishing the data exist, even though the results for pigments hardly vary.
- The company is required under the REACH system to register its waste that is re-used. This is a labour-intensive process. The high additional costs mean that the re-use of the waste has to be questioned. The company believes that waste should generally be excluded from the registration obligation.
- On the basis of its experience to date, the company is concerned that dossiers will be handled differently in the various Member States. It believes that dossiers should be evaluated at a European level.
- The uncertainty that the discussion about the REACH system has generated and the unforeseeable associated costs are already having an adverse effect on investment. Transfer of production to Asia is conceivable.

Solutions proposed by the company:

Ciba Spezialitätenchemie Lampertheim GmbH, as an importer and manufacturer of a large number of substances and preparations with numerous downstream users, will have to draft registration dossiers for many individual substances and document numerous uses of the substances by the downstream users. This will increase the cost of its products considerably.

- The registration process could be rendered less onerous by allowing similar substances with similar properties to be grouped together, as in the substance group and analogy concept in Annex IX to the REACH proposal. With dangerous substances, the use of groups of exposure scenarios would also make the registration process easier. The criteria for recognition, however, are not fixed - they should be pragmatic and be uniform throughout the EU.
- Existing substance data – of demonstrated quality – should be recognised. This is not explicitly permitted under Section 12 of the draft proposal.
- Dossiers should be evaluated at an EU level to ensure uniform implementation.
- It should be investigated whether waste under Section 5 of the REACH proposal can be exempted from the registration obligation, particularly as it is already covered by specific waste regulations.

The product: "tp print"

"tp print Staufereiche kolonial" is a high-resistance film based on PVC (polyvinyl chloride) manufactured by the company using a colour pigment from the firm Ciba. This product is used in particular designs / colours for the lamination of door and window sections. to be used outdoors A total of 72 colour and design variants are available. This product contains 19 substances (including the above-mentioned colour pigment that is not regarded as dangerous under German chemical regulations). The colour pigment falls into the REACH class 10 – 100 t/a and registration would be mandatory for this downstream use – as well as for most of the other 18 substances (depending on the production quantities).

The company: Konrad Hornschuch AG

The company is a medium-sized enterprise in the plastics processing industry with close to 800 employees. It develops and manufactures films and coated materials at its site in Baden-Württemberg. The company manufactures consumer products and industrial products for very differing applications. The product range extends from self-adhesive films for end users (d-c-fix®) through films and artificial leather products for the automotive, fashion and furniture industries, to innovative films for door and window sections and metal laminations (skai®).

A total of approximately 700 different chemical raw materials and preparations from different manufacturers are used, of which around 40 % are sourced within Germany and around 57 % from other EU Member States. Many of these raw materials and preparations are speciality chemicals and are modified by the suppliers for a particular purpose. These are used in approximately 2,500 preparations for in-house use and ultimately for the production of approx. 4,400 products for sale.

The strength of the company lies in its wide product range and its competence in the special field of surface lamination – where innovation is essential. It is highly dependent on its ability to respond flexibly to the needs of customers and on a short time to market. Changes to formulations are made for approximately 20% of its products annually. Around 40% of its current turnover is based on products that have been developed within the last 5 years.

The problems from the perspective of the company:

- Even small increases in costs (e.g., as a result of the REACH system) would result in an increased number of PVC lamination films being imported into the EU from the Far East. The REACH system will not prevent such imports, and it should be remembered that the imported products are produced with lower standards than the EU in terms of the occupational health of the workforce, the protection of the environment and the health of consumers.

- Products developed by the company, in which substances are used in quantities of between 1 and 10 t/a are used, and which are made exclusively for customers, would no longer be produced for cost reasons, as the customers would not accept the price rises. The distortion of competition in favour of non-EU countries would impact substantially on profitability of the company, leading to a loss in workplaces and reduce its innovativeness.
- The company is concerned that speciality chemicals required for many of the products that it sells will not be registered by suppliers for cost reasons and thus will no longer be available. It will not be possible to maintain the current product quality if some of the raw materials are no longer available. The time that is lost because of the registration process will mean it will no longer be possible to react rapidly to the needs of customers. This will reduce the range of products available (niche products will no longer be produced and the variety will be restricted) and the products will be replaced by standard ones. In addition, it is expected that finding substitutes for the raw materials that are no longer available will be a very time consuming, and thus expensive, process.
- The feasibility of registration of downstream uses by the substance manufacturer is considered doubtful. Substance manufacturers often have no direct contact with downstream users (e.g., upholsterers and shoe manufacturers) as intermediate companies or distributors are involved. If there is direct contact, then downstream users will refuse to disclose the uses to protect their know-how (in most cases their only competitive advantage).

Solutions proposed by the company:

The company is a downstream user with a very large product range. As a medium sized company, it has no opportunity at present to transfer production to countries outside the EU. A fall in profits will result in a reduced range of products and a reduction in the number of workplaces in the company. The company proposes the following:

- A review of the requirements of the REACH system relating to the import of products from non-EU countries, so that domestic producers (downstream users) are not disadvantaged.
- A uniform implementation through substance/product import controls through the EU Member States / review of core aspects in accordance with requirements that are uniform throughout the EU (similar to product monitoring under the German Equipment and Product Safety legislation).
- Simplification of the downstream registration process using wide-ranging exposure categories on a risk-based foundation (VCI proposal).
- The removal of duplication of regulations must be kept in mind.

The product: Window and door fittings

Steel, nonferrous metals and plastics are used for the manufacture of fittings for doors and windows. The preparation Lanthane 311, sourced from another company, is used for the finishing of the zinc surfaces of the metal components. This preparation, free of chromium(VI), provides outstanding protection against corrosion and rust for several years and the metal surfaces are given an attractive silver sheen. Lanthane 311 is essential for the production processes of Gretch-Unitas GmbH. The product has been approved by the company after comprehensive testing and is used as a coating for approx. 70% of all the parts it manufactures.

The company: Gretsch-Unitas GmbH

This family-owned company has approx. 3,700 employees in 9 countries engaged in the production of over 60,000 individual parts for door and window fittings. It has 850 employees in Ditzingen who are involved in the production of door locks, bolts and accessories. The company has a worldwide marketing network with most of its products exported to other EU countries. More than 5,000 products are imported from outside the EU.

The problems from the perspective of the company:

- The main problem for the company is that it uses 400 speciality chemicals, some of which are classed as dangerous or even as CMR substances. Some of these substances will have to be subject to a complex registration process or will require approval by the suppliers. These speciality chemicals are often only produced in small quantities by the suppliers. The costs of registration or approval cannot be passed on, or to only a limited degree, so that the viability of continued production is questionable. Of 90 substances used by Gretsch-Unitas in quantities < 1 t/a, around 30 are at risk. This would have far-reaching consequences for the company – for instance it would have to do without certain product characteristics, undertake expensive studies to find substitutes, modify production processes etc. Any rapid changeover to substitutes is not possible because of the stringent approval requirements for production technology within the company. Its suppliers have not yet made any statement on their continued production. It is assumed that the impact of the REACH system and its knock-on effects are not yet sufficiently known.
- As a standard user the company is indirectly affected by the registration of the substances and preparations in use. It has to expect price rises from its suppliers. In view of the quantity in which its supplier is estimated to produce Lanthane 311 (> 100 t/a), it does not expect that the producer will cease production.
- The company imports products from other countries, including over 5,000 articles from countries such as China. It is not certain how much administrative work will be required under the REACH system, or the cost of such work. The import of door locks requires

the registration of the hydraulic oil they contain. The company hopes to be able to pass on the use of a hydraulic oil that is approved for use in Europe to the Chinese manufacturer. It is not clear whether this will work and it would presumably lead to price rises for the imported product. If it were to register the product itself it would delay market launch by 6 - 12 months.

- In general, the company is very uncertain of the consequences of the REACH system in terms of its administrative workload and costs. These cannot be foreseen at present. The situation has a severe effect on the budgeting of the company and its ability to develop strategies for production and marketing in the global marketplace.

Solutions proposed by the company:

The problems seen here are typical of those that a user of substances and preparations that fall under the REACH system will encounter, in particular if it uses small quantities. It is dependent on its suppliers and cannot predict the future manufacturing policies of those suppliers. It has to expect price rises. This generates a great deal of uncertainty for the continued existence and further development of its own product range.
This company, similarly to many other companies in Baden-Württemberg, produces high-tech products that require adequate training of its employees and high production technology standards. The company fears that the pressure to switch production to countries outside of the EU will increase if the substances and preparations required for production are no longer available within the EU, or only at a price that prevents economic production.
It anticipates considerable difficulties for both manufacturers and users as they attempt to predict the impact of the REACH system on their companies. The system appears to be too complicated and there is the fear that a regulation that is not accepted by those it affects will not be implemented in practice. Many companies have not yet paid sufficient attention to the impact of the REACH system.

➢ The use of “One substance – one registration”, i.e., the single registration of a substance, would simplify the REACH system. However, this would not necessarily solve the likely problem of cessation of production where the quantities of substances and speciality chemicals are low. That could only be prevented by changing the REACH proposal to reduce the associated costs. Examples of such changes include the use of simplified exposure scenarios / exposure categories, the recognition of existing laboratory data, and a simple computer-supported and standardised registration process.

The product: Sika Tack Plus Booster®

The preparation - Sika Tack Plus Booster®~- is a single-component polyurethane adhesive for use with automotive glazing. It is classed as “corrosive” under the toxic substance regulations. The catalyst in Sika Tack Plus Booster® accelerates the curing process and allows vehicle windows to be replaced quickly, even under adverse weather conditions (low temperatures and/or and rain). The catalyst is present in the product at an approximate concentration of 1% by weight and brings about a rapid and bubble-free curing of the adhesive. The catalyst is used in quantities of between 1 and 10 t/a. Products with similar properties are produced by 4 manufacturers within the EU and 4 manufacturers outside the EU. The product is manufactured in Switzerland and imported into Germany. The preparation contains a further 10 different constituents, of which 8 are likely to be registered.

von denen voraus-

The company: Sika Deutschland GmbH

Sika Deutschland GmbH is a subsidiary of the Sika Group that has its headquarters in Switzerland. The Group has more than 8,500 employees in 85 different production and marketing companies in 66 countries. Sika is a leading manufacturer of speciality chemicals. Its core competences are products for the construction industry and industrial materials, (sealants and adhesives).
Sika Deutschland GmbH has approx. 1,000 employees at 3 sites, with its German head office in Baden-Württemberg. Approximately 1,800 preparations and 250 products are manufactured and marketed in Germany. A further 300 preparations and 100 products are imported from Switzerland. A wide range of substances, preparations and products are manufactured, in some cases in high quantities annually. The company provides its clients in trade and industry with competent advice and services, centred on the products and services of Sika-Bauchemie and Sika-Industrie. Sika also supplies process materials that are tailored to the fabrication facilities and procedures of its clients. The product considered here was developed in co-operation with the automotive manufacturer DaimlerChrysler. It is an important component for the repair of glazing for DaimlerChrysler vehicles.

The problems from the perspective of the company:

- The company believes that the increased costs that will result under the

REACH system, especially for production quantities between 1 and 10 t/a, would have to be absorbed as they could not be passed on in the present economic climate in the construction and automotive sectors. It is not possible to make a reliable statement on possible cost increases for this class of production quantities.

- The company is concerned that special constituents of preparations that are only produced and used in quantities in the range 1 – 10 t/a (e.g., the catalyst in Sika Tack Plus Booster®) may no longer be available in the future for cost reasons. The restriction of complex and high quality formulations for special customer needs and system solutions will endanger the competitiveness of the company.
- For use-related substance registration with the customer (downstream user) the agreement entered into generally involves know-how protection. The competition in existence in reality, however, forces the company to keep this information confidential and not disclose it to other substance manufacturers or competitors. This rules out the possibility of forming consortia with substance manufacturers or competitors for the joint registration of substances and downstream uses. In addition anti-trust laws would also prevent this.
- With use-related registration (e.g., substitutes for catalysts in glazing adhesive), not only are additional costs expected, there will also be an unacceptable time delay and restriction of innovations and changes to formulations.
- The administrative burden expected for the registration process will be too high. The company proposes that the Safety Data Sheets in common usage be developed further and that steps be taken to standardise them and make them more available in the EU Member States. In addition, the company believes that existing data and practical experience should be used to draft a list of “adequately tested substances” so that manufacturers of preparations can access data on such substances more readily in future.

Solutions proposed by the company:

The company is a manufacturer of substances and preparations that co-operates closely with users to solve problems and is therefore very dependent on its ability to react flexibly to the needs of customers. The cost aspects and possible time delays for use-related registration of chemical substances and the difficulty of finding substitutes if speciality chemicals disappear from the market are of particular importance to it – the number of uses could be drastically reduced.

- The approach envisaged for the formation of consortia needs to be revised, both for the protection of know-how and for anti-trust reasons.
- The proposal to draft a list of “sufficiently tested substances“ should be taken up – without acceptance by those involved the “New European Chemical Policy” cannot function.
- Existing data should be used.
- The use of exposure categories for risk assessment is to be given preference and duplication of regulations is to be avoided.
- The European Chemical Policy should be developed further in “small practicable steps”. This would meet with acceptance on the part of the substance and preparation manufacturers involved, as well as the downstream users.

The product: Special adhesive for repair glazing

DaimlerChrysler AG uses a single-component glazing adhesive with accelerator for repairs to the glazing of motor vehicles. The special adhesive is easy to work and cures rapidly. It is intended for use in series production. The product was developed through close co-operation between its manufacturer Sika GmbH and DaimlerChrysler. Sika GmbH also participates in this project with the same product, as an example of a manufacturer/user relationship.

The company: Die DaimlerChrysler AG (DCAG)

DaimlerChrysler AG has a global workforce of over 360,000, with approx. 210,000 of these in Europe and approx. 80,000 – 90,000 in Baden-Württemberg. Its range of products includes cars, utility vehicles, buses, automotive accessories and services. Some 4,000 different substances and preparations are needed for the manufacture of vehicles. Many of these preparations remain – in some cases in changed form – on the vehicle (e.g., coatings and adhesive), or are required for the driving of the vehicle (e.g., engine oil, brake fluid, radiator antifreeze, windscreen wash fluid). The range of spare parts, marketed globally, comprises approx. 300 substances and 300 preparations (bodywork polishes, repair coatings and all preparations used for operation of the vehicle) for Mercedes-Benz, Smart, EVO-Bus or Chrysler. The company does not manufacture substances or preparations itself, it imports them from countries outside of the EU. Approximately 200 personnel are engaged in the further development of substances and preparations.

The problems from the perspective of the company:

- The company fears that important components of the adhesive will no longer be available. This would necessitate changes in its technical properties. This product was developed – as with almost all preparations used for manufacture or during operation – in close co-operation with the manufacturer for this special use. Fundamental requirements for the use of substances, preparations and products, especially in series production, include compatibility with the materials used, adherence to quality and safety standards and occupational health and environmental protection considerations. If products are no longer available, or if the composition of tested products is changed, then complex testing will be required – imposing a substantial financial burden on the company and costing it time. In addition, the registration process involves substantial costs that companies outside of the EU do not have to bear. This gives companies outside of the EU an advantage over EU companies. The flexibility of companies within the EU is reduced and job losses are likely.
- This product reduces the curing time from at least 4 hours to 1 hour. This reduces the total repair time to a few hours (benefiting the customer) and the space required in the workshops / production lines (for series production) is reduced substantially.

- Changes to formulations for service products with properties that are relevant to safety are a particular problem. These products have to be available in unchanged form for a period of decades because of guarantee and repair obligations.
- The global nature of the operations of the company means that substances and preparations have to be imported from non-EU countries. These imports would have to be registered under the REACH system if individual constituents are contained in quantities >1 t/a. This makes a vehicle manufacturer such as DaimlerChrysler a dealer in chemicals.
- The company also imports products (such as motor vehicle parts or entire vehicles) that can contain a variety of substances. It is not at present clear how these substances / preparations will have to be handled as constituents of products that fall under the REACH system.

Solutions proposed by the company:

The long development times for vehicles and the fact that they are used over a number of years means that DaimlerChrysler AG is particularly dependent on the unchanged composition of chemical products and their availability in the longer term, so that it can maintain quality and safety standards. The suppliers would have to carry out the registration of the substances contained in these products (except for the products imported by the company). The close relationship between DaimlerChrysler AG and its suppliers, coupled with its position as a major customer, means that the situation will be more favourable than that of KMU in terms of the availability of substances and preparations.
The process could be improved considerably through a single registration of the individual substances. KMU, and also large enterprises, would profit from this since the costs of registration would be divided proportionately between the different companies. At the same time the number of animals required for experimentation purposes would be reduced.
The use of exposure scenarios and extended Safety Data Sheets would only be possible if outside consultants were used. As with KMU, the company simply lacks much of the expertise required (for instance to perform the animal studies). Exposure scenarios that cover a wide range of uses, or the use of exposure categories, would save money and provide greater flexibility.
A uniform electronic format for the transmission of structured content of the Safety Data Sheet would bring very substantial cost savings, reduce the workload and improve the quality of the data. This would considerably improve communication between the competent authorities, manufacturers and users.

- Revision of the REACH proposal to include “One substance – one registration”
- The purpose of usage should be defined more broadly for trade users and exposure scenarios should be replaced by exposure categories.
- Introduction of a uniform electronic structured format for the transmission of the contents of Safety Data Sheets.

5. Results and Discussion

Under the REACH proposal of 29.10.2003, a manufacturer or importer of substances on their own, in preparations and under certain conditions in products, that are manufactured or imported in quantities above 1 tonne per annum has to submit a registration dossier to the European Chemicals Agency. The registration of a substance must include data on its properties, its uses and how it should be safely handled. The data to be provided is dependent on the quantities in which the substance is manufactured. The data relevant to safety are passed on down the supply chain so that downstream users that use the substance for their own production purposes can do so safely and with responsibility, without endangering the health of their employees or consumers, or impacting adversely on the environment. The European Chemicals Agency will store the data in a central database and will not disclose confidential data to the public upon request. The Agency will check the data for completeness. The EU Commission has estimated that 80% of all registration dossiers will not require any further treatment at the EU level. The national regulatory authorities may, however, request additional tests. In addition, they will monitor adherence to statutory requirements.

Approximately 20% of the registration dossiers submitted by manufacturers or importers will have to be reviewed at the EU level. The regulatory authorities of the individual EU Member States will evaluate the dossiers. This evaluation will be carried out in all cases where animal studies are proposed as such studies should not be performed wherever possible. The REACH proposal therefore envisages the joint usage of test and study data and encourages the use of non-animal testing to derive data. The dossier evaluation should also ensure that the information contained in the dossier corresponds to the requirements of the REACH proposal. The regulatory authorities of the Member States should further evaluate every substance for which they have justified reason to believe that it presents a danger to human health or the environment. The substance evaluations to be carried out should be listed in an ongoing plan that is drawn up by the regulatory authorities of the Member States and is structured in accordance with priority criteria formulated by the Agency. The outcome of this evaluation is that the regulatory authorities may require additional information.

The use of substances that give particular cause for concern should be limited to certain purposes and only be permitted within the framework of authorisation by the EU Commission. Such substances include those that are carcinogenic, mutagenic and toxic to reproduction (CMR substances), persistent, bioaccumulative and toxic substances (PBT substances) and those that are very persistent and very bioaccumulative (vPvB substances), as well as those that have a similar adverse effect on health and/or impact on the environment such as those with an endocrine action. If the risks associated with the use of such substances are sufficiently managed then the approval will be granted. In cases of doubt, the EU Commission will weigh up the benefits to society and industry of the substance on the basis of the documentation submitted and the availability of substitutes. It will then decide on whether the substance is to be approved for use. The EU Commission should also have the power to impose limitations on the manufacture and usage of substances throughout the EU. These would have to be controlled by the EU Member States to ensure that the associated risks are justifiable.

5.1 The registration of substances - workload

Of the 18 companies that participated in the survey, 14 were manufacturers and/or importers of substances, preparations or products for which they assume that registration will be required.

a) Costs and time requirements

All of the companies fear that the proposal will result in substantial time delays for innovations and market launch, as the unregistered uses of existing substances will have to be registered retroactively. This will have a decisive negative impact on the ability of the company to bring a product to market quickly.

A total of 10 companies provided information on the estimated costs of registration for the substance selected. The costs of authorisation were not investigated. The costs given were determined in part on the basis of prices quoted by laboratories to carry out the investigations required, or were based on values derived through the experience of companies that are members of the VCI. Some companies could use their experience of the registration of new substances. The estimation of the registration costs for the substances considered here led to very different results in the individual companies.

The estimated values are also not absolutely reliable because companies have had different experience with registration costs. Furthermore, the REACH proposal allows leeway for interpretation and decisions, for instance on the scope of investigations or on the recognition of older data or on the use of data in the literature.

A total of 7 companies provided data on the total costs of registration for substance quantities in the range 1 – 10 t/a: 4 companies estimated costs in the range €42,000 to €93,000 and 3 in the range €120,000 to €152,000. One of the manufacturers stated that the registration costs would increase from €120,000 to €370,000 if DNEL / PNEC data have to be established.

One company provided an estimate of €152,000 for the registration costs for the quantity class 10 – 100 t/a.

The 2 companies with substances in the quantity class 100 – 1000 t/a estimated the costs of registration at €800,000 and €1 million respectively.

The costs estimated by the companies were therefore, on average, markedly above those established by the VCI. The costs for registration of existing substances given by the VCI, on the basis of registration of new substances by its member companies, are given below. The estimated costs shown are based on the assumption that data for existing substances is recognized and that there is not a substantial requirement for analysis.

Production classes	
1 – 10 t/a	€20,000
10 – 100 t/a	€240,000
100 – 1000 t/a	€400,000

Medium sized companies with a large number of substances in quantities that lie just above the threshold of 1 t/a or 10 t/a will have relatively high registration costs compared to their turnover because of the large number of registrations. This affects, for example, manufacturers and importers of fine chemicals and speciality chemicals, as well as formulators that import substances. One importer and manufacturer of fine chemicals would have to register 475 substances. An authorisation obligation might be required for up to 300 substances, with very considerable costs.

Two of the steps in the registration procedure are particularly time consuming and costly:

1. The performance of analyses and tests, either internally by the company, or by an external laboratory on its behalf, for the determination of data required under Section 9, especially the performance of toxicity tests where required.
2. The performance of a Chemical Safety Assessment (CSA) and the drafting of a Chemical Safety Report (CSR) with assessment of exposure and a risk description in which all of the specified uses are to be considered.

The following further aspects were raised in the survey and are of importance for the cost of substance registration:

b) Work required to satisfy the existing obligations under German legislation for dangerous substances (Gefahrstoffverordnung)

In the discussion of the costs associated with registration under the REACH proposal, the argument was made that the companies already had obligations to obtain information under the Gefahrstoffverordnung. The data obtained could be used under the REACH system, and the costs of deriving that data could be subtracted from those incurred in producing the data need under the REACH system. However, the results of the survey indicate that these costs are so low in relation to the high costs of registration that they can be neglected in the estimation of the registration costs. With one exception, the costs were less than 1% of the costs estimated for registration. The most time consuming aspect to date has been the performance and documentation of the hazard analysis for the substances. In comparison to the current time requirement, the time required for documentation and registration will rise markedly.

c) Documentation of the uses of downstream users

The general consensus amongst the companies was that the documentation of the many downstream uses would present difficulties. Firstly, the number of uses is very large and secondly, the users are not always prepared to disclose their uses to the supplier of a substance to protect their know-how. In one example, a product of a typical formulator comprises 4 substances that the company manufactures itself and 21 substances that it buys from other companies. The company manufactures a total of 300 substances and 1200 preparations. Another manufacturer has 10,000 customers with approx. 50,000 uses. The documentation and reporting of all these uses hardly seems possible.

d) Simplification through the use of a basic database

A further measure that would reduce costs would be to move away from basing the scope of testing on production quantities envisaged in the REACH proposal for the substance safety evaluation and to use the VCI database as a basic source of data for (eco)toxicological assessment. This basic database would then be supplemented by further toxicological tests, depending on the particular exposure situation. In 1997 all of the VCI member companies in Germany undertook to voluntarily set up this database for all substances (including intermediates). The VCI database now covers approximately 96% of all of the substances produced in quantities above 1 t/a.

This VCI database could therefore be used as an initial source of data for the substance safety evaluation under the REACH system. The VCI estimates that the costs of substance safety evaluation for substances produced in large quantities could be reduced by approximately 80%. However, it needs to be clarified whether the (eco)toxicological tests envisaged in the VCI system are sufficient for a basic toxicological assessment of a substance. The data already available could be supplemented by specific (eco)toxicological studies where this is necessitated by particular exposure scenarios / production quantities. The Chemicals Agency should make the decision on this.

e) Criticism of the scope of applicability

Companies expressed the view that a number of products be exempted from the registration obligation, or that the scope of testing be reduced:

- Waste to be recycled: Under the REACH system companies would have to prepare registration dossiers for waste that is to be recycled. The additional costs that they incur could make recycling uneconomic so that it would simply no longer be carried out. This would be contrary to the recycling policy of the EU and waste should therefore be exempt from registration requirements.

- Process chemicals: A company would have to register a substance that is used as a process chemical and is fully reacted in chemical terms and thus no longer present in the product. Any impact of the substance on consumers or the environment can be ruled out. A reduced test program for the manufacturing process in question would be sufficient.

- Sinter materials: The manufacturer of enamelled pots would have to register 15 enamelled frit formulations and apply for the approval of some additives for the downstream - a complex authorisation process. The sintered finished product is completely inert and does not release any harmful substances that would be ingested by humans or impact on the environment. This already has to be demonstrated at present under food safety legislation. The company expects not only that its competitors outside the EU will have advantages, but also that it would impact adversely on innovativeness and know-how protection. The company would like sintered products to be exempt from the registration obligation.

- Alloys: There are fears that alloys could also be classed as preparations and have to be classified accordingly. This would be out of proportion to the actual potential dangers of some metal alloys. One company proposes that alloys be defined as “special” preparations.

To reduce the amount of work required, alloys should generally be regarded as a use within the evaluation of the metal.

- Ores and minerals: The REACH system covers the import of ores and naturally occurring materials containing dangerous substances such as certain heavy metals. In view of the dangerous properties of many nonferrous metals, the EU Commission recommends in Annex III, No. 8 of the draft proposal that not all minerals and ores be exempted from the registration requirement, but only those that are not classified as dangerous under the Directive 67/548/EWC. One of the companies participating in the survey feared that raw materials would no longer be imported into the EU, but would end up in non-EU countries where the REACH system does not apply, and would be processed under less stringent occupational health and environmental protection standards.

- Similar substances or substance groups: In the view of some companies, the registration of every single substance in a group of similar substances (such as pigments) is not absolutely necessary. One way of reducing costs would be to group similar substances together. Certain substance groups, e.g., mineral oils and all enamel frit formulations are assigned a single EINECS number. It is not clear whether such substances can be grouped together to form substance groups under the REACH system as this is subject to interpretation by the individual national authorities. This is a cause of considerable uncertainty about costs for the companies.

f) Additional remarks of companies on the registration procedure

- The majority of the companies in the survey consider the complex requirements of the REACH proposal as too onerous, in terms of content and the commitment of personnel to deal with the system. Participation in this survey alone stretched the resources of some companies – they required up to 14 working days for it.
- The companies in many instances have data available on the substances, but the data was not derived in accordance with GLP requirements. Annex IX of the proposal allows recognition of data that is meaningful and documented. The costs of registration and the number of animal experiments required would be reduced if such data could be used. The recognition of such data is up to the competent national authorities.
- The scope of investigation to determine information to be provided for registration purposes under Section 9 and Annexes V to VIII is open to interpretation in individual cases. In cases of doubt the decision is up to the competent national authorities.

  The last 2 points relate to decisions to be made by the national authorities that have far-reaching financial consequences. A number of companies in the survey expressed the concern that in their experience, e.g., with the registration of new substances, the German authorities adopted a very rigorous stance when deciding on matters open to interpretation. Differences in the decision-making processes and variations in their implementation within the EU could result in distortions of competition in the European market. Decisions on such matters should be made at the European level to ensure uniform implementation within the Member States.

- One company found that upon requesting prices for the necessary investigations that there were insufficient personnel resources to establish substance data under the REACH system, in particular too few toxicologists. This would lead to a bottleneck.
- A revised REACH proposal should make it easier to introduce standardised elements into the process and provide support to companies through "Technical Guidelines" of the Commission and competent national authorities.

  In summary:

  - The registration of substances under the REACH system is costly, time consuming and ties up personnel.
  - Under the draft proposal, the decision on the scope of studies required in individual cases, the recognition of existing substance data and the grouping of similar substances to form substance groups is to be made by the competent authorities of the EU Member States. These decisions will have a decisive influence on the total costs of registration – they should therefore be made at the EU level to ensure consistency.
  - The companies propose that certain products be exempted from the obligation to register constituents, or that the scope of testing be reduced.

5.2 Assessment of the safety of substances (CSA/CSR)

Under Section 13 (4) of the REACH proposal, for dangerous substances in quantities greater than 10 t/a, an assessment of exposure and a risk description are to be provided as part of a Chemical Safety Assessment (CSA). The assessment of exposure embraces the development of exposure scenarios and exposure estimation taking the recommended measures into consideration. The exposure scenario should include the conditions of the method of manufacture of the substance and how it is used during its lifecycle. It should also be stated how the exposure of humans and the environment to the substance is managed by the manufacturer or user (risk management). Exposure scenarios are to be drafted for all the stated uses of a substance. Exposure scenarios may be grouped together for a number of different individual uses of a substance. They are consequently a very complex instrument to provide comprehensive information on the fate of substances in the environment and the exposure of humans. An important aspect of this approach is that the manufacturer is obliged to include the different uses and resultant exposures in the assessment. The assessment of the exposure situation is a central element of the REACH system, but is also a controversial aspect in terms of practicability:

a) Exposure scenarios and downstream use

The questions about the development of exposure scenarios were a particular challenge for the companies. The subject is a multi-faceted one and the wording of the REACH proposal on what form the exposure scenarios are to take is imprecise. In addition, the various terms are used in different ways by those discussing them. These factors not only stretch the companies in the survey, they are a challenge for individuals who deal with this subject all the time.

Those users that would have to draft their own CSAs and CSRs, because their use is not foreseen in the registration documents by the manufacturer, envisaged difficulties in dealing with this aspect. Manufacturers of substances and preparations felt that too much was being asked of them to present all the possible uses of their products. Some examples are given below to illustrate this:

The manufacturer of a hydraulic oil additive stated that it was unaware of the conditions under which its customers and downstream users used the additive, as the market for intermediates involved middlemen and distributors.

If it is assumed that there are 25 customers, each with 4 downstream uses of the product, this yields at least 100 possible exposure situations, all of which have to be established, checked, documented and assessed. This would require approx. 125 working days. Taking a concrete corporate example with approx. 10,000 customers and approx. 50,000 uses, this would necessitate a very considerable effort to draft the CSAs and CSRs. If the substances are considered to be hazardous then exposure scenarios and risk assessments would also be required. If there are changes to processes that are only disclosed afterwards then the system is no longer workable.

A downstream user of this manufacturer consequently fears that the additive it purchases – only produced in small quantities (approx. 10 tonnes per annum) by the manufacturer – will have to be registered as a dangerous substance with exposure scenarios for 85 uses and that its production will cease because of the registration costs of up to approx. €370,000. The product would have to be re-formulated – as would 84 other preparations – and intensively tested with the danger of product loss if no suitable substitute could be found.

The situation is particularly difficult for manufacturers if the substance or preparation they manufacture can be used in very different applications. The manufacturer of a preparation for the textile finishing industry sees possible uses for its product in laundries and in the leather, paper, cosmetics, construction and plastics industries. However, it is not aware of the details and considers a documentation of exposure scenarios to be impossible.

The preparation of detailed exposure scenarios is not possible for a manufacturer and importer of speciality chemicals used for research and development purposes as these uses are not disclosed by downstream users for confidentiality reasons. The company primarily supplies its products to R & D facilities around the world and operates a very effective distribution centre for this in Baden-Württemberg. The manufacturer is considering reducing the manufacture of dangerous substances in Germany to below 1 t/a to avoid having to register them within the EU, and the need to draw up exposure scenarios for dangerous substances produced in quantities > 10 t/a. Manufacture of its products at sites outside of the EU and marketing from those sites would be perfectly feasible for the company. If this step were taken by companies in the chemicals industry then Germany could loose its position as a major site for the manufacture and distribution of speciality chemicals.

b) Simplification of exposure scenarios through the use of groups

The envisaged CSA already allows the assessment of chemical safety to be applied to other substances or substance groups with similar properties. One manufacturer of speciality chemicals believes that the costs of drawing up a CSA/CSR for colour pigments with similar characteristics through groups of exposure scenarios could be reduced to approx. €3,000 per substance. If detailed exposure scenarios are required then the costs would be up to €50,000 per substance. However, the possibility of forming groups is viewed very differently. For instance, in the textile industry exposure is dependent on a large number of parameters (temperature, metering rate, use of an open/closed system etc.). The number of possible configurations is too high for generalisations. The company does not believe that the formation of groups is meaningful in this case.

A further complicating factor for substance manufacturers is the wording used for exposure scenarios in the REACH proposal, i.e., the expression “These exposure scenarios may be as comprehensive or specific as necessary.“ (Annex I, 5.1.1.) is a very vague one. This allows the authorities considerable latitude in the assessment of the data submitted to them. Companies, however, require clearly formulated and precise requirements. Not only small companies, but also large ones, with employees who have been trained in occupational health, regard this aspect of the proposal as too unclear. Affected companies are not in general able to arrive at a realistic cost assessment for the CSA with assessment of exposure and risk description since the amount of work required for this cannot be estimated at present.

c) Simplification of exposure categories

For most of the manufacturers and users who participated in the survey the envisaged use of exposure scenarios is neither efficient nor practicable as a manufacturer cannot be aware of all of the uses of its products. In addition, the obligation to draw up exposure scenarios under the current REACH proposal is not dependent on the actual exposure or risk, but only on the quantity of product (> 10 t/a for the dangerous substance in question).
The VCI has drawn up a model in which exposure categories are combined with a minimum data set on toxicological data. 3 exposure categories are specified:

a) Main route by which the substance enters the body (oral, inhalative or dermal)
b) Ways in which the substance enters the environment (air, water, soil, biota)
c) Duration of exposure (single exposure or short-term, occasional, repeated or long-term)

The exposure categories are subdivided into basic areas of use (industrial, trade or private) and into tolerable exposure levels/stages. The combination with the proposed VCI data set yields a limit value-oriented approach to exposure and risk assessment without a concrete description of use. This would also help maintain confidential information. Downstream users can then measure workplace levels, consult the toxicological data and make comparisons with guideline values for the workplace and environment.

The user therefore assumes responsibility for the use of the substance.
In addition, the VCI database could be used as the primary data source for a substance safety assessment under the REACH system. Depending on the particular exposure situation, or if the substance is produced in high quantities, then the basic data set may be augmented by specific (eco)toxicological investigations.

d) Further development of the existing Safety Data Sheet

The anticipated administrative burden for the preparation of the CSAs and CSRs is viewed by most of the companies as too high. They have proposed an extension of the Safety Data Sheets (SDS) already proven in practice and standardisation so that they can be compared with one another in different EU Member States. Their availability should also be increased. In addition, it is suggested that existing data and experience in practice be used to draw up a “List of sufficiently tested substances” that would be available throughout the EU and maintained by the regulatory authorities. Manufacturers of preparations would be able to more readily consult this list to obtain information about the substances they use. In general, the companies desire a further development of the European Chemical policy in “practicable steps” on the basis of the SDS generally recognized throughout Germany. This would be more readily accepted by the substance and preparation manufacturers and downstream users.

All of the companies were of the opinion that the REACH system could yield a practicable substance safety assessment only if the exposure assessment is simplified.

In summary:

- The communication of downstream uses has to be simplified or grouped together (without disclosing special uses).
- Possible exposures are to be grouped together in categories. Exposure situations are to be considered together (either designated as exposure scenario or exposure category).
- The drawing-up of exposure categories in combination with the VCI database could serve as the first step for the practicable implementation of the substance safety evaluation and would involve the companies in a positive manner. For substances that are produced or imported in higher quantities, or for certain exposure situations, it would be necessary to extend the VCI data base – a decision that would be made by the central Chemicals Agency. In such cases a usage-related exposure scenario could also be used.
- The further development of the Safety Data Sheet already recognized in practice (with corresponding safety assessment), and its implementation throughout the EU should be given further consideration, rather than its existence being threatened by a new complex Chemical Safety Report (CSR).

5.3 Protection of innovation and know-how

Baden-Württemberg is home to a number of companies that have specialized in the production of innovative high-performance products that are sold worldwide. This necessitates highly qualified personnel, modern production processes and research and development that brings results. The companies need to be able to respond rapidly to the needs of their customers. On average, for the companies in this study, approx. 20% of the chemical formulations they manufacture have to be changed annually. For some companies this value may be as high as 35 - 40%.

The main reasons given for changing the formulation are a request by the customer (39%), new developments (27%) and a reduction in impact on the environment and occupational health (26%). The companies have to be able to react quickly to market requirements and the needs of their customers. 16 of the 18 companies in the survey considered their ability to meet customer requirements and their ability to react flexibly as being important/very important for their success.

A major reason for the companies being able to compete with other companies is their ability to react very quickly to market requirements. The average length of the innovation cycle in this sector is 62 months, but the companies here require just 20 months or so for completely new developments and an average of 5 months for simple changes to formulations. The development times depend on the sector and vary between1 month and 180 months.

The companies in the survey manufacture over 3,000 substances, 15,000 preparations and 80,000 products between them. It is therefore obvious that considerable effort has been, and continues to be, devoted to the development of the know-how and innovations.

The companies were very concerned that under the REACH system they would loose this competitive advantage and the flexibility they need to be able to respond to market requirements with the required innovation and speed:

a) Disclosure of information to suppliers

The maintenance of confidentiality for sensitive data is of pivotal importance to companies. The communication of information on the use of a substance or preparation and the production process that is required under the REACH system is a requirement that the companies are unwilling to comply with. The problem is particularly severe for smaller downstream users, especially those with niche products. Even the disclosure of the fields in which the substances are used is regarded as too much information. Time-consuming studies are required to establish the possible uses of substances or preparations. Disclosure of data could allow other companies to skip the expensive studies and offer products that are comparable at a lower price. This was confirmed by one user of a preparation manufactured by a company that is completely unaware of its special properties. Even if the downstream usage of a product is notified to the manufacturer, it cannot automatically be assumed that it is prepared to register this usage. This is apparent from a consideration of the use in aerosols of substances that are flammable, pressurized and regarded as hazardous. Users fear that the substance suppliers will decline to register their special use, or do so only unwillingly, for cost reasons or for product liability reasons.

Approximately 35% of the users in the survey assume that the company that supplies them is not prepared to register the product it supplies.

For one manufacturer that has specialised in the production of enamel frits that are resistant to chromic acid, its 57 different enamel formulations are a decisive advantage in the face of intense competition from within Europe and elsewhere in the world. It cannot pass information on its formulations to its suppliers just as another company cannot disclose information on electroplating. For this small enterprise its know-how development and its 720 preparations are essential to its business. The company also avoids filing applications for patents as this would mean disclosing confidential data. A total of 6 out of 9 formulators stated that they would not be able to pass information on to the manufacturer because of their need to protect confidential data. 8 out of 9 formulators stated that they were unable to pass information on substances to their competitors. To avoid disclosure of know-how, the downstream users would have to undertake their own safety assessment of substances, independently of suppliers. This would involve a commitment of personnel resources and costs that could not simply be passed on through price rises.

Sections 10 and 17 of the REACH proposal allow the formation of consortia and the joint submission of data for registration by the consortia. The purpose of forming such consortia is to reduce costs and the need for animal experiments. However, the companies in this survey do not believe that consortia can be formed because of the need to protect know-how. If substance registration is specific for the application then the protection of know-how may be agreed contractually with customers. However, relevant information cannot be disclosed to competitors with similar system solutions as would be required with the formation of consortia and the passing-on of information jointly. The manufacturer of one “product under guarantee” illustrated this point - it can only guarantee the characteristics of its products through comprehensive and costly tests. It cannot, under any circumstances, pass the relevant information to its 4 competitors on the market within the framework of a consortium. Furthermore, clarification is required on whether international or national anti-trust laws would fundamentally prevent the formation of consortia.

b) Hindrance of innovativeness and time delays in bringing products to market

The ability to bring products rapidly to market contributes substantially to the success of innovations. 77% of the companies in the survey stated that the ability to bring products to market quickly was particularly important for them. The companies, however, believe that the REACH system will cause considerable time delays. The delays that result from the time taken to prepare a registration dossier and the registration process were estimated by the companies at between 12 and 18 months. A period of 12 to 15 months would be required for the registration of new substances. Under the present chemical regulations for existing substances, the administrative burden for the companies has been lower, and could be handled in parallel to product development. The companies will take the workload for registration into consideration when making decisions on the research and development of new substances. If the workload is considered too high, then they may refrain from developing new substances.

A considerable problem for the development of innovations is that downstream users are dependent on the developments of their suppliers. Developments are often the

result of co-operation between downstream users and manufacturers. The manufacturer of PVC films for doors and windows has to carry out comprehensive tests of the substances to establish their ability to withstand weathering. Alternative raw materials have to be available within a few days for investigation purposes during the laboratory and production phases, even though they may not have been registered by the manufacturer initially for such purposes. The risk for the downstream user is that the supplier will not register the substance at all, or not for this use.

c) Restriction of product variety and removal of niche products from the market

A further consequence of the proposal could be a reduction in the variety of products available within the EU and the trend towards standard solutions on the market. One company in the textile sector anticipates a considerable restriction in the variety of inks and the quality of inks, since the removal of substances used in small quantities from the market will hinder innovation on the part of the ink suppliers. This would have a negative affect on the competitiveness of the companies operating in the fashion industry, where an ability to react rapidly is essential.

The following proposals have been derived from the results of the survey:

- "One substance – one registration" managed by an institution of the EU that is independent of Member States and companies, could avoid the problems of know-how protection since confidential data would not have to flow through the suppliers. This would also avoid the necessity for the formation of consortia by competing companies. The costs of the registration process would be allocated by the institution between the companies - the particular circumstances of small and medium sized enterprises could be taken into consideration here. In this respect this approach differs from the concept presented by Hungary/the UK[6].
- An alternative would be a 2-stage approach for the registration process - which would accommodate the need for know-how protection of downstream users. Manufacturers would register a wide range of possible uses and this data would be passed on to the downstream users. The users then notify their special uses to the registration authorities that have to maintain confidentiality. This approach would have to be accompanied by a simplification of the preparation of exposure scenarios or the use of exposure categories (VCI).
- Where products have to be developed within short time frames (for example dyes used in the fashion industry), the possibility of a simplified downstream registration would ensure the flexibility and innovativeness of the company.

5.4 Import of substances and products

The import of substances, preparations and products is of critical importance for the companies in the survey. 14 out of 18 companies import substances/products from non-EU countries and 15 companies export to non-EU countries. Approximately 91,000 substances and around 3,000 preparations are imported from those countries. This compares with the import of approximately 5,000 products.

[6]One substance – one registration: a joint proposal from Hungary and the UK (Non-paper of the EU, 2004)

The companies can be affected at one of 2 levels by the REACH proposal in terms of the import of substances and products:

a) As an importer that has to register substances and preparations in accordance with Section 5 and products in accordance with Section 6,

b) as a company that manufactures substances, preparations and products in accordance with the REACH system and has to compete with imported products.

a) Advantages for imported products

Companies that produce products that fall under the requirements of the REACH system anticipate new difficulties: Their production costs will inevitably rise. Products that are manufactured outside of the EU are generally subject to less rigorous occupational health and environmental protection regulations compared to European standards. The companies consider themselves to be at a disadvantage compared to products manufactured in countries outside of the EU. These companies therefore want the REACH proposal to be changed to remove these disadvantages.

For instance, the manufacturer of enamel cookware in Baden-Württemberg anticipates that manufacturers based outside of the EU, who do not have to register their products under the REACH system, will be able to export their products into EU Member States without difficulty as the enamel layer means that toxic substances are not released if the cookware is used properly. The manufacturer in Baden-Württemberg, by contrast, will have to register the enamel frit as a substance.

In the textile sector, on the basis of tests carried out to date, there is the fear that textile products such as T-shirts that are imported will contain a higher level of toxic substances when they reach the consumer in the EU.

In addition, the provisions in Article 6 of the proposal for the general registration obligation for substances contained within products allows considerable scope for interpretation in terms of the conditions for release (1.c and 2.d) and the knowledge of the producer or importer on the probability of release (2.c).

For products produced within the EU it can be assumed that the application of the provisions of REACH to the starting materials will provide data on the products in terms of environmental protection and health protection and that these characteristics will also be determined. For the importer of products, by contrast, registration is only necessary if it has a knowledge of substance release characteristics, or if it is informed of those characteristics (> 1 t/a). The importer of products is therefore in a better situation since it is not subject to the demonstration obligation for starting materials that apply to a producer within the EU. The REACH proposal should therefore be changed so that an importer of products has to demonstrate a knowledge of the probability of release. This would mean that the requirements would be closer to those that the manufacturers of products in the EU have to meet. However, this is only a partial solution.

The expert committee for environmental matters (SRU) regards the obstacles to the registration of substances in products as being substantial since all of the conditions presented in Section 6, paragraphs 1 and 2 have to be satisfied, for registration to be required.

The SRU considers that the provisions of Section 6 are not enforceable, in particular for imported products, since the authorities responsible for ensuring that the conditions are satisfied would have to be in possession of the information at the time of the controls – and this is not possible since the information is only generated in the course of registration.

b) Dependence of suppliers and the non-availability of imported substances

The importers of substances and preparations are subject to the same provisions under the REACH proposal as manufacturers and formulators within the EU. The difficulty for them is that they are dependent on the availability of data, the quality of that data and, not least, the supply policies of the manufacturers outside of the EU, for the registration of substances and preparations.

A formulator in the textile finishing industry fears that manufacturers outside of the EU will have no interest in the complete disclosure of formulations, thus protecting their know-how, because the quantity imported into the EU is too low relative to the production quantity outside of the EU. Any disclosure of formulations would give competitors elsewhere in the world a competitive advantage. This could affect the import of approximately 200 raw materials and preparations for the German formulator. These may then be no longer available.

It is assumed that the workload for the registration process will not be lower for importers than for manufacturers in the EU. Some companies reported that additional work is necessary because of the poor quality of the Safety Data Sheets. The SRU also reports that it has found that only 38% of the terms used and approximately 25% of the Safety Data Sheets are actually satisfactory in all respects[7]. It is therefore hardly to be expected that available data on the assessment of substances from countries outside of the EU (e.g., the Far East) will be of the same quality as that required for registration under the REACH system.

Companies are uncertain of how products imported under the REACH system that contain "operating agents / constituents" are to be treated. One company in the automotive industry imports motor vehicles, ready for sale, from subsidiaries in non-EU countries. These motor vehicles contain agents such as engine oil and gear oil, coolants and windscreen washing agents etc. Another company imports door locks that contain a hydraulic oil. The company cannot assume that the Chinese manufacturer will use a hydraulic oil that has been registered in the EU.

These companies need to know whether these constituents have to be registered under the REACH system. Many companies that import complex products expect to face considerable workloads/expenses.

c) Circumvention of registration requirements

The companies also believe that there was a danger that manufacturers based in non-EU countries would export their products to the EU through different distributors to circumvent the maximum quantities threshold. One manufacturer of chemicals anticipates that medium-sized enterprises in the EU that produce chemicals on a large scale will be considerably disadvantaged. Producers based in Asia with a production volume > 1,000 t/a can export chemicals into the EU in quantities below 1,000 t/a through each of approximately 60 distributors.

[7] SRU Expert report May 2004

The distributors - who are responsible for the registration procedure - are exempted from the onerous registration obligations for substances in excess of 1,000 t/a for a transition period of 6 years, with a lower obligation to supply information. The preparation of the registration dossier required under the REACH system for chemicals manufactured on a large scale by domestic manufacturers (with a 3-year transition period) would allow competitors from outside the EU to use the data available at a later date without incurring costs. The company regards this as an indirect subvention of competitors outside the EU.

Companies with production sites in Germany are also considering ways in which they could bypass the registration obligation: A manufacturer of fine chemicals, that uses Germany as a base from which to send its chemicals to all parts of the globe, is considering whether to control the import quantities through organisational measures. The costs of registration would be kept low by keeping the quantities below the relevant thresholds. Germany would then loose its importance as a major site for exports.

- The advantages that imported products have over products manufactured within the EU is a grave problem. The changes proposed to Section 6 can only deliver a partial solution and have to be compared to the requirements of the WTO to assess conformity.
- The European Chemicals Policy and legislation will have to be applied at an international level.

5.5 Harmonisation of legal requirements and enforcement

Two thirds of the companies in the survey regarded the harmonisation of national legislation and EU legislation as one of the most urgent requirements. The companies want clear and unambiguous regulations, without conflicting requirements for different legal jurisdictions. Any duplication of requirements must be removed.

Examples of the problems that will be encountered include the conflict between the EU Directive on Waste (75/442/EWC) and the German recycling legislation and the REACH proposal. If waste in waste treatment plants or recycling plants is not exempted from the registration obligations under the REACH system then this would make the recycling of waste more expensive and could threaten the existence of recycling facilities.

The EU Waste Directive 75/442/EWC and the Medicinal Products Directive 93/42/EC have been cited as examples of statutory requirements that are adequate, and where the REACH system would only be a duplication.

The companies are also concerned about the consistency of implementation of the statutory requirements. In other words agreements should be reached at an international level that would have to lead to further changes in European law making. An example cited was the *"Globally Harmonized System for the Classification and Labelling of Dangerous Chemicals* (GHS)".

The conclusion drawn from the statements on the harmonisation of the legal framework is that the simplification associated with the REACH system through the rescission of 40 Directives and 2 regulations is not comprehensible. The requirement for harmonisation in the near future and reconciliation of legal requirements appears to be justified.

The desire for harmonisation of the legal framework was closely tied to a requirement that implementation of the REACH system be uniform throughout the EU. The companies emphasized the point that – on the basis of their experience to date – they expected considerable differences in the way in which the REACH system would

be implemented within the EU. They fear that companies will be treated differently in different countries in terms of the evaluation of the dossiers, or that import controls will be carried out at different frequencies and adopting different standards.

It is regarded as beneficial if the organisation of the registration procedure be handled by a European institution that collects the registration data centrally, whilst maintaining its confidentiality, and orders the relevant studies etc. to be carried out, using companies it selects. In addition, this institution should check implementation of the requirements at a national level through checks of particular points. The European Economic and Social Committee also sees advantages if dossiers and substances are evaluated centrally by the Chemicals Agency, but in close co-operation with the authorities of the individual Member States[8].

The companies want to see the introduction of the following:

- Harmonisation of statutory requirements, especially removal of duplication
- An independent European institution that, as a service provider, is independent of companies and organises substance registration whilst maintaining confidentiality and which decides on the allocation of costs between companies
- Evaluation of dossiers at a European level rather than a national level
- National institutions that provide advice on registration
- Uniform implementation of the requirements, e.g., for import controls
- Controls of critical aspects, analogously to the Equipment and Product Safety Act in accordance with the European Product Safety Directive

5.6 Importance of the non-availability of substances for the companies

Questions relating to the non-availability of substances and the impact in technical, economic and consumer terms, were of particular importance to the companies. A number of the companies assumed that manufacturers or importers would not be prepared to register certain substances because of the high costs. As a result, these substances would no longer be available and the import of primary raw substances would be endangered. The substances would then be removed from the market not because of any danger to humans or the environment, but simply because the costs of registration under the REACH system would be too high in relation to the turnover and profit.

The most important consequences of the absence of substances from the market include the following:

a) The search for substitutes is time-consuming and will lead to time delays and changes in quality

If substances are no longer available than suitable substitutes will have to be found. The companies point out that the development of new products using other substances is a costly process and will involve time delays, supply problems and changes in quality. They estimate that the cost of developing a product using new substances could run to €150,000, and one company estimates the cost of testing a new substance at €1 million, based on its experience with the registration of new substances..

[8] Opinion of the European and Economic Social Committee of 30.04.2004 (2004/C112/24)

The development of new products will involve time delays. It can take up to 18 months to develop new products to the stage where they are ready to be launched on the market. This requires comprehensive testing and the products have to be re-approved. The time delays could result in supply problems and the imposition of penalties. For example, companies that supply the automotive industry or manufacture medicinal equipment must have their products certificated for the use in question. If, for example, the formulation of paints used in the automotive industry is changed because certain substances are no longer available as a result of the registration process, then re-certification will be required and will take at least 4 - 6 months. With disposable syringes, the certification for the printing inks used for marking takes 1 - 2 years.

New formulations may involve a deterioration in quality and changes to technical properties. An example of the poorer technical properties is the longer curing time for adhesives, resulting in an increase in the time required for production and repair. A processor of plastics is concerned that the absence of speciality chemicals means that it will no longer be able to maintain its current product quality. If pigments are changed then it will no longer be possible to reproduce the colour of various products and colour fidelity - an important quality criterion - will be in danger. If laboratory and fine chemicals are no longer delivered then this will impact adversely on special uses in research and diagnostics.

b) Reduction in the range of products manufactured

Some of the companies in the survey could not see any way in which substitutes could be found for substances that disappear from the market, because of the costs involved. The only alternative is to cease manufacture of the products or to switch production to a country outside of the EU. The result would be a reduction in the range of products available and the increased use of standard products. This would remove the competitive advantage of companies in Baden-Württemberg that manufacture a range of products to meet the individual needs of their clients.

The following measures are proposed to reduce the workload for registration and thus reduce the danger of substances no longer being available:

- The use of groups of exposure scenarios or exposure categories to estimate risk.
- The recognition of suitable data already available on physico-chemical and toxicological properties.
- Avoidance of repetition in the study of substances through the use of a suitable model – “One substance – one registration“.

5.7 Economic consequences for the companies

Various aspects of the new European Chemicals Policy that will have economic consequences were mentioned briefly in the above sections of the report. The most important of these are:

a) Cost increases will reduce turnover and threaten jobs

One result of the survey and a fact that is not disputed in the discussion of the REACH proposal is that this complex procedure will result in price rises. The costs estimated by the companies for the registration of substances were on average markedly above the costs determined by the VCI. It was not possible to carry out more exact calculations within the framework of the survey. One company anticipated a twofold increase in the sale price of its products. In some cases it was found that the cost of complying with the REACH proposal would be higher than the annual profit obtained for that product. For instance, one company has an annual profit of €350,000, but estimates the cost of registration of the product at over €1 million – 3x its profit. It would therefore be uneconomic to continue the manufacture of that product.

Companies reported that they had refrained from making investments because of the uncertainty surrounding the introduction of the REACH system and the associated unforeseeable risks attached to it. All of the companies were agreed that the cost rises would make their products less competitive in price-sensitive markets. An increase in the price of their products was not feasible and the result would be a segmentation of the market and corresponding fall in turnover.

The companies in the survey believe there is the danger that customers would search for other suppliers and switch to other products. Price rises and a fall in turnover could threaten the existence of the company. As a result, some companies could withdraw from the market or switch production to countries outside of the EU, with a resultant loss of jobs. Large companies are in a better position to avoid the cost increases through the REACH system by switching production to other countries. Smaller companies might be forced to give up production of those products.

b) Companies would be less competitive through a reduction in quality, delays, impediments to innovation and disclosure of confidential information

The companies in Baden-Württemberg are successful for a number of reasons - the high quality and wide range of their products and their advanced technical characteristics, the innovativeness of the companies, their special expertise, their ability to respond rapidly to customer needs and their flexibility. The companies believe that these competitive advantages would be lost as a result of the introduction of the REACH system.

Examples drawn from the companies' product ranges show that a reduction in the availability of substances will result in changes to the quality of their products. For example, even small changes in the formulations of printing inks and dyes used in the textiles sector will reduce quality. An example of a deterioration in performance for the user is the non-availability of substances for electroplating of the cylinder walls of engines, resulting in a marked loss in the performance of the engine.

The registration procedure itself, or the fact that substitutes need to be found for substances that are no longer available, will result in time delays. The companies in the survey that supply the automotive industry must have their products certificated, a process that takes at least 4 - 6 months. Other companies with products used in the food industry must show that those products are compatible with food, or that they are physiologically inert, a process that takes 1 - 2 years. Other companies are dependent on their ability to bring fashion dyes rapidly to market. Delays for these companies mean that they will be at a disadvantage compared to their competitors who do not have to comply with the requirements of the REACH system.

Innovations will be hindered by the absence of substances from the market, the costs associated with registration and the tying up of personnel by the registration process.

The disclosure of information on the use of substances and formulations will also be an advantage for competitors outside the EU. Those competitors will no longer need to devote their own resources to development work.

c) Imports are favoured over manufacture within the EU

Importers can use organisational measures to reduce the workload under the REACH system. Products from countries outside of the EU can be split between a number of importers so that each importer does not reach the threshold under the REACH system. For instance, if a single importer brings less than 1 t/a of a substance into the country then registration is not necessary. This gives them a considerable advantage over producers in the EU.

Importers also have an advantage over manufacturers within the EU for the import of products that contain hazardous substances. One reason for this is that the substances present in products only have to be registered if the importer has a knowledge of their release, or can obtain such knowledge. A manufacturer within the EU would have such knowledge as a result of the application of the provisions of the REACH system to the starting materials. Such a manufacturer cannot argue that it has inadequate knowledge of the release of hazardous substances.

Imported products and cheaper products of poorer quality and possibly containing impurities – referred to as low-level products - are favoured in the marketplace.

- The companies believe that the workload involved in the registration of substances will lead to cost rises.
- Companies in the EU will be at a disadvantage compared to those outside of the EU because of a loss in quality, time delays, reduced innovation, disclosure of information and withdrawal of substances from the market. Jobs are at risk.
- The uncertainty surrounding the introduction of the REACH system means that companies are already cutting back on investments.

6. Conclusions and recommendations

Although the aims of the European Commission White Paper on European Chemicals Policy have found widespread approval from all those affected, the REACH proposal in its present form has been criticised by various bodies with opposing arguments. The possible economic consequences, in particular, are a subject of controversy.
The aim of this study was to assess the anticipated impact of the REACH system on various companies in Baden-Württemberg. It is apparent from the numerous examples given that the companies expect a substantial impact - in terms of workload and economic consequences. As a result, the success of individual products, or of entire product ranges, will be put at risk. In some cases the profitability of the company is threatened.
The companies in Baden-Württemberg are mostly medium sized enterprises that specialise in innovative high-performance products, often produced in small quantities and a wide variety of types. The companies have to be able to react rapidly and flexibly to market requirements and adapt their products accordingly, or develop new ones. This know-how is their main resource. However, because of the cost structures in Germany and the intense competition with companies around the world, the companies have only a small amount of latitude in economic terms. They therefore consider themselves to be particularly affected by the additional workload that will be required under the REACH system. The results of this survey show that the REACH system in its present form would be expected to impact considerably on employment levels in Baden-Württemberg.

However, the economic impact is only one aspect of the REACH proposal. The rationale of the proposal is to improve the knowledge base for substances and provide information on the safe handling of the substances within the EU. Such a regulatory framework must not be restricted to the EU. International regulations relating to the information to be supplied for chemicals are long overdue and would lead to a real improvement in the health of personnel and consumers and a reduction in environmental impact around the world. Without such regulation on an international scale, the implementation of the REACH proposal will mean that production is increasingly switched to cheaper countries outside of the EU that have low less stringent requirements for the protection of health and the environment. This would put companies within the EU at a disadvantage. In addition, the import of inadequately tested products from outside the EU would impact adversely on the environment and health of consumers in the EU.

The statements of some companies indicate that the relocation of production facilities to countries outside of the EU would not be a difficulty and some of them are already considering such a move. A European Chemicals Policy that forces companies to relocate their production facilities will not achieve its aim of sustainable protection of human health and the environment.

The fears of the companies are understandable. They would like the regulations to implement the European Chemicals Policy to be

- simple
- formulated in terms that are comprehensible
- not excessively increase the organisational workload or costs
- effectively protect the health of humans and the environment
- not impact negatively on competitiveness.

The examples drawn from the companies showed that the REACH proposal in its present form does not satisfy requirements in a number of areas and requires revision. The practicality of the REACH system needs to be re-assessed critically. The Landesanstalt für Umweltschutz proposes that the EU Commission consider the following recommendations and assess their feasibility:

- **Simplification and cost reduction through the model "One substance – one registration"**

  Under the proposed REACH system, each manufacturer or importer is required to carry out its own registration of substances. This will result in a large number of unnecessary investigations of similar substances within the companies and within the Chemicals Agency.

  The setting up of an Institution that is independent of companies and the individual countries under the governance of the EU (e.g., a Chemicals Agency) that administers the registration procedure centrally and requires identical substances to be only registered once would be a considerable improvement. Each substance would be assigned a registration number and all substances would have to be registered with the Agency by all companies, stating production quantities, within a specified time frame. The institution would have an obligation to maintain the confidentiality of all corporate data - a condition that is of considerable importance to the companies concerned. The necessary investigations will then be carried out after review of the data by the companies. The Institution will decide on how costs are to be allocated between the various companies that produce the same substance. This approach goes beyond the proposal made by Hungary/ the United Kingdom.

  This would not only save costs but also reduce the need for animal experimentation.

  Different proposals have been made for the model "One substance – one registration, and these should be investigated. The proposals that consortia be formed for the registration procedure cannot be implemented in practice because of the impact on the competitiveness of the companies and because of antitrust legislation.

  This proposal differs from the concept presented by Hungary and the UK that envisaged manufacturers or importers of a substance carrying out pre-registration within a certain time frame. In the process they would declare their intention to register a certain substance in a certain quantity class. The list of pre-registered substances would then be published by the Agency. Other producers who also wish to register the same substance, and users of that substance that have substantial data on it, would have to provide that information within a certain time period to the forum for the exchange of substance information (SIEF) under Section 27. The forum would then organise the registration. The substance data is collected and presented to the agency and may need to be supplemented for registration purposes. The Agency decides on the cost allocation between the various companies that produce the same substance. All of the approaches that have been proposed to date represent a simplification of the process for the registration of substances produced in large quantities, but at the same time present disadvantages for manufacturers of small substance quantities or speciality chemicals. For this reason, the proposals submitted need to be revised to take account of the needs of SMEs.

- **Simplification of the registration procedure through the use of a basic data set**

A further cost-reducing factor would be to move away from the scope of testing on the basis of the production quantities to assess the safety of substances and to adopt the VCI data as a basic data set for (eco)toxicological assessment. However, it needs to be clarified whether the (eco)toxicological tests envisaged in this data set are sufficient for a basic toxicological assessment of a substance.

The data in this basic data set would then be augmented by data from further toxicological tests, depending on the actual exposure situation. In 1997, all of the member companies of the VCI undertook to voluntarily compile this data set for all substances (including intermediates). This VCI basic data set now covers approximately 96% of the substances that are produced in quantities > 1 t/a.

- **Simplification of the exposure assessment**

The manufacturer or importer of a substance is obliged to include all uses and resultant exposures for the substance in its safety assessment of dangerous substances produced in quantities > 10 t/a. This is hardly feasible In view of the large number of uses and the necessity to protect confidential information. The workload for the companies is too onerous and, moreover, is not justified for the benefits that will be obtained.

The preparation of exposure scenarios for the substance uses is envisaged within the framework of exposure assessment. The REACH proposal provides only vague information on how the exposure scenarios are to be framed and the instrument of exposure scenarios on the whole appears to be too complex in its present form for the companies. A simplification of the exposure assessment as follows is required:

- The procedure for the notification of downstream uses needs to be simplified / allowed in summary form (without disclosure of special uses).
- Possible exposures must be standardised in summary form. Exposure situations are to be grouped together (either as exposure scenarios or exposure categories).
- The use of exposure categories, combined with the VCI basic data set, could serve as a first step for the practical implementation of the substance safety assessment and would be welcomed by all involved. For the substances produced or imported in higher quantities, or for corresponding exposure situations, it would be necessary to expand the data in the VCI data set - with responsibility for this assumed by the central Chemicals Agency. In such cases usage-related exposure scenarios could be taken into consideration.

- **Further development of the Safety Data Sheet**

  The Safety Data Sheet – now widely adopted by companies – should be used throughout the EU and its data quality improved (to include a safety evaluation), rather than being replaced by a Chemical Safety Report (CSR) that is new and complex and will endanger the existence of the SDS. Measures should be introduced to ensure that Safety Data Sheets are of comparable quality throughout the EU.

- **Harmonisation of legal requirements of the EU at an international level**

  It is essential that substance legislation be standardised and harmonised in the near future to meet requirements in practice. Any duplication of regulations must be eliminated. The companies in this survey could not comprehend the stated saving of 40 Directives and 2 German ordinances announced in the wording to the REACH proposal.

  The issue of an improved REACH proposal at the EU level must be accompanied by efforts to implement a corresponding international chemical legislative framework in the near future. This is necessary to prevent unintentional adverse effects of the European Chemicals Policy on the protection of the environment and human health on a global scale, to the detriment of companies based in the EU. The disadvantages to manufacturers within the EU as a result of imported products are of particular importance here.

- **Uniform implementation of the REACH system throughout Europe**

  Many companies have expressed the fear that the European Chemicals Policy will be implemented differently within the EU Member States. These differences may be manifest at the level of national dossier evaluation for the registration or in the review of Safety Data Sheets or import controls. These fears are justified – given the considerable inadequacies of Safety Data Sheets and the classification of preparations established by the EU. The following measures would assist uniform implementation throughout the EU:

  - Dossier evaluation at a European level by the Chemicals Agency, and not at a national level
  - Investigation of particular points analogously to the European Product Safety Directive
  - Regular evaluation of implementation by national authorities by the Chemicals Agency
  - Decisions to be made on aspects open to interpretation at a European level.

- **Creation of a level playing field for imported and domestic products**

  The companies regard the disadvantages to companies within the EU as very considerable.

  The hurdles for the registration of substances in products from countries outside of the EU, as given in Section 6, are considered to be too high. The requirements for the general registration of substances in products allow too much latitude in their interpretation in those points that relate to the conditions for substance release (1.c and 2.d) and the knowledge of the producer or importer of the probability of release (2.c). In addition, it will hardly be possible to test imported products since the information required for this will only be generated upon registration.

  As a consequence, it is to be assumed that the trend towards switching production to countries outside of the EU and the import of the products will continue to increase. This means that producers within the EU Member States will be disadvantaged. Mechanisms need to be put in place to ensure that imported products are not favoured over products produced within the EU that are governed by the REACH system.

- **Cost reductions through recognition of appropriate existing substance data on physicochemical and toxicological properties**

  There is already a large volume of data available within the companies on the 30,000 substances of relevance to the market – although this data has not been obtained using Good Laboratory Practice as required under the REACH system. However, provided that the data has been derived correctly and is sufficiently documented, there is no reason why it cannot be used. To prevent unnecessary, new and expensive studies, as well as unnecessary animal experiments, Section 12 and Annex IX should be supplemented in relation to the recognition of existing substance data such that the quality criteria for the recognition of existing substance are specified explicitly.

- **Review of the necessity for registration of certain substances and specification of the criteria for group registration**

  It should be investigated whether registration is required for particular substances / substance groups where these are already subject to other legal requirements. For instance, waste for recycling is included under the REACH system. This may put the recycling/re-use of waste - promoted under the recycling legislation - at risk. The high registration costs under the REACH system mean that waste producers and recycling plant alike will be disinclined to recycle these wastes.

  It is also necessary to check whether process chemicals, alloys, enamel frits, ores and naturally occurring materials can be exempted from the registration obligations under certain circumstances. The work required for registration should be commensurate with the actual hazard potential.

  Criteria should be specified for group registration for substances that are similar or groups of similar substances (such as pigments). This could be easily done for substances that have the same EINECS number, such as enamel frits.

- **Support for the registration process**

  Irrespective of the revision and simplification of the REACH proposal, the companies consider it necessary – especially for SMEs – to be given advice on the registration process that is competent and binding, e.g., through "REACH service providers". The results from the survey show that most of the SMEs do not have the personnel or financial resources to undertake registration without assistance. It should be clarified whether advice should be given at an EU or national level. These "REACH service providers" should also be available for data research purposes.

- **Further proposals for changes to the REACH proposal**

  With those products, such as dyes for use in textiles in the fashion industry, where the ability to respond quickly to market requirements is critical, it should be investigated whether the manufacture and import of substances necessary for the development process can be exempted initially from registration. Registration could then be carried out before market launch of the product.

  In addition to a substantial simplification of the registration procedure, the EU Chemicals Agency could provide examples of the registration of basic chemicals and chemical elements, markedly increasing the acceptance of the companies involved and communicating the "rules" of registration. This would provide a concrete example of the registration procedure, the evaluation and authorisation of substances.

  Data exchange between companies and the registration and evaluation authorities should also be made easier through the provision of uniform data formats. All of the registration steps should be possible online.

The Landesanstalt für Umweltschutz regards all of the above proposals as particularly important aspects of the REACH proposal that should be revised. In addition, this report contains further points that the EU Commission should consider. These have not been repeated here as some of them are matters of detail.

Glossary

BWIHK	Chamber of Industry and Commerce Baden-Württemberg
CMR substances	Substances that are carcinogenic, mutagenic and / or toxic to reproduction
CSA	***C**hemical **S**afety **A**ssessment* An assessment of the safety of substances. This is a risk assessment in which the company undertaking registration takes into consideration risk management measures that it will either use itself for its own purposes, or will propose to downstream users for their use.
CSR	***C**hemical **S**afety **R**eport* This provides a comprehensive evaluation of substance safety
DNEL	***D**erived **N**o **E**ffect **L**evel* Lower limit, below which the substance has no effect
Downstream user	Natural or legal person with a base in the community, not identical to the manufacturer or importer, that uses a substance in the course of its industrial or trade activities, or in a preparation
EINECS	***E**uropean **In**ventory of **E**xisting Commercial **C**hemical **S**ubstances*
EU	**E**uropean **U**nion
Exposure category	Collation of similar exposure situations to form a group, following VCI standardisation of exposure situations (take-up route, mode of usage, frequency and duration). The term is used in this report in the manner adopted by the VCI
Exposure scenario (REACH)	An exposure scenario is a combination of conditions that are used to represent how a substance is manufactured or used during its lifecycle, and how the manufacturer or importer manages the exposure of humans and the environment, or makes recommendations on the management of downstream uses.
GLP	**G**ood **L**aboratory **P**ractice
IHK	**I**ndustrie- und **H**andels**k**ammer [Chamber of Industry and Commerce]
Importer	Natural or legal person with a base in the community that is responsible for importing a substance, preparation or product
LfU	**L**andesanstalt **f**ür **U**mweltschutz Baden-Württemberg [Baden-Württemberg Institute for Environmental Protection]

Manufacturer	Natural or legal person with a base in the community that manufactures a substance in the community
PBT substances	Substances that are **p**ersistent, **b**ioaccumulative and **t**oxic
PEC	***P**redicted **e**nvironmental **c**oncentration*
PNEC	***P**redicted **N**o-**E**ffect **C**oncentration*
Preparation	Suspension, mixture or solution comprising 2 or more substances
Product	An object, comprising one or more substances or preparations, given a specific form, surface or shape in the course of its manufacture that determines its final function to a greater extent than its chemical composition
REACH	**R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals Draft proposal for a new EU regulatory framework for chemicals, issued 29.10.2003
SDS	**S**afety **D**ata **S**heet The most widely-adopted instrument for the communication of relevant information by manufacturers, importers or downstream users to parties further down the supply chain
SMEs	**S**mall and **m**edium sized **E**nterprises
SRU	**S**achverständigungs**r**at für **U**mweltfragen Committee of Experts for environmental matters
Substance	A chemical element and its compounds in a naturally-occurring state, or produced through a manufacturing process, including additives necessary to ensure product stability and any contaminants introduced through the manufacturing process, with the exception of solvents that can be separated from the substance without adversely affecting its stability or changing its composition.
t/a	Tonnes per annum
UVM	Ministerium für Umwelt und Verkehr Baden-Württemberg [Baden-Württemberg Ministry for Transport and the Environment]
Use	This covers the processing, formulating, utilisation, storage, making available, treating, filling into containers, transferring from 1 container to another, mixing or manufacture of a substance/preparation/product or any other use.
VCI	**V**erband der **C**hemischen **I**ndustrie [Association of the German Chemical Industry]

vPvB substances	***V**ery **p**ersistent and **v**ery **b**ioaccumulative substances*
WTO	***W**orld **T**rade **O**rganisation*