



White Paper for the Reform of Chemicals Policy:
From Concept to Implementation

**Requirements, Experiences and Perspectives
in Relation to Information Flow**

Documentation of the results achieved in the discussions of the working groups in
the "Product Chain Chemicals Policy" project set up by the Verband der
Chemischen Industrie (German Chemical Industry Association) under the direction
of the Öko-Institut e.V.

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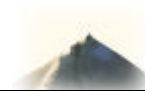
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Preamble

To investigate the "Organisation of information flow in the product chain", the Verband der Chemischen Industrie e.V. or VCI (German Chemical Industry Association) together with some of its member associations is carrying out the "Product Chain Chemicals Policy" project.

In August 2000, the Öko-Institut e.V. was commissioned by the VCI to direct the working groups established as part of this project and supply content input.

Four working groups were set up, each of which examined a specific substance or group of substances by way of example. The member associations of the VCI that participated in the discussions were the Association of the Plastics Processing Industry (VKE), Association of the Printing Ink Industry, Association of the Paint Industry (VdL) and Industrial Association for Organic Colorants and Pigments (IFOP). Manufacturers, traders and downstream users were also represented in the working groups. The names of the participants are given in Appendix 6 at the end of this Report. The activities of the working groups were guided by a project steering committee, which was composed of representatives of companies and the management of the VCI and trade associations (see also Appendix 6). In the steering committee, a supervisor was appointed for each working group.

The brief of the Öko-Institut included not only direction of the working group sessions and the supply of content input but also discussion of the results achieved by the working groups in the project steering committee, preparation of recommendations for the legislators and documentation of the results of the working groups in the form of this final Report.

The final Report has been written as a documentation of the results by the Öko-Institut e.V. The summary contained in it, with recommendations for the legislators, was based on the results of the working group sessions and agreed with the steering committee and supervisors of the working groups.

Summary: Recommendations for legislators

The "Product Chain Chemicals Policy" project, commissioned by the VCI (German Chemical Industry Association) and carried out by the Öko-Institut e. V. in collaboration with VCI trade associations, completed its working group phase on February 28th, 2002. The project selected four substances (existing and new substances) in specific use scenarios to examine how the requirements of the EU White Paper on Chemicals Policy will affect the actors in the product chain in terms of "registration" under the REACH system. Manufacturers, producers of preparations and downstream users (large companies and SMEs) participated in the project.

The cases studied showed that the risk assessment required by the EU White Paper can be implemented throughout the product chain, if the following recommendations are taken into account in the new chemicals legislation of the European Union.

The recommendations are concerned only with a few crucial aspects of registration in the product chain and not with the whole subject of registration. Neither do they touch on questions arising in the product chain with regard to the system of "approval" under REACH. It has become clear during the project that the way legislation on registration duties under REACH is framed will be critically important for efficient implementation of the risk management of chemicals to protect human health and the environment.

The way the legislation is framed will be equally important for the innovative capacity and competitiveness of all European actors in the product chain: manufacturers and importers of substances, manufacturers and importers of preparations, industrial and commercial processors of substances and preparations and manufacturers and importers of products. The legislators must carefully weigh these implications in all solution options and listen to all the actors involved in consultations.

The recommendations

1. Simplification of risk assessments in the chain

The White Paper clearly makes industry responsible for the safety of its products. It extends this responsibility to the entire production and processing chain. Given the requirement that exposure and risk must be evaluated throughout the product chain, this represents a major advance over the current legislation from the manufacturers' viewpoint, because in many cases the information they need for their risk assessments on exposure during use and further processing of their substances is not available. Particularly in the case of substances that have been on the market for decades, there are often likely to be uses and exposure patterns of which the manufacturers are unaware.

The practical examples worked through in the project clearly demonstrated the complexity of the product chains. The variety of substances used by preparation manufacturers and – what is often forgotten – the preparations also used by them and the diverse exposure scenarios that manufacturers have to consider make risk assessments difficult. Simplification is therefore urgently required, which dispenses with detailed registration of all individual uses (often insignificant in terms of quantity and risk) and instead encourages cooperation and communication within the product chain, empowering the actors along the chain to take responsibility themselves for safe use and disposal of chemicals. The practical suggestions and proposals for simplification that evolved from the project are summarised as follows.

2. Statutory duties of manufacturers and importers¹

- a) Manufacturers or importers of substances must carry out a preliminary risk assessment for registration, which addresses the intended uses and includes the necessary risk reduction measures².
- b) Legislators should however not stand still here. From the experience gained during the project, the complex reality of the exposure conditions in the processing areas is often not covered simply by evaluating the intended uses. Legislators should therefore make it possible for manufacturers or importers to specify in the registration dossier exposure categories and concentration ranges ("band widths") that would ensure safe use. The categories should be so defined and delineated that downstream processors in the product chain, when carrying out a risk assessment for their processing stage, can check independently – and at acceptable cost – whether their uses and exposure patterns fall within the permissible concentration ranges or not. It will therefore be unnecessary for further processors to disclose the exact use to substance producers. It will also reduce the need for further processors to provide exposure data "upstream" to manufacturers or importers. This proposal was consistently supported by all working groups in the project and is followed through in the form of an example – based on a rough structure for exposure categories with the main absorption pathways for humans and the environment - in Appendix 2 of the Report. The proposal needs further refinement and testing in an extended pilot project, as suggested in recommendation 8. The project would also study whether and to what extent **industry-specific standard exposure patterns** could be determined by the trade associations in the VCI and made available to substance manufacturers to use in their assessment for registration purposes. In this way, the generally medium-sized member companies of the trade associations could be saved from the need to carry out their own complicated and costly individual assessments.
- c) Notwithstanding their duties under a) and b), to impose a statutory obligation on manufacturers or importers to invest the effort and cost required to cover every single use known to them (e.g. uses which perhaps account for only a very small proportion of the quantities they market) would be unreasonable. Manufacturers and importers, too, must have the right to exclude certain uses (e.g. on the grounds of health and environmental protection).

3. Statutory duties of downstream users³

- a) The White Paper sees downstream users as having a duty to evaluate the safety of their products for the part of the lifecycle to which they contribute and to provide manufacturers or importers with information about intended uses and exposure patterns for risk assessment of the substances. This also includes uses that differ from the uses originally intended by the manufacturer. The primary aim, however, is to ensure that the usual range of uses today – many of which are not even known to the manufacturers at present – is covered

¹ The White Paper is predicated on the assumption that manufacturers or importers have a duty to register substances.

² These include specifying the intended uses, carrying out a risk assessment (with the individual steps of hazard identification and exposure estimation) and specifying risk reduction measures, which must be described in the safety data sheet.

³ Preparation manufacturers and other processors of substances and processors and users of preparations.

by risk assessments through communication and cooperation between manufacturers and users.

- b) To impose statutory duties on further processors to provide information to registering manufacturers or importers on exposure patterns and uses that differ from the intended uses of the manufacturer is not practicable. There must be know-how protection for uses that differ from the manufacturer's intended uses. In the manufacture of preparations, particularly, the use of certain chemicals as additives is often protectable know-how, which is frequently not even disclosed to the supplier⁴. In relation to exposures occurring as part of the manufacturer's intended uses, further processors should, at the request of the registering manufacturer or importer, make available the non-confidential information on exposure patterns required for registration. The legislators should encourage this in a suitable way.
- c) However, in future, according to the REACH model, there will be **legal consequences**, if cooperation and communication do not take place in the product chain at the stage when the substance is being registered by the manufacturer: processors risk having to perform costly registration and testing duties (Actions 5 A and 5 C of the White Paper) where their uses and exposure patterns are not specified in the manufacturer's registration dossier and therefore not covered by the preliminary risk assessment. Substance manufacturers or importers may in future only produce or import within the framework of the registered uses and exposure categories (proposal under **2b**); they therefore "restrict the market" if they "restrict registration". These common interests of the manufacturers and processors and the market forces resulting from them are a strong incentive for cooperation and communication between the actors in the product chain right from the stage when substances are being registered by the manufacturers.
- d) Independently of communication within the product chain, the White Paper places statutory duties on downstream users to inform the authorities of uses that were not envisaged by the manufacturer or importer and therefore could not have been addressed in the preliminary risk assessment (Action 5 C of the White Paper). A practicable solution could be the procedure described under **2b**). According to this, costly testing and registration duties for downstream users will only arise if the use involves substantially different exposure patterns from those evaluated by the manufacturer.

4. Step by step registration

As an additional control, legislators are recommended to adopt a **step by step approach** in registration. First of all the substance producer should register in line with the exposure patterns, as proposed under **2b**). A sufficient period of time should then be allowed to give downstream users the opportunity to check whether there is a possible need for additional registration, as part of communication and cooperation with manufacturers. In a second step, when this period has expired, downstream users should be obliged **to inform the authorities (Action 5 C of the White Paper)** of any use which has not been envisaged by the manufacturer and which in some cases may not be covered by the exposure patterns registered by the manufacturer. This approach will spare further processors considerable irritation and legal uncertainty. It will also save the authorities from having to deal with uncoordinated and often superfluous notifications on substance uses.

The proposed **step by step approach** will not lead to downstream users withholding their cooperation from manufacturers. Their main priority will be to ensure as far as possible that

⁴ The model for exposure categories proposed under 2b) could solve this problem.

their uses are covered by the substance producer's registration. This common interest will encourage communication and cooperation.

5. Exemption criteria

In many cases, constituents present in minor quantities (e.g. additives) do not play a significant role in the risk assessment of preparations. It is therefore recommended that existing **exemption criteria** (e.g. from the Preparation Directive) should be used or, if they are unsuitable, new ones should be developed. Such exemption criteria should enable substances used in preparations below certain specified concentrations to be exempted from registration. The validity of the risk assessment should not be jeopardised by this.

6. Role of the central database

The central registration database at the expanded European Chemicals Bureau (ECB) can provide important support in ensuring the necessary flow of information within the product chain and notification of authorities and the public. A good example is the formation of consortia of different producers for registration purposes. The database is, however, no substitute for the clear allocation of responsibility between suppliers and purchasers. In addition, the legislators must ensure copyright protection of test data (protection of priority claims) and protection of other confidential information belonging to the actors in the product chain. User groups and their specific data access rights should be defined in accordance with this need for protection. It is also important to specify who is responsible for the accuracy and up-to-dateness of the database.

7. Unresolved questions

The project has made clear the **great concern** felt by preparation manufacturers that a large proportion of substances produced only in small quantities for special uses will in future no longer be manufactured and therefore disappear from the market completely because of the high registration costs for substances exceeding a production volume of 1 tonne per annum – and even higher for larger production volumes (volume thresholds). These substances will then no longer be available for companies and industries carrying out further processing (e.g. paint, printing ink, adhesives and plastics industries) and so gaps will be created in the downstream value chains.

Another **great concern** of all European manufacturers in the product chain is the expected sharp rise in imports of finished products manufactured outside Europe with the aid of substances and preparations not subject to the registration constraints and costs under the REACH system. This will give enormous competitive advantages to non-European producers and at the same time compromise the aim of the REACH system to provide improved protection for human health and the environment. This concern is shared by chemical traders, who in many cases act as importers. The additional costs incurred for testing and registration of substances will in future also place the entire export trade in substances and preparations from the EU at a disadvantage.

These problems areas must be thoroughly investigated in further consultations on implementation of the White Paper. OECD-wide political consensus for the White Paper concept, which unfortunately has not so far been achieved, should be urgently sought to minimise the competitive losses to European industry. In any case, however, the legislators are asked to examine and implement **all sensible simplifications** to the registration process. This also includes reviewing existing statutory regulations on industrial safety and consumer



protection.

The yardstick for this must be whether the aims of the new chemicals policy are achieved, i.e. the safe use and disposal of chemicals throughout the product chain by all actors involved and transparency in relation to the chemicals present in different uses. For this reason, practical refinement of the White Paper requirements is necessary so that the new legislation can be efficiently implemented by all actors, including small to medium-sized companies.

8. Extended pilot project

It is recommended that as part of further consultations on the new legislation, a pilot study should be carried out with a larger number of substances to examine duties and information exchange within the product chain and registration of substances with the authorities. This study should be conducted jointly by the authorities, industry and other participants to validate recommendations 1 to 7 developed in the project.

I Background and objectives of the project

In February 2001, the EU Commission presented a White Paper on the reform of chemicals policy in Europe. Among the key elements in the proposed strategy are statements on the responsibility of industry for the safety of chemicals. In the White Paper, this responsibility is extended to the entire production and processing chain and focused by the concept of "intended use". **A key question here is how the information flow along the product chain can be organised. The White Paper does not so far specify this sufficiently in practical terms.**

In the "Product Chain Chemicals Policy" project being carried out by the VCI and its member associations, four substances/substance groups were examined by way of example as a basis for discussing and preparing recommendations on how the duties and cooperation of different actors might be arranged in practice over various stages in the value chain. The difficulties associated with the complex patterns of intended use and communication of information were to be highlighted and possible solutions prepared. The project was carried out during the period September 2001 to February 2002.

The VCI commissioned the Öko-Institut e.V. to direct the project, supply content input and document the activities of the working groups. Its function was to assist dialogue within the working groups and play a mediating role, working on solutions in cases where conflicts of interest arose with regard to the provision of information.

II Designing and carrying out the project, limitations of the project approach

In the working groups, four substances/substance groups were chosen as models to examine patterns of use, what the product chain looked like, what information flows were required, what difficulties were associated with obtaining and passing on information and what possible solutions seemed sensible.

The specific chemicals studied by way of example in the working groups (WGs) were also intended to highlight the particular problems of the respective trade associations.

- WG 1: Flame retardants (RDP (resorcinol diphosphate, existing substance)/BADP (bisphenol A diphosphate, new substance)) as additives for flame-retardant monitor housings (Association of the Plastics Processing Industry);
- WG 2: Cobalt dryers and degassing agents as additives in paints and coatings (Association of the Paint Industry);
- WG 3: DMEA (N,N-dimethylethanolamine) in the printing ink sector (Association of the Printing Ink Industry);
- WG 4: Rhodamine B for the organic colorants and pigments sector (Industrial Association for Organic Colorants and Pigments).

Care was taken to ensure that both existing and new substances were represented in the examples chosen. In terms of companies, large, medium-sized and small companies were represented.

Each working group held three sessions. The steering committee also met three times, the last occasion being on March 11, 2002, when there was a thorough debate on the recommendations that should be submitted to the legislators. In between the different sessions, detailed tasks were carried out by the participants within their own companies. In all working groups, product chains were mapped, patterns of use discussed and debates on different specific aspects held and documented. In the second half of the project (December 2001 – February 2002), the interim results were reviewed and expanded with the aid of trial risk assessments of the four sample substances carried out by the actors. The aim of this was to map out the required concept and process and not to quantify end points and

exposures. On the basis of these trial assessments, it was possible to specify duties in practical terms for use as a model.

In the working groups, the exposure category approach was discussed and expanded as an essential risk assessment tool (see also Appendix 2). These discussions were not concerned with how the concentration bands should be determined or the data on which such a determination should be based.

It was also not possible within the project to quantify registration costs in relation to the data situation.⁵ The question of how additionally needed information would be passed on from manufacturers to users was examined only briefly in the project in terms of requirements for safety data sheets and technical data sheets. Detailed technical proposals on this are now available from the European working group "Information Flow Through the Supply Chain", which is working intensively on this subject.

The four sample substances studied certainly do not reflect the complexity of the problem of "Information flow along the product chain" in every aspect but do highlight the key questions.⁶ By reference to specific sample substances, the project made it possible to work through a large number of unresolved questions – from the different perspectives of manufacturers, traders and users. The product chains studied not only identified problems and a need for clarification but also pointed the way to possible solutions for individual issues.

By way of qualification, it should be noted that it was not possible to include all actors in the product chain in the discussions. While primary manufacturers and producers of preparations were represented in all working groups, it was only possible within the given framework of the project for finished product manufacturers, traders, consumers and waste disposal companies to participate on individual occasions or to be consulted in supplementary discussions. This contact revealed that many downstream users are not yet sufficiently clear about the tasks that will confront them as set out in the EU White Paper and that many small and medium-sized companies in the product chain have very little personnel capacity for dealing with additional issues.

Despite these qualifications, it was possible to discuss the essential questions regarding information flow in the product chain within the project framework on the basis of the four chosen examples. In this Report, important discussion results and recommendations are presented for further work on the subject.

III Outline of the problem, requirements of the White Paper and key questions

III.1 Outline of the problem

Chemicals are used in many different application contexts on their way from the manufacturer to ultimate disposal. They are often first used in the product chain as raw materials for preparations. Organic basic chemicals from the primary manufacturer can, for example, be used by the first downstream preparation producer to make degassing agents of complex composition, which in turn are only a starting material for the production of additional preparations, e.g. furniture coatings, by the next downstream user. It is only this furniture coating, composed of many individual components, which is then used by professional or

⁵ Cost considerations are the subject of the European Business Impact Study, which was completed in spring 2002 and is to be published.

⁶ So the problems of registration from the manufacturers' viewpoint could be studied at greater depth in an additional working group on a solvent with many intended uses.

private users. Possibly years later, the coated product is renovated or taken for disposal. The following chart shows such a product chain based on the example of a furniture coating constituent (an enlarged version of the chart is given in Appendix 1 of this Report).

AG 2: Additives in the paints and coating sector

Cobalt dryer product chain

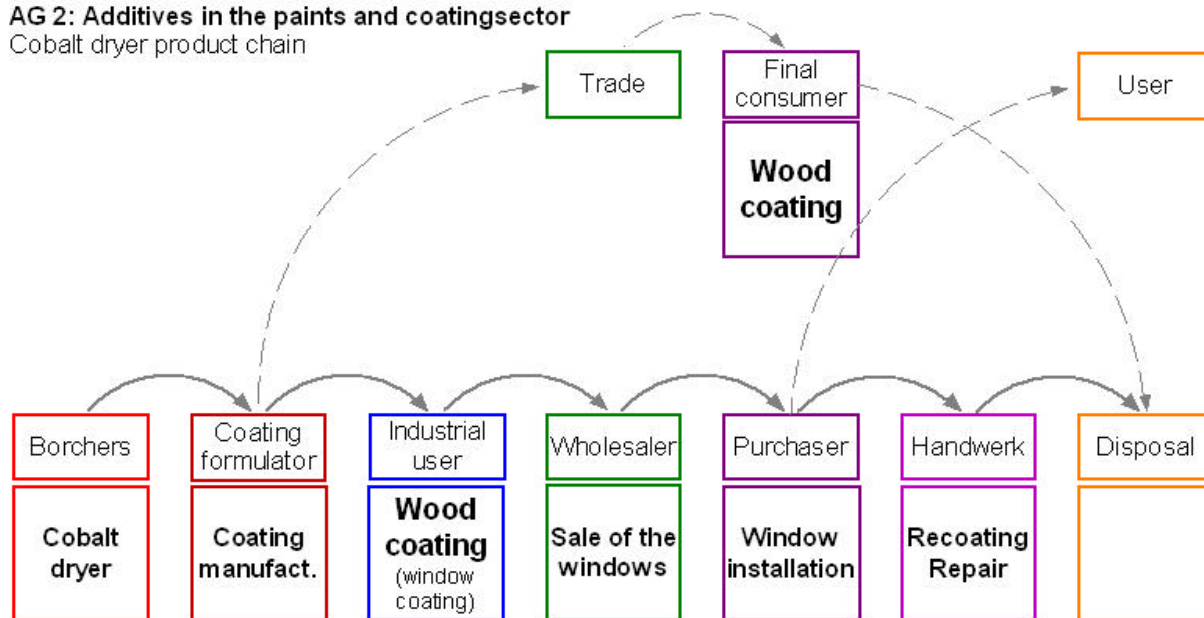


Fig. 1 Product chain for "cobalt dryers as constituents of furniture coatings"

It should be borne in mind here that individual companies can sometimes use several thousand raw materials – in quantities ranging from one kilogram to several tonnes. In addition, it should be remembered that in many cases manufacturers do not know all the uses for their substances in the product chain, even if the users regard them as "current" uses. Many uses represent specialist knowledge on the part of preparation producers, which they are reluctant to pass on either to the substance manufacturer or other preparation producers.

Against this background, the principle of "shared responsibility" has to ensure the safety of humans and the environment in handling chemicals throughout all these use structures. This presupposes a comprehensive knowledge and assessment of substance properties, contexts of use and exposure situations. The information must not only be available in the product chain but must be evaluated in a structured and targeted way. For all actors in the product chain, this gives rise to tasks which manufacturers and downstream users find very difficult to estimate in terms of scope and feasibility. Practically based approaches are obviously required, which take into account the complexity of the tasks faced and the boundary conditions for communication between the actors. Because of the many individual substances, preparations and exposure situations to be taken into account, simplifications

are required at various levels to ensure effective implementation of the principle of shared responsibility in the product chain.

III.2 Requirements of the White Paper

Key objectives of the strategy for chemicals assessment presented in the White Paper are risk assessment throughout the product chain, assumption of responsibility for risk management by all actors in the chain and transparency in relation to the chemicals present in different uses. This gives rise to special requirements for information flow in the product chain, which were picked up and discussed in the project.

The underlying principle here of shared responsibility is addressed at many points in the White Paper for the reform of chemicals policy (the relevant texts are collected in Appendices 4 and 5 of this Report). Four text extracts from sections 2.3, 4.1 and 5.1 should be quoted at this point because they make clear the central statements and requirements of the White Paper relating to information flow in the product chain:

Key elements of the proposed strategy

I "Making industry responsible for safety"

Responsibility for generating knowledge about chemicals should be placed on industry. Industry should also ensure that only chemicals that are safe for the intended uses are produced and/or placed on the market. The Commission proposes to shift responsibility to companies for generating and evaluating data and assessing the risks of the substances in the context of use. The companies should also provide adequate information to downstream users" (Section 2.3, Key elements of the proposed strategy, page 8).

II "Extending responsibility along the manufacturing chain"

Downstream users, as well as manufacturers and importers, of chemicals should be responsible for all aspects of the safety of their products and should provide information on use and exposure for the assessments of chemicals. Producers of preparations and other downstream users will be obliged to assess the safety of their products for the part of the lifecycle to which they contribute, including disposal and waste management" (Section 2.3, Key elements of the proposed strategy, page 8).

III "Registration"

Registration requires a manufacturer or importer to notify an authority of the intention to produce or import a chemical substance and to submit a dossier containing the information required by the legislation. The registration dossier will include the following information: ... intended uses, estimated human and environmental exposure ... preliminary risk assessment covering the intended uses ... proposed risk management measures" (Section 4.1, Registration, page 18).

IV "Obligation of downstream users to perform testing"

Downstream users must assume responsibility for the safety of their products. Authorities should be empowered to require downstream users to carry out additional testing **where uses differ from those originally envisaged by manufacturers or importers and the resulting exposure patterns also differ substantially from those evaluated by them.** Additional testing programmes should be developed in close consultation with the authorities" (Section 5.1, Data generation, page 22).
"The Commission proposes that the authorities must be informed about any downstream use which has not been envisaged by a manufacturer or importer and which has not therefore been addressed in the preliminary risk assessment" (Chapter 5.3, Information to be provided by industry to the authorities, page 23).

III.3 Key questions for the working groups

With reference to these and other statements in the White Paper on responsibility and information flow along the product chain (see Appendices 4 and 5), **key questions** were developed, which were discussed in the working groups of the "Product Chain Chemicals Policy" project and determined the structure of the discussions in the working groups. These key questions can be summarised as follows:⁷

1. What do the patterns of use look like? To what extent are they known?
2. What do the terms "intended use" and "current use" specifically mean?
3. What does the value chain for the selected scenarios look like in detail?
4. What exposures occur in the product chains and where?
5. What substance- and process-related information is needed? Are costly exposure measurements required?
6. What are the obligations that emerge from this for the actors involved? What cost allocations are practicable?
7. Is the required information available? From whom? How can it be obtained?
8. What obstacles and difficulties are envisaged by the actors involved at specific points in the value chain? What importance should be placed, in particular, on the need of substance manufacturers and further processors for protection from uncontrolled use of costly test results for product risk assessment by third parties (free-riders)?

The approach followed in the discussions on these questions was always, what practical solutions can be envisaged for the problems identified, how can these solutions be implemented in the new EU legislation – and what obstacles appear insurmountable.

⁷ These key questions and the relevant memo points are detailed in Appendix 3 of this Report.

Important discussions on the key questions in the working groups are reproduced in the next chapter (IV) and then summarised.

The recommendations developed in the individual sub-points relate to different actors in the product chain. In addition to these, recommendations for the legislators were prepared, which precede the main body of the final Report as part of the summary. The recommendations are based on the following documented discussion results.

IV. Results

Product chains in today's technological economy are not only complex (see Section IV.1) but frequently also opaque. To ensure that manufacturers and downstream users can carry out their responsibilities appropriately with regard to the safe use of substances, an open exchange of information throughout all stages of the value chain, both downstream and upstream, is absolutely essential (see Section IV.2). As an organisational aid to channel the diverse information, the White Paper introduces the terminology of "intended use"; in the working groups, this organisational aid was analysed in depth (see Section IV.3). What information should flow from whom at what point in time plays an important role in the debate on the EU White Paper (see Section IV.5). But the structural effects of the EU White Paper, such as loss of flexibility (see Section IV.6) and potential market losses (see Section IV.7), must also be taken into account in the specific development of strategy.

A further question that must be asked is how the objectives of the White Paper with regard to greater transparency and safety can be better reconciled with the goals of economic, technical and time-scale feasibility (see Section IV.8).

Storing the data in a database appears to be a solution option that would provide transparency on the part of the authority and be practical as far as public interest is concerned. However, potentially damaging effects on competition must be excluded here (see Section IV.9). The possibilities for simplifying risk assessments along the product chains were thoroughly studied in the project (see Section IV.10).

Finally, it should be stressed that all potentially affected actors must be involved in the discussion process to ensure a wide and sustainable basis for the new strategy (see Section IV.11).

IV.1 The product chains in reality

In all four working groups, product chains for the sample substances studied were constructed (see Appendix 1). The real complexity entailed in the task of ensuring "Information flow along the product chain" only became apparent in this work on specific product lines and actor situations. In Section III.I, this complexity is shown in more detail. In all the cases studied, considerable difficulties were encountered by the preparation producers due to the number and diversity of individual substances and preparations used and by the manufacturers and formulators due to the number and diversity of exposure scenarios. These difficulties were aggravated by the often insufficient clarity in the requirements of the EU White Paper.

- **In view of the many different raw materials and preparations used, all the working groups recommended** that intensive efforts should be made to seek possibilities for simplification by sharper focusing, categorisation and grouping at all levels, in other words to seek simplification in risk assessment all along the product chain (see also Section IV.10 and further below).
- The necessary practical definition of responsibilities (specified obligations) should be shaped by the actors involved to ensure the necessary practical relevance and

therefore feasibility of implementation (see also Section IV.5 and further below.)

For the risk assessments, information on subsequent disposal of the products is also required. In many cases, this is not available. For example, the use of bisphenol A for surface coating of thermal papers led to unexpected environmental pollution in recycling the thermal paper. In the working groups, it became clear time and again that recycling is not sufficiently defined in the White Paper.

IV.2 Information flows: Directions and requirements

The necessary information requirement for risk assessment of substances can only be ensured by information exchange between substance manufacturers and users. The "lack of knowledge about use contexts and associated exposures" which has clearly become the bottleneck in the present system for assessing existing substances can only be solved by greater involvement of users and correspondingly intensified communication. Manufacturers wishing to register their intended uses have to rely on information on exposure situations from downstream users. Previously this information was not available in many cases. The exchange of information between manufacturers and users envisaged as part of the registration process in the White Paper should lead here to a fundamental improvement in the data situation – while ensuring know-how protection for downstream users (see Section IV.3).

In the working groups, it became clear that information flows in both directions are required. The exchange of information in the product chain "downstream" from manufacturers/importers to downstream users is at present already taking place on a statutory basis (e.g. in the form of safety data sheets and technical data sheets). The information flows "upstream" from users to manufacturers are at present restricted in most cases to discussion of application-related questions. A systematic information flow upstream from users to manufacturers for the purposes of risk assessment is not taking place at present.

- In the working groups, it became clear that for chain-wide risk management, upstream and downstream information flows are required.
- In view of the fact that there are more than 100,000 user plants, the trade associations will have a special role to play as multipliers and intermediaries between the individual users (often small and medium-sized companies) and the manufacturers.

IV.3 Classification of intended uses and exposure categories

The distinction between "intended use" and "non-intended use" is helpful for an initial discussion of substance uses but requires further clarification. In the discussions, it became clear that:

1. Within the intended use (e.g. use of additives as flame retardants in plastics), there can be considerable diversification and manufacturers will neither be able nor wish to cover all the fine distinctions (different plastics grades, widely varying plastics applications).
2. In the case of quite significant proportions of the total production quantity, manufacturers are sometimes ignorant of the intended use (e.g. "bazaar" colours). The situation in the chemicals trade is extremely varied.
3. Non-intended uses could not be identified in all product lines.

4. In many cases, intended uses are also corporate know-how, particularly among preparation producers. Here the possibility of obtaining information ("Has the application been registered by the manufacturer as an intended use?") is required, while ensuring know-how protection. In this context, the involvement of the registration centre has also been discussed (see IV.9, point 5).
5. Completely unexpected, exotic applications of substances way outside their intended use were the exception rather than the rule in the product chains studied. In many cases, they were excluded by specific statutory regulations applying to the substance (fictional example: the use of Rhodamine B in ice cream). In such cases, no further consideration of these applications is required in the registration process. In these unexpected applications, the principle of shared product responsibility removes the burden from the manufacturers. They can no longer be made responsible for uses they did not intend or register. In the past, such uses, not supported by manufacturers and unknown to them, have resulted in unexpected environmental pollution (for example the use of brominated flame retardants as an additive for hydraulic fluids or in the oil industry for drilling fluids). According to the requirements of the White Paper, such non-intended uses must in future be registered by the user and supported with risk assessments.
6. Manufacturers should register intended uses that are as broadly defined as possible. In this way, they can ensure that many different current uses are covered and therefore do not need to be additionally registered by users. At the same time, the intended use should not be so generally described that it no longer permits differentiated information on the presence of chemicals in the product chain and therefore prevents an important objective (transparency in the use of chemicals) from being achieved. In the working groups, a considerable need for discussion was recognised here. It also became clear that in the trial risk assessments, which were carried out in all four working groups, it is always necessary to start from specific uses so as to represent properly the complex exposure situations that occur. Reliance on the 55 use categories from the Technical Guidance Documents (TGDs) at this stage would not have led to meaningful risk assessments, despite the relatively high degree of differentiation between these categories, in view of the complex exposure situations in the chain.
7. The risk assessments in the working groups also showed that simply quoting intended uses for risk management in the chain is not sufficient. For risk assessment, the crucial question is what exposure situations occur in the uses. With the sample substances studied, it became clear that the many different individual exposures occurring in the individual chains can be reduced to a manageable number of exposure types (these may be described as "exposure categories"). When registering their intended uses, manufacturers then cover a range of these exposure categories (which are linked to their intended uses) at the same time. A more exact study of this approach in the working groups using a coarse grid of such exposure categories (printed in Appendix 2) showed that this categorisation of exposure situations could be an important aid in facilitating exposure assessment in the product chain.
In this approach, users should check whether, because of similar exposure situations, their intended uses, while not cited as intended uses by the manufacturer, are nevertheless covered by the manufacturer's risk assessment. This procedure can be considerably facilitated with the aid of exposure categories (see Section IV.10, point 1 and Appendix 2; a practical example is shown there to illustrate the approach). The categorisation of exposure situations should be an aid to risk assessment. Targeted analyses and assessments of individual exposure situations should continue to be an option.
8. In the working groups, another subject discussed was when notification and registration duties should arise for downstream users in the case of uses that differ from the intended

uses registered by the manufacturer (see Action 5 C of the White Paper). With reference to the exposure situations occurring in these differing uses, there are two possible options: **Option 1:** Users are only required to register the non-intended uses if the exposure situations associated with them are not covered by the registered exposure categories. The advantage of this approach is that it is unnecessary to register uses that are covered in terms of exposure categories.

Option 2: Downstream users must register differing uses in each case. Additional testing would however only be required if the exposure conditions were not covered by the registered exposure categories. This approach entails certain registration costs for downstream users.

The option 2 approach can give the authorities an overview of the types of non-intended uses for which substances are being employed. The consulting institute⁸ therefore recommends this approach. It is important to ensure, however, that simple registration of uses where the risks are covered by the exposure categories can be completed at low cost. A highly simplified duty of registration is recommended. In a pilot project designed to examine the simplification options described in the Report (see Section IV.10 and IV.8), this proposal can be tested using selected companies in the product chain as an example. The representatives of the VCI and the trade associations believe that a duty of registration should not apply if the differing use is covered by the registered exposure categories. A duty of registration would not increase product safety and would therefore cause unnecessary bureaucracy for industry and the authorities. From this perspective, it must be sufficient if users properly document their risk assessment procedure and retain the documentation for inspection by the authority. If the authority carries out a check and finds that in reality the use is not covered by the registered exposure categories and should therefore be registered, then users have violated their duty of registration and will be liable for a fine. That must be a sufficient sanction.

IV.4 Current uses

Analysis of individual application sectors and the substance quantities they consume shows that the substance quantities purchased by the associations of preparation producers are insignificant in volume terms from the manufacturers' viewpoint. For example, DMEA is an important additive in the printing ink industry and a well established current use in that industry. However, the total quantity consumed in Germany by the printing ink industry is less than 1% of the total production volume of this substance. "Printing ink production" is a use that was not even originally known to the substance manufacturer. Neither is it an intended use of the manufacturer, as the trial risk assessment in the working group showed.

- It is important to ensure that the registration requirements of the EU White Paper for such uses do not involve substance manufacturers in significant extra expenditure. This would probably lead to a failure on the part of manufacturers to register these (quantitatively insignificant) uses. As a consequence, preparation producers would then have to register these uses themselves. If this involved high costs, the substance would then no longer be available to small and medium-sized companies.
- It is therefore important for substance producers and users to liaise with each other right from the substance registration phase. In this phase, manufacturers should invite their customers to co-operate. In cases where the differing use does not involve a need for know-how confidentiality, there is an opportunity to include it in the registration of the substance manufacturer. There are however other cases in which users are not willing to disclose their differing uses to the substance manufacturers. This is where the proposed system of exposure categories can help. The subsumption of uses with

⁸ Öko-Institut e.V., Ökologische Netze, FoBiG - Forschungs- und Beratungsinstitut Gefahrstoffe GmbH.

comparable exposure patterns and risk assessments under a broadly defined intended use can probably tone down the problem in many cases. These possibilities for systematising exposure assessment were discussed in more detail in Section IV.3 and will be investigated further in Sections IV.9 and IV.10 (see also Appendix 2).

IV.5 Specification of duties for information flow

Key statements on responsibilities, tasks and duties in relation to information flow are contained in the core statements of the White Paper, which were quoted in Section III.2. In the four working groups, an attempt was made to define these responsibilities in more detail using specific sample substances. The aim was to derive a specification of duties for the individual actors involved.

The discussions in the working groups showed that the responsibilities for information flow described in the White Paper are not defined precisely enough. For one thing, it remains unclear what stages in the product chain manufacturers must cover in registering their intended uses. It also remains unclear how detailed the risk assessments should be for registration. The required exchange of information upstream and downstream (see Section IV.2) is not specifically defined.

- Against this background, it is important to establish clearly the responsibilities of manufacturers and users.
- Manufacturers should assess the exposures occurring for all their intended uses along the entire product chain and make recommendations for risk management. However, for this purpose, the downstream actors must provide them with the necessary information on exposure patterns, which the manufacturers themselves often do not have.

IV.6 Consequences of the duty of registration for suppliers

At the present time, substance manufacturers and preparation producers can purchase their raw materials flexibly from different producers throughout the world within the framework of existing legislation. The White Paper imposes additional duties on European producers of substances and preparations: they must ensure that their raw material suppliers have registered the substances they purchase from them or they must register the raw materials themselves as importers. Non-European producers of substances and preparations are only subject to these obligations when they export to Europe but not in supplying non-European customers who market their products worldwide and therefore also in Europe. European manufacturers of substances and preparations are therefore faced with considerable competitive problems in world markets as compared with non-European producers.

A purely European implementation of the EU White Paper could therefore lead to considerable flexibility losses in the selection of raw materials, additional costs and serious disadvantages in international competition for European manufacturers of substances and preparations. In the working groups, therefore, the need for international harmonisation of chemicals policy within the framework of the OECD was emphasised. Today, as a result of national legislation, there are already access restrictions for preparation producers and manufacturers in some markets, e.g. because of additional test conditions involving extra costs (for example, US standards on ink fluids).

In this respect, preparation producers are sometimes harder hit than manufacturers. This applies particularly to chemicals purchased in small amounts, if the preparation producer is

not one of the manufacturer's major customers. Possible ways of reducing the additional work involved should be explored.

IV.7 Effects of the duty of registration on the import of finished products

The area of finished products containing substances and preparations has not so far been regulated in detail in the White Paper – apart from the fact that a working group has been appointed. It appears therefore that there is no plan so far to subject finished products to the same detailed registration regulations as substances and preparations. An exception will probably apply if relevant emissions occur in the use or disposal of such products.

If the registration process in Europe involves considerable costs, which will lead to corresponding price increases by manufacturers of substances and preparations, it might become commercially desirable for their customers to import the products directly – in the case of Rhodamine B, for example, non-European-coloured paper rolls or non-European-produced ballpoint pen cartridges. This would give rise to serious competitive disadvantages for European (paper and cartridge) manufacturers.

- These competitive disadvantages must be avoided. Internationally harmonised regulations are important for this.

IV.8 Exposure estimates and risk assessments

Experience with EU existing substance assessment has shown that very detailed, comprehensive risk assessment procedures (comprehensive risk assessment) lead to enormous delays in substance assessment. It would be wrong to stipulate use of the extensive TGD (Technical Guidance Documents) for risk assessment by downstream users without examining possibilities for simplification. In the EU "Risk Assessment" working group, there appears to be a tendency to want to continue these procedures.

Trial risk assessments were carried out in all four working groups. They discovered that a single risk assessment throughout the product chain was feasible, since the necessary cooperation took place. In practice, however, it will not always be possible to count on this for various reasons. At the same time, it was also clear that this type of single risk assessment presupposed a number of requirements. Besides availability of sufficient information on the substance, it was also important that users – particularly small and medium-sized companies – were not asked to prepare risk assessments that were too detailed. **Practical simplifications were needed that would nevertheless produce reliable results** – for a detailed discussion of this point, see Section IV.10, and for information on exposure categories, see also Appendix 2⁹.

IV.9 Functions of the central database at the ECB

It is likely that different manufacturers will supply the same substance for – from their perspective – different intended uses. A central database at the European Chemicals Bureau (ECB), in which substances, patterns of use and associated risk assessments are contained, can facilitate various tasks imposed on manufacturers and downstream users as part of registration procedures. At the same time, it would be important with such a database

⁹ This subject has also been directly addressed in the White Paper: "Amendment, improvement and simplification of risk-assessment procedures: In order to meet the goals of this White Paper, a continuous research effort has to be made both at Community and national level to cover the many knowledge gaps. At the Community level, the Commission, through its Framework Programmes for Research, Technological Development and Demonstration, is supporting research in a number of other areas, e.g. improvement and simplification of risk-assessment procedures" (Section 3.2, page 15).

to ensure fair cost allocation and confidentiality of corporate know-how.

The possible functions of the database in relation to information flow are set out as follows. The database can, however, never be a substitute for clear allocation of responsibility between suppliers and purchasers.

1. Supplier transparency: chemicals and application-specific information as a sales product. Downstream users should have the option of consulting the relevant documentation to find out which manufacturers supply the substance for their application. There is already a large degree of supplier transparency within the VCI. For customers, it will be important under the requirements of the EU White Paper to purchase from a manufacturer who not only supplies the substance but can also demonstrate that it has been duly registered and can make suitable suggestions as to its safe use. Such a manufacturer supplies a combination of both the substance and application-specific information and in this way is sometimes differentiated from competitors but possibly also by a higher price as compared with non-European or present suppliers.

2. Checking uses. Preparation producers should be able to check themselves or have someone check at the registration office (i.e. not necessarily at the database location) whether their substance uses (which they notify to the registration office under a confidentiality agreement) are covered by intended uses. However, safety data sheets will still be of paramount importance because they should not only disclose the manufacturer's intended use but also – according to the proposal developed in the project – the exposure categories that might possibly cover the differing use.

3. Survey of the data position for risk assessments. During the process of registration, the registration database should permit an analysis to be made as to whether there are already risk assessments which, because they relate to similar substance properties or similar exposure scenarios, could also be used for other individual cases.

4. The task of cost allocation in registration. The database can perform useful services in forming consortia for joint registration of several manufacturers or, if necessary, of manufacturers and downstream users. If a substance that has already been registered is registered by a second manufacturer or importer, a fair allocation of the costs must be ensured (and the initial registrant not disadvantaged by second/third/etc. registrants simply adopting the data set required for registration). **The experience gained from new substance registration should be used here:** informing the second registrant of existing registration, duty to make contact, mutual agreement on reasonable cost allocation (this is also required to ensure there is no duplication of animal tests)¹⁰. The working groups assume that these questions could be fully resolved in practice. The EU Commission attaches great importance to information rights.

5. Know-how protection for additives and preparations: In the preparation-producing industry, additives are often employed in applications other than their intended use (fictional example: use of a corrosion inhibitor as an additive in an ink fluid). Such cases involve corporate know-how that the preparation producer does not wish to disclose to the manufacturer (sometimes users ensure that manufacturers cannot identify the non-intended uses by purchasing the substance through other divisions of the company). However, under the present proposals in the EU White Paper, preparation producers must ask in every case

¹⁰ This should not result in market exclusions. These are to be feared if the subsequent registrant has to acquire the registration documents from the first registrant at a prohibitive price and this then compels the second registrant to cease production for economic reasons. This would inevitably lead to concentration in the market.

whether the raw material is registered for the intended use and if the use differs from the registered use they must register it themselves. The safety data sheet should itself supply the necessary information so that preparation producers do not have to inform manufacturers of their use. **But if, instead of asking the manufacturer, preparation producers could approach the registration office directly – while ensuring confidentiality – this would be an additional option for know-how protection.**

6. The legislators must ensure copyright protection of test data (protection of priority claims) and protection of other confidential information belonging to the actors in the product chain. User groups and their specific data access rights should be defined in accordance with this need for protection. It is also important to specify who is responsible for the accuracy and up-to-dateness of the database.

IV.10 Possible ways to simplify registration duties

In discussing allocation of registration duties to users and manufacturers, the working groups tried hard to find possible ways of simplifying the registration process. A whole range of options was identified.

1: Simplification of risk assessment, development of exposure categories. The possibility was examined of considerably simplifying individual, substance-specific risk assessment by developing **exposure categories** that would be linked to **exposure bands** (band width of permissible concentrations/doses) and **proposals for risk management measures** (industrial safety and environmental protection).

The exposure categories should cover all important exposure situations in the product chains (absorption pathway, duration and frequency of exposure, exposed group). The categories should be defined and delineated in such a way that downstream processors in the product chain, when carrying out a risk assessment for their processing stage, can check independently – and at acceptable cost – whether their uses and exposure patterns fall within the permissible concentration ranges or not.

In the working groups, this possibility of simplification through systematisation was discussed using a structuring proposal for exposure categories developed by Dr Fink (VCI) – with the main absorption pathways for humans and the environment.

This proposal, consistently supported by all working groups in the project, needs further practical refinement. The (fictional) example in Appendix 2 of the final Report is used to explain the option proposed here. It also shows the rough structure for exposure categories already mentioned. The categorisation of exposure situations is intended as an aid to risk assessment. Targeted analyses and assessments of individual exposure situations should continue to be an option.

On various occasions, the working groups discussed whether the exposure categories could supplement or replace the assessment of intended uses. The consulting institute¹¹ recommends that exposure categories should be used only as a supplementary aid. In the view of the institute, intended uses should be cited to ensure the necessary transparency in relation to the presence of chemicals in the product chain.

2: Determination of industry-specific standard exposure patterns. At trade association level, typical exposure scenarios, associated risk assessments and proposals for risk management measures should be determined for the industry in question (e.g. for operations such as "stirring paints together", "spray coating" etc.). Individual companies can refer to

¹¹ Öko-Institut e.V., Ökologische Netze, FoBiG - Forschungs- und Beratungsinstitut Gefahrstoffe GmbH.

these.

3: Subsumption of uses. Downstream users who employ substances for non-intended uses must submit their own risk assessments. Experience in the working groups showed that through communication in the product chain, it is possible to clarify whether, for the expected exposure scenarios in the specific use, there are already risk assessments from other fields of use that would also cover the risks in the new use areas. (Example: the use of DMEA as a pH stabiliser in the paint industry is covered by the registration of the manufacturer. Its use as an additive in the printing ink industry, on the other hand, is not known to the manufacturer but – as discussions between the manufacturer and user in the working group showed – is covered by the risk assessment for the paint industry.) In many cases, it is feasible to assess exposure scenarios with relatively high exposures in risk assessments and to specify the required industrial safety measures. If these are taken, it is likely that numerous other uses will also be covered in which lower exposures occur.

4: Determination of exemption criteria for the assessment of preparations. In many cases, additives used in insignificantly low volumes will also play only a minor role in terms of the risk potential of the preparation. There should be exemption criteria which permit the number of substances to be considered in the risk assessment procedure for a preparation to be limited, without reducing the informative value of the risk assessment (consideration of hazardous properties, quantities used and expected exposure patterns).

5: Additional option to the individual product approach/formation of product groups. Additional options to the purely individual product approach through the possibility of forming product groups should be tried. In product grouping, the context of use (and hence the expected exposure patterns) and dangerous substance content should be taken into account. Examples of successful, industrial safety-related product groupings can be seen in the GISBAU product groups created by the construction industry employers' liability insurance association. In some cases at the present time, safety data sheets, too, are being prepared jointly for groups of comparable products. The possibility of basing group-related risk assessments and risk reduction proposals on these should be examined using specific examples.

6: Determination of volume thresholds for registration duties downstream. In the product lines studied, downstream users (individual companies) sometimes use several hundred raw materials. The quantities of substance they purchase can range from 1 kilogram to several tonnes. While the White Paper contains clear volume thresholds in relation to the registration requirements for manufacturers and importers, so far no volume thresholds have been discussed for the case where substances are employed for non-intended uses. In the further process of legislation, it is important to clarify whether the volume thresholds for individual manufacturers and importers, taking into account human and ecotoxicological properties, also apply to individual downstream users. This was discussed at various times in the working groups.

7: Synergistic use of existing regulations. In fulfilling duties to estimate exposures and specify risk reduction measures, use should be made of the requirements and measures in existing legislation. Duplications should be avoided and synergies exploited. There is a need to examine at what points the requirements of the EU White Paper can be covered by verification of compliance with currently valid industrial safety and product-related legislation (German Chemicals Act and Dangerous Substance Regulations, Product Liability Act, Electronics Waste Regulations, Preparation Regulations etc.).

8: Step by step registration. As an additional control, legislators are recommended to adopt a **step by step approach** in registration. First of all the substance producer should register

(specifying exposure patterns, as described under point 1). A sufficient period of time should then be allowed to give downstream users the opportunity to check whether there is a possible need for additional registration, as part of communication and cooperation with manufacturers. In a second step, when this period has expired, downstream users should be obliged **to inform the authorities (Action 5 C of the White Paper)** of any use which has not been envisaged by the manufacturer and which in some cases may not be covered by the exposure patterns registered by the manufacturer. This approach will spare further processors considerable irritation and legal uncertainty. It will also save the authorities from having to deal with uncoordinated and often superfluous notifications on substance uses. The proposed **step by step approach** will not lead to downstream users withholding their cooperation from manufacturers. Their main priority will be to ensure as far as possible that their uses are covered by the substance producer's registration. This common interest will encourage communication and cooperation.

IV.11 Awareness of the problem among users

The EU White Paper development phase will soon be completed. Many industrial users are not yet aware of the subject of the chemicals policy/EU White Paper. Customers/users in many cases do not know what duties of cooperation and, if necessary, registration will be imposed on them. Although discussions are taking place with customer associations at trade association level – e.g. TEGEWA (Association of the Textile Auxiliaries, Leather Auxiliaries, Tanning agents and Detergents Industry), it cannot at present be assumed that there is sufficient awareness outside the VCI and its member associations.

The subject of information flow in the product chain should therefore be discussed to a greater extent outside the chemical industry and its trade associations.

V. Most important results of the review

The most important results of the discussions described in the sub-sections of Section IV are summarised below. They also form the basis of the recommendations for legislators, which precede this final Report.

1. **Complexity:** The real complexity entailed in the task of ensuring "Information flow along the product chain" for manufacturers and users only becomes apparent in work on specific product lines and actor situations. The four sample substances studied perhaps do not reflect this complexity in every aspect but do highlight the key questions.
2. **Problem of number and diversity:** In all the cases studied, considerable implementation difficulties arise for preparation producers due to the number and diversity of the individual substances and preparations used, and for manufacturers and formulators due to the number and diversity of exposure scenarios.
3. **Problem of lack of clarity:** The requirements of the EU White Paper on obligations in the product chain are greatly in need of clarification.
4. **Information needs "upstream" and "downstream":** The "lack of knowledge about use contexts and associated exposures" which is recognised as a bottleneck in the EU risk assessment system for existing substances can only be solved by intensive communication between manufacturers and users and simplification/categorisation of exposure scenarios. The concept of exposure categories (see Appendix 2) is regarded as very helpful.
5. **"Intended use", "non-intended use":** Exotic uses seem to be the exception. The rule tends to be: 1. A wide diversification of "intended uses" during the course of the product chain, over which manufacturers have only a limited view, 2. "Unknown uses" that are

- significant in volume terms (e.g. high-volume products on the market) and 3. "Current uses" that are insignificant in volume terms as far as manufacturers are concerned but very important for users.
6. **"Current but non-intended uses"**: As a result of the registration requirements in the EU White Paper, "non-intended uses" in the product chains studied can lead to considerable additional costs for preparation producers if, during the substance registration phase, there is no communication with downstream users and manufacturers define the "intended use" narrowly. The aim should therefore be early communication so that current uses are covered as far as possible. Nevertheless, manufacturers must retain the option of excluding certain applications they do not support from registration. What is also important for preparation producers is provision of the most comprehensive information possible about substance risks in the safety data sheet and in the registration dossier of the manufacturer.
 7. **Loss of flexibility**: In the case of manufacturers of substances and preparations in the European Union the duty of registration for imports can lead to loss of flexibility and competitive disadvantages as compared with manufacturers outside the European Union. Relocation of formulators to areas outside the European Union is therefore conceivable.
 8. **Market losses through imports**: The duty of registration can lead to market losses through the import of finished products made with constituents that have not been subject to the constraints of registration. Relocation of European finished product manufacturers to areas outside the European Union is therefore also conceivable.
 9. **Exposure estimates and risk assessments must be feasible**: Very comprehensive, substance-specific risk assessment processes are not feasible either for manufacturers or downstream users. The TGD (Technical Guidance Documents) of the EU Existing Substance Regulations are generally unsuitable as a model. In the discussions in the working groups, numerous possibilities for simplification were discussed (exposure categories, industry-specific standard exposure patterns, subsumption of uses, specification of exemption criteria for preparations, product grouping, volume thresholds, exploitation of synergies with existing regulations).
 10. **Protection of test data, uses and exposure sources** from unauthorised access by third parties must be ensured. Niche applications are often the core business of formulators and must not be disclosed, even to substance suppliers. This point must also be taken into consideration in setting up a registration database at the ECB. No sensible differentiating criteria between "confidential" and "non-confidential" areas have so far emerged in the project.
 11. **Many downstream users outside the VCI and its member associations are still not aware of the problems.**
 12. **With the four sample substances studied, trial risk assessments were carried out successfully. The prerequisite for this was cooperation between the actors in the working groups.** It is expected that by using the simplification options that have been identified (exposure categories, industry-specific standard exposure patterns, subsumption of uses, exemption criteria, product grouping, volume thresholds, synergies with existing regulations, see Section IV.10), the costs of risk assessment can be significantly reduced.



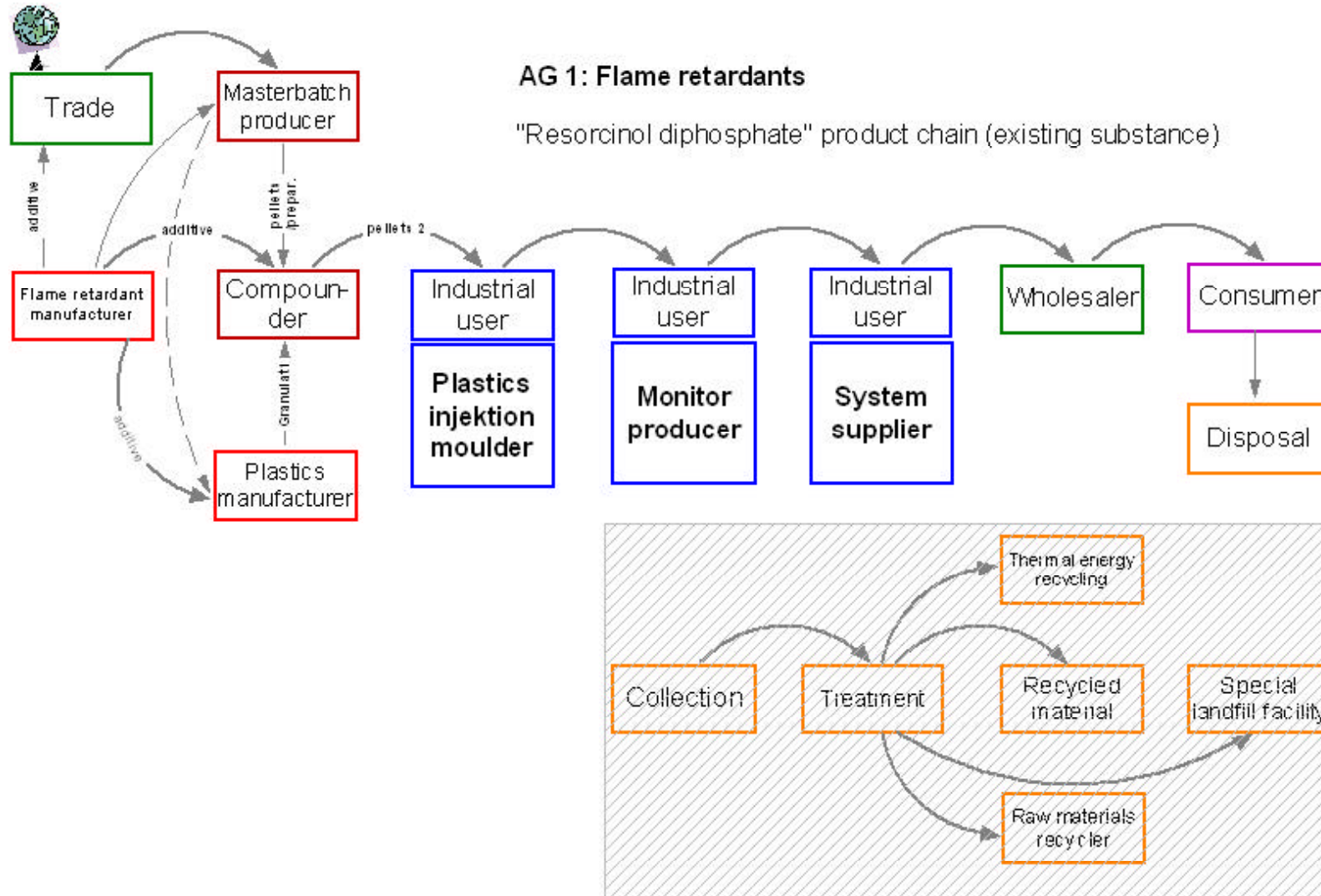
It is recommended that as part of further consultations on the new legislation, a pilot study should be carried out with a larger number of substances to examine duties and information exchange within the product chain and registration of substances with the authorities. This study should be conducted jointly by the authorities, industry and other participants to validate the recommendations developed in the project.



VI. Appendices

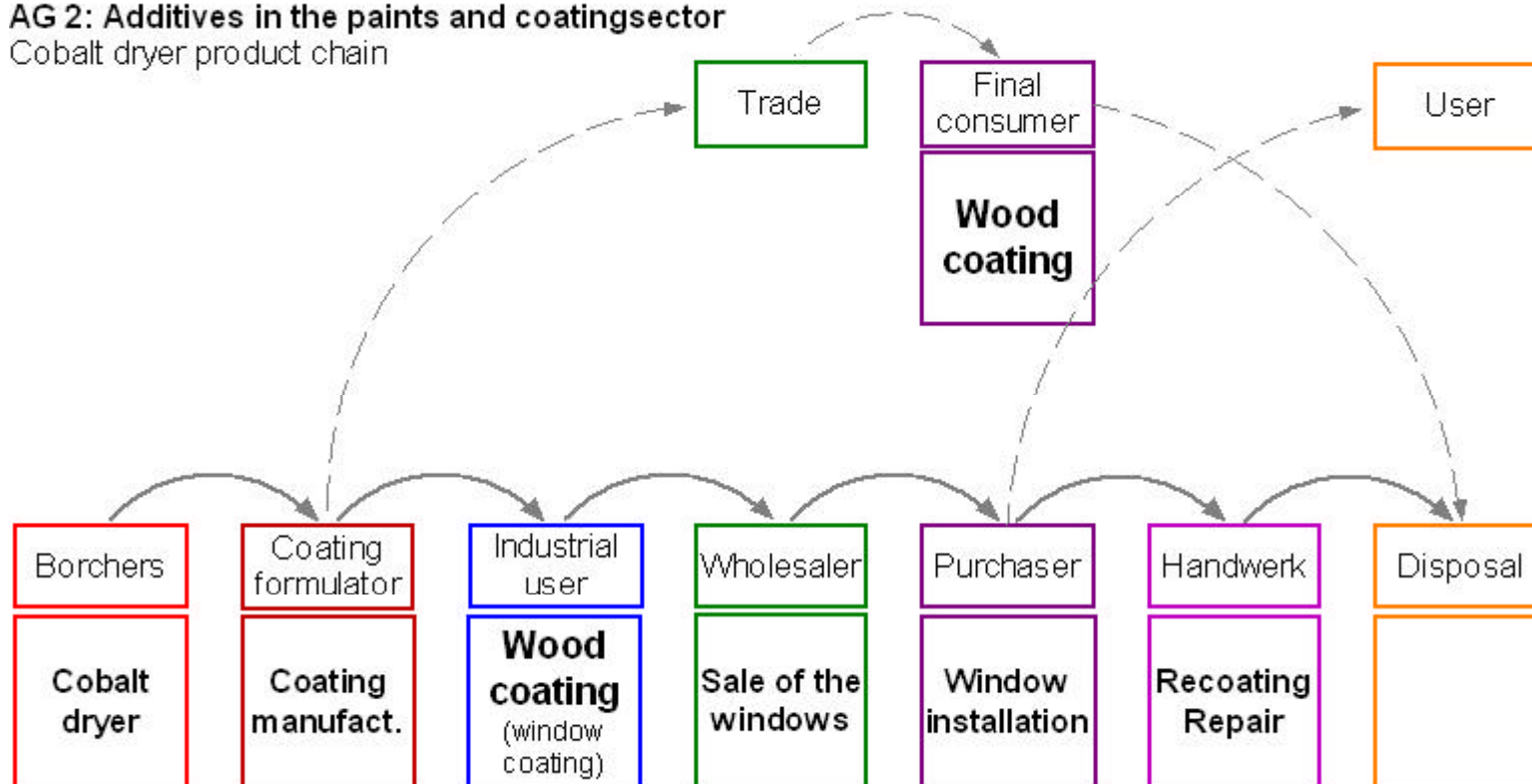
Appendix 1: The product chains studied

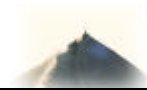
The following charts show the product chains that were discussed in the four working groups.



AG 2: Additives in the paints and coating sector

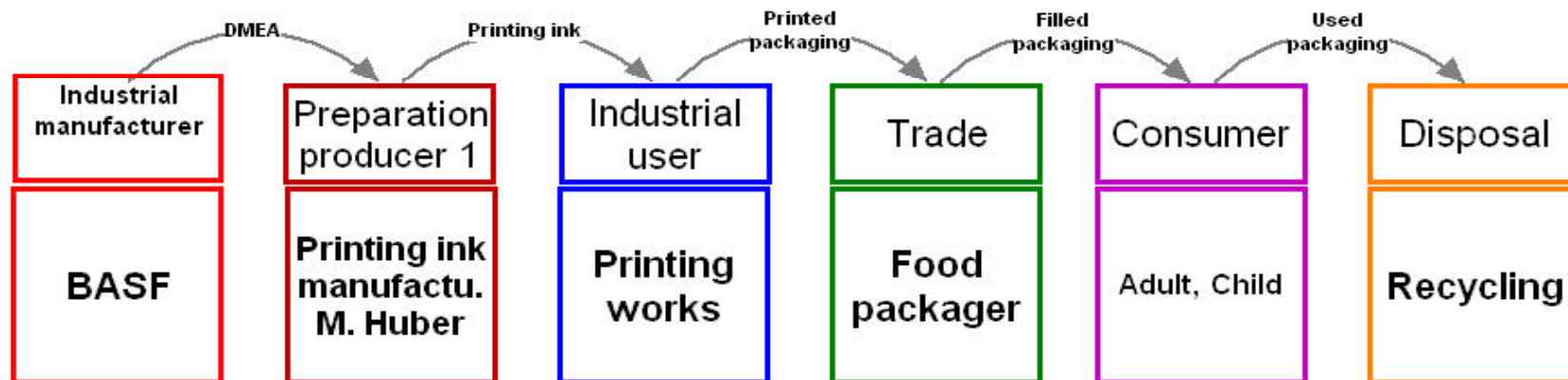
Cobalt dryer product chain



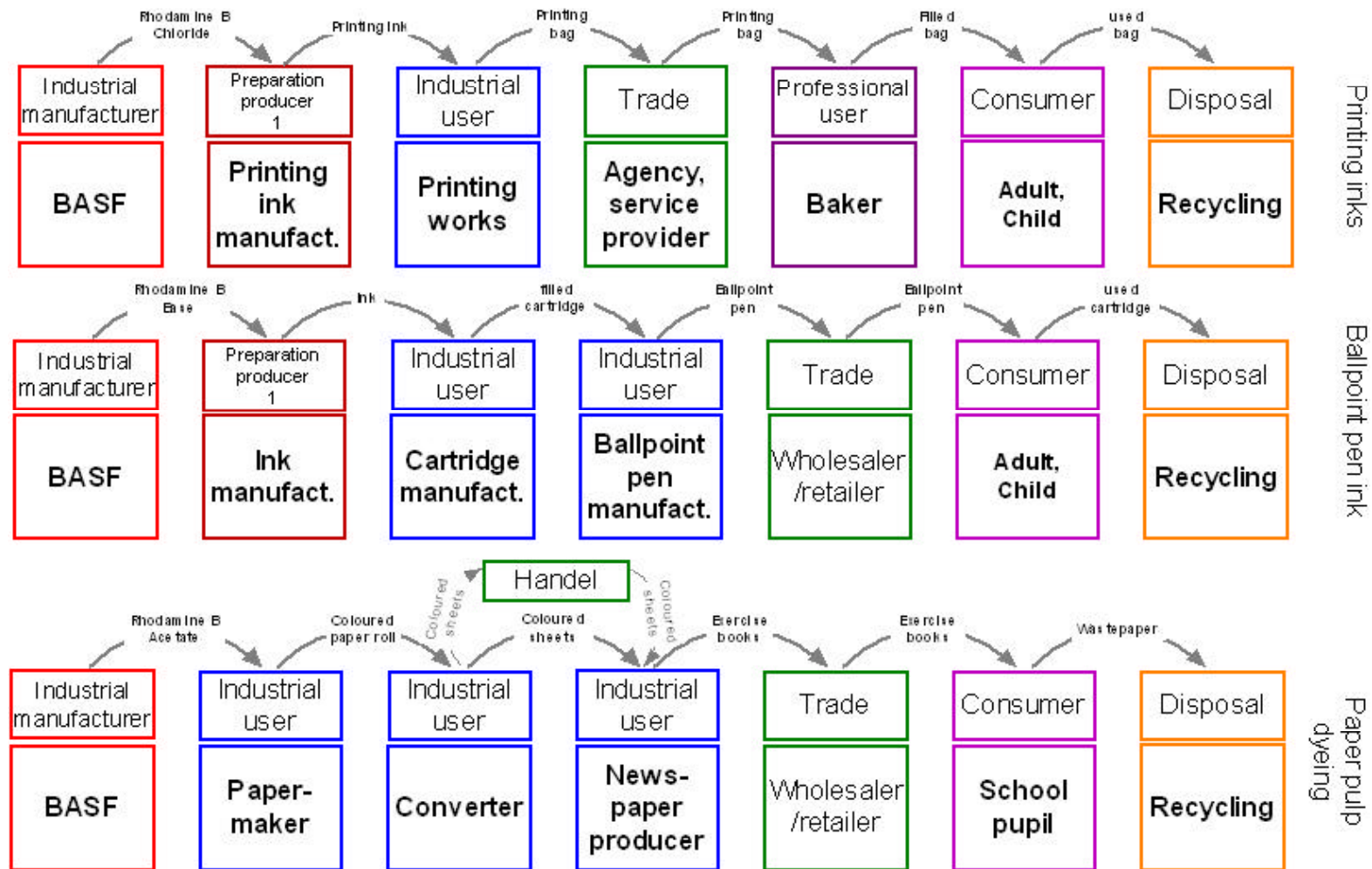


AG 3: DMEA in the printing ink industry

"Printing ink manufacture" product chain



AG 4: Rhodamine B Product chains



Appendix 2: Exposure categories as an aid and their use

The proposal of exposure categories, consistently supported by all working groups, still needs practical refinement. The following (fictional) example is intended to clarify the option proposed here.

In the working groups, a draft classification of exposure situations developed by Dr Fink, Verband der Chemischen Industrie e.V., was used as a basis for defining the concept of exposure categories in practical terms (see sub-section 2 of this Appendix). The classification clarifies what is meant by "standard exposure situations" (e.g. repeatedly occurring dermal exposure in industrial use).

In the working groups, there was no discussion on how the concentration bands for the exposure categories should be determined or the data on which such a determination should be based, nor on how existing industrial safety limits could be included.

1. Example: Additive for use in emulsion paints

Stage 1: Registration by the manufacturer

Intended use: additive for emulsion paints

Associated exposure situations taken into account in the registration:

- **Exposure situation 1:** Manufacturing plant: pumping off a volatile solvent into an open production tank

Associated exposure category: **C 1.2**, inhalative exposure in industrial use, occasional, repeated, short-term exposure:

- **Exposure situation 2:** Preparation producer, manufacture of an emulsion paint in a continuous process, wastewater generation, release via in-house wastewater treatment unit

Associated exposure situation: **E 1.2 W**, environmental exposure, wastewater pollution, continuous discharge, local pollution:

- **Exposure situation 3:** Medium-sized painting and decorating company, brush application of emulsion paint, skin contact possible

Associated exposure category: **B.2.2**, dermal exposure in professional use, occasional exposure:

- **Registered set of exposure categories: C 1.2, E 1.2 W, B.2.2, including concentration ranges**

Stage 2: Exposure analysis by the user

Case 1: A manufacturer of cooling lubricants uses the additive

Exposure analysis shows: Exposure situations occur that are comparable with the registered exposure situations 1-3 and can be assigned to the same exposure categories (e.g. skin contact, B.2.2). The quoted concentration ranges are complied with.

Consequence: Although the application is not the same as the manufacturer's intended and registered use, the downstream user does not need to carry out any costly risk assessments for the application.

Case 2: A manufacturer of furniture coatings uses the additive

Exposure analysis shows:

Exposure situations occur that are **comparable with the registered exposure situations 1-3** and belong to the same exposure categories. The concentration bands are complied with and so there is no need for additional action in registering the new use. However, another exposure situation is also important:

Exposure situation 4: Private user, sanding down a painted wooden window, breathing in dust, occasional, repeated

Associated exposure category: C.3.2, inhalative exposure with dust, consumer use, occasional, repeated, short-term exposure

This exposure situation is not covered by the manufacturer's registered set for use in paints and must be registered with the authority independently by the user with a risk assessment. The manufacturer of the furniture coating can seek the cooperation of the additive manufacturer on this. If the furniture coating manufacturer does not wish to do this for reasons of know-how protection or the additive manufacturer does not wish to cover exposure category C.3.2 as part of the cooperation, then the furniture coating manufacturer must undertake the risk assessment himself or have it carried out.



2. Draft of a system for exposure categories

Dr Fink, Verband der Chemischen Industrie

Industrial use (high level of training/expert knowledge, good standard of monitoring, high technical requirements can be met)

Professional use (only moderate technical requirements can be realistically met or none at all, expert knowledge and training vary – use by specialist companies comparable with industrial use, exposures often similar to those for consumers but more long-term)

Consumer use (no technical or other protective measures realistic – except for gloves/goggles, no expert knowledge, sensitive group, children, sick people)

A Oral, direct exposure

A 1 industrial use	A 2 professional use	A 3 consumer use
A 1.1 single exposure (accident)	A 2.1 one-off situation (accident)	A 3.1 single exposure (accident)
		A 3.2 longer-term exposure (release from finished products, e.g. German Food and Consumer Articles Act)

B Dermal exposure

B 1 industrial use	B 2 professional use	B 3 consumer use
B 1.1 single exposure	B 2.1 single exposure	B 3.1 single exposure (accident)
B 1.2 occasional exposure	B 2.2 occasional exposure	B 3.2 occasional exposure
B 1.3 continual/repeated exposure	B 2.3 continual/repeated exposure	B 3.3 continual/repeated exposure

C Inhalative exposure

C 1 industrial use	C 2 professional use	C 3 consumer use
C 1.1 short-term, single exposure	C 2.1 short-term, single exposure	C 3.1 short-term, single exposure
C 1.2 occasional, repeated, short-term exposure	C 2.2 occasional, repeated, short-term exposure	C 3.2 occasional, repeated, short-term exposure
C 1.3 repeated, longer-term exposure/continual exposure	C 2.3 repeated, longer-term exposure/continual exposure	C 3.3 repeated, longer-term exposure/continual exposure

E Environmental exposure

E 1 industrial use	E 2 professional use	E 3 consumer use
E 1.1 single exposure (accident)	E 2.1 single exposure (accident)	E 3.1 single exposure (accident)
E 1.2 continual/long-term exposure (local/regional)	E 2.2 continual/long-term exposure	E 3.2 continual/long-term exposure
E 1.3 long-term exposure (Europe-wide/global)	E 2.3 long-term exposure (Europe-wide/global)	E 3.3 long-term exposure (Europe-wide/global)

Appendix 3: Key questions and memo points for the working groups

The White Paper proposals for information flow along the product chain (see Appendix 1) raise the following key questions and memo points, which were discussed in the working groups of the "Product Chain Chemicals Policy" project.

Key questions¹²:

1. What do the patterns of use for the sample substance look like? To what extent are all uses known?
2. What do the terms "intended use" and "current use" mean specifically in relation to the sample substance?
3. What does the value chain for the selected scenarios look like in detail?
4. What kind of exposures (environment, industrial safety, consumers) occur (no measurements) in the selected scenarios and at what points in the value chain?
5. According to the requirements of the EU White Paper, what substance- and process-related information is needed for the sample substance in the scenarios at the individual points in the value chain? Are costly exposure measurements by substance manufacturers or preparation producers required by their customers?
6. What are the obligations that emerge for the actors involved in the selected scenarios in the value chain? How can a proper balance of interest and, if necessary, allocation of costs be achieved between manufacturers and downstream users?
7. Is the required information available? If yes, from whom? If no, how can it be obtained?
8. What obstacles and difficulties are envisaged by the actors involved at the individual points in the value chain? What importance should be placed, in particular, on the need of substance manufacturers and further processors for protection from uncontrolled use of costly test results for product risk assessment by third parties (free-riders)? What practical solutions do you see to these difficulties? What obstacles seem insurmountable?
9. How could these solutions be implemented in the drafting of the new EU legislation?

In the discussions in the working groups, the following memo points were taken into account:

- **Memo point 1:** The data situation with regard to the different sample substances varies considerably.
- **Memo point 2:** Depending on the size of the company (large/small or medium-sized company), there are different options for action.
- **Memo point 3:** How can preparation producers determine exposure on their customers' premises? What costs arise here?
- **Memo point 4 (supplement to key question 2):** The allocation of data determination duties between manufacturers and downstream users depends, according to the

¹² During the course of the project, the key questions were adapted to the specific situation in the working groups.



White Paper, on "intended use". To what extent is the definition of intended use at the discretion of the manufacturer and how far do actual uses have to be considered beyond the intention of the manufacturer? Can the many different uses and scenarios be grouped into categories so that that the coverage provided by the "intended use" in each case relates to specific categories?

- **Memo point 5:** How can data that are not confidential be protected from unauthorised commercial use (e.g. safety data sheets)? In safety data sheets, data sometimes have to be included that represent know-how and determination of this data incurs a financial cost. By "copying" this non-copyrighted data, competitors could possibly gain a competitive advantage.
- **Memo point 6:** There is a conflict of interest between the different actors in the product chain. Manufacturers who carry out costly tests for risk assessment, when passing on these test results to customers, would like if possible to tie the customers to themselves and prevent unauthorised use of the results by competitors. Their customers on the other hand would like the freedom to select their suppliers (keyword: market economy). This problem arises throughout the product chain, not just in the relationship between the substance manufacturer and preparation producer.
- **Memo point 7:** How will the compliance of manufacturers and downstream users with their registration duties be monitored? How can it effectively be ensured that all market participants fulfil their duties?
- **Memo point 8:** Value chains in which the information flow functions well should also be documented.

Appendix 4: Core statements in the White Paper on information flow in the product chain

This appendix collects the core statements from the different chapters of the White Paper on chemicals policy to form a specification of duties for the actors. This compilation is intended to be used as a frame of reference to support the work of the groups in the "Product Chain Chemicals Policy" working groups.

The role, rights (more precisely: duties ...) and responsibilities of industry – that is the title of Chapter 5 of the EU White Paper. In this chapter, there are also core statements on the duties of "downstream users". In other chapters of the White Paper, too, scattered statements can be found that are important for studying information flow along the product chain and the duties associated with this.

In the following text, extracts from the different chapters of the EU White Paper on the principle of shared responsibility and the product chain are grouped together. Text passages on registration procedure have not been taken into account, since this is not the subject being studied by the working groups.

This compilation is intended as an aid for the working groups so that in discussing the individual sample substances they do not lose sight of the original starting points for debate but can base their work on the EU White Paper.

Appendix 5 contains four further supplementary text passages from the White Paper.

Core statements from the EU White Paper on information flow and the principle of shared responsibility

Core statements from Chapter 2: The European Union chemicals policy

Key elements of the proposed strategy

I "Making industry responsible for safety: Responsibility for generating knowledge about chemicals should be placed on industry. Industry should also ensure that only chemicals that are safe for the intended uses are produced and/or placed on the market. The Commission proposes to shift responsibility to companies for generating and evaluating data and assessing the risks of the substances in the context of use. The companies should also provide adequate information to downstream users" (Section 2.3, Key elements of the proposed strategy, page 8).

II "Extending responsibility along the manufacturing chain: Downstream users, as well as manufacturers and importers, of chemicals should be responsible for all aspects of the safety of their products and should provide information on use and exposure for the assessments of chemicals. Producers of preparations and other downstream users will be obliged to assess the safety of their products for the part of the lifecycle to which they contribute, including disposal and waste management" (Section 2.3, Key elements of the proposed strategy, page 8).

III "Substitution of hazardous chemicals: Another important objective is to encourage the substitution of dangerous by less dangerous chemicals, where suitable alternatives are available. The increased accountability of downstream users and better public information will create a strong demand for substitute chemicals that have been sufficiently tested and are safe for the intended use" (Section 2.3, Key elements of the proposed strategy, page 9).



Core statements from Chapter 3: Knowledge about chemicals

IV Risk assessment of chemicals "... Any risk assessment of chemicals is composed of two distinct elements: (1) an evaluation of the properties that are intrinsic to the chemical and (2) an estimation of exposure, which depends on the use of the chemical (Chapter 3, page 11). ... Precise knowledge of intrinsic properties and the exposure arising as a result of a particular use is an indispensable prerequisite for making decisions on the safe management of chemicals" (Chapter 3, Knowledge of chemicals, page 12).

V "Action 3 C: Exposure-triggered testing: The current testing regime for new substances has been criticised for not taking sufficiently into account different exposures of humans and the environment to chemicals. Hence, the future system should include sufficient flexibility to waive or extend the required testing as appropriate according to particular exposure scenarios. For example, testing requirements for strictly controlled and rigorously contained intermediates should be reduced" (Section 3.1, Action 3 C, page 14).

VI Exposure and use: Adequate knowledge about exposure is an absolute requirement for any reliable risk assessment.

Action 3 G: "Obligation of manufacturers, importers and downstream users to assess exposure. The general shortage of exposure data must be addressed. Exposure estimates or, if appropriate, analytical determination of the exposure should be obligatory for manufacturers and downstream users (formulators or industrial users) of chemicals. (Further details on this proposal are given in chapters 4 and 5.)" (Chapter 3.3, Exposure and use, page 16).

Core statements from Chapter 4: A new system of chemicals control – the "REACH" system

VII "Registration: Registration requires a manufacturer or importer to notify an authority of the intention to produce or import a chemical substance and to submit a dossier containing all the information required by the legislation. ... The registration dossier will include the following information: ... intended uses, estimated human and environmental exposure ... preliminary risk assessment covering the intended uses ... proposed risk management measures" (Section 4.1, Registration, page 18).

VIII "Accelerated risk management of other substances: Specific use of substances which do not have one of the properties listed under the authorisation system but for which restrictions are needed should be addressed in an improved and accelerated procedure. #(2) The obligation on companies to submit a preliminary risk assessment will provide authorities with valuable and comprehensive information on whether or not the chemical substance in question can be handled safely, thereby avoiding unacceptable risks for workers, the population at large and the environment" (Section 4.4, Accelerated risk management of other substances, page 21).

Core statements from Chapter 5: Role, rights and responsibilities of industry

IX "Data generation. The current system only establishes duties for producers and manufacturers to test chemicals but not for downstream users. The role of downstream users in testing of chemicals needs to be further considered.

Action 5 A: Obligation of downstream users to perform testing. Downstream users must assume responsibility for the safety of their products. Authorities should be empowered to

require downstream users to carry out additional testing **where uses differ from those originally envisaged by manufacturers or importers and the resulting exposure patterns also differ substantially from those evaluated by them.** Additional testing programmes should be developed in close consultation with the authorities" (Section 5.1, Data generation, page 22).

X "Risk/safety assessment: Action 5 B: Manufacturers and downstream users to perform risk assessment. Industry should have responsibility for performing risk assessments. This will require the manufacturer or importer as well as the downstream user to carry out adequate risk assessments for substances and preparations" (Section 5.2, Risk/safety assessment, page 23).

XI "Information to be provided by industry to the authorities. Industry should provide authorities with information about all substances as set out in Chapter 4. Below the Chapter 4 thresholds, industry should generate the necessary safety data and keep the records available.

Action 5 C: Obligation of downstream users to inform authorities. The Commission proposes that the authorities must be informed about any downstream use which has not been envisaged by a manufacturer or importer and which has not therefore been addressed in the preliminary risk assessment" (Section 5.3, Information to be provided by industry to the authorities, page 23).

XII "Information to be provided by manufacturers and importers to downstream users, other professional users and consumers. Information relevant to the safe use of chemicals must be available to all users, including consumers. Fundamentally, the safety system depends on the quality and comprehensibility of the information passed on down the production chain. ...

... The Commission proposes to establish a working group ... to clarify the following questions:

... examining the current information requirements with a view to expanding them in order to enable users to carry out risk assessment" (Section 5.4, Information to be provided by manufacturers and importers to downstream users, other professional users and consumers, page 23 et seq.).

XIII "Property rights for test data. The specific provisions in Directive 67/548 and Regulation 793/93 for sharing test data and testing costs were designed to avoid duplicate animal testing. However, such provisions also have a benefit for industry because they reduce the overall testing costs. Furthermore, legislation for sharing test data and the costs of testing is essential to ensure fair competition, otherwise some companies might delay testing in the hope that competitors producing the same substance would be obliged to do it before them and pick up the full costs.

The introduction of exposure-triggered testing and new obligations on downstream users to carry out testing could accentuate this problem. For example, if a downstream user carried out additional testing because of substantially different exposure patterns from those foreseen by a manufacturer of the substance, the latter might use these data to enlarge the scope of the uses of the substance. This would increase the number of potential customers and the marketed volumes, in some cases at a disadvantage to the original downstream user. Such a system would encourage the manufacturers to strictly limit the number of intended uses to a minimum, waive testing as far as possible and wait for downstream users to complete the testing. This would be a clear distortion of competition.

Action 5 E: Property rights for test data. Anyone who generates test data under the new system should be encouraged to share the data. For the use of such data, a fair and equitable contribution should be paid to the generator of the data" (Section 5.5, Property rights for test data, page 24).

Appendix 5: Additional statements in the EU White Paper on aspects that might also be important for information flow

A 1: Additional statement on exposure-triggered testing: "- the general testing requirements will be modified to incorporate exposure-triggered testing where appropriate" (Section 3.2, Development of alternative methods, page 15).

A 2: Additional statement on preparations: "Current notification requirements cover substances placed on the market on their own or as constituents of preparations" (Section 3.1, page 14).

A 3: Additional statement on products: "Action 3 E Obligations for substances marketed as constituents of products: "... As regards substances in products that can lead to significant exposure of humans and the environment, the Commission proposes to set up a working group which would identify the product categories (e.g. toys or textiles), the relevant exposure situations and all other practical implications. On the basis of this working group's findings, producers or importers should be requested to identify products containing such substances and provide any relevant information" (Section 3.1, page 14).

A 4: Additional statement on improvement and simplification of risk assessment procedures: "To meet the goals of this White Paper, continuous research efforts have to be made both at Community and national level to cover the many knowledge gaps. At Community level, the Commission, through its Framework Programmes for Research, Technological Development and Demonstration, is supporting research in a number of other areas, e.g. improvement and simplification of risk assessment procedures" (Section 3.2, page 15).



Appendix 6: Members of the working groups and the steering committee and participants in the discussions with the chemical trade

"Product chain project" steering committee

Members	Company/association
Dr Horst von Holleben	for the Verband der Chemischen Industrie e.V. ¹ , chairman of the steering committee
Dr Rüdiger Baunemann	Verband der kunststofferzeugenden Industrie e.V. ²
Dr Dietmar Eichstädt	Verband der Lackindustrie e.V. ³
Dr Dieter Fink	Verband der Chemischen Industrie e.V.
Dr Alex Föller	Industrieverband Organische Farbstoffe und Pigmente ⁴ in the VCI
Dr Martin Kanert	Verband der Druckfarbenindustrie e.V. ⁵
Dr Manfred Marsmann	Bayer AG
Hans Hermann Nacke	Verband der Chemischen Industrie e.V.
Dr Peter Orth	Verband Kunststoffherstellende Industrie e.V.
Reinhard Raackow	Wacker Chemie GmbH
Dr Gerd Romanowski	Verband der Chemischen Industrie e.V.
Dr Walter Seufert	BASF AG
Dr Hans-Jürgen Wiegand	Degussa AG

Working group 1: Flame retardants as additives for flame-retardant monitor housings

Members	Company/association
Dr Rüdiger Baunemann	Verband der kunststofferzeugenden Industrie e.V., supervisor of the working group
Dr Dieter Drohmann	Great Lakes Sales (Germany) GmbH
Dr Stefan Grutke	BASF AG
Dr Wichard Pump	BAYER AG
Dr Annett König	BAYER AG
Friedrich Koch	Siemens AG
Dr Dieter Fink	Verband der Chemischen Industrie e.V.
Dr Horst von Holleben	for the Verband der Chemischen Industrie e.V., chairman of the steering committee
Dr Klaus Schneider	Forschungs- und Beratungsinstitut Gefahrstoffe GmbH ⁶ – FoBiG
Frank Ebinger	Öko-Institut e.V. ⁷
Philipp Wolf	Öko-Institut e.V.



Members	Company/association
Dr Dirk Bunke	Öko-Institut e.V.

Working group 2: Additives for the paints and coatings sector (cobalt dryers and degassing agents)

Members	Company/association
Dr Dietmar Eichstädt	Verband der Lackindustrie e.V., supervisor of the working group
Heinrich Bartholemy	Technische Beratungsstelle des deutschen Maler und Lackierhandwerks ⁸
Dr Dieter Fink	Verband der Chemischen Industrie e.V.
Wilfried Hansemann	Verband der Lackindustrie e.V.
Dr Horst von Holleben	for the Verband der Chemischen Industrie e.V., chairman of the steering committee
Meike Klemm	Verband der Lackindustrie e.V.
Dr Christian Srna	Verband der Lackindustrie e.V.
Dr Andreas Steinert	Borchers GmbH
Norbert Wilterius	NOVEM Car Interior Design GmbH
Dr Klaus Schneider	Forschungs- und Beratungsinstitut Gefahrstoffe GmbH - FoBiG
Philipp Wolf	Öko-Institut e.V.
Frank Ebinger	Öko-Institut e.V.
Dr Dirk Bunke	Öko-Institut e.V.

Working group 3: DMEA in the printing ink industry

Members	Company/association
Dr Martin Kanert	Verband der Mineralfarbenindustrie ⁹ , supervisor of the working group
Dr Matthias Andrae	BASF AG
Klaus Hanke	Michael Huber München
Dr Dieter Fink	Verband der Chemischen Industrie e.V.
Dr Horst von Holleben	for the Verband der Chemischen Industrie e.V., chairman of the steering committee
Ismene Jäger	Ökologische Netze
Philipp Wolf	Öko-Institut e.V.
Frank Ebinger	Öko-Institut e.V.
Dr Dirk Bunke	Öko-Institut e.V.



Working group 4: Rhodamine B

Members	Company/association
Dr Alex Föller	Industrievereinigung Farbstoffe und Organische Pigmente in the VCI, supervisor of the working group
Dr Andreas Oberlinner	BASF AG
Dr Bernd Polzin	Dokumental
Dr Horst von Holleben	for the Verband der Chemischen Industrie e.V., chairman of the steering committee
Dr Dieter Fink	Verband der Chemischen Industrie e.V.
Ismene Jäger	Ökologisches Netze
Frank Ebinger	Öko-Institut e.V.
Philipp Wolf	Öko-Institut e.V.
Dr Dirk Bunke	Öko-Institut e.V.

Discussion with the chemical trade on February 21, 2002

Participants	Company/association
Dr Bruno Stephan	Verband des Chemiefachhandels e.V. ¹⁰
Heinz-Werner Dobbertin	Chemie-Sicherheit-Beratung GmbH
Dr Heinrich van Megen	Brenntag AG
Dr Dieter Fink	Verband der Chemischen Industrie e.V.
Dr Horst von Holleben	for the Verband der Chemischen Industrie e.V., chairman of the steering committee
Dr Gerd Romanowski	Verband der Chemischen Industrie e.V.
Frank Ebinger	Öko-Institut e.V.
Dr Dirk Bunke	Öko-Institut e.V.

VCI/CEFIC coordination meeting on February 1, 2002 in Frankfurt/M.

Participants	Company/association
Dr Bias	BASF AG
Mr Boudon	UIC



Participants	Company/association
Dr Dirk Bunke	Öko-Institut e.V.
Mr Chesnau	BP
Dr Föller	TEGEWA ¹¹
Dr Förster	DuPont
Dr Horst von Holleben	for the Verband der Chemischen Industrie e.V., chairman of the steering committee
Dr Kistenbrügger	CEFIC
Meike Klemm	Verband der Lackindustrie e.V.
Dr Orth	Verband der kunststofferzeugenden Industrie e.V. - VKE
Dr Paetz	Bayer AG
Dr Raackow	Wacker Chemie AG
Mr Ringstroem	Kemikontoret
Mr Jan Vernon	RPA

- 1 German Chemical Industry Association
- 2 German Association of the Plastics Processing Industry
- 3 German Association of the Paint Industry
- 4 German Industrial Association for Organic Colorants and Pigments
- 5 German Association of the Printing Ink Industry
- 6 Institute for Research and Consultation on Dangerous Substances
- 7 Institute for Applied Ecology
- 8 Technical Advisory Centre for German Painters and Decorators
- 9 German Association of the Mineral Pigments Industry
- 10 German Chemical Traders Association
- 11 Association of the Textile Auxiliaries, Leather Auxiliaries, Tanning Agents and Detergents Industry