Nordic Workshop on Socio-Economic Analysis (SEA) in the new chemicals legislation – REACH.

2-3 March 2005, Helsinki, Finland

A REPORT FROM THE WORKSHOP

Organised by a working group under the Nordic Council of Ministers
The Nordic Chemicals Group, The Nordic Risk Management Group

CONTENTS

APPENDICES

Preface

During two days representatives from Nordic authorities responsible for chemical risk management and an expert from Risk and Policy Analysts Ltd (United Kingdom) met in Helsinki, in March 2005 to discuss ways to improve the quality[1] of Socio-Economic Analysis (SEA) with respects to SEAs' future use in the new European chemical legislation REACH (Registration, Evaluation and Authorisation of Chemicals). The workshop was initiated and organised by the Nordic Risk Management Group, subordinated to the Nordic Council of Ministers for the environment.

Point of departure for the discussions where the Annex XV (Socio-Economic Analysis) of the REACH proposal which outlines the information that may be addressed in an application for authorisation or in connection with a proposed restriction. In the annex it is however also stated that it is the responsibility of the applicant or other interested parties to determine the level of detail and scope of the SEA. The Nordic countries has a common view that current 'Socio Economic Analysis' used so far has to be further developed with regard to future use of SEA in REACH. Due to the limited time the workshop however focused on three themes: (1) information on substitutes, (2) benefits for health and environment and (3) dynamic consequences.

The following aims were set for the workshop:

- to exchange experiences of current work on SEA with the aim to identify ways how the know-how developed could be transferred to future SEAs
- to raise knowledge and understanding among the Nordic authorities on the possibilities and limitations in the work with SEAs
- to identify important elements of the current SEA methodology, and the application thereof, that should be further developed with regard to the future use of SEA in the context of REACH
- to provide input to the guidance documents that are being prepared in relevant REACH implementation projects (RIPs).

.

One result of the workshop is the following report in which summaries of the presentations and conclusions from the discussions on development of SEA are presented. The aim of the report is to give input to the work undertaken by the consortias in REACH Implementation Projects, RIP 3.9 (Guidance document on SEA) and RIP 4.4 (Guidance document on Annex XIV dossiers) and to the Nordic countries regarding the Council negotiations on titles VII (Authorisation), VIII (Restriction) and Annex XV (Socio-economic analysis) of the REACH proposal. Presentations are attached as appendices.

[1] Methodology/models, data-input, scope and administrative aspects such as the authority of the SEA-committee etc.

The Nordic Risk Management Group consists of representatives from the regulatory authorities from the five Nordic countries:

- Denmark: Anette Albjerg Ejersted, Danish Environmental Protection Agency
- Finland: Kirsi Sihvonen, National Product Control Agency for Welfare and Health (Chair person of the Group)
  Heikki Salonen, Finnish Environment Institute
- Island: Haukur Runar Magnusson, Environment and Food Agency of Island
- Norway: Kari Aa, Norwegian Pollution Control Authority
- Sweden: Göran Gabrielsson, Swedish Chemicals Inspectorate

The Nordic Risk Management Group would like to express its gratitude to all who contributed the successful workshop, the Nordic Chemicals Group, workshop speakers, workshop participants and the secretary help from the Finnish National Product Control Agency for Welfare and Health.

May 2005

Nordic Risk Management Group

1 Background

1.1 General

The European new chemicals legislation (REACH) is anticipated to enter into force in 2007. REACH covers Registration, Evaluation and Authorisation of CHemicals and it will replace the current legislation concerning existing substances (Regulation 793/93), new chemicals and classification and labelling (Directive 67/548) and also marketing and use restrictions (Directive 76/769).

The Commission (COM) has adopted its proposal for a Regulation concerning REACH on the 29th October 2003. Before the Regulation enters into force the Commission and Member States (MS) have decided about the interim period (from November 2003 to March 2006 or 2007) when necessary guidance and training material will be produced and necessary changes for the present working structures towards REACH will be created. Therefore the Commission has launched a programme for REACH implementation projects (RIPs).

In the REACH proposal, industry is invited to submit a socio-economic analysis (SEA) if it cannot be shown that the risks of a specific use of a substance under authorisation are adequately controlled. Also under restriction procedure, industry and other stakeholders are invited to submit an SEA or input for one for a substance, or a specific use of a substance, for which restrictions have been proposed. A Member State submitting a restriction dossier may also provide an SEA as may the Chemical Agency preparing a restriction dossier on request of the Commission. In the REACH proposal the Agency will have committees to prepare opinions during the preparation work; a Risk Assessment Committee and a Committee for Socio-economic Analysis. This SEA Committee shall be responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions and any other questions that arise from the operation of the Regulation.

During the interim period one of the RIP-projects' aim is to prepare a guidance document for SEA (RIP No: 3.9).

1.2 Socio-economic analysis (SEA)

According to the current legislation for existing substances (Reg. 793/93/EEC) the rapporteur of a substance prepares a strategy for limiting risks, which are identified in the evaluation phase. If marketing and use restrictions are recommended, an analysis of the advantages and drawbacks and of the availability of alternatives should be submitted. Thus some kind of SEA has been conducted on a case-by-case basis according to the Technical Guidance Document on Development of Risk Reduction Strategies (European Commission, January 1998).

Also when an MS has notified a national ban of a chemical an SEA, e.g. a cost-benefit analysis, has been conducted to show that the positive impacts of the proposed risk reduction measures outweigh the negative impacts.

In addition, OECD has developed guidance documents on the use of SEA in chemicals risk management. In other contexts cost-benefit analysis, risk-benefit analysis etc. have been used. Thus terminology and nature of analysis and methodology has varied depending of the working area.

The Nordic Risk Management Group has a common view that current 'Socio-Economic Analysis' (SEA)[2] used so far has to be further developed with regard to future use of SEA in the new European chemical legislation, REACH. SEA will be used in two different purposes in REACH. Companies seeking authorisation for the use of chemical substances with intrinsic properties of very high concern (SVHC) have the possibility to show that the socio economic benefits outweigh the risk from further use of the substance. SEA will also be used when authorities in the Member States aim at restriction for a chemical substance or a specific use of that substance.

The Annex XV (Socio-Economic Analysis) of the REACH proposal outlines the information that may be addressed in an application for authorisation or in connection with a proposed restriction. According to the Annex XV an SEA may include the following elements concerning impacts of a granted or refused authorisation or a proposed restriction:

- impact on the applicant, or impact on industry, or impact on all other actors in the supply chain, downstream users and associated businesses
- impacts on consumers
- social implications (job security, employment)
- availability, suitability and technical feasibility of alternatives and economic consequences thereof
- wider implications on trade, competition and economic development (in particular SMEs)
- other regulatory or non-regulatory measures (in the case of a proposed restriction)
- the social and economic benefits of the proposed restriction
- any other relevant issue

1.3 REACH implementation project (RIP) 3.9

Before the Regulation will enter into force the intention of the Commission is to prepare necessary guidance and training material for industry and Member States. During this Interim period the Commission has launched a programme for REACH implementation projects (RIPs). One of the RIPs is intended for a preparation of a guidance document for SEA (RIP No: 3.9). The aim of the RIP project is to prepare guidance for industry, which shall specify when and how to

[2] Here synonymous with e.g. "impact assessment", analysis of advantages and drawbacks, "risk reduction strategy report"

conduct a socio-economic analysis under REACH. The project will be divided into two phases, the scoping study and the main project.

A project description for the RIP-project emphasises that guidance should strive for making SEA outputs as comprehensive, consistent and user-friendly as possible.

A related RIP-project (RIP 4.4) shall prepare a guidance document for Annex XIV dossier. A Member State or the Agency preparing a proposal for restriction of a substance compile a dossier that fulfils the requirements laid down in this Annex.

1.4 Workshop themes

As the Annex XV describes, a wide variety of elements could be included in the preparation of SEA. Because a workshop of reasonable length cannot handle all the elements, it was considered realistic to concentrate on few issues that are regarded as important in the authorities' point of view. In the light of experience from the previous use of SEA in the Nordic countries and within the EU the following three main areas of development has been identified as most important;

Information on substitutes – Alternative chemical products and/or alternative technical solutions. When dealing with substitution it is important to adopt functional thinking, i.e. to consider what function the chemical substance provides and in what way this function can be replaced, using not only an other chemical substance but also by using a technical solution. When dealing with issues of authorisation or restriction in REACH it will be of vital importance to gain knowledge about accessible substitutes or substitutes that will be accessible in the near future. It can also be fruitful to consider if the restriction in itself can provide basis for new innovations. Nevertheless it is not often in the interest of the company seeking authorisation, or the company producing the chemical substance subject for restriction, to leave information on possible substitutes. Dealing with this theme it is therefore important to discuss different issues on how to gather the information needed to prepare an SEA.

Benefits for health and environment – In SEAs today benefits for health and environment are often described in non monetary terms often due to lack of suitable tools. It is not unusual that an SEA ends up with monetary drawbacks for industry/society to be weighted against non monetary benefits for health and environment. For the future use of SEA in REACH it is important that health and environmental benefits, when possible and ethically acceptable, can be valued in a way that they can be compared to costs for the industry. It is also important to develop means to measure economic benefits from substitution such as the prevention of costs for decontamination of land, lowered healthcare costs etc.

Dynamic consequences – Socio economic consequences on the EU market from non-granted authorisation or restriction of chemical substances. SEAs today

often lack consideration of dynamic benefits and more or less only puts focus on direct/momentarily economic drawbacks for the companies producing a chemical substance targeted for restriction. To get a broader picture of all relevant socio-economic impacts in question it is important that SEAs in the context of REACH also consider impacts on a wider scale (externalities) and from a longer time perspective. Dynamic benefits on the EU-market are e.g. direct and indirect economic consequences such as prospects for innovation and development of new techniques and in the long run improved business and opportunities for companies producing substitutes or alternative techniques.

2 Presentations of the workshop

Ms **Katariina Rautalahti** from the National Product Control Agency for Welfare and Health (FI) welcomed the participants to the workshop. She outlined briefly the organization of the Finnish administration dealing with the safety of chemicals. She also highlighted the selected themes (Information on substitutes; Benefits for health and environment; Dynamic consequences) on which the workshop is intended to concentrate on current occasion.

Mr **Jukka Malm** from the Finnish Environment Institute (FI) gave an overview on EU's Chemicals Policy reform – what are the main objectives and means of the Commission proposal for REACH Regulation. The registration process is aimed to get industry to assess and ensure safe use of chemicals all along their life cycle. In addition to that for substances of very high concern an authorization will be required prior to their use and marketing. In this context has a socio-economic analysis a significant role to play. The same applies to issuing marketing and use restrictions, which will also be accelerated based on better means provided by REACH. Mr Malm also touched the future role and tasks of the Chemicals Agency and the status of the REACH negotiations. The entry in force of REACH is currently anticipated in mid 2007.

Ms **Meg Postle** from Risk & Policy Analysts Ltd (UK) gave a general introduction for Socio-Economic Analysis (SEA). SEA has been used in various sectors of public administration to back up legislative decision making. A comprehensive SEA often covers:

- direct impacts on businesses, regulators and other stakeholders
- impacts on human health and the environment
- indirect and wider economic effects
- competition, employment and trade issues
- impacts on small and medium sized enterprises

Stages of SEA typically are: (1) defining the problem, (2) defining the objectives of SEA, (3) identifying options and (4) analyzing the impacts of the options. When options are being defined a baseline scenario should always be considered. There are a large number of methods or analytical tools available that can be used for assessing the impacts of the different kinds of options. So far the microeconomic modeling with aggregation to macro level has not been

used in cases where the SEA has been compiled for risk reduction for individual chemicals. A data collection for the new substances is even more challenging task than it is in the cases of existing chemicals. A resulting report should provide a firm base for drawing conclusions and should:

- present information on each option
- describe analytical approach and data, state assumptions and uncertainties
- give a clear summary of costs and benefits – aggregated and individually
- show distributional effects
- indicate other policy considerations

Mr **Espen Langtvet** from the Norwegian Pollution Control Authority (NO) dealt with the experiences of using the cost-benefit analysis (CBA) in Norwegian environmental management. The CBA typically includes the following stages:

- description of environmental problem
- goals to achieve
- discussion on how to achieve goals
- description of benefits
- description of costs
- drawing conclusions (are the benefits greater than costs)
- defining distributional effects

Experience shows that the benefits are often very difficult to asses in terms of number of persons exposed, effects on persons exposed and effects on nature. In addition to this, it is even more difficult to give a monetary value to these kinds of benefits. Instead, it is normally easier to asses the costs that are often based on the input from the industry. Indirect costs are often the most controversial issue as regards the assessing the costs. The practice has shown that the costs are typically overestimated and the benefits are frequently undervalued. The drawing of conclusions has often been very difficult since all the benefits have not been possible to calculate. How can the ratio of benefits versus costs be defined in those cases?

Mr Langtvet provided the participants with a document (in Norwegian) that contained a CBA for the regulation to ban the use of lead in shot gun cartridges.

Ms **Åsa Thors** from the Swedish Chemicals Inspectorate (KemI) (SE) gave a presentation discussing the legislative framework for the use of SEA in Sweden, how KemI conducts an SEA and aspects that needs to be improved. She also addressed two examples of different kind of analysis carried out and the methods used there.

In Sweden binding provisions and authority ordinance exist for the authorities to carry out an SEA in case where new regulations are to be compiled or old regulations are to be amended. Before the decision concerning a regulation is made the ordinance and the provision calls for:

- consideration if it is the most suitable action
- evaluation of the costs and other impacts and documenting the evaluation in an impact assessment

- giving actors and interested parties an opportunity to give their opinions on the issue and the impact assessment
- requesting permission from the government before taking a decision that will lead to significant cost for those who will be affected
- analyzing especially the impacts on small enterprises

In practice the authorities can decide the level of ambition and methods to be used by themselves, since the provisions does not give any guidance on how the analyses should be conducted or to what extent. According to the provision there are however certain issues that have to be addressed in an SEA. Those are; a description of why there is a need to regulate, costs due to the regulation, competition terms, control issues and the need for information. The analysis should be carried out in an extent that is called for in a particular case, i.e. it should be proportionate to the issue and the problem. However, there are one internal guidance document to be used when the SEAs are carried out at KemI.

The two examples dealt with application of the SEA in the context of compilation of the risk reduction strategies for DEHP (Bis(2-ethylhexyl) phthalate) and mercury. In both cases a reference group containing also representatives of the industry was set up. As a whole the commitment of the industry was quite different in these cases contributing to the fact that the time consumed and the participation of consultants was quite different. Ms Thors also delivered documents prepared for the evaluation of risk reduction measures in both cases. Consultants have been used when conducting a more quantitative analysis and also in certain cases that have called for advanced technical knowledge.

Ms Thors pointed out that if the quality of SEAs are improved this can be the key to a greater success in the work with risk reduction in the EU. Other issues that need to be improved are data gathering, guidance, feedback as well as the evaluation of benefits for society, especially concerning health and environment.

Mr **Guy Ahonen** from the Swedish School of Economics and Business Administration (FI) presented a web based tool that can be used to make accurate cost-benefit analysis on projects where work environment is to be improved. The tool can compile realistic calculations where all kind of costs caused by the incomplete utilizing of the labour force can be calculated. The tool also calculates the benefits that are gained by avoiding these costs by carrying out e.g. improvements of working conditions. The tool can easily be adapted to reflect the actual situation of the company in question. Mr Ahonen gave an illustration concerning a real life situation where an investment for improvement of the working conditions caused the cost of 50 000 euros annually and where the model could calculate that the benefits were 500 000 euros per annum. The quantification of the benefits contributed to the successful investment decision in this case.

Mr Ahonen has used this model for many projects and it has been used to give basis for legislative changes in occupational health settings.

Ms **Meg Postle** from Risk & Policy Analysts Ltd (UK) gave an overview of the requirements for SEA under REACH proposals, of the key issues under the current approach to the development of risk reduction strategies and of the possible approaches under REACH. SEA is relevant concerning the authorization and restriction of substances. Industry can submit an SEA to support its application for the authorization for the continued use of a substance, where it can be shown that the benefits outweight the risks and there are no substitutes. Authorities can submit an SEA when preparing a proposal for a restriction. Industry and other stakeholders can also submit an SEA in response to proposed restriction. An SEA should deal with the following issues:

- impacts of refused authorization / restriction on industry and consumers
- social impacts: job security and employment
- availability of alternatives
- wider implications
- for restrictions: costs and benefits of other regulatory measures

As a part of the REACH interim strategy projects the Commission has launched the Implementation Project 3.9. The purpose of the study is to investigate the state of the art of the use of SEA and prepare the project for the developing the Guidance for carrying out SEA. The project will be carried out under the lead of RPA. An achievable and appropriate approach based on data likely to be produced under REACH is probably the most realistic choice for a starting point of the study. One of the key issues will be how the results should be presented to support authorization or restrictions. One item to explore is the possibility to develop a software tool for the use of industry and Authorities.

Ms **Lone Wibroe** from BST Denmark (DK) introduced a substitution of hazardous chemicals in the occupational health settings in Denmark. According to the Council Directive 98/24/EC of chemical agents at work, the employer shall ensure that dangerous substances and materials at the workplace are eliminated, replaced or reduced to a minimum. In Denmark measures shall be taken especially by replacing a dangerous substance or material with a substance or material or working process that is non-hazardous, less hazardous or causes less nuisance. Where the use of a less dangerous substitute will lead to considerable differences in technical properties or expenses, all technical and financial consequences shall be weighted up against all safety and health considerations. If it is not possible to substitute to a lesser dangerous alternative the employer must be able to provide documentation for this on demand to the Danish Working Environment Service. There is however more interest than just the legal demands which motivates the employers to substitute dangerous chemicals. This is for instance factors as customers demands, concerns for the employees health and suppliers certifications. Ms Wibroe has learned during her work that industry is itself working with searching substitutes for hazardous chemicals, but authorities do not often know this work. The consultant has created a database program for a network (www.catsub.dk), which is supported by Danish Working Environment Authority, the European Agency for Safety and Health at Work and Danish EPA. For the time being the database contains 230 descriptions of substitution and new examples are on its way. This kind of forum for open discussion of substitution possibilities in Europe could be ideal and therefore the need to have it in English is desirable.

Mr **Lars Drake** from the Swedish Environment Protection Agency (SE) gave a presentation on estimation of non-market values. When discussing welfare economics one issue is what you want to 'sacrifice' in order to achieve something, thus a willingness to pay might play a role. Basic assumptions are rational and independent actors, consumers maximize utility and producers maximize profit. Encountered problems but also solutions have been found:

- utility can not be measured but willingness to pay can be measured
- the utility of different individuals can not be compared, but different solutions can be compared using various criteria and WTP (willingness to pay)
- many effects of production and consumption are not valued on the market but non-market values can be estimated

Mr Drake presented groups of environmental valuation methods, which can be divided into direct methods, indirect methods and non-welfare methods. Mr Drake also highlighted that the cost of medical treatment and production loss due to sick leave are quite well known for several types of illness and injuries and dose-response relations for the use of chemicals are known in some cases and more or less unknown in other. However the cost of suffering is less well analysed or even is impossible to analyse and the effects of the use of chemicals on ecosystem services are not either well known.

Mr **Osmo Kuusi** from the Government Institute for Economic Research (FI) gave a presentation on new solutions or substitutes of old chemicals in SEA process. Also new solutions has potential health and social impacts, both negative and positive. However, if the new solution is promising, there might be a need to promote the new one and not only restrict the old one. Experience from the work with GMOs (Genetically modified organisms) were given. Mr Kuusi has used successfully the so called Delfoy –method, where panels of 10-40 persons from different expertise have discussed about possible new solutions. The experience has been that if those who represent the old solution evaluate a substitute the evaluation is likely to be biased.

3 Summaries of discussions

3.1 General conclusions

This section summarises the overriding conclusions drawn and central areas for development identified in the course of discussions during the workshop. The basis for discussions was the REACH proposal as it is written in the Commission proposal. Under the following subsections more specific conclusions on substitution, benefits for health and environment plus dynamic consequences are listed.

The importance of choosing right scenarios. Under the REACH regime SEA will become an important part of the basis for decision for granting an

authorisation as well as when preparing EU marketing and/or use restrictions for substances. When taking decision it is of vital importance to be able to distinguish consequences due to authorisation or restriction and consequences due to other factors, such as for example fluctuations in the trade cycle. An SEA should therefore include at least two scenarios: one scenario describing a situation where the Member State or the Commission gives an authorisation or do not act towards a marketing and/or use restriction of the substance, i.e. a baseline, and a second scenario analysing consequences from taking action. Both scenarios shall describe advantages as well as drawbacks from a socio-economic point of view.

Comprehensive SEAs can be excessively costly. If an MS wants to initiate a restriction of a substance, or of a specific use of a substance, within the REACH system the MS may submit an SEA. If there will be a future demand for a "full scale" SEA this could be a hindrance for such initiatives.

A "full scale" SEA is very costly and take a lot of time therefore an SEA should be proportional to the magnitude of the risk that the specific substance, or use/exposure of that substance, give raise to. Two general situations can be distinguished when dealing with substances up for restriction or authorisation;

- Extensive/clearly identified risk = Restriction-limited SEA, Authorisation-extensive SEA
- Limited/uncertain risk = Restriction-extensive SEA, Authorisation-limited SEA

As there is a need for a proportional adaptation of SEAs depending the magnitude of the risks, minimum requirements for information on alternative should be given. Also minimum requirements and documentation on trying to find alternatives is needed in order to see transparent what efforts an industry has made.

Transparency is important for the credibility of an SEA. It is essential to clearly point out what assumptions, uncertainties and system boundaries/scope the SEAs are based upon. A sensitivity analysis discribing the relation between possible measures to take and impact/consequence thereof should be performed in order to, as far as possible, optimise future measures.

Broad view needed. When analysing costs for industry in the context of restriction/authorisation one should not only consider the direct costs for the company manufacturing/importing a substance. Costs should also be regarded from a broad socioeconomic/dynamic point of view, i.e. the drawback for one company might be the advantage for another company. Negative consequences in one sector of business might be counterbalanced in a socio-economic view by benefits for another sector.

Knowledge on substitutes needs to guaranteed. Earlier experience shows that there have been problems with industry neither being willing nor being able to share information on prospects and obstacles to substitute substances of very high concern (SVHC) with alternative substances/technologies. Under the

REACH regime it is therefore important to develop routines on how to sufficiently gain knowledge on feasible substitute solutions within the authorisation- and restriction procedures. There are two key aspects for attaining this information; being able to ask the right questions (e.g. having technical expertice and having a good knowledge about the industry/market) and being able to get in contact with stakeholders willing to share this information. The Nordic countries believe that both of these key aspects should be considered when discussing the tasks of the SEA committee.

Efficient process and an SEA Committee with appropriate powers needs to be assured. In REACH Restrictions (Title VIII) an MS that submit a restriction dossier may also provide an SEA. The MS will have to carry all costs for making an SEA, such as time and effort including possible costs for consultants. In REACH Authorisation (Title VII) it is the company seeking authorisation for continued use of a SVHC that may conduct an SEA, if the risks from the use of the SVHC are not adequately controlled. The SEA should then show that the benefits from the continued use outweigh the risks and that there are no feasible substitutes. The company is not likely going to address the prospects of potential substitutes and not address the potential dynamic benefits, i.e. profits for competitors or other sectors, which could come from not granting an authorisation.

The Agency will on its website invite all interested parties to give input on the SEA with information on feasible alternatives. Due to measures to protect the company seeking authorisation the use of the SVHC will probably not be very specific, it will probably be described in more general terms, therefore it is a apparent risk that other companies that may have feasible alternatives do not understand that their substance/technical solution may be a possible alternative for the SVHC. Experiences from the use of stakeholder consultations e.g. on a webpage show that this form of consultation do not attract companies that may have possible substitutes (experiences from the RoHS-directive[3]). Under the REACH regime there should be a complementary approach to collect information on feasible substitute solutions. Such complementary approach should be more active, i.e. effort has to be made to ensure that sufficient information reach companies that have developed, or has the ability to develop, substitute solutions.

The SEA committee in the Agency then have the opportunity to examine the SEA and give their opinion upon the proposal and its impacts before the COM makes a decision. In the light of what have been mentioned above it is therefore highly important to further discuss the role and authority of this SEA committee. It is important that the SEA committee will be able to

- validate the data in the SEA,
- make the company seeking authorisation present more data,
- initiate further studies to gather more information from stakeholders, e.g. other companies and NGOs etc, using independent consultants and/or research institutions.

[3] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

3.2 Substitution

Minimum documentation on trying to find alternatives needs to be defined. Companies applying for authorisation may submit an SEA to support the continued use of a substance, where it can be shown that the benefits outweigh the risks and that there are no substitutes. It is important that there are some kind of minimum requirements and documentation that has to be fulfilled by the company applying for an authorisation. The requirements could include demands on the companies to be able to show in what way they have tried to find a substitute solution (alternative chemical substance and/or technologies). A Danish representative shared positive experiences from a similar approach used in Denmark today. In Denmark the companies have to present documentation from different suppliers/subcontractors, which they have consulted in their search for substitutes regarding the working environment field.

Minimum requirements for information on alternatives needs to be elaborated. In order to promote that substitution contributes to adequately controlled risks and to prevent substitution leading to a shift in risk (health to environment or vice versa) or even higher risks there is a need to have some minimum requirements for information on alternatives. REACH Registration will provide at least basic information of the intrinsic properties of the major part of the substances on the EU market. But there is a rather long time span, fifteen years, for the registration of all substances in quantities over 1 ton/year manufactured or imported. For substances that are manufactured or imported in quantities under the registration limit there will be scarce information. Information on possible risks with alternative technologies, e.g. nanotechnology, also needs to be further developed.

The independence of research institutes & consultants which industry and/or Member States are using (confidentiality). Under the REACH regime there will be a shift in responsibilities from authorities to industry. But the authorities will still bear the burden of validating the information submitted by the industry, even if there are minimum requirements on information. In order for the authorities to do so there will most certainly be situations where there is a need to use consultants and/or research institutes. In the case of SEA there will be a need to validate information on substitutes/ the lack of substitutes. The use of consultants with good market and technology expertise has shown very valuable for example in the Swedish work investigating substitutes for mercury. Therefore it is important that there also in the future will be independent research institutes that can provide services for the authorities under REACH. This point is also valid in the context of a complementary approach to stakeholder consultations (experiences from the RoHS-directive) in the authorisation procedure as a more active way of investigating feasible substitute solutions (with a need for certain confidentially).

Substitutes of low volume / less knowledge / less requirements at REACH. For a substitute of low volume there will probably be less information at the moment of replacing a hazardous substance. In the future the tonnage level is

expected to raise and requirements for further information according to REACH increases. The new information might reveal new risks that has not taking into the consideration. Special attention should be paid to the use of all available data of a substitute.

List of substances meeting the criteria for authorisation should be made publicly available. Substances that meet the criteria in article 54 of REACH may be included in Annex XIII. The number of SVHC that could be included in the authorisation procedure are approximately 1000-2000 substances with CMR- and PBT/vPvB-properties[4]. Prior to a decision to include substances in Annex XIII there is a need to prioritise among the substances. According to article 55 there will inter alia be a need to take account of the Agency's capacity to handle applications for authorisation. The list of substances in Annex XIII will be publicly available but that will perhaps not be the case for the rest of the substances waiting to be listed in the annex. Therefore there is a need to make the gross list of substances meeting the criteria in article 54 publicly available in order to promote substitution of these substances. In the context of SEA this approach would also give industry, and in a wider context also the authorities, better possibilities to identify alternative substitute solutions for the listed substances.

Focus should be on the whole lifecycle / costs of waste handling should be considered. When discussing ways to promote substitution of hazardous substances in articles a Norwegian representative mentioned that there might be a good idea to consider complementary administrative measures such as the legislation on hazardous waste. The usage of a hazardous substance in an article can lead to an administrative burdensome and costly waste handling of the article. In some cases the extra administrative burden can be a strong incentive for substitution. When assessing benefits from a substitution one should therefore also consider costs that can be avoided through the substitution from a lifecycle perspective. Also a Danish representative stressed the potential of administrative burdens as a way to promote substitution. In a case where a restriction of a substance is considered, it might be fruitful to regard the potential incentive for substitution that can be reached by using other legislative tools.

Substitution is rather a tool than a goal in REACH context. It was pointed out that substitution is not a goal in the current REACH proposal. Substitution is a tool that can be used if the risks from the use of substances are not adequately controlled and if the applicant can't show that the benefits outweigh the risks within the REACH authorization procedure.

3.3 Benefits for health and the environment

[4] CMR=Carcinogenic, Mutagenic, toxic for Reproduction
PBT=Persistent, Bioaccumulative, Toxic
VPvB=very Persistent, very Bioaccumulative

Elaboration of quantitative models desirable. Qualitative data will though still play an important part of SEAs. The main purpose of making quantitative analyses is utterly to clarify the consequences from e.g. a restriction to the decision-makers as far as possible. Generally, the more quantitative an analysis is the more robust it appears to be. But the current and also the future possibilities for quantification of benefits for health and environment are limited due to e.g. lack of suitable data from the risk assessments. The effects on ecosystem services from the use of chemicals are not very well known. There is little basis for economic value estimates today. Quantitative analyses are also more resource intensive. Further more there might be costs and benefits that are ethically unacceptable to measure. Therefore it will still be a need for qualitative approaches in SEAs under the REACH regime. This means that it is important that benefits for health and environment that are only measurable in qualitative terms are given the same weight as quantitative costs.

The methods presently used for evaluating benefits are not fully adapted to the area of chemical risk management. There is also a lack of experience of using the valuation methods in this area. In the short run there is an imminent need to increase to knowledge and use of existing methods. In the longer run there is need to adapt these methods so that they better fulfill future demands.

Benefits for health are easier to value than environmental benefits. The currently available methods for valuating are in some ways more adapted for measuring benefits for health than for environment. More specific data may also be available on impact on health from the use/exposure of certain chemicals.

There are cases in which there is a conflict between health and environmental quality. If the situation is such that health effects can be more easily assessed, in comparison with environmental effects, there is a risk that health effects will overshadow environmental effects in SEAs. When assessing impacts of substitution this may give raise to shifts in risks, from risks to health to environmental risks. Also shifting the risk to opposite way (from risk to environment to health) needs to be avoided.

Current risk assessment methodology does not provide information which is sufficiently detailed to be useful to quantify benefits using existing valuation methods. This quantification is needed for valuing health and environmental benefits from the non granting of an authorisation or a restriction of a substance, or a certain use of a substance. Information on dose-response and the number of affected people/animals and/or plants (organisms) are needed. The problem is though that the currently used methodology for making risk assessments does not always deliver such detailed information. Also in the future we will have to do with partly insufficient data when analyzing benefits for health and environment.

General format for valuing health and environmental factors is needed. When considering benefits for health and environment there are different methods to value these factors. Different methods can give different values. When using for example the method of stated preferences it is quite obvious that the answers can vary depending on whom and how you ask. Health benefits and

costs are however often more easy to value. For example, the cost of medical treatment and production loss due to sick leave are quite well known for several types of illness and injuries. One way to facilitate the assessment of benefits for health and perhaps especially for environment could be to decide upon general values of certain effects, i.e. to make some kind of price list.

Need for transparency concerning the application of methods. Under the REACH regime there will be situations where decisions have to be taken on the basis of insufficient data. It is therefore of high importance that the limitations, assumptions and uncertainties of the applied models are pointed out.

Avoided costs can be seen and should be treated as benefits and should be included in the SEAs. Through substitution of hazardous substances society will benefit in ways of less negative impact on health and environment both from a short and a longer time horizon. When analyzing benefits from substitution it's important to also consider potential future costs that may be avoided through the substitution of a hazardous substance. Costs that can be avoided through substitution could for example be costs for decontamination of land, lowered healthcare costs and production loss due to sick leave. One good example could be the current costs for industry for the historic use of asbestos.

Costs are typically overestimated and benefits underestimated in cost benefit analyses. Experiences from several cases of substitution of hazardous substances shows that the costs that initially were put forward by the industry were overestimated. Therefore there is a need to validate input from industry to SEAs under the REACH regime. See line of argument above regarding the authority of the SEA committee and the use of independent consultants and research institutions.

Postponing decisions also causes costs. Time is often a relevant factor in relation to assessment of cost and benefits. Negative consequences for health and environment may often increase if a decision for a restriction is postponed, but the direct costs for industry may at the same time decrease if a longer transitional period is granted.

3.4 Dynamic consequences

Dynamic consequences needs to be taking into account which mean a longer and wider perspective in SEAs. Direct and indirect economic consequences such as innovation/development of new techniques, opportunities for companies producing substitutes or alternative techniques has to be taken into account. In connection to substitution there is also the need to adapt a dynamic perspective. Negative impact for one company/sector from a restriction or a non-granting of an authorisation might be balanced by benefits for another company or industry sector. This has to be taken into account in SEAs under the REACH regime.

Without longer and wider perspective costs might be overestimated and several benefits will be missed. There are examples from earlier initiatives to restrict the use of certain hazardous substances where the consideration of a

dynamic perspective has given quite a different picture of the measures to be needed. In the case of methyl tertiary buthyl ether (MTBE – an additive in gasoline) banning of the substance was not needed due the foreseen technical progress. The upswing of the use of MTBE ceased and turned down in a couple of years due to the modern technique.

Different solutions regarding different innovation scenarios. In some cases there might be more than one possibility of substitution. Therefore there might be a need to make a comparison with substitutes and choose the 'champion' for the SEA.

Need to promote new innovations. If it is shown that there is a risk and a need for substitution but yet no real substitute is available, there might be a need to promote new innovations. The mechanism to find promising innovations could be created e.g. contacts with other industries, universities and research institutes. The property rights must still be taken into account.

APPENDICES

1. Programme of the workshop
2. Speakers and participants of the workshop
3. Presentations of the workshop

APPENDIX 1

PROGRAMME

Nordic Workshop on the *Socio-economic analysis (SEA) in the new chemicals legislation – REACH*

2 – 3 March 2005

Hotel Arthur, Vuorikatu 19[*], Helsinki

The Workshop will be chaired by Director Jukka Malm, Finnish Environment Institute

1st day

12.00 – 12.10	Welcome *Katariina Rautalahti, Head of Chemicals Department, National Product Control Agency for Welfare and Health (FI)*
12.10 – 12.45	Introduction to REACH – objectives and means *Jukka Malm, Director, Finnish Environment Institute (FI)*
12.45 – 13.45	What can SEA be – different models and area of use today *Meg Postle, Director, Risk and Policy Analysts Ltd (UK)*
13.45 – 14.15	Coffee
14.15 – 14.45	The practical use of cost-benefit analysis in Norwegian environmental management *Espen Langtvedt, Special Adviser, Norwegian Pollution Control Authority (NO)*
14.45 – 15.15	The practical use and experience of SEA at KemI – the work with Governmental tasks investigating national bans of hazardous substances *Åsa Thors, Senior Technical Officer, Swedish Chemicals Inspectorate (SE)*
15.15 – 16.00	The use of the potential-model in making cost-benefit analysis of work environmental projects *Guy Ahonen, Professor, Swedish School of Economics and Business Administration (FI)*
16.00 – 16.30	Discussion
	Dinner at 7 pm

[*] http://www.hotelarthur.fi

2nd day

09.00 – 09.45	SEA in REACH and RIPs – future use of SEA and the work with guidelines to industry and MS *Meg Postle, Director, Risk and Policy Analysts Ltd (UK)*
09.45 – 10.15	Presentation with focus on theme 1: Information on substitutes *Lone Wibroe, Project Manager, BST Denmark (DK)*
10.15 – 11.00	Discussion on theme 1
11.00 – 11.30	Coffee
11.30 – 12.00	Presentation with focus on theme 2: Benefits for health and environment *Lars Drake, Associate Professor, Swedish EPA (SE)*
12.00 – 12.45	Discussion on theme 2
12.45 – 13.45	Lunch
13.45 – 14.15	Presentation with focus on theme 3: Dynamic consequences *Osmo Kuusi, Senior Researcher, Government Institute for Economic Research (FI)*
14.15 – 15.00	Discussion on theme 3
15.00 – 15.30	Coffee
15.30 – 16.15	Presentation of conclusions *Nordic Risk Management Group*
	End of workshop