“EU-Workshop on Socio-Economic Analysis under REACH regarding authorisations and restrictions”

12 & 13 March 2007, Berlin

- Report and documentation of the Conference -

Organised by the German Federal Environment Agency (UBA) and the German Ministry for Environment, Nature Conservation and Nuclear Safety

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I Participants

More than 120 experts from all over Europe attended the workshop. They were representatives of ministries and administrations, the EU-Commission, companies, NGOs and research organisations.

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22		Françoise	Duplat	Orgalime - The European Engineering Industry Association	Brussels	Belgium
23		Raina	Dureja	The Association of Latvian Chemical and Pharmaceutical Industry	Riga	Latvia
24		Elina	Karhu	European Commission	Bruxelles	Belgique
25		Jose Ignacio	Elorrieta	Direction General for Environmental Quality and Impact Assessment	Madrid	Spain
26		Henrik Hallgrim	Eriksen	Ministry of the Environment	Oslo	Norway
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28		Francis E.	Farrugia	Malta Standards Authority	Valletta	Malta
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33		Lisbeth	Frisenborg	DHI Wasser & Umwelt	Stuttgart	Germany
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71	Dr.	Giuseppe	Malinverno	SOLVAY S.A.	Milano	Italy
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90	Dr.	Eckehard	Rosenbaum	Federal Ministry of Economics and Technology	Bonn	Germany
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103	Dr.	Veronique	Steukers	Albemarle	Louvain-La-Neuve	Belgium
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108		Lisette	van Lith	Lyondell Chemical Europe	Rotterdam	The Netherlands
109		René	van Sloten	European Chemical Industry Council (Cefic)	Brussels	Belgium
110		Eric	van Wely	DuPont de Nemours International SA	Le Grand-Saconnex	Switzerland
111		Michel	Vander Straeten	ENIA - European Nickel Industry Association	Brussels	Belgium
112	Dr.	Richard	Vogel	Federal Institute for Risk Assessment (BfR)	Berlin	Germany
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114		Suzanne	Wiandt	BAuA Federal Institute for Occupational Satety and Health	Dortmund	Germany
115	Dr.	Karin	Widmann	THOR GmbH	Speyer	Germany
116		Justin	Wilkes	WWF	Brussels	Belgium
117	Dr.	David	Wilson	LDA International	London	United Kingdom

118		Judith	Winterstein	Adelphi Consult	Berlin	Germany
119		Miranda	Xepapadaki-Tomara	Permanent Representation of Greece	Brussels	Belgium
120		Piotr	Zabadala	Ministry of Economy	Warsaw	Poland

II Programme

The workshop was aimed at substantiating the boundary conditions and criteria for the application of socio-economic-analysis (SEA) according to the new European law on chemicals. The main issue was how to conduct a SEA according to the REACH-Regulation. With this purpose in mind, the conference provided a basis for an exchange of experience regarding methodologies, procedures and criteria. It also offered an opportunity to discuss how socio-economic criteria might be weighted.

Workshop agenda

Day 1

Session chairs:
Klaus Günter Steinhäuser
Federal Environment Agency (UBA), (Germany) - morning
Petra Greiner
Federal Environment Agency (UBA), (Germany) - afternoon

09.00 Registration

09.30 Welcome and introduction
Astrid Klug, Parliamentary State Secretary, Ministry for the Environment, Nature Conservation and Nuclear Safety, (Germany)

09.45 Introductory Presentation on SEA under REACH
Sebastian Gil, European Commission, DG Environment

REACH Implementation Project (RIP) 3.9: Technical guidance document on carrying out a socio-economic analysis

10.00 Report on preliminary study - RIP 3.9-1
Meg Postle, Risk and Policy Analysts Ltd (RPA), (U.K.)

10.20 Report on the status of the subsequent project - RIP 3.9-2
Michael Sorensen, Entec UK Ltd., (U.K.)

10.40 Comment on the methodical approach in RIP 3.9.-1:
Which existing and standardised methods could be resorted to for the realisation of a SEA under REACH and which core procedural rules would be necessary?
Carl Otto Gensch, Institute for Applied Ecology (Öko-Institut), (Germany)

11.00 Questions and discussion

11.30 Coffee break

Use of SEA in other decision making contexts

12.00 Annex F of the Stockholm Convention on Persistent Organic Pollutants (POPs) on socio-economic considerations
Reiner Arndt, Ministry for the Environment, Nature Conservation and Nuclear Safety, (Germany)

12.20 SEA in risk-reduction in the Existing Substances Regulation
Eliisa Irpola, Environment Institute (SYKE), (Finland)

12.40 Questions and discussion

13.15 Lunch break

SEA in national decision-making regarding chemicals

14.20 A Swedish perspective
Åsa Thors, Swedish Chemicals Agency (KemI), (Sweden)

14.40 A U.K. perspective
John Roberts, Department for Environment, Food and Rural Affairs (Defra), (U.K.)

15.00 Questions and discussion

15.30 Coffee break

16.00 Discussion - with experts from the session and the audience
"How can the existing findings on criteria for a SEA be used under the new regime of REACH?"
Chair: **Meg Postle**, Risk and Policy Analysts Ltd (RPA), (U.K.)
Sebastian Gil, European Commission, DG Environment
John Roberts, Department for Environment, Food and Rural Affairs (Defra), (U.K.)
Åsa Thors, Swedish Chemicals Agency (KemI), (Sweden)
Michael Sorensen, Entec UK Ltd., (U.K.)

17.30 Concluding remarks
Petra Greiner, Federal Environment Agency (UBA), (Germany)

17.45 Reception

19.00 Close of day 1

Day 2

Session chair:
Sabine Gärtner
Ministry for the Environment, Nature Conservation and Nuclear Safety, (Germany)

SEA in the Industry

09.00 Industry perspective of SEA under REACH
René van Sloten, European Chemical Industry Council (Cefic), (Belgium)

09.20 Eco-efficiency analysis and SEEbalance
Peter Saling, BASF, (Germany)

09.40 Questions and discussion

10.00 Coffee break

The role of SEA in substitution

10.30 The SubChem project (Sustainable substitution of hazardous chemicals)
Lothar Lißner, Cooperation Centre Hamburg, (Germany)

10.50 SEA and substitution - lessons from Directive 793/73
Martin Frank Mogensen, Environmental Assessment Institute (IMV), (Denmark)

11.10 Non-market values
Lars Drake, Swedish Chemicals Agency (KemI), (Sweden)

11.30 Questions and discussion

12.00 Discussion - with experts from the session and the audience
"What are the impacts SEA has on the decision whether a substance is substituted?"
Chair: **Lars Drake**, Swedish Chemicals Agency (KemI), (Sweden)
René van Sloten, European Chemical Industry Council (Cefic), (Belgium)
Peter Saling, BASF, (Germany)
Lothar Lißner, Cooperation Centre Hamburg, (Germany)
Martin Frank Mogensen, Environmental Assessment Institute (IMV), (Denmark)

13.15 Concluding remarks
Klaus Günter Steinhäuser, Federal Environment Agency (UBA), (Germany)

13.30 Close of day 2

III Reports and Statements – Short introductions[1]

1. **Welcome and introduction** *by Astrid Klug, Parliamentary State Secretary in the Ministry for the Environment, Nature Conservation and Nuclear Safety, Germany*

The statement outlines the fundamental changes REACH implies for the legal system on chemicals. It also describes the role of socio-economic analysis under the regime of REACH and the goals of the workshop.

2. **Introductory presentation on SEA under REACH** *by Sebastian Gil, European Commission, DG Environment*

In his presentation, Sebastian Gil describes the socio-economic analysis in the authorisation and restriction procedures of the REACH-Regulation.

3. **Technical Guidance Document on carrying out a SEA under REACH: Report on preliminary study – RIP 3.9-1** *by Meg Postle, Risk and Policy Analysts (RPA), United Kingdom*

In her presentation, Meg Postle reports on the results of the preliminary study on a Technical Guidance Document on carrying out a SEA, the REACH Implementation Project (RIP) 3.9 -1.

4. **Technical Guidance Document on carrying out a SEA under REACH: Report on the status of the subsequent project – RIP 3.9.-2** *by Michael Sorensen, Entec UK, Ltd., United Kingdom*

In his presentation, Michael Sorensen reports on the status of the Technical Guidance Document on carrying out a SEA in REACH Implementation Project (RIP) 3.9.-2.

[1] The power point slides of the presentations can be downloaded from the conference website: http://www.reach-sea-eu-workshop.de.

5. **Technical Guidance Document on carrying out a SEA under REACH: Comment on the methodical approach in RIP 3.9.-1** *by Carl Otto Gensch, Institute for Applied Ecology (Öko-Institut), Germany*

This presentation describes which existing and standardised methods can be adopted for the realisation of a SEA under REACH. It also discusses which fundamental procedural rules will be necessary.

6. **Annex F of the Stockholm Convention on Persistent Organic Pollutants (POPs) on socio-economic considerations** *by Reiner Arndt, Ministry for the Environment, Nature Conversation and Nuclear Safety, Germany*

In his presentation, Reiner Arndt illustrates the use of SEA in the context of the Stockholm Convention on Persistent Organic Pollutants (POPs).

7. **SEA in risk-reduction in the Existing Substances Regulation** *by Eliisa Irpola, Finnish Environment Institute (SYKE), Finland*

The presentation describes the use of socio-economic analysis in the Existing Substances Regulation and examines which elements of the corresponding Technical Guidance Document should be carried forward to REACH.

8. **SEA in national decision-making regarding chemicals: A Swedish perspective** *by Åsa Thors, Swedish Chemicals Agency (KemI), Sweden*

The presentation reports on the Swedish experience of socio-economic analysis with national decision-making regarding chemicals.

9. **SEA in national decision-making regarding chemicals: A UK perspective** *by John Roberts, Department for Environment, Food and Rural Affairs (Defra), United Kingdom*

In his presentation, John Roberts talks about the experience the United Kingdom has of using socio-economic analysis as part of the work on regulating chemicals and how that experience might be helpful in preparing for REACH.

10. **Industry perspective of SEA under REACH** *by René van Sloten, European Chemical Industry Council (CEFIC), Belgium*

The presentation describes the role of socio-economic analysis under REACH from the perspective of industry. It also enumerates the key criteria for industry und comments on RIP 3.9-1.

11. **Eco-efficiency analysis and SEEbalance** *by Peter Saling, BASF, Germany*

In his presentation, Peter Saling introduces the method known as SEEbalance, developed by the University of Karlsruhe, the University of Jena, Öko-Institut e.V. and BASF with support from the German Federal Ministry of Education and Research.

12. **The SubChem project (sustainable substitution of hazardous chemicals)** *by Lothar Lißner, Cooperation Centre Hamburg, Germany*

This presentation describes substitution regulation under REACH. It also illustrates the deficits which substitution has shown in practice, as well as the main factors involved in the decision whether to substitute or not to substitute.

13. **SEA and substitution – lessons from Regulation 793/73/EEC** *by Martin Frank Mogensen, Environmental Assessment Institute (IMV), Denmark*

Martin Frank Mogensen presents the results of the recent report “Challenges for economic analysis under REACH – what can we learn from previous experience?” compiled by the Danish Environmental Assessment Institute. The final version is to be published in spring 2007.

14. **Non-market values** *by Lars Drake, Swedish Chemicals Agency (KemI), (Sweden)*

In his presentation, Lars Drake gives an estimate of non-market values. He describes, inter alia, various types of non-market values and evaluation methods and suggests some conclusions.

IV Report and Statements – Summaries

1. **Welcome and introduction** *by Astrid Klug, Parliamentary State Secretary in the Ministry for the Environment, Nature Conservation and Nuclear Safety, Germany*

REACH brings about a fundamental change in the legal system on chemicals. Part of this change is that the use of substances of concern will require an authorisation procedure. In addition there is a proven tool: restriction measures for the production and the use of substances of concern. Either – the denial of an authorisation or restriction measures – might interfere seriously with the economy. Both, therefore, require a thorough impact assessment: Are the economic and social consequences of a potential ban of a substance proportionate to the risk presented by the use? This question is dealt with by socio-economic analysis. Up to now impact assessments have often been largely narrowed down to an analysis of the direct economic impacts for the industrial sector concerned only. Impulses that could come from potential restriction measures and that could strengthen industry's innovation capacity have been neglected. In addition, savings for the national economy as a result of reduced healthcare costs or the avoidance of "repair measures" in the environmental sector have not been taken into consideration. Therefore, it is time to establish socio-economic analysis as a tool, which takes into account how society as a whole functions. It must, in a balanced way, deal with the interests of industry as well as with environment and health, both of which are equally important assets. This workshop aims at achieving greater clarity on the concept and the rules of socio-economic analysis and its application. Above all, it should be possible to agree on a common approach with uniform steps, uniform criteria and uniform system limits. Hence, for socio-economic analysis a harmonised approach is absolutely necessary.

2. **Introductory Presentation on SEA under REACH** *by Sebastian Gil, European Commission, DG Environment*

REACH foresees an authorisation procedure for the use of substances of high concern (CMR, PTB, vPvB and equivalent concern). It also includes the possibility of imposing restrictions on production and use of substances of very high concern:

- **Authorisation:** The rules of authorisation (Title VII of REACH) will apply from 1 June 2008. They aim at ensuring that risks from substances of very high concern are properly controlled. Furthermore, they lay down that those substances should be progressively substituted by alternative substances or technologies wherever this is economically and technically feasible. Manufacturers, importers and downstream users applying for authorisation shall be obliged to analyse the availability of alternatives, considering their risks and the technical and economical feasibility of substitution. The EU-Commission must grant an authorisation if risks are adequately controlled. If risks which are not adequately controlled remain, it may only grant an authorisation if socio-economic benefits outweigh the risks and if there are no suitable alternatives. Interested parties are invited to submit information on alternatives.

- **Restrictions:** The restrictions are a "safety net". They can be initiated by Member States and the European Commission. The provisions concerning restriction (title VIII of REACH) will apply from 1 June 2009. Any proposal for restriction (Annex XV dossier) prepared by a Member State or the European Chemicals Agency (upon request from the European Commission) shall include information on hazard and risk, available information on alternatives (concerning risks, availability, technical and economical feasibility), justification and information on any stakeholder consultation. It may also include socio-economic analysis. Furthermore, third parties are invited to submit a socio-economic analysis or input to a SEA.

The decision about authorisation and restriction will be made by the European Commission. In both procedures it will be based upon the opinions of the Socio-Economic Analysis (SEA) Committee and the Risk Assessment Committee. In this way, socio-economic analysis supports decision making: weighting the socio-economic benefits associated with the use of the substance versus the risks of its use. For the preparation of a SEA the European Commission shall prepare guidance. A scoping study – RIP 3.9-1 – is already finalised and available on the website of the European Chemicals Bureau (ECB). The work on the final draft Technical Guidance Document (TGD) started in November 2006 und will be finalised by November 2007.

3. **Technical Guidance Document on carrying out a SEA under REACH: Report on preliminary study – RIP 3.9-1** *by Meg Postle, Risk and Policy Analysts (RPA), United Kingdom*

The presentation outlines the objective and approach of the study and the structure of the Final Report. It illustrates that the study is aimed at providing a preliminary report investigating the current state of the art concerning the application of socio-economic analysis (SEA) to chemical risk management and the need of guidance for different stakeholders when developing either a SEA or inputs to one during the REACH authorisation and restrictions procedures. The study identifies and reviews the relevant background on the use of SEA in chemical risk management, establishes the state of the art in SEA applied to chemical risk management, analyses the decision chains and the requirements for SEA under the authorisation and restrictions processes, reviews presentational formats and methods, identifies what types of software tools may be of value and develops case studies. The Final Report contains illustrative frameworks for the Guidance based on 'best practice' (Part A), supporting information on impact assessment (Part B) as well as consultation, case studies and checklists (Annexes). In her conclusions and recommendations, Meg Postle underlines the importance of flexibility in the Technical Guidance Document: There are different users such as large and small companies and third parties. They will make use of the Guidance in different manners. Furthermore, up-dates and new developments in SEA and other relevant assessment practices will have to be included in the Guidance. The presentation also recommends proportionality of a SEA. It outlines that the guidance should stress areas where specific expertise may be required. It also describes what is expected of the Guidance, e.g. accessibility to all users, details of the criteria according to which SEA may be assessed, as well as software tools.

4. **Technical Guidance Document on carrying out a SEA under REACH: Report on the status of the subsequent project – RIP 3.9.-2** *by Michael Sorensen, Entec UK, Ltd., United Kingdom*

In his presentation, Michael Sorensen describes the objectives, working plan, status and preliminary findings of RIP 3.9.-2. The key objective is to develop the (draft) final

guidance document, which shall be finished in November 2007. The review of RIP 3.9.-1 shows that it contains a consistent and logical structure for the analysis and a comprehensive coverage of specific economic tools. It includes first steps towards providing practical guidance. However, the presentation also makes clear that still more is needed to make it operational. The review also gives evidence that there are differing needs concerning the restriction proposals and the applications for authorisation. In addition, the third parties involved will also require specific guidance. In RIP 3.9-2, case studies on restrictions and authorisation will be carried out. Industrial sectors or industry associations participating in case studies can benefit by gaining experience of undertaking a SEA or providing input to one and reflecting the needs of the users. The preliminary findings of methodological issues outline that the baseline of SEA might be the continued use(s) of the substance and use(s) in question. In addition, it shows that the system boundaries are determined by the type of impacts that are examined, geographical and time factors.

5. **Technical Guidance Document on carrying out a SEA under REACH: Comment on the methodical approach in RIP 3.9.-1***, by Carl Otto Gensch, Institute for Applied Ecology (Öko-Institut), Germany*

In a first step, the presentation describes the specific background for the comments and recommendations of the Institute for Applied Ecology concerning management of chemicals under REACH and the development and application of methods focusing on the whole life cycle of substances. It goes on with outlining the different kinds of alternatives examined within the scope of a SEA: substance level, material / component level and product level / design changes. So far, evidence suggests that alternatives are only sought at the substance level. The Guidance Document should therefore provide best practice examples illustrating different levels of substitution. Annex XVI says, that the level of detail and scope of SEA is the responsibility of parties with an interest regarding an application for authorisation and/or proposals for restrictions, and that the information provided can address the socio-economic impacts at any level. The presentation recommends that the guidance should include best practice examples in order to avoid misunderstandings. It also illustrates that RIP 3.9.-1 concentrates on methods based on the concept of economic efficiency. Thus, it will be necessary to convert environmental and health impacts into monetary

values. Such a conversion has been discussed for many years, resulting in a broad range of concepts and methods. But until today, no consensus has been achieved. Hence the presentation favours the avoidance of a conversion of environmental and health benefits or risks into monetary values. Instead, the methods of Life Cycle Assessment, Life Cycle Costing and Social Life Cycle Assessment should be taken into consideration. Finally, it recommends that the Guidance Document should include some key procedures developed in the context of Life Cycle Assessment.

6. **Annex F of the Stockholm Convention on Persistent Organic Pollutants (POP) on socio-economic considerations**, *by Reiner Arndt, Ministry for the Environment, Nature Conversation and Nuclear Safety, Germany*

To begin with, Reiner Arndt gives a definition of **P**ersistent **O**rganic **P**ollutants (POP). He also describes the impacts and releases of POPs and outlines the content of the Stockholm Convention. He gives an overview on POPs presently covered by the Convention and POPs proposed for future incorporation. He makes clear that identifying a POP necessitates a complex process. As regards the proposed additional POPs, the Stockholm convention foresees the following procedure:

- **Screening** (Annex D)**:** The screening includes chemical identity, persistence, bio-accumulation, potential **l**ong **r**ange environmental **t**ransport (LRT), adverse effects, existing POP/field data and new estimations of POP.

- **Risk profile for additional POP** (Annex E)**:** The risk profile implies an assessment of potential long range environmental transport and of significant adverse effects. The assessment examines the sources (production, uses and releases), a hazard assessment (interaction with other chemicals), environmental fate (bio-accumulator factor), monitoring data, local exposure and LRT exposure, national and international hazard and risk information, status under other Conventions.

- **Risk Management evaluation** (Annex F)**:** If a chemical is identified as a POP, it will be subject to the control regime of the Stockholm Convention. The substance shall be phased out, or at least there shall be a reduction of releases. This stage of the process demands socio-economic considerations. They

include efficacy and efficiency of possible control measures, alternatives (costs, risks, efficacy and accessibility), positive and negative impacts of control measures on health, agriculture, biota, economic aspects, social costs as well as waste, disposal implications, stockpiles, access to information, status of control and monitoring capacity and any other action taken. Beyond this, the presentation describes the still ongoing process and content of the risk management evaluation of additional POPs.

7. **SEA in risk-reduction in the Existing Substances Regulation**, *by Eliisa Irpola, Finnish Environment Institute, Finland*

The presentation outlines the **E**xisting **S**ubstances **R**egulation (ESR): The rapporteur shall evaluate the risk of a substance to man and environment and suggest, where appropriate, control measures for limiting these risks. Where the measures include restrictions on the marketing or use of the substance, there shall be an analysis of the advantages and drawbacks of the substance and of the availability of replacement substances. Under the ESR, there also is a Technical Guidance Document (TGD) on Development of Risk Reduction Strategies. To develop a risk reduction strategy under the ESR, it is necessary to identify the stages in the substance life cycle where risks need to be limited. There is also a need to identify the risk reduction options and tools. Following this, the most appropriate risk reduction strategy should be selected. Based on past experience, the presentation illustrates the most appropriate approach to risk reduction which includes the following elements: effectiveness, practicality, economic impact and monitorability. The analysis of advantages and drawbacks aims at providing available information and at comparing different aspects for the restriction. The extent of the analysis is decided on a case by case basis. The scope includes not only the restriction of the substance, but also net advantages and drawbacks of substitutes. In addition, the analysis of advantages and drawbacks deals with uncertainty, compares alternative control measures and recommends consulting other parties in the European Union on a wide basis. The presentation also illustrates the qualitative and quantitative analysis involved in the comparison of advantages and drawbacks and describes socio-economic analysis under ESR in practice. It examines the advantages and disadvantages of assessments and the strengths and weaknesses of the current

TGD. In addition, it gives answers to the following questions: Is quantification of costs or benefits required in order to make the case that socio-economic benefits outweigh the risks? What weight should be given to direct costs compared to wider economic and trade effects? How much effort should be put into analysing and reporting any uncertainties? Should there be guidance on consultation with interested parties when preparing a SEA? What types of methodology could be used in comparing costs and benefits?

8. **SEA in national decision-making regarding chemicals: A Swedish perspective,** *by Åsa Thors, Swedish Chemicals-Agency (KemI), Sweden*

In her presentation, Åsa Thors describes the circumstances under which a mandatory impact assessment regarding chemicals has to be carried out in Sweden. It is required for all new and amended regulations, even when a regulation is implemented as a consequence of a European directive. It should take place as soon as possible whenever a new or amended regulation is being considered and before the authority decides on a regulation. Before a decision is made, an assessment has to take place as to whether the solution proposed is the most suitable action. The costs and other impacts have to be evaluated. Potential impacts on small enterprises have to be analysed separately and as soon as possible. Concerned industry representatives and authorities have to be consulted before a decision is taken. The Authority Ordinance gives no guidance on how the analysis should be conducted or to what extent. The presentation reports on experiences and current work. It also specifies what KemI likes to see in a SEA under REACH: a balanced basis for decision-making, improved analysis of impacts on environment and human health, long-term impacts, substitution and dynamic effects.

9. **SEA in national decision-making regarding chemicals: A UK perspective,** *by John Roberts, Department for Environment, Food and Rural Affairs, United Kingdom*

John Roberts reports that if there is a proposal for a new policy or a new regulation the UK Government system demands an impact assessment. This aims at ensuring that the costs and benefits of any new policy are properly identified from the outset, and where possible quantified and set out in monetary terms. Stakeholders including industries which will be affected have to be consulted, and the results published and presented to the Parliament. The proposed regulation has to be compared with other possible ways of achieving the outcome – for example voluntary approaches. In addition, impact assessments have to be undertaken examining the implications of competition in the markets affected, and identifying whether disproportionate costs would be imposed on specific sectors, such as small businesses. As part of this policy a number of impact assessments have been prepared during the last few years, which showed some lessons: Getting data is a serious problem. The baseline – the "do nothing" option is subject to frequent change. Sometimes interesting data does emerge. For example, for nonylphenol, it became clear that 80 % of the burden could be removed at a cost to industry of less than £ 25 million, the next 18 % could be removed for an extra £ 40 million, but the last one or two percent would cost another £ 110 million. Another issue is to identify the benefits of regulation – the improvements to human health, and the reduction in damage to ecosystems which will follow from reduced exposure to a hazardous chemical. John Roberts argues that he does not think that any of the UK impact assessments have really robust quantitative assessments of the benefits of regulating a substance. Frequently, it is very difficult to say what specific benefits there will be to the ecosystem, or how many days of ill health or premature deaths will be avoided in practice. This makes it difficult to demonstrate that the benefits will exceed the cost. Therefore, the impact assessments undertaken in the UK have usually described the benefits in general, unspecific and unqualified terms. John Roberts makes clear that impact assessments should highlight uncertainties, for example by setting out a range of estimates for costs and benefits, and by considering the consequences of changes in key assumptions. As regards lessons for REACH, he underlines the need for industry to be given very good guidance. The approaches of the assessment should also be practical and should not burden industry excessively. Above all, the aim should be to enable the REACH process to deliver a better protection of health and the

environment, but in ways which do not damage the competitiveness of European industry.

10. **Industry perspective of SEA under REACH,** *by René van Sloten, European Chemical Industry Council (CEFIC), Belgium*

At the beginning of his presentation, René van Sloten describes the role of socio-economic analysis in REACH. He outlines that the industry regards socio-economic analysis as an important element in the decision process regarding continued use of substances. He also illustrates that the application of the substitution principle in the authorisation procedure was the key issue in the negotiations between the Council and Parliament and that the substitution principle has been strengthened by the outcome. Furthermore, the presentation describes the basics of the authorisation procedure and names the SEA related articles. It also explains in which cases applicants will get an authorisation. It outlines the following key criteria for industry: the European Commission's guidance document will be non-binding, the choice of methodology and relevant factors in the document ought to be flexible and the results fully transparent, an endless iterative process should be avoided. The SEA should not be overly complicated. It should be possible to draw up a SEA without specialised consultants. Key data need to be credible and of good quality. When health or environmental benefits are quantified, double-counting shall be avoided. The baseline of a socio-economic analysis should be "business as usual". The presentation also comments on the results of RIP 3.9-1: It states that innovation might be more costly than indicated in the RIP 3.9-1 reports and argues for changes and further guidance. Health and environmental benefits are difficult to monetise. Therefore 'socio-eco-efficiency' is rather more preferable than monetisation. The presentation also expresses the wish that the SEEbalance methodology should be included as one of the possible eco-efficiency methodologies.

11. **Eco-efficiency analysis and SEEbalance,** *by Peter Saling, BASF, Germany*

The presentation begins by underlining that SEEbalance is based on the three pillars of sustainable development. Economy, ecology and society are given equal weight. It

describes the method as a comprehensive assessment of products and processes. Products are analysed with a “cradle-to-grave”-approach from the angle of the customer. The assessment includes different product alternatives for a defined “user benefit”. The final result compares the alternatives with each other and leads to a ranking of different products or processes with regard to their sustainability. Peter Saling states that various different analyses have already been performed successfully using this method in fields such as packaging, nutrition, cosmetics, energy supply, varnishes and pigments, chemicals and plastics. He also states that the method has been recognised by several national and international institutes and authorities. Furthermore, eco-efficiency as part of SEEbalance has been validated by the German TÜV. The presentation describes the standard procedure of SEEbalance. It gives general information on the calculation of costs involved in this methodology and examples of cost factors evaluated in SEEbalance. In addition, it illustrates the social assessment, the evaluation of eco-efficiency and the decision-making process. Finally, Peter Saling describes his view of the minimum requirements for a SEA as the basis for the RIP 3.9-2 process. He also suggests using SEEbalance for authorisation and restriction processes under REACH.

12. **The SubChem project (Sustainable substitution of hazardous chemicals),** *by Lothar Lißner, Cooperation Centre Hamburg, Germany*

Lothar Lißner begins with explaining the provisions under REACH regarding substitution: If there are existing suitable alternative substances or technologies, applicants for authorisations must prepare substitution plans. If not, they should provide information on research and development activities, if appropriate. The European Commission may amend or withdraw any authorisation on review if suitable substitutes become available. On the other side, even if there is no adequate control of the risk of the use, an authorisation may be granted if the socio-economic benefits outweigh the risks and if there are no suitable alternative substances and processes. When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the European Commission, including whether the transfer to alternatives would result in reduced overall risks to human health and the environment, and whether technical and economic alternatives are feasible for the applicant. The presentation also shows that

substitution is not a new idea. In fact, it has been around for over twenty years. Many EU-Directives demand substitution. But practice shows a lot of deficits. Thus, Lothar Lißner outlines that most enterprises do not follow the simplest rules. For example, about 1.3 million British companies handle chemicals. When questioned, only 16 % were able to state the applicable law for handling chemicals or the limit values for the substances in the workplace. In the face of deficits such as these, Lothar Lißner asks how substitution can work. The main factors affecting the decision not to substitute are uncertainty, the principle of never changing a running process and technical or economical difficulties. Substitutes are also less tested and integration in the production chain makes innovation beyond enterprise borders necessary. The presentation also illustrates the main factors to substitute and the major NON-Substitution-strategies for risk reduction und examines what those experiences mean for substitution requirements under REACH.

13. **SEA and substitution – lessons from Regulation 793/73/EEC***, by Martin Frank Mogensen, Environmental Assessment Institute (IMV), Denmark*

The presentation describes the focus of the study: to analyse past experience with SEA in relation to Council Regulation 793/93/EEC and to the US 'Toxic Substance Control Act'. The study is based on a sample of 22 Risk Reduction Strategies conducted under 793/93/ECC and 7 reports conducted by the US-EPA under similar US regulations. The main observed constraints were access to data (EU + US), limited focus on benefits (EU + US), non-systematic coverage of impacts (EU) and non-systematic coverage of uncertainty as well as assumptions and limitations (EU). Against this background, the presentation outlines the strong need for improved access to data, for more focus on benefits and systematic coverage of impacts. It also describes, that there is only a low level of uncertainty analysis in EU reports, that no sensitivity analyses are conducted and that there is a low degree of coverage of assumptions and limitations. Furthermore, Martin Frank Mogensen states that substitution has been analysed in 19 out of 22 EU reports. This analysis focused mainly on environmental and health effects. None of these 22 EU reports assessed alternatives with the same degree of detail as they assessed the existing substance. Looking ahead, the presentation asks some crucial questions on whether more socio-economic analysis will also mean more substitution of hazardous chemicals.

14. **Non-market values** *by Lars Drake, Swedish Chemicals Agency (KemI), Sweden*

Lars Drake outlines that the comparison of risk and economic values is the basis for decisions on authorisations and restrictions. He lists different types of non-market values: direct use value, indirect use value, option value, existence value and bequest value. He also reports what they measure: Peoples willingness to make sacrifices, mostly of private material consumption, in order to bring about improvements in the environment or health status; as well as individual preferences versus expert knowledge. He also illustrates the problems with aggregation, equity and measuring. For example, utility can not be measured, but willingness to pay can be. In addition, the utility of different individuals cannot be compared, but different solutions can be. Furthermore, many effects of production and consumption are not valued in the market, but non-market values can be estimated. The presentation describes different groups of environmental valuation methods: revealed preferences (production function, hedonic price, travel cost, defensive expenditure), stated preferences (contingent values, choice experiments) and methods not based on welfare theory (human capital, political decisions, replacement costs, restoration costs). It also illustrates the estimation of health and environmental values. In his conclusions, Lars Drake states: Economic analysis is part of REACH. Biased analyses are expected. There are difficulties in measuring environmental effects. Methods exist but none is very good. There are few studies on this issue relating to chemicals. Additionally, it is expensive to carry out some types of analysis, therefore those cannot be recommended in single cases. A risk index can be used as a cardinal scale. It can be transformed into economic values using a few economic analyses. This could be very useful for the SEA committee.

V Discussion

During the two days of the workshop the following issues, statements and questions were referred to or discussed:

1. Methodology

- There must be flexibility and proportionality in the socio-economic analysis.
- The guidance should be flexible but there is also a need for good examples, e.g. you should have answered that and that.
- Socio-economic analysis must be practical. Simple is beautiful.
- Socio-economic analysis is a learning process.
- We need openness and not just fixed values.
- The perfect studies – we have not seen them.
- There is a need for transparency, which can be established by involving stakeholders. In addition, there is a need for an open debate about what can help achieve transparency.
- Should the guidance on socio-economic analysis promote a certain method? Or might it be better to offer flexibility in this issue?
- The kind of methodology also depends on the information being available. Therefore the guidance should make it clear what kind of information is necessary to adapt the methodology.
- We need tools and examples of life cycle analysis, which should be flexible.
- REACH will show that there is a lack of benefit studies; universities will take up the issue and conduct studies.
- We need more socio and scientific research. One problem is that we mainly consider the economic costs.

a Boundaries of a SEA

- What are the system boundaries? Types of impacts and effects? Geographical and time perspectives?
- It is important to define the aims of analysis before you start.

- It is necessary to focus on the main impacts. Should / could there be a checklist for this purpose?
- Socio-economic analysis should view the whole life cycle.
- The time issue has to do with time limits. We discount the future. How should uncertainty be addressed?
- We have to face the fact that the socio-economic analysis is a bottleneck: Time and money are limited. Therefore we have to ask what absolutely has to be in there.
- What is the baseline of socio-economic analysis and alternatives? Is it the continued use of the substance?

b Assessment of alternatives within a SEA

- How can alternatives be identified and how should they be assessed? For example fire retardants. One alternative is to change the construction standards. But it is not realistic to examine all the alternatives.
- The European Chemicals Agency will give information concerning alternatives on its website.
- It is difficult to get information about alternatives, whether from industries or NGOs. Some have experience in obtaining information through one to one discussions. But this method is very time-consuming.
- Temporal impacts are important for substitutions: What could the future technology be?
- While substitution is difficult for a single company, it is less so for a branch. Therefore we should invite companies to work together on this issue.
- Branch agreements are the best way for substitutions.
- How will branch-wide substitution influence socio-economic analysis?
- There are different definitions of substitution. It should not only include technical but also organisational measures. We observe that chemicals are increasingly replacing qualified labour, e.g. smoothing a floor by chemicals instead of doing it by workmanship.
- How can substitution be performed? What will be the method?

c Uncertainty / Lack of data

- How can we treat uncertainty in the socio-economic analysis?
- Until now there has been a lack of data. Yet this might change as a result of the registration procedure under REACH.
- Every sector knows a lot about its own sector. But it does not necessarily know the health and environmental costs. No enterprise has such data. What can we do to improve this situation?
- One way to get more information might be through a consultant as an information broker.
- It is dangerous to rely entirely on information contributed. There are other means to elicit information. Perhaps on the winners side.
- In the view of the chemical industry, the applicant will do the utmost to provide the necessary information. But maybe he will not be able to do this.
- The ideal is a full cost-benefit analysis. But in reality we learn a lot about costs and we have to ask about the benefits.

d Estimation of costs and non-market values

- How can costs be assessed?
- There are short term economic costs and long term ecological and health costs. How can you get the balance right?
- The applicant for authorisation has an interest to present his information for socio-economic analysis in a way which is the best for him. The tendency will be to overestimate costs. How can this meet the need for a real picture in the socio-economic analysis process?
- It is necessary to avoid partiality.
- We should calculate in terms we already know.
- It is easer to quantify the short term costs than the long term benefits. Is there a way to resolve this problem?
- There are various methods for quantifying health effects. But they are all very subjective.
- How can we evaluate human health and environmental risks in a better way? And how can we bring them into the assessment process?

- What is the price of a human being? This implies that a value for a statistical life exists; it is an ethical question. A lot of participants of the workshop also underlined they have problems with the statistical life concept for different reasons.
- In the Netherlands, we have a new report concerning estimation of human health effects. It shows that the direct health effect is not as high as expected. But this changes if you look at the hospital costs.
- There is another problem: the eco-systems of different member states do not have the same value. Therefore we need to standardise value.

2. Technical Guidance Document

- What level of detail is necessary for a socio-economic analysis? And how can the need for details be met by a general guideline?
- The existing Technical Guidance Document (TGD) should be carried into REACH and complemented by further amendments. Though TGD is not always best practice, it is practical reality.
- Should there be special treatment for small and medium sized enterprises? Is the size of a company an ideal criterion? Or would it be better to look to company earnings?
- Shall we be given specific guidelines on socio-economic analysis or merely one general one? This question is still under discussion.
- Do case studies on socio-economic analysis already exist? The European Commission has invited companies to come forward with case-studies. But experience shows that nobody seeks to attract attention to certain substances. If anybody wants to propose case-studies they can address them to the European Commission.

3. Procedure

- Which substances should go to socio-economic analysis?
- Stakeholders should be encouraged to take part in the consultations. But there is no legal duty to consult stakeholders.

- When should stakeholders be consulted and introduced: at the very outset of the socio-economic analysis or later?
- What conditions will apply to third parties giving input to socio-economic analysis? All contributions by third parties must be considered insofar as they contain useful information. The decision as to what is useful might well be a political one.
- If a small or medium enterprise undergoes an authorisation procedure and learns that a big company has already received an authorisation for the same substance and the same use(s), will it benefit from the former authorisation decision? If one party has been granted an authorisation it can be shared with others. But they would have to pay a fee.
- When a company requests an authorisation, it has to communicate with its downstream-users. What is the level of these consultations? How detailed should these consultations be?
- What is the role of the European Chemicals Agency in the socio-economic analysis? The Socio-Economic Committee of the Agency will conduct the socio-economic analysis.
- If a company does not undertake a socio-economic analysis, will the Agency do so? It is the duty of the applicant to conduct a socio-economic analysis. If he does not do so, he weakens his own position.
- Does the Agency only assess the information they get from the applicant? They can decide to go further. But the goal is that the applicant makes the case with the primary responsibility being on his side.
- Who has to pay for this extra analysis performed by the Agency? It will financed by the fees.

4. Miscellaneous

- Risk assessment and socio-economic analysis cannot be separated.
- What is the relation between risk assessment and risk reduction?
- There should also be a set of criteria for risk perception.
- One problem of risk reduction strategies is that they examine just one substance and one application.
- There is also a need to keep the EU-Market-Balance.

- We (the chemical industry) demand that the European Commission and NGOs examine what is happening outside the European Union, especially concerning products coming into the European Market from outside.
- The impact of REACH will be huge. We should not talk in terms of winners and losers. In reality it is a moving baseline over time.
- Future generations are the winners. The losers bear the costs now.
- The total effect on the side of losers is huge yet it is not so big if you look at just one single loser.
- Besides losers and long term winners there are also short term winners. But they are not well organised. How can this be changed? How can the short term winners be better organised?
- Will BASF offer SEEbalance free for all, especially for small and medium enterprises? Yes, in principle we will make it available, but only without the database. Experience is required to use SEEbalance. In general, it is also doubtful whether small and medium companies have the know-how to conduct SEE-balance.
- We do not have a legal problem, but a lack of enforcement.
- Classification leads to a label.

VI Conclusions

1. **Concluding remarks of the first day**, by Petra Greiner, Federal Environment Agency (UBA), Germany

In her concluding remarks, Petra Greiner underlines the need for transparency in the preparation of socio-economic analysis. Consideration should also be given to the situation of small companies. Still more work and research is necessary to assess the benefits of measures. Further points which shall be considered for future guidance on SEA-performance under REACH include the uncertainty of the assessments, establishing “checklists” and the need for pragmatic solutions.

2. **Concluding remarks of the workshop**, by Klaus Günter Steinhäuser, Federal Environment Agency (UBA), Germany

In his concluding remarks, Klaus Günter Steinhäuser summarises the crucial questions discussed during the two days of workshops. He makes clear that the conference has provided a number of answers, for example concerning the information that can be expected to be submitted by the applicants, the appropriate system boundaries, the appropriate baseline and the flexibility of the guidance. He also describes the main results of the discussions and some lessons learned.