# *Environmental Impact Assessment for Socio-Economic Analysis of Chemicals: Principles and Practice*

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# *Environmental Impact Assessment for Socio-Economic Analysis of Chemicals: Principles and Practice*

## CONTENTS

## EXECUTIVE SUMMARY


- This report describes the requirements for, and illustrates the application of, a methodology for a socio-economic analysis (SEA) especially as it might be adopted in the framework of REACH.

- Socio-economic analysis weighs the costs of any restrictions on the production and use of chemicals against the benefits to human health and the environment.

- The reasons why industry needs to understand the principles and practices of socio-economic analysis are: (1) to carry out, where appropriate, a SEA as an argument for authorisation (this is an industry responsibility), and (2) to be able to contribute as stakeholders in socio-economic discussions with regulatory authorities when a SEA is used as a basis for justifying restrictions.

- The focus of this report is on the ecological impacts of chemicals rather than on their human health impacts. This is where many of the most profound ecological and economic challenges are, and the ECHA guidance for socio-economic analysis associated with both restrictions and authorisation in the REACH process identifies the need for more work in this area.

- The report argues for as much quantification as possible, with the ideal of monetisation so that a cost-benefit analysis can be carried out. Without quantification the ecological benefits of restrictions on chemicals (including failure to authorise) may well be presented in emotive terms that are hard to counter on the basis of the economic benefits that might be lost from restricted use or the banning of a chemical.

- An ecological benefits assessment involves two components. One is the extent to which ecological effects are or may be ameliorated by restrictions on a chemical, and the other is the monetary value that is put on the ecosystems so protected.

- There are enormous challenges in ascribing monetary values, especially to non-marketed ecological goods or services. However, environmental economics has made great strides over recent years in developing appropriate methodologies to enable this to be achieved. This report draws attention to the appropriate sources.

- A substantial part of the challenge for valuation in benefits assessments is in identifying and quantifying the ecological impacts themselves in appropriate terms. The problem is that ecological risk characterisations and assessments do not express effects in terms of ‘impacts’ that can be valued.

- This report draws attention to a number of possible scenarios whereby the outputs of risk characterisations might be linked to quantified ecological impacts through such methods as species-sensitivity analysis, smart modelling, making connections to ecological quality status and using an ecosystem services approach. None of these methods is developed to the extent that they could be applied in case studies. There will be a need for pioneering efforts in these areas.

- The challenge of conducting a socio-economic analysis becomes even harder when only hazard criteria are available as is the case for substances of very high concern. The report takes the view that most of these chemicals will be degradable in the environment and in organisms, and therefore should be amenable to standard risk characterisations. However, the expectation is that the SEA arguments will have to be particularly convincing to allow authorisation.

- Finally, socio-economic analysis needs to bring together risk assessment and economic considerations. This requires that ecologists and economists, scientists and regulators understand each other's needs and languages. The establishment of a forum to facilitate this is to be encouraged.

# 1. INTRODUCTION

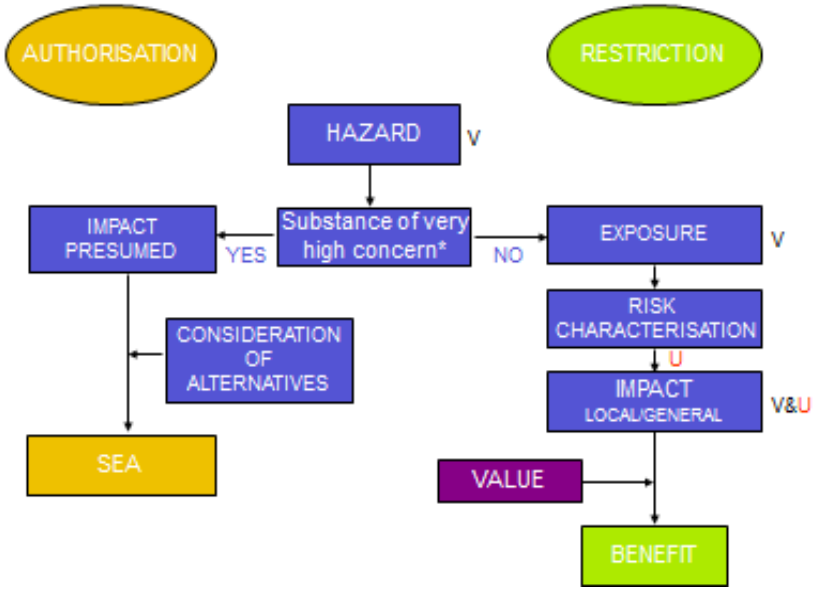
Industrial chemicals are essential to modern society and bring benefits in the form of improved health, food supply, goods, general lifestyle and well-being. Some chemicals, if they enter the environment, can cause problems for human health and ecosystems and it is important to identify the potential hazardous endpoints, quantify the risk that genuine harm will occur and develop strategies to mitigate that risk. Mitigation may involve risk control, risk reduction or risk elimination. An example of risk control is the setting of environmental quality standards, typically as maximum concentrations in environmental compartments. To understand the risks/hazards posed by chemicals and their use, the EU REACH legislation has required that the uses and environmental endpoints of manufactured chemicals are assessed so that appropriate measures can be assessed. A small number of chemicals will be found to present specific problems in that they persist in the environment (do not degrade), are taken up in biological systems where they may exert toxic effects and become concentrated producing serious damages in the long term. Simple risk control strategies are insufficient for this situation. If alternatives, with equivalent industrial function and having controllable environmental risk, can be found then replacement is a natural control approach and the risk can be eliminated. However, if alternatives do not exist, or if they exist and pose similar risk, then policy makers face a difficult decision between risk reduction (controls on usage) and risk elimination (remove the chemical and its useful dependent products) from the market. Socio-economic analysis (SEA) has been developed to assist decision making, to help assess on the one hand the societal benefit of maintaining use of the chemical (and the manufactured products dependent on the chemical) and, on the other hand, the potential long-term consequences of it (or candidate replacements) in the environment. This report describes the requirements for, and illustrates the application of, SEA methodology as it might be adopted in the framework of REACH. For simplicity, only simple usage versus environment is discussed in detail, but in all practical cases the possibility of alternatives should be included to find an optimal and cost-effective solution.

Under REACH, there are provisions to use SEA to grant an authorisation to substances of very high concern (Article 60); and in decisions about restrictions (Article 68) (EU, 2006). 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 costs for the action to be worthwhile. These routes for a SEA under REACH are illustrated in Figure 1.

Under REACH, the reasons why industry needs to understand the principles and practices of socio-economic analysis are: (1) to effect, where appropriate, socio-economic analysis as an argument for authorisation (this is an industry responsibility), and (2) to be able to contribute as stakeholders in socio-economic discussions with regulatory authorities when a SEA is used as a basis for justifying restrictions.

*Figure 1: Scheme on environmental impact assessment routes under REACH*

*(boxes refer to elements of assessment)*




* For environmental assessments, substances of very high concern (SVHC) are decided on the basis of PBT thresholds or if there are equivalent concerns. Under the precautionary principle there is a presumption that these will lead to impacts and take substances down the authorisation route.

V: Variability: toxicological sensitivity (species and life stages) and exposure (space and time).

U: Uncertainty.

This report aims at making a contribution to the understanding of these principles and practices of socio-economic analysis especially in the context of REACH. The terms of reference that formed the basis of the work are summarised in the following text box.

TERMS OF REFERENCE

- To review relevant existing principles and practices.
- To establish a user-friendly framework for the assessment of environmental impacts for use in socio-economic analysis (SEA) focusing on REACH.
- To identify the information required in addition to PEC/PNEC assessments in order to conduct a SEA.
- To outline how environmental scientists can interact with economists in valuing ecological systems.
- To provide guidance on required types of expertise and resources for capacity building.

However, there was no attempt to 're-invent the wheel'. There are guidance documents on the application of socio-economic analysis for both authorisation and restrictions (ECHA, 2008a; 2009; 2011) and a few case studies have already been carried out by other organisations for specified chemicals under REACH (see the non-comprehensive list in following text box).

- Nickel; Medium chain chlorinated paraffins (MCCP) (WCA, 2010).
- Glycol ether used in cleaning agents, paints, chemical intermediates (ECHA, 2008b).
- Flame retardant in textile applications; Unknown substance bioaccumulative, but not persistent, toxic to aquatic and soil organisms used in pigments, metal treatment formulations, tanning salts (RPA, 2006).
- 1,2,4-Trichlorobenzene (TCB) in drinking water; Nonylphenol (NP) in sewage sludge; Tetrachloroethylene (TCE) in ground water; Polychlorinated biphenyls (PCB) in fish (DHI, 2005).
- CMR substance in wire enamels (Saling *et al*, 2007).

Rather the emphasis will be on benefits analysis, at the interface of risk assessment, environmental impact assessment and the assessment of the monetary values used for the impacts. Such issues would be part of socio-economic analysis focusing on environmental/ecological issues. This is where many of the most profound challenges are and the guidance for socio-economic analysis associated with both restrictions and authorisation in the REACH process indicate that more work is required to develop appropriate methodology for environmental/ecological assessments. Analysis of human health benefits are better developed and more tractable, partly because the issues relating to exposure (and thus impacts) are better known and partly because the values of the impacts have been established more often than those for the environment.

The report begins by briefly considering the principles of SEA, before going on to address the main challenge: How can risk characterisations be translated into possible impacts that are valued? Developing a SEA requires a systematic approach to the collection and evaluation of data, and guidance on this is given in Chapter 4. Chapter 5 describes a classical case study where impacts from an antifouling chemical on shellfisheries could be assessed and valued in marketplaces. However, in general the SEA will not be as straightforward from assessments arising out of REACH and possible ways forward are described in Chapters 6 and 7.

Where possible, the issues are illustrated through case studies on chemicals. These are used for illustrative purposes and do not imply any status for the chemicals under the REACH legislation.

## 2. WHAT IS SEA AND WHY IS IT IMPORTANT IN DECISION MAKING?

The principles of socio-economic analysis are based on welfare economics and are well covered in the guidance documents (ECHA, 2008a; 2009; 2011).

To express this formally a change in ecological benefit (ΔB) from an intervention, for example by restricting the production and use of a chemical, is a function of the likely ecological impact avoided (ΔE) and what value (V) is put per unit of E that is protected. Thus, the ecological benefit is a function of the ecological impact avoided and the value attached to that impact; algebraically: $\Delta B = \Delta E.V$.

The costs (ΔC) of the intervention are a function of producer and consumer effects of losing a quantity of the chemical (ΔQ). Again, in algebraic terms this is: $\Delta C = f(\Delta Q)$. From an economic standpoint, ΔB has to exceed ΔC to justify an intervention, otherwise society loses. A comparison of ΔC with ΔB is referred to as a cost-benefit analysis[1]. The impact E might be expressed as individuals in a species, species in a community or as ecosystem services such as fish production; but one needs to know how much of the chemical has to be given up (ΔQ) in order to enjoy the improvement (ΔE) if the costs of the intervention are to be assessed. It is this link that is critical to the analysis and that is difficult to establish. This is because ecological impacts are difficult to capture from the usual ecotoxicological tests that are carried out as a basis for the risk characterisation; this is discussed in more detail in the following chapter. The relationship between Q and E is expressed in terms of concentration/dose-response relationships.

Thus, in order to carry out a cost-benefit exercise as a basis of a socio-economic analysis it is necessary to know how much nature or ecological function is saved by an intervention and how it is valued (V).

Understanding what is meant by costs and benefits can cause confusion. The description above expresses costs and benefits for restrictions, i.e. the benefits represent the improved ecological conditions and the costs represent what has to be given up by producers and consumers to achieve these. The costs and benefits for the current use of a chemical are the mirror image of these, i.e. the benefits are what producers and consumers get from the use of the chemical and the products it is in, whereas the costs represent the associated impacts on the environment. For REACH, CBA (cost-benefit analysis) are expressed in the former terms for restrictions and in the latter terms for authorisation of uses.

Related to this is the complication that both sides of the cost-benefit equation can contain environmental advantages, i.e. there are trade-offs. A good example is the use of tributyltin as an

[1] In practice it can be quite complicated to carry out a cost-benefit analysis, since there are normally several impacts, and account must also be taken of the time profile of the costs and benefits. A 'good practice' cost-benefit analysis also takes account of uncertainties in the estimates of ΔC and ΔB.

antifouling coating for ships covered in Chapter 5. The ecological benefits of banning this substance came from enhanced productivity of shellfisheries. However, antifouling agents also confer environmental advantages by enhancing fuel efficiency and hence reducing energy use and green-house gas emissions. Clearly these environmental benefits should be included in the costs of restrictions. There are two messages arising from this. Firstly, it is important to consider all the environmental implications of any restriction and this is especially important in comparing substitutes. Secondly, the ability to convert all costs and benefits into common monetary units greatly facilitates these kinds of analysis, although this is difficult to achieve in practice.

The values (V) used in a CBA should be those of the public affected by the intervention. The basic principle is that a policy intervention is only worthwhile if it enhances the welfare of those affected and hence is based on their preferences. Generally, these preferences are expressed in expenditures on goods and services that take place through markets; but not all factors that influence welfare are traded and this is especially the case for ecological ones. Here non-market values are assessed by the economists either through surveying those affected or observing behaviour in surrogate markets. The estimation of non-market values associated with environmental services and with key ecological functions is now a well-established area of research among professional economists, and there are clear guidelines on how studies should be conducted and estimates derived. The range of approaches is well described in Ten Brink, 2011; Tisch *et al*, 2010; Hanley and Barbier, 2009.

An issue that comes up often in estimating the value of services gained or lost through changes to an ecosystem is whether it is permissible to take monetary values derived from similar ecosystems valued in another context and/or in another location. Clearly there will be some differences, but there are also similarities and the process of 'benefit transfer' − which is the application of values from one site and study to another − is also well studied and guidelines are available. In this context, one should note that the magnitude of uncertainties associated with the V are often less than that associated with the ΔEs and so a greater effort may be needed to improve the physical estimates than to refine the valuations. Sources of monetary values for ecological entities include the Environmental Valuation Reference Inventory (https://www.evri.ca/Global/Splash.aspx), and are referred to in papers presented at the European and World Congress of Environmental and Resource Economists (http://www.eaere.org/) and at the BioEconom conferences (http://www.ucl.ac.uk/bioecon/05respap.html). Other databases include COPI (Braat and Ten Brink, 2008), EVRI (1997), ENValue (2004), EcoValue (Wilson *et al*, 2004), Consvalmap (Conservation International, 2006), CaseBase (FSD, 2007), ValueBaseSwe (Sundberg and Söderqvist, 2004), ESD-ARIES (UVM, 2008) and FEEM (Ojea *et al*, 2009) (see www.es-partnership.org for access to most of these databases).

Assessing an impact and the likelihood of it occurring, i.e. carrying out ecological risk assessment, is a task for natural scientists. There are three important conclusions arising from

understanding the needs of the socio-economic analysis for the form that this risk assessment should take. Firstly, the assessments should be for ecological entities that matter for the people affected at whatever scale, i.e. should be value relevant (US EPA, 2009). Secondly, the risk assessments should express how much of this nature is likely to be saved by an intervention so that the benefit can be quantified, i.e. should be in the form of a dose-response (concentration-effect) relationship. Thirdly, the results will also have some error bounds and these need to be presented and taken into account when deciding on possible policy actions.

Clearly these requirements are somewhat challenging and may not be achievable in particular studies. As a consequence two alternative approaches have been developed. One is multi-criteria decision analysis, where a given intervention (e.g. a reduction $\Delta Q$) is evaluated in terms of a range of 'cost items' and 'beneficial impacts'. These items and impacts may or may not be represented in monetary terms but the whole combination is given a score by weighting the individual components. This allows one to include non-monetary factors (such as distributional impacts) but the process of giving weights is controversial.

Another approach that can be taken when obtaining monetary values (V) is not possible but there is a clear public desire to avoid a damage $\Delta E$ is to calculate the cost of different options for achieving the improvement $\Delta E$ and then select the option with the lowest cost. This is referred to as a cost effectiveness analysis (CEA) approach and is frequently adopted when valuation is not feasible and when some action has strong public support. Examples of CEA being applied to evaluate options for achieving environment-related objectives are in the published literature. For example, Macmillan *et al* (1998) evaluated the cost-effectiveness of three government grant options for woodland ecosystem restoration in Scotland. Several examples exist of CEA being used to evaluate petroleum hydrocarbon remediation techniques such as landfilling, bioremediation, soils washing (Day *et al*, 1997), landfarming (Maila and Cloete, 2004), and in situ bioreclamation (Wilson and Brown, 1989). Finally, some CEA examine more general environmental objectives, such as the cost-effectiveness of incentive payment programs relative to traditional top-down regulatory programmes to promote biological conservation in Finland (Siikamaki and Layton, 2006).

The chemical assessment of an alternative is not a trivial enterprise. Often this is applied in a context of a lower hazard material identified as a replacement for one with a higher hazard potential. However, there are potential risks, product life cycle and efficacy-in-use considerations, and economic outcomes that warrant attention. For example, a lower hazard material may not provide the same efficacy as a higher hazard material. This would result in a greater environmental exposure, and possibly risk as well. A high hazard material may not impart a risk to the environment; however, product reformulation may have significant economic consequences.

# 3. ISSUES WITH THE USE OF RISK CHARACTERISATIONS

From an environmental perspective, benefits relate to reduced risks and ultimately reduced impacts on ecological systems, for example, in terms of reduced biodiversity losses and reduced ecosystem service.

REACH refers broadly (Article 1) to ensuring that those involved, *"manufacture, place on the market or use such substances that do not adversely affect human health or the environment"*, where 'environment' means the ecological compartments that are defined more precisely in Annex 1 (EU, 2006).

These kinds of protection goals are set by legislators on the basis of advice from experts. Brock *et al* (2006) recognise four basic principles of ecological protection goals: pollution prevention; ecological threshold; community recovery; and functional redundancy. Another way of thinking about this is in terms of protecting the structure (biodiversity), process (energy flows and cycles of matter) and services to the economy that we obtain from ecosystems. There are complex relationships between these that are far from fully understood by the experts so even if it was possible in principle to define ecologically optimum states from the science this is certainly not possible in practice. Process and service and their capacity to resist and recover from disturbance are presumed to correlate with biodiversity (no species no process; no process no service): Yet this is complicated because in terms of process and service some species are likely to be redundant and others especially important. An underlying presumption in REACH is that by protecting the most sensitive species the rest should follow. This is in line with the precautionary principle that is specifically referred to in the regulation (Article 1, para. 3). But this could be expensive and not necessarily what the public wants.

Certainly these ecological protection goals are not always recognised or understood and hence valued by the public. Informing these public values raises difficult questions about the extent to which this imposes expert values and if that introduces inappropriate bias in valuation in technically challenging circumstances (Christie *et al*, 2006).

The US EPA Science Advisory Board report: 'Valuing the Protection of Ecological Systems and Services' advocates (in the executive summary) measuring ecological risk in value-relevant terms (US EPA, 2009). Valuation *"should seek to measure the values that people hold and would express if they were well informed about the relevant ecological …factors involved"*.

Protection goals have to be operationalised as assessment endpoints and indicators.

The relationship between protection goals and assessment endpoints is not straightforward in 'hazard/risk-based' assessments because substances can be manufactured, used and disposed of

very broadly. Hence, it is often difficult to identify the specific ecosystems and their components that might become exposed except in terms of broad habitat compartments. For REACH, the assessment endpoints are defined more explicitly in annexes to the regulation and the Technical Guidance Document (EU, 2006; ECHA, 2008c).

Substances of very high concern under REACH are defined in terms threshold levels of criteria that indicate potential to persist in the environment, accumulate in organisms and be very toxic (so-called PBT − persistent, bioaccumulative, toxic − criteria) and these are specified more precisely in Annex XIII of the regulation. These are hazard criteria − given that they indicate potential to cause problems and do not consider likely exposure. Nevertheless, the underlying presumption is that persistence leading to accumulation in the environment and organisms and/or high levels of toxicity at low concentrations would seriously threaten ecosystems, and substances with these kinds of properties are subject to authorisation.

Alternatively, in the risk-based approach of REACH likely exposure concentrations (PEC) are compared with threshold concentrations likely to lead to no adverse ecological effects (PNEC). PEC/PNEC ratios (Risk Characterisation Ratios = RCR) above 1 trigger management actions. RCR involve both exposure and effects assessments and this is why they are labelled as risk characterisations in the EU; but they do not give explicit assessments of probability of adverse ecological effects at specified concentrations of the chemical under consideration. RCR are carried out for all the environmental compartments recognised in Annex 1 of the REACH Regulation; i.e. aquatic, sediment, soil etc. PNEC are usually obtained from observing effects in simplified 'ecosystems' (often one or a few species). The most simplified tests involve a consideration of effects on survivorship. More involved tests consider effects on reproduction and development. All these criteria are ecologically relevant in that they affect the extent to which species can persist and hence ultimately biodiversity and ecosystem processing. There are, nevertheless, uncertainties in extrapolating from standard laboratory tests on a few species to nature and these are recognised by use of application factors (PNEC = effect endpoint/application factor) that are larger when the information available is most limited. The approach is intended to be a tiered one such that if the RCR is above one more ecologically realistic tests are carried out with reduced uncertainty factors to challenge the initial RCR. The underlying presumption, though, is that protecting the most sensitive species on the basis of realistic/reasonable worst case presumptions will achieve protection of the broader ecological goals as discussed above. Finally the RCR can be computed for different geographical scales; PNEC remain the same but PEC are varied to reflect local, regional and continental conditions.

Relating hazard criteria to ecological entities that can be valued is not easy. As already noted, if substances can persist and/or are taken up into the bodies of organisms or can have toxic effects at very low concentrations, it is presumed that they should be managed by banning, phasing out and substitution. In such cases, the problem is often that no precise measure can be provided for

the impact ΔE. Consequently ascribing monetary value and benefit to a restriction of Q (to zero) is difficult.

Risk-based criteria also raise challenges for SEA and especially cost-benefit analysis. The assessment endpoints are far removed from ecological entities that are valued and are so technical that they have to be interpreted by experts. In other words the RCR does not give a direct assessment of ΔE; i.e. how much ecosystem will be saved by the management strategy (ΔQ). In fact the relationship between RCR and ecological impact is likely to vary with the chemical. Moreover, the assessments often do not relate to specific ecosystems since many industrial chemicals have widespread production and/or use through the EU and the world. This creates a problem for ascribing monetary values in terms of which ecosystems are to be considered and which group of people is affected; so whose values are to be used and of what? This is most serious for broad-scale regional assessments. However, even local assessments that could in principle consider specific effects on specific ecosystems are based on the same generalised PNEC as used at broader ecological scales. Many of the SEA carried out under earlier EC chemicals legislation failed to implement quantitative cost-benefit analysis because of difficulties in interpreting the RCR (IMV, 2007).

A major conclusion from this chapter is that the outputs from risk/hazard assessments have to be related to ecological impacts that are valued if they are to be used in CBA/SEA – and should also indicate how much nature is saved by any reductions in exposure arising from the interventions. The outputs from REACH assessments are not in this form. The following chapters indicate how these difficulties might be addressed.

# 4. A SYSTEMATIC APPROACH TO COLLECTING DATA FOR A SEA

When preparing a benefits analysis for a SEA, it is essential to begin with a systematic data collection.

It is important to try addressing connections between hazard and risk criteria, and ecological impacts. In doing this one needs to consider not only the potential severity of ecological impacts but also their geographical extent – since both will be important in identifying likely benefits arising from any amelioration.

It is also important to consider if there are possible substitutes for the chemical and to evaluate their respective advantages and drawbacks. The assessment of substitutes may present additional difficulties particularly in terms of access to appropriate data.

Making these kinds of assessments will require judgments to be made. This needs to be done systematically and with transparency.

The questionnaire (see Appendix A) represents one way of doing this. It was developed from the requirements of REACH and the associated documentation for SEA. This has been streamlined to provide a simplified summary of the environmental impact assessment information required for a socio-economic analysis.

Completed questionnaires/templates collected for the chemicals referred to in this report are given in the Appendices B - E.

In compiling the case study examples a number of general conclusions can be drawn namely:

- There were only a limited number of chemicals available with data on effects in the field/environment that could be compared to laboratory-derived data.
- There were only a limited number of chemicals available with socio-economic data.
- Information on historical production tonnages and uses can be difficult to obtain.
- Access to comparative information on potential substitutes may be difficult.

## 5. SITE-SPECIFIC IMPACTS ARE EASIER TO HANDLE

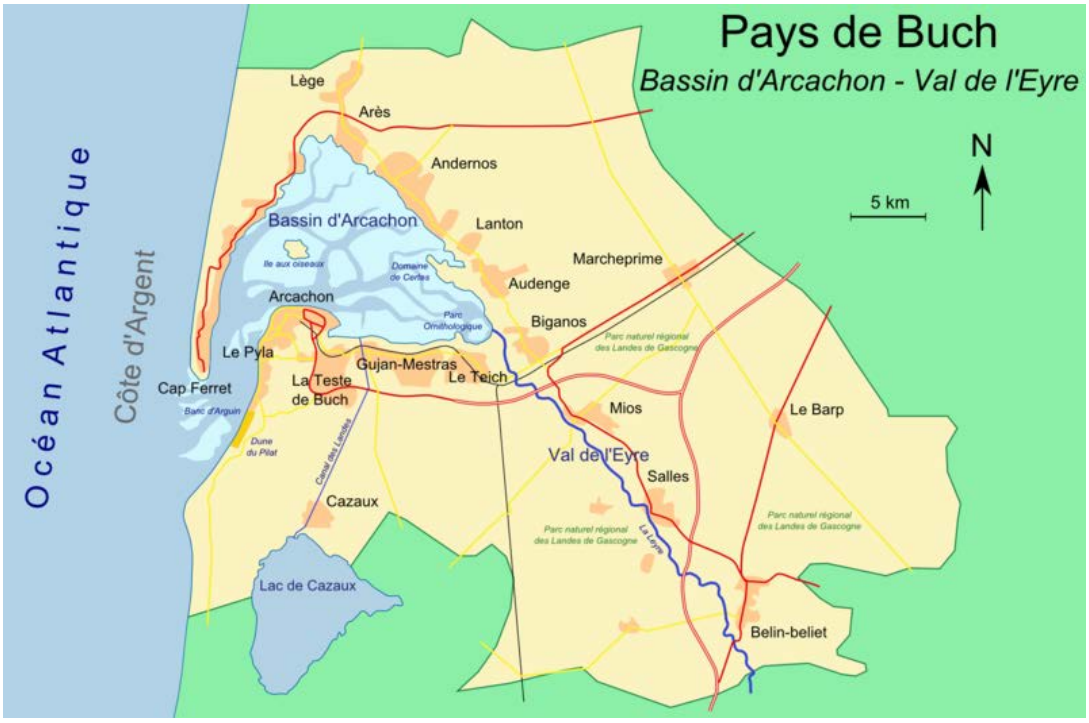
A classic example where CBA has been applied is the banning of tributyltin (TBT) as an antifouling paint. This report uses this as an example of how CBA might be applied to chemical regulation in 'ideal circumstances'.

A questionnaire/template relating to the benefits analysis of TBT is given in Appendix B, which also includes the relevant references. TBT has endocrine disrupting effects at very low concentrations and as a result it was banned. The impacts of TBT could be valued because they related to shellfisheries that provide food items traded in market places. Moreover site-specific effects could be followed.

***Analysis of costs and benefits at the local level in France***

The first study that looked at the environmental impacts of TBT, and also estimated the economic cost of those impacts, was for the Bay of Arcachon in France (Alzieu, 1991, 2000; Ruiz *et al*, 1996). The bay is located between the Gironde estuary and the Spanish border on the Atlantic Coast (see Figure 2). Oyster production here dates back to the 18th century and in a normal year production is around 10k-15k tons. The bay is also heavily used by pleasure craft with summer traffic ranging from 10,000 to 15,000 boats.

*Figure 2: Bay of Arcachon; a site of oyster production*



From 1975 to 1982 spatfall (the mass of larvae) became very low and in some years failed completely while it remained satisfactory in neighbouring areas. The cause was established as water pollution in the form of tributyltin acetate, which was found to be highly toxic in laboratory experiments to the survival and growth of oyster larvae. The most likely source of this pollution was from the antifouling materials of the small boats also using the bay.

From various studies it was estimated that the equivalent of the PNEC for this by product of TBT (referred to as the no observed effect level − NOEL) was around 20 ng/l. At the same time the actual concentrations were found to be much higher, i.e. around 100 ng/l. Furthermore, experiments showed that the spatfall was extremely sensitive too when the NOEL was exceeded. The result was a fall in oyster production of the order of around 28,000 tons between 1979 and 1983, representing a loss of around US$47 million in the prices of that time. The loss was reduced from 1983 onwards as the French government restricted the use of antifouling paints on boats less than 25m in length (i.e. those likely to enter the bay) and by 1984 production was back to normal levels.

Against this environmental benefit of the ban on the use of TBT-based paints one has to assess the cost. The analysis presented by Alzieu (see Appendix B) estimates the cost at US$0.3 million as that was the size of the market in TBT-based paints of the pleasure craft in Arcachon Bay. On this basis the costs of the ban would be considerably less than the benefits of restoring oyster production.

In the reported analysis a number of corners have been cut and there are some errors of method. On the losses from the exceedence of the NOEL or PNEC standards it is not clear whether these are net of the costs of operations or not. It looks as if they are gross figures, in which case the costs of production should be deducted. Furthermore a more accurate relationship between loss rates and exceedences should be established.

When was it, for example, that the concentrations increased and how did they evolve? Unfortunately no data are available for that period for this to be done. As far as the costs of a ban are concerned the figures given are not the correct ones. It is not the cost of TBT-based paints that matters but the difference between the costs of the substitutes and those of TBT-paints. This information is not provided, but it is available in principle and could be relevant. For example, there was a US Navy study which estimated that TBT-based paints reduced fuel consumption by 15 percent and reduced the frequency of painting of hulls from 5 years to 7 years (US Navy, 1984). If correct this would provide a sound basis for calculating the costs of substitutes to TBT-based paints. It would also provide data on a possible benefit of TBT paints in terms of reduced fuel use, $CO_2$ emissions etc.

In this context one might also estimate the other measures that could be taken by pleasure boats, such as not entering the bay. It is possible that such a solution would be a lower cost option than the one that was chosen. If implemented a ban on such boats would result in loss of recreation in a preferred spot and the loss of benefits associated with that. These can be measured but require some detailed investigation.

In spite of these limitations the study shows clearly that the case for restrictions can be made much more clearly and effectively when there is a potential economic loss. In this case the study came rather late. It would have been better to have estimated potential losses *ex ante*, and imposed a ban at the outset. The question is whether this can be done for future chemicals and what is the potential for such analysis in future regulations.

***DEFRA analysis***

A more comprehensive analysis of the benefits of the partial ban on marine TBT-based paints imposed in July 1987 was carried out by DEFRA (Department for Environment, Food and Rural Affairs) for the United Kingdom (Giacomello *et al*, 2006). The following benefits were identified:

1. Commercial values of shellfish.
2. Value of shellfish to individual consumers who collect them for their own consumption.
3. Recreational activities of collection of shellfish.
4. Collection of invertebrates for bait.
5. Indirect impacts on commercial catch of fish such as lemon sole resulting from their increased access to feeding on shellfish.
6. Indirect impacts on catch rates of other species by recreational anglers.
7. Recreational bird watching, where species such as the redshank and oyster catcher could have been affected by the presence of TBTs.
8. Waste treatment services performed by invertebrates. By reducing the number of such species TBT would have reduced the waste treatment ability and the water quality. This would affect water companies and industrial users who have to treat water to a certain standard before use. The costs of measures to meet the WFD good ecological standard criteria would also have risen as a result of the presence of TBTs.
9. Through bioturbating sediments marine invertebrates contribute not only to burying contaminants more quickly, but also bringing to the surface new nutrients from deeper layers, and processing organic matter into smaller particles and dissolved substances. These latter functions are referred to as nutrient cycling, and represent an important ecological function of the TBT-affected species.
10. TBT caused the local extinction of some species such as the dogwhelk, which have an option value attached to them because valuable commercial applications may result from a better understanding of their properties.
11. Non-use values may exist for species and landscapes, some of which were affected by the presence of TBTs.

Of these 11 possible benefits the study only quantified two: The commercial value of shellfish (item 1. above) and the values of nutrient recycling (item 9. above). For all the rest it was deemed too difficult to obtain the required physical and monetary data.

The valuation of commercial shellfish includes native oysters, pacific oysters, whelks, periwinkles, cockles, scallops and mussels. For each of these the study recognised that the ideal approach would be to establish a 'dose-response' relationship between the level of TBT and the rate of production and then to calculate the benefits in terms of the shift in the supply of the shellfish, using the typical supply-demand analysis commonly deployed to value the benefits of interventions in the supply of goods and services. In practice this has not been possible as the data are too limited. So essentially what has been done is to compare the catch rates during the period before the ban when TBTs were prevalent (1972-1986) with the catch rates after the ban (1986-2001) and attribute the difference to the ban. To account for the fact that other factors may also be present in explaining the difference a 'causality relationship' is taken from one study in the Crouch estuary, where a 94 percent reduction in TBT from 1986 to 1992 resulted in a 50 percent increase in native oysters. This 50 percent factor is applied to any increase between the pre- and post-ban periods as a default assumption of the size of the impact, but a sensitivity analysis is also carried out taking the percent attributable to the ban as 10 percent and 100 percent as well.

The data show that there are many other factors at play in determining the evolution of the catch of shellfish and the authors have to resort to some ad hoc adjustments to account for some of these (such as declines in prices, changes in quality of products etc.). Indeed in some cases, such as a perceived loss of development of a market they could not make any adjustment because the quantitative data were simply not there. The final figures (which include native oysters, pacific oysters, whelks, cockles, scallops and mussels but not periwinkles) are presented as a present value, using a real rate of interest of 2.7 percent. They range from £7 million to £11 million.

The other item valued was nutrient cycling, for which a decline of 50 percent in the functions was also assumed (based on a halving of the number of benthic species in the upper Crouch estuary). The total affected area of UK estuaries is 0.5 million hectares and a unit value of nutrient cycling services of US$21,000/ha/yr is taken from a study in the US by Costanza *et al* (1997). The resulting benefits from the ban then turn out to be £43 million. With lower/higher declines in functions the damages are proportionally lower/higher.

The total estimates for benefits of the partial ban are then put at around £51 million in the 'base case', with a lower bound of £10 million and a higher bound of £102 million. Note that the total is dominated by the nutrient cycling benefits (it makes up more than 85 percent of the total).

Against these benefits the study estimates some of the possible costs of the ban, in terms of additional anti-fouling expenses. For most recreational users it was assumed to be no increase in cost as the price of substitute anti-fouling paints was not found to be higher than that of the paints they replaced. However, it was assumed to be an impact on those pleasure craft that participated in racing, where tolerance of fouling is much lower. The additional cost was estimated at £400 per year due to the need to apply two coats per year instead of one. This yielded a total cost of about £37 million.

One can draw a number of conclusions from this study. Firstly there is quantitative evidence of damages from TBT at the national level. The actual estimates can be questioned from an economic viewpoint (e.g. they should have looked at net gains and losses and not gross ones and the time period they estimate the benefits might be questioned) as well as a scientific one but the principle issue is whether they are credible enough to determine policy. Here the gains in shellfish are probably of the right order of magnitude, although there are a large number of uncertainties. But the nutrient cycling benefit estimates are much more questionable. The study on which they are based has been subjected to lot of criticism and the transferability of the global figure like that would, in the opinion of the authors, certainly not stand up in any court of law as appropriate for compensation payment in a specific situation such as this. More work is needed to strengthen the cost-benefit calculations.

The second point to note is that a large number of impacts are not quantified in physical or monetary terms, and some of them are likely to be important and significant. From the list given above, items 5, 7 and 8 are likely to be important.

This means that some weight has to be given to the ‘intangible’ or non-quantified benefits. If, for example, the costs and benefit ranges overlap, as they do in this study, one could cite these benefits as tipping the balance in favour of regulation.

Thirdly is the issue of *ex ante* regulation. All the evidence considered is historic and it is of some academic value to know that the regulators (probably) took the right decision. But could the analysis have been done to inform the policy maker? The answer is almost certainly no. The DEFRA study notes that even where the REACH system identifies hazardous properties of new compounds, this does not automatically translate to realised risks and environmental damage. Some monitoring of the use of the compound is necessary for this purpose. For example, REACH does not contain any provisions for post-registration environmental monitoring that would allow for a timely assessment of damages and a redefinition of the regulation.

# 6. OTHER POSSIBLE APPROACHES TO MEASURE IMPACT IN VALUE-RELEVANT TERMS

The major challenge for carrying out a quantified CBA is to quantify ecological impacts. The TBT case study shows how this might be done if there are specific effects that can be monitored. But this will be rarely possible for REACH analysis because they will usually be based on anticipated effects from very limited data that may not even be expressed in terms of concentration/dose-response relationships. Some possible ways forward are described in the following.

## *6.1 An example showing how SSD might help*

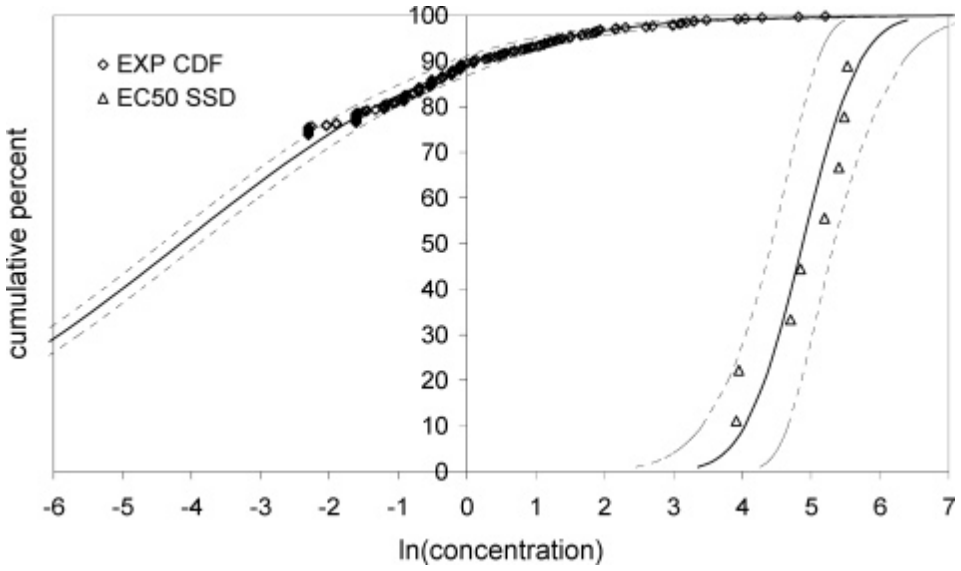
Higher-tier species sensitivity distributions (SSD) provide a potential for a more quantitative, probabilistic risk-based assessment and hence a more appropriate basis for cost-benefit analysis. Sometimes sufficient data are available on the effects of a chemical on a large enough number of species to express variability in sensitivity to the chemical between species in the form of a statistical distribution (species sensitivity distribution = SSD) and to use this as a basis for predicting the number of species affected (e.g. impaired survival or reproduction) at a particular concentration. This is more like a risk assessment in which $-\Delta E$ would represent likely loss of species and V would be the monetary value put on these either directly or from ecosystem service loss estimates (see Section 6.3).

An example showing a possible way of using this in valuation is provided by the case study on trichlorobenzene (TCB). The questionnaire/template setting out the details of this chemical is provided in Appendix C. The key points are that it is an important intermediate; but it can escape and have potential effects on both the aquatic and terrestrial ecosystems. Figure 3 shows an SSD for soil invertebrates together with exposure distributions at specific sites. At maximum exposure, more than 60% of species are impacted. But most sites have exposures affecting less than 5% species. Management could be applied to the sites where exposure is greater than this and be carried out in the most cost effective way. However the benefit of this could be estimated from the reductions in number of species impacted because soil invertebrates affect soil fertility and hence agricultural productivity – and this influences the monetary value of products in markets.

However, there are some caveats in using SSD (Forbes and Calow, 2002). In particular the species used are rarely, if ever, representative of any ecosystem – they are not a random sample but a grouping of what is available. Also the endpoints can be a mixture of variables including both survivorship and reproductive effects in different species. Hence in the EU, SSD have not been used for probabilistic assessment per se but to derive PNEC, i.e. to predict that exposure concentration likely to have minimum effect (usually defined as affecting <5% of

species) and using this as the PNEC. SSD have been used more broadly in North America (Posthuma *et al*, 2001).

***Figure 3: Soil species sensitivity distribution for trichlorobenzene (re-drawn from: Zolezzi et al, 2005)***




The upper curve represents cumulative number of sites exceeding specific exposure concentrations. The lower, sigmoid curve represents the cumulative number of species with effects (specified by $EC_{50}$) at specific concentrations. Concentrations are expressed in terms of mg/kg soil.

## *6.2 Smart modelling*

Another possible approach might be to focus on the probability of adverse impacts on populations through modelling (Forbes *et al*, 2008; 2010). Here, the ecotoxicological data used as a basis for risk characterisation would be fed into models to make predictions about likely changes in population density and/or biomass as a result of exposure. This could be done for one or a few species that are particularly important and/or particularly valued. The -ΔE would be some expression of the reduction in size and/or likely extinction of the population under consideration and the V would be the monetary value put on this by the public (e.g. the value put on a species of fish from the marketplace).

ECETOC has had an active focus on the risk assessment of PBT (persistent, bioaccumulative, toxic) chemicals over several years (ECETOC, 2005; 2011). Central to this program is the recognition of the necessity of higher tier assessments, for both exposure and effects, for these materials of concern to help reduce the uncertainties inherent in deterministic risk assessments. The use of population modelling is a stepwise progression utilising available data on these

chemicals, and presenting value-relevant outcomes that, conceptually, can be compared to SEA outputs to guide the regulator's decision making.

An example is the musk xylene (MX) case study presented in Appendix D (references cited there). The (former) EU Technical Committee on New and Existing Substances (TCNES) considered this material a vPvB; however, in a risk context, earlier deterministic risk assessments identified the risk quotients as below 1. Proactively, the responsible industry banned this substance, but retrospectively, the RCR (risk characterisation ratio) would indicate that ecological impacts should be minor, if any. At this point in time, the socio-economic impacts of replacing this material have been addressed (i.e. products have been reformulated and the costs associated with this have been expended).

While the outcomes would likely have been the same (i.e. a ban of the chemical) it can be inferred that had population models been used to assess this material at a higher tier, more informative outputs of ecological impact, which risk managers are charged with protecting, could be compared against SEA outputs of monetary values ascribed by civil society. Questions that arise, for example, might include:

- Are the population level impacts significant?
- Will replacement materials prove to have a greater effect on the environment?
- What are the social and economic impacts of replacing or banning this material (e.g. loss of jobs, economic impact)?

For MX it seems clear that the ban was acceptable from an SEA perspective.

Another example, presented as a hypothetical case study, would be a comparison between population and socio-economic impacts of human pharmaceuticals and the risk management questions that arise from the analysis (e.g. as in ethinyloestradiol, see Appendix E). This is a potentially life-saving pharmaceutical with known ecosystem impacts at the local scale. Clearly, the societal impact is such that a ban is not practical, and for the sake of the example it was considered that a substitute is unavailable. The risk manager would need to consider:

- What are the costs associated with proper handling of the material on the local and regional scale?
  - Collection of waste products.
  - Consideration of advanced wastewater treatment systems.
- How significant are impacts to local flora and fauna? Are they measurable/monitorable? What is the scale of this impact?

A last example, to take this hypothetical case a step further, would be to consider a pharmaceutical with both positive and negative ecological impacts, for example, synthetic female hormones used in birth control pills. If it could be demonstrated that these have an ecological impact through wastewater discharge, a risk manager would also have to consider the efficacy of non-hormonal alternatives and the impact potential human population changes can have from an ecological and economic standpoint. The point here is that through these examples, SEA and an understanding, through modelling, of population level effects provide for sound risk management and social policy.

### *6.3 Using the ecosystem services approach*

This is a general approach that recognises that people get valued services from ecosystems in the form of biomass (e.g. fish, game and lumber), support (e.g. pollination and nutrient cycling), regulation (e.g. modulating climate change) and recreation/aesthetics (MEA, 2005). The approach would be to try and relate the outputs from the risk characterisations to service impacts that could be valued. One example is the assessment of the impact of TBT on the supporting services from nutrient cycling in the marine ecosystem (see Chapter 5). The Panel on Plant Protection Products and their Residues of the European Food Standards Authority has issued an opinion advocating the use of ecosystem services as a way of identifying specific ecological protection goals in the context of assessing the risk from plant protection products (EFSA, 2010). The EFSA Panel on Plant Protection Products and their Residues (PPPR) concluded that most of the key drivers of ecosystem services were related to population level responses and so there is a link with the 'smart modelling approach' discussed in the previous Section (6.2).

There is currently a considerable amount of academic interest in ecosystem services and a mounting research programme (e.g. SETAC programmes). However, most of this is somewhat generic. In order to be useful in socio-economic analysis the linkages between risk characterisations and assessments and services need to be quantitative. This will likely involve mapping the linkages between the impacts covered in the risk assessments and ecosystem processes, and then mapping the linkages between the processes and the services. All of these are non-trivial tasks. Moreover, once service impacts have been specified they need to be valued appropriately with care being taken not to count values more than once in all the complexity. Finally, the monetary values have to be relevant to the socio-economic settings in which they are applied. Because of the effort required to assess these values properly there will inevitably be a temptation to extrapolate from other studies. This should be done with caution and with appropriate adjustments for the change in circumstances. Using global values as in the assessment of impact of TBT on marine ecosystem services (Chapter 5) will almost certainly overestimate the values being applied.

### *6.4 Using general ecological criteria in the Water Framework Directive*

The EU Water Framework Directive (EU, 2000) specifies ecological quality criteria in broad terms and, amongst other things, requires that controlled water bodies meet good ecological quality status by 2015. Some work has been carried out in the UK to assess how the public values these criteria (DEFRA, 2007). Willingness-to-pay surveys have been used to assess the monetary value put on generally improving the quality status of waters by translating these quality criteria into things that matter and that can be understood by the public, e.g. in terms of improved household recreational benefits from fresh waters in better ecological quality status.

Thus, if changes in the risk characterisations under a REACH assessment could be related to changes in ecological quality status, then a monetary value could be put on the benefits using the broad-scale values referred to above. Brouwer *et al* (2007) used similar broad-scale measures in the development of a so-called ecological ladder of quality status presented as part of the AquaMoney Project. Using such broad-scale values might be particularly appropriate in valuing the ecological benefits derived from changes in regional risk characterisation as a result of management implemented under REACH.

Of course making the connection between reduced risk from REACH actions and improved ecological quality status will be challenging to say the least. Moreover, broad-scale valuations of the type envisaged here involve uncertainties, e.g. if all the appropriate benefits are covered and if the samples of people used in the surveys are representative. These are areas that could be open to future development through research involving multidisciplinary co-operation between economists and ecologists.

# 7. CHALLENGES ASSOCIATED WITH AUTHORISATION

There are at least two reasons why socio-economic analysis for authorisations under the REACH legislation ought to be of particular interest to industry. Firstly, the responsibility for carrying these out as a basis for authorisation lies formally with those wishing to make the case, i.e. producers and users. From REACH (Art.60) *"an authorization may only be granted if it is shown that socio-economic benefits outweigh the risks to human health or the environment arising from the use of the substance and if there are no suitable alternatives"* (EU, 2006). (Notice here that benefits are switched with costs as discussed in Chapter 2). Secondly, hazard criteria are used as one basis for identifying substances of very high concern that are subject to authorisation and, as already noted (Chapter 3), it is particularly difficult to use these to assess likely impacts and hence the valued costs to the environment of continued use.

In this chapter, we first describe the general principles of the authorisation process, then consider how comparative risk assessment and the economic feasibility of using substitutes are of importance, and finally suggest how PBT substances (and substances of equivalent concern) might be handled in a cost-benefit analysis.

## *7.1 How authorisation works*

Authorisation applies to substances of very high concern. Arguments to allow authorisation can follow one of two routes. One is to demonstrate that substances can be adequately controlled; but this cannot be applied to 'non-threshold' substances and so excludes PBTs and vPvBs. The other route available to the PBTs and vPvBs is to demonstrate that the socio-economic benefits of retaining the substances outweigh the costs to human health and the environment.

## *7.2 Substitution, comparative risk assessment and economic feasibility*

Part of the underlying philosophy of REACH is to ensure that harmful substances are replaced by less harmful ones. If substitutes exist and they are less harmful it is unlikely that an authorisation would be granted. So when there are substitutes it is important that the risk that they pose to human health and environment are considered and compared with the equivalent risks from the chemical that is subject to authorisation. It is likely that this comparative risk assessment will need to be persuasive, even though the data available on substitutes are often less extensive than those for the substance they are replacing.

Another test for rejected authorisations, though, is that the substitutes need to be economically feasible. There is no standard definition of 'economic feasibility' but it is clear that the intent is that the benefits relative to costs of the substitute should be greater than those for the substance

being replaced. So the focus here would be on demonstrating a substantial loss of benefit to producers and consumers from a decision against authorisation compared with substitutes. The focus would be on financial and social costs of substitution and the financial costs of replacement. These would be industry specific and are not considered further here.

### *7.3 Carrying out cost-benefit analysis on PBT and substances of equivalent concern*

ECETOC has noted in companion reports that refinement options are available for reducing the uncertainty in the assessment of PBT materials such that meaningful risk quotients can be derived (ECETOC, 2005; 2011). However, for those chemicals whose properties and exposure patterns are such that the refinement options are insufficient to allow a meaningful risk characterisation, it may be concluded that these chemicals result in accumulation in the environment and biota. In such cases, socio-economic analyses will have to establish and value the impact of the chemicals. In the case of substances causing cumulative and irreversible effects, there may be no optimum concentration from a cost-benefit perspective (Pearce, 1998). With these kinds of chemicals the environmental costs of continued use would increase without limit so that the benefits from using the substances would be bound to be exceeded sooner or later. As noted in Section 7.2 any socio-economic justification of using these kinds of chemicals would have to emphasise big benefits from continued use and lack of suitable alternatives, presumably with a credible timetable for replacement.

On the other hand there are uncertainties about what constitutes a truly cumulative chemical. Most chemicals degrade in the environment and in organisms with time and often do so to less harmful products. Certainly there has been considerable debate about the extent to which the P and B criteria in REACH signal irreversible accumulation of harmful products (ECETOC, 2005; 2011). These uncertainties are presumably one of the reasons why REACH allows for the use of socio-economic analysis to justify continued use, i.e. authorisation, of these chemicals.

Most PB chemicals identified by criteria under REACH, or any existing legislation, will not be irreversibly cumulative in the strict sense described above. Hence they should be amenable to standard procedures of risk characterisation. Two ECETOC reports have demonstrated how chemicals identified as PBT can be addressed using risk characterisation ratios (ECETOC 2005; 2011). On this basis it has also been possible to demonstrate that, despite its PBT classification under REACH, musk xylene has an RCR less than one in most environmental compartments (Appendix D).

If substances of very high concern are amenable to risk characterisation assessments then it follows that they should also be amenable to socio-economic analysis according to the standard principles and practices elaborated in Chapters 2 and 3. The challenges as ever will be to

translate the risk characterisations into impacts that can be valued. However, given the uncertainties associated with these kinds of substances and the precautionary framework of the legislation it is likely that these SEA will have to be particularly convincing. Both costs and benefits should be expressed as transparently and as quantitatively as possible, along with associated uncertainties. This means following the systematic approach outlined in Chapter 4 and applying appropriate impact assessment and valuations.

# 8. CONCLUSIONS AND SUMMARY OF MAIN ISSUES

The hardest part of a cost-benefit analysis is assessing the benefits of restrictions on human health and environment and the costs of authorisation on the same targets. This is particularly the case for assessing ecological benefits. Here we have made a start in providing guidance on how ecological benefits analysis might be achieved for assessments involving chemicals and especially within the context of REACH. The report argues for as much quantification as possible, with the ideal of monetisation, because without that the ecological benefits of restrictions on chemicals (including failure to authorise) may well be presented in emotive terms that are hard to counter on the basis of the benefits that might be lost from restricted use or the banning of a chemical.

An ecological benefits assessment involves two components. One is the extent to which ecological effects are ameliorated by the restrictions on chemicals and the other is the monetary value that is put on the ecological entities so protected.

Capturing the monetary values that the public puts on ecological entities is the province of environmental economics. There are enormous challenges here in ascribing values, especially to non-marketed ecological goods and services. However, environmental economics has made great strides over recent years in developing the appropriate methodology to enable this to be achieved. Hence, this report has not dwelt on ecological valuation, rather taking the view that if ecological impacts can be defined then usually appropriate values can be obtained. There is a rich literature on environmental economics and ecological valuation and the report directs readers to key works.

Possibly a bigger challenge than valuation for benefit assessments is defining the ecological impacts themselves. The problem is that the ecological risk characterisations do not express effects in terms of impacts that can be valued; in particular in terms of things that matter for the public. There is, therefore, a need for translating risk characterisations into impacts on valued ecological entities; but this is easier said than done. The most straightforward case is where the management of exposures can be linked directly to impacts on ecological entities; and especially if the latter have market values. This was illustrated by the classical example of the effects of tributyltin on shellfisheries. But these kinds of situations are likely to be uncommon for industrial chemicals. Instead the report points to a number of possible scenarios whereby the outputs of risk characterisations might be linked to valued impacts through such methods as species-sensitivity analysis, smart modelling and by making connections to ecological quality status as defined in the water framework directive. None of these approaches is developed to the extent that we were able to find standard case studies to support the proposals. So there will be a need for pioneering efforts in these areas.

The ecosystem services approach is increasingly being forwarded as a useful way of mapping ecological impacts into valued effects. This report counsels some caution in this approach. The

basic idea is that ecological changes should be mapped into possible changes in ecosystem structures and processes and thence to effects on such things as agricultural production and recreation that can be valued. This kind of conceptualisation is reasonably straightforward and can be helpful in suggesting the possible implications of exposures or managing them. However, unless the mappings can be made quantitative there is a danger that judgements, expert and otherwise, might be confused with the more comprehensive process of valuation.

All these challenges become even more acute for substances of very high concern. The reasons are twofold. Firstly, if the substances are truly persistent and bioaccumulative then there is no optimum environmental load and cost-benefit analysis cannot be applied. Secondly, hazard measures, such as PBT criteria, cannot be used as a basis of cost-benefit analysis. This report takes the view that most of the chemicals identified as substances of very high concern under REACH will be subject to some degradation in the environment and hence ought to be amenable to risk assessment, impact assessment and socio-economic analysis. Under REACH it will be an industry responsibility to use socio-economic arguments as a basis for justifying authorisations. These arguments will need to be particularly convincing and this report emphasises the clarity that comes from quantified analysis of appropriate costs and benefits as a good basis for making the case for authorisation.

In the face of all this complexity there will be a tendency to avoid monetisation in socio-economic analysis. For example, keeping the different effects and the costs and benefits in different terms and then making judgements about trade-offs and priorities. The difficulty is that these judgements involve the values of those making them and these may neither be transparent nor reflect the general values of the public. This is is problem with multi-criteria analysis. This is why this report urges as much quantification and monetisation as possible. Certainly vaguely expressed value judgements from industry, or the consultants representing them, are hardly going to make much impression in the socio-economic analysis associated with arguments for authorisation.

It is obvious that there are some deep issues of risk assessment and economics in carrying out effective socio-economic analysis for risk management. The experience of the Task Force behind this report is that differences in language and theoretical frameworks between risk assessors and economists can add to the difficulties. This argues for the development of multidisciplinary teams to steer socio-economic assessments at an earliest stage in the process as possible. Clarity in briefings and all relevant issues from the industry-side will be essential. Clarity and, as far as possible, jargon-free advice will be needed from both technical risk assessment and economic analysis. There is a need, outside the pressures of regulations, to set up appropriate forums where risk assessors, economists and risk managers can develop more user friendly, but rigorous, approaches to socio-economic analysis.

## GLOSSARY[2]

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| Authorisation | REACH Regulation sets up a system under which the use of substances with properties of very high concern and their placing on the market can be made subject to an authorisation requirement. Such substances are included in *Annex XIV* of the Regulation and may not be placed on the market or used without an authorisation. |
| Bioaccumulation | The net result of uptake, distribution and elimination of a substance due to all routes of exposure. |
| Biodiversity | Totality of species of plants, animals and microbes in a particular place, ranging in scale from local to global. |
| Community recovery | The process of return of biota to a place after human impact that caused losses. |
| Concentration / dose-response | Relationship between the amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the change developed in that organism, system, or (sub)population in reaction to the agent. |
| Cost-benefit analysis | Analysis which quantifies, in monetary terms where possible, costs and benefits of a possible action, including items for which the market does not provide a satisfactory measure of economic value. |
| Deterministic risk assessment | Expressing the likelihood of impact in terms of a single-number index, such as the ratio of exposure to critical effect concentration (cf. probabilistic risk assessment below). |
| Ecological benefit | Human advantage obtained from improved condition of ecosystems. |
| Ecological effect | Impact on ecological systems, from reductions in size of populations to reductions in biodiversity (see above). |
| Ecological / environmental compartment | That part of an overall environmental system consisting of physical, chemical and biological parts that is biological. |

[2] These definitions were mainly taken from ECHA, 2008a; ECHA, 2011; IPCS, 2004.

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| Ecological / environmental services | The benefits that people derive from ecosystems ( structure and processes) that can be valued in monetary terms, such as food from fishing and hunting, environmental clean-up from the metabolism of harmful substances, flood defences from reed beds and cultural and recreational activities involving nature. |
| Ecological impact | Changes in ecological systems caused by humans. |
| Ecological threshold | Some ecological state that if exceeded will lead to dramatic effects. |
| Economic impact | Costs and benefits to manufacturers, importers, downstream users, distributors, consumers and society as a whole. In principle, social and environmental impacts should be included in a truly economic analysis. |
| Ecosystem | Collection of plants, animals and microbes in a particular place that interact with the physical and chemical surrounds to cause cycles of matter and flows of energy. |
| Endocrine activity | Modulation of endocrine processes that may or may not give rise to adverse endocrine effects. |
| Environmental impact | Impact on all environmental compartments. Covers all use and non-use values of the affected environmental compartments. |
| Exposure | Concentration or amount of a particular agent that reaches a target organism, system, or (sub) population in a specific frequency for a defined duration. |
| Exposure assessment | Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives). |
| Functional redundancy | There is a relationship between the number of species in an ecosystem and the process of material and energy fluxes. However, in some ecosystems some species can be lost without apparent effect on the processing of matter and energy. This is often referred to as functional redundancy. |
| Habitat | Physical space containing population of a species or collection of species of interest. |
| Hazard | Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub) population is exposed to that agent. |

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| Hazard assessment | A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub)population could be exposed. |
| Health benefit | Human advantage obtained from improved condition of environment that impinges directly on human health. |
| Health impact | Impact on human health including morbidity and mortality effects. Covers health related welfare effects, lost production due to workers' sickness and health care costs. |
| Monetisation | Putting a monetary value on something – see below. |
| Monetary value | An index of public preference either obtained from market information or in the case of non-market goods such as biodiversity from various indirect techniques that seek to quantify preferences through surveys and/or surrogate markets. |
| Multi-criteria analysis | A technique that involves assigning weights to criteria, and then scoring options in terms on how well they perform against those weighted criteria. Weighted scores are then summed, and can then be used to rank options. |
| Persistence | A chemical that resists degradation processes and is present in the environment for a long time. Specific criteria have been established in Persistent Organic Pollutant (POP) protocols, and in the REACH TGD. In the latter persistent (P) and very persistent (vP) refers to chemicals that have degradation half-lives above certain trigger values in surface water, sediment and soil. |
| Population modelling | Various mathematical techniques for describing and predicting the sizes and dynamics of animal, plant and microbe populations. |
| Predicted environmental concentration (PEC) | The concentration of a chemical in the environment, predicted on the basis of available information on certain of its properties, its use and discharge patterns, and quantities involved. |
| Predicted no-effect concentration (PNEC) | Environmental concentration which is regarded as a level below which the balance of probability is that an unacceptable effect will not occur. |
| Probabilistic risk assessment | Likely impact of an activity taking account of variability and uncertainty (cf. deterministic risk assessment above). |

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| Restriction | Any condition for or prohibition of the manufacture, use or placing on the market of a substance. The substances restricted under REACH and the conditions of their restrictions are included in Annex XVII of the Regulation. |
| Risk assessment | A process intended to calculate or estimate the risk to a given target organism, system, or (sub) population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: Hazard identification, hazard characterisation, exposure assessment, and risk characterisation. |
| Risk characterisation | The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system, or (sub)population, under defined exposure conditions. |
| Risk characterisation ratio | Index that compares exposure concentration with critical effect (no-effect) concentration. |
| Risk control | Managing likely impact. |
| Risk elimination | Excluding likely impact. |
| Risk management | Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk management comprises three elements: Risk evaluation; emission and exposure control; and risk monitoring. |
| Risk reduction | Managing likely impact to the extent that it is lowered. |
| Social costs | Denotes the opportunity cost to society and includes also external costs or externalities. |
| Social impact | Any relevant impact which may affect workers, consumers and the general public and is not covered under health, environmental or economic impact (e.g. employment, working conditions, job satisfaction, education of workers and social security). |

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| Socio-economic analysis (SEA) | The socio-economic analysis (SEA) is a tool to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where the action is not implemented. Under the REACH authorisation procedure, an SEA is a compulsory part of an application for authorisation whenever the risks to human health or the environment from the use of an Annex XIV substance are not adequately controlled. Also when adequate control can be shown, an SEA may be produced by an applicant in support of this application. An SEA may also be produced by any third party in support to information on alternatives. |
| Species-sensitivity distribution | Concentration-response relationship across a group of species. The responses are expressed in terms of various measures of likely adverse effects. The groups can either be natural or constructed collections of species. The frequency distributions are often expressed as cumulative number of species affected against increasing concentration of the chemical under consideration. |
| Toxicity | The inherent property of a substance to cause adverse biological effects at specific concentrations. |
| Uncertainty | This is a state characterising a situation where related parameters are not known or fixed or certain. It stems from a lack of information, scientific knowledge or ignorance and is a characteristic of all predictive assessments. Uncertainty can have a significant effect on the type and amount of evidence that must be collected in undertaking an SEA and taken into account in communicating the outcome. |

## ABBREVIATIONS

| | |
|---|---|
| BCF | Bioconcentration factor |
| CAS | Chemical Abstracts Service |
| CBA | Cost-benefit analysis |
| CEA | Cost-effectiveness analysis |
| CMR | Carcinogenic, mutagenic and reprotoxic |
| COPI | Cost Of Policy Inaction (Database) |
| DEFRA | UK Department for Environment, Food and Rural Affairs |
| ECB | (Former) European Chemicals Bureau |
| ECHA | European Chemicals Agency |
| $EC_{50}$ | Effect concentration (50%) |
| EE2 | 17α-ethinyloestradiol |
| EFSA | European Food Safety Authority |
| ENVALUE | Environmental Valuation |
| ESD | Ecosystem Service Database |
| ESR | Existing Substances Risk Assessment |
| EU | European Union |
| EVRI | Environmental Valuation Reference Inventory |
| EXTOXNET | The Extension Toxicology Network |
| FEEM | Fondazione Eni Enrico Mattei |
| FELS | Fish early-life stage |
| FSD | Foundation for Sustainable Development |
| IFRA | International Fragrance Association |
| IMO | International Maritime Organization |
| IMV | Environmental Assessment Institute, Denmark |
| IPCS | International Programme for Chemical Safety |
| IPPC | Integrated pollution prevention and control |
| MCCP | Medium chain chlorinated paraffins |
| MEA | Millennium Ecosystem Assessment |
| MX | Musk xylene |
| NOEC | No-observed effect concentration |
| NOEL | No-observed effect level |
| NP | Nonyphenol |
| OSPAR | Oslo Paris Convention |
| OSPARCOM | Oslo and Paris Commission (Environmental Regulations for the European Community) |

| | |
|---|---|
| PBT | Persistent, bioaccumulative, toxic |
| PCB | Polychlorinated biphenyls |
| PEC | Predicted environmental concentration |
| PNEC | Predicted no effect concentration |
| PPPR | Plant protection products and their residues |
| RAR | Risk Assessment Report |
| RCR | Risk characterisation ratio |
| REACH | Registration, evaluation, authorisation and restriction of chemicals |
| RIFM | Research Institute for Fragrance Materials |
| RPA | Risk & Policy Analysts |
| SEA | Socio-economic analysis |
| SETAC | Society of Environmental Toxicology and Chemistry |
| SSD | Species sensitivity distribution |
| STP | Sewage treatment plant |
| SVHC | Substance of very high concern |
| TBT | Tributyltin |
| TBTO | Bis(tributyltin)oxide |
| TCB | Trichlorobenzene |
| TCE | Tetrachloroethylene |
| TCNES | (Former) Technical Committee for New and Existing Substances |
| TGD | Technical guidance document |
| UNECE | United Nations Economic Commission for Europe |
| UNEP | United Nations Environment Programme |
| US | United States |
| US EPA | United States Environmental Protection Agency |
| V | Value |
| vB | Very bioaccumulative |
| VOCs | Volatile organic compounds |
| vPvB | Very persistent, very bioaccumulative |
| WFD | Water Framework Directive |

## BIBLIOGRAPHY

Alzieu C. 1991. Environmental problems caused by TBT in France: Assessment, regulations, prospects. Mar Environ Res 32:7-17.

Alzieu C. 2000. Environmental impact of TBT: The French experience. Sci Total Environ 258:99-102.

Braat L, ten Brink P. 2008. Cost of policy inaction: The case of not meeting the 2010 biodiversity target. Report 118 (312 pp) ISSN 1566-7197. Alterra, Wageningen, The Netherlands.

Brock TCM, Arts GHP, Maltby L, Van den Brink PJ. 2006. Aquatic risks of pesticides, ecological protection goals, and common aims in European Union Legislation. Integr Environ Assess Manag 2:20-46.

Brouwer R, Barton D, Bateman I, Brander L, Georgiou S, Martin-Ortega J, Navrud S, Pulido-Velaquez M, Schafsma M, Wagtendonk A. 2007. Economic valuation of environmental and resource costs and benefits in the Water Framework Directive: Technical guidelines for practitioners. AquaMoney Project. IVM – Environmental Assessment Institute, Copenhagen, Denmark.

Christie M, Hanley N, Warren J, Murphy K, Wright R, Hyde T. 2006. Valuing the diversity of biodiversity. Ecol Econ 58:304-217.

Conservation International. 2006. Consvalmap: Conservation International Ecosystem Services Database. [http://www.consvalmap.org]

Costanza R, d'Arge R, de Groot R, Farber S, Grasso M, Hannon B, Limburg K, Naeem S, O'Neill RV, Paruelo J, Raskin RG, Sutton P, van den Belt M. 1997. The value of the world's ecosystem services and natural capital. Nature 387:253-260.

Day SJ, Morse GK, Lester JN. 1997. The cost effectiveness of contaminated land remediation strategies. Sci Total Environ 201:125-136.

DEFRA. 2007. The benefits of Water Framework Directive programmes of measures in England and Wales. Final report to DEFRA re CRP Project 4b/c from NERA and ACCENT. Department for Environment Food and Rural Affairs, UK.

DHI. 2005. The impact of REACH on the environment and human health. Report to DG Environment. ENV.C.3/SER/2004/0042r. Revised final report. DHI Water and Environment, Denmark.

ECETOC. 2005. Risk assessment of PBT chemicals. Technical Report No. 98. European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels, Belgium.

ECETOC. 2011. Risk assessment approaches for PBT/vPvB or POPs. Technical Report No. 112. European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels, Belgium. *In preparation*.

ECHA. 2008a. Guidance on socio-economic analysis – restrictions. European Chemicals Agency, Helsinki, Finland.

ECHA. 2008b. Applying socio-economic analysis as part of restriction proposals under REACH. Workshop proceedings. European Chemicals Agency, Helsinki, Finland.

ECHA. 2008c. Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.8: Characterisation of dose[concentration]-response for human health. Guidance for the implementation of REACH. European Chemicals Agency, Helsinki, Finland.

ECHA. 2009. Addendum to the guidance on Annex XV for restrictions and to the guidance on socio-economic analysis (SEA) – restrictions. European Chemicals Agency, Helsinki, Finland.

ECHA. 2011. Guidance on the preparation of socio-economic analysis as part of an application for authorisation. European Chemicals Agency, Helsinki, Finland.

EFSA Panel on Plant Protection Products and their Residues (PPPR). 2010. Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010; 8(10):1821 [55 pp]; doi:10.2903/j.efsa.2010.1821. [www.efsa.europa.eu/efsajournal.htm]

ENVAlue. 2004. Environmental Valuation Database. Developed by New South Wales Environmental Protection Agency, New Zealand.
[http://www.environment.nsw.gov.au/envalue/]

EU. 2000. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. Official Journal of the European Community L 327:1-72.

EU. 2006. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

EVRI. 1997. The Environmental Valuation Reference Inventory (EVRI). Developed by P. De Civita P, F. Filion and J. Frehs of Environment Canada. [www.evri.ca]

Forbes VE, Calow P. 2002. Species sensitivity distributions revisited: a critical appraisal. Hum Ecol Risk Assess 8:473-492.

Forbes VE, Calow P, Sibly RM. 2008. The extrapolation problem and how population models can help. Environ Toxicol Chem 27:1987-1994.

Forbes VE, Calow P, Grimm V, Hayashi T, Jager T, Palmqvist A, Pastorok R, Salvito D, Sibly R, Spromberg J, Stark J, Stillman RA. 2010. Integrating population modelling into ecologal risk assessment. Integr Environ Assess Manag 6:191-192.

FSD. 2007. Nature Valuation and Financing CaseBase. Foundation for Sustainable Development, Wageningen, The Netherlands. [http://www.eyes4earth.org/casebase]

Giacomello AM, Guha P, Howe P, Jones KC, Matthiessen P, Shore RF, Sullivan C, Sweetman A, Walker L. 2006. The Benefits of Chemical Regulations: Four case studies: TBT, Methiocarb, DDT and PCBs. Report to DEFRA.
[http://www.thereachcentre.com/uploaded/Benefits%20of%20Chemical%20Regulation.pdf]

Hanley N, Barbier E. 2009. Pricing nature: Cost-benefit analysis and environmental policy. Edward Elgar Publishing, Massachusetts, USA.

IMV. 2007. Challenges for economic analysis under REACH. What can we learn from previous experience? Environmental Assessment Institute, Copenhagen, Denmark. ISBN: 87-7992-050-0.

IPCS. 2004. IPCS Risk Assessment Terminology. Harmonization Project Document No.1. International Programme on Chemical Safety, World Health Organisation, Geneva, Switzerland.

Macmillan DC, Harley D, Morrison R. 1998. Cost-effectiveness analysis of woodland ecosystem restoration. Ecol Econ 27:313-324.

Maila MP, Cloete TE. 2004. Bioremediation of petroleum hydrocarbons through landfarming: Are simplicity and cost-effectiveness the only advantage? Reviews in Environmental Science and Bio/Technology 3:349-260.

MEA (Millennium Ecosystem Assessment). 2005. Ecosystems and human well-being: Synthesis. Island Press, Washington, DC, 160 pp.

Ojea E, Nunes P, Loureiro ML. 2009. Mapping of forest biodiversity values: A plural perspective. Fondazione Eni Enrico Mattei Working Papers, 264 pp.

Pearce D. 1998. Competing paradigms for managing environmental change. In Pearce D, ed, Economics and Environment. Essays on Ecological Economics and Sustainable Development. Edward Elgar, Cheltenham, UK, pp. 313-322.

Posthuma L, Suter II GW, Traas TP. 2001. Species sensitivity distributions in ecotoxicology. CRC Press, Boca Raton, FL, USA, 616 pp.

RPA. 2006. REACH implementation project 3.9-1: Preliminary study for a technical guidance document on carrying out a SEA or input for one. Final report, part A. Risk & Policy Analysts in association with Syke on behalf of EU Commission DG Joint Research Centre.

Ruiz JM, Bachelet G, Caumette P, Donard OF. 1996. Three decades of tributyltin in the coastal environment with emphasis on Arcachon Bay, France. Environ Pollut 258:99-102.

Saling P, Kölsch D, Seibert K. 2007. Case study for RIP 3.9; a socio-economic analysis about a CMR substance in wire enamels. Final report.

Siikamaki J, Layton DF. 2006. Potential cost-effectiveness of incentive payment programs for biological conservation. RFF DP 06-27. Resources for the Future, Washington, DC, USA.

Sundberg S, Söderqvist T. 2004. ValueBaseSWE: A valuation study database for environmental change in Sweden. Beijer International Institute of Ecological Economics: The Royal Swedish Academy of Sciences, Stockholm. [ www.beijer.kva.se/valuebase.htm]

Ten Brink P (ed). 2011. The economics of ecosystems and biodiversity in national and international policy making. Earthscan, London, UK, 352pp.

Tisch R, Ozdemiroglu E, Phang Z, Bateman, I. 2010. Benefits and costs of conserving biodiversity and ecosystem services. Draft Final report for EU Commission DG Environment. Eftec, London, UK.

US EPA. 2009. Valuing the protection of ecological systems and services. A report of the EPA science advisory board. EPA-SAB-09-012. US Environmental Protection Agency, Washington, DC, USA.

US Navy. 1984. Environmental assessment. Fleetwide of organotin antifouling paint. US Naval Sea Systems Command, Washington, DC, 128 pp.

UVM. 2008. Ecosystem Service Database (ESD) / ARIES. Developed by University of Vermont, USA. [http://esd.uvm.edu]

WCA. 2010. Application of approaches for converting environmental risk assessment outputs into socio-economic impact assessment inputs when developing restrictions under REACH. Final Report to Luxembourg Environment Agency from WCA Environment Limited.

Wilson SB, Brown RA. 1989. In situ bioreclamation: A cost-effective technology to remediate subsurface organic contamination. Ground Water Monit Remediat 9(1):173-179.

Wilson MA, Costanza R, Troy A. 2004. The EcoValue Project. Retrieved from the University of Vermont EcoValue. [http://ecovalue.uvm.edu]

Zolezzi M, Cattaneo C, Tarazona JV. 2005. Probabilistic ecological risk assessment of 1,2,4-trichlorobenzene at a former industrial contaminated site. Environ Sci Technol 39(9):2920-2926.

# APPENDIX A

## *Suggested template for the preparation of an environmental impact assessment for socio-economic analysis of chemicals*

1. Substance and CAS

2. Manufacturing/use in tonnes pa

   *a. Current*
   *b. Trends in production/use*

3. Uses (main ones)

4. Brief 'storyline' describing connections between production, use and ecological effects This is intended as a summary to describe any known or likely ecological impacts arising from the use of the substance.

   *a. In which environmental compartment/ecosystem have impacts been observed? Include brief description of affected species/ecosystem services and an indication of the extent (localised or widespread).*
   *b. Have any economic costs been attributed to the impacts?*

5. Is the substance a PBT or vPvB under REACH?

6. Is there any evidence of specific ecological impacts due to persistence and/or bioaccumulation and can these be quantified (it may be necessary to use expert judgement)?

7. Is it a substance of equivalent concern (e.g. endocrine disruptor)?

8. Is there any evidence of specific ecological impacts on certain populations through endocrine disruption?

9. Is there any evidence of a risk characterisation ratio (RCR) > 1 for any ecological compartment?

10. If the RCR is > 1, is there any evidence of ecological impacts on certain species or populations, and/or biodiversity, and/or ecosystem processes, and/or ecosystem services? Can any of these be quantified (it may be necessary to use expert judgement)?

11. Has any economic cost been attributed to the impacts specified under questions 6, 8, or 10?

12. Has any type of cost-benefit or socio-economic analysis been performed? If so, give a brief summary.

13. Have any environmental risk management options already been adopted by industry, for example under voluntary initiatives?

14. Is the substance already being reviewed under existing legal frameworks, such as REACH, ESR, WFD, IPPC, OSPARCOM?

15. Are there any alternatives or substitutes? If so, are they cost effective and practical? Is there any information on their ecological impacts?

16. Other relevant information.

# APPENDIX B

## *Tributyltin*

### 1. Substance and CAS

There are a large number of tributyltin (TBT) compounds containing the ($C_4H_9$) Sn moiety. Most of the economics-related literature on TBT compounds is generic and does not provide information on specific moieties. Where information on specific moieties was available, the focus was made on bis(tributyltin)oxide (TBTO) (CAS 56-35-9) as a representative compound.

### 2. Manufacturing/use in tonnes pa

#### *a. Current*

No estimates of current manufacturing/use of TBT compounds in anti-fouling paint and related applications could be located. This likely reflects the fact that TBT compounds are no longer used in anti-fouling paints.

#### *b. Trends in production/use*

Production figures for TBT-based anti-fouling paints in Europe and/or specific European countries are limited. The International Programme on Chemical Safety (IPCS, 1990) reported that production of TBTO in Germany was 103 tonnes, with 70% of this amount being exported. The IPCS (1990) also provides usage figures for the Netherlands and indicates that, in 1985, an estimated 10 x 104 kg of TBT was used in antifouling paints.

Estimates of worldwide production levels are also available. For example, the United Kingdom Department of the Environment (1986) estimated that worldwide production of TBT anti-fouling paints in 1980 was 2-3 x 103 tonnes.

### 3. Uses (main ones)

TBT is a broad spectrum organometal pesticide. TBT compounds have been used as a molluscicide, in anti-fouling paints applied to marine vessels and equipment, as wood preservatives, as biocides in water treatment systems (industrial and commercial cooling towers and related systems) and in other applications (UNEP, 2006; Arkema Inc, 2011; IPCS, 1990).

The predominate source by which TBT compounds enter the environment is via anti-fouling paint applications. TBT in treated wood may pose a hazard to terrestrial organisms that live

near a treated wood source, but hazards to the terrestrial environment are generally thought to be low (IPCS, 1990).

## 4. Brief 'storyline' describing connections between production, use and ecological effects

**a.** ***In which environmental compartment/ecosystem have impacts been observed?***
*Include brief description of affected species/ecosystem services and an indication of the extent (localised or widespread).*

Use of TBT compounds in anti-fouling paints is a major pathway by which TBT enters the aquatic environment (US EPA, 2003). Upon entering the aquatic environment, one removal pathway is photodegradation, but only in very shallow clear waters and in the first few centimeters of the water column. Aquatic photodegradation does not impact persistence of TBT in the environment.

The aqueous transformation product TBT is expected to be very slightly mobile in sediment and soil in the pH-range of 6.5 to 8. Absorption potential to sediment and soil is predicted to be significantly lower at pH < 6.5 and pH > 8. Given the very low volatility of TBTO, volatilisation to air is assumed to not be a relevant route of distribution. TBTO is not expected to undergo long-range transport via air in vapour phase.

The use of TBT compounds in anti-fouling paints began in the mid 1960s. When first introduced, these were 'free association' type paints, with TBT physically incorporated into the paint matrix, resulting in a high early release and very short half-life. Copolymer paints were later introduced where the TBT moiety is chemically bonded to a polymer backbone, resulting in a slower, lower and more prolonged release (IPCS, 1990). In 1999, the International Maritime Organization (IMO) initiated development of a treaty to ban the application of TBT-based anti-fouling paints by January 1, 2003 and a ban on the use of TBT by January 1, 2008 (Champ, 2003).

The proposed focus of this case study is on the use of TBT in anti-fouling paints, and these were the predominate source by which TBT compounds enter the environment. Additionally, the continued persistence of TBT in sediment (see below) may result in TBT concentrations that exceed toxicity thresholds in some marine environments (EC, 2002; 2008).

**b.** ***Have any economic costs been attributed to the impacts?***

Several studies have estimated the economic costs associated with environmental impacts of TBT (Alzieu 1991, 2000; Giacomello *et al*, 2006; Ruiz *et al*, 1996). Economic

impacts have been measured in terms of costs related to declines in commercial shellfish production. Further details about these studies are provided in Chapter 5.

**5. Is the substance a PBT or vPvB under REACH?**

TBT degrades in approximately 1-3 months under aerobic conditions, but may persist for > 2 years in anaerobic soils. TBTO transforms in aqueous solution to TBT. Due to the low water solubility of TBT and related properties, it may bind to suspended organic material or inorganic sediments and precipitate to the bottom sediment. Estimated half-life of TBT compounds in water is between 4 and 225 days depending on salinity of the water, with fresh-water having reported half-lives of 6 to 25 days. Sediment degradation studies report half-lives ranging from over 1 to 15 years (EXTOXNET, 1996; EC, 2008).

TBT is reported to bioconcentrate up the marine predator food chain, with the agents tending to bioaccumulate in oysters, mussels, crustaceans, molluscs, fish and algae (EXTOXNET, 1996). Some laboratory investigations in molluscs and fish have reported bioconcentration factors up to 7000 (IPCS, 1990).

The log Kow for TBTO is highly dependent on the pH of the testing conditions. Results for log Kow range from 3.2 (pH 6.0, at 20 degrees C) to 4.05 (estimated) (EC, 2008). The octanol/water partition coefficient (log Pow) ranges between 3.19 and 3.84 for distilled water and is 3.54 for sea water (IPCS, 1990).

TBTO is classified by the European Union as fulfilling the vPvB criteria.

**6. Is there any evidence of specific ecological impacts due to persistence and/or bioaccumulation and can these be quantified (it may be necessary to use expert judgement)?**

TBT is highly to very highly toxic to a number of aquatic species, particularly crustaceans (EXTOXNET, 1996). Classification of TBT compounds in Directive 67/548/EEC is N; R50-53: Very toxic to aquatic organisms. May cause long-term adverse effect in the aquatic environment (EC, 2008). In general, the larvae of most species tested are more sensitive to TBT effects compared with adult species (IPCS, 1986).

**7. Is it a substance of equivalent concern (e.g. endocrine disruptor)?**

There is evidence that TBT is an endocrine disrupting compound (see below).

**8. Is there any evidence of specific ecological impacts on certain populations through endocrine disruption?**

Endocrine effects have been observed among various aquatic species at the ng- to µg-level of TBT (EC, 2008). Imposex, the development of male characteristics in females, has been observed in experimental studies of TBT exposure in several snail species (at ~ 0.05 µg/L of TBT) and in dogwhelks (at < 3 ppt TBT) (IPCS, 1986).

**9. Is there any evidence of a risk characterisation ratio (RCR) > 1 for any ecological compartment?**

UNEP (2006) estimated PEC and PEC/PNEC ratios for four environmental release scenarios: 1) Release to surface water from the manufacture of TBTO; 2) release to surface water from the manufacture of TBT self-polishing co-polymer paints; 3) release to surface water from dockyard procedures; and 4) release to surface water from the use of TBT on ships in marine, brackish or freshwater environments. The results suggested that PEC for TBT in surrounding water in areas where shipping intensity was high were greater than the PNEC, with the ratio for all four exposure scenarios being > 1. The freshwater environment was considered the most sensitive to TBT due to presence of more sensitive species and greater accumulation due to lower water exchange rates.

NOEC values from standard and non-standard long term effect studies on TBT compounds were reported to range from <1 to several ten µg TBT 1-1 (EC, 2008).

**10. If the RCR is > 1, is there any evidence of ecological impacts on certain species or populations, and/or biodiversity, and/or ecosystem processes, and/or ecosystem services? Can any of these be quantified (it may be necessary to use expert judgement)?**

Several historical case examples exist, e.g. Arcachon Bay (France). Chapter 5 provides further details on several studies that have quantified ecological impacts, and the methods used to quantify those impacts.

**11. Has any economic cost been attributed to the impacts specified under questions 6, 8, or 10?**

One of the significant costs is related to compliance methods available to ship owners. These include removal vs. over-coatings, vs. sealers of paint on the ships' hull. Information on costs and effectiveness of each of these options appears to be quite sparse. It may be necessary to directly contact several shipping companies to obtain personal communications as to these parameters.

Another source of cost to ship owners will be increased fuel costs. Use of TBT as an anti-foulant in paints and coatings helps improve the speed and operating economy of commercial ships by significantly reducing fouling from barnacles, algae, tubeworms, hydroids, and other fouling species (Arkema Inc, 2011).

One cost aspect that appears to have received only limited attention to date is cost associated with removing TBT contaminated dredged materials from harbours and waterways. Champ (2003) estimates dredging-related costs may be 5-15 fold higher than normal. The perspective taken in this type of analysis will be important to consider (i.e. port and harbour authorities, chemical manufacturers, the public, ship owners, shipyards, paint manufacturers, or some combination of these).

A final issue as noted by Champ (2003) relates to methods and costs associated with enforcing the global ban on use of TBT in anti-fouling paints.

**12. Has any type of cost-benefit or socio-economic analysis been performed? If so, give a brief summary**

Several cost-benefit analysis studies of the banning of TBT as an antifouling paint have been conducted (see Chapter 5 for a description of these studies).

**13. Have any environmental risk management options already been adopted by industry, for example under voluntary initiatives?**

Several risk management options may be worthy of consideration in this case study. For example, it may be informative to examine various means of complying with the existing TBT ban, such as application of an over-coat or sealer to existing TBT-based painted hulls versus removal and disposal of that paint and replacement with substitutes / alternatives. It may also be informative to consider certain aspects that appear to have received limited attention to date, such as the costs and benefits associated with various remediation methods for 'spent' marine paints containing TBT compounds. Evans (1999) highlights two possible remediation options which include treatment of contaminated waste waters and development of offshore ports with well-mixed waters to reduce pollution. If information on the costs of these technologies is not available, it may be possible to examine the 'break even' cost at which these technologies would become economically efficient.

**14. Is the substance already being reviewed under existing legal frameworks, such as REACH, ESR, WFD, IPPC, OSPARCOM?**

Directive 76/769/EEC (amended by Regulation 782/2003/EC) forbids the use of organo-stannic compounds as biocides in 1) free association paint; 2) as biocides on water crafts, related equipment (e.g. cages, floats, nets), and submerged or partially submerged appliances or equipment; and 3) in treatment of industrial waters. Tributylin compounds are also identified as 'hazardous priority substances' under the Water Framework Directive (2000/60/EU) (EC, 2008).

**15. Are there any alternatives or substitutes? If so, are they cost effective and practical? Is there any information on their ecological impacts?**

Several authors have noted that, at least during the time when the ban was being implemented, no adequate substitutes existed that had been proven to perform at least as well as TBT in environmental and economic cost-benefit analysis (Abbot *et al*, 2000; Evans, 1999). However, UNEP (2006) reports that several alternative tin-free anti-fouling systems are commercially available in Europe (copper acrylate, other copper systems with or without booster, non-stick biocide-free products), and other alternatives are under development. However, as noted above, the toxicity and long-term environmental impacts of these alternatives are not fully assessed, and the performance of most alternatives is lower and the price is generally higher than that of TBT-based paints.

Locating detailed performance and pricing information on substitutes may require direct contact with anti-fouling system manufacturers.

**16. Other relevant information**

TBT compounds are no longer used in anti-fouling paints. However, contamination from previous usage may still exist today in some harbours and waterways.

While use of TBT compounds in anti-fouling paints has received considerable economic attention to date, there may be several interesting options for conducting this case study. For example, it may be possible to include some of the factors not completely considered to date. As noted by Champ (2003), important aspects of the ban that have received limited attention include how to safely remove, treat and dispose of marine anti-foulants, and the party/ies responsible for the costs associated with future dredging and disposal of TBT-contaminated ports and harbours.

Several potential 'unintended consequences' of the ban on TBT compounds have been noted in the literature. For example, Champ (2003) suggested that 'regulated' nations may transfer

removal and disposal of TBT from ships to 'unregulated' countries, with 'unregulated' countries possibly unknowingly accepting the environmental and human health risks to gain economic benefits from removing TBT from ship hulls. Finally, Abbott *et al* (2000) also suggest that the ban will contribute to a substantial increase in the consumption of fossil fuels and a corresponding rise in carbon dioxide and sulphur dioxide emissions, along with increased ship repair and 'transfer' of related activities to 'unregulated' countries.

| **Potential key input variables** | **Information source** | **Comment** |
|---|---|---|
| Number of ships in commerce with TBT anti-fouling paint. | 28,038 ships in global commerce, with 70%-80% containing TBT (Champ, 2003). | Only historical information is readily available, although if focus of case study is on retrospective assessment this may not be problematic.<br>Ship figures for Europe or European countries not readily available, but may be possible to estimate based on global figures available. |
| Method and costs for remediating existing painted ship hulls containing TBT compounds. | Direct removal.<br>Over-coating.<br>Over-coating with sealer (Champ, 2003). | No information on costs and/or effectiveness of each option identified.<br>May require direct contact with shipping or paint manufacturer. |
| Removal of TBT containing anti-fouling paints from ship hulls via washing vessels in dry dock (hydroblasting) with discharge to local waterways.<br>Washdown to remove saltwater etc. (an additional source of potential 'runoff contamination'). | > 100,000 gallons of hydroblasting for paint removal for large ships. Paint removed in particle sizes < 10 microns (Champ, 2003).<br>24-30 hours of continuous work for hull washdown with 10-15 men using pressure wands (Champ, 2003).<br>Concentrations measured in shipyard wastewaters: Up to 5,000,000 ng/l (ppt) (Champ, 2003).<br>Waste water from washdown (salt removal) and hydroblasting (paint removal) may contain up to 6 milllion ppt TBT (Fox *et al*, 1999; Johnson, 1999 – cited by Champ, 2003). | May require direct contact with shipping or paint manufacturer. |
| Dredging contaminated ports and waterways to remove TBT contaminated sediments. | Dispose solids at hazardous waste site.<br>150,000 $yd^3$ of sediment via barge and rail to Utah from Staten Island cost US$17 million (>$110/$yd^3$) (Champ, 2003). | Current cost figures not available, but existing costs could be adjusted for inflation and converted to Euros. |
| Monitoring and enforcement costs. | Underwater hull inspection.<br>Monitoring costs. | No information on monitoring methods (e.g. underwater inspection etc), effectiveness or costs available.<br>May require direct contact with shipping, paint manufacturer, or port authority regulators. |

| Potential key input variables | Information source | Comment |
|---|---|---|
| Increased fuel consumption, increased frequency of drydocking to repaint ship hulls due to ban of TBT. | US$5.7 billion annually (estimated by Rouhi, 1998 – cited by Evans, 1999 – as total 'benefit' to shipping industry via use to TBT).<br>22 million additional tonnes of carbon dioxide and 0.6 million additional tonnes of sulphur dioxide generated due to increased fossil fuel consumption from ban on TBT (global warming and acid rain concerns, respectively (Evans, 1999).<br>Cost of fouling on the performance and running costs for a single ship estimated in early 1990s. Ship made international journey when antifouling coating was failing and another journey when ship had new antifouling. Additional expenses: $78,000 (77% extra cost). A second ship showed 58% extra cost (Abbott *et al*, 2000). | Paper by Abbott *et al* (2000) has detailed estimates of daily ship operating costs at port and at sea (e.g. crew wages, overtime, pension, ship repairs, diesel, insurance, depreciation costs, etc).<br>Information obtained from unique 'experiment' where two ships travelled international journeys with and without fouled hulls and costs were tabulated. |
| Predicted no effect concentration (PNEC) for impact on oysters or cause of imposex in gastropods. | The PNEC for the most sensitive oyster species is ~ 2 ng/l (IPCS, 1990).<br>PNEC varies by species of marine organisms but are < 0.1 µg/l (IPCS, 1990). | Most severe documented impacts on shellfish involve populations of molluscs, with impacts on oyster beds in France being the best documented (Evans, 1999). |
| 'Lag period' for benefit accrual associated with TBT concentration reductions. | Oyster farming in Arcachon Bay returned to previous production levels within two years of the 1982 French ban (Evans, 1999). | |
| Alternative anti-fouling paints | Evans (1999) discusses adverse environmental impacts of several alternatives, including Irgarol 1051 and copper-based paints and potential environmental copper contamination. | Quite sparse information about effectiveness and potential adverse effects of alternative anti-foulant paints are available. |
| Service life of anti-fouling paints. | The self-polishing copolymer formulations have a service life of 3-5 years vs. ~18 months with earlier anti-foulants (Abbott *et al*, 2000). | The figure cited is performance compared with the first generation anti-fouling paint technologies. It may be difficult to locate service life information for new alternative systems. |
| Cost of applying anti-fouling paints to ship's hull. | Cost of one anti-fouling paint application for a ship >25 m in length is equal to between 1-2 months' operating profit (~US$157,838) (Abbott *et al*, 2000). | |

## References

Abbott A, Abel PD, Arnold DW, Milne A. 2000. Cost-benefit analysis of the use of TBT: The case for a treatment approach. Sci Total Environ 258(1-2):5-19.

Alzieu C. 1991. Environmental problems caused by TBT in France: Assessment, regulations, prospects. Mar Environ Res 32:7-17.

Alzieu C. 2000. Environmental impact of TBT: The French experience. Sci Total Environ 258:99-102.

Arkema Inc. 2011. TBTO (Tributylin Oxide). [http://www.arkema-inc.com/index.cfm?pag=17]

Champ MA. 2003. Economic and environmental impacts on ports and harbors from the convention to ban harmful marine anti-fouling systems. Mar Pollut Bull 46(8):935-940.

EC. 2002. Opinion on the non-food aspects of 'assessment of the risks to health and the environment posed by the use of organostannic compounds (excluding use as a biocide in antifouling paints) and a description of the economic profile of the industry.' C2/VR/csteeop/lip/12062003. European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), Brussels.
[http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out188_en.pdf]

EC. 2008. ECB – summary fact sheet. PBT Working Group – PBT List No. 95. European Commission.

Evans SM. 1999. Tributyltin pollution: the catastrophe that never happened. Mar Pollut Bull 38(8):629-636.

EXTOXNET. 1996. Pesticide information profile: Tributyltin. The Extension Toxicology Network. [http://extoxnet.orst.edu/pips/tributyl.htm]

Fox TJ, Beacham T, Schafran GC, Champ MA. 1999. Advanced technologies for removing TBT from ship washdown and drydock runoff wastewaters. Proceedings of Oceans '99, Seattle, Washington, Vol 4. The Marine Technology Society, Washington, DC, USA, pp 63-72. (Cited by Champ, 2003.)

Giacomello AM, Guha P, Howe P, Jones KC, Matthiessen P, Shore RF, Sullivan C, Sweetman A, Walker L. 2006. The Benefits of Chemical Regulations: Four case studies: TBT, Methiocarb, DDT and PCBs. Report to DEFRA.
[http://www.thereachcentre.com/uploaded/Benefits%20of%20Chemical%20Regulation.pdf]

IPCS. 1986. Pesticide Safety Data Sheet. Data sheet on pesticides number 65: bis(tributyltin) oxide. International Programme on Chemical Safety. The United Nations Environment Programme, the International Labour Organisation, and the World Health Organization. [http://www.inchem.org/documents/pds/pds/pest65_e.htm]

IPCS. 1990. Environmental Health Criteria 116: Tributyltin compounds. International Programme on Chemical Safety. The United Nations Environment Programme, the International Labour Organisation, and the World Health Organization.
[http://www.inchem.org/documents/ehc/ehc/ehc116.htm]

Johnson D. 1999. Discharge of tributyltin in state of virginia waters. In Proceedings of Oceans '99, Seattle, Washington, Vol 4. The Marine Technology Society, Washington, DC, USA, pp 41-50. (Cited by Champ, 2003.)

Rouhi AM. 1998. The squeeze of tributyltins. Chem Eng News 76(17):41-42.

Ruiz JM, Bachelet G, Caumette P, Donard OF. 1996. Three decades of tributyltin in the coastal environment with emphasis on Arcachon Bay, France. Environ Pollut 258:99-102.

UNEP. 2006. Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (26 November 2006). Draft Decision Guidance Document for Tributyltin Compounds. United Nations Environment Programme.
[http://www.pic.int/incs/crc3/n14)/English/K0654009%20CRC3-14.pdf]

United Kingdom Department of the Environment. 1986. Organotin in antifouling paints: Environmental considerations. Pollution Paper No. 25. Department of the Environment, London, UK. (Cited in International Programme on Chemical Safety. 1990. Environmental Health Criteria 116: Tributyltin compounds. The United Nations Environment Programme, the International Labour Organisation, and the World Health Organization.)

US EPA. 2003. Ambient aquatic life water quality criteria for tributyltin (TBT). EPA 822-R-03-031 - Final. United States Environmental Protection Agency, Office of Water, Washington, DC, USA. [http://www.epa.gov/waterscience/criteria/tributyltin/tbt-final.pdf]

# APPENDIX C

## *Trichlorobenzene*

### 1. Substance and CAS

1,2,4-Trichlorobenzene, CAS No. 120-82-1.

### 2. Manufacturing/use in tonnes pa

In 2002, about 6,000 tonnes were manufactured in Europe (information received from EuroChlor). Overall, it is difficult to estimate exposure because a major source is unintentional release from existing electrical equipment, though legislation should be reducing this.

### 3. Uses (main ones)

1,2,4-TCB is used as an intermediate in closed systems in the manufacture of herbicides and higher chlorinated benzenes. It is also used as a process solvent, as a dye carrier in the textile industry, in metal working fluids, and sprays as corrosion inhibitor.

Significant quantities may still be in use in electrical equipment, and this may be a source of unintentional release. 1,2,4-TCB can also be released during combustion of materials containing organochlorine compounds.

### 4. Brief 'storyline' describing connections between production, use and ecological effects

Based on current emission scenarios detailed in the EU Risk Assessment document on 1,2,4-TCB, the compound presents a risk, through certain use patterns, to aquatic and terrestrial environments, and also to important organisms in sewage treatment plants (ECB, 2003).

### 5. Is the substance a PBT or vPvB under REACH?

In terms of persistence, 1,2,4-TCB is not readily hydrolysable and its estimated degradation half-life in air is 30 days. Screening tests for its biodegradability have suggested that it is not readily biodegradable, but is estimated to be inherently biodegradable. Based on environmentally relevant soil and sediment degradation tests, half-lives of more than 200 days have been estimated. Studies of degradation in water have produced half-lives either just below the P cut-off, or far longer. From this data, it was deemed by the ECB's Technical Committee for New and Existing chemical Substances (TC NES) sub-group that

1,2,4-TCB fulfils the P criterion, but probably not vP, due to conflicting evidence for degradation in surface water (ECB, 2008).

Bioconcentration factors from laboratory tests with fish range from 120-3200. Field bioaccumulation data indicated bioconcentration factors that were higher. Therefore, the substance also fulfils the B criterion of the PBT assessment.

The lowest chronic NOEC from toxicity studies for crustaceans and fish is 0.04 mg/L. Two tests on crustaceans have produced NOECs in the same order of magnitude, and all other NOECs are in the range of 0.1-0.5 mg/L. 1,2,4-TCB does not fulfil the T criterion of the EU PBT guidelines, however the lowest NOEC (0.04 mg/L) is not very far from the T cut off and uncertainty remains with regard to mammalian toxicity.

TC NES concluded that, based on the available data, 1,2,4-TCB should be regarded as a substance fulfilling PBT-criteria. Although 1,2,4-TCB does not meet the T-criterion, the fact that it is very close to the cut off, that uncertainty remains as to mammalian toxicity, and that the substance has the potential to travel several thousand kilometres in the atmosphere before being degraded, have led TC NES to the aforementioned conclusion.

**6. Is there any evidence of specific ecological impacts due to persistence and/or bioaccumulation and can these be quantified (it may be necessary to use expert judgement)?**

There is no known evidence of field effects of P and B. High elimination rate constants suggest that 1,2,4-TCB does not accumulate up the food chain.

**7. Is it a substance of equivalent concern (e.g. endocrine disruptor)?**

No evidence has been reported.

**8. Is there any evidence of specific ecological impacts on certain populations through endocrine disruption?**

N/A.

**9. Is there any evidence of a risk characterisation ratio (RCR) > 1 for any ecological compartment?**

In the ECB report (2008), it is recorded that $PEC_{local,\ water}$ is between one and two orders of magnitude greater than the measured surface water concentrations, however the estimations

were based on points 100 m from the source, whereas the measured data are from unknown distances from the sources (presumably greater). The $PEC_{regional,\ sediment}$ value of 0.38 µg/kg ww sediment was in the same level as the lower part for the measured concentration range. This was deemed to be acceptable.

Valid long-term toxicity studies were available for fish, invertebrates and algae, so $PNEC_{aquatic\ organisms}$ could be calculated by applying an assessment factor of 10 to the lowest reported NOEC (fish, 21 d: 0.04 mg/L) of these toxicity studies, resulting in a $PNEC_{aquatic}$ of 0.004 mg/L. A PNEC for sediment dwelling organisms (0.09 mg/kg ww) was calculated using the equilibrium partitioning method, due to the fact that there were insufficient reliable toxicity data for this compartment. Reliable acute toxicity studies for soil organisms were available, hence the $PNEC_{soil}$ (0.05 mg/kg soil) could be derived by applying an assessment factor of 1000 to the lowest toxicity value (24 h $EC_{50}$, soil microorganisms, respiration test = 50 mg/L). Two $PNEC_{microorganisms}$ were calculated (0.35 and 0.09 mg/L), one based on a sludge test (35 mg/L) using an assessment factor of 100, and one based on a ciliate growth inhibition test (0.91 mg/L) with an assessment factor of 10. For $PNEC_{secondary\ poisoning}$ (0.6 mg/kg bw/d), an assessment factor of 10 was applied to the NOAEL oral for rat (6 mg/kg bw/d).

The calculation of the risk characterisation ratios indicate that, for some scenarios, there was a need for risk reduction measures in the aquatic, sewage treatment plant (STP) and terrestrial environments. It was in the processing scenarios where concerning PEC/PNEC ratios had been calculated, and ratios calculated for the production scenarios were all less than 1. It was deemed that sufficient information and testing data had been collated to characterise each environmental compartment effectively.

| | |
|---|---|
| Surface water: | 0.002 - 17 |
| $STP_{ciliates}$: | 0.31 - 21.5 |
| $STP_{bacteria}$: | 0.08 - 5.6 |
| $STP_{microorganisms}$: | 0.08 - 21.5 |
| Aquatic sediment: | 0.002 - 21 |
| Soil: | <<0.9 - 21 |
| Secondary poisoning: | all <1. |

**10. If the RCR is > 1, is there any evidence of ecological impacts on certain species or populations, and/or biodiversity, and/or ecosystem processes, and/or ecosystem services? Can any of these be quantified (it may be necessary to use expert judgement)?**

Limited data are available for effects in the field on phytoplankton and mesocosm studies with invertebrates (Lay *et al*, 1985). There is a probabilistic ERA (environmental risk assessment) for a TCB contaminated site (Zolezzi *et al*, 2005).

**11. Has any economic cost been attributed to the impacts specified under questions 6, 8, or 10?**

Not known.

**12. Has any type of cost-benefit or socio-economic analysis been performed? If so, give a brief summary**

Not known.

**13. Have any environmental risk management options already been adopted by industry, for example under voluntary initiatives?**

It is recommended to consider marketing and use restrictions at EU level for all uses of TCB except as an intermediate. Where appropriate, marketing and use restrictions of articles containing TCB should be considered.

**14. Is the substance already being reviewed under existing legal frameworks, such as REACH, ESR, WFD, IPPC, OSPARCOM?**

TCB is also a priority substance for risk assessment under European Commission regulation EEC793/93 on the evaluation of risk from existing substances, and is also a priority substance listed on the European Pollutant Emission Register (Directive 96/61/EC), EC Directive 76/464: Pollution of the aquatic environment by dangerous substances (plus daughter directives); it is also on the list of 11 substances under review as potential 'priority hazardous substances' under the Water Framework Directive. Solvent emissions are regulated under the EC Solvents Directive. Trichlorobenzene is identified as a priority substance ('List 1') by the OSPAR Commission for the Protection of the Marine Environment of the North East Atlantic, of which the UK is a signatory. The OSPAR strategy aims, amongst other things, to reduce and avoid emissions, losses and discharges of substances on 'List 1'. As far as theVOCs (volatile organic compounds) are concerned the main international legislation is the UNECE Convention on Long-Range Transboundary Air Pollution and the Basel Convention.

**15. Are there any alternatives or substitutes? If so, are they cost effective and practical? Is there any information on their ecological impacts?**

Reduction rather than substitution appears to be the management strategy.

**16. Other relevant information**

N/A.

**References**

ECB. 2003. European Union Risk Assessment Report. 1,2,4-Trichlorobenzene. EUR 20540 EN. European Chemicals Bureau. EU Commission, Joint Research Centre, Ispra, Italy.

ECB. 2008. Results of the evaluation of the PBT/vPvB properties of: 1,2,4-Trichlorobenzene, PBT Working Group. European Chemicals Bureau, EU Commission, Joint Research Centre, Ispra, Italy.

Lay JP, Schauerte W, Müller A, Klein W, Korte F. 1985. Long-term effects of 1,2,4-trichlorobenzene on freshwater plankton in an outdoor model ecosystem. Bull Environ Contam Toxicol 34(1):761-769.

Zolezzi M, Cattaneo C, Tarazona JV. 2005. Probabilistic ecological risk assessment of 1,2,4-trichlorobenzene at a former industrial contaminated site. Environ Sci Technol 39(9):2920-2926.

# APPENDIX D

## *Musk xylene*

### 1. Substance and CAS

Musk xylene (MX); CAS No. 81-15-2.

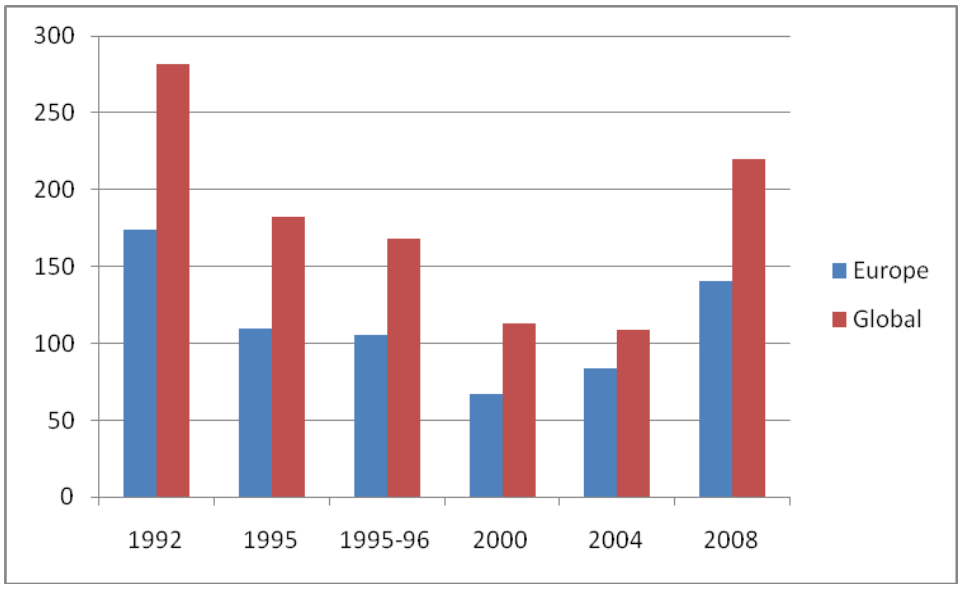
### 2. Manufacturing/use in tonnes pa

#### *a. Current*

MX is currently banned for use in fragrance preparations by the International Fragrance Association.

#### *b. Trends in production/use*

Prior to the ban, the historical volume of use (tonnes/year) was reported to IFRA as:




### 3. Uses (main ones)

Formerly used in perfumery for a variety of product types.

**4. Brief 'storyline' describing connections between production, use and ecological effects**

*a. In which environmental compartment/ecosystem have impacts been observed? Include brief description of affected species/ecosystem services and an indication of the extent (localised or widespread)*

MX has been observed, and continues to be reported in the peer-reviewed literature, as present in various environmental compartments. Specifically, biota, fresh and marine waters, sediments, and soils. MX is frequently reported as part of human biomonitoring studies. Risk quotients have been reported as <1 for all environmental compartments. No direct impacts to these environmental compartments (e.g. adverse impacts, loss of species) have been documented.

*b. Have any economic costs been attributed to the impacts?*

No reported economic impact studies have been performed. As there is no known environmental impact, any economic impact due to its environmental behaviour is not known nor is any economic impact anticipated.

**5. Is the substance a PBT or vPvB under REACH?**

Yes. MX is on the SVHC list and subject to review under the WFD (potentially deriving an Environmental Quality Standard).

**6. Is there any evidence of specific ecological impacts due to persistence and/or bioaccumulation and can these be quantified (it may be necessary to use expert judgement)?**

In the current literature, MX has been identified as persistent and bioaccumulative, however, actual impacts (e.g. loss of species, population reductions or other impacts) have not been reported.

**7. Is it a substance of equivalent concern (e.g. endocrine disruptor)?**

Quoted from the addendum to the RAR (EC, 2005):

"*… Musk xylene and not 2-amino- and 4-aminomusk xylene, was demonstrated to be a very weak agonist in the E-screen assay (Bitsch* et al*, 2002). Binding to the estrogen receptor from rainbow trout and clawed frog showed binding of 2-amino- and 4-amino-musk xylene, and not for musk xylene itself (Chou and Dietrich, 1999). These results are in conflict with each other. Furthermore, this weak estrogenicity has only been demonstrated* in vitro*, and no effects were found in the 90-day dermal repeated dose assays on reproductive organs,*

*and in a peri/postnatal toxicity study on reproductive performance of the in utero exposed off-spring. It can be concluded that there is no substantiated evidence that musk xylene can cause endocrine disrupting effects*."

**8. Is there any evidence of specific ecological impacts on certain populations through endocrine disruption?**

See response to item 7 above.

**9. Is there any evidence of a risk characterisation ratio (RCR) > 1 for any ecological compartment?**

The latest risk assessment for MX was published in 2005 (EC, 2005). No RCR was reported as greater than 1. The concern raised for further assessment was based on MX's potential for persistence and bioaccumulation (see under item 6).

**10. If the RCR is > 1, is there any evidence of ecological impacts on certain species or populations, and/or biodiversity, and/or ecosystem processes, and/or ecosystem services? Can any of these be quantified (it may be necessary to use expert judgement)?**

N/A.

**11. Has any economic cost been attributed to the impacts specified under questions 6, 8, or 10?**

The fragrance industry banned the use of MX for all uses. As there is no known environmental impact, any economic impact due to its environmental behaviour is not known nor is any economic impact anticipated.

**12. Has any type of cost-benefit or socio-economic analysis been performed? If so, give a brief summary**

No SEA has been performed.

**13. Have any environmental risk management options already been adopted by industry, for example under voluntary initiatives?**

Yes, industry banned the use of this fragrance ingredient.

**14. Is the substance already being reviewed under existing legal frameworks, such as REACH, ESR, WFD, IPPC, OSPARCOM?**

Yes, there may be non-RIFM/non-IFRA constrained manufacturers seeking to register MX under REACH. As noted above, MX is on the current list of materials under the WFD for review for a possible EQS (Environmental Quality Standard).

**15. Are there any alternatives or substitutes? If so, are they cost effective and practical? Is there any information on their ecological impacts?**

Perfumery is a complicated, creative process. As such, one to one substitution is not often a consideration in the development of a fragrance. Reformulation of products is an expensive process within the consumer product companies. Loss of a single ingredient can result in thousands of fragrance formulae undergoing reformulation. Many of the consumer products for which these fragrances are added must also be re-evaluated and re-qualified for their stability, efficacy, hedonics, and safety as a result of the fragrance modification. In general, reformulated fragrances may be more expensive for use in consumer products, as in the case of MX, a long used ingredient is being replaced. Furthermore, other fragrance materials may need to be synthesised at a higher quality to reduce any MX impurities.

Currently other fragrance materials have not been identified as PBTs. The more common fragrance ingredients reported in the literature are the polycyclic musks (AHTN: 6-acetyl-1,1,2,4,4,7-hexamethyltetraline and HHCB: 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethyl-cyclopenta-γ-2-benzopyran). These materials have been determined to neither present environmental risks at their current use levels nor be identified as PBTs.

## 16. Other relevant information on musk xylene

| Classification | Risk assessment methodology | Outcome |
|---|---|---|
| Proposed vPvB – SVHC under REACH (Annex XIII).<br>vP: The results of two biodegradation tests clearly showed no (ready) biodegradability. In an ocean die-away test, the metabolites stayed in the water phase while the parent compound musk xylene volatilised. In addition, the ratio metabolites:parent compound was still close to one after 159 days, which shows no rapid degradation and therefore the half-life in water significantly exceeds the criterion of 60 days.<br>vB: Musk xylene has a log $K_{ow}$ of 4.9. Experimental bioaccumulation studies for musk xylene in fish showed a wide range of BCFs, among which values above the vB criterion of 5,000 l/kg.<br>Borderline Toxic: Some NOECs for specific aquatic toxicity tests were found to be at or below the threshold value of 10 µg/l. However, these results were considered inconclusive with respect to the screening of Toxicity (T) for the purpose of the PBT assessment. MX is classified as Carcinogenic Category 3, although it is realised that it is a borderline case. | PEC/PNEC method using information available as described in the TGD to assess risks to water, sediments, soil and predators from known uses of MX. | - Conclusion in RAR (EC, 2005): *There is a need for further information and/or testing. This conclusion is reached, because the substance is considered a PBT candidate chemical. A further PBT-testing strategy is proposed.*<br>- Addendum in RAR (EC, 2010) : (Because of its vPvB status) *There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.*<br>- PEC/PNECs in all compartments <1.<br>- MX reduces in the environment to amino metabolites.<br>- In the aquatic environment, MX metabolites PEC/PNEC, based on limited data, would appear to be < 1. |

## References

EC JRC IHCP. 2005. PBT assessment of musk xylene (5-tert-butyl-2,4,6-trinitro-m-xylene). Risk Assessment Report. European Commission, Joint Research Centre, Institute for Health and Consumer Protection, Ispra, Italy.

EC JRC IHCP. 2010. PBT assessment of musk xylene (5-tert-butyl-2,4,6-trinitro-m-xylene). Addendum to the final report (2005) of the risk assessment. European Commission, Joint Research Centre, Institute for Health and Consumer Protection, Ispra, Italy.

# APPENDIX E

## *Ethinyloestradiol*

### 1. Substance and CAS

17α-ethinyloestradiol (EE2); CAS No. 57-63-6.

### 2. Manufacturing/use in tonnes pa

#### *a. Current*

165 kg/a in EU (Source: IMS Health – MIDAS database), except the Netherlands (FARMINFORM – FI-ROM/Aventis-Pharma) and France (GERS – Groupement pour l'élaboration et la réalisation de statistiques).

#### *b. Trends in production/use*

No major change expected.

### 3. Uses (main ones)

Pharmaceutical; oral contraceptives.

### 4. Brief 'storyline' describing connections between production, use and ecological effects

#### *a. In which environmental compartment/ecosystem have impacts been observed? Include brief description of affected species/ecosystem services and an indication of the extent (localised or widespread)*

Oestrogenic effects such as feminisation of fish have been reported close to municipal sewage effluents in several countries and locations (Jobling *et al*, 1998; Sumpter and Johnson, 2005; Bjerregaard *et al*, 2006).

The contribution of ethinyloestradiol to the observed effects is unclear, but most likely natural oestrogens are the main contributors (Jobling *et al*, 2006).

#### *b. Have any economic costs been attributed to the impacts?*

No.

**5. Is the substance a PBT or vPvB under REACH?**

As a pharmaceutical, EE2 is not regulated under REACH.

**6. Is there any evidence of specific ecological impacts due to persistence and/or bioaccumulation and can these be quantified (it may be necessary to use expert judgement)?**

The above mentioned potential effects in fish populations are related to ecotoxicological activity, not persistence or bioaccumulation.

**7. Is it a substance of equivalent concern (e.g. endocrine disruptor)?**

EE2 has reproductive inhibiting effects by design, therefore it is an endocrine disruptor.

**8. Is there any evidence of specific ecological impacts on certain populations through endocrine disruption?**

Fish have been demonstrated to be most sensitive species to exposure in the low or sub-ng/L range (Fenske, 2005; Kidd *et al*, 2007; Länge *et al*, 2001; Parrot and Blunt, 2005; Schäfers *et al*, 2007; Zha *et al*, 2008). Amphibians may also be sensitive but less than most fish species studied (Caldwell *et al*, 2008).

**9. Is there any evidence of a risk characterisation ratio (RCR) > 1 for any ecological compartment?**

It is under debate, whether the aquatic compartment is subject to a RCR > 1 because of the sensitivity of fish populations.

**10. If the RCR is > 1, is there any evidence of ecological impacts on certain species or populations, and/or biodiversity, and/or ecosystem processes, and/or ecosystem services? Can any of these be quantified (it may be necessary to use expert judgement)?**

Oestrogenic effects such as feminisation of fish have been reported close to municipal sewage effluents in several countries and locations. The contribution of ethinyloestradiol to the observed effects is unclear, but most likely natural oestrogens are the main contributors. (see references under item 4 a). A risk quotient of < 1 has been determined for pharmaceutical products containing EE2, but this based on specific products, not the sum of all EE2 marketed in various formulations.

**11. Has any economic cost been attributed to the impacts specified under questions 6, 8, or 10?**

No.

**12. Has any type of cost-benefit or socio-economic analysis been performed? If so, give a brief summary**

An impact assessment is presently prepared in the context of the WFD evaluation of EE2.

**13. Have any environmental risk management options already been adopted by industry, for example under voluntary initiatives?**

No.

**14. Is the substance already being reviewed under existing legal frameworks, such as REACH, ESR, WFD, IPPC, OSPARCOM?**

Ethinyloestradiol is listed as a potential hazardous substance under OSPAR and is proposed as a priority substance/priority hazardous substance under WFD.

**15. Are there any alternatives or substitutes? If so, are they cost effective and practical? Is there any information on their ecological impacts?**

Ethinyloestradiol is the only available oestrogen in oral contraceptives. It is unlikely that alternatives will be developed in a foreseeable time period for this application.

**16. Other relevant information**

As noted in Section 6.2, research is starting to be published on population level impacts that could arise from exposure to EE2 in the environment (e.g. Grist *et al*, 2003). These data need to be carefully weighed against the socio-economic benefits of EE2 to assist any future regulatory decision making.

### References

Bjerregaard LB, Korsgaard B, Bjerregaard P. 2006. Intersex in wild roach (Rutilus rutilus) from Danish sewage effluent-receiving streams. Ecotoxicol Environ Saf 64:321-328.

Caldwell DJ, Mastrocco F, Hutchinson TH, Länge R, Heijerick D, Janssen C, Anderson PD, Sumpter JP. 2008. Derivation of an aquatic predicted no-effect concentration for the synthetic hormone, 17alpha-ethinyl estradiol. Environ Sci Technol 42(19):7046-7054.

Fenske M. 2005. An environmentally relevant concentration of estrogen induces arrest of male gonad development in zebrafish, Danio rerio. Environ Toxicol Chem 24(5):1088-1098.

Grist EPM, Wells NC, Whitehouse P, Brighty G, Crane M. 2003. Estimating the effects of 17α-ethinylestradiol on populations of the fathead minnow Pimephales promelas: Are conventional toxicological endpoints adequate? Environ Sci Technol 37(8):1609-1616.

Jobling S. Nolan M, Tyler CR, Brighty G, Sumpter JP. 1998. Widespread sexual disruption in wild fish. Environ Sci Technol 32:2498-2506.

Kidd KA, Blanchfield PJ, Mills KH, Palace VP, Evans RE, Lazorchak JM, Flick RW. 2007. Collapse of a fish population after exposure to a synthetic estrogen. Proc Natl Acad Sci U S A 104(21):8897-8901.

Länge R, Hutchinson TH, Croudace CP, Siegmund F, Schweinfurth H, Hampe P, Panter GP, Sumpter JP. 2001. Effects of the synthetic estrogen 17α-ethinylestradiol on the life-cycle of the fathead minnow (Pimephales promelas). Environ Toxicol Chem 20(6):1216-1227.

Parrot JL, Blunt BR. 2005. Life-cycle exposure of fathead minnows (pimephales promelas) to an ethinylestradiol concentration below 1 ng/L reduces egg fertilization success and demasculinizes males. Environ Toxicol 20(2):131-141.

Schäfers C, Teigeler M, Wenzel A, Maack G, Fenske M, Segner H. 2007. Concentration- and time-dependent effects of the synthetic estrogen, 17α-ethinylestradiol, on reproductive capabilities of the zebrafish, Danio rerio. J Toxicol Environ Health 70(9):768-779.

Sumpter JP, Johnson AC. 2005. Lessons from endocrine disruption and their application to other issues concerning trace organics in the aquatic environment. Environ Sci Technol 39(12):4321-4332.

Zha J, Sun L, Zhou Y, Spear PA, Ma M, Wang Z. 2008. Assessment of 17α-ethinylestradiol effects and underlying mechanisms in a continuous multigeneration exposure of the Chinese rare minnow (Gobiocypris rarus). Toxicol Applied Pharmacol 226:298-308.

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* Prof Calow was a member of the Scientific Committee at the time of this Task Force; he was then at the University of Roskilde, Denmark.

** Mr Shillabeer retired from his company and the Task Force in February 2010.

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# ECETOC PUBLISHED REPORTS

## *Monographs*

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No. 3 Risk Assessment of Occupational Chemical Carcinogens (Published May 1985)
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No. 30 Genetic Susceptibility to Environmental Toxicants (Published October 2001)
Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis, Volume 482, Issues 1-2, Pages 1-115
www.sciencedirect.com/science/journal/00275107
No. 31 Guidance on Evaluation of Reproductive Toxicity Data (Published February 2002)
No. 32 Use of Human Data in Hazard Classification for Irritation and Sensitisation (Published July 2002)

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Toxicology Letters, Volume 138, Issues 1-2
www.sciencedirect.com/science/journal/03784274

No. 34 Toxicogenomics in Genetic Toxicology and Hazard Determination (Published August 2005)
Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis, Volume 575, Issues 1-2
www.sciencedirect.com/science/journal/00275107

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Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis, Volume 600, Issues 1-2
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www.sciencedirect.com/science/journal/13835718

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Toxicology Letters, Volume 172, Nos. 1-2
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