



***Counting the Costs and Benefits of  
Chemical Controls:***

***Role of Environmental Risk  
Assessment in Socio-Economic  
Analysis***

***4 June 2008, Brussels***

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## **ECETOC WORKSHOP REPORT No. 13**

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## FOREWORD

The Annual Technical Meeting of 2006 was organised as a 'Futures Workshop' to explore the directions of ECETOC activity for the coming years. Over the ensuing 12 months a comprehensive Science Strategy has been developed composed of 13 'Strategic Science Areas'. One of these areas, and the most novel one for ECETOC, is *Science in Society*. This area is intended to recognise that the communication of risk in environmental and health policy needs improving. The concept of risk assessment is poorly understood by the public and consequently treated with suspicion. In particular, many members of the public consider that zero risk is the ideal target for environment policy.

The motivation behind *Science in Society* is a better acceptance of the scientific basis of risk assessment. In order for progress to be made in this direction it is important for the public, in the broadest sense of the term, to be convinced that it is the better approach compared to a zero risk policy. Pre-requisites to this are the recognition that all products in commerce have a value to some part of society and that the restriction of these products will result in a cost to be absorbed somewhere in the value chain.

As ECETOC has always been associated with risk assessment based on best available scientific information, it seems obvious that we need also to be involved in the promotion of its acceptance. Recent European legislation has explicitly recognised that restriction of chemical substances in commerce has a cost and that the benefit of the restriction must exceed this cost. What is not clear so far is how to use scientific concepts of risk in the calculation of the cost and benefit. This interface between economists and actuarial scientists on the one hand and natural scientists and risk assessors on the other requires an understanding of the founding concepts of each other's disciplines. The Annual Technical Meeting reported herein was held as the first step for ECETOC to explore this interface and the future contribution that ECETOC might make to the development of this embryonic discipline.

Dr. N. Carmichael  
Secretary General

*Counting the Costs and Benefits of Chemical Controls:  
Role of Environmental Risk Assessment in Socio-Economic Analysis*

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## 1. EXECUTIVE SUMMARY

- This report arises from a workshop organised to explore the contribution that ECETOC might make to the cost-benefit and socio-economic analyses of environmental protection interventions that involve chemicals. The focus was on REACH but broader issues were also considered.
- A distinction was made between identifying the possible lives and/or ecological entities saved by an intervention (from risk assessment) and the values that are ascribed to these. Risk assessments are carried out by natural scientists and valuations by economists—but both would gain from understanding the needs and the contributions of each other. *A major general recommendation was that ECETOC should play a key part in facilitating this and building inter-disciplinary collaboration.*
- For assessing both the costs and benefits of an intervention it is important that risks and their causes are identified and expressed appropriately. It was recognised that the current practices of risk assessment did not generally deliver what was required for fully quantitative cost-benefit analyses. This is an area that needs further urgent attention and, given its remit to promote science-based risk assessment, ECETOC ought to play a lead role.
- Valuations of human lives, human health and ecological entities involve assessing the preferences of society as a whole. This is the province of welfare economics. However, it was emphasised that there is a role for natural science, and hence ECETOC, in making links between human health status and capacity for work and recreation, and especially between ecosystem processes and the services that they deliver to society.
- Five main themes were identified for further possible action by ECETOC. These were:
  1. Appropriately quantifying changes in impact associated with proposed risk reduction strategies;
  2. informing the valuation of impacts of chemicals on health and ecosystems by enabling and encouraging collaborations between natural scientists and economists;
  3. supporting the process of socio-economic analysis, for example by facilitating the creation of multi-disciplinary teams;
  4. developing one or more exemplary case studies – learning by doing through a Task Force;
  5. playing an active role in cross-disciplinary networking and capacity building.

## 2. INTRODUCTION

Under REACH there are provisions to use socio-economic analysis (SEA) in decisions about both authorisation (Article 60) and restrictions (Article 68) of chemicals (EU, 2006), and similar provisions are used as derogations in the EU water and environmental liability legislation. This requires that the benefits from environmental protection should be greater than the cost to society for the action to be worthwhile. SEAs are often defined more precisely (but possibly more narrowly) as cost-benefit analyses (CBAs). Many of the issues for SEAs and CBAs have roots in the social and economic sciences, but to value benefits there needs to be a quantitative assessment of the likely amount of harm avoided in the systems of interest. This amounts to a requirement for good risk assessments, a central interest of ECETOC. The aim of this workshop was to explore whether there is a role for natural sciences<sup>1</sup> and for ECETOC in the development of SEAs and CBAs.

Quite a lot of attention has been given to the valuation of human lives in CBAs and SEAs, yet the valuation of ecological entities and services remains more challenging. Indeed there were provisions for SEAs and CBAs in the Existing Substances Legislation (EU, 1993), which REACH replaces, but few of the risk reduction strategies (RRSs) that emerged from this were accompanied by transparent and quantitative CBAs for the very reason that few were based on good ecological risk assessments. This workshop therefore focused on the challenges associated with ecological valuations in CBAs and SEAs.

To put these issues into a broader perspective it is worth noting that environmental protection almost always impacts on the economy: Generally for the benefits that accrue there will be some costs to society. There are those who argue that these costs are always worth paying since the protection of nature should be held above all else. Others take the view that some kind of balance should be struck; that at least costs and benefits should be made clear and taken into account in formulating policy and legislation. Thus, in the European Treaty we find:

*“Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community.....and... shall take account of*

*- the potential benefits and costs of action or lack of action,*

*- the economic and social development of the Community as a whole ....”.*

These tensions are likely to surface in the more general debates about competitiveness and sustainability over the next few years in Europe—and this will be of key relevance for industries in Europe, including the chemicals’ industry. So this workshop should also be seen as a timely introduction to some of the core issues in that broader sustainable development debate.

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<sup>1</sup> Throughout this report ‘natural sciences’ is meant as ‘opposed to the social sciences’.

The workshop was convened by ECETOC to discuss the above issues. There were invited experts from academia, regulatory authorities, and industry and these involved a mix of natural scientists and economists. The following is an outline of how the workshop was structured.

Initial presentations by invited speakers:

- shared key concepts and case studies of SEA/CBA that are of relevance to the chemical industry;
- showed key importance of quantifying environmental impacts (through risk assessment) in developing SEA/CBA.

The workshop participants were then divided into four groups for breakout sessions. Each group was given the same questions to address:

- Assess the contribution of natural sciences (ecology) to SEA/CBA.
- Define key criteria for ecological valuation in developing SEA/CBA.
- Specify the input of environmental risk assessment (ERA) into SEA/CBA.
- Identify those aspects of SEA/CBA in which ECETOC members would want and would not want to become engaged (as part of its future work programme).
- Recommend how industry could develop the capacity to undertake SEA/CBA.

A plenary session followed the breakout sessions to discuss the recommendations for ECETOC.

### **3. BACKGROUND PAPER:**

#### **Counting the Costs and Benefits of Chemical Controls – Some Principles, by Peter Calow, Workshop Chairman**

The aim of this paper is to provide background on the principles, practices and challenges associated with working out the costs and benefits of environmental protection measures as related to chemicals. It emphasises the assessment of benefits rather than costs since that is the most challenging part of the exercise. It also emphasises ecological issues in line with the approach of the meeting.

#### ***Background and aims of socio-economic analysis (SEA) and cost-benefit analysis (CBA)***

- It is often necessary, in developing environmental policy, to make decisions about options where resources are limited and there are trade-offs. The aim of SEAs is to do this in a way that maximises social welfare.
- Fundamentally, if the benefits of the intervention can be shown to be greater than costs (determined by cost-benefit analysis), it is presumed that the welfare of society will be enhanced, though there may be problems about upon whom the costs and the benefits fall. Thus, if it can be shown that the costs of a restriction on a chemical for industry (producers) and consumers (because of restrictions on the products they need and desire) are less than the benefits to human health and /or the environment, this would support the restriction, and vice-versa. To make such a comparison it would be ideal to have everything in the same units – and economists favour money as an indicator of our preferences and willingness to pay for them.
- It is to make these issues transparent for policymakers and regulators that requirements for SEAs are included in some EU instruments. For example, under REACH there are possibilities to carry out SEAs to save chemicals from no authorisation (Article 60) and in decisions on restrictions (Article 68) (EU, 2006). There have been similar requirements under the Existing Substances Regulation (EU, 1993), but because of the inherent difficulties few risk reduction strategies (RRSs) have been accompanied by transparent and quantitative CBAs (IMV, 2007).

#### ***Principles and methodology***

- The social and economic impacts of a measure can be expressed in terms of the values that we put on options. In welfare economics' terms these are expressions of individuals' values

(welfare/utility) – preferences - aggregated across society and corrected for temporal differences through discounts.

- The *cost* (C) of restrictions of chemicals can be assessed relative to impacts on producers and consumers in real marketplaces - taking account of employment and international trade effects.
- The *benefits* (B) of the restrictions of chemicals for human health and ecosystems are external to these markets and have to be valued. Values of human life in this context are estimated from how much, as individuals, we are prepared to pay to reduce risk (e.g. in purchasing safety equipment) or to accept in compensation for increased risk (e.g. salary for a risky job)—these being derived from surveys or observations on consumer behaviour/wage levels etc. Nature valuation depends on the value that we ascribe to the use and/or existence of nature, again derived from survey, or consumer behaviour (e.g. effect of proximity to nature resource on price of housing) and/or from the connections between ecosystem services and the economy (e.g. in generating biomass [fish and game] for consumption; in controlling such things as climate and flooding that would be costly to replace by engineering solutions; and by impacting such things as pollination and soil quality that support agricultural productivity and thus connect with food markets).
- From a welfare economics' standpoint B has to exceed C to justify a restriction otherwise society loses.

### ***What part for natural science (risk assessment) in SEA and vice versa?***

- Risk assessment informs SEA, on the one hand by identifying the causes of environmental problems, without which there could be no management option and hence no cost (C) assessment, and on the other hand by quantifying effects in terms of increases in human death rates or ecological degradation without which it would not be possible to estimate benefits (B). The latter is particularly important. Economic valuation gives a value per unit nature and/or human life (V/U). To get the overall benefit of a restriction from this, V/U has to be multiplied by the extent of ecological damage avoided and/or lives saved by the restriction ( $\Delta U$ )—that can only be obtained from a good risk assessment. Thus, very simply  $B = f(\Delta U \times V)$  (Callow, 2008).
- This argues for an effective dialogue between risk assessors and economists on what is needed in the CBA and what can be delivered by the natural scientists. One reason for the lack of good CBAs in the RRSs of the Existing Substance Regulation was the lack of equally good and quantitative risk assessments (IMV, 2007). Moves to more hazard-based

assessments, a possible outcome of REACH especially in the authorisation process, may not be helpful in this respect and may emphasise costs rather than benefits in SEAs.

- There is an argument for the even closer involvement between ecologists and economists in the valuation process itself.  $V$  should relate to values put on lives and/or ecosystems in particular places (i.e. point source effects) because, amongst other things, it will depend on socio-economic circumstances. However, for many industrial chemicals the consequences of releases into the environment and the consequences of restrictions can have broad effects on different social and geographical groups and on ecological systems as well as human health. Hence, getting values from the specific valuation of particular habitats and species from localised surveys, or extrapolating from one place to another (value transfer), may not be very helpful. Here the valuation of impacts on ecosystem services might be a more appropriate method; i.e. making connections between effects on ecosystem processes (by ecologists) and their consequences on markets (by economists).

### ***Taking account of uncertainty***

- $\Delta U$  is subject to variability that in principle we understand and can describe in the risk assessment (e.g. differential sensitivity of age-classes and species to a contaminant) and uncertainty (e.g. unknown/unexpected effects of chemicals, such as endocrine disruption).
- But  $V$  is similarly subject to variation (re socio-economic circumstances) and uncertainties (such as unknown/unexpected ecosystem services).
- The precautionary principle urges raising the  $\Delta U$  and  $V$  to take the uncertainties into account.

### ***Conclusions***

- SEA is fundamentally about public values. And risk assessment needs to be kept free of public values—it is evidence driven. The assessment of  $\Delta U$  is distinct from the assessment of  $V$ .
- Yet doing the risk assessment properly for CBA and SEA would benefit from collaboration between risk assessors and economists.
- Similarly economists strive to exclude bias from the assessment of public values—they should be generally representative of the public affected by the intervention. The views of

ecological experts might thus distort the value put on nature relative to the population as a whole.

- Yet getting the values right in terms of how ecosystems are affected would benefit from the input of specialist ecologists.
- So there is an argument for a demarcation between risk assessment and risk management as is current practice. But there are also arguments for more active collaboration between ecologists and economists in capturing public values. Careful consideration needs to be given to the institutions and forums that might be needed to facilitate this.
- Similarly special consideration should be given to how natural scientists and economists can work together to take account of uncertainties and address the challenges of the precautionary approach.

## 4. PRESENTATIONS

### 4.1 *Socio-economic analysis – demands on chemical safety assessment*

**Matti Vainio** from ECHA<sup>2</sup> talked about the requirements of the REACH regulation for manufacturers and importers of substances and authorities to apply safety assessment methodologies to ensure that the manufacture, marketing or use of substances do not adversely affect human health or the environment. If risk management measures implemented by the manufacturers, importers and downstream users are not sufficient, a Member State (or the ECHA, if the Commission so requests) may prepare an Annex XV restriction dossier to initiate a proposal for a restriction, i.e. any condition for or prohibition of the manufacture, use or placing on the market a substance. In the context of this restriction procedure<sup>3</sup>, a SEA of the benefits and costs could be carried out to help – and not to replace – decision making.

Benefits and costs to be considered in a SEA are economic, social and environmental and health related. The analysis should compare the restriction scenario with the baseline (or business-as-usual) scenario. In order to define the restriction scenario, available information on risks and technical and economical feasibility of the alternatives may also play a relevant role.

In order to carry out a SEA the chemical safety assessment (CSA) needs to provide information on hazard, exposures and risk related to the substance (and alternatives) that can be used in such analysis. A comprehensive CSA is a very helpful starting point to get information on alternatives, costs and risk management options. SEA needs to be conducted as an integral part – not an ‘afterthought’ – of the preparation of a restriction proposal.

Both economists and natural scientists should also ‘learn-by-doing’ SEAs. A SEA can be based on qualitative, semi-quantitative or quantitative data. The level of the analysis, and e.g. whether to endeavour to monetise the impacts, has to be proportionate to the problem. One would expect that the more significant the effects of a policy intervention are on health, the environment or the economy, the higher are the demands for quantifying the effects, including their valuation. Likewise, in less significant or rather straightforward cases qualitative description of risks and impacts may be sufficient.

The technical guidance document of preparing a restriction proposal has been made public in June 2007 (ECHA, 2007) and the guidance on SEA in the restriction procedure in May 2008 (ECHA, 2008). At the time of writing, the guidance on SEA concerning authorisation was being finalised.

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<sup>2</sup> The views expressed do not necessarily represent those of the European Chemicals Agency.

<sup>3</sup> This presentation will concentrate on restriction process. The issues raised here are similar but not identical in the authorisation case where a manufacturer, importer and/or downstream user may prepare an SEA as part of his authorisation application.

Different views may exist whether one should concentrate research on ‘what happens’ (i.e.  $\Delta U$  in Section 3) or what the value of ‘what happens’ is (i.e.  $V$  in Section 3). It should be noted that if  $\Delta U$  is unknown any information of its value cannot be applied. Research underpinning the analysis needs to first ensure that  $\Delta U$  is estimated and that it is compatible with  $V$ . Only then can one use the values. At the same time economists carrying out research on values need to ensure that their results are compatible with  $\Delta U$ . Thus, collaboration between natural scientists and economists is crucial. It is likely to be challenging and rewarding.

#### **4.2 Socio-economic analysis to keep a CMR- or PBT-chemical in the market place**

**Peter Saling** explained that, in the context of REACH, SEA is a required method to analyse all relevant impacts (i.e. both positive and negative changes) of granting authorisation compared to refusing authorisation. The SEA comprises both a study and subsequent documentation comparing the social and economic impacts of the manufacturing, import and/or use of a substance with the risks to human health and the environment in order to demonstrate if the socio-economic benefit of continued use of the substance outweighs the risks.

A SEA is used to compare two different scenarios: ‘Applied for use’ (continued use of the Annex XIV substance for the uses applied for); and ‘Non-use’ (a refused authorisation, i.e. where the Annex XIV substance cannot be used). The key challenge is being able to use the information available to identify and quantify the impacts of these scenarios in a proportionate and robust way. These impacts should then be compared to underline the case for whether the socio-economic benefits of continued use of the substance outweigh the socio-economic costs.

The SEEBALANCE<sup>®</sup> method has been developed by Karlsruhe University, Jena University, the Öko-Institut e.V. and BASF, supported by the German Federal Ministry of Education and Research (BMBF) (Saling *et al*, 2002; Kölsch *et al*, 2008; Saling and Kesten, 2007; Schmidt *et al*, 2004). It was a follow-up to the eco-efficiency analysis, since it integrates the social dimension for measuring social aspects. It was adapted in several aspects to the needs of the REACH legislation.

SEEBALANCE<sup>®</sup> is a multi-criteria analysis which should enable companies to generate essential information for the REACH authorisation process to keep products without feasible alternatives on the market. The essence of the SEEBALANCE<sup>®</sup> method is the assessment of sustainability of a substance in combination with a specific use or relevant uses by defining a ‘functional unit’. The eco-efficiency analysis, which represents the ecological and economical assessment within SEEBALANCE<sup>®</sup>, is designed as a holistic process for assessing and comparing products and processes. Since its implementation, it has been used in more than 350 cases.

As an example, a case study from RIP 3.9-2 (REACH implementation project), that was a precursor of the guidance document for carrying out a SEA, was presented. A chemical substance for wire coating processes has been evaluated with a life-cycle approach to the SEA under the REACH guidance (Saling *et al*, 2007). One goal of the case study has been to test and assess the framework developed in the RIP. A further goal has been to show the applicability of the methodology used as a possible method for working out a SEA within the authorisation process in accordance with the RIP framework. Economic, environmental and social results for this case study were presented. Furthermore, it was shown how a final result and recommendations for the decision-making process of the socio-economic committee can be generated.

### 4.3 *SEA and REACH: Challenges and opportunities*

According to **Meg Postle**<sup>4</sup>, there are two key provisions within the REACH Regulation that could be used to place EU-wide regulatory constraints on industrial chemicals. These are the Authorisation process (Title VII) and the Restrictions process (Title VIII) (EU, 2006).

The Authorisation process is aimed at the progressive reduction of risks associated with substances of very high concern (SVHC). Substances subject to authorisation will be prioritised by ECHA, with there then being two routes to gaining an authorisation for specific applications. The first is the adequate control route, which does not require a SEA, and the second route is through demonstrating that there are no technically or economically feasible alternatives and that the socio-economic benefits of continued use outweigh the risks.

The Restrictions process is aimed at addressing risks to human health or the environment which need to be addressed on a Community-wide basis, and is therefore the legal replacement for the Existing Substances Regulation (EU, 1993) which is repealed by REACH. The preparer of a restrictions dossier may submit a SEA alongside the more technical dossier, while interested parties may comment on this dossier and/or submit their own SEA (ECHA, 2008).

The presentation reviewed the role of SEA in both of these processes. It covered:

- The types of impacts that can be considered within a SEA.
- The differences between SEAs prepared for restrictions dossiers and risk reduction strategies prepared under the Existing Substances Regulation.
- The steps involved in preparing SEAs under REACH, based on the RIP 3.9 guidance.

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<sup>4</sup> Meg Postle is also the principal author of an OECD technical guidance document on SEA (OECD, 2002).

- The challenges or key issues that will need to be addressed by those involved in preparing SEAs in each of the steps.
- Some of the opportunities to industry and others with regard to the quality and scope of SEAs under REACH.

The presentation also illustrated the importance of some of the key issues identified in the presentation through reference to a case study prepared for RIP 3.9-2. This includes the importance of carrying out thorough assessments of the feasibility of alternatives, including the impacts of their adoption, and problems in comparing the environmental (and health) risks posed by non-threshold substances to other environmental risks and to non-toxic effects.

#### **4.4 Case study: *Completing an SEA for octylphenol***

**Ed Hawker** talked about a case study for SEA. 4-tert-octylphenol (OP) is a high production volume chemical predominantly used in the production of rubber for tyres, although it is also used in the production of insulating varnishes, printing inks, paints, textiles and pesticides. It was identified as the most likely immediate replacement for nonylphenol (NP), currently the subject of marketing and use restrictions under Council Directive 76/769/EEC (EU, 1976).

A detailed environmental risk evaluation report (RER) was commissioned by the Environment Agency to investigate the risks associated with OP (Environment Agency, 2005). Based upon the RER, the UK proceeded to develop a risk reduction strategy (RRS) to address the risks identified in the RER (DEFRA, 2008). Based upon the RRS, a regulatory impact assessment (RIA) was drawn up which considered a number of risk management options (RMOs), and a recommendation submitted to the Commission in 2007<sup>5</sup>. The primary recommendation made was for a marketing and use restriction at UK level, for all uses of OP except for a number of uses which would be granted a five-year derogation.

The presentation discussed the assessment of the costs and benefits of the RMOs and the implications that this may have for SEAs under REACH. There were two key aspects of the assessment highlighted in the presentation:

- **Proportionality.** In this case, the assessment of the costs and benefits was purely qualitative. This is because the initial assessment found that in some cases, the costs of a restriction would be disproportionate due to the potential safety implications of a restriction and the time and testing cost involved. For the remaining uses, industry consultation suggested that

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<sup>5</sup> The partial Regulatory Impact Assessment is currently not published.

the costs would be minimal. As a result, further assessment of the options was not felt to be necessary.

- Estimating the benefits. The benefits were assessed qualitatively, highlighting a potential improvement in human health and environmental outcomes as a result of a restriction. The difficulty in estimating dose-response functions and quantifying impacts is a continuing area of difficulty for decision makers.

#### ***4.5 Economic assessment of the Water Framework Directive in the UK***

The main aims of **Nick Hanley**'s presentation were to:

- Focus on the challenges associated with 'ecological valuations' in cost-benefit analysis (CBA) (Hanley *et al*, 2001).
- Show how these have been addressed in the context of likely water quality improvements under the Water Framework Directive (WFD) (EU, 2000).

CBA seeks to express the gains and losses to society from a particular action—such as enacting a stricter piece of environmental legislation—in monetary terms. But valuing ecological changes in such terms is difficult, since no market prices exist to signal the value of ecological improvements or ecosystem services to society. Moreover, there is uncertainty over the cause-effect relationship between changes in human actions, and the ecological results. There is also uncertainty over how these ecological results will translate into changes which individuals are aware of. A guiding principle of CBA is that individuals' preferences should be used to measure the benefits of, e.g. a reduction in pollution to a river. However, for many ecological impacts, preferences may be vague, which means that people will be unsure how much they are willing to pay for such environmental improvements.

Several methods exist for valuing non-market 'goods' such as river ecology or landscape quality. These can be classified into:

- Revealed preference methods—such as the travel cost method to estimate anglers' benefits from water quality improvements. Revealed preference approaches are based on actual behaviour, but cannot measure 'non-use' values.
- Stated preference methods, which can measure both use and non-use values. The main stated preference methods in use are contingent valuation and choice modelling.

Within the UK and US, there has been a long tradition of use of cost-benefit analysis as part of policy appraisal, e.g. for transport schemes and flood defence schemes. In the last 15 years, environmental valuation has become part of this exercise. For water, the use of CBA in the setting of environmental improvement targets for private sector water companies by the environment agencies in the UK has increased in recent years. Within the WFD, CBA plays a significant role, for example in terms of ‘disproportionate cost’ assessments, and in national and regional level assessments of the overall ‘regulatory burden’ of the WFD, and in identifying gainers and losers.

However there are a number of problems in applying CBA to WFD implementation. These include:

- What actions will be required to meet Good Ecological Status on individual water bodies?
- What will be the ecological outcomes of these actions, relative to business-as-usual?
- What values do the public put on these outcomes?

In the UK, contingent valuation, travel cost methods and choice modelling have all been used to look at benefits of ecological improvements of water bodies. Some recent studies are Hanley *et al*, 2006a, b.

In conclusion, economic valuation methods can be used to estimate the benefits of ecological improvements to water-bodies under the WFD, at the river, catchment or national level. This is yielding benefit figures in euros which can be compared with costs, under different policy scenarios. However, a number of significant challenges remain. These include scientific uncertainty over the ecological effects of management actions, preference uncertainty on part of those who will benefit from these actions, and uncertainty on how many people will benefit from improvements. There is a need for acceptable ‘benefits transfer’ methods to get around the financial and time requirements of case-specific studies.

#### ***4.6 Cost benefit analysis of the CAFE programme***

**Pete Roberts** explained how the Clean Air for Europe Programme (CAFE) worked to develop a forward view on how air quality improvements could be achieved in order to reduce environmental damages and adverse impacts on human health. These are expressed by the European Union’s Thematic Strategy on Air Pollution which was a direct product of the CAFE programme (EU, 2005).

Air quality improvements require emission reductions and these involve cost, for example via the installation of abatement equipment. The consequent reduction in concentrations of atmospheric pollutants then has to be translated into benefits that reflect expected improvements in health and environment. The monetisation of these benefits, especially of the reduction in the mortality risk associated with exposure to fine particulate matter, was a novel and key feature of CAFE.

The process of accounting for the external costs of air pollution in Europe has been developed over a long period of time by research under the ExternE program<sup>6</sup> and its successors NewExt<sup>7</sup> and NEEDS<sup>8</sup>. The objective is to capture as far as is possible all (adverse) impacts of anthropogenic emissions and monetise them so they can be judged on a common basis. For the moment, the methodology struggles to capture values for ecosystem impacts but considerable progress has been made on health impacts.

Health impacts are two-fold. There are chronic effects attributed to pollutant exposure over a long period of time. These can be detected by looking at statistical relationships between health outcomes in the population and environmental factors. There are acute effects which can be directly observed in the population in the short period following an episode of high pollution. For policy purposes in Europe the statistical link between fine particle concentration and life expectancy found in US studies is used to assess a mortality risk due to fine particles. The link between high ozone concentrations and mortality rate is used to quantify an acute mortality rate. In the CAFE process health effect valuations from the NewExt project were used to monetise health effects. These were somewhat larger than those found later by the NEEDS project and by a UK study sponsored by DEFRA (2004).

The CAFE cost-benefit analysis was reported in a series of three papers<sup>9</sup>. CONCAWE was very active in the stakeholder process that helped the methodology to be refined. CONCAWE reported the range of valuations obtained in studies in Report 4/06 'Analysis of the CAFE cost benefit analysis' which is available from [www.concawe.org](http://www.concawe.org) (link publications) and introduced a Monte Carlo analysis to assess how the range of opinions on valuation could be combined with uncertainty over costs to interpret the cost-benefit of options considered under CAFE. Combined with a proper marginal analysis the end point of the Thematic Strategy ambition is obtained. The review of the National Emissions Ceilings Directive is now in process using the overall approach of CAFE but with data modified in several ways (EU, 2008). This is because the CAFE energy scenarios for 2020 need to be updated to take into account the effect of the decision of the European Council of March 2007 to reduce European greenhouse gas emissions by 20% and to have 20% renewable by 2020.

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<sup>6</sup> [www.externe.info](http://www.externe.info)

<sup>7</sup> [www.ier.uni-stuttgart.de/forschung/projektwebsites/newext](http://www.ier.uni-stuttgart.de/forschung/projektwebsites/newext)

<sup>8</sup> [www.needs-project.org](http://www.needs-project.org)

<sup>9</sup> [www.cafe-cba.org/reports](http://www.cafe-cba.org/reports)

#### ***4.7 Shall we go home now? A summary of the presentational session***

Following these presentations, **David Taylor** provided his thoughts and initial conclusions in order to stimulate further discussion. He noted that a SEA, at first sight, may seem an easy task to a layman but the presentations had demonstrated that it is a complex undertaking and the choices to be made are not necessarily obvious.

A cautionary approach is already taken in the evaluation of risk but is also needed in analysing benefits. For example, it is well known in the pharmaceutical industry that the initial use for which a drug is developed may not be the major use which emerges later. Similarly, there is an increasing awareness of potential risks in nanotechnology, but an adequate SEA needs to take a precautionary approach to the potential benefits. Also the consequences of industrial actions need more careful analysis. For example, in environmental risk assessment the concept of PEC/PNEC (predicted environmental concentration/predicted no effect concentration) is well established as an indicator of potential environmental damage, but there is still no adequate understanding of the actual environmental impact. If a SEA is to compare benefits against impact, a much better understanding of impact is required.

An environmental impact analysis would include values that society puts on environmental protection. But such values differ depending on nationality, the ecosystem to protect etc. In addition, valuations may differ depending on the stakeholder, i.e. whether they are a regulator, a consumer or industry. So, more work is needed to better understand the consequences of actions.

A key issue is that SEA is not about finding the ‘best technological alternative’ because the developmental process has already identified what this is. The question that will rather emerge is whether one can use this ‘best alternative’ and what the cost to society and the environment will be. Probabilistic risk assessments may help in this respect. But they have been carried out in the past, without convincing the population at large. A better quantification of environmental damages is needed (at least to understand upper and lower limits) and a valuation of ecosystems needs to be factored into this.

Hence, SEA raises enormous challenges. ECETOC could make a contribution to address some of those challenges, notably in improving the science of environmental impact analysis.

## 5. REPORTS FROM BREAKOUT GROUPS

### 5.1 Breakout Group I

Chair: Saskia van der Vies

*Rapporteur*: Stuart Marshall

Stavros Georgiou

Alain Heilbrunn

Jenny Holmqvist

Tim Kedwards

Antoine Leplay

Diana Maurer

Pete Roberts

Bruno Schmit

Frank Schnöder

Henk Vrijhof

Andrea Weigel

### **Contribution of natural sciences to SEA/CBA and key criteria for ecological evaluation**

*(Proposed role for ECETOC in italics)*

- Variation in natural systems
  - Need appropriate descriptions of variation in environmental compartments – spatial, temporal.
  - Needed to discriminate stressor effects from natural variation.
  - *Could take form of probabilistic approaches.*
  - *Learning from determination and definition of good ecological status – structure and/or function.*
- *Need to engage with economists to frame questions and feed into monetary/societal valuations.*
- *Need for guidance/framework to assess the magnitude of effects of chemicals,*
  - *for example, levels of protection for diversity;*
  - *for example, species sensitivity distribution (SSD) – 95%, 90% etc. Each may come at different cost, e.g. is it acceptable to reduce algal species diversity but not the number of fish species?*
- *Learning from agrochemical/biocides work on assessing ecologically acceptable concentrations (recovery?).*
- Is there a need to agree standard metrics e.g. diversity indices?

- *A lot of this is currently available. So a focus could be the development of frameworks. Focus could be on the magnitude of impacts. This could include projections of increasing/decreasing effects over time. Case studies are always valuable.*

### **Input of ERA in SEA**

- Clear concentration and effect relationships help.
- Magnitude of impact on individual species populations and community diversity.
- Should the scope be on ecotoxic effects or also other impacts?
- *Needs to be translated into easily understandable concepts for economists/regulators and lay people. This may best be achieved via multidisciplinary initiatives.*
- Scale of emissions/exposure – linked to magnitude of impact and likelihood of impact.
- *Some concerns about SEA for vPvB where ecotoxic impacts are not demonstrated. If risk assessment is not accepted because of uncertainties how will a SEA be able to cost the 'impact'?*

### **5.2 Breakout Group II**

Chair: Steve Rumford

*Rapporteur:* David Farrar

Neil Carmichael

Sebastian Gil

Elina Karhu

Philippe Lemaire

Peter Saling

Diederik Schowanek

Oliver Straub

David Taylor

Hans-Jürgen Wiegand

Marc Willuhn

### **Key points from the discussion**

- ECETOC should engage with the environmental economists. A workshop?
- There is a need to identify the size of the problem. For example, under REACH, how many substances will require a SEA because of a proposal for restrictions? How many are required due to a request for authorisation?

- Extrapolation from PEC/PNEC ratio >1 to actual environmental impact. When is a change an adverse change? Need to define the magnitude of the decrement that requires attention. Who decides what is adverse or significant?
- Need to move from the observed effect on a species (in the laboratory) to impact at the population level. Need to understand population dynamics. Use of probabilistic risk assessment? Appropriate methodology should be defined.
- Need to bridge the uncertainty gap between PBTs and candidates for long-range transboundary air pollution. Impact of PBTs on higher mammals.
- Concern about vPvBs –no ‘T’ (toxicity)—how to quantify the risk? Explore relationship between bioaccumulation and effect at low levels using more sensitive markers/biomarkers. Threshold of Ecotoxicological Concern (in terms of critical body burden?).
- Encourage use of life-cycle based tools to evaluate alternate solutions.

### 5.3 *Breakout Group III*

Chair: David Owen

*Rapporteur*: Fraser Lewis

Steven Broekx

Annick Carpentier

Yuri de Bruin

David Gartside

Nick Hanley

Ed Hawker

Christa Hennes

Sylvia Jacobi

Adriana Lipkova

Karin Sanne

Corinna Weinz

#### **Major themes from the morning session**

- Low level of understanding of SEA/CBA in the chemical industry.
- SEA is a good structured approach for this type of analysis but is very data hungry.
- Lots of assumptions included—validity?
- When would a SEA within REACH be carried out?
  - When ‘risk assessment fails’?
  - When a risk assessment cannot be done?

- REACH currently conducts deterministic risk assessment (PEC/PNEC)—SEA will require risk assessment approaches to ‘quantify’ the level of impact.
- Need for comparative risk assessment to help identify suitable alternatives and quantify their risk/impact.
- SEA allows balancing different risks—human vs. environment by ascribing monetary value.
- SEA will be very resource intensive.
- SEAC (Socio-Economic Analysis Committee) is not a scientific body.

### **Major challenges for the scientists**

- Develop a monetary value for the various endpoints in risk assessment.
  - What are the ‘effects of concern’ which need a monetary value assigned—protection goals?
- How do we characterise the risk sufficiently to quantify an impact?
  - Probabilistic approaches?
  - Ecosystem analysis?
  - Harmonisation of approaches.
- How do we do this within REACH where there are mandatory data requirements (limited)?
- How do you determine the incremental impact of individual chemicals in a SEA/CBA?
- Is there a consistent approach for conducting and evaluating SEA/CBA on chemicals within the regulatory framework e.g. harmonisation/definition of parameters?

### **Opportunities/Priorities for ECETOC**

The overall view was that this is a worthwhile topic for ECETOC and warrants further discussion. Initial suggestions:

- Development of risk assessment approaches which can quantify environmental impact as in input to SEA/CBA.
  - Need options for use with limited data sets (REACH).
- Raising the awareness/competency of industry to SEA/CBA.
  - Joint workshop with an Environmental Economics group.
  - Networking e.g. Session at EAERE (European Association of Environmental and Resource Economists).
- How much can the chemical industry learn from other industrial sectors?
- Task force to trial construction of a SEA for an example chemical—learn by doing.

#### **5.4 Breakout Group IV**

Chair: John Doe

*Rapporteur*: Johannes Tolls

Malyka Galay Burgos

Denis Huchette

Henry King

Jeff Lewis

Meg Postle

Jochen Rudolph

Maik Schmahl

Matti Vainio

Nico Van Belzen

#### **General recommendations**

- In order to warrant that analyses be accepted by stakeholders, the methodology employed should be peer-reviewed, and the underlying assumptions made transparent. To that end, credibility can be built by establishing a framework for doing socio-economic analysis.
- Proper assessment of the actual impacts requires the use of appropriate assessment/extrapolation factors. In that light, the appropriateness of the factors used in risk assessment needs to be reviewed.
- A socio-economic analysis needs to be informed by economists and by toxicologists / ecotoxicologists. A true interdisciplinary cooperation between them is a prerequisite for the success of the effort.
- The focus of ECETOC with regard to socio-economic analysis should be on establishing the facts on the impact of chemicals on human health or on the environment.

#### **Proper assessments of impact of chemicals on human health**

- The data produced in current toxicity testing (and in the testing for the REACH requirements) constitute appropriate input to the prediction of health consequences of substances.
- Based on these data, the severity of the effects and the proportion of the population can be predicted.
- An appropriate framework including algorithms can be developed to assess the effect of chemicals on health.
- The inclusion of demographic information and of information of sensitivities of relevant subpopulations can contribute to improve the analysis.

*Recommendations:*

- Develop framework and test it using EU-database (development sponsored by EUROSTAT).
- Evaluate appropriateness of assessment factors; possibilities to factor in exposure and demographic information. Starting point for case studies could be the JACC (Joint Assessments of Commodity Chemicals) documents.

**Proper assessments of impact of chemicals on the environment**

- The data produced in standard ecotoxicological testing inform ecological risk assessment but lack the realism required for environmental impact assessment.
- Obtaining additional laboratory test data and modelling the results in species sensitivity distributions provides a means to enhance the ecological relevance of the analysis.
- Options for further improvements such as mesocosm studies may need to be explored.

*Recommendations:*

- Develop framework for environmental SEA using the above elements and test it in case studies.
- Use case studies to explore advanced effect assessment approaches such as mesocosm studies and ecoepidemiology to inform the assessment.

## **6. SUMMARY AND RECOMMENDATIONS**

Throughout the Workshop the distinction between measuring changes in impact resulting from authorisations and restrictions ( $\Delta U$ ) and valuing the units saved (V/U) was maintained. Given its remit, the ECETOC interests should emphasise the clarification of  $\Delta U$  but there were possible exceptions. With these considerations in mind the Workshop recognised five main themes that would be appropriate for ECETOC to pursue further.

### ***6.1 Appropriately quantifying changes in impact***

This was considered to be most challenging and hence critical with respect to ecological impacts. To date, most ecological risk assessments under the Existing Substances Regulation had involved only risk characterisation ratios ( $RCR = PEC/PNEC$ ) and these were inappropriate for cost-benefit analysis. The ecological units experiencing impacts needed to be characterised in terms of individuals in populations, species, communities and ecosystem processes. Further work was needed on defining when and how risk assessment should go beyond RCRs. A special case involved hazard driven authorisations based on PBT and CMR criteria. The only way to save chemicals that fail authorisation on this basis would be through a SEA—and yet a CBA would not be possible without a full risk assessment. These are obvious areas for ECETOC involvement.

### ***6.2 Informing the valuation of impacts of chemicals on health and ecosystems***

The values used in SEAs are public values. They are derived from research carried out by experts in different disciplines. Such research is challenging because the connections between impacts and the values that the public put on them are complex. For example, from a human health perspective more work needs to be carried out on how we value avoiding ill health—morbidity rather than only mortality. Research on morbidity would need knowledge of medical experts, experts in the impacts of chemicals and experts in valuing the impacts. Similarly, the connections between impacts on ecological units and the services that we derive from ecosystems involve complex, not well understood interactions. Furthermore, the methodologies to value ecosystem services are still being developed with a clear need for ecologists and economists to collaborate in clarifying these linkages. ECETOC could play a part in enabling these collaborations.

### ***6.3 Facilitating the process of socio-economic analysis***

SEAs are multidisciplinary and therefore are best developed by teams whose members can bring in different disciplines. There will be no barriers to communication when a common understanding of aims and approaches exists. ECETOC could play an important role in facilitating the development of these ‘dream teams’ in member companies.

### ***6.4 Developing an exemplary case study – learning by doing through a Task Force***

One way of making a contribution to all the preceding themes would be to establish a multidisciplinary task force. This would develop one or more case studies on SEAs involving one or more substances.

### ***6.5 Networking and capacity building***

All these themes (6.1 to 6.4) might be informed by knowledge in organisations that have experience in SEA from other fields and disciplines. ECETOC could facilitate networking with such organisations. Similarly all the themes could help ECETOC members to build capacity for carrying out SEAs in their own companies.

## ABBREVIATIONS

B	Benefit
C	Cost
CAFE	Clean Air for Europe Programme
CBA	Cost-benefit analysis
CMR	Carcinogenic, mutagenic, reprotoxic
CONCAWE	Oil companies European association for environment, health and safety in refining and distribution
CSA	Chemical safety assessment
DEFRA	(UK) Department for Environment, Food and Rural Affairs
EAERE	European Association of Environmental and Resource Economists
ECHA	European Chemicals Agency
ERA	Environmental risk assessment
EU	European Union
EUROSTAT	Statistical office of the European Communities
NP	Nonylphenol
OECD	Organisation for Economic Co-operation and Development
OP	4-tert-octylphenol
PBT	Persistent, bioaccumulative, toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
RCR	Risk characterisation ratio
REACH	Registration, evaluation, authorisation and restriction of chemicals
RER	Risk evaluation report
RIA	Regulatory impact assessment
RIP	REACH implementation project
RMO	Risk management option
RRS	Risk reduction strategy
SEA	Socio-economic analysis
SEAC	Socio-Economic Analysis Committee
SSD	Species sensitivity distribution
SVHC	Substances of very high concern
T	Toxicity
vPvB	Very persistent, very bioaccumulative
V/U	Value per unit
WFD	Water Framework Directive

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## APPENDIX 1: WORKSHOP PROGRAMME

*Wednesday 4 June 2008*

08.30-09.00	Registration and coffee	
09.00-09.10	<b>Welcome</b>	Neil Carmichael Secretary General of ECETOC
09.10-09.40	<b>Keynote Address: Socio-Economic Analysis – Demands on Chemical Safety Assessment</b>	Matti Vainio, ECHA
09.40-10.00	<b>Socio-Economic Analysis to keep a CMR- or PBT-Chemical in the Market Place</b>	Peter Saling, BASF
10.00-10.20	<b>SEA and REACH: Challenges and Opportunities</b>	Meg Postle, Risk and Policy Analysts
10.20-10.40	<b>Case Study: Completing an SEA for Octylphenol</b>	Ed Hawker, UK Department of Environment, Food and Rural Affairs
10.40-11.00	Coffee Break	
11:00-11:20	<b>Economic Assessments of the WFD in the UK</b>	Nick Hanley, Stirling University
11:20-11:40	<b>Cost-Benefit Analysis of the CAFE Programme</b>	Pete Roberts, Shell / CONCAWE
11:40-12:00	<b>‘Shall we go home now?’ A summary of the morning session</b>	David Taylor, AstraZeneca
12.00-13.00	Lunch	
13.00-13.10	<b>Introduction to the Breakout Group Discussions</b>	Peter Calow
13.10-15.00	<b>Breakout Group Discussions</b>	
15.00-15.15	Coffee Break	
15.15-16.30	<b>Report from the Rapporteurs and Summary</b>	Moderator: Peter Calow
16.30-16.40	<b>Closing Remarks</b>	Jochen Rudolph Chairman of the Board of ECETOC

Close of Workshop

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## ECETOC WORKSHOP REPORTS

- | No.    | Title   |
|--------|---|
| No. 1  | Workshop on Availability, Interpretation and Use of Environmental Monitoring Data. 20-21 March 2003, Brussels   |
| No. 2  | Strategy Report on Challenges, Opportunities and Research Needs Arising from the Definition, Assessment and Management of Ecological Quality Status as Required by the EU Water Framework Directive Based on the Workshop EQS and WFD versus PNEC and REACh - Are They Doing the Job? 27-28 November 2003, Budapest |
| No. 3  | Workshop on Use of Human Data in Risk Assessment. 23-24 February 2004, Cardiff  |
| No. 4  | Influence of Maternal Toxicity in Studies on Developmental Toxicity. 2 March 2004, Berlin   |
| No. 5  | Workshop on Alternative Testing Approaches in Environmental Risk Assessment. 7-9 July 2004, Crécy-la-Chapelle   |
| No. 6  | Workshop on Chemical Pollution, Respiratory Allergy and Asthma. 16-17 June 2005, Leuven   |
| No. 7  | Workshop on Testing Strategies to Establish the Safety of Nanomaterials. 7-8 November 2005, Barcelona   |
| No. 8  | Workshop on Societal Aspects of Nanotechnology, 9 November 2005, Barcelona  |
| No. 9  | Workshop on the Refinement of Mutagenicity / Genotoxicity Testing. 23-24 April 2007, Malta  |
| No. 10 | Workshop on Biodegradation and Persistence. 26-27 June 2007, Holmes Chapel  |
| No. 11 | Workshop on the Application of 'Omics in Toxicology and Ecotoxicology: Case Studies and Risk Assessment, 6-7 December 2007, Malaga  |
| No. 12 | Workshop on Triggering and Waiving Criteria for the Extended One-Generation Reproduction Toxicity Study, 14-15 April 2008, Barza d'Ispra  |

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