



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).



Acknowledgements

We, the strategic partners in SPORT would like to thank the many highly motivated and committed volunteers in companies, authorities, trade associations and the Commission Services who were involved in the eight SPORT sub-projects. Without their efforts and the resources they dedicated to SPORT, the completion of the project and the timely reporting of its results would have been impossible. We would also like to thank the Consultant for the very professional job.

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

Authors:

Andreas Ahrens
Dirk Jepsen
Kerstin Heitmann
Ökopal GmbH

Frank Claus
iku GmbH

Hamburg, July 2005

Imprint



ÖKOPOL – Institute for environmental strategies

Nernstweg 32 – 34

D – 22765 Hamburg

Tel.: 0049-40-39 100 02 0

Fax.: 0049-40-39 100 02 33

<http://www.oekopol.de>

info@oekopol.de

Authors:

Andreas Ahrens

Dirk Jepsen

Kerstin Heitmann



iku GmbH

Olpe 39

D - 44 135 Dortmund

Tel.: 0049-231-31891

Fax: 0049-231-31894

<http://www.iku-gmbh.de>

iku@iku-gmbh.de

Frank Claus

Index

0	Introduction	3
1	Set-up of SPORT and recommendations	5
1.1	Objectives, scope and organisation of SPORT	5
1.1.1	Setting up SPORT	5
1.1.2	Objectives of SPORT	6
1.1.3	Scope of SPORT	7
1.1.4	“Workability” in the context of SPORT	8
1.1.5	Means to facilitate workability.....	8
1.2	Recommendations by the three strategic partners	9
1.2.1	Setting up and running co-operation among registrants	9
1.2.2	Sharing of responsibility between M/Is and DUs.....	10
1.2.3	Involvement of customers in the registration process	11
1.2.4	Registration dossier and safety assessment.....	11
1.2.5	Dossier compilation – technical issues	13
1.2.6	Compliance – approaches and ambition	13
1.2.7	Information supplied to DUs	14
1.2.8	Use of transported intermediates under contractual control	14
1.2.9	Preparations	14
1.2.10	Registration of complex natural substances	14
1.2.11	Consistency with other legal requirements	14
1.2.12	Available resources	15
2	Strategy to test REACH	16
2.1	The testing approach	16
2.1.1	Tested elements of REACH	16
2.1.2	The eight cases	17
2.1.3	Substances, companies, markets	20
2.1.4	Boundaries and limitations of SPORT.....	23
2.2	Facts and figures of findings	24
2.2.1	Pre-registration, SIEF and consortia	24

2.2.2	The registration dossier	25
2.2.3	Completeness check	26
2.2.4	Dossier evaluation	27
2.2.5	Information to customers	28
3	Reflection on SPORT experience	29
3.1	Workability	29
3.2	Identified drivers of workability - recommended solutions	31
3.2.1	Setting up and running co-operation among registrants	31
3.2.2	Sharing of responsibility between Manufacturer and DU	33
3.2.3	Involvement of customers.....	35
3.2.4	Registration dossier and safety assessment.....	36
3.2.5	Dossier compilation – technical issues	39
3.2.6	“Compliance” – approaches and ambition.....	40
3.2.7	Information supplied to Downstream Users of substances	44
3.2.8	Use of transported intermediates under contractual control	44
3.2.9	Issues related to preparations	45
3.2.10	Issues related to registration of complex natural substances	46
3.2.11	Consistency with other legal requirements.....	47
3.2.12	Available resources	48
3.3	Concluding remarks	49
	List of Annexes	51

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.

SPORT Report

Annex 5: SPORT process

Authors:

Andreas Ahrens,
Dirk Jepsen,
Kerstin Heitmann
Ökopol GmbH

Frank Claus
iku GmbH

Hamburg, July 2005

Index

1	Working process in SPORT	2
1.1	Institutions and roles	2
1.1.1	SPORT Steering Group.....	2
1.1.2	SPORT Contact Group.....	3
1.1.3	The independent consultant	3
1.1.4	Sub-project working groups.....	3
1.2	Three phases of the SPORT exercise	4
1.2.1	The preparation phase	4
1.2.2	The testing phase	5
1.2.3	The reporting phase	6

1 Working process in SPORT

The working process under SPORT was based on a number of institutional arrangements which turned out to be important for a comparably smooth process. The strategic partners agreed on the core set even before the project started and fixed it in the so called “high level rules” (see annex 6). Some further details have been worked out by the consultant during the exercise.

1.1 Institutions and roles

1.1.1 SPORT Steering Group

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

Voting 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)

Each of these Partners got three voting seats and three non-voting seats.

In a spirit of transparency, further observers from trade unions, regional networks and environmental organisations participated in the Steering Group. These observers attended the meetings on the Steering Group level, 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.

Steering Group meetings were chaired by an independent professional – Mr. Roger Trugano - and were also attended by advisors (the consultant team leaders). The work of the Steering Group chair was supported by one person from Cefic, acting as the SPORT secretariat.

The Steering Group met five times throughout the project. The Steering Group defined the objectives and set the time frame for SPORT. Besides the general high level rules, it endorsed the more detailed process rules and the support materials provided by the consultant. It discussed and finally agreed on the draft of the overall SPORT report as prepared by the consultant.

1.1.2 SPORT Contact Group

A group of two Steering Group members together with the SPORT secretariat formed the *SPORT Contact Group*. The SPORT Contact Group accompanied the consultants' team in everyday's issues and helped co-ordinating the various players in authorities and industry. They provided advice regarding issues of minor importance when votes by the Steering Group were not regarded as essential.

1.1.3 The independent consultant

In order to organise the complex processes, to support the participants and to ensure neutral observation and reporting, the SPORT project was facilitated by an independent Consultant. After an EU-wide tendering procedure, Cefic contracted Ökopol for this job.

Ökopol established a team of European consultants for its support. All partners in this consultant team had long time experiences with regard to the REACH. They acted in clearly divided roles. While Ökopol and iku took responsibility for the different aspects of the overall project lead, experts from CIT, DHI/DTC, Öko-Institut, FOBIG, RPA, TNO and UMCO acted as facilitators for the single sub-projects during the testing.

The SPORT consultant team supported managing, scoping and structuring the SPORT processes based on the high level rules as agreed in the Steering Group. They also proposed detailed project or process rules and drafted a plan of materials and working assumptions, adjusted to the needs of the sub-projects. The sub-project facilitators acted as observers (in close co-operation with the sub-project chair) and wrote the sub-project reports, whereas the project leaders (Ökopol and iku) wrote the final overall report.

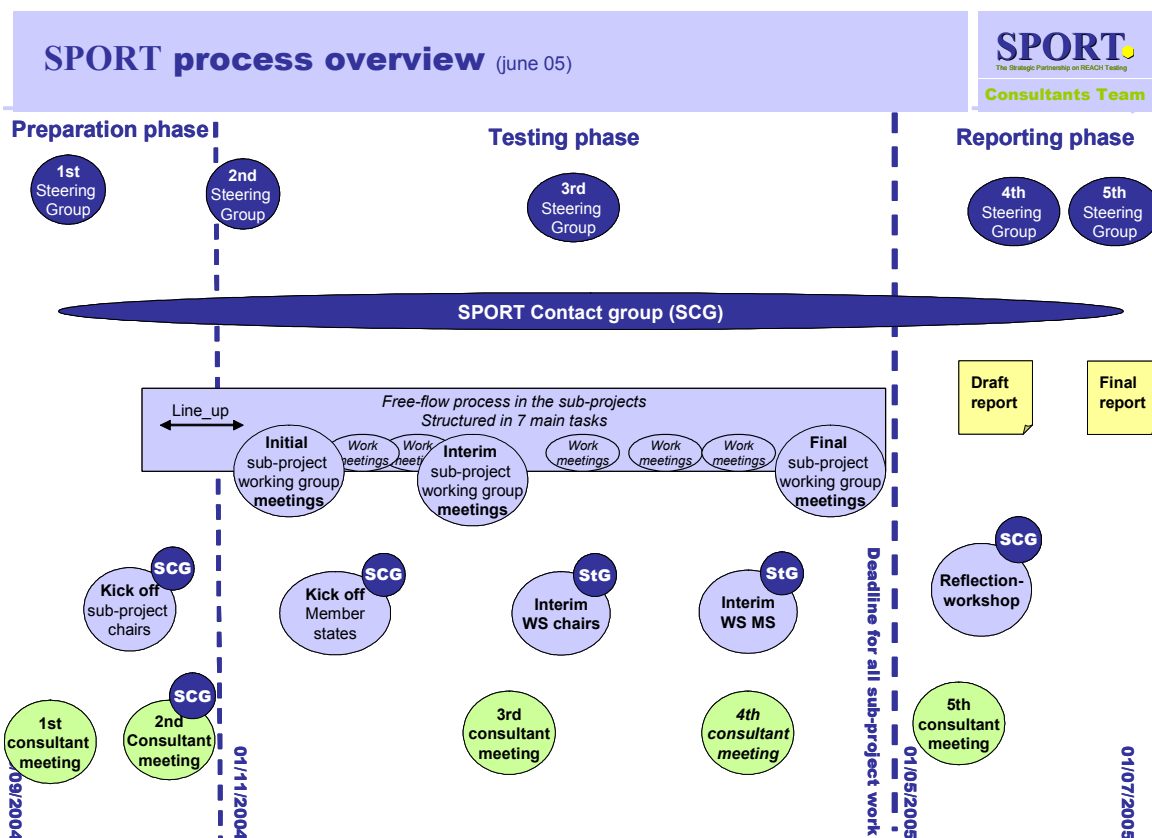
1.1.4 Sub-project working groups

The eight sub-project working groups were each formed by a chair from industry, a Member State representative and a Commission representative as an observer. Competitors and customers of the lead company were further possible participants to be involved. The working groups formed the core structure of SPORT. The chairs in the sub-projects took the responsibility for the sub-projects' work plans. They collected all relevant data and organized communication and co-operation during the exercise. The ECB performed the completeness check of the registration dossiers. The Member State authorities in each of the sub-projects took over responsibility for the dossier evaluation.

A Commission's helpdesk answered specific questions with regard to the REACH proposal.

1.2 Three phases of the SPORT exercise

The whole SPORT exercise was divided in three main phases: Preparation, testing (including interim workshops) and reporting (including reflection workshop). The following scheme shows this overall structure and the main meetings during SPORT:



1.2.1 The preparation phase

SPORT has tested the Commission's proposal for a new regulatory regime. Member States as well as industry and other stakeholders have been intensively discussing their proposals for modifying the draft regulation during the past 1 ½ years. In addition, no guidance on practical implementation at the company and member state level exists at this point. Thus, acceptance of the conclusions drawn from SPORT was assumed to depend very much on transparency about how the REACH testing took place and how the experience gained from the exercise will be used.

The Steering Group has selected eight substances or groups of substances for which the registration was tested in the eight sub-projects. The substances were selected based on a number of criteria:

- willingness of producer to take part in SPORT
- low and high production volume substances represented in the sample
- intermediates, industrial uses, professional uses and consumer uses represented in the sample
- specialities and multipurpose substances represented in the sample
- well known substances with comparably much information available

In some of the sub-projects two Member States took over the dossier evaluation in order to test to which extent their evaluation differs.

In order to provide a proper setting for the whole exercise in line with the transparency requirement, Ökopol prepared a number of documents aiming to support a smooth start in the sub-projects, e.g. a detailed description of the 7 main tasks to be carried out, clear process rules for all participants and reporting/observation sheets to document the experience gained during the sub-project work.

1.2.2 The testing phase

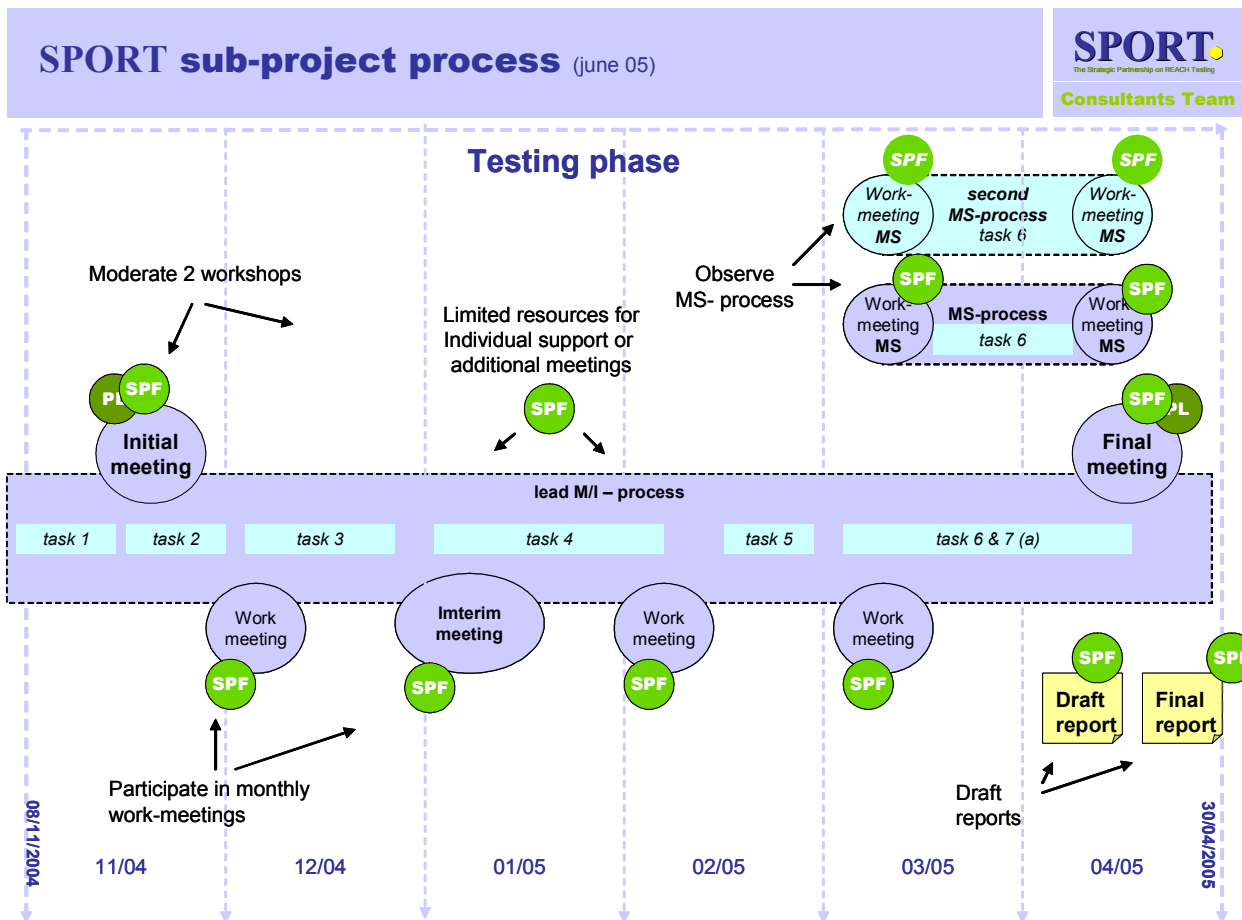
The testing phase was the core activity of SPORT, and it was during this phase that the “free-flow” testing in sub-projects took place.

Each sub-project started with an initial workshop moderated by a person from iku and observed by the sub-project facilitator. At this workshop, the content of the sub-project tasks, the time lines, the process rules and the prepared materials were explained to the sub-project participants. This workshop constituted the initial sub-project working group meeting.

In each sub-project, the personal face-to-face contact between the sub-project facilitator and all participants, or at least the main players, was ensured by several direct working group meetings – e.g. at the lead company’s premises. At these meetings, the status of the sub-project work, the main results, the possible problems and the additional needs for clarifications were addressed.

A second moderated workshop stood at the end of the work in each sub-project. Here the sub-project report based on a proposal by the sub-project facilitator was discussed and agreed. Also a list of draft recommendations was compiled.

The following figure gives an overview on the different elements, the time frame of the process and the points where the sub-project facilitators were involved:



1.2.3 The reporting phase

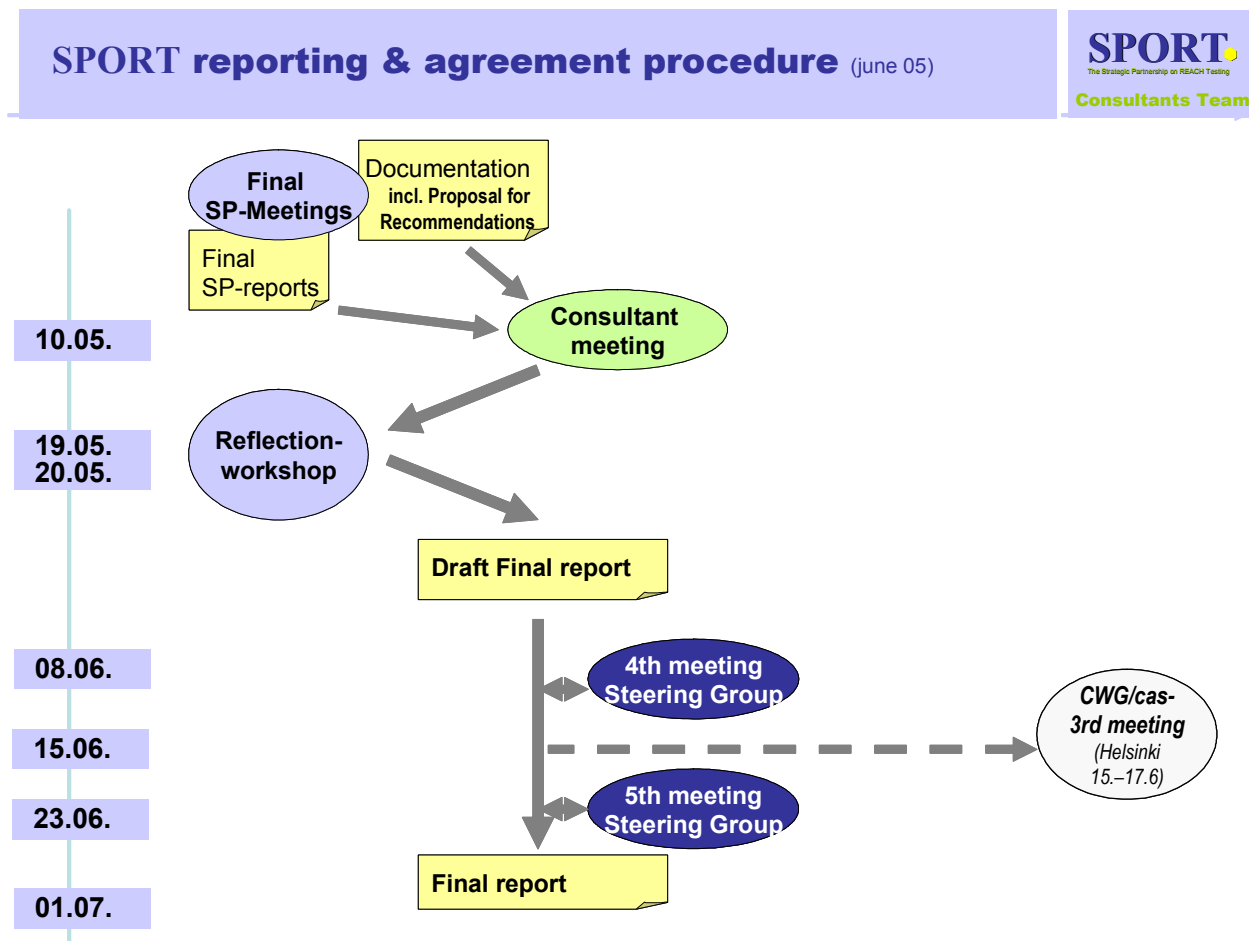
The experience gained was documented in 8 sub-project reports and the documentation of the final sub-project working group meetings. In addition, the lead companies and the Competent Authorities of the Member States reported in two interim workshops (February 24th and April 12th 2005) on observations and lessons learned until then. No conclusions or recommendations were made at these workshops.

Based on the draft recommendations collected during the final meetings in the 8 sub-projects a list of about 150 recommendations was compiled (see Annex 3). In order to reduce this to a manageable number and to a manageable complexity of recommendations respectively, a stepwise working procedure was carried out:

- Consolidate similar or identical recommendations from different sub-projects into one recommendation;
- Work out a preliminary analysis during a consultant team meeting (10th of May);

- Discuss and change the sub-project's recommendations with the participants of the SPORT exercise in the reflection workshop in order to derive the overall SPORT recommendations (documentation see Annex 2);
- Revise the list of draft recommendations and link it systematically to the workability issues identified (see chapter 3 of the report).

The following picture shows this multi-step procedure:



Based on these recommendations by the participants, included in the final report prepared by Ökopol (see chapter 3 of the SPORT report), the strategic partners drafted and agreed on a summary describing the set up of SPORT and the common recommendations derived from the experience (see chapter 1 of the SPORT report).