

Pilot Trial of Cefic Thought Starter

Final Report

prepared for
Cefic

RPA
March 2002

**PILOT TRIAL
OF
THE CEFIC THOUGHT STARTER**

Final Report – March 2002

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Cefic

by

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Executive Summary

The Pilot Trial

In February 2001, the European Commission adopted a White Paper setting out its strategy for a future Community Policy on Chemicals. The strategy calls for the collection and scrutiny by public authorities of data for chemicals currently on the market through the REACH process (the Registration, Evaluation and Authorisation of Chemicals). In response, Cefic has prepared a 'Thought Starter' aimed at ensuring REACH is implemented in a manner that is practical, effective and workable for industry.

To test the appropriateness of the Thought Starter, 11 chemical companies (manufacturers and importers, with some also undertaking downstream use) agreed to take part in a three-month pilot trial. For the purposes of the trial, the principles and procedures set out in the Thought Starter were transformed into an implementation plan which provided the basis for the work undertaken by the 11 companies. This report summarises the conclusions reached from the pilot trial.

Conclusions

When rigorously carried out in accordance with the implementation plan, the Thought Starter appears to provide a good basis for implementing REACH in a cost-effective manner. By following the plan and its procedures related to substance-tailored testing, companies were able to identify where test data in addition to the minimum Thought Starter requirements would be necessary to demonstrate that no unacceptable risks would arise from a particular use.

However, the extent to which the procedures could be followed rigorously was affected by the degree to which downstream users were willing or able to co-operate in the gathering of detailed exposure and risk management information. Developing mechanisms to improve information exchange between producers and users of chemicals is therefore a key issue, which affects the ability of companies to fulfil several of the requirements of the Thought Starter.

The Thought Starter proposes a tiered, risk-based, substance tailored information provision regime. Because of this, it may provide a significantly less resource intensive means of achieving the White Paper's objectives than the initial proposals set out in the White Paper.

One of the companies submitting a dossier for a substance produced in quantities greater than 100 tonnes per year (t/y), and which followed in detail the activities as set out in the Implementation Plan, estimated the costs of fulfilling the requirements of the Thought Starter at around €150,000. These costs can be compared with estimates that have been developed by Cefic and the Commission for meeting testing requirements of the White Paper alone. Cefic estimates that the costs of Level 1 testing (which would apply to such a substance) would be in the order of €500,000 (assuming no data already exist). The Commission's estimate is €250,000 for Level 1 data. In addition, there would be costs of information

exchange with downstream users and co-producers, determining exposure, undertaking a risk assessment, completing IUCLID, etc. Thus, the costs of fulfilling the requirements of the Thought Starter appear to represent significant savings, particularly when aggregated over thousands of chemicals.

A number of detailed findings also emerged, even within the short time-scale of the pilot trial. These are summarised in Table 1 overleaf.

Recommendations

Based on the findings, the report makes a series of recommendations for ensuring that REACH can be implemented in a cost-effective way. These are:

- companies should be encouraged to examine ways in which the Thought Starter could be implemented for their substances and to begin developing links with co-producers and users;
- competent Authorities should consider developing databases of appropriate contact points within producer and user companies, to help in the development of such links;
- the use of exposure categories to classify key exposure routes and scales should be examined as a basis for risk assessment whilst protecting commercially-sensitive information; and
- further development of the Thought Starter to address the technical issues identified in the pilot trial should be considered, especially in relation to determining substance-tailored testing and taking account of the level of information available from downstream users.

Table 1: Key Findings from the Pilot Trial
<p>Collection of Tonnage Data</p> <ul style="list-style-type: none"> • Companies hold information on the uses and production tonnage of their substances and hazard data collected for regulatory, marketing or management purposes. • Even collecting their own production data can be problematic in complex companies where different locations and people are involved in production. • Where a substance is contained within a preparation or formulated product, it can become difficult to calculate tonnages accurately.
<p>Involvement of Co-Producers</p> <ul style="list-style-type: none"> • Some indication is needed of likely level of production by other manufacturers within and outside the EU, to give a context for hazard data. • Involving co-producers can be complex and time-consuming. Knowing the right people to contact, and making use of trade association sector groupings can help but there is currently no mechanism to bring non-EU producers to the table.
<p>Physico-Chemical and Hazard Data</p> <ul style="list-style-type: none"> • Industry has gaps in its hazard data that cannot always be justified. The gaps would be even larger if non-GLP data were excluded; there are also areas of testing where no guidance is available. • Problems arise where substances are complex, or are marketed as a preparation (where data may concern properties of the solvent rather than the substance). One of the pilot substances was part of a series of overlapping complex substances. • In one case the initial use of a substance was industrial, it was then incorporated into a preparation for professional use and could be present in end products. A distinction should be made between the first use of a substance (covered by the SDS) and subsequent uses. One option would be to adopt threshold concentrations, below which subsequent uses do not need to be included. • Most companies experienced few problems in putting data into IUCLID but many found it awkward to work with, and it can be problematic for small companies and where there is lack of experience with IUCLID.
<p>Use Data/Exposure Information</p> <ul style="list-style-type: none"> • Downstream users were not aware of the White Paper and did not understand what is required of them under REACH. Clearly awareness will improve post-regulation. • In some cases, this led to the data provided being insufficiently detailed to provide a basis for understanding how exposure is controlled or why it would be negligible. Two companies indicated that some uses of pilot trial substances were not included in the TGD. • Downstream users did assist with some substances, particularly where manufacturers could draw on an existing sector grouping, and their input proved very helpful. Some expressed concern, though, about commercial sensitivity and the public availability of the data. • Companies employed a range of means to contact users, including questionnaires. Detailed questionnaires are more likely to generate the data needed (but are harder for users to answer). • Downstream user input is important for higher volume chemicals, where use may occur at multiple locations relying on varying processes. • Where information from users is lacking, companies could register known and intended expected uses based on generic exposure scenarios. Because this could result either in additional testing and other costs or in limiting the testing and other costs. • It is not clear to what extent modelling information, based on health and safety and environmental regulations, and the literature can be used to fill these gaps. • Some problems arose because of the wide range of uses of a substance, making it difficult to provide technical data for each and specify the exact regulatory controls that apply without 'writing a book'. The information provided must be proportionate.
<p>Resources</p> <ul style="list-style-type: none"> • The pilot trial was short, so it was difficult in this context to initiate dialogue properly. If there had been proper dialogue, more resources would have been required.
<p>Evaluation</p> <ul style="list-style-type: none"> • The lack of complete data from downstream users introduced considerable uncertainty into the information on exposures provided in the dossiers. From a manufacturer/importer viewpoint, further information could negate the need for additional testing. • Control measures currently in place and their relative performance, including any specified by legislation, could also reduce requirements for testing and more detailed risk assessment.

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1. INTRODUCTION

1.1 Background to the Pilot Trials

In February 2001, the European Commission adopted a White Paper setting out its strategy for a future Community Policy on Chemicals. The aim of this strategy is to ensure a high level of protection for human health and the environment, while at the same time guarding the effectiveness and efficiency of the internal market, and stimulating innovation and competitiveness in the EU chemical industry. The strategy sets out a range of proposed changes to the current system of chemicals regulation, with a key aspect being the collection and scrutiny by public authorities of key data for chemicals currently on the market. The key mechanisms for the control of chemicals are referred to as REACH, referring to the Registration, Evaluation and Authorisation of CHEMicals, that comprises the basis for the future process of assessment and control.

The White Paper proposals provide only an outline of how such a system might be implemented, with the details yet to be formalised by the Commission. In response, and with the aim of ensuring that REACH is implemented in a practical, effective and workable manner for the industry, Cefic has developed a 'Thought Starter on REACH: An initial proposal for translating the REACH System into Practice' (Cefic, 2001), which sets out an approach for implementing the REACH procedure.

In order to test the appropriateness of the Cefic 'Thought Starter', a number of chemical companies agreed to take part in a pilot trial of the approach. The aim of the pilot trial has been to simulate what could happen in practice, to develop estimates of the costs and effort required in meeting the REACH requirements (across all parties involved), and to identify the types of data gaps and other issues that are likely to arise in practice.

1.2 Approach to the Trials

The pilot trials of the Thought Starter have been undertaken voluntarily by 11 companies. The companies represent both manufacturers and importers and some are also professional or downstream users of chemicals, purchasing substances from other companies which they then use to produce other substances or products.

The companies were asked to nominate chemicals for the trials, with the aim being to include substances that vary in terms of:

- the volumes at which they were produced and sold within the EU, with some high production volume chemicals and others of much lower production volumes;
- the likely health and environmental hazards posed from their use;
- the availability of data, including some chemicals that are part of the International Council of Chemical Associations (ICCA) process so that lessons learned from this initiative could be shared with the pilot trials; and

- the uses to which the substances are put, including chemicals used primarily as an intermediate, those for professional use and those used in consumer products.

The Steering Group for the study comprised representatives from Cefic, the UK Chemical Industries Association (CIA), the Verband der Chemischen Industrie E.V. (VCI) of Germany and the Union des Industries Chimiques (UIC) of France, with meetings chaired by BP. Risk & Policy Analysts Ltd (RPA) was commissioned by Cefic to act as the neutral Secretariat to the pilot trials. This stemmed in part from the work that RPA had carried out for the UK Government in preparing a partial (or preliminary) regulatory impact assessment of the EU White Paper proposals and thus our familiarity with the outline REACH system. RPA's role included the following activities:

- assisting with communication between companies and dissemination of background materials;
- acting as a third party to provide a mechanism for the collection of confidential information;
- acting as a central point for the submission of registration dossiers in electronic form;
- evaluating registration dossiers in terms of the degree to which they were consistent with the Thought Starter requirements, the likely adequacy of the information provided and determining whether a risk is adequately controlled by existing regulation;
- simulating the likely role of the Competent Authority during the evaluation stage, (based on our experience in undertaking risk assessment and chemical management harmonisation studies for the Commission and risk reduction strategies for the UK government under the current regulatory system);
- examining authorisation issues; and
- preparing this summary of experience from the pilot trial exercise.

1.3 Organisation of the Report

This report summarises the findings of the pilot trials. The focus is on those aspects of the Cefic proposals that make REACH practical and the areas where difficulties still exist.

The report has been organised as follows:

- Section 2 provides an overview of the Thought Starter and a description of the scope of the pilot trials;
- Section 3 discusses the activities undertaken and information submitted to RPA during the trial, and identifies information gaps and problem areas;
- Section 4 examines the resource estimates provided by the participants as to the time and effort required to prepare dossiers in line with the Cefic Thought Starter; and
- Section 5 summarises our conclusions, lessons learned and recommendations for the way forward.

2. THE CEFIC THOUGHT STARTER

2.1 Guiding Principles

The Cefic Thought Starter sets out a decision making procedure for each of the key components within the REACH process. In developing this procedure, Cefic adopted a series of guiding principles out of concern for the need to “cope with the immense amount of information in a concise and efficient way”. These principles are:

- a) Make best use of existing legislation, e.g. IPPC, Cosmetics Directive;
- b) Make use of available reliable information to the maximum extent needed;
- c) Generate relevant and appropriate information, applying the principle of proportionality and only in so far as for intended uses and exposures necessary;
- d) Documentation of data is the responsibility of industry and should be accessible on a need to know basis to authorities;
- e) Avoid complexity;
- f) Minimise animal testing; and
- g) Develop close co-operation between the central entity and the chemical industry.

With the above in mind, proposals were put forward for the three main components of REACH. These proposals are summarised below owing to their importance to the way in which the pilot trial was undertaken, the work undertaken by the participating companies and the conclusions then drawn. For a more detailed discussion readers should refer to the full document by Cefic.

2.2 Registration

The Thought Starter suggests that the registration process can be broken down into discrete components, allowing each to be treated separately. This should facilitate the ability of different entities to work co-operatively in registering a chemical, should they so wish. However, the system must also allow the scope for an entity to take the option of registering individually, if it considers it to be necessary or appropriate.

The key components of registration are:

- Phase 1 – Declaration;
- Phase 2 – Forming Consortia;
- Phase 3 – Information Gathering;
- Phase 4 – Preliminary Risk Assessment; and
- Phase 5 – Registration.

The work undertaken as part of these pilot trials was concerned with Phases 2 to 5, with the participating companies submitting Registration Dossiers. RPA then checked the comprehensiveness of these Dossiers against the requirements of the Thought Starter.

Under the Thought Starter, registration would be required for all non-polymer substances placed on the market, exceeding 1 tonne per year. Cefic has identified a “core information set”, related, or proportional, to a substance’s intended uses and the tonnage of each substance placed on the market. As the potential for exposure increases, the basic requirements for information provision also increase, and some uses may require further additional information. The three use categories identified for determining likely exposure are:

- *Industrial use* - substances used in the industrial/commercial sector and handled in controlled systems or in binding matrices, which only give rise to insignificant release rates;
- *Professional use* - for all purposes in the industrial and commercial sectors; and
- *Consumer Use* - substances which reach the public consumption sector.

The details of the information to be provided are set out in Annex 1 to this report. As can be seen from this Annex, the need for *in vivo* data is kept to a minimum.

The Thought Starter also proposes that the registration process is tiered. The registration of substances placed on the market in quantities greater than 10 tonnes per year would be completed within five years after new legislation comes into force and registration of substances placed on the market between 1 and 10 tonnes per year (t/y) would be completed after eight years. All documentation of the registration data would be the responsibility of industry and would be in a format accessible to authorities.

2.3 Evaluation

Cefic proposes that evaluation takes place within a reasonable and definitive timeframe, in order to provide legal safeguards, to enable the enterprises involved to plan for the future and for the system to work effectively. It is also proposed that, if the data and information provided as part of the Registration Dossier are insufficient for an appropriate risk assessment, the regulators have the ability to require the consortium or company concerned to provide the required information also within a reasonable and definitive timeframe. If there are indications of unacceptable risks, regulatory action can be taken.

In line with this, Cefic proposes a tiered, risk-based substance tailored information provision regime for those substances submitted to the evaluation phase. The evaluation process will only apply to substances above 100 tonnes and to substances below this level that are prioritised on their properties and uses.

Depending on the results of the toxicological and eco-toxicological information gathered from Registration, further supplementary testing for long term effects may be required and tailored on a case-by-case basis depending on intended use and exposure of the substance. This would provide an efficient route for ensuring an adequate level of protection for man and the environment, whilst allowing a progressive and realistic evaluation of the properties of chemical substances.

2.4 Authorisation

Cefic proposes that authorisation would only apply to those substances which match agreed criteria, and which have been through the registration and evaluation procedure. The use of substances, which are already adequately controlled by other legislation, should be considered as authorised. Furthermore, it is suggested that those substances of “very high concern” that go through authorisation should be limited in scope (e.g. restricted to CMRs of Category 1 and 2, and POPs having the characteristics laid down in the Stockholm Convention on POPs).

If the substance is not already adequately controlled, industry should be required to provide further information within an agreed timeframe. Regulators should be required to respond to this within an agreed timeframe. Unless the substance gives rise to severe concern due to exposure, the enterprise may continue to market the substance in the interim.

Based on the content of the White Paper, any decision on authorisation for specific uses would be based on:

- a risk assessment;
- a full socio-economic analysis;
- the availability and the impact of alternative substances (substitutes); and
- risk reduction measures to minimise exposure to acceptable levels.

Uses which do not give rise to concern or which are already adequately controlled would be exempt from this procedure.

2.5 The Companies and Chemicals

As noted above, 11 companies participated in the pilot trials (note that one company has reported too late for inclusion of their findings in this report but they will be included in the final report). Table 2.1 lists the companies and the chemicals that they used in the trials. In some cases, precise details of the substance and its uses are not given as the information is considered commercially sensitive. Although the details have been provided to RPA, the sensitivity of releasing such detailed information was emphasised by a number of the companies. They stressed the importance of confidentiality in protecting their competitiveness within their existing markets vis-à-vis their competitors.

Tonnage data for several of the substances is also commercially sensitive and thus the relevant figures are not given here for each of the substances listed in the Table. However, it is important to note that each of the tonnage bands as defined in the White Paper is represented:

- five of the substances are produced by the pilot companies in quantities greater than 1000 t/y;
- three are produced in quantities between 100 and 1000 t/y; while
- two are produced in quantities below 100 t/y.

Table 2.1: The Pilot Trial Companies and Characteristic Chemicals		
Companies	Chemical	Uses
Atofina	Bromo isopropane	Intermediate
BASF	Sudan Blau 673	Dye used in mineral oils
Bayer	Fluorescent Brightener	Brightener used in paper and other applications
BP	Ethanol	Intermediate, solvent used in pharmaceuticals, paints, inks, agrochemicals, detergents, food and cleaning sectors; also potentially used as an anti-freezing agent, a cleaning/washing agent and potentially as stabiliser
Cognis	Sulfuric acid, mono-C12-C16 alkyl esters, sodium salts	Used in emulsion polymerisation
Dow	Trichloroethylene	Intermediate, as a solvent for metal degreasing and rubber adhesives used in mining
Lubrizol	A dithiocarbamate ester	Additive in lubricants
Rhodia	2-nitroaniline	Intermediate
Rhodia	bromodifluorobenzene	Intermediate
Rohm and Haas	Primene 81-R (C12-C14 tertiary alkyl amines)	Various (commercially sensitive)
Shell Chemicals Ltd	Hexylene glycol	Intermediate, and used in industrial coatings, lubricant, leather and textile processing, antifreeze, cosmetics, pesticides/biocides and other
Thomas Swan	2,2-dibenzamidodihenyl disulphide	Used in rubber and polymer processing

3. THE PILOT TRIAL

3.1 The Implementation Plan

For the purposes of the pilot trial, the principles and procedures set out in the Thought Starter were transformed into an Implementation Plan by the Steering Group. This Plan then provided the basis for the work that was undertaken by the 11 companies.

The Plan consists of a series of different steps or actions:

- Collection of hazard and tonnage data;
- Supply of classification and labelling data;
- Description of uses (for intended uses);
- Preparation of exposure information;
- Description of existing risk management and preparation of a preliminary risk assessment;
- Updating of safety data sheets;
- Evaluation of the registration dossiers; and
- Authorisation of substances of “very high concern”.

A copy of the relevant phases and the activities undertaken within each of them is provided in Annex 2. The remainder of this Section discusses each step in turn, highlighting the issues that arose and providing our views as a neutral reviewer on the adequacy of what was provided.

3.2 Collection of Hazard and Tonnage Data

3.2.1 Overview of Activities

This first step in implementing the Thought Starter essentially involves the following actions:

- 1) defining the appropriate use categories: industrial, professional and/or consumer (with this then expanded upon as part of the collection of use data – see 3.4.1);
- 2) agreeing tonnage data and appropriate hazard data with co-producers;
- 3) identifying any arguments which support increases or reductions in the hazard datasets;
- 4) sharing hazard data with co-producers and identifying any gaps;
- 5) agreeing mechanisms for cost sharing; and
- 6) entering data into IUCLID.

As a starting point, all of the companies were able to categorise the use of the chemical in terms of whether it best related to industrial, professional or consumer use, or a combination of these. They were also able to provide tonnage data for their own production, with these and hazard data collected routinely for regulatory (including voluntary initiatives), marketing and product management purposes. One company did note though that obtaining tonnage data even within a company can be

difficult as companies can be complex organisations, with several different locations and people involved in the production of a given substance. In addition, where a substance is then contained within a preparation or formulated product, it can become difficult to calculate tonnages accurately. This problem is compounded in the case of imported substances.

Providing accurate data on tonnage was identified as an issue by participants. Although a few of the chemicals may only be produced by those participating in the pilot trials, many of the chemicals are produced by others within the EU and outside it. For those chemicals, where the substance is also being assessed as part of a wider international initiative (such as the ICCA programme), the pilot trial participants were able to provide total production data; including in one case the percentage of global demand by use category. We believe that it is important for some indication of likely levels of production by other manufacturers within and outside the EU to be provided wherever possible as it gives an important context for considering hazard, use and exposure data and thus potential risks (within the context of the Thought Starter). However, registration (and associated testing and other data requirements) only has to take into account the level of production of the company or the consortia that is putting forward the registration.

The incorporation of a pre-registration phase into REACH may help in this regard by enabling companies to identify co-producers or the central entity to generate data on total tonnages.

Many of the companies were not able to provide data on EU or global production volumes. In a few cases, this was because co-producers refused to become involved in the pilot trials while, in other cases, co-producers were not approached for the purposes of the pilot trials for various reasons.

The main issues to arise during this stage are discussed below.

3.2.2 Involvement of Co-Producers

A key component of this first phase of activity concerns the formation of consortia with co-producers of a chemical with the aim of information and cost sharing. Within the REACH process, there are no formal mechanisms that, in essence, ensure that co-producers/importers come together to share information for the Registration process (as under the US HPVC Challenge programme and the ICCA Initiative). Although companies could expect to save costs by participating in a consortium, other factors relating to the commercial sensitivity of production volumes and associated use categories may act as a barrier to information sharing. In addition, where one producer already holds hazard data, they may not wish to share that data with other producers without some compensation for the costs they incurred in generating that data. In at least one case, the inclusion of the tonnage produced by the co-producer would have put the substance into the next tonnage band in terms of testing requirements.

Table 3.1 summarises the experience of the companies participating in these pilot trials in involving co-producers.

Table 3.1: Involvement of Co-Producers			
Company	Co-producers in EU	Co-producers outside of EU	Participation by Co-producers
Atofina	Yes	Not addressed in trial	Co-producers were not willing to participate, as they felt the trials would be too time consuming, but did provide some confirmatory data on uses
BASF	No	No	No known co-producers
Bayer	Yes	No	Contacted co-producer by no response received; did not contact other non-EU co-producers for pilot trial
BP	Yes	n/a	A consortium has been set up for registration of the chemical under the biocidal products regime. Although not contacted for this study, the consortium works together
Cognis	Yes	Yes	Co-producers were contacted but have not responded
Dow	Yes	No	Ad hoc group of producers worked together on dossier and data collection
Lubrizol	No	No	Not relevant as is a new substance
Rhodia: ONA	No	Yes	Co-producers of ONA were not identified for the purposes of the trial but details on production volumes are known. Have written to all Chinese and Indian producers
Rhodia: BDFB	Yes		BDFB was first notified in the UK. Have written to all Chinese and Indian producers
Rohm and Haas	No	Yes	There are no co-producers inside the EU, the chemical is essentially imported into the EU from the US
Shell Chemicals Ltd	Yes	Yes	Existing US consortium was willing to participate, but short time frame did make involvement practicable. Focus was instead on involving the EU co-producer, who was not willing to participate over concern at the scope of the pilot trial
Thomas Swan	Yes	n/a	Co-producer unwilling to participate owing to concerns over competitiveness as there are only two producers within Europe

As can be seen from the table, within these pilot trials there was mixed success in involving, or gaining the interest of, co-producers. In practice, one would expect more co-operation to take place and for consortia to be formed under REACH. In this regard, it is important to note that reasons given for not participating included the fact that this exercise was only a pilot trial and that time and resource pressures made it impractical.

However, the pilot trails have highlighted the difficulties that can arise in trying to finding the right contact person in a co-producing company. The experience of more than one of the companies was that this can be both difficult and time consuming. Again this suggests that some form of pre-registration, in which companies nominate key contact points. These contact points could act not only as a focal point for

communication but are also likely to be critical to facilitating the development of consortia and to the provision of data. The identification of contact points should not be limited to producers and importers, as it would also assist in involving downstream users within the overall process.

Where co-producers do act in co-operation, savings at the individual company level can obviously be realised. This is emphasised by some of the companies' involvement in other chemical risk data sharing exercises. For example, BP and other producers of synthetic ethanol are members of a Cefic sector group (the Ethyl Alcohol Group). In order to notify ethanol under the biocidal products regulation, the sector group contracted consultants to make contact with producers and to agree funding of the work. Although one would not expect such sector or cross industry groups to be formed for all chemicals, it does suggest that further consideration should be given to how companies producing chemicals falling into related 'groups' or for particular end-uses can be brought together for data sharing purposes. However, even where such sector groups readily exist, the agreement of data sharing and funding arrangements can take longer than might be expected. In the case cited above for the notification of ethanol as a biocide, the process took around 6 months.

3.2.3 Physico-Chemical and Hazard Data and Data Gaps

The core set of hazard data required under the approach set out in the Cefic Thought Starter varies from the data requirements as indicated in the White Paper. Many of the pilot trial companies perceive the White Paper as adopting a 'tick box' approach to the need for hazard data and are concerned that such an approach will result in unnecessary animal and other tests. Cefic argues that testing should be clearly tailored to the substance, the quantities used and exposure routes. Where a particular test would not add value in terms of managing human health or environmental risks, companies should be able to justify not providing that test (in other words, the requirements for the test being waived).

For some of the substances, companies held more than the minimum data set as required under the Thought Starter. Data had been collected for other purposes, such as internal initiatives to upgrade the quality of health and safety data held on products, or for voluntary and other programmes such as the ICCA initiative and assessments under the Existing Substances Regulation (ESR).

In the majority of cases, the data on physico-chemical properties and hazards were provided in accord with the Thought Starter, with only a few data missing, which were either not applicable for the form of the substance or the company indicated that further testing would be required to meet the requirements of the Thought Starter. However, in four cases (of the eleven), the data *provided* on physico-chemical properties, toxicity and ecotoxicity was significantly below that required and thus did not result in a suitable basis for a risk assessment of the substance. In some cases, this data may have been available to the company but was not reported for the purposes of the trial.

One company noted that data problems could arise due to the fact that existing data did not fit into the standardised form as required by IUCLID - 'a problem of round

pegs not fitting into square holes'. In a few cases, the submitting company indicated that there would have been greater gaps in the data had there been a requirement for all physico-chemical, toxicological and ecotoxicological data to have been provided through methods based on Good Laboratory Practice (owing to the fact that much of this data was produced prior to GLP for many existing substances).

Gaps in environmental fate and pathway data, toxicity data and ecotoxicity data also existed in a number of the submissions. In some cases, no reasons were given as to why these gaps were justifiable, while in other cases good justification was provided.

In general, companies indicated that they would want to resist proposals for animal testing and would seek to discuss any such requirements with Competent Authorities. Aside from these concerns, the arguments for not providing data that we believe were the weakest were those where it was stated that controls were in place that would limit exposure to safe levels, thus negating the need for the relevant tests. When such arguments were backed up with a clear description of what the controls were and how this affected exposure, the arguments were generally considered to be appropriate. However, such supporting details were not always provided. For example, it was argued that worker safety related controls (sometimes not specified in detail) would limit exposure. Although this may be the case with regard to workers, the ability of such controls to also limit environmental emissions and consumer exposure was not necessarily made clear or adequately addressed. If the existence of controls is to be used as a reason for not undertaking specific tests, then sufficient information needs to be provided to demonstrate that such controls address all potential exposure pathways. Existing legislation should not provide the main justification for not undertaking specific tests, but should instead be viewed as one part of a set of wider arguments demonstrating that further testing is not necessary.

For one of the chemicals, an interesting difference arose between the submitting company's conclusion with regard to the ecotoxicity of the substance under consideration and that indicated on a co-producer's safety data sheet (SDS) (although the co-producer did not cooperate in the trial). The submitting company classified the substance as very toxic for aquatic organisms with possible long-term effects (R50/53), while the co-producer's SDS indicates a classification of only R53 (as it does not take account of the invertebrate toxicity test provided by the submitting company). This highlights the importance of companies working together and sharing data, to ensure both that risks are properly managed and that, during the Evaluation stage, Competent Authorities do not question data provided in registration dossiers. In this regard, it is interesting to note that if the quantities produced by the co-producer were taken into account in Evaluation, they might raise the total tonnage produced above the HPV threshold (although this cannot be verified with data from the co-producer). The introduction of a pre-registration stage should help in identifying such cases, enabling co-producers to be working to a common volume. Again though, it must be remembered that the White Paper indicates that the thresholds for data requirements relate to the tonnage covered by a single registration.

In other cases, the need to undertake further testing in order to fill gaps was identified by the pilot company in its registration dossier, while in other cases it was accepted

that it was likely to be necessary following discussions with RPA (acting as the “in loco” competent authority).

3.2.4 Substance versus Preparation

For one of the chemicals, data were not always available for the substance itself but only for the preparation in which it is isolated and sold. As a result the data relate to either the substance or the preparation. This use of combined data raises a question as to whether the package of data is sufficiently specific to the substance of concern. For example, data are provided for most of the required physico-chemical parameters but many of these relate to the solvent component (which makes up ca. 40% of the preparation), rather than the preparation or the substance itself. It is argued that this is appropriate as the ‘substance is only isolated in a solvent’ and that use of these data will result in an overestimation of the risk as the risks associated with the solvent will be greater than the substance. Furthermore, it is stated that, in practice, it is not possible to handle the substance without the solvent (it is a very viscous liquid). It is further argued that, in such cases, where a substance is never manufactured or used in its pure form, that it may be more appropriate if the data relate to the substance as marketed.

Such arguments may not be accepted however by a Competent Authority. Instead, it may be counter argued that those data that appear to relate to the solvent and not to the substance may not provide sufficiently specific information on the substance.

3.2.5 UVCB Substances

Some of the substances that were examined are UVCB substances (UVCB stands for substances of unknown or variable composition, complex reaction products or biological materials), here having ranges of C-chains. Such substances, even if they are composed of several components, are regarded as single substances by definition. In such cases, the ability to use QSAR and analogy approaches could be important. The use of these approaches could reduce the need for new testing by enabling data already available on other substances in between or near to the C-chain ratio to be used instead. In addition, it may not be possible to carry out some forms of testing (such as partition coefficients and vapour pressure) on UVCB substances; with such tests only applicable to single components.

Thus, where appropriate, grouping these closely related substances could be of significant value in reducing the testing requirements placed on industry.

3.2.6 Use Category Assumptions

For two of the substances, the use category which should be assumed for the purposes of preparing the registration dossier was not clear cut. Because the substances are used industrially, it was assumed by the submitting companies that the core information set, as detailed in the implementation plan, was required. However, in both cases, the use pattern could also possibly be included under the ‘professional’ use category and for one of the substances possibly even ‘consumer’ use, since the

substance is blended in additive packages and is also present in products purchased by consumers¹.

In the above cases, if consumer use were to be assumed, further tests (sensitisation test and genetic toxicity (Ames) test) would be required. In one of the cases, the company recognised that these tests would be required at the higher production tonnages, along with other tests, assuming just professional use. It had not, however considered other steps down the supply chain. One strategy that was suggested for dealing with such situations in terms of identifying data requirements is for data requirements to be defined in terms of the most stringent actual use category (industrial, professional, consumer). If the Thought Starter dataset for the tonnage supplied for the consumer use is more comprehensive than the dataset for the tonnage supplied for industrial use, then the more comprehensive consumer use dataset should apply.

The question of what is the appropriate use category is obviously important to the assumptions that are made concerning possible exposure. While use and exposure can be readily communicated on the first step down the supply chain, it clearly becomes increasingly difficult as one moves further down the supply chain. It may become particularly difficult where there are several different downstream professional users, making identification of the final use of a product containing the substance problematic.

3.2.7 Availability of Additional Data

In most cases, the companies had some additional test data to that required by the Thought Starter (see Annex 1). These data, which are summarised in Table 3.2, may have been generated for internal responsible care related purposes, or may have been produced in response to further data needs under voluntary initiatives such as the ICCA HPV programme.

It is of interest to note that where companies followed the approach set out in the Implementation Plan, the need for further test data was highlighted through the preliminary risk assessments and by following decision trees on substance tailored testing. This issue is addressed further in Sections 3.5 and 3.6.

1 The Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances (European Commission, 1996) indicates that a consumer product is “a product which can be purchased from retail outlets by members of the general public and may be ... an article containing the substance”.

Table 3.2: Availability of Further Test Data (in addition to that required by the Thought Starter)			
Company	Availability of Further Test Data	Reason for Data	Consistency with Thought Starter and Substance Tailored Testing Approach
Atofina	Additional tests were conducted because of the chemical structure of the substance	From structure, long term effects were expected	Not known
BASF	Second genotoxicity test and summary paper on tests and conclusions for coloured fuels	Concern over the use of Ames test results	Main issue relates to use of data for both substance and for solvent in which it is used
Bayer	Chronic ecotoxicity studies and toxicity to soil dwelling organisms	ICCA initiative and own studies	Use of decision trees for substance tailored testing suggest need for further tests for some exposure scenarios
BP	Vast dataset available, but very little in form of standard OECD test protocols	Research on the health effects of drinking alcoholic beverages	If an absolute hazard based approach is taken (using data based on alcohol abuse and ignoring dose levels and 'normal handling and use' considerations) the conclusion would be that the substance fits the definition of a Cat 1 carcinogen and Cat 1 reprotoxic substance. Thus need for unnecessary further testing would probably be identified and would trigger authorisation requirements
Cognis	Additional ecotoxicity and toxicological data	Internal purposes	Lack of downstream user information makes reaching a conclusion difficult
Dow	Further ecotoxicity and toxicological data available	Level of use over a long period of time and its regulation	Has also been assessed under the Existing Substances Regulation
Lubrizol	All data necessary for Base Set new chemical notification	No replies received	By following the Thought Starter additional data requirements were identified
Rhodia: ONA	None	Data being produced for classification purposes with relation to transportation	No further tests recommended under Thought Starter
Rhodia: BDFB	Are currently undertaking some further testing based on acute toxicology data of Annex VIIB	Data being produced for classification purposes with relation to transportation	No further tests recommended under Thought Starter
Rohm and Haas	None	None	By following the Thought Starter additional tests were identified
Shell Chemicals Ltd	90 day repeat dose and developmental toxicity studies	Data produced for existing regulatory requirements	No further tests identified in line with outcome of ICCA and SIAM
Thomas Swan	Additional ecotoxicity data available	Data produced for internal purposes as part of Responsible Care	Thought Starter highlighted need for more detailed risk assessment and probably further test data

3.2.8 IUCLID Data Sets

For most of the companies, no problems arose in putting data into the IUCLID data set, although many found it awkward to work with in terms of entering data and saving files in a format which would allow them to be submitted electronically. It should be noted though, that those individuals amongst the participating companies who were not typically involved in using IUCLID felt that it was designed for experts.

A few companies faced administrative problems in submitting IUCLID data sets for the purposes of these pilot trials (in at least one case, owing to the fact that several versions have been brought out since data for the substance were first entered), but most of these arose owing to the circumstances of the pilot trial. Where IUCLID data sets were not provided, the submitting companies provided 'robust summaries' of hazard data instead.

Companies did emphasise the need for IUCLID to be made more user friendly. In particular, it was felt that smaller companies with less expert resources to call upon may face great difficulty in entering the appropriate data. As a minimum, it was suggested that a proper context sensitive help system needs to be developed, with much more extensive user friendly error trapping so that it is apparent what the problem is when inputting error messages arise. More options as to the nature of the training courses (more extensive, short courses, etc.) were identified as being essential.

3.3 Supply Classification and Labelling Data

3.3.1 Overview of Activities

The sole activity required in this step is the development of classification and labelling proposals. Classification and labelling data were provided by most companies. The information appeared appropriate, setting out the risk phrases that should pertain to the substances according to Directive 67/548.

Other issues were raised by participants, however, which highlight the types of issues that could arise in the future. These are summarised below.

3.3.2 Data Provided

Queries arose initially over the classification and labelling data submitted for the UVBC substance. Discussions clarified the data being used and why. In the classification and labelling of such substances, it is common practice to take data based on test results for the substance in preference to data over information on single components.

For another of the substances, two different tests had been undertaken on genotoxicity with these tests giving different results (Ames test positive, in-vitro cytogenetic test negative). Although both sets of data are included in the safety data sheet, they are

not both used for classification and labelling purposes (with the Ames test results considered more reliable being used even though there being no legal requirement for in-vitro tests for classification and labelling).

In another case, the data used in the original notification (indicating sensitisation) of the chemical did not agree with more recent test results (which were negative for sensitisation). Discussions with the Competent Authority were required to agree the resultant classification.

3.4 Use Data

3.4.1 Overview of Activities

The third set of activities relates to the need to provide more detail on how a chemical is used. In this stage, the implementation plan requires that uses are further defined (i.e. in greater detail than simply through categorisation into the three general use categories defined for the purposes of establishing what sets of core hazard data are required using the tables presented in Annex 1). The Implementation Plan to the Thought Starter suggests that uses should be defined in more detail (for example, in relation to the 55 categories set out in the Technical Guidance Document on Risk Assessment (TGD – see first footnote) or using some other categorisation basis). For each of these more specific types of use, brief technical descriptions are to be provided and, if significant downstream exposures might occur, then downstream users should be involved in describing the circumstances of such exposures.

3.4.2 Success in Involving Downstream Users

In practice, the companies adopted flexible approaches to collecting use data, with the need for pragmatism being stressed.

As might have been expected going into the pilot trial, the involvement of downstream users and the short timeframe for completion of the trials became a key issue in undertaking this stage of the work. For many chemicals, the ability to obtain reliable use and exposure data from downstream users will be central to producers/importers ensuring that the preliminary risk assessment is as realistic as possible.

In the absence of actual data, the use of the generic exposure scenarios, such as those set out in the risk assessment TGD (for example, by using the EUSES model), could lead to the need to undertake additional testing and risk assessment work, lengthening the time to registration. This could potentially be avoided should more detailed data on the conditions of use, worker exposure and environmental emissions data be available from downstream users. In addition, if downstream users fail to provide information on their uses of a substance, then those uses may not be registered by the producer/importer, making it necessary for the downstream user to undertake the registration for the use to remain in compliance with the REACH system.

The question thus becomes one of how best to encourage downstream users to provide an input into the registration process. What mechanisms would be most appropriate for involving downstream users in a cost-effective manner?

In trying to address this question, two of the companies prepared questionnaires aimed at eliciting use and exposure information from downstream users. The questionnaires varied in their approach, with one attempting to generate a fairly high level indication of uses and likely exposure and the other attempting to gain much more detailed data (see also Annex 3). In our view, the second questionnaire may be more likely to generate the types of information required for the preparation of quantitative preliminary risk assessments.

Because it will be easier to answer the questions set out in the more general questionnaire, however, downstream users may be more likely to respond to it (although no conclusions can be drawn as to whether this would be the case in practice from this pilot trial).

These questionnaires were distributed amongst the participating companies and subsequently used by several. Table 3.3 summarises the companies' experience with trying to involve downstream users (i.e. their customers).

For most of the substances, little detailed information was provided by downstream users on how the substance was used and on likely environmental and human exposures. In some cases, this did not pose significant difficulties to the submitting company as they had sufficient knowledge of how the chemical was used to develop reliable exposure scenarios for the uses of concern. In a few cases, however, the lack of data from downstream users caused real difficulties to the submitting company in preparing the preliminary risk assessment and completing the registration dossier.

This in turn raises questions over how companies would respond in practice under such circumstances, with there being considerable debate on this issue in one of the project meetings which was attended by most of the participating companies. The two basic responses to this situation were:

- the submitting company would register uses known and expected by them using generic exposure scenarios; or
- the submitting company would register only those uses for which adequate information was provided by their customers, with all other uses then becoming 'unintended' uses which would have to be registered by downstream users.

The first response raises concerns that, by relying on generic information, the company may incur additional testing and other costs in providing adequate hazard and risk assessment information to demonstrate that no unacceptable risks will arise through likely uses of the chemical. If the market is large enough for the chemical, this may be financially viable; but for many substances, it may not be a financially viable response.

Table 3.3: Involvement of Downstream Users			
Company	Method of Informing Downstream Users of Trial	Willingness of Downstream Users to Participate	Additional Comments
Atofina	By e-mail and by phone	3 major European users participated (representing 90% of sales)	Can foresee significant problems in gaining exposure data for all intended uses
BASF	Not informed	N/a	Customers not informed as use is very special and well defined so exposure is well understood
Bayer	By e-mail using high level questionnaire	1 out of 3 approached responded	Response was qualitative but useful. Those not responding passed request on but did not answer within pilot trial time scale
BP	Contacts through various routes using detailed questionnaire	Problems in getting main users to respond, but some responses received late in pilot trial	Experience more generally suggests that major users are likely to respond but that more difficulty arises in getting those less familiar with the regulatory regime to participate, although some will ultimately participate
Cognis	Directly and by e-mail	4 out 8 responded with some information	Information provided was not sufficient to identify areas of potentially significant exposures with no volumes, or other data provided
Dow	Directly, including meetings	Meeting held and further information provided by some of the key users	Experience was very good in terms of gaining additional information on quantities for different uses
Lubrizol	Letters sent out to users	No replies received	
Rhodia: ONA	Direct discussions and contact by telephone	No participation	One user of ONA is located outside the EU and was not interested in participating. Question over the exact use of this intermediate by non-EU users in this regard (use in metal cutting fluids raised at SIAM)
Rhodia: BDFB	Direct discussions and contact by telephone	No participation	User of BDFB in the short term as an intermediate for agrochemicals is outside EU
Rohm and Haas	Contact by telephone and e-mail	5 out of 6 customers approached participated	Background information on the pilot trial was sent by e-mail
Shell Chemicals Ltd	By e-mail	1 out of 6 contacted customers responded	Customers/distributors were sent a letter and questionnaire. Not clear why other 5 did not respond
Thomas Swan	Initial contact by post, with follow up by phone and fax	36 questionnaires despatched, with no replies received	Although no-one refused to participate, no responses were provided within the pilot time scale

The second response could obviously reduce the submitting company's market for a substance, depending on compliance with REACH by downstream users with regard to 'unintended' uses. This problem could be compounded where a substance is used in a range of formulations which have various different end-uses across a number of industry sectors. In these circumstances, the onus will be placed on downstream users to register specific uses of chemicals, including the preparation of preliminary risk assessments for those uses. This may require considerable skill development amongst such users as they may be unfamiliar with what is required and may lack the relevant expertise. It could also be argued that in some cases they may even have difficulty in contacting the appropriate outside expertise owing to this unfamiliarity.

However, it should be noted that downstream users did assist with some of the trials. This included providing detailed use information and their safety data sheets for products containing the pilot substance (which proved very helpful to the pilot company). One company had a particularly positive experience. In this case, the German VCI called together an ad hoc group which included other producers, users and their associations. In this case, the lack of alternatives, amount of information already available, together with the level of existing regulation is viewed as key drivers to users joining actively in the exercise. The result of this has been downstream users contributing by providing further details on use, and measured and estimated emissions data.

Concern was expressed by some of those downstream users who participated in the trials, however, as to the public availability of the data (highlighting the potential commercial sensitivity of detailed use data).

Finally, it is interesting to note that for some of the pilot chemicals, users are located outside the EU. It may, therefore, be particularly difficult to gather the necessary use and exposure data in such cases. This raised questions over the way such uses might be treated in REACH. Where non-EU users fail to "participate" by identifying intended uses, will EU producers will lose these markets? Or, will this production volume be categorised as exports, with the nature of uses not considered further?

3.4.3 The Data Provided

The problems in gaining information from downstream users obviously affected the quality of the information included within the registration dossiers, and thus available for use in a preliminary risk assessment. Unfortunately, the ability to adopt other approaches to data collection and to chase downstream users was constrained in this pilot trial by the need to complete the dossiers within three months.

Within this context, the two main issues to arise from the information provided are:

- a failure to provide enough data for the reviewer to understand how a substance is used throughout the product life (i.e. data that constitutes an adequate 'technical description' of use). This included, in our view, defining uses at too general a level to allow an adequate assessment of exposure scenarios and preparation of a detailed enough preliminary risk assessment (see also Section 3.6 below); and

- a failure to provide data on the quantity of the substance accounted for by each of the intended uses of the substance. Such data is not only important for the preliminary risk assessment, but is also likely to be critical to Competent Authorities understanding the significance of potential unintended uses.

With regard to the first of these issues, some companies did not agree with our view that their dossier failed to provide sufficient detail. They argued instead that the approach to providing detail should be one based on proportionality and plausibility (with regard to hazard and exposure). For chemicals with numerous different uses, providing “technical descriptions of use” for every application would require an enormous amount of effort. Instead, the aim should be to keep the information package as concise and focused as possible.

With regard to the second of the two issues, the collection of data on the tonnage sold to different uses posed a problem for more than one company. Such data may not be readily available, requiring companies to collate it from customers and internal sources. For other programmes (such as the ICCA programme), the companies have made their own estimates and used information from country specific product registers. It is noted though that even with the co-operation of downstream users it is often difficult to identify how the last 5% to 10% of the tonnage is used for high production volume chemicals.

Besides the issue of information from downstream users, two of the companies indicated that some of the uses of the pilot substances were not included in the 55 categories defined in the TGD, highlighting the need for flexibility as to how use categories are defined. They had to define their uses more specifically in order to complete the preliminary risk assessment (as the uses were not conducive to the application of the generic scenarios defined in the TGD). Other companies noted that even where the standard use categories may be more or less appropriate, there may be some ambiguity in the function provided by a substance, with more than one being relevant.

On a further note, one of the companies noted the importance of being able to undertake Process Oriented Research and Development without having to notify this, in order to develop its use for other applications.

3.5 Preparation of Exposure Information

3.5.1 Overview of Activities

The degree to which downstream users provided information and the extent to which the various uses were defined in detail impacted on the level of exposure information provided in the dossiers. Under the Cefic Thought Starter, registration dossiers are required to provide the following information:

- for each category of intended use, descriptions of the nature of the principle exposures which occur – human and environment – throughout the life cycle;

- any intended exposures that may be potentially of significance should be defined together with the provision of exposure measurements or modelling data; and
- available exposure information should be entered into IUCLID.

3.5.2 Data Provided

In practice, two distinct approaches can be identified from the data submitted for the pilot trial:

- 1) detailed exposure scenarios are provided, including how the chemical is handled, processing methods, and monitoring and/or other data on Occupational Exposure Limits (OELs) and actual releases to the environment. This also includes details of the *specific* controls in place to reduce exposure; and
- 2) general information is provided, but not at a level of detail that provides sufficient information to understand how exposure is controlled.

Although the first approach obviously requires more effort than the second (and requires a greater level of information from downstream users), it fulfils the intentions of the Thought Starter. It provides a clearer basis for understanding and agreeing the preliminary risk assessment and relevant risk management activities (existing and proposed). Where this approach was adopted, few issues arose in reviewing the exposure assessment components of the dossiers and fewer questions also arose in assessing the preliminary risk assessments.

Again, however, the need for the approach taken to be proportional to the associated risks was called for by the pilot companies. Further, criteria for guiding companies on the level of detail required for different types of intended use, intended exposure and associated risk management combinations were requested.

One of the substances is categorised as being used in industrial coatings, however an examination of the Swedish Products Register indicated (probably incorrectly²) that 13 of the 232 industrial coatings products on the Register are categorised as being consumer products. Whilst the substance is of relatively low hazard, experience under the Existing Substances Regulation would tend to indicate that the consumer product uses would need to be characterised in detail if they are to be registered as intended uses (or if downstream users were to register such a use as an “unintended use”).

2 Pilot trial companies noted that such entries can occur as they know of no mechanisms for removing ‘dead’ products from these registers. If such registers are to be relied on to a greater in the future, then there should be some way for manufacturers to access them without compromising confidentiality so that their validity can be checked.

More specific points are:

- in some of the submissions, all potential exposure routes are identified and reasons are given as to why specific routes are not likely to be significant. In our view, this approach is the most satisfactory;
- in other cases, reasons were given but not enough information was included to provide the reader with an adequate understanding of why exposure would be negligible; or data were given for some exposure scenarios but not others without adequate discussion of why (although in a number of cases this was likely to be due to a lack of information from downstream users and/or time and resource constraints within the timeframe of the pilot trials); and
- in a few cases, potentially significant exposure routes throughout the supply chain were not addressed (although most others were), in particular with regard to post formulation stages or end-use by consumers.

In general, the companies held some exposure data, with this often having been developed owing to Responsible Care audits and through existing relationships with customers (although such information may not cover all users and uses related to sales of the substance by co-producers).

As noted above, some of the reasons for life cycle exposure data not being provided within the submissions stem from the poor response by downstream users to the request for information. Indeed, one of the pilot trial companies commented that the exercise highlighted the need to establish more contacts with individual customers in order to be able to assess all of the handling and environmental scenarios required to develop accurate human and environmental exposure information. This will be particularly important for higher volume chemicals given that the product could be used at multiple locations which may rely on varying processes.

However, even where downstream users do participate, there may still be gaps in the documented data that are readily available; for example, such gaps existed in worker handling scenarios, environmental releases and residuals in end-products. Often this is because gathering such data is not regarded as a priority.

A question raised by one of the participants in this regard concerns the ability to provide good data for major uses but not minor uses. What percentage of the tonnage produced needs to be accounted for in detailed knowledge of the end use? Furthermore, if data gaps exist, to what degree can modelling information based on health and safety and environmental regulations (together with literature) be used to fill these gaps?

3.6 Existing Risk Management and Preliminary Risk Assessment

3.6.1 Overview of Activities

A series of actions are set out in the Implementation Plan for the Thought Starter, with regard to establishing the nature of existing risk management actions and preparing the preliminary risk assessment. These include that:

- all existing legislative controls should be identified for the principal routes of exposure associated with intended uses;
- the measures used to achieve compliance with these controls should be described, seeking input from downstream organisations as necessary;
- the nature of the entity complying with the controls should be described, (e.g. professionally qualified, skilled and experienced, unskilled, consumer);
- the exposure routes where risk is not explicitly controlled by existing legislation or where there is only low confidence in measures or ability of the entities to comply with the existing controls should be identified;
- further cost-effective control measures should be suggested (and agreed with downstream organisations as appropriate);
- if chemicals are toxic/very toxic determine if there is a widespread exposure of concern to consumers or the environment;
- if there are widespread exposures of concern, provide a quantitative measure (PEC/PNEC ratio, etc.) to indicate the risk; and
- enter the above information into the IUCLID.

Although in evaluating dossiers, conformity with the above actions formed the basis for our assessment, the Steering Group has since noted that this is one of the areas where Cefic's thinking has developed further (with the Implementation Plan only acting as a preliminary basis for applying the Thought Starter). In particular, the reliance on legislative controls is seen as too constraining, given the importance of the various types of voluntary and non-regulatory measures that are taken by companies to reduce and manage risks to health and the environment.

3.6.2 Risk Management Data

In relation to the implementation plan, some of the registration dossiers failed to provide the information required, for example:

- relevant existing measures (whether regulatory or non-regulatory) were not identified;
- the actions used to achieve compliance with existing risk management measures, or the entity complying with the measures, were not specified with this being particularly important where it was unclear whether the measure was based in legislation or not; and
- exposure routes that are not explicitly controlled by existing legislation were not identified, nor were the areas where there is low confidence in compliance with existing controls highlighted (as this would provide a basis for indicating further cost-effective control measures that could be implemented).

The failure to provide such information will in part be as a result of the limited time within the trial for submission of registration dossiers. It will also be due to the lack of co-operation from downstream users. We believe that, in general, this indicates the need for manufacturers/importers to initiate the collection of such data from their customers (or relevant trade associations) as part of collecting information on use and exposure patterns.

One of the participating companies suggested the need for the Thought Starter to be more specific in terms of the monitoring and other downstream data related to risk management required to ensure that the preliminary risk assessments provide reliable results. In this regard, the company recommended that regular industrial hygiene monitoring of a typical downstream users should be suggested as this would help validate assumptions. However, some of the other participants felt that this was unrealistic.

Another company suggested that SDSs could be given an increased legal status as an integral part of the Registration dossier. Statements on intended uses and controls would change from recommendations to compulsory measures. Downstream users who could not comply with the given measures would then have to prepare their own risk assessment given that their use would become an “unintended” use. Again, however, this was not universally supported.

3.6.3 Approach to Preliminary Risk Assessment

In line with the approach set out in the implementation plan, not all of the companies prepared preliminary risk assessments that provided PEC/PNEC ratios (predicted environmental concentrations to predicted no effects concentrations), with some adopting a more qualitative approach. In some cases, in reviewing the submissions, we did not always find the more qualitative assessments to be convincing. In our view, some of the more qualitative assessments provided insufficient information to give us confidence in the conclusions drawn. There is an obvious issue of proportionality in terms of what is required in the preliminary risk assessment.

A more general problem, however, may arise where there are multiple producers not acting as a consortium. In such cases, a single manufacturer preparing an environmental risk assessment would need to know not only the intended uses but also the volumes at the regional and continental level in order to calculate PEC/PNEC ratios in accordance with current risk assessment guidelines (i.e. the TGD).

In several cases, the participating companies identified the fact that they needed to go beyond a qualitative assessment and provided quantitative assessments for key end-points. In one case, a quantitative measure of risk was provided using default assumptions and a possible risk was identified. These findings then provided the basis for identifying the further testing required to refine the assumptions used in the risk assessment, in particular the most appropriate safety factor.

Instead of using a TGD-based approach to the calculation of PEC/PNEC ratios, two of the companies applied the ECETOC approach that is currently under development. These assessments provide a useful example of how this method could help to justify

that no further testing information is required (although in this case the only intended use is as an intermediate).

3.7 Safety Data Sheets

This step within the implementation plan involves preparing SDS based on the information produced during the previous steps. Where there are co-producers, the SDS would be exchanged in order to identify any significant differences arising. Such differences would then need to be resolved: experience indicates that such agreement can take time to reach especially where producers outside the EU are involved.

Most companies provided safety data sheets as required, and where they were not provided, this was due more to time constraints than any other considerations. The only issues raised in relation to safety data sheets are those discussed above under classification and labelling (i.e. inconsistencies between co-producers - see Section 3.3).

3.8 Evaluation of the Registration Dossiers

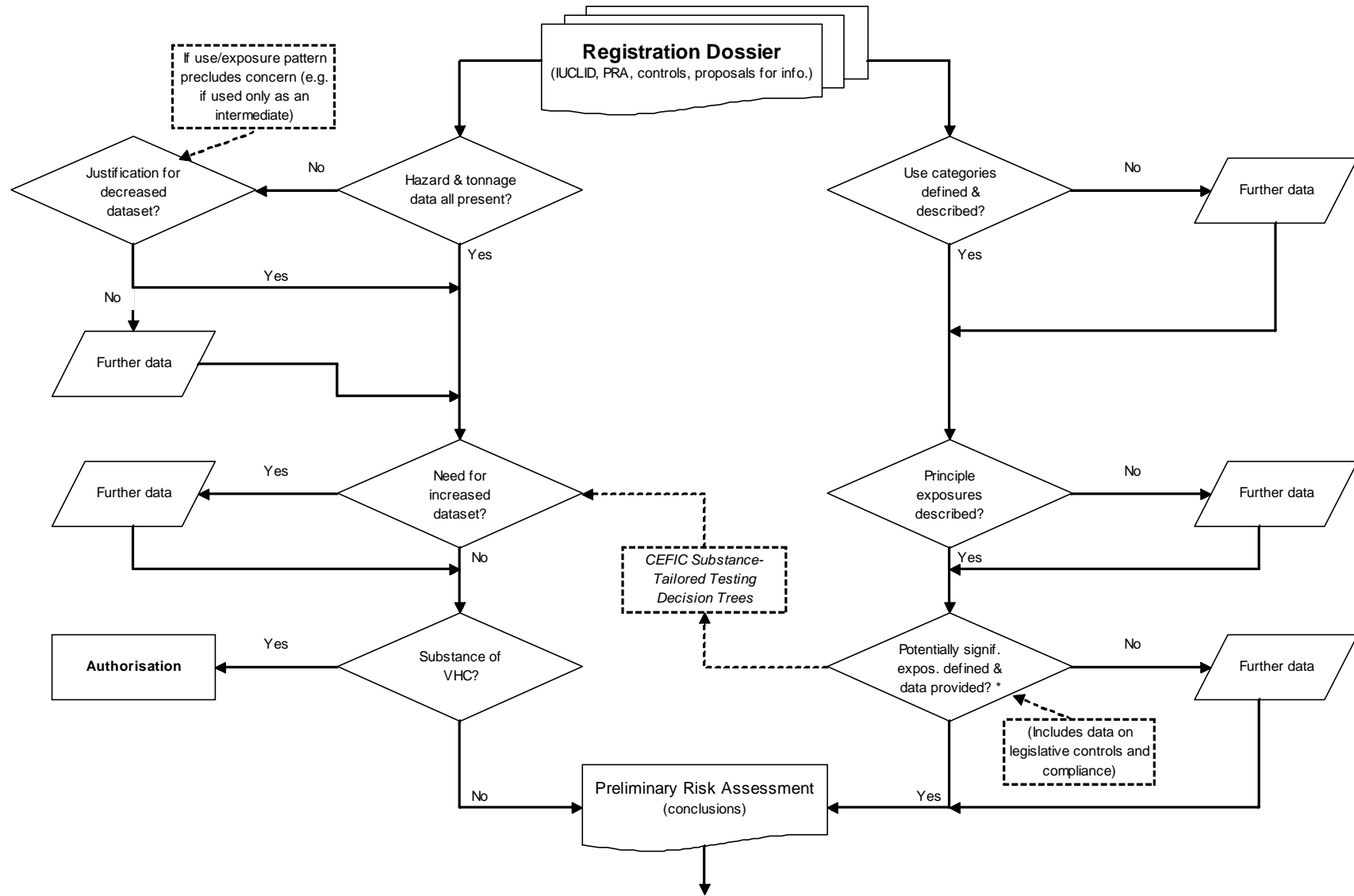
3.8.1 Overview

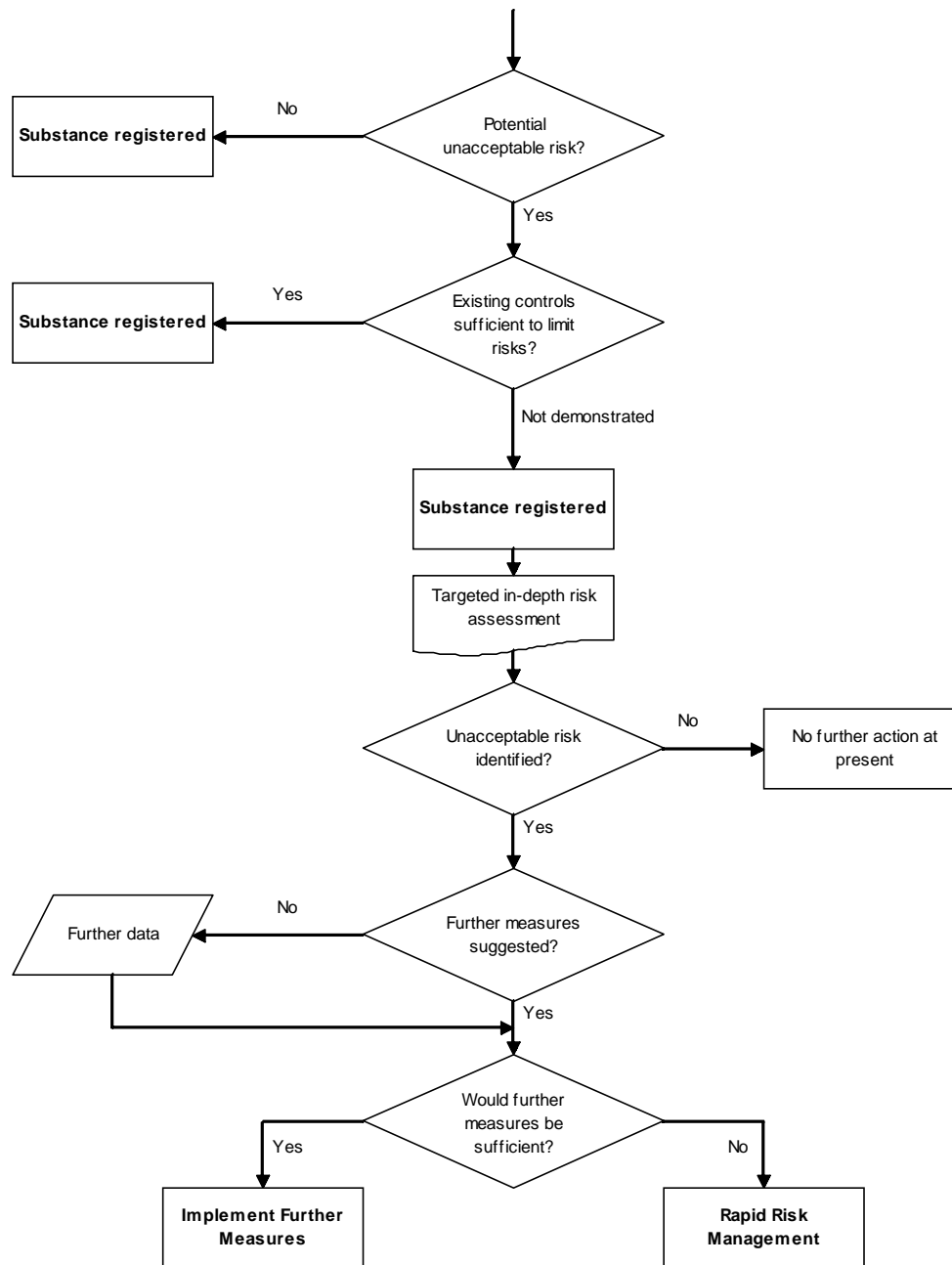
Under REACH, the evaluation of the registration dossiers will be undertaken for those substances being registered in quantities greater than 100 t/y. Based on these proposals, not all of the substances considered in this trial would go through a formal evaluation process.

At the start of the pilot trials, it had been hoped that one or more of the Competent Authorities representing the main countries of the participating companies would also participate. Unfortunately, none of these authorities felt able to participate, owing to concerns over their ability to remain independent and to resource the work. Three dossiers have been sent to the ECB for Evaluation, and the ECB is discussing its views with the companies concerned.

The result has been that, for the purposes of this report, RPA has examined the registration dossiers and responded to the participating companies as to their adequacy with regard to the Thought Starter. This work has essentially involved:

- comparing the dossier submissions to the requirements as set out in the implementation plan (i.e. are the data as required by the plan);
- considering the likely adequacy of the submissions in terms of the degree to which they ensure that potential risks are managed to the degree that no unacceptable risks arise.





3.8.2 Main Issues Identified in Responding to Submissions

In checking the adequacy of the dossiers against the implementation plan and the overall level of information provided, the approach set out in the decision tree given in Figure 3.1 was followed. Standard forms were also prepared for recording what data were submitted (with an example form given in Annex 3). Participants were provided with feedback on their submissions, including our views on the adequacy of the information.

Many of the key issues that were identified through the checking process have been discussed above, as they relate to the provision of information under each of the steps of the implementation plan:

- the need to confirm information on potential uses that may have a significant effect on any substance tailored testing regime; this included identifying whether (in practice) the company would support this use;
- the need to develop/improve the decision trees provided to RPA to aid in decision making on substance tailored testing strategies. In at least one case, this would have suggested that further testing was required given the calculated PEC/PNEC ratios;
- the importance of more complete data from downstream users, as this introduced considerable uncertainty into the information on exposures provided as part of the dossiers; from a manufacturer/importer perspective, further information from downstream users could negate the need for additional testing;
- in addition, better data on the control measures (regulatory and non-regulatory) currently in place and their relative performance (particularly where non-regulatory) could also reduce requirements for testing and more detailed risk assessments; and
- in terms of further testing requirements, the likely need for more information on the basis of: (i) the estimated relative exposure for the exposure routes that were characterised; and (ii) the hazard data presented and the risks identified for those exposure routes that were characterised. This included identifying (and/or discussing with the pilot company) the most appropriate additional tests given the substances properties, exposure routes and tonnages produced.

RPA was not contracted to undertake any search of the scientific literature with the aim of identifying hazard data not considered by the companies, or indeed what may be available in addition to that required under the Thought Starter. Instead the aim was to determine whether or not the Thought Starter and the information that would be provided under it, appears to provide an appropriate basis for implementing REACH in practice.

3.9 Authorisation

3.9.1 Overview of Activities

Two of the chemicals examined in the pilot trials would be classified as a ‘substance of very high concern’ (SVHC) owing to their being a Category 1 or Category 2 CMR (reprotoxic). The Cefic Thought Starter assumes that all SVHCs will go through registration and evaluation prior to their going through authorisation. Thus, the work required under the implementation plan essentially involves expanding upon the level of detail provided in earlier phases, with key activities being:

- determining whether the chemical meets the criteria as being a SVHC;
- identifying those uses with exposure routes that are not explicitly controlled by existing legislation and where there is only a low confidence in the measures or ability of the organisations to comply with existing controls;
- demonstrating that exposure of people or the environment is negligible throughout the lifecycle through technical descriptions that clearly show that significant exposures cannot occur; and
- where negligible exposures cannot be robustly demonstrated, identify the social and economic consequences of banning use.

3.9.2 Data Provided

In line with the above, one pilot company provided an indication of the types of detailed data that were available to demonstrate that exposure is negligible. The substance is currently subject to regulation and restrictions on use. It is used as an intermediate at a limited number of sites. Data show that it is used in well controlled closed systems with no regular exposure, with measures also being in place to reduce workplace exposure (through occupational limit values) and emissions to air and water; wastes are treated. However, reliable data are only available for the production site, and the pilot company recognised that further data were required to demonstrate that use of the substance is clearly controlled at user installations.

A second company also provided exposure assessments for the three uses for which authorisation would be sought. In this case, however, authorisation would be sought for more than just use as an intermediate, including two professional uses; one of these would take place in semi-open systems. Although an indication was provided of how exposure from the professional uses would be controlled under German legislation, no information was provided on controls in other EU countries.

In neither of the two submissions, was a socio-economic justification for further use provided. Instead, justification was based on the fact that the substances were already strictly regulated. We believe that in the case where uses include semi-open processes, such a justification is unlikely to be sufficient. A socio-economic assessment, setting out why the substance is used in preference to any alternatives should be prepared. This should address cost, technical performance, processing and comparative risk issues.

4. RESOURCE REQUIREMENTS

4.1 Introduction

As part of the trial, participating companies were asked to keep detailed records of the staff time and other resources required to complete the REACH process in line with the Cefic Thought Starter. In many cases, this involved the companies making estimates. The short time-scale of the trial meant that companies drew on information already collected for other purposes, such as the ICCA HPV programme and other initiatives. Although companies attempted to estimate the effort that would have been required to gather only the information required for the Thought Starter, it was not always possible to do this with any degree of accuracy.

In estimating the costs associated with the pilot trial, a standard cost of €1,000 per person-day of time input has been assumed. Actual costs will, of course, vary in line with the seniority of the person involved and from company to company. Time input estimates are given, as well as costs, as this may be important in terms of the availability of staff to carry out the REACH process. Some of the expertise required to carry out the tasks under the Thought Starter can be provided by external experts and consultants, but there are certain tasks that can only be carried out by staff internal to the company.

4.2 Involvement of Co-producers and Downstream Users

As noted in Section 3 of the report, involvement of co-producers and downstream users was a major issue in the trial.

During the trial, the participating companies had limited success in involving co-producers. The exceptions generally arose where participants could draw upon existing groupings of producers; in this case, involvement of co-producers required only one or two days input (€1,000 to €2,000). Some co-producers did not respond to requests for information, while others refused to participate or provided only limited information. Seeking the involvement of co-producers required limited effort from participating companies, generally only a few days in contacting co-producers by telephone, email or in writing. The elapsed time, however, could be considerable and in some cases involving co-producers would have required longer than the three months of the trial. Experience with other activities, such as the ICCA HPV programme and registration under the Biocides Regulation, indicates that putting together formal consortia of co-producers can take anything from six months to one year. This can be particularly problematic where co-producers are located outside the EU.

The cost implications of the failure to involve co-producers were not significant for the pilot trial, but could be significant once REACH becomes a legal requirement. If co-producers do not co-operate, opportunities to reduce the overall costs of the REACH process by sharing information could be lost. Nevertheless, there are potential concerns about co-operation.

The ICCA process has demonstrated that, in order to avoid problems under competition law, sharing of information on production volumes needs to be carried out within the framework of carefully-drafted contracts. There have also been problems within the ICCA programme of identifying lead companies for a number of chemicals. This was not a problem experienced in the pilot trial, where all the participants had volunteered to act as lead companies. Problems have also arisen under the ICCA programme where a consortium consists of one large company and a number of smaller ones, with the smaller companies expecting the larger one to carry out the majority of the work. In the US, this problem has been solved by the use of contractors to carry out the work, with each consortium partner contributing to the cost under an agreed cost-sharing formula.

During the trial, participants also experienced difficulty in obtaining data from downstream users. This posed problems in terms of access to use and exposure information that could have potentially significant cost implications. The elapsed time required to contact downstream users varied; some users responded to participants within one week, others had not responded by the time the three month period of the trial was over. Experience outside the pilot trial indicates that establishing effective information exchange and validation of data with users could take six to nine months. Users were also concerned about the prospects of having to undertake such activities for thousands of substances.

Within the trial time-scale, contact with users was generally limited to contacts by email and telephone. Participants focused their efforts on contacting key users who were willing to co-operate. The estimated time inputs required by participants to contact downstream users ranged from one to 12 person-days (equivalent to approximately €1,000 to €2,000), depending upon the numbers of users contacted and the degree of co-operation. The average time input from participants was one person-day per user. One participant estimated that similar time inputs would be required from each user company. Thus where there were useful discussions between participants and users, the total time input required would be two days per user (one day from the participant and one day from the user). This is equivalent to €2,000 per user for each substance and could amount to a significant level of resources where companies need to register a large number of substances with a large number of downstream users.

The type of staff member involved in discussions with users varied between participants. They included technical sales staff, senior product stewards and experts. Similar types of staff were involved from user companies; one of the difficulties in the trial was identifying the person in the user company with the right level of expertise. Experience elsewhere, for example with the ICCA HPV programme, indicates that business-level involvement is important for success in information exchange with users.

4.3 Preparing Hazard and Tonnage Data

Estimates of the resources required to prepare hazard and tonnage data varied considerably between participants. In some cases, the data required for the pilot trial

had been collected in connection with other initiatives such as the ICCA programme. In others, data had been assembled over a number of years as part of the companies' general activities. In these cases, it proved difficult to calculate the cost and time that would have been required to collect only the information required under the Thought Starter. In this respect, the pilot trial substances may not be representative of the bulk of substances covered by the REACH process. Given the short time-scale of the trial, it is likely that participants selected substances for inclusion within the trial that had more data available than average. The estimates of resources required for the pilot trial are therefore likely to be at the low end of the range of actual costs.

Estimates of the resources required to generate the data required by the Thought Starter varied from one to five person days (equivalent to €1,000 to €5,000) where data were already available in an appropriate format. Up to 40 days of expert time (equivalent to €40,000) were required where data needed to be collated from a range of sources. The estimated elapsed time required to establish the hazard data required by the Thought Starter ranged from a few weeks up to 1 to 2 years, where testing needed to be carried out from scratch. Experience under the ICCA HPV programme indicates that an elapsed time of 6 to 9 months is not uncommon.

The other costs associated with preparing hazard and tonnage data depended on the extent of additional testing required to complete data gaps. Estimated additional costs of testing to meet the Thought Starter requirements varied from €4,000 for measurement of a single environmental end-point to €200,000 to €400,000 where full testing would be required.

For the substance within the pilot trial that would be subject to authorisation, considerably more effort had been expended to obtain detailed data on hazard and tonnage. One company estimated that collecting the data required under the Existing Substances Regulation had required 300 days input, equivalent to €300,000. In addition, the costs of testing as an input to risk assessment were estimated at €500,000.

4.4 Classification and Labelling

In the majority of cases, resources required for classification and labelling in this trial were limited because it had already been carried out for other purposes. Costs were generally below €1,000, equivalent to one person-day time input. Two respondents, however, quoted cases where disputes with competent authorities over the results of testing had led to delays of up to three years in reaching agreement on classification and labelling. This could also result in significant costs, in one case estimated at up to €400,000, if there was a requirement to repeat the tests that formed the basis of the dispute.

In the case of one of the substances that would be required to undergo authorisation, time inputs associated with EU proposals to classify the substance as a Category 2 carcinogen were estimated at approximately 50 days (€50,000). This related to the time inputs of toxicologists in a number of companies.

4.5 Use Data

The level of effort required to generate use data depended on the extent to which downstream users were involved and the number of such users. Use data required least effort when there was a limited number of users and the use was well understood (e.g. intermediates used only in well controlled systems). The process was most complex, and required the greatest resources, when there was a large number of different potential uses.

Companies that sent out pre-designed questionnaires to users requesting use data found that this required only limited resources - time inputs of one to two days (€1,000 to €2,000) for the participating company and an estimated 0.5 days (€500) for each user company. However, this approach often did not generate a high level of response. One participant held discussions with key customers, rather than sending out questionnaires. This resulted in a better response but required five days input (€5,000). One company was able to draw on a pre-existing ad hoc group involving producers and users. In this case, for a substance subject to authorisation, 10 days input (€10,000) in total was required to generate detailed use data, with five days of this (€5,000) involving discussions with users.

If users did not co-operate, companies were either required to generate data themselves or to proceed using the data that were already available. In a number of cases, use data had already been gathered by participating companies under the ICCA HPV programme or in relation to regulatory requirements. Generally, less than one day was required to convert it to the form required by the Thought Starter. Sources for this information included industry estimates and the use of national product registers; one company estimated that gathering use data from these sources had required three person-days (€3000). Another company had collected data in connection with preparation of a risk assessment under the Existing Substances Regulation. This had involved systematic contact with trade associations representing potential users and had been carried out by a consultant at a cost of €4,000. However, the effort had achieved only limited success. The costs for the trade association representing the major end use were estimated at 60 to 100 person days (€60,000 to €100,000).

One company, which had limited data available on uses before the trial began, gathered information from reviews within the business (to combine with information from customer discussions). This required a time input of 15 person days (€15,000). Another company estimated that five hours input (approximately €600) was required to estimate uses based on sales data. Clearly, the resources required to gather data from internal sources depends upon the way in which the data are held within the company. Where data are already held centrally, resource requirements will be limited; gathering data held at separate business units will be more costly.

The extent of input from users also affected time-scales; in general a longer time-period was required where data was gathered from users but better information resulted. Estimates of elapsed time where users were involved varied from a few weeks to several months (the latter based on experience with the ICCA programme).

4.6 Exposure Information

The resources required to develop exposure information was critically dependent upon the degree of involvement of downstream users and also on the nature of the substance. In two cases, trial participants indicated that exposure to the substance during intended use was negligible and therefore gathering exposure data required few additional resources. In one case, 0.5 person-days (€500) had been spent estimating potential exposure from accidents.

Where users were willing and able to provide exposure information, only limited resource inputs were required from producers. These were estimated at one to four days (€1,000 to €4,000), depending on the number of customers. Where information from users was insufficient or unobtainable, trial participants had to gather data from other sources. This included literature searches, industry estimates and crude modelling of worst-case scenarios.

One company had gathered information using these approaches for a risk assessment under the Existing Substances Regulation. The cost of a literature survey covering 12 products was estimated at €40,000 and modelling costs at €4,000 (although these costs included generation of a basic risk assessment). Converting this information into the form required by the Thought Starter required a further two days input (€2,000). Another company indicated that using industry estimates to fill gaps in data from users required one day (€1,000) for the Thought Starter, compared with three days (€3,000) for the ICCA HPV programme.

4.7 Existing Risk Management and Risk Assessment

As Section 3 notes, the trial participants' approach to meeting the Thought Starter requirements on establishing existing risk management measures and carrying out risk assessments varied. This has led to variations in the resource requirements estimated by different participants. The resource requirements are also affected by the extent to which the required information was already available and the degree of involvement of downstream users.

For a number of the participants, the information required for this step of the Thought Starter was already available. Putting the information into the form required by the Thought Starter took only one to two days (€1,000 to €2,000). For one participant, problems had been caused by the large volume of available data, most of it relating to non-relevant uses of the substance. The company estimated that, if starting from scratch, it would have spent €35,000 hiring a consultant to review the data and summarise relevant information. One company estimated the total cost of putting together existing information on use and exposure, existing risk management and carrying out the risk assessment at €60,000. This involved inputs from staff in a range of departments throughout the company.

Other participants were unable to complete a risk assessment within the time-scale of the trial due to the lack of information from downstream users. One such company had input seven days (€7,000) into preparing a risk assessment on the basis of

available data; another had input one day (€1,000). A third company indicated that further effort in discussion with users, requiring considerable resources, would have been required for a thorough risk assessment as available data were too general.

One participant contrasted these costs with the costs of €140,000 to €400,000 to produce a full risk assessment in line with the TGD.

4.8 Safety Data Sheets

For a number of the trial participants, safety data sheets had already been prepared, so that the costs associated with this step were zero. Where safety data sheets had to be adjusted or updated, estimates of inputs ranged from below one to five days (less than €1,000 to €5,000).

4.9 Overall Resource Requirements

The total costs of undertaking the pilot trial varied considerably between participants, depending mainly on the amount of information that was already available and the degree of input from users. Estimated total time inputs varied from 11 days or below (three companies) to over 100 days. The two companies estimating input at over 100 days included one of the companies whose substance was subject to authorisation. This company estimated its inputs at over 360 days. The remaining participants estimated their inputs as between 30 and 60 person-days. Few additional costs were incurred during the trial itself, but participants' estimates of the costs of testing carried out prior to the trial, on which they could draw to complete the Thought Starter, ranged from €40,000 to €500,000).

Two participants provided estimates of the overall costs of completing the process as set out in the Thought Starter. One company estimated the total cost as approximately €150,000, together with un-costed inputs from customers. Another estimated the costs of its own staff time, together with input from users at €25,000 to €30,000 in total.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

When rigorously carried out according to the Implementation Plan, the Thought Starter appears to provide a good basis for implementing REACH in a cost-effective manner. There are some areas where further work is needed in developing how different activities are to be carried out and with what level of detail. In particular, greater attention is required on mechanisms to improve information exchange between producers and users of chemicals, as this affects the ability of companies to fulfil several different requirements of the Thought Starter.

The key issues are:

- problems in establishing contact with the appropriate person within co-producers or users to begin a dialogue on information exchange;
- unwillingness of co-producers to exchange information because of concerns over competition issues;
- unwillingness or inability of users to provide the information needed for full implementation of the Thought Starter because they are unaware of the requirements of the REACH system and/or do not have the resources or expertise to provide the information required;
- difficulties in specifying existing controls and their effectiveness and in preparing adequate risk assessments on the basis of available information from co-producers and users; and
- the need for further development of the decision trees providing the basis for making decisions on further substance tailored testing requirements and determining how concepts such as ECETOC can be integrated into the Thought Starter if considered appropriate.

To some extent, the problems concerning information exchange may be resolved when REACH becomes a mandatory requirement. This appears to be illustrated by experience with the US HPV programme. However, some of the issues and problems surrounding information exchange are likely to remain and will need to be addressed.

A key concern expressed by several of the companies participating in the pilot trials focused on the degree to which REACH would adopt a 'checklist' approach to the provision of physico-chemical and hazard data (with all data required regardless of value added in risk management terms). This together with the potential need to prepare quantitative risk assessments for all dossiers raises serious concerns over the possible implications for staff, financial and time resources.

Indeed, the Commission itself estimated the costs of undertaking testing as being €5,000 for base set data, €250,000 for Level 1 data and €325,000 for Level 2 data (as given in the White Paper for testing in accordance with the Annexes of Directive

67/548/EEC). Cefic's worst case estimates of the costs of testing (assuming no data are already existing) are considerably higher at : €200,000 to €250,000 for base set data ; €500,000+ for Level 1 data ; and €1 to 2 million for Level 2 data. Added to these are the costs of information exchange with downstream users and co-producers, undertaking a risk assessment, completing IUCLID, etc.

These figures can be compared to the costs of adopting the Cefic Thought Starter as the approach for implementing REACH as estimated by the pilot trial companies. One of the companies submitting a dossier for a substance produced in quantities greater than 100 t/y, and which followed in detail the activities as set out in the Implementation Plan, estimated the costs of fulfilling the requirements of the Thought Starter at around €150,000. These are clearly lower than the costs of completing the full set of Level 1 testing requirements, translating to savings of €100,000 when compared to the Commission's estimated testing costs alone. This is a significant savings when aggregated over thousands of chemicals. There are also likely to be significant savings in time inputs when following the Thought Starter, which could be important in terms of the total demands on staff time arising from the application of REACH to a large number of substances.

5.2 Recommendations

5.2.1 Use of the Thought Starter

The Thought Starter as it currently stands should be presented as a valuable starting point in providing a pragmatic way forward in fulfilling the requirements of REACH. Chemical companies should be encouraged to examine ways in which the Thought Starter could be implemented for their products. In particular, it would be useful for companies to begin developing links with co-producers and users, through relevant Trade Associations and more directly with customers.

5.2.2 Improving Information Exchange with Users

The pilot trial has highlighted the importance of co-operation between producers and users of chemicals to ensure that the REACH process can be conducted in a cost-effective manner. It has also highlighted the potential barriers to such co-operation including, most significantly, concerns about the implications for competition.

There are a number of ways in which information exchange could be improved. Suggestions arising from this exercise are set out below. Table 5.1 summarises some of the key lessons to come out of the HERA programme.³

3 Human and Environmental Risk Assessment of Ingredients of European Household Cleaning Products. For a summary of lessons learned see Scailteur, Solbe & Scharer (2002): HERA: Experiences from an Ongoing Voluntary Risk Assessment Project, www.heraproject.com 18th March.

Table 5.1: Experiences from the HERA Voluntary Risk Assessment Project

HERA (Human and Environmental Risk Assessment) is a voluntary industry initiative launched in 1999 that involves downstream users marketing household detergents and cleaning products and the producers supplying the chemicals that they use. The goal was to demonstrate, for real chemicals, that chemical producers and users could prepare risk assessments using a common approach in an effective, transparent and timely manner. This has involved stakeholder input and making the methodology and assessment reports public.

The focus of the project is on making the most efficient use of existing hazard and exposure data through application of (Q)SARs and the grouping of chemicals. From the onset, it was decided to develop a targeted risk assessment approach, derived from the TGD. The scope was defined as chemicals used in European household detergent and cleaning products, with the focus being on consumer use and disposal. For the first phase, covering about 18 substances and families, chemicals were chosen to represent each of the major functional families, together with some EU priority chemicals.

The main lessons from the project so far are summarised below.

- Chemicals covered by the HERA project have specific features, including high use volumes, a relatively short supply chain, extensive exposure of consumers and the discharge of chemicals to the environment after use. The HERA approach may not be appropriate for sectors that do not share these features.
- There is a need for commitment at the highest level in the companies involved to ensure success of the project and that appropriate resources are forthcoming.
- Communication priorities differ; downstream users that sell direct to the public wish proactively to communicate relevant information on risks to consumer health and the environment to ensure public confidence. Producers are more focussed on risks during production and distribution and allocate a lower priority to end-user communication.
- Frameworks are needed to organise collaboration between producers and users, especially where there is no history of collaboration. This includes an acceptable and flexible budgetary system.
- Barriers to co-operation arise from competition law concerns and from the value of proprietary data; the next phase of the project will pay increased attention to overcoming these barriers.
- Establishing common exposure scenarios is feasible though not simple.
- Producers and users have access to different but complementary information. It takes time, effort and encouragement to get all relevant information. Sending out questionnaires is not usually enough. Companies differ in organisation and data systems and some find it easier to respond than others. Active communication, both within organisations and externally, is of paramount importance. Knowledgeable contact points within each company, established from the outset, are extremely helpful.
- Resolving difficulties in supplier/user collaboration can be difficult and time consuming; examples include unexpected mismatches in use volume estimates. There is also a need to co-ordinate requests for data from downstream users, to enable them to manage their responses better.
- In order to ensure that the lessons learnt are not forgotten, records must be kept and regularly reviewed. Rigorous documentation is needed to record decisions made throughout the process.
- There are both benefits and disadvantages where data on particular chemicals or families is also being collected for other programmes, such as the HPV initiative. Collaboration can result in efficiencies, more complete data sets and higher quality assessments. But there can be drawbacks in the form of delays and rework in some cases.

Identifying Relevant Contact Points

In terms of identifying the right contact person within co-producers or users, the example of the approach used by the CIA may be useful. The CIA has developed a list of senior contacts within each member company. It is the responsibility of this person to identify an appropriate colleague to deal with CIA communications/requests if they cannot do so themselves. It would not be appropriate for trade associations to do this in relation to the REACH process; instead, Competent Authorities should examine the feasibility of adopting a similar approach (although there are always, of course, problems with keeping such databases current).

One option would be to introduce a requirement for companies affected by REACH to nominate a responsible person (similar to the requirement to nominate someone responsible for health and safety), with their name required as part of any pre-registration process included in REACH. This person would then be responsible for identifying relevant sources of data within the company.

Encouraging Information Provision by Users and Co-producers

One option for encouraging information provision by customers would be for manufacturers/importers to work with downstream user associations to create focal points for information exchange. The downstream user associations could identify individuals within the associations who could help to advise member companies on REACH. The associations could also potentially act as neutral screening bodies for receipt and collation of commercially sensitive data. This could help to address the concerns of users about providing detailed use information to their suppliers and could also provide a basis for co-operation between co-producers that would bypass some of the concerns about commercial confidentiality.

In practice, however some trade associations have found members reluctant to provide them with commercial data of any kind. As an alternative, the feasibility of setting up a central data base that is wholly independent could be examined.

Aiding Risk Assessment in the Absence of Detailed Data

In order to provide adequate data for risk assessment, whilst protecting commercially sensitive information, data could be collected in relation to use categories. Companies would then be asked to provide reliable data on environmental releases and human exposure where this is available.

An approach being developed by the VCI is the use of 'exposure categories' to classify the key exposure routes and scales (e.g. single or repeated exposure, local or widespread). The relevant exposure categories for each substance, based on known uses, would form the basis for risk assessment. Any other uses of a substance that resulted in the same categories of exposure would then be deemed also to be covered by the registration.

Effective Planning for Information Exchange

The pilot trial demonstrated that gaining appropriate information from downstream users could take a considerable period of time. Thus, any information exchange process will need to begin early on in the registration process. This will enable downstream users to organise themselves to respond to such requests, including potentially the use of an independent body, as well as providing adequate time for them to collect the necessary data and allow follow up on the data received.

Care will also be needed in the scheduling of chemicals for registration and in setting deadlines for the completion of certain activities. This includes:

- setting priorities for the registration of individual substances;
- making these clear to downstream users with deadlines for information provision; and
- identifying alternative approaches and information exchange formats for obtaining data from both large and small users.

5.2.3 Addressing More Technical Issues

The recommendations outlined above should also help resolve some of the more technical issues that we believe need to be addressed in further developing the Thought Starter. In particular:

- although preliminary decision trees for determining substance tailored testing requirements were provided to us (and through us to the participating companies), they were only applied by one company. This may be because they were not fully developed and were difficult to follow in the format first presented. However, we believe that further effort should be put into developing such trees; and
- in conjunction with the development of decision trees, consideration should be given to the provision of additional advice on preparing risk assessments. It was obvious from the dossiers submitted in the pilot trials that further detailed descriptions of what should be included in the risk assessments is required. This should include a clear delineation of when qualitative risk assessments are likely to be acceptable and when more quantitative assessments should be viewed as necessary.

In developing this further guidance, we believe that account should be taken of the quality and level of information on downstream uses and how they are controlled. For example, should there be an increased emphasis on quantitative risk assessments, based on modelling of generic scenarios, where information on exposure is limited compared to cases where there is detailed and reliable information that provides a clear and demonstrable indication that risks are well controlled?

The White Paper also recognises the importance of substance tailored testing, based on the use of decision trees taking into account available information, the properties of the chemical and use and exposure. There is obviously an opportunity to provide continuing support to the development of associated guidelines.

In our view, a key way of achieving this is to undertake further comparative analyses of the detailed risk information that stems from the use of proposed substance tailored approaches compared to those of the ESR risk assessments and the outputs of the ICCA initiative. The focus of such analyses should be on determining whether the more pragmatic approaches provide sufficiently reliable information for future risk management. Suggestions from the ECB on the adequacy of the selected pilot trial submissions provided to them for review will also be important in this regard.

ANNEX 1:

**CEFIC PROPOSALS ON
CORE INFORMATION SETS OF HAZARD DATA
FOR REGISTRATION**

Proposed Hazard Data by Tonnage and Exposure Potential

Table 1

The following proposal for information requirements are presented as guidelines.
At each level based on:

- intended use and exposure,
- the application of expert judgement,
- the consideration of the chemical structure of the substance, (e.g. using (Q)SAR),
- family grouping,
- available toxicological or eco-toxicological information and

more or less (waiving) information may be considered necessary.

Tonnes per annum placed on the Market	Number of substances (estimated)	White Paper Testing proposal	Cefic Proposal		
			Industrial Use	Professional Use	Consumer Use
> 1000	2600	Annex VIII level 2	C	C	C
100 - 1000	3000	Annex VIII level 1	B	B (+ 28 day repeated dose)	B (+ 28 day repeated dose + reprotox screening + algae + fish)
10 - 100	4700	Annex VIIA	B	B	B (+ 28day repeated dose + reprotox screening)
1 - 10	19700	In vitro	A	A	B
0 - 1	???	-	No systematic testing		

A, B and C indicate the level of information to be provided related to tonnage and use:

- A** = Core information set (see Figure 2A)
- B** = A + sensitisation + Ames test
(see Figure 2B)
- C** = B + completion to Annex VII A or equivalent (Figure 2C)

Figure 2A – “Core Information Set” for substances placed on the market above 1 tonne per year

This relates to the exposure scenarios in Industrial and Professional Uses indicated by an “A” in columns 4 and 5 of figure 1. The additional information listed in Figure 2B would be required for Consumer Use.

Hazard Type	Property	
Physico-Chemical data	Melting point	*
	Boiling point	*
	Relative density	*
	Vapour pressure	*
	Partition coefficient octanol/water	*
	Water solubility	*
	Flash point	*
Environmental fate and pathway	Biodegradation	*
Eco toxicity	Acute toxicity (daphnia)	*
Toxicity	Acute toxicity – INGESTION, DERMAL, INHALATION	1 route
	Skin irritation	*
	Eye irritation	*
Total	12 tests	

Figure 2B – Additional “Core Information Set” for substances placed on the market above 10 tonnes per year

This is over and above the “Core Information Set” in figure 2A. This relates to the exposure scenarios indicated by a “B” in columns 4, 5 and 6 of figure 1 for Industrial and Professional Uses. Additionally a 28 day Repeated Dose Toxicity Study and a Screening for Reproductive Toxicity are required for Consumer Use.

Hazard Type	PROPERTY	
Toxicity	SKIN SENZITIZATION	*
	GENETIC TOXICITY BACTERIAL TEST (AMES)	*
TOTAL	2 TESTS	*

For substances placed on the market above 100 tonnes per year

The “Core Information Set” for industrial Use is that set out in figure 2A and 2B. In addition a 28-day Repeated Dose Toxicity Study is required for Professional Use and Consumer Use. Further, studies required for Consumer Use are a Screening for Reproductive Toxicity, an Aquatic Toxicity Algae Study and an Aquatic Toxicity Fish Study.

Figure 2C – Completion to Annex VIIA or equivalent for substances placed on the market above 1000 tonnes per year

This requires completion of the information sets in figure 2A, figure 2B and figure 2C, i.e. to the Annex VIIA requirements of Directive 67/548/EEC or equivalent (e.g. SIDS under the refocused OECD HPVC Programme) indicated by a “C” in figure 1.

HAZARD TYPE	PROPERTY	
PHYSICO CHEMICAL DATA	SURFACE TENSION	*
	FLAMMABILITY	*
	EXPLOSIVE PROPERTIES	*
	SELF-IGNITION TEMPERATURE	*
	OXIDIZING PROPERTIES	*
ENVIRONMENTAL FATE AND PATHWAY	HYDROLYSIS	*
ECO TOXICITY	ACUTE TOXICITY (FISH AND ALGAE)	*
	BACTERIAL INHIBITION	*
	ABSORPTION/DESORPTION SCREENING TEST	*
TOXICITY	ACUTE TOXICITY – INGESTION, DERMAL, INHALATION	SECOND ROUTE
	MUTAGENECITY (NON BACTERIOLOGICAL TEST)	*
	REPEATED DOSE 28 DAYS SCREENING FOR REPROTOX	
TOTAL ANNEX VIIA (A+B+C)		

ANNEX 2:
PILOT TRIAL IMPLEMENTATION PLAN

CEFIC Thought Starter - Draft Implementation Plan

Hazard and Tonnage Data

Lead with Industry, Authorities to provide feedback, with Consultant assisting as necessary.

Action	Participant			
	Coproducers	Authority	Consultant	Associations
Define appropriate use category - industry, professional or consumer. If more than one category applies, use the most severe unless the proportion of the chemical involved is negligible.	X			
Agree appropriate tonnage range and appropriate hazard data to be generated, according to Thought Starter guidelines. (Appendix 1)	X			
Identify any arguments relating to the specific chemical which support an increase or decrease in the dataset defined in Appendix 1. Prepare these arguments for submission to the Authorities.	X			
Share available hazard data - identify gaps v. outcome of previous two actions	X			
Identify cost of filling data gaps - testing or QSAR, plus administration	X		X	
Agree a mechanism for sharing costs	X			
Enter the hazard data in IUCLID	X			

Supply Classification and Labelling

Lead with Industry, Authorities to provide feedback, Associations to assist co-producers if required.

Action	Participant			
	Coproducers	Authority	Consultant	Associations
Based on the above hazard data and existing classification guidance, develop appropriate classification and package labelling proposals.	X			
Enter information into IUCLID and submit to Consultant	X		X	

Use Data - (for Intended Uses)

Lead with Industry, Authorities to provide feedback.

Action	Participant			
	Coproducers	Authority	Consultant	Associations
Define category(ies) of use, selecting from 55 categories in TGD	X			
Provide brief written technical description of use. If significant exposures might occur downstream, <i>seek the involvement of downstream users in describing the circumstances if necessary.</i>	X			
Enter information into IUCLID and submit to consultant	X		X	

Exposure Information

Lead with Industry, Authorities [Consultant] to provide feedback.

Action	Participant			
	Coproducers	Authority	Consultant	Associations
For each category of intended use identified in the previous section, describe the nature of the principle exposures which occur - human (eg skin, inhalation...) and environment - throughout the lifecycle. Take account of normal and abnormal operations, short and long term, as well as continuous or batch operation.	X			
Define any exposures that may potentially be of significance (see previous and next sections) and provide exposure measurements or modelling data.	X			
Enter exposure information in IUCLID & submit to consultant	X		X	

Existing Risk Management, plus Preliminary Risk Assessment

Lead with Industry, Authorities [Consultant] to provide feedback.

Action	Participant		
	Coproducers	Authority	Consultant
For all principle routes of exposure associated with intended uses, identify all existing relevant legislative controls	X		
Describe the measures used to achieve compliance with these controls. <i>Seek input from downstream organisations if necessary.</i>	X		
Describe the nature of the entity complying with the controls - eg professionally qualified, skilled and experienced, unskilled, consumer.	X		
Identify those exposure routes where risk is not explicitly controlled by existing legislation, or where there is only low confidence in the measures/abilities of organisations to comply with existing controls.	X		
Suggest further cost-effective control measures that might be implemented. <i>Agree these with downstream organisations if appropriate.</i>	X		
For the routes identified in the last activity, if the chemical is toxic or very toxic - to people - determine whether widespread consumer exposure occurs. If the chemical is toxic/very toxic to the environment, determine whether the chemical is mainly discharged to the environment in some way during its life/disposal.	X		
If the previous activity has positive outcome(s), provide a quantitative measure (PEC/PNEC ratio etc) to indicate the risk.	X		
Enter all the above information in IUCLID	X		

Safety Data Sheets

Lead with Industry, Authorities [Consultant] to monitor.

Action	Participant		
	Coproducers	Authority	Consultant
Exchange datasheets and identify any significant differences between them. Resolve these differences.	X		
Collect updated SDSs and enter them in IUCLID individually*	X		

Evaluation

Lead with Consultant. Ideas and suggestions to be provided by Industry

<u>Action</u>	<u>Participant</u>		
	<u>Coproducers</u>	<u>Authority</u>	<u>Consultant</u>
Review the above information and draw up a decision tree - is the information adequate, using Appendix 1 as a reference? is other information needed? are any proposals - from coproducers, above - for further hazard testing appropriate? are the risks identified being adequately controlled? is there a significant possibility of other significant risks? would the proposed additional management measures - if any - be necessary/sufficient? what other measures are needed?		X	Or Consultant if authority not available.
Define the criteria which indicate that rapid risk management would be appropriate		X	

Authorisation

Industry working with the Authority and Consultant to:

<u>Action</u>	<u>Participant</u>		
	<u>Company</u>	<u>Authority</u>	<u>Consultant</u>
Determine from above hazard data whether the chemical meets the criteria of 'very high concern' - currently, a Cat 1 or 2 CMR, or a POP. If it does, do the following:	X	X	X
Identify those uses with exposure routes where risk is not explicitly controlled by existing legislation, or where there is only low confidence in the measures/abilities of organisations to comply with existing controls. (This will have largely been done already - see above.) Exclude from these laboratory and other excepted uses.	X	X	X
For uses determined in the previous activity, demonstrate that exposure of people or the environment is negligible throughout the lifecycle. Either provide a technical description of circumstances of use which clearly shows that significant exposure cannot occur, or provide exposure measurements which confirm this.	X	X	X
If negligible exposure cannot be robustly demonstrated, identify the social and economic consequences of banning the use. Cost - in financial and risk terms - any realistic alternative technologies.	X	X	X

ANNEX 3:
EXAMPLE SUMMARY OF DETAILED DATASETS

CEFIC PILOT TRIALS - Review of Industry Data Submissions	
Company Name	Company X
Substance	Chemical Y (an HPV)
1. Organisational	
Co-producers	Three additional partners under ICCA (A)
2. Hazard and tonnage data	
Use category	Wide range of uses (A)
Tonnage range	Over 1000 tpa
Agreed data required	Identified in (C)
Arguments for more/less data	No recommendations for further testing
Sharing data	European co-producer not willing to co-operate
Identify data gaps	Would discuss with ECB or perform (C)
Costs of filling gaps	0.5 man days
Mechanism for sharing costs	N/A (see above)
Hazard data into IUCLID	Yes
Comments on adequacy	
3. Classification and labelling	
Develop appropriate proposals	Yes
Proposals into IUCLID	Yes (A)
Comments on adequacy	
4. Use data	
Define use categories	Yes (many in (A))
Brief technical description of use	Described in (B)
Potential significant exposure downstream?	Some of these have been identified (B)
Info. from d/s users on describing use	Practically none
Data into IUCLID	Yes (most of it, but some in (B))
Comments on adequacy	
5. Exposure information	
Describe principal exposures for each use	Not done systematically
Define potentially significant exposures	Yes - but really manufacturing only (A) and (B)
Provide exposure measurements or modelling data	Yes - but only for human health exposure during manufacture
Data into IUCLID	No
Comments on adequacy	
6. Existing risk mant plus prelim. risk assessment	
Legislative controls for all exposure routes	Only OELs given
Measures to achieve compliance (d/s user input)	Not explicitly
Nature of entity complying with controls	Not explicitly
Exp. routes where no explicit control/low compliance	Not explicitly
Further possible control measures (d/s user input)	Practically no downstream user input
Widespread consumer use (if toxic/v. toxic)?	Not toxic (only classification required for irritation)
Mainly discharged to environment (if toxic/v. toxic)?	Not toxic for environment
PEC/PNEC (if last outcome positive)	N/A
Data into IUCLID	Yes
Comments on adequacy	
7. Safety data sheets	
Exchange datasheets and identify differences	No problems reported (C) but SDSs not supplied
Resolve any differences	European co-producer not willing to co-operate
Updated SDSs into IUCLID (separately)	Unknown
Comments on adequacy	
8. Evaluation	
Review above information	
Draw up decision tree	
Is information adequate?	

Other information needed

Any proposals for further testing appropriate?

Are risks adequately controlled?

Significant possibility of other risks?

Would proposed RMMs be sufficient?

Other measures needed?

Criteria for rapid risk management

Comments

9. Authorisation

Is chemical of very high concern?

Exp. routes where no explicit control/low compliance

Demonstrate negligible (tech. description or measurements)

Comments on adequacy

10. Communication

Data suitable for public domain

Presentation

Justified measures to protect competitiveness

Comments

11. Reporting

References

(A) IUCLID Data Set

(B) SIDS Initial Assessment Report

(C) Registration Feedback Form