



The SPORT Report

Making REACH work in practice

5 July 2005

SPORT is a strategic partnership of the European Commission, Member States and Industry (Cefic, UNICE, UEAPME and DUCG).



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Brussels, July 2005

The strategic partners

European Commission: *DG Enterprise & Industry, DG Environment and DG JRC*

Member States: *Finland, France, Germany, Italy, the Netherlands, United Kingdom*

Industry: *Cefic (European Chemical Industry Council), DUCC (Downstream Users of Chemicals Co-ordination Group), UEAPME (European Association of Craft, Small and Medium-sized Enterprises) and UNICE (Union des Industries de la Communauté Européenne)*

SPORT Report

Final Report

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0 Introduction

SPORT – the *Strategic Partnership on REACH Testing* - is part of the Interim Strategy initiated by the European Commission in October 2003 upon the adoption of its proposal for a new chemicals regulation, - “REACH” (Registration, Evaluation and Authorisation of Chemicals). The objectives of strategic partnerships within the Interim Strategy were, *inter alia*, to assist the development of procedures and formats and to identify actions that can improve the workability of REACH.

Cefic submitted a proposal for a pilot trial of selected REACH steps (registration and dossier evaluation) to the Commission in February 2004. It was approved by the Commission Working Group on the Practical Preparations for REACH at its 1st meeting on 28 May 2004.

Cefic formed a broad industry coalition with UNICE, UEAPME and DUCC. The industry coalition proposed a list of substances as candidates for testing registration and dossier evaluation. At the SPORT preparatory meeting on 31 August 2004 a final list of eight case studies was selected by the three partners – industry, Commission and Member States. The main selection criterion was maximisation of the learning potential from the case studies (details on the selection arguments see chapter 2.1.2).

The overall goal of the SPORT exercise was to test the workability of the registration and of the dossier evaluation steps of the REACH proposal, in order to identify solutions where problems are found, to improve understanding of REACH, and to provide input to the REACH Implementation Projects.

In November 2004, 29 chemical companies, the Competent Authorities from nine Member States and the European Chemicals Bureau set out to simulate the registration as well as the dossier evaluation steps of REACH. In addition, 25 companies using chemicals were involved. The work was carried out in eight sub-projects and covered about 50 substances.

The overall SPORT report consolidates the findings from the eight sub-projects, from two interim workshops as well as from the reflection workshop (Darmstadt 19/20 May 2005), and derives common conclusions. The underlying reports and documentation are annexed to this document. Also attached are the list of draft recommendations compiled during the final meetings of the sub-projects and the list of compliance issues identified in the dossier evaluation (Annexes 3 and 4). A detailed description of the structure and of the timelines of the SPORT process can be found in Annex 5.

Chapter 1 includes an overall summary of the SPORT set-up (Chapter 1.1) as well as a selection of proposed solutions (recommendations) agreed upon by all three strategic partners (Chapter 1.2).

In Chapter 2 the elements of REACH tested in SPORT are described and the corresponding findings are presented as “facts and figures”. In addition, the limits of the SPORT exercise are indicated.

Chapter 3 presents the results and recommendations from the eight sub-projects as reflected at the reflection workshop in May 2005 in Darmstadt.

For the majority of the recommendations the addressee has not been specified during SPORT. For some recommendations, the addressee may be obvious, for others discussion will be needed in the follow-up of the SPORT exercise.

1 Set-up of SPORT and recommendations

1.1 Objectives, scope and organisation of SPORT

1.1.1 Setting up SPORT

SPORT stands for “Strategic Partnership on REACH Testing”. The project was based on equal participation and joint management by the three strategic partners, i.e. the European Commission, the Member States and industry, including small and medium enterprises as well as Downstream Users, who all together formed the SPORT Steering Group.

SPORT is a ground-breaking strategic partnership for testing proposed legislation at Community level¹ and could serve as a blueprint for the future.

There were three major success factors for SPORT:

1. Companies and authorities volunteered for the role play in the sub-projects and lived up to their commitments;
2. Clear governance structure of SPORT and clear rules (SPORT High Level Rules: see Annex 6) agreed upon before the project commenced;
3. Analysis of the exercise by an independent consultant.

The structure of the SPORT project included a Steering Group and eight sub-project working groups, one per substance or substance group. Moreover, the establishment of a contact group, a secretariat as well as a contract with an independent consultant enabled the implementation and the daily management of the project.

The Steering Group

The Steering Group represented the three partners and supervised the project as the highest decision-making authority for all aspects of the project.

Members were:

- The Commission Services (DGs Enterprise, Environment and JRC);
- Member States: Finland, France, Germany, Italy, The Netherlands, United Kingdom;
- Industry: Cefic (European Chemical Industry Council), DUCC (Downstream Users of Chemicals Co-ordination Group), UEAPME (European Association of Craft, Small and Medium-sized Enterprises) and UNICE (Union des Industries de la Communauté européenne)

¹ A similar project had been carried out at regional level by the government of the German Federal State of North Rhine-Westphalia before SPORT commenced.

Steering Group meetings were chaired by an independent professional and attended by advisors (e.g. the facilitator) and observers².

In a spirit of transparency, the observers attended Steering Group meetings and interim workshops, got access to papers and were able to provide input at the meetings. However, they did not participate in the sub-projects and were not involved in the decision-making.

The sub-project working groups

The sub-project working groups were chaired by a representative of the lead M/I company and composed of:

- Participating Manufacturers and Importers,
- Where appropriate, participating Distributors and/or Downstream Users,
- The Commission Services as observers,
- Lead Member States,
- An expert advisor from the independent facilitator.

Each sub-project was intended to run as close to a real life situation (“free-flow³”) as possible. The “free-flow” method applied to both horizontal and vertical collaboration. Horizontal collaboration is for example relevant in the SIEF or in a voluntary industry consortium. Vertical collaboration and communication is relevant regarding the information on use and exposure up and down the supply chain. Both types of co-operation were supposed to be developed by the Manufacturers/Importers (M/Is) and Downstream Users (DUs) themselves.

The Commission Services provided an e-mail-based help desk for the interpretation of the REACH proposal in the context of SPORT.

1.1.2 Objectives of SPORT

SPORT has tested certain elements of the REACH system (around registration) from the perspective of Manufacturers, Importers, Competent Authorities and to a more limited degree of Downstream Users, in a free-flow approach. The interpretation of the SPORT results has to duly take the objectives of SPORT as well as its scope into account, which were both agreed upon by the involved partners. The objectives were:

² WWF, EEB, TUTB/ETUC, ECEAE, the European Network of Chemicals Regions and the OECD were invited as observers.

³ **free-flow** means: Manufacturers, Importers and Downstream Users on the one hand as well as Competent Authorities on the other hand, tried to implement the REACH requirements without further technical guidance going beyond the guidance notes already part of Annex I to IX.

- To provide input to and to use the (intermediate) results of REACH Implementation Projects (RIPs), in order to try out as well as to feed into the guidance and tools being developed; to identify additional requirements for guidance, guidelines, tools, methodologies, approaches beyond those already incorporated in the Commission's Interim Strategy work plan;
- To test and to establish the workability of pre-registration, registration and dossier evaluation steps in REACH, i.e. organisational set-up and requirements (of REACH);
- Where workability problems are being encountered in SPORT, to identify solutions to these problems and find support of the partners;
- Where the REACH proposal does not specify how certain parts of REACH work or have to be carried out in practice, to make assumptions and test these;
- To improve the understanding of the REACH processes of all participants.

1.1.3 Scope of SPORT

The intended scope of SPORT was to cover Titles I to V and Title VI - except Chapter 3 - of the Commission's REACH proposal, i.e.:

- Pre-registration, including the formation of a Substance Information Exchange Forum (SIEF) if applicable;
- Generation of a complete registration dossier by industry (in accordance with Art. 9 of the REACH proposal). This involves the inclusion of any "identified uses" from Downstream Users (DUs) and of information flows up the supply chain;
- Completeness check by the Commission Service simulating the role of the Agency;
- Examination of testing proposal and examination of registration dossier for compliance with the regulatory purpose of REACH ("dossier evaluation") by one or more EU Member State Competent Authorities;
- Communication of the relevant information down the supply chain and feedback from Downstream Users.

Any first attempt at putting a regulatory structure into practice will encounter certain constraints and shortcomings. In the case of SPORT for example:

- It was not possible to test the formation of SIEFs as not all M/Is of a substance participated in the project, and as the electronic tools were not available yet.
- Communication of relevant information down the supply chain (distribution of an extended Safety Data Sheet (eSDS)) could not be tested as thoroughly as intended because of lack of time and methodological problems.
- Since the most relevant RIPs had started only together with or later than SPORT, testing the concepts developed in the RIPs was not possible, but SPORT results will be fed into the RIP process.

1.1.4 “Workability” in the context of SPORT

SPORT confirmed that workability is not a static, inherent characteristic of REACH, it rather characterises the ability of companies and authorities to fulfil their duties (or tasks) as laid down in the legislative proposal. This ability is determined by

- The clarity of the legal text, which facilitates the actors’ understanding and correct interpretation of the REACH system and its requirements;
- The available tools, methods and procedures to fulfil the duties;
- The timeframe to reach compliance;
- The resources (manpower, skills, expertise, financing) available to operate the system;
- The readiness of actors to change roles and attitudes.

During the SPORT exercise a number of questions related to the understanding of the draft legal text occurred. Some could be clarified in the sub-projects, some were clarified by the Commission’s helpdesk, some remained open till the end of the practical work in the eight sub-projects. The process of developing a common understanding of the REACH system turned out to be a time-consuming exercise. This experience can be interpreted from different perspectives:

- The paradigm shift connected with the REACH system requires time and resources for mind-setting processes.
- The proposed regulation provides the opportunity to develop tailor-made solutions in a diverse chemicals market. The development of such solutions is an investment of time and resources that may pay off in the end.
- The legal proposal provides much room for interpretation causing high transaction costs for finding a common understanding.
- The legal proposal is demanding, even though anticipating that learning curves will occur and standard routines will be developed.
- The proposed system is very complicated and will not be workable in practice.

All these interpretations of the SPORT experience are found among the participants in SPORT.

1.1.5 Means to facilitate workability

SPORT was carried out at a time when the REACH framework was still under development and thus not complete. Only the draft legal text existed, but technical guidance and tools for practical implementation were not yet available. Testing certain elements of the REACH system at this stage consequently led to the finding that:

- It is difficult to understand and implement the system as it stands (based on the legal text alone);

- Practical guidance, all necessary tools and an IT system have to be in place before REACH starts and companies and authorities have to deliver.

SPORT shows that in several areas, guidance, tools, Agency and/or Member State help-desks and learning curves can improve the workability of REACH, but it also shows that this alone may be not enough. Other types of action may be needed as well to make the system work, e.g.

- Adjustments and clarifications in the legal text (including the annexes);
- Adjustments of internal structure within companies and authorities (communication, co-operation, workflows);
- Processes which lead to a change in mindsets and the current way of working;
- Further assistance to less experienced registrants and Downstream Users.

1.2 Recommendations by the three strategic partners

The SPORT experience leads to a number of recommendations for the further development and implementation of the REACH system. To identify the most suitable form of action with a view to implementing the recommendation is left to consideration in the follow-up of SPORT. Such action may include adjustments in the legal text, development of further guidance and tools, adjustment of internal processes in industry and authorities, and organisation of mind-setting processes.

Chapter 3 gives a complete account of the workability areas and related recommendations as they were developed by the participants in the eight sub-projects and summarised by the independent consultant.

The following recommendations are supported by all three partners. However, these proposals should be understood as options, not as the only possible solutions.

1.2.1 Setting up and running co-operation among registrants

Develop working procedures that facilitate co-operation between companies

The SPORT experience suggests that companies not obliged to register or only obliged to register at a later stage, such as smaller volume Manufacturers or Downstream Users hold data from testing vertebrate animals. These would however not be accessible to registrants under the REACH mechanisms as currently foreseen. Duplication of vertebrate tests could be a consequence. One way of resolving the problem is for REACH to also support data sharing (related to tests on vertebrate animals) with such companies.

SPORT demonstrated that - from a single company's perspective - the administrative burdens of hazard data sharing can be higher than the potential cost savings related to testing. Experience showed that forming consortia is not always the most cost efficient way to share data.

During SPORT, companies were very sensitive about CBI and compliance with competition law. To make work in consortia easier, guidance from DG Competition regarding the possible application of competition law as regards REACH would be helpful.

Also, a standard template for consortia agreement, cost sharing and CBI matters by industry would help to avoid multiple discussion of the same matter.

Establish mechanisms which support grouping of substances

REACH in principal supports the grouping of substances for the purpose of read-across from substance to substance (if there is a documented rationale for that). However, the SPORT experience shows that specific tools and mechanisms are needed to bring the owners of the relevant information into contact with each other. One solution could be a pre-registration mechanism that facilitates potential registrants for a group of substances getting in contact with each other. This however includes guidance on which criteria to apply in order to identify substances that would qualify for a group. Considering existing OECD work could be useful.

Also, clarification is required on how to register groups or categories of substances. Furthermore, a suitable IUCLID 5 version should support this and include facilities that enable registration of groups with easy read-across, cross-referencing mechanisms and a one-off information entry for that. On the other hand, the grouping of substances must not provide free-riding opportunities. This can for example be achieved by the “letter of access mechanism” as foreseen by REACH.

1.2.2 Sharing of responsibility between M/Is and DUs

Clarity on new roles and responsibilities

The implication of the “identified use” and “conditions of use” concepts of REACH for liability and accountability was a point of discussion in SPORT.

The respective rights and duties must be clear to Manufacturers, Importers and Downstream Users. This is a pre-requisite in order to operate the system. For example: Who has the responsibility to carry out the safety assessment for a particular use and related exposure, and who has to ensure that the appropriate risk reduction measures are applied by DUs? Also, the conditions under which a registrant can choose not to cover a use made known to him by a customer need to be spelled out. And if so, whether it is the duty of the Manufacturer to stop selling the substance for such use, and/or to communicate the use as advised against in the Safety Data Sheet.

The SPORT experience points to the need to overcome “language” barriers of various kinds (e.g. national languages, expert jargon) in the supply chain in order to avoid misunderstandings on who in the chain is responsible, liable or accountable for what under REACH.

1.2.3 Involvement of customers in the registration process

During SPORT, some of the registrants' customers or distributors were not willing or not able to provide information on their own or their customers' uses and the related exposure. This is particularly an issue when the registrant is at the same time the competitor of his customer or when he supplies the competitors of his customer. SPORT also identified that the risk assessors in a registrant's company sometimes had difficulties in setting up communication with other departments that are closer to the customer. In addition, there was uncertainty on the type of information and on the level of detail needed to describe the conditions of safe use and hence on what to ask the customer.

This SPORT experience leads to a number of recommendations:

Establishing working procedures for communication with DUs

The information exchange on "identified uses" and "conditions of use" (including risk management measures) should largely take place before registration. In order to avoid multiple bilateral communication between suppliers and customers on the same content, the setting up of sector-to-sector-communication processes and of information exchange platforms could be useful. Standard tools are an important pre-requisite for obtaining the necessary information from Downstream Users as well as a standard "language" with regard to description of uses and conditions of use. However, these tools also need to provide for sufficient flexibility in order to address specific exposure issues or uncertainties.

Workable exposure scenarios

Generic standard exposure scenarios (including standard risk management packages) for uses should be developed in order to help the customer not to disclose business details on use conditions to his supplier if he wants to keep them confidential.

A database should be set up for standard risk management measures, which are suitable to sufficiently control the risks of different substances in a range of uses.

Standard descriptions for "identified uses" and standard unit operations (handling and processing) should be developed and linked to standard exposure scenarios. These can be generic or more specific.

1.2.4 Registration dossier and safety assessment

Use of existing information

REACH suggests to develop the registration dossier by starting with existing and available information, and to then evaluate these data against the standard information requirements. This includes information derived from QSAR models or read-across from related substances. If the standard information requirements are adapted, a justification should be given as to why the information nevertheless serves the purpose. There is a need for common guidance addressed to industry and authorities on how to determine

the sufficient level of justification if standard information requirements are adapted in a registration dossier.

Clarification and guidance is needed for selecting between available information (such as a number of studies for the same endpoint) for hazard assessment. This also applies to presenting this information (summaries and robust study summaries) as well as to demonstrating the need for further information (testing proposal) in the dossier. In particular, guidance is needed for the use of non-GLP data and non-standard studies.

Annex I of REACH provides the possibility to use the CSR for one substance for another substance (with similar use and exposure patterns as well as with a comparable hazard and fate profile). Guidance is needed on when and how one CSR can apply to more than one substance.

Tools

The new technical guidance(s) on chemicals safety assessment (CSA) should be tiered. It should allow for iterative work, e.g. through generic conservative assessment at the lower tier (e.g. use and exposure categories). The guidance should be clear enough to be workable for persons who are not specialised in risk assessment. It should provide flexibility for special cases (use by experts) while making the system simple for standard cases (and non-experts).

There is a need to further develop IT-based modules for exposure estimation and risk characterisation.

QSARs should be further developed as a tool in hazard assessment. It could be an option to provide a list of validated and accepted QSARs (including the domain where they are valid) in the technical guidance.

The CSA should be targeted at those types of hazard for which the substance has been identified as being dangerous.

Current substance assessments

SPORT identified that some Member States made decisions on SIDS based data sets which were inconsistent with the evaluation of the OECD. This situation should be avoided.

Information from assessments at OECD or EU level should be regarded as accepted under REACH without further evaluation, unless new information has become available. Endpoints not covered within OECD SIDS (e.g. sensitisation) are to be processed in the way requested under REACH. The registration of a substance with a completed EU risk assessment and risk management strategy should not undergo dossier evaluation and should be accepted without reformatting existing documents, unless the conclusions have been changed. However, information related to new requirements should be added (e.g. SDS, exposure scenarios and DNELs).

1.2.5 Dossier compilation – technical issues

Setting up a uniform registration data system

For all elements of the system the right balance between harmonisation/standardisation and flexibility has to be found. IT systems and tools should be tested and validated before REACH enters into force. Full upward compatibility with IUCLID 4 is needed.

Formats and procedures for preparing the registration dossier (including a powerful IT support) and procedures for dossier evaluation should be harmonised and guidance should be provided. The formats should support registration by consortia as well as dossiers covering groups of substances based on read-across. The system should support a quick completeness (and compliance) check prior to submission by the registrant.

The various legal entities of one company should have the possibility to submit one registration dossier for the same substance.

Standardisation/harmonisation in general

Standardisation of "language", phrases, IT suitability, tools and templates should be facilitated. In particular, information flow on risk management and conditions of use in the supply chain needs a large degree of standardisation. Standard IT-readable formats for SDS and phrases (facilitating the translation into national languages) are needed as well.

1.2.6 Compliance – approaches and ambition

The automated completeness check of the dossier should allow (as far as technically possible) checking whether the information in the electronic dossier is relevant or not for the purpose of registration. This is important to identify fields with information that is not relevant for the registration purpose and hence cannot satisfy the completeness requirements.

During SPORT it became obvious that most of the participants were uncertain on how to solve a possible dispute between the registrant and the Member State Authorities. They were also uncertain about the legal consequences of a non-compliant dossier, or the consequences of missing the deadline to respond to a draft Member State decision or of being in disagreement about a testing proposal. Clarity on consequences will contribute to better understanding of the whole system.

A mind-setting process on the function of the compliance check in the REACH system is needed in order to develop a common understanding across Europe and to facilitate the paradigm shift envisaged.

Criteria and procedures for priority setting related to compliance checks should be developed in order to target the evaluation at those areas (substances, markets, uses, actors) where the registration does not demonstrate adequate control of risks.

Member States conducting evaluation should have a standard template available for their responses to testing proposals or in order to communicate the result of their dossier evaluation.

1.2.7 Information supplied to DUs

SPORT did not manage to test the information supply to the customer and his response (Task 7 of SPORT) as thoroughly as intended. A few workability issues were identified (see Chapter 3.2.7) but no recommendations were made.

1.2.8 Use of transported intermediates under contractual control

When considering the requirements of Article 16 under SPORT, the registrants found it practically and legally impossible to monitor their customers with a view to ensuring their compliance with the conditions set out in Article 16.4 (a) - (g). A system of contractual commitments by customers is being proposed as an alternative.

1.2.9 Preparations

SPORT showed that Manufacturers of substances which are exclusively sold in preparations may hold testing data for the preparations rather than the single substance. Guidance is needed on how to make use of such data for the registration of the single substances under REACH.

When preparing a Safety Data Sheet for such a substance, the registrant was confronted with the question of how to work out the exposure scenario for the preparation, ensuring safe use for all its components. One option is to determine the conditions of safe use in such cases, referring to the components having the highest hazard and exposure potential (e.g. based on physical-chemical properties). This would be based on the assumption that no other more stringent protective measures would be needed, taking the other components into account.

1.2.10 Registration of complex natural substances

There is a wide variability in the composition of natural substances, e.g. essential oils. Also, the composition of crude and marketed essential oils differs. Guidance and clarification is needed on how to determine the “substance identity” of substances occurring in nature and how to carry out testing and hazard assessment for these substances. This issue should be addressed in the RIPs accordingly.

1.2.11 Consistency with other legal requirements

REACH requires Manufacturers and Importers to derive a DNEL and to carry out an exposure assessment as well as a risk characterisation related to workers health. At the

same time, the Manufacturers and Downstream Users have to carry out a risk assessment under legislation following the EU Chemical Agents Directive (98/24/EEC), including keeping exposure below the OELs, if assigned. SPORT participants felt that duplication of work or even conflicting requirements should be avoided and that guidance is needed on how to use the potential synergy between both systems in practise.

1.2.12 Available resources

For those companies familiar with current legislation on *Existing Substances* and/or the notification of *New Substances* it was easier to prepare a registration, whereas for companies without this experience the risk assessment methodology as such is a challenge. Based on the SPORT experience, it can be furthermore expected that even those companies familiar with comprehensive risk assessment do not necessarily have the capacity (resources and skills) to operate a system with a much larger throughput of substances per unit of time. Simplification of processes is needed, especially in order to match the expertise as well as the accessible resources of SMEs. Early preparation and adjustment of internal working procedures is necessary as well.

It was also a common concern of the registrants involved in SPORT that the Downstream Users are not yet sufficiently aware of their duties under REACH and the possible consequences for their business. More active information for Downstream Users is needed and guidance on how to prepare for the REACH system.

2 Strategy to test REACH

2.1 The testing approach

2.1.1 Tested elements of REACH

SPORT focussed on the registration requirements of REACH, including dossier evaluation and feedback of Downstream Users in response to the REACH Safety Data Sheet. Seven tasks were carried out in each SPORT sub-project:

- (1) Achieving a common understanding in the sub-project working group and defining the starting point of SPORT;
- (2) Preparation for pre-registration;
- (3) Pre-registration (including simulation of the Substance Information Exchange Forum [SIEF]), and subsequent work in voluntary industry consortia;
- (4) Compilation of a complete registration dossier (including CSR) and an extended Safety Data Sheet; involvement of companies using the substance at formulators' level or further down the supply chain;
- (5) Completeness check by the "Agency" (ECB);
- (6) Dossier evaluation (compliance check), evaluation of test proposals (by one or two Member States) and feedback on the appropriateness of the CSR and the extended Safety Data Sheet;
- (7) Feedback on the extended Safety Data Sheet by Downstream Users.

The timing of the seven tasks and the involvement of the different SPORT participants is visualised in figure 1.

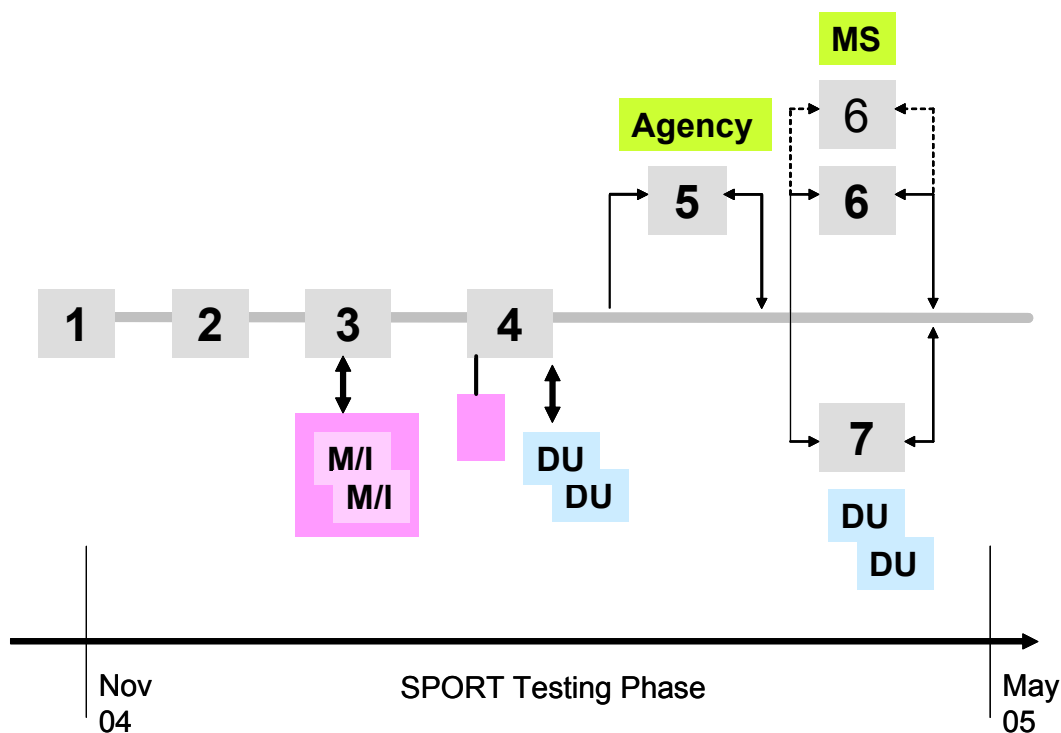


Figure 1: Tasks carried out in the SPORT testing phase
 (M/I = Manufacturer or Importer; DU = Downstream User)

2.1.2 The eight cases

The figures 2a-c provide an overview on the eight cases which formed the basis of SPORT. Figure 2a contains information on basic case design in SPORT. Figure 2b reflects the information based on which the cases were initially selected, and figure 2c provides a brief summary on the selection arguments. In brief, the cases had the following characteristics:

- Arkema: High production volume (HPV) transported intermediate with a second low production volume (LPV) use (marketed intermediate); second use not subject to registration in SPORT;
- BASF: A group of four HPV and LPV solvents (pentanols) for intermediate, industrial, professional and consumer use; professional and consumer use not subject to registration in SPORT;
- CHT: LPV substance used in textile finishing chemicals becoming part of the finished textile product;
- Clariant: HPV transported intermediate with a second LPV use (industrial);
- Cognis: Group of 24 HPV and LPV tensides (alkyl sulphates) for industrial, professional and consumer use; to be registered in a consortium;

- Dow: Group of four HPV and LPV solvents (propylene glycol n-butyl ethers) for industrial, professional and consumer use;
- EFFA: Group of 15 HPV and LPV fragrance components and essential oils for consumer use; to be registered by an informal consortium;
- Fuji: LPV photographic chemical becoming part of the film-material; to be registered by an informal consortium.

Substance Name ⁴	Methane sulphonyl chloride	Category of pentanols	Fatty acid - C18-condensate	o-Chlorobenzaldehyde	Category of alkyl sulphates	Category of propylene glycol n-butyl ethers	Category of linalool (esters), lavender oil	Disodium 4,5-dihydroxybenzene-1,3-disulphonate (Tiron)
Lead company	Arkema	BASF	CHT	Clariant	Cognis	Dow	EFFA/IFF	Fuji
Full title	Arkema	BASF AG	CHT R. Beitlich GmbH	Clariant GmbH	Cognis Deutschland GmbH & Co. KG	Dow Europe GmbH	European Fragrance & Flavour Association /IFF	Fuji Photo Film BV
Place	Paris (FR)	Ludwigshafen (DE)	Tübingen (DE)	Sulzbach (DE)	Düsseldorf (DE)	Horgen (CH)	Brussels (BE)	Tilburg (NL)
Lead MS & Institutes	France Ministry of Ecology, INRS	Germany BAuA	Austria UBA	Netherlands Ministry of Social Affairs	Italy National Health Institute	Sweden Kemi France Ministry of Ecology	Netherlands RIVM France Ministry of Ecology	Finland SYKE Slovak Republic CCSP
Shadow MS	-	Poland	Lithuania, Cyprus	-	Greece	-	Malta	Latvia
Facilitator	CIT (FR)	UMCO (DE)	Öko-Institut (DE)	FOBIG (DE)	DHI (DK)	TNO (NL)	TNO (NL)	RPA (UK)
Use types registered	Intermediate	Intermediate Industrial	Industrial	Intermediate Industrial	Dispersive	Dispersive	Dispersive	Industrial
Volume	HPV	HPV and < 1,000 t/a	< 100 t/a	HPV	HPV and < 1,000 t/a	HPV and < 1,000 t/a	HPV and < 100 t	< 100 t
Report agreed at final meeting	19.04.05	18.04.05	20.04.05	21.04.05	20.04.05	19.04.05	26.04.05	21.04.05

Figure 2a: Overview on the eight cases in SPORT

⁴ see Annex 1 for CAS numbers and further information

Criteria in selecting the SPORT cases	Arkema	BASF	Clariant	CHT	Cognis	Dow	EFFA	Fuji
Intermediate	Yes	Yes	Yes	No	No	No	No	Yes
Industrial use	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Professional use	No	Yes	No	No	Yes	Yes	Yes	?
Consumer use	No	Yes	No	No	Yes	Yes	Yes	No
Specific use in preparations for consumers	?	Yes	No	No	Yes	Yes	Yes	?
The substance is subject to other EU legislation	No	No	No	No	Yes	No	Yes	No
Use resulting in inclusion into or onto a matrix	No	No	No	yes	some uses	No	No	Yes
Substance data are readily available, no (significant) data gaps	No	?	No	?	?	Yes	No	No
Information requirements will be fulfilled with derived data (QSAR) and/or by reading across.	Yes	Yes	Yes	?	Yes	Yes	Yes	Yes
Substance belongs to a group of chemicals (joint risk assessment could be possible)	No	Yes	No	No	Yes	?	?	No
The substance could be released from articles	unlikely	unlikely	No	?	?	?	?	?
The substance is being toll manufactured	?	?	No	No	?	?	?	No
The substance is also marketed via Distributors	?	Yes	?	?	Yes	Yes	?	No
The substance(s) has been assessed in other national, regional or international programmes	No	No	No	No	Yes	Yes	Yes	No

Figure 2b: Information basis for the selection of SPORT cases

Company	Reasons for selection as a SPORT priority (learning potential)
Arkema	<ul style="list-style-type: none"> ▪ Transported intermediate ▪ coverage of EU member states
BASF	<ul style="list-style-type: none"> ▪ category approach, read-across to be tried out ▪ marketed grades are mixtures of isomers/product streams ▪ very broad supply chain and use pattern ▪ significant volumes are imported
Clariant	<ul style="list-style-type: none"> ▪ substance has a dual use: Intermediate and minor direct use ▪ application of Annex IX to be tested
CHT	<ul style="list-style-type: none"> ▪ registrant is a smaller chemicals manufacturer ▪ registration in low tonnage band

Company	Reasons for selection as a SPORT priority (learning potential)
Cognis	<ul style="list-style-type: none"> ▪ wide dispersive use ▪ broad and deep supply chain ▪ both large and niche applications ▪ partly exempted (use in cosmetics) ▪ category approach for hazard data to be tried out (read-across and (Q)SAR) ▪ grouping for risk assessment and CSR (a HERA for a group of alkyl sulphates has been completed) ▪ targeted risk assessment to be tried out ▪ substance ID is an issue as well as the usefulness of CAS/EINECS numbers ▪ sodium alkyl sulphate was subject to the NRW pilot trial (focused on a single niche application) ▪ large number of producers and importers (not reflected in the ECB database) ▪ very strong interest from a DU organisation (plaster board manufacturers)
Dow	<ul style="list-style-type: none"> ▪ read across and category approach to be tried out ▪ OECD initial hazard assessment completed; sponsor US; low priority concluded; assessed in a category ▪ substance ID issues (different isomeric mixtures from different suppliers) ▪ broad and partly deep supply chain ▪ wide dispersive use, incl. coatings, detergents ▪ possibly HERA RA approach for the detergent applications ▪ possibility to apply the ECETOC Targeted RA approach to workers and consumer use scenarios
EFFA	<ul style="list-style-type: none"> ▪ the substance is a UVCB (unknown and variable composition, complex reaction products, or biological materials); ▪ certain components of lavender oil have undergone an OECD initial hazard assessment ▪ certain uses are covered by other legislation (food, cosmetics) ▪ wide dispersive use
Fuji	<ul style="list-style-type: none"> ▪ substance being imported by a non-chemical company with lesser experience in chemicals management.

Figure 2c: Selection arguments for the SPORT cases

2.1.3 Substances, companies, markets

29 potential **registrants**⁵ – 16 of which were substance Manufacturers - were involved in the eight sub-projects. Most of the registrants were very large companies with the exception of the Manufacturer of textile finishing chemicals (about 500 employees) and the Manufacturers of essential oils in the fragrance case. SPORT covered different **types of substances** or groups of substances:

- Two companies each registered a group of substances mainly used i) as an intermediate or as a **solvent** in industrial processes (4 pentanols) and ii) as a solvent in industrial processes and in preparations in wide disperse use (4 propylene glycol n-butyl ethers). Both groups contained substances at a production level above 1,000 tons and between 100 and 1,000 tons per year (Dow and BASF case).

⁵ 13 being part of the fragrance consortium in SPORT (EFFA case)

- A group of six large manufacturers forming a consortium registered a group of 24 alkyl sulphates being largely used as **surfactants** (Cognis case).
- Two large chemicals manufacturers each registered a **transported intermediate** at a tonnage level above 1,000 t/a (Arkema and Clariant case).
 - During the pre-registration phase, Clariant co-operated with two potential partners with regard to information exchange on potential data sharing (SIEF). This manufacturer also registered a second application of the substance for industrial use in a tonnage band below 100 tons.
 - Arkema imports the registered intermediate and did not co-operate with other companies during SPORT. Here also, a second use was identified. However, it was not registered during the SPORT exercise.
- An informal consortium of two large substance Manufacturers, two representatives of **essential oil** Manufacturers, seven fragrance houses and two Manufacturers of cosmetics and household products, registered a group of ten single substances (linalool and linalyl derivatives) as well as five complex substances (essential oils). All these substances are used in fragrances for cosmetics, cleaners and other household products (EFFA case).
- An informal consortium of one very small substance Manufacturer and two large importing industrial users in the **photographic** industry registered one substance in a tonnage band between 10 and 100 t/a. This included the import of the substance by the industrial user (Fuji case).
- A medium-sized manufacturer of **textile finishing chemicals** registered one substance manufactured for the use in textile finishing preparations marketed by its own company (CHT case).

The following groups of **Downstream Users** were actively involved in providing information for the registration dossiers:

- 15 formulators, most of them located in the two cases where substances are supplied into wide disperse use (Dow solvents and EFFA fragrances);
- Five Distributors, four of them in the alkyl sulphate case (Cognis) and one in the solvent case (Dow);
- Four users of final preparations or substances in industrial processing related to photographic industry (three in the Fuji case) and related to textile finishing industry (one in the CHT case).

In addition to the direct co-operation in the sub-project, about 550 questionnaires (450 in the Cognis case) were sent out to customers in order to collect information on uses and conditions of use, on exposure situation and on risk management measures. The response rate of the approached companies was between 5% (Cognis) and nearly full response (Dow, EFFA), with a trend to better response rates and more useful information when approaching a lower number of selected customers in a more targeted way.

After submitting the registration dossier, in six of the eight sub-projects Safety Data Sheets were sent out to customers (25 in total) for feedback. 14 responses were received, most of them related to the fragrance case (EFFA), the solvent case (Dow) and one of the intermediate cases (Clariant).

Overall, the **SPORT** exercise did not cover certain types of companies, levels in the supply chain or markets, for example:

- The majority of companies volunteering to pilot REACH were manufacturers of large volumes and experienced in substance assessment programmes at EU or OECD level.
- No SMEs according to the common EU definition (less than 250 employees and less than 50 million EURO annual turnover) were directly involved in the SPORT exercise at the level of registrants. However, in three cases companies with very little or no experience in risk assessment (other than risk assessment for worker protection legislation) were confronted with the task of compiling a registration dossier.
- Only four industrial users of chemicals were involved in the SPORT exercise (three of them in the photographic sector, one in textile finishing). In this context, "industrial user of finished chemicals" means industrial installations other than formulators or users of intermediates. Hence, the exposure- and risk-management-related elements in the REACH registration have only partly been tested. The SPORT exercise was mainly focussed on the immediate Downstream Users (customers of the registrants).

Sub-project	Arkema	BASF	CHT	Clariant	Cognis	Dow	EFFA	Fuji	Total
Substances	1	4	1	1	24	4	15	1	51
Potential Registrants	1	1	1	3	6	1	13	3	29
DU customers	0	0	1	cbi	0	4	9	1	15
Distributors	0	0	0	cbi	4	1	0	0	5
Final users of preparations	0	0	1	cbi	0	0	0	3	4
DU questionnaires sent out (task 4)	30	41	6	10	450	5	9	1	552
Responses (task4)	7	4	1	3	28	5	8	1	57
Safety Data Sheets sent out (task 7)	0	0	1	4	2	8	9	1	25
Responses (task 7)	0	0	1	4	0	4	4	1	14

Figure 3: Characteristic of sub-projects (substances and companies)

2.1.4 Boundaries and limitations of SPORT

SPORT tested parts of REACH that are key elements of the REACH registration process.

SPORT was not an impact assessment of REACH. Thus, it is not possible to predict impacts related to costs, markets, innovation, competitiveness, environment or health from the findings of SPORT.

SPORT focussed on processes, in particular the workability of the selected REACH mechanisms. The substances in the sub-projects were selected solely for the purpose of testing the selected REACH mechanisms. Substance evaluation (according to REACH Art. 43a to 46) was not a SPORT task.

All players took part on a voluntary basis. On this basis, the strategic partners and the lead companies tried to convince certain other industrial partners to also join the exercise.

Following the high level rules, the facilitators focussed on the observation and analysis and therefore limited their input to the sub-project work to a minimum necessary for the clarification of the tasks. They did not give specific expert advice on how to fulfil REACH requirements. Only if a sub-project was at risk of getting stuck or losing track without external input, more expert advice was supplied to the participants, following the SPORT process rules.

The test had a number of limitations that should be kept in mind when interpreting the results:

- Data-sharing based on the SIEF platform could not really be tried out since a) partners knew each other in advance and b) other M/Is did not participate.
- SPORT task number 7 (Downstream User applies the information received from his supplier) was carried out to a lesser extent than envisaged.
- Registration of substances by SMEs could not be fully explored within SPORT.
- Companies and authorities concentrated on one substance or group of substances in SPORT. Hence parallel work on various substances as it will occur under REACH was not tested. On the other hand, the timeframe for dossier evaluation in SPORT was much shorter than is foreseen in REACH.
- For SPORT, no guidance and IT systems were available to facilitate dossier compilation. These elements of the REACH system are only under development now.
- SPORT was a voluntary exercise and hence no participant could be forced to provide particular information or to fulfil certain other duties foreseen in REACH. This may have had an impact for example on the flow of information up the chain under SPORT.

2.2 Facts and figures of findings

The facts and figures presented in this chapter have been compiled from different sub-project reports. Please note that all these cases have their particularities and that there are some uncertainties around the “hard figures” derived by simple counting operations. Figure 4 provides an overview on some of the key figures related to the data sharing approach, the dossier compilation, the dossier evaluation and the completeness check.

Sub-project	Arkema	BASF	CHT	Clariant	Cognis	Dow	EFFA	Fuji	Total
SIEF	No	Informal	No	Informal	Informal	No	Informal	Informal	5
Consortia	No	No	No	No	Yes	No	Informal	Informal	1+2
Group of substances	No	Yes	No	No	Yes	Yes	Yes	No	4
OECD assessment used	No	No	No	No	No	Yes	Yes	No	2
Annex V + VI info missing	No	No	Yes	Yes	No	Yes	Yes	Yes	5
ES in SDS	No	No	Yes	Yes	No	Yes	No	No	3
PNEC and DNEL	No	Yes	No	No	Yes	No	No	Yes	2
Dossier complete	Yes	Yes	(Yes)	No	(Yes)	Yes	(Yes)	(No)	6
Grouping inconsistent	n.a.	No	n.a.	n.a.	Yes	No	Yes	n.a.	2 of 4
Testing proposal missing	n.a.	Yes	n.a.	n.a.	Yes	Yes	Yes	n.a.	4 of 4

Figure 4: Overview on key figures related to the seven SPORT tasks (n.a.: not applicable).

2.2.1 Pre-registration, SIEF and consortia

REACH requires companies to share information, related to (eco)toxicological properties of substances (derived from testing of vertebrate animals) after pre-registration via the Substance Information Exchange Forum (SIEF). The proposal might also facilitate the exchange of non-vertebrate animal data on a voluntary basis by the same mechanism. In addition, REACH includes a number of mechanisms, such as voluntary consortia formation, that may facilitate co-operation among registrants in general with a view to fulfilling their duties related to registration, such as agreement on a single data package, classification and labelling as well as Chemical Safety Assessment for a substance.

In **SPORT**, the *Substance Information Exchange Forum (SIEF)* could not really be tested since i) not all M/I of a substance participated in SPORT, and ii) those potential partners involved in SPORT knew each other beforehand. However, most companies prepared the pre-registration document for submission to the ECB (acting as the Agency in SPORT).

The eight sub-projects within SPORT chose different strategies to organise data sharing and co-operation on a registration dossier:

- Three registrants neither tested the SIEF mechanisms, nor other forms of sharing vertebrate studies, nor co-operation for submission of the registration dossier (Arkema, Dow, CHT case).
- In one sub-project, setting up a formal consortium was tried out. This included stock-taking on available information held by the partners (Cognis case).
- Two companies started from an existing, informal network of companies, hence the SIEF was not needed to exchange information. During SPORT, the existing informal network was used for information exchange and for working on a joint dossier (Fuji and EFFA case).
- One company discussed data sharing with two other companies producing and/or marketing the same substance. This discussion was close to testing the SIEF (Clariant case).

2.2.2 The registration dossier

REACH is designed in a way that standard information requirements (driven by tonnage bands) are laid down in several annexes to the legal text (Annexes IV to VIII) and that exemptions, adaptation or waiving of these requirements have to be justified by the registrant. The guidance note on fulfilment of Article 9 and Annex IV to IX suggests making use of all kinds of existing information on substance properties before new tests are carried out (also reiterated in each of the introductions to Annex V to VIII).

In **SPORT**, two registrants used information from existing OECD substance assessments (SIDS). These were the two propylene glycol n-butyl ethers (PnB + DPnB) in the Dow case as well as linalool and linalyl acetate in the EFFA case. One registrant used the EU risk assessment on musk compounds to obtain guidance on how to carry out the risk assessment for the fragrance compounds under SPORT.

In order to make use of existing information three companies used QSAR models (EFFA, Fuji, CHT case). Furthermore, in five cases read-across was applied (Dow, BASF, Cognis, EFFA and CHT).

In none of the eight cases a test proposal related to Annex VII or VIII was made. However, five registrants included testing proposals related to Annex V and VI (Clariant, Dow, EFFA, CHT, Fuji case.)

In SPORT a number of instruments and approaches to exposure assessment and risk characterisation were also tried out, which industry regarded as new and being a contribution to increase the efficiency of the REACH system:

- The “targeted risk assessment” as proposed by ECETOC was used in three of the sub-projects (Fuji, EFFA, Dow).
- Targeting exposure assessment and risk characterisation to the compartment for which hazardous properties have been found was tried out in one sub-project (Dow).

- The “use and exposure category” approach as proposed by the German VCI was tested in one sub-project (Cognis), leading to an exposure matrix in the annex to the SDS.
- A data matrix approach to communicate the hazard data of a group of substances was applied in 2 sub-projects (Fuji and Cognis) as an alternative to single substance data files.

Apart from the instruments for hazard and exposure assessment, in two cases (BASF and Dow) industry tried to follow the rationales which had been prepared for the OECD/ICCA documents (robust study summary reports, grouping, exposure categorisation, identification of further work).

Further information on these approaches can be found in the sub-project reports.

2.2.3 Completeness check

The aim of the completeness check under **REACH** is to conduct an automated check of the completeness of the submitted dossiers. Upon submission, the registrant receives a registration number and a registration date from the Agency. In case of a non-complete dossier, the Agency asks the registrant for additional information within a given deadline. The Agency will reject the registration if the registrant fails to complete the dossier within this deadline. The Agency communicates the result of the completeness check to the relevant Member State including any additional information submitted by the registrant.

The completeness check is foreseen to be an automated procedure as a facility in the IUCLID 5 software. Thus the registrant can check before submission whether the dossier will be regarded as complete.

The completeness check does not involve an evaluation of the submitted information and includes the following steps:

- Check of the existence of the main dossier elements;
- Check of the existence of the endpoints required at the registered tonnage level;
- Check of the presence of data or statements for each endpoint, i.e. derogation or waiving statement, read-across, letter of access to relevant reference or testing proposal.

The completeness check in **SPORT** is different from a situation under REACH regarding the following points:

- In SPORT, it was agreed that in order to minimise the copying of information from existing documentation to the registration template, it was allowed to make reference to attached documents in the data fields. Thus, any reference given to an attached document was accepted as valid information - provided that the document referred to included relevant studies. This procedure may include an element of interpretation where the reference does not point to a specific study but to an attached file in general.

- According to an agreement in SPORT, the registrants were allowed to exclude specific parts of the registration, e.g. due to lack of data or time constraints. These parts were excluded from the completeness check.
- Use of read-across was assumed for registration of groups of substances even if this was not justified or indicated at the individual endpoints.
- Testing proposals under REACH cannot include information requirements according to Annex V and VI as this information should be included through registration. In SPORT, proposals for testing of endpoints pertaining to these Annexes were, however, accepted.

The main results of the completeness check under SPORT are:

- Three dossiers were regarded as complete (Arkema, BASF, Dow case).
- Three dossiers were accepted as complete with minor gaps in information (CHT, Cognis and EFFA case), although the ECB indicated some difficulties in identifying appropriate waiving and read-across statements in the EFFA case.
- One dossier was regarded as incomplete because the partners in the consortium did not submit individual registrations (specification of registrants' substance identity and substance use [Fuji case]).
- One dossier was regarded as incomplete since not compliant with the REACH requirements leading to major data gaps (Clariant case).

2.2.4 Dossier evaluation

The evaluation of the individual **REACH** registration dossier by the Competent Authority of the Member State includes two elements: i) the mandatory examination of testing proposals related to tests in Annexes VII and VIII, and ii) at the choice of a Member State (whether to and to which extent a dossier is evaluated), examination of compliance of the technical dossier with Article 9.1 a to i as well as the adaptation of standard information requirements of Annexes V to VIII.

In none of the **SPORT** cases did the Member State experts accept the dossier as being in compliance with the REACH requirements. The analysis of comments (see Annex 4) suggests that the following issues were the major reasons for non-compliance⁶ (starting with the most frequent issues):

- Information for endpoints on Annex V or VI was missing in five of the eight cases. Partly, the registrants proposed studies to close these information gaps, and Member States evaluated some of these proposals although not being their task in the REACH real life. In some of the cases the Member States indicated that waiving arguments were missing or they did not accept the waiving argument presented.

⁶ Comments on the CSR and the SDS other than those related to justification on adaptations of standard information are not included here.

- The group of substances addressed in the dossier(s) was considered not consistent in itself (chemistry or hazard profile of substances different) (EFFA, Cognis) or insufficiently justified (Dow) in three of the four “grouping cases”.
- In four cases the Member States indicated that the key studies were not identified in the dossier and/or that robust study summaries were missing.
- In four cases, the Member States highlighted that the justification for non-classification was not provided or they did not accept it (Dow, EFFA, Fuji, Arkema).
- In three cases the Member States indicated that submitting one dossier for a number of substances or for a number of registrants is not in line with REACH requirements (Dow, EFFA, Fuji case).
- No testing proposals were made related to information requirements on Annex VII and VIII. In four cases, the Member States did not accept the presented (or not presented) reasoning that testing related to Annex VII and VIII information is not needed (EFFA, BASF, Cognis, Dow).

2.2.5 Information to customers

REACH obliges suppliers of dangerous substances or preparations to communicate information generated during the REACH process to their customers. This information includes i) the „identified use(s)“ of a substance (relevant to the corresponding customers), ii) the corresponding conditions of use including measures to sufficiently control the risk (exposure scenario) and iii) a safe exposure level in part 8.1 of the SDS (based on DNEL/PNEC).

In six **SPORT** sub-projects Safety Data Sheets were sent out for feedback to 25 companies. In three of the sub-projects, the extended Safety Data Sheets did not contain an exposure scenario, and in four of the sub-projects they did not contain a DNEL or PNEC. No Safety Data Sheet contained both types of new information.

Responses were received from 14 Downstream Users in five sub-projects including a variety of views on the usefulness of the Safety Data Sheets. Two companies identified additional uses.

3 Reflection on SPORT experience

This section is based on the results of the Reflection Workshop held in Darmstadt on 19/20 May. In this workshop, the experience documented in the 8 sub-project reports and the solutions proposed in the final sub-project meetings were discussed among the SPORT participants.

The expert views expressed by the Member States' participants are without prejudice to the official opinions of their governments.

The Commission acted as (the only) observer in the sub-projects and the workshop, and it did not express an opinion on the recommendations at the workshop.

The proposed solutions were not tested in detail during SPORT for their impact on workability.

3.1 Workability

In the understanding of the participants at the Darmstadt Workshop, "workability" characterises the ability of companies and authorities to fulfil their duties as laid down in the legislative proposal (including its annexes) being determined by:

- The clarity of the legal text, facilitating the ability of actors to understand the REACH system and to correctly interpret the requirements;
- The available tools, methods and procedures to fulfil the duties;
- The timeframe to reach compliance;
- The resources (manpower, skills, cash) available to operate the system;
- The readiness of actors to change roles and attitudes.

Workability is not a static, inherent characteristic of REACH but depends on a number of dynamic drivers. Taking into account the SPORT experience (see chapter 3.2) such drivers are for example:

- The better the actors can understand the REACH system and correctly interpret its requirements the better the system will deliver.
- Resources available at company level depend on the market type and the competitive market position of the company. Suppliers and users of textile finishing chemicals, many of them SMEs, are for example exposed to intensive global competition in the textile and textile dye market. Up to now innovation has been closely related to the diversity of substances produced in relatively small amounts (e.g. 300 substances in a 500 person company). Also, large Manufacturers of speciality fine chemicals will have to manage a high number of low volume substances during the phase-in under REACH. Other companies, producing a limited number of bulk chemicals for the global market in large production sites are in a quite different position when implementing REACH.

- Tools, methods and guidance will become available in the future. Much depends on whether the development of skills in industry to carry out safety assessment will match with these tools when the system starts. Also, the skills of the authorities to evaluate a high number of dossiers in a relatively short time will be important. Many of the current tools and guidance for risk assessment have been developed for scientists or experts in regulatory toxicology. The purpose was to assess in depth a limited number of priority existing substances (under the Existing Substance Regulation 793/93) and/or a limited number of uses for newly notified substances. Compared to this, the system efficiency under REACH versus the performance under the current legislation needs to be largely increased to deliver⁷, assuming a rapidly increasing number of experienced experts is not likely to occur. Therefore the new tools, methods and guidance need to be understandable for a larger number of less experienced persons. Also, they must allow for decision making at a relatively low level of detail for the majority of substances and uses to be assessed.
- Learning curves in understanding and operating the REACH system will occur. The steepness of the learning curves will again depend on resources available to companies and authorities as well as on support launched by trade and industry associations or state agencies.
- Readiness and ability of companies to adapt to the new roles is largely driven by traditions in communication and co-operation with customers, suppliers, competitors and authorities and by concerns about the security of confidential business information. The more parties are involved the longer it will take to set up proper co-operation. The experience from SPORT indicates that existing networks of suppliers and customers built on personal relationships and trust provide an advantage compared to those clusters where informal networking has to be learned in view of REACH or remains impossible in general. Also the co-operation and structures within companies are crucial: Without close co-operation between the marketing and customer service departments, the health and safety staff, the product safety staff and the regulatory affairs departments it is difficult to fulfil the duties as laid down in the draft regulation.
- Readiness and ability of authorities to adapt to the new roles is largely driven by the current institutional set-up and the traditions in organising the work and using certain methods.
- The time needed for interactions in the market on the one hand and the various deadlines fixed in the legislative proposal on the other hand play a critical role in the system. This is related to synchronisation of information flows and the identification of potential co-operation partners (e.g. pre-registration deadlines and working with the SIEF). It is also related to the timeframes available to negotiate co-operation, to col-

⁷ 100 substances in 10 years assumed for the *EU Existing Substance Programme* and 3,000 substances per 10 years assumed for the notification of new substances.

lect and provide information and to respond to decisions of business partners and authorities.

3.2 Identified drivers of workability - recommended solutions

3.2.1 Setting up and running co-operation among registrants

REACH requires companies to share information related to the (eco)toxicological properties of substances derived from testing vertebrate animals during pre-registration via the *Substance Information Exchange Forum* (SIEF). The proposal may also facilitate the exchange of non-vertebrate animal data on a voluntary basis by the same mechanism. In addition, REACH includes a number of mechanisms, such as voluntary consortia formation, that may facilitate co-operation among registrants in general with a view to fulfilling their duties related to registration, such as agreement on a single data package, classification and labelling and Chemical Safety Assessment for a substance.

The **SPORT** experience shows that setting up and running co-operation can be done in various ways. However, there are a number of common difficulties identified during the SPORT exercise:

- Registrants have been very sensitive to CBI. Some companies felt that even the exchange on the availability or necessity of certain tests may indirectly disclose too much information on volumes and markets. The extent to which CBI is a barrier to exchange of the specific types of information required to be communicated under REACH was not analysed in detail in SPORT.
- Registrants of the same substance are competitors and hence direct or indirect exchange of details on production volumes and markets is a confidential business information (CBI) issue. Also it can lead to conflicts with antitrust legislation. In the view of one company, European antitrust legislation requires that REACH consortia including more than 10% of the market share may need to allow any other Manufacturer or Importer of the substance to join the consortium in order to comply with EU competition law (see Commission Notice 2001/C 368/07). In practice this would limit the free choice of partners and triggers the need to consider a lot of formal aspects before a consortium contract can be signed, e.g. opt out rules for partners, cost sharing, value of existing information brought into the consortium, protection of intellectual property. Setting up and running a consortium on a formal basis can trigger considerable management efforts getting out of proportion compared to the benefits for the partners.
- In two SPORT sub-projects a “group of substances” was subject to co-operation among potential registrants. In both cases, the grouping had not been done based on clear criteria and in one case it was even difficult to clarify where the identity of one substance ends and, in terms of composition, a new identity starts. The experience shows that a stepwise approach is needed in order to clarify among the potential partners of a consortium which substances to cover through co-operation.

- The organisation of the documents in the registration dossier was difficult for the registrants as well as for the Member States evaluating the dossier. Cross references from document to document or duplication of information through copy and paste were the issues here. For the workability of REACH a well functioning IT system for documentation and exchange of information collected by groups of companies or legal entities is a must. It needs to be in place when work under REACH commences.
- In order to gain from co-operation and cost sharing options, identification of partners and synchronisation of information flows are key issues. During the SPORT exercise, it was noticed that co-operation of companies intending to register similar substances that would possibly qualify as belonging to a “group of substances”, is not well supported by the system yet. Such registrants do not get access to the relevant data of the other substances, since the SIEF is organised substance-wise.

Recommended solution

Working procedures facilitating co-operation between competitors

1. The pre-registration information related to the tonnage band and the registration deadline should not be available at SIEF level since this information may lead to disclosure of confidential business information.
2. Submission to the SIEF of information on animal tests held by a potential registrant should be obligatory. Any other information (indicating that data for certain endpoints exist) should be fed into the SIEF on a voluntary basis.
3. In particular, REACH should encourage data sharing (related to vertebrate studies) also with companies not joining a SIEF or which register at a very late stage of the phase-in process.
4. Sharing of information on vertebrate studies should always be mandatory. However, REACH should not force companies into consortia for this purpose, since consortia forming is only one of various options to co-operate in data and cost sharing. Also, the cost saving potential of the SIEF should not be overestimated: the administrative burdens of coming to an agreement on hazard data sharing can be higher than the potential cost savings related to testing.
5. In order to make work in a voluntary consortium easier, guidance with a high legal status regarding the possible application of competition law would be helpful.
6. A standard template for consortia agreement would help to avoid multiple discussion of the same issues. The same applies for guidance on cost sharing and protection of intellectual property rights.
7. REACH should support synchronisation of information flows among registrants. Alternatives to the tonnage-driven pre-registration deadlines would possibly be more suitable for that. Companies should at least be encouraged to make information per substance available at one single point of time.

8. The timeframe set out in Article 28 to request existing studies identified via the SIEF and to allow for finding agreement with the holder of the data should be prolonged to facilitate data sharing.

Establish mechanisms which support grouping of substances

REACH supports the grouping of substances and read-across from substance to substance (if there is a documented rationale for that); however appropriate tools are not available yet. Mechanisms are needed to bring the corresponding owners of information into contact with each other.

1. Clarify how to register groups of substances;
2. Consider the OECD principles to determine and justify a “category” or “group” of substances;
3. Bring potential registrants across a group of substances into contact with each other through suitable pre-registration mechanisms. There is a potential role for the Agency (if candidates for grouping are identified) and for industry associations to support such a process;
4. Make sure that companies can only register substances with a reference to a group if they have a letter of access as is also the case when using information on the same substance (prevent free-riding);
5. Facilitate grouping and registration by suitable IUCLID 5 version, enabling the registration of groups with easy read-across and referencing mechanisms.

3.2.2 Sharing of responsibility between Manufacturer and DU

REACH introduces the concept of “*identified use*” into the supplier-customer relationship: REACH requires the Chemical Safety Report of a Manufacturer or Importer to address all their identified uses. According to definition 25 under Article 3, these are uses intended by any actor in the supply chain (including the registrant’s own use), or uses that are made known to the registrant by an immediate Downstream User and that are covered in the Safety Data Sheet communicated to the Downstream User concerned.

Art. 29.7 and 34.5 require the DU to follow and to further communicate appropriate information on the „*identified uses*” communicated in the SDS. Art. 31 sets out an obligation for the DU to communicate back any information that might call into question the appropriateness of *risk management measures* on “*identified uses*” communicated to him.

A DU has the right to make known a use to his supplier but must provide enough information to allow the assessment of that use. Ideally this will happen before registration occurs. However, if the substance is supplied to a DU and the DU is outside the conditions of safe use described in the exposure scenario, then within 12 months he must either succeed in making it an *identified use* or carry out an own Chemical Safety Report. Of course the DU can choose to carry out an own CSR anyway for confidentiality reasons.

The REACH proposal allows the generation of wide (covering one or more uses) or narrow exposure scenarios. If the M/I does not want to include a use known to him or made known to him, then he must not continue to supply the substance to that DU; if the justification for not including that use was for health or environmental reasons, then this information should be recorded in the SDS (heading 16, and their Annex IV submission).

The **SPORT** experience shows that the registrants had difficulties in translating this concept into suitable action during the dossier compilation. Deep and broad supply nets lead to cascades of involved actors in the supply chain. Distributors have been identified as bottlenecks in the information flow up and down the supply chain. But at the same time they could also be a valuable source of information.

It was the common feeling among SPORT participants that the communication on uses and conditions of use needs to take place before the registration, and not after the supply of the Safety Data Sheet of a registered substance. In addition, the complexity of items to be communicated needs to be limited and thus will lead to less complex exposure scenarios as well. The SPORT registrants also expressed the need to clarify in the legal text whether or not the DU's right to communicate any use outside the conditions of use (communicated in the suppliers' SDS) does automatically trigger an obligation on the registrant to include it in his "identified uses". This is to:

- Reduce legal uncertainties related to liability and accountability between suppliers and customers before the first Safety Data Sheet is delivered;
- Avoid a high number of bilateral and multiple clarifications in the supply nets after substance registration.

Recommended solution

Clarification of new roles and responsibilities

1. The Manufacturer or Importer should be responsible for providing information on safe levels of exposure (based on DNELs and PNECs) for identified [*supported*] uses and the subsequent risk management measures to the Downstream Users. A use should be regarded as being supported by M/I if it is demonstrated to be safe in the CSR and communicated in the Safety Data Sheet. Demonstration of safe use can for example be based on tiered risk assessment (including categorisation of exposure and use).
2. Registrants in SPORT are of the view that Manufacturers or Importers should only be obliged to include the supported uses in the registration. Member States, however, expressed the opinion that registrants should be obliged to include (all) uses in the registration that they can support based on environment and health considerations. Legal uncertainties in the indication of use must be avoided.
3. There is an obligation for Downstream Users to carry out an own safety assessment for uses not covered in the M/I communication. If agreed, the M/I may carry out the safety assessment for the DU (in such cases).

4. The feasibility of information about safe use throughout the complex supply chain could be checked in a “SPORT 2” project.⁸

3.2.3 Involvement of customers

REACH requires *M/I* to carry out a Chemical Safety Assessment and to communicate the exposure scenarios that set out the conditions of safe use to their customers. REACH requires the DUs to either comply with these conditions, if they are applicable to their use, or to carry out their own Chemicals Safety Assessment. This division of responsibility would require new forms of communication, co-operation, agreements and contracting in the supply chain. The process of identifying uses and generation of exposure scenarios for DU uses is described above (3.2.2) but the REACH proposal does not require suppliers to actively contact their Downstream Users (e.g. by using questionnaires). However, Manufacturers who wish to offer a high level of service to their customers may wish to do so.

The **SPORT** experience is mainly related to the involvement of Downstream Users and users of transported intermediates so that the registrant gets the information needed to compile the registration dossier. The duties of the DUs and intermediate users under REACH were not tested during the SPORT exercise.

4 of the potential 29 registrants (4 out of 8 cases) involved in SPORT had difficulty identifying all the uses and the conditions of use of their product in the market. This refers to:

- Uncertainty on the type of information and level of detail needed to describe the “identified uses”, the conditions of use and the appropriate risk management measures for the purpose of safety assessment;
- Low rate of useful DU responses to the questionnaires sent out during SPORT and uncertainty on the validity of the information;
- Broad and deep supply chains may require communicating with DUs in all EU languages;
- Distributors and formulators not willing to inform about the uses of their customers, in particular if the supplier is a potential competitor or supplies potential competitors;
- Ability of the DUs to provide the requested information or misunderstandings occurring due to the different “languages” and “jargons” spoken in the chain;
- General difficulty carrying out exposure assessment for the full life cycle of the substance based on information from single customers. Uncertainty about to which extent Downstream User organisations will become active to support efficient communication up the supply chain;

⁸ SPORT 2 stands for a possible follow-up of the current SPORT project with more focus on the REACH requirements related to Downstream Users.

- Difficulties in interpreting Article 16 with regard to the “strictly contained use” and the “product stewardship” requirement. The companies concerned felt that it cannot be the duty of the supplier to ensure (in the meaning of “enforce”) compliance of his customers.

Recommended solution

Establishing working procedures for communication with DU

1. Processes of information exchange with the customers and with the customers of the customers should be in place before registration. This may include appointment of a focal point in DU organisations helping to set up the required infrastructure between M/I and DUs and between the DUs.
2. Registrants and DUs could use a structured and standardised questionnaire for communication with their direct customers (multi-language). As a guiding principle, this should be related to potential exposure during unit operations (handling) and not to individual products and processes.
3. Extend the existing concept of standard phrases (in all EU languages) for the extension of the SDS.

Workable exposure scenarios

1. Develop generic standard exposure scenarios (including standard risk management packages) for certain uses. This should happen on the initiative or under the lead of Downstream User organisations (sector or branch). This may help the customer not to provide business details on use conditions to his supplier.
2. Set up a database for standard risk management measures (or standard exposure scenarios) that are suitable to sufficiently control the risk for different substances in a range of uses. This may include development and validation of measures as well as feeding-in and maintaining the database. Such a step-by-step process could be facilitated by a platform (like the SIEF) for exchanging information among industry. Priority could possibly be given to consumer and professional use.
3. Develop standard descriptions for “identified uses” based on standard unit operations (handling) and link these to standard *exposure scenarios*. As a first tier, the development and application of quantified *use* and *exposure categories* may be useful.
4. Develop guidance on when to set up generic or more specific exposure *scenarios*.

3.2.4 Registration dossier and safety assessment

REACH is designed in such a way that standard information requirements (driven by tonnage bands) are laid down in several Annexes to the legal text (Annexes IV to VIII) and that exemptions, adaptation or waiving of these requirements have to be justified by the registrant. Column 2 of Annexes V to VIII provides for specific adaptation conditions, whilst Annex IX allows for more general use of alternative methodologies or general waiv-

ing of tests in Annexes VII and VIII. The guidance note on fulfilment of Article 9 and Annex IV to IX suggests to make use of all kinds of existing information on substance properties before new tests are carried out (also reiterated in each of the intros to Annex V to VIII). Furthermore it suggests considering information on use, existing risk management and exposure in determining which relevant information gaps exist (see steps 1-3 in introduction to Annex IV). In addition, where a new test contained in Annexes VII and VIII is needed, the registrant includes a testing proposal in his registration dossier; the evaluating authority will confirm that the test is required before the registrant carries it out. In some cases the application of Annexes V and VI will require a test in Annexes VII and VIII to be carried out (e.g. positive results in the *in vitro* mutagenicity tests carried out).

During the **SPORT** exercise most registrants had difficulties in evaluating existing information against the standard information requirement and in subsequently arguing why an existing piece of information is sufficient or not to satisfy the requirement. The most frequent comment made by the Member States regarding the dossier evaluation was about the absence or insufficiency of proper arguments for read-across, waiving of certain endpoints or using results from a non-standard test or non GLP testing. Complementary to that, the most frequent recommendation from the final sub-project meetings was that guidance and clarification is needed on these questions. Other workability issues highlighted in the sub-project reports were for example:

- Uncertainties over how to interpret the requirements in column 2 of Annex VI to VIII: How to determine exposure/risk driven i) needs to carry out further testing or ii) the options to waive required standard information in cases where no exposure and risk assessment is required in the CSA;
- Uncertainty on the applicability of existing QSARs, or no validated QSARs available at all;
- Lack of tools and methodology for carrying out exposure estimates.

Recommended solution

1. It should be possible to use the CSR for a substance (with similar use and exposure patterns as well as a comparable hazard and fate profile) for another substance. Dossier evaluation should however still be based on individual registrations. Clearly, there is guidance needed on if and how to apply one CSR to more than one substance.
2. Clarification and guidance is needed for selection across available information on hazard assessment, for presentation of this information (summaries and robust study summaries) and for presentation of the need for further information (testing proposal) in the dossier. In particular, guidance is needed for the use of non-GLP data and non-standard studies.
3. The generation of new valid data for substance identity and physical-chemical properties under non-GLP conditions may be acceptable, if sufficiently justified, for example documented by original test protocols.

4. The new technical guidance(s) on chemicals safety assessment (CSA) should be tiered. It should allow for iterative work, e.g. through generic conservative assessment at the lower tier. Categorising use and exposure may be useful. The guidance should be clear enough to be workable for persons who are not specialised in risk assessment. It should provide flexibility for special cases (use by experts) while making the system simple for standard cases (and non-experts).
5. In the further development of guidance under the RIP process, the potential merits of generic borderline and cut-off values should be considered.
6. Make the Chemical Safety Assessment concept in REACH more flexible than suggested in the current proposal.
 - The CSA should be targeted at those types of hazard for which the substance has been identified as being hazardous.
7. Information from assessments at OECD (related to hazard assessment) or EU level should be regarded as accepted under REACH, unless new evidence requires re-evaluation.
 - Registration of a substance with a completed EU risk assessment and risk management strategy
 - should not undergo substance and dossier evaluation
 - should be accepted without reformatting existing documents
 - information related to new requirements should be added (e.g. SDS)
 - OECD hazard assessments of fulfilled endpoints should be accepted without further evaluation, unless there is new evidence.
 - The CSA should focus on areas recommended as priority in the OECD assessments, unless there is new evidence from other studies.
 - Endpoints not covered within OECD SIDS (e.g. sensitisation) are to be processed in the way requested under REACH.
 - It should be possible in future to import OECD data templates into IUCLID.
8. There is a need to further develop IT based modules for exposure estimation and risk characterisation, including options for risk management, standard efficacy for such measures and other default values for emission and exposure estimates. This should be based on well-documented and accepted models.
9. QSARs should be further developed as a tool in hazard assessment. A list of validated and accepted QSARs (including the area where they are applicable) should be provided in the technical guidance.

Industry participants regretted that it is not possible under the current REACH proposal to apply exposure-driven waiving (according to Annex IX) to Annex VI endpoints.

3.2.5 Dossier compilation – technical issues

If two or more Manufacturers/Importers of a substance exist in the EU, Article 10 of the **REACH** proposal allows registrants to voluntarily form a consortium for the purpose of registration; that is to prepare a joint technical dossier of information and/or a joint Chemical Safety Report. This should not be confused with the SIEF, which facilitates the mandatory sharing of vertebrate animal data and the voluntary sharing of other data. Parts of the registration dossier according to Article 9 are to be submitted by the lead company only, other parts are to be submitted by each registrant separately.

REACH also allows i) to read-across from substance to substance regarding their inherent properties, and ii) to use the exposure and risk assessment for one substance (the Chemical Safety Report) also for another substance.

REACH defines the Manufacturer or Importer as a legal person established in the community. Thus for EU companies who are manufacturing or importing a substance in different legal entities established in the EU, these entities have to submit separate dossiers.

The registration dossier will be submitted electronically via an updated version of IUCLID (IUCLID 5) and a specific REACH-IT mechanism.

The **SPORT** experience shows that the multiple options to group and the multiple obligations to separate information led to confusion on how to organise the registration document in the most efficient and transparent way. In particular, the Competent Authorities found it difficult to handle the document packages handed over for evaluation in some of the cases. The following problems were highlighted in the sub-project reports:

- Most of the CA evaluators used the CSR to understand and check for compliance of certain items in the technical dossier. The CSR is especially necessary as it contains arguments for waiving. However, the link between the information in the technical dossier and CSR was not always easy to trace.
- Cross references between the different elements in the dossier were generally difficult to follow.
- It was felt that the grouping of substances with similar properties is not well supported in the current rules for registration. A consortium option for groups of substances is not foreseen yet.
- The “legal entity” registration rule may multiply the number of dossiers for the same substance to be processed in the system.

Recommended solutions

Set up a uniform registration data system supporting grouping

As a guiding principle, in all elements of the system, the right balance between standardisation and flexibility has to be found.

1. The IT system and IT tools should be tested and validated before REACH enters into force.
2. Standard formats and guidance are needed on how to present the identity of a substance to be registered and the variation of its composition.
3. Standardise formats and procedures for preparing the registration dossier (including a powerful IT support).
4. Harmonise procedures for dossier evaluation and work out guidance.
5. The registration system should provide for only one-time entry and referencing of technical data.
6. The format should in particular support registration by consortia and dossiers covering groups of substances based on read-across.
7. The system should also allow for quick completeness (and compliance) checks prior to submission.
8. There should be the possibility that a consortium is represented by one person only when liaising with authorities.
9. The various legal entities of one company should have the possibility to submit one registration dossier for one and the same substance.
10. Clarify the consequences of a non-compliance of the dossier (within the legal framework) related to a draft decision of the Member State and
 - The ability to answer within 30 days;
 - A possible disagreement about the test proposal.
11. Full backward compatibility of REACH IT tools with IUCLID 4 is needed.

Standardisation in general

- General standardisation is needed related to phrases, language, IT suitability, tools and templates.
- In particular, information flow on risk management and conditions of use in the supply chain needs a large degree of standardisation.
- Standard IT readable formats for SDS are needed, so that DUs can work directly with the information. The number of different phrases and level of detail in the SDS should be limited to allow for translation into national languages.

3.2.6 “Compliance” – approaches and ambition

The evaluation of the individual **REACH** registration dossier by the Competent Authority of the Member State includes two elements: i) the mandatory examination of testing proposals related to tests in Annexes VII and VIII, and ii) at the choice of a Member State (whether to and to which extent a dossier is evaluated) examination of the compliance of the technical dossier with Article 9.1 a-i and the adaptation of standard information requirements of Annexes V to VIII. The outcome of the evaluation is a decision requiring a

registrant to carry out further information gathering. If a testing proposal is rejected or the Competent Authority finds a dossier to be non-compliant, then the registration as such is not rejected and Manufacture/Import of the substance can continue.

The experience in the **SPORT** exercise indicates that some requirements in the legal text are still difficult to interpret for registrants and authorities, without further explanation through guidance. Beyond that, the understanding of the REACH system as such is still quite different among the Member States and between companies and authorities.

Reasons for non-compliance

The SPORT sub-projects spent a considerable amount of time working out the dossier. In four of the eight cases teams of experienced persons (related to risk assessment) were involved. Nevertheless, in all cases the Member State experts did not accept the dossier as being in compliance with the REACH requirements. The analysis of comments (see also annex 4) suggests that the following issues were the major reasons for non-compliance⁹ (starting with the most frequent issues):

- The group of substances addressed in the dossier(s) is not consistent in itself (chemistry or hazard profile of substances) or insufficiently justified. However, in two of the four cases the evaluating Member State indicated that the grouping approach as such was acceptable;
- Key studies not identified in the dossier and/or robust study summaries are missing.
- Justification for non-classification not provided or not accepted;
- Organisation of the registration dossier not in line with REACH requirements;
- Testing proposals not accepted, or waiving argument for Annex VII/VIII endpoints missing or not accepted;
- Information for endpoints on Annex V or VI missing and waiving argument missing as well or not accepted;
- Justification for application of non-standard information or non-GLP information missing.

One dossier was, among other reasons, non compliant since the registrant deliberately made the choice not to follow the draft REACH requirements.

Additional comments with regard to the CSA/CSR address insufficiencies in exposure assessment and derivation of PNEC or DNEL.

⁹ Comments on the CSR and the SDS other than those related to justification on adaptations of standard information are not included here.

Understanding of “compliance”

The term “compliance”-check suggests that non-compliance may have direct legal consequences. The type of sanction possibly triggered by failing to meet the 30 days deadline for responding to the draft CA decision, or by failing to meet the request for further information or for modified testing, remained unclear for companies and CAs in the SPORT exercise.

Expected level of detail

The level of ambition in evaluating the content of the registration dossiers was different among the Member States. This is related to the:

- Understanding of the dossier evaluation as a detailed proof-read or as an overall plausibility check;
- Level of scientific detail to which the Member States evaluators checked certain elements in the dossier;
- Flexibility to justify read-across from substance to substance for each single endpoint or only for selected endpoints;
- The extent to which GLP data are expected;
- The extent to which the evaluators made own detailed proposals for the design of testing;
- The regular inclusion of the CSR in the compliance check.

Criteria for priority setting

Taking into account that the evaluation of testing proposals is mandatory and may need dossier evaluation anyway, Member States raised the question about criteria in order to select dossiers for compliance. The proposals included for example:

- Any dossier could be interesting for compliance check;
- Concentrate on classification information in the dossier;
- Use the dossier evaluation to identify candidates for substance evaluation, restrictions or authorisation rather than considering the compliance of the dossier in detail.

Other issues

Based on the analysis of the Member States’ comments and the outcome of the interim workshop some other issues and partly diverging views among Member States were expressed as well. Partly this is related to differences in the interpretation of the legal text, partly related to differences in scientific views and partly related to a different understanding of roles. For example:

- A) Environmental exposure assessment and risk characterisation is not needed for dangerous substances that are only classified based on physical-chemical or toxic hazards. B) According to REACH it is needed.

- A) One technical dossier and one CSR for a group of substances would be desirable rather than receiving dossiers and CSRs for each single substance in the group. B) A separate registration dossier and a separate CSR is needed for each single substance in a group.
- A) In order to determine the appropriate standard information requirement the single production volumes of partners in the consortium have to be cumulated. B) The highest single volume of one of the partners determines the standard information requirement. However, cumulation at registration level is not required.
- A) Testing proposals can be derived from the dossier; no separate format is needed. B) Testing proposals should be presented in a separate format.
- A) In cases where testing is proposed, Member States should check whether test results are already available. B) In such cases, the registrant should demonstrate that no appropriate study results are available to him.
- Concerning the question whether or not a quality assurance system related to REACH information would be beneficial, some Member States indicated that they see an enforcement problem rather than a quality problem. Also, it should be made clear whether quality of hazard data or exposure data is meant.

In summary, the **SPORT** experience shows that the interpretation of the draft legal text, the level of ambition and expected detail, as well as the understanding of the own role is different among the Member States. This gives in particular rise to the question how to achieve a common understanding on the role of the compliance check in the system and how to define the “quality” of a dossier accordingly.

Recommended solution

1. An intelligent completeness check system is needed for identifying fields with obviously non-compliant information.
2. Also criteria and procedures for priority setting related to compliance checks should be developed.
3. Dossier evaluation under REACH should include the possibility to discuss between the registrant and the Member State, before the Member State takes a decision. Registrants should also have the possibility to challenge the decision.
4. A mind setting process on the function of the compliance check in the REACH system is needed in order to develop a common understanding across Europe. This also applies to those actors importing into the EU via representatives but filling their dossiers themselves.
5. Common guidance for the evaluators is needed on how to trace and evaluate those pieces of information in the registration dossier which are most relevant for safe handling and use of the registered substance
6. Evaluating Member States should use a template for their responses to testing proposals to communicate the result of their dossier evaluation.

3.2.7 Information supplied to Downstream Users of substances

REACH obliges suppliers of dangerous substances or preparations to communicate information generated during the REACH process to their customers. This information includes i) the „identified use“ of a substance (relevant to his customer), ii) the corresponding conditions of use and measures to sufficiently control the risk and iii) a safe exposure level in part 8.1 of the SDS (derived from DNEL/PNEC). This is to be done by extension of the current Safety Data Sheet requirements, and where a Chemical Safety Assessment has been carried out by also attaching the relevant Exposure Scenarios as an Annex to the SDS.

In six **SPORT** sub-projects Safety Data Sheets were sent out for feedback to 25 companies. In three of the sub-projects, the extended Safety Data Sheets did not contain an exposure scenario and in four of the sub-projects they did not contain a DNEL or PNEC. In three cases the evaluating Member State found the extended SDS insufficient and/or not different from the current SDS. This was also confirmed by five of the responding Downstream Users.

Responses were received from 14 DUs in five sub-projects. Half of the companies found the additional information on conditions of use and exposure thresholds useful or would have liked even to receive more information. The other seven companies found the additional information not very useful or much too specific. Two companies identified additional uses.

The registrants mostly did not succeed in extending the safety sheet in a way that their customers found useful. This may be partly related to the fact that the key element of extension, the exposure scenario, was missing in three of the six cases. In the registrants' view, the information on use obtained from the Downstream Users was insufficient to work out an exposure scenario. It may however also be the result of the fact that the customers did not really feel they had a problem before or were not aware of their duties under REACH and hence could not really judge whether the extended SDS is useful or not.

Due to the fact that the extended safety data did not contain all the required information (exposure scenario plus DNEL/PNEC) in any of the six relevant cases, it is difficult to draw additional conclusions or derive proposals from the response of the Downstream Users.

3.2.8 Use of transported intermediates under contractual control

For isolated transported intermediates $\geq 1,000$ t/a, **REACH** does not foresee exposure assessment according to Annex I and standard information requirements going beyond Annex V. According to Article 16.4 (a) to (h) the registrant can benefit from this exemption when the activities take place under strict contractual control. This includes for example rigorously contained handling at all stages of the life cycle as well as a product stewardship system operated by the Manufacturer.

During the **SPORT** exercise one company found it difficult to understand what “rigorous containment” means in practice. Beyond that, two companies felt that they cannot fulfil the responsibility to monitor whether their customers work in compliance with the conditions established in Article 16.

Recommended solution

1. With respect to Article 16.4, the M/I should be obliged to inform his customers that the substance has been registered under Article 16 and explain what “strictly controlled” means in the particular case. The customers should be obliged to confirm in writing that he is working under such strictly controlled conditions.
2. The supplier should not have the obligation, as set out in Article 16.4 (h), to physically monitor whether his customers are in compliance with the requirements of Article 16.4 (a) to (g). Clarification in the legal text is needed on how to ensure that customers comply with the conditions of use communicated by the supplier.

3.2.9 Issues related to preparations

REACH is a substance-based system and hence the standard procedures and requirements as laid down in REACH refer to substances, as used on their own, in preparations or in Articles. The REACH proposal refers to the “conventional method”¹⁰, to the calculation rules and to the cut-off criteria determining the hazard of a preparation, as laid down in the current EU Preparation Directive [1999/45/EC]. In Article 13 of REACH, the cut-off values of the Preparations Directive are also used to determine a threshold concentration below which a Chemical Safety Assessment is not required for the use of a dangerous substance as a component of a preparation. Annex Ib of the draft REACH regulation establishes a method for carrying out a Chemical Safety Assessment for the whole preparation instead of its single components but only where an SDS is worked out for a preparation. The “preparation CSR” is never registered.

The **Sport** experience indicates a number of difficulties regarding substances in preparations. Companies manufacturing textile finishing chemicals (and possibly also other sectors) do not sell single substances but preparations. The components in the preparation are partly manufactured in the own company (and have to be registered under REACH), and are partly bought from other companies in form of single substances or in form of a preparation (and have to be registered by the suppliers). This leads to the following difficulties:

- The registrant in the corresponding **SPORT** case has quite a number of own test results available, derived from the testing of the whole preparation. It is not clear from the REACH proposal to which extent this existing information can be used to satisfy the standard information requirements in Annex V and VI.

¹⁰ The hazard profile of a preparation is determined by the hazard classification of its single components. Testing of whole preparations is possible but is the exception.

- During the 11 year phase-in period of REACH, the extended Safety Data Sheet for the registered substances and Safety Data Sheets for not yet registered substances have to be merged at the formulators' level in order to provide their customers with consolidated safety advice. It is not clear for the company how to do this.
- The Manufacturer of the textile finishing preparation (including the substances from own manufacture) buys certain components of the preparation from direct competitors. This leads to some difficulties in communicating "identified uses" and conditions of use in the chain without disclosing "innovative uses" to the direct competitor.

Recommended solution

Clarification needed for substances marketed in preparations

1. Existing testing data on preparations as a whole should be regarded as one of the possible sources to satisfy the standard information requirements for substance registration under REACH. Guidance is needed.
2. The conditions of safe use of the substance-mix within the preparation may be determined by the components with the highest hazard and exposure potential, assuming that no other or more protective measures would be needed taking the other components into account.
3. An extended SDS for preparations based on single components should only be required when the related hazard assessments and exposure scenarios have become available during the phase-in time of REACH.

3.2.10 Issues related to registration of complex natural substances

The **REACH** system is based on the "substance" concept of the current chemicals legislation. A single substance may contain various components, depending on its source in nature, the extraction process or the manufacturing process by chemical synthesis. Substances extracted from plants, like the essential oils for example, may vary in composition over a wide range. According to Annex III, registration under REACH is required if the substance occurring in nature meets the criteria of being dangerous.

In one of the **SPORT** cases, the compilation of a registration dossier for essential oils was tried out. The informal consortium of registrants was faced with a number of difficulties:

- Essential oils are produced by single farmers or co-operation of farmers. It is not clear how these companies could fulfil the duties of a Manufacturer under REACH.
- The composition of marketed essential oils and crude essential oils differs and thus the question is at which stage of the production chain registration is required.

- The oils have a wide range of composition and physical-chemical properties. Thus, a testing strategy is needed to derive a representative picture of the hazard profile of an essential oil.
- The EINECS number covers a whole range of very different composition of oils. The source and the method of extraction are much better descriptors for the quality of an essential oil compared to the EINECS number.

Recommended solution

1. Guidance is needed for identification, definition and registration of natural extracts (RIP 3.10).
2. The natural extracts should have a phase-in-status if there is a suitable EINECS number; however, separate registration for substances under the same EINECS number may be needed.

3.2.11 Consistency with other legal requirements

Under the **REACH** system, substances are to be registered and assessed with regard to hazard, exposure and risk. The conditions of safe use and the appropriate risk management measures are to be documented by the registrant. At the same time certain substances and uses of substances are regulated under more specific product and marketing legislation (e.g. cosmetics, biocides, food, animal feed). If these regulations provide or will provide for the same principles of risk and safety assessment as laid down in REACH, the substances or uses are exempted from REACH or regarded as registered.

Registrants under REACH are obliged to establish the conditions of safe use including appropriate risk management measures. The result of the Chemical Safety Assessment necessarily overlaps with the national requirements on workers health, safety and environmental protection. The aim is to facilitate efficient implementation of risk prevention and management rather than to replace the existing legislation on protection of workers health and the environment.

Parallel to the introduction of the EU REACH system, international harmonisation of chemicals hazard assessment, risk assessment and chemicals management takes place at OECD and UNEP level (see also 5.2.4)

During the **SPORT** exercise a limited number of issues were identified that may create workability problems:

- Registration under REACH related to the EU Cosmetic Directive is not clear.
- Possible differences between OELs and DNELs related to workers protection are difficult to handle.
- The same applies to the level of detail required under REACH with regard to exposure assessment at work places.

Recommended solution

1. Avoid duplication of work (e.g. information available from cosmetic and food regulations) or uncertainties on how to apply the current regulatory thresholds (OELs related to workers health, environmental quality targets or emission standards) in relation to the DNELs and PNECs that will become available under REACH.
2. Develop guidance on the level of detail needed in workers exposure assessment and on how to work with the DNEL in cases where OELs exist.
3. Requirements and procedures related to hazard and risk assessment should (where appropriate) be internationally harmonised in order to facilitate the use of completed assessments. This includes, for example, the EU Programme, the OECD Programme, the US *High Production Volume Chemicals (HPV) Challenge Programmes*, or the work under the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

3.2.12 Available resources

The **REACH** system aims to phase-in about 30,000 existing substances within an 11 years timeframe. Manufacturers and Importers will have to carry out Chemical Safety Assessment, comprising a hazard assessment based on standard information requirements (not just available data) as well as exposure and risk assessment for dangerous substances. The obligation to carry out a CSA only applies to substances manufactured or imported in quantities of more than 10 t/a, which are expected to represent about one third of the substances to be registered. Downstream Users will have to compare the information received from their suppliers with their own conditions of use and the conditions of use of their customers. A risk assessment related to worker protection is obligatory based on the EU Chemicals Agent Directive. Therefore, most companies are likely to have some experience in this field, although in practise these assessments may be often of a very qualitative and generic nature. The current practise in this field is not necessarily the same as what will be required under REACH. Furthermore, only large chemicals suppliers have considerable experience with the current programmes related to existing and new substances.

The **SPORT experience** indicates that Chemical Safety Assessment (covering all life cycle stages of a substance) is a new task for nearly all of the companies. For companies that have not yet been involved in the *EU Existing Substance Programme* and/or in notification of new substances, the risk assessment methodology as such is also a challenge. But even those persons having been involved in a comprehensive risk assessment, do not necessarily yet have the skills to operate a system with a much larger throughput of substances per time. It was also a common concern of the registrants involved in SPORT that the Downstream Users are not yet sufficiently aware of their duties under REACH and the possible consequences for their business.

Recommended solution

Set up support structure for less experienced registrants or DUs

1. DUs should be more informed about REACH and its possible consequences for them. An active information programme should be launched.
2. Helpdesks should be able to respond to registrants' questions within a short time and in the national language.
3. REACH requirements should match expertise and resources available to SMEs without however compromising the level of protection of humans and environment intended in REACH.
4. The new technical guidance(s) on Chemical Safety Assessment (CSA) should be tiered. It should allow for iterative work, e.g. through generic conservative assessment at the lower tier. The guidance should be clear enough to be workable for persons who are not specialised in risk assessment.

Some of the proposed solutions under chapter 3.2.2 to 3.2.4 may also facilitate support to less experienced registrants or Downstream Users.

3.3 Concluding remarks

It should be kept in mind that the recommended solutions themselves are only one part of the SPORT output. Another relevant output is, for example, the practical experience gained during the process which every participant will use to find his own way in the further discussion about the legislative proposal and in preparation for REACH implementation in a few years from now. Also, the deliverables produced during SPORT (tools to collect information on use and exposure, technical dossiers, Chemical Safety Reports, extended SDS, Member State response based on dossier evaluation) are examples that may be a valuable input into the ongoing RIP process¹¹.

During the initial discussion of the recommendations, the consultant group made a number of observations. These may be useful for a better understanding of the recommendations presented here:

- The vast majority of recommendations made by the SPORT participants refer to i) the need for technical guidance on how to implement the requirements in practice, ii) clarification on the meaning of certain legal requirements as such or iii) certain changes in the legal text. It was not always clear which of these three actions was really being addressed by a recommendation.

¹¹ Note: These deliverables partly contain confidential business information. Hence they cannot be circulated to the RIP working groups. Deliverables publicly available are documented in the sub-project reports as annexed.

- Only very few recommendations were made regarding the need to develop new forms of internal communication and working styles within companies and within authorities, with a view to managing the process of phasing existing substances into REACH. The same applies to forms of co-operation among potential competitors. Although these workability issues became obvious during the SPORT experience, the participants' recommendations do not reflect them.
- The number of really controversial recommendations (split views) within the sub-projects and across the sub-projects was quite limited. However during the reflection workshop and the subsequent discussion about the overall SPORT report it also became obvious that quite a number of controversial issues still exist.

The strategic partners agreed on a special mode called "free flow" that was suggested by Cefic. The main argument for the free-flow mode was to use industries' creativity for new and possibly unusual ways to identify and validate solutions to workability problems encountered in SPORT, or to reach the goals of the new legislation in a more efficient way compared to the current legislative proposal.

Our observations show only little evidence of new ways and new ideas for tools within SPORT that found acceptance by the Member States. There may be a number of explanations for that, which include for example:

- The timeframe prevented the participants from creating and trying out solutions in an iterative way.
- Most companies kept the rule that SPORT was set up to test workability issues of REACH under the premises of following the Commissions legislative proposal.
- On the side of the Member States, that every signal of acceptance related to alternative approaches could be misunderstood as precluding the Member States' position in the legislative process.
- Current legislation was on the mind of many players during the exercise and the intended paradigm shift has not yet taken place.

Nevertheless, SPORT contributed to better understanding of the REACH requirements and their practical implications. This may be a good basis to work on creative and pragmatic solutions where difficulties were experienced.

List of Annexes

(documents provided on compact disk):

Annex 1: 8 SPORT Sub-project reports:

- Arkema SPORT final report
- BASF SPORT final report
- CHT SPORT final report
- Clariant SPORT final report
- Cognis SPORT final report
- Dow SPORT final report
- EFFA SPORT final report
- Fuji SPORT final report

Annex 2: Workshop documentation:

- Interim Workshop chair workshop (24 February 2005 in Brussels):
- Interim Member State Workshop (11 April in Brussels)
- Reflection Workshop (19/20 May 2005 in Darmstadt)

Annex 3: SPORT recommendations database

- Annex 3_SPORT recommendations

Annex 4: SPORT compliance issues database

- Annex 4_SPORT compliance issues

Annex 5: The SPORT process

- Annex 5_SPORT process

Annex 6: The SPORT High Level Rules

- Annex 6_High Level Rules

Annex 7: SPORT acronyms

- Annex 7_acronyms