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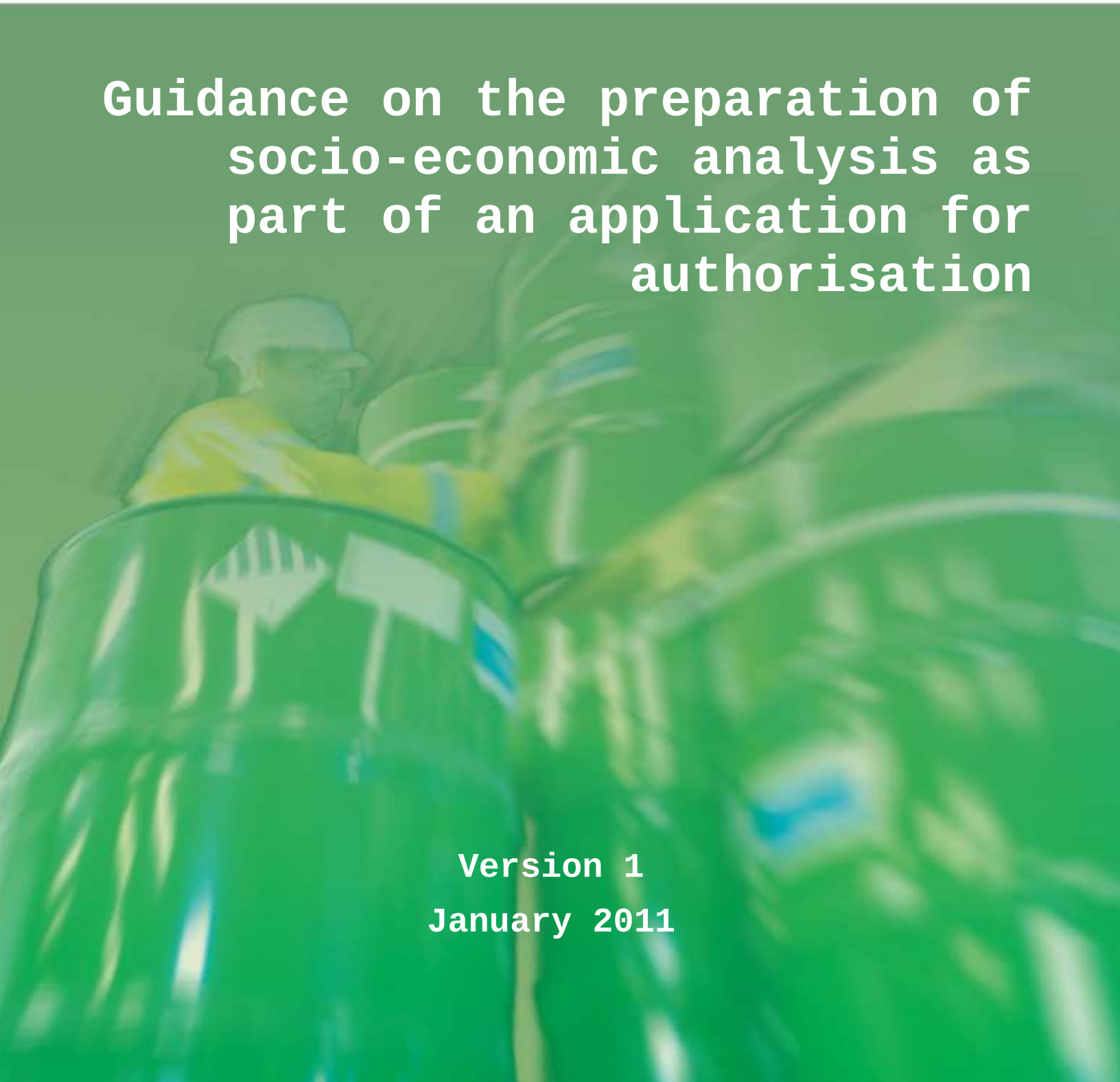
Guidance on the preparation of socio-economic analysis as part of an application for authorisation



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European Chemicals Agency
Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

PREFACE

This document describes the socio-economic analysis under the REACH procedure on applications for authorisation. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006.[1]

[1] 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 (OJ L 396, 30.12.2006, corrected version in OJ L136, 29.5.2007, p.3).

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GLOSSARY

A glossary of all technical and socio-economic terms used within the guidance is provided below. Any words shown in *italics* can also be found within this glossary. The *European Chemicals Agency (ECHA)* also has a glossary of terms relevant to REACH which can be found on using the following link: http://guidance.echa.europa.eu/

Actors in the supply chain	All *manufacturers and/or importers* (M/I) and/or *downstream users* (DU) in a supply chain (Art 3(17)). Within this guidance, the term is also used to include consumers and the supply chain for *articles*. It may additionally refer to actors in the supply chains for alternative substances as well as alternative techniques. See also *Supply chain*.
Adequate control route	An *authorisation* shall be granted if it is demonstrated that the risk to human health and the environment from the use of a substance arising from the intrinsic properties specified in *Annex XIV* is adequately controlled in accordance with section 6.4 of Annex I {Art. 60(2)} and taking into account Article 60(3). See also Guidance on the preparation of an application for authorisation.
Agency	European Chemicals Agency (ECHA).
Alternative	An alternative is a possible replacement for an *Annex XIV* substance. It should be able to replace the function that the *Annex XIV* substance performs. The alternative could be another substance(s) or it could be a technology (i.e. a process, procedure, device, or modification in end product) or a combination of technical and substance alternatives. For example, a technical alternative could be a physical means of achieving the same function of the *Annex XIV* substance or perhaps changes in production, process or product that removes the need for the *Annex XIV* substance altogether.
Analysis of alternatives	A systematic search for *alternatives* that can be documented and presented in an application for *authorisation.* This analysis is the *applicant's* evidence to demonstrate that the t*echnical* and *economic feasibility* of *substitution* of the possible alternatives has been analysed and their risks compared to the *Annex XIV* substance. The aim of this analysis should be to determine if use of the alternative would lead to an overall reduction in *risk.* Guidance on conducting an analysis of alternatives can be found in the Guidance on the preparation of an application for authorisation.
Annex XIV	Annex XIV of REACH lists all substances which are subject to authorisation under REACH. The use and placing on the market for a use of substances listed on Annex XIV is prohibited from the "sunset" date unless an authorisation has been granted for that use or unless an exemption applies.
Annualised cost	Presentation of annualised costs (or equivalent annual costs) is a process whereby non-recurrent (e.g. capital, plant down-time) costs of a measure are equalised over its lifetime using the relevant *discount rate*. This is presented as a yearly cost (with equal annual payments) assuming that it follows the profile of an annuity. For example if a measure costs €100k to install and it is assumed that the lifetime is ten years and the discount rate is 4% then the

	annualised costs are around €12k per year. The annualised costs can be calculated as the annualisation factor multiplied by the non-recurrent costs. The annualisation factor is equal to: $\text{Annualised investment} = \frac{\text{investment cost} * \text{discount rate}}{1 - ((1+\text{discount rate})^{-\text{lifetime of the investment}})}$ In the above example this is: €100k * $0.04/(1-((1+0.04)^{-10})$= €12.3k per year.
(Total) Annual costs	The sum of the annualised non-recurrent costs and the yearly operating costs. Using the example above of a measure that costs €100k to install with a yearly operating cost of €10k over its lifetime, the total annual costs are approximately €22k, which is equal to the sum of annualised capital costs (€12k) plus the operating cost (€10k).
Applicant	The legal entity or group of legal entities submitting the *authorisation application.*
Applied for use scenario	Term that commonly describes the "baseline" or "business as usual" situation that would arise if the authorisation is granted
Article	Article means an object which, during production, is given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition.
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. This authorisation requirement ensures that risks from the use of such substances are either adequately controlled or outweighed by socio-economic benefits. An analysis of alternative substances or technologies will be a fundamental component of the authorisation process.
Authorisation application	The documentation submitted to the *Agency* applying for use of substances included in *Annex XIV.* See also Guidance on the preparation of an application for authorisation.
Available (alternative)	Accessible and able to replace the *Annex XIV* substance.
Baseline scenario	Term that describes the "business as usual" situation that would arise if no additional action was taken. In the application for authorisation this is called "applied for use" scenario.
Benefits	The positive implications, both direct and indirect, resulting from some action. This includes both financial and non-financial information.
Capital cost	Investment or one-off cost that has a lifetime of several years.
Chemical safety assessment (CSA)	Chemical Safety Assessment is the process aimed at determining the risk posed by a substance and, as part of the exposure assessment, developing exposure scenarios including risk management measures to control the risks. Annex I contains general provisions for performing a CSA. The CSA consists of the following steps:

	- Human health hazard assessment - Human health hazard assessment of physicochemical properties - Environmental hazard assessment - PBT and vPvB assessment If, as a result of this hazard assessment, the registrant concludes that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC (for substances) or has PBT/vPvB properties, this triggers further steps in the chemical safety assessment: - Exposure assessment - Risk characterization..
Chemical safety report (CSR)	The chemical safety report documents the chemical safety assessment for a substance on its own, in a mixture or in an article or a group of substances. Guidance on developing a CSR can be found in Guidance for the preparation of the Chemical Safety Report In other words, the chemical safety report (CSR) is a document which details the process and the results of a chemical safety assessment (CSA). Annex I of the REACH Regulation contains general provisions for performing CSAs and preparing CSRs.
Comitology procedure	In accordance with Article 202 of the Treaty establishing the European Community (ECT), it is the task of the Commission to implement legislation at the Community-level. In practice, each legislative instrument specifies the scope of the implementing powers conferred on the Commission by the Council of the European Union. In this context, the Treaty provides for the Commission to be assisted by a committee, in line with the procedure known as "comitology". Further details can be found at: http://europa.eu/scadplus/glossary/comitology_en.htm Authorisation Decisions under REACH will be adopted by comitology. See also *Regulatory procedure*.
Committee for Socio-economic Analysis (SEAC)	The Committee for Socio-economic Analysis (SEAC) is an *Agency* committee that is responsible for preparing the opinion of the *Agency* on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of the REACH Regulation relating to the socio economic impact of possible legislative action on substances. The SEAC consists of at least one but no more than two members from the nominees of each Member State appointed by the Management Board for a renewable term of three years. The Committee members may be accompanied by advisers on scientific, technical or regulatory matters.
Compliance costs	The difference in the cost to the applicant and the up and downstream users (i.e. the supply chain) comply*ing with a "non-use"* scenario as compared to the 'applied for use' scenario. Compliance costs include the capital and operating costs that would accrue to the sectors affected by the "non-use" scenario.
Consumer surplus	Denotes the net benefit that a consumer derives from consuming a good. It is equal to the absolute amount the consumer would willingly pay for a good less the amount they actually have to pay (i.e. the market price).

Costs	The negative implications, direct and indirect, resulting from some actions. Includes both financial and non-financial information.
Cost benefit analysis (CBA)	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*. (See Appendix F.1 for more information.)
Cost effectiveness analysis (CEA)	Is widely used to determine the least cost means of achieving pre-set targets or goals (though it is not restricted to this use). CEA can be used to identify the least cost option among a set of alternative options that all achieve the targets. In more complicated cases, CEA can be used to identify combinations of measures that will achieve the specified target. (See Appendix F.3 for more information.)
Damage costs	Damage cost is the cost incurred by repercussions (effects) of, for example, environmental impacts (such as effects resulting from the emission of and exposure to pollutants). This could include, for example, the degradation of land or human-made structures and health effects. In environmental accounting, it is part of the costs borne by economic agents.
Demand curve	a curve relating the price of a product to the amount demanded (per unit time) of that product.
Depreciation	An accounting term referring to the reduction in "book" or accounting value of capital equipment during its working life. Strictly speaking it is not necessary to use this concept directly in assessing the costs of "non-use" scenarios but may be helpful when the residual value of capital is estimated.
Direct costs	The additional resources that a sector or economic interest has to employ in complying with a policy. For example, the cost of fitting abatement equipment to reduce pollution, or the additional cost of protective equipment. See "Compliance cost".
Discounting	A method used to convert future costs or benefits to present values using a *discount rate*.
Discount rate	Used to convert a future income (or expenditure) stream to its present value. It shows the annual percentage rate at which the present value of a future Euro, or other unit of account, is assumed to decrease over time.
Distributional impacts	These show how a proposal may affect different regions, workers, consumers, and industries along the supply chain.
Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user.
Economic feasibility	Analysis of the economic implications of the adoption of an *alternative.* Economic feasibility is normally defined as a situation where the economic benefits exceed the economic costs. For more details on how the concept is applied in authorisation applications; see Section 3.7 in the Guidance on the

	preparation of an application for authorisation.
Economic impacts	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. In much literature, e.g. the EU guidelines for Impact Assessment (European Commission 2005a), a distinction between economic, social and environmental impacts is made – i.e. providing a more narrow interpretation of the term economic. In order to facilitate a comparison with EU literature, we employ this distinction between impact categories in this guidance.
Economic lifetime	The length of time that a piece of capital equipment will last, given a defined level of maintenance expenditure.
Environmental impacts	Impacts on all environmental compartments. Covers all use and non-use values of the affected environmental compartments.
Existence value	The economic value placed by people on the continued existence of an asset for the benefit of present or future generations. In the case of the latter it is sometimes referred to as bequest value.
Expected value	The weighted average of all possible values of a variable, where the weights are the probabilities (applies to all type of variables).
Externalities	The non-market impacts of an activity which is not borne by those who generate them.
Financial impact	Costs and benefits incurred by identified actors in relevant supply chains. Financial costs will generally include taxes, subsidies, depreciation, capital charges and other *transfer payments*. N.B. Specific terms are explained further in section 3.4 on economic impacts.
Gross Domestic Product (GDP)	A measure of the total output of an economy in a year. It equals the market value of the net output within the borders of a country. It is equal to total Gross Domestic Income.
GDP deflator	An index of the general price level in the economy as a whole, measured by the ratio of gross domestic product (GDP) in nominal (i.e. cash) terms to GDP at constant prices.
Hazard assessment	Hazard assessment consists in using the information about the intrinsic properties of the substance to make an assessment of hazard in the following areas: 1) Human health hazard assessment 2) Human health hazard assessment of physicochemical properties 3) Environmental hazard assessment 4) PBT and vPvB assessment
Health impacts	Impacts on human health including morbidity and mortality effects. Covers health related welfare effects, lost production due to workers' sickness and health care costs.
Hedonic pricing	Deriving values by decomposing market prices into their constituent characteristics.

Impacts	All possible effects – positive or negative – including economic, human health, environmental, social and wider impacts on trade, competition and economic development.
Impact period	The period during which the impact is either triggered (called "Impact triggering period") or realised (called "Impact realisation period"). Impact *triggering* period should be representative for the changes that will happen when the non-use scenario(s) are introduced. Impact *realisation* period relates to the time period over which these impacts will materialise. The difference between the two is caused by a lag when the impact is realised.
Incremental costs	The costs that can properly be attributed to a "non-use" scenario, taking into account of what would have happened in the absence of the "non-use" scenario (i.e. the "applied for use" scenario).
Inflation	A change in the overall level of prices in an economy. For example, suppose that the prices of all goods in an economy rise by 5% during the course of a year, but relative prices of different goods remain unchanged. The rate of inflation is then 5%.
Internal costs	Internal costs are the costs of a "non-use" scenario that are borne by the person performing the action in the "non-use" scenario. For example, the internal cost of driving a car is the time cost and the financial cost of doing so (see also "external costs")
Investment cost	Capital or one-off cost that has a lifetime of several years.
Latest application date	Annex XIV (list of substances subject to Authorisation) will specify for each substance included in that Annex a date or dates, at least 18 months before the sunset date(s), by which applications for authorisation must be submitted if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s) until a decision on the application for authorisation is taken.
Manufacturer / Importer (M/I)	Any natural or legal person established within the Community who manufactures a substance within the Community (manufacturer) or who is responsible for import (importer) (Art 3(9) and (11)). Within this guidance the term is also used for suppliers of alternatives.
Marginal costs	The additional cost of making a small change in some variable. For example, the cost of making an additional unit reduction in emissions.
Market value	Market Value is the price at which an asset would trade in a competitive market. Market value is different from market price if the market is distorted /inefficient.
Monte Carlo analysis	A technique that allows assessment of the consequences of simultaneous uncertainty about key inputs, taking account of correlations between these inputs.
Multi-criteria analysis (MCA)	A technique that involves assigning weights to criteria, and then scoring options in terms of how well they perform against those weighted criteria. Weighted scores are then summed, and can then be used to rank options.

Net present value (NPV)	Present value is the discounted value of a stream of future costs and/or benefits. Net Present Value (NPV) is the value today of a project, an investment or policy. It is calculated as the sum of discounted streams of costs and benefits related to the activity in question.
Nominal price	The market price of a good or service at a point in time is called the nominal price. By contrast, the "real" price is the price of the good after factoring out the effects of inflation (a rise in the general price level) over time.
Non-threshold substance	A substance for which it is not possible to determine a threshold for effects (DNEL or PNEC) in accordance with Annex I of the REACH Regulation
Non-use scenario	Term that describes the scenario in which an authorisation application for use of a substance is not granted.
One-off cost	Cost that has a lifetime of several years, e.g. investment or capital costs. Also called fixed cost (as opposed to variable or operating or recurrent costs)
Operating cost	Recurrent or variable cost that reappears every year and usually depends on how much a particular machine produces. Examples are raw material costs, labour costs, energy costs or maintenance costs.
Operating income	Difference between operating revenue (=sales) and operating expenses (=all production costs). Operating income is one of the accountancy terms that express the profit of a company.
Opportunity cost	The benefit that could have been derived from using a given amount of resources in alternative "non-use" scenario, that is the value of foregone net-benefits created by the "next best" alternative.
Persistent Bioaccumulative Toxic (PBT)	The criteria for PBT substances are defined in Annex XIII of the REACH Regulation.
Polluters pays principle	The principle that the polluter ought to bear the cost of abating pollution and/or of compensating those affected by the pollution.
Present Value	The future value of an impact expressed in present terms by means of *discounting.*
Price elasticity	A measure of the responsiveness of demand to a change in price. If demand changes proportionally more than the price has changed, the good is "price elastic". An elasticity of 1 means that an 1% increase in price leads to a fall in demand of 1%. An elasticity of 0.5 means that a 1% change in the price leads to a fall in demand of 0.5%. If demand changes proportionally less than the price, it is "price inelastic".
Price index	A measure of the amount by which prices change over time. General price indexes cover a wide range of prices and include the GDP deflator and the Harmonised Index of Consumer Price (HICP). Special price indices apply to individual commodities or types of commodity.
Private costs	The costs to a group or sector of implementing a policy. To be distinguished from social costs.

Producers surplus	Denotes the difference between the true cost to a producer of producing a good (or volume of goods) and the price at which they can sell the goods.
Pure time preference	Pure time preference is the preference for consumption now, rather than later.
Real price	The price of a good or service after inflation has been stripped out, i.e. the nominal (i.e. cash) price inflated or deflated by a general *price index*, e.g. RPI or GDP deflator, relative to a specified base year or base date.
Real terms	The value of expenditure at a specified general price level (i.e. a cash price or expenditure divided by a general price index).
Recurrent cost	See "operating cost"
Regulatory procedure	Procedure for the adoption of implementing legislation that involves a vote by a Committee composed of the representatives of the Member States. The Council and the European Parliament have a role to play in accordance with Article 5 of Council Decision 1999/468/EC as amended by Council Decision 2006/512/EC. Authorisation proposals under REACH will be adopted in accordance with this regulatory procedure.
Relocation of production	Relocation of production is used in a generic manner describing either a situation where a production unit closes down in the EU and a new unit is opened up outside the EU, or where a non-EU supplier increases its production to offset reduced/removed production in the EU.
Residual value of capital	Relates to investment costs (e.g. buildings or equipment) that a firm has had to make to produce a good or a service prior to the introduction of or knowledge of the "non-use" scenario whose the impact is being analysed.
Response	The behavioural response of actors and of the market in relevant *supply chains* to each *RMO scenario*.
Revealed preference	The inference of willingness to pay for something which is non-marketed by examining consumer behaviour in a similar or related market.
Risk assessment	A procedure for determining the risk that a substance poses to health and the environment
Risk management measure (RMM) and Operational Conditions (OCs)	These terms are used for concrete risk management measures and operational conditions taken by Industry to control the exposure to the substance of concern. RMMs include e.g. containment of process, local exhaust ventilation, gloves, waste water treatment, exhaust air filters. More generally risk management measures include any action, use of tool, change of parameter state ***that is introduced*** during manufacture or use of a substance (either in a pure state or in a mixture) in order to prevent, control, or reduce exposure of humans and/or the environment. OCs include e.g. physical appearance of a mixture, duration and frequency of use/exposure, amount of substance, room size and ventilation rate. More generally the operational conditions include any action, use of tool or parameter state ***that prevails*** during manufacture or use of a substance (either in a pure state or in a mixture) that as a side effect might have an impact on exposure of humans and/or the environment. Registrants document, where required, risk

	management measures and operational conditions in an Exposure Scenario (ES) as a part of their Chemical Safety Report (CSR).
Sensitivity analysis	A "what-if" type of analysis to determine the sensitivity of the outcomes of an analysis to changes in parameters. If a small change in a parameter results in relatively large changes in the outcomes, the outcomes are said to be sensitive to that parameter.
Social costs	Denotes the opportunity cost to society and includes also external costs or externalities.
Social impacts	All relevant impacts which may affect workers, consumers and the general public and are not covered under health, environmental or economic impacts (e.g. employment, working conditions, job satisfaction, education of workers and social security).
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 the applicant in support to his application. An SEA may also be produced by any third party in support to information on alternatives. http://echa.europa.eu/reach/sea_en.asp
Socio-economic route (authorisation)	An *authorisation* may be granted if it can be demonstrated that the risk to human health or the environment from the use of the *Annex XIV* substance is outweighed by the socio-economic benefits and if there are no *suitable alternative* substances or technologies {Art. 60(4)}. See also Guidance on the preparation of an application for authorisation.
Stated preference	Willingness to pay for something that is not marketed, as derived from people's responses to questions about preferences for various combinations of situations and controlled discussion groups. (See Appendix C.2 for more information.)
Substance function	The function of the *Annex XIV* substance for the use/s being applied for is the task or job that the *Annex XIV* substance performs.
Substances of very high concern (SVHC)	1. CMRs category 1 or 2 2. PBTs and vPvBs meeting the criteria of Annex XIII and 3. substances – such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties (but not fulfilling the criteria of Annex XIII), for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points 1 and 2. Such 'substances of equivalent concern' will be identified on a case-by-case basis in accordance with the procedure set out in Article 59 of the REACH Regulation

Substitution plan	A commitment to take the actions needed to substitute the *Annex XIV* substance with an alternative substance or technology within a specified timetable. Guidance on developing a substitution plan can be found in the Guidance on the preparation of an application for authorisation.
Suitable alternative	An *alternative* that is *technically* and *economically feasible* for replacement of the *Annex XIV* substance where transferral to the alternative results in reduced overall risks to human health and the environment (as compared to the *Annex XIV* substance) taking into account risk management measures and operational conditions. It must also be available (e.g. can be accessed in sufficient quantity and quality) for transferral. See also Guidance on the preparation of an application for authorisation.
Sunset date	Annex XIV (list of substances subject to Authorisation) will specify for each substance included in that Annex the date (called "the sunset date") from which the placing on the market and the use of that substance shall be prohibited. That is unless an exemption applies or an authorisation is granted or an authorisation application has been submitted before the latest application date also specified in Annex XIV, but the Commission decision on the application for authorisation has not yet been taken.
Supply chain	In this guidance, the supply chain is the system of organisations, people, activities, information and resources involved in moving a substance from supplier to customer i.e. *manufacture/importers* (*M/I*) to *downstream users* and consumers, including use of articles containing the *Annex XIV*/ alternative substance. It also refers to supply chains for alternative techniques. See also *Actors in the supply chain*.
Supply curve	A curve relating the amount supplied of a product (per unit time) to the market price for the product.
Switching point or switching value	The value of an uncertain cost or benefit at which the best way to proceed would switch, for example from approving to not approving a project, or from including or excluding some extra expenditure to preserve some environmental benefit.
Technical feasibility	Relates to an *alternative* substance or technology which is capable of fulfilling or replacing the function of the Annex XIV substance, without compromising the functionality delivered by the substance and its use in the final product. See also Guidance on the preparation of an application for authorisation
Third party or Interested Third Party	Any organisation, individual, authority or company other than the applicant or the *Agency*/*Commission* with a potential interest in submitting information on *alternatives* or other information, e.g. on socio-economic benefits arising from use of the *Annex XIV* substance and socio-economic implications of a refusal to authorise.
Transfer payment	Transfer payments or 'transfers' refer to the transfer of value between sections of society. They do not represent an overall cost to society, simply a redistribution of value. Taxes and subsidies are examples of transfer payments.

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.
Unsuitable alternative	A term used in this guidance for an alternative that has been analysed as part of the Analysis of Alternatives where it is demonstrated that the alternative is not technically or economically feasible, is not available for use or does not reduce risks. The term is in particular used in this guidance to describe situations where the likely response from the supply chain to a refused authorisation would be to use the alternative that is considered unsuitable by the applicant. N.B. This is further detailed in Section 2.3.2.
Upstream supplier	Suppliers of raw materials or intermediates required in order to manufacture a substance.
Very Persistent and very Bioaccumulative (vPvB)	The criteria for vPvB substances are defined in Annex XIII of the REACH Regulation.
Wider economic impacts	Impacts that have macro-economic implications. Such impacts may include trade, competition, economic growth, inflation, taxes and other macro-economic effects.

ABBREVIATIONS

AoA	Analysis of Alternatives
CBA	Cost Benefit Analysis
CEA	Cost Effectiveness Analysis
CMR	Carcinogenic Mutagenic or toxic for Reproduction
CPI	Consumer Price Index
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
DU	Downstream User
EC	European Commission
ECHA	European Chemicals Agency
EU	European Union
GDP	Gross Domestic Product
HICP	Harmonised Index of Consumer Prices
ILO	International Labour Organization
MCA	Multi-Criteria Analysis
M/I	Manufacturer/Importer
MS	Member State
PBT	Persistent, Bio-accumulative and Toxic
PEC	Predicted Environmental Concentration
PED	Price Elasticity of Demand
PNEC	Predicted No-Effect Concentration
R&D	Research & Development
RA	Risk Assessment
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RPI	Retail Price Index
SEA	Socio Economic Analysis

SEAC	Socio Economic Analysis Committee
SME	Small and Medium-sized Enterprises
SVHC	Substance of Very High Concern
TGD	Technical Guidance Document
TtWA	Travel to Work Area
VOI	Value of Information
VSL	Value of a Statistical Life
vPvB	very Persistent very Bio-accumulative
WTP	Willingness to pay

1 INTRODUCTION TO THE GUIDANCE DOCUMENT

This document provides technical guidance on how to undertake socio-economic analysis (hereafter called SEA) as part of an authorisation application. The user of this guidance should be familiar with the authorisation process and also the guidance provided on how to prepare an authorisation application (see Guidance on the preparation of an application for authorisation).

In the context of REACH, SEA is an approach used to describe and analyse all relevant impacts (i.e. both positive and negative effects) of granting an authorisation compared to refusing to grant the authorisation. **In an SEA one needs to analyse and document whether the socio-economic benefits of continued use of the substance outweigh the risks of continued use for human health and the environment.** An SEA included in an authorisation application and contributions from third parties are used in the decision-making process (by the SEA Committee of the Agency and the European Commission) to assess the benefits and costs of granting / refusing the authorisation.

Annex XVI of the REACH Regulation outlines the information that may be addressed by those conducting a socio-economic analysis (SEA) and submitting an SEA with an application for authorisation, as specified in Article 62(5)(a). Annex XVI sets out what an SEA as part of an application for authorisation may include:

- *Impact of a granted or refused authorisation on the applicant(s).*
- *The impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences such as impact on investment, research and development, innovation, one-off and operating costs (e.g. compliance, transitional arrangements, changes to existing processes, reporting and monitoring systems, installation of new technology, etc.) taking into account general trends in the market and technology.*
- *Impacts of a granted or refused authorisation … on consumers. For example, product prices, changes in composition or quality or performance of products, availability of products, consumer choice, as well as effects on human health and the environment to the extent that these affect consumers.*
- *Social implications of a granted or refused authorisation. For example job security and employment.*
- *Availability, suitability and technical feasibility of alternative substances and/or technologies, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned. In the case of an application for authorisation, the social and/or economic impacts of using any available alternatives.*
- *Wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries) of a granted or refused authorisation. This may include consideration of local, regional, national or international aspects.*
- *In the case of a … refused authorisation the benefits for human health and the environment as well as the social and economic benefits. For example, worker health, environmental performance and the distribution of these benefits, for example, geographically, population groups.*

– *An SEA may also address any other issue that is considered to be relevant by the applicant(s).*

Annex XVI also states that:

> "*However, the level of detail and scope of the SEA, or contributions to them, shall be the responsibility of the applicant for authorisation, or, in the case of a proposed restriction, the interested party. The information provided can address the socio-economic impacts at any level.*"

The authorisation procedure applies to substances of very high concern {Article 55}. The overall authorisation process involves several steps including:

- identification of substances of very high concern;
- listing them on a candidate list and prioritisation of substances for inclusion in Annex XIV;
- the listing of these substances on Annex XIV (list of substances subject to authorisation);
- applications for authorisation;
- granting or refusing of authorisations; and
- reviewing granted authorisations.

A detailed description of the process up until a substance is included in Annex XIV is described in the Guidance on Annex XIV inclusion and the development of an application and review report is described in the Guidance on the preparation of an application for authorisation (Chapter 1). As already noted, the users of this SEA guidance are assumed to be familiar with the Guidance on the preparation of an application for authorisation, which it supplements.

Timing for submission of information

The timescale for the submission of information within the authorisation application process is set out in detail in the Guidance on the preparation of an application for authorisation (please refer to Section 1.5.3 and Figure 6 of that guidance).

There are two routes for an authorisation application; herein referred to as the 'socio-economic route' and the 'adequate control route' (see the Guidance on the preparation of an application for authorisation). The subsequent sections describe these two routes and where an SEA might be required or used within each route.

1.1.1 Socio-economic route

If the applicant **cannot demonstrate adequate control**[2] of risks arising from the use of the Annex XIV substance in his CSR, then he can **only** be granted an Authorisation if he demonstrates that:

- There are no suitable alternatives to the Annex XIV substance; **and**
- The socio-economic benefits of use of the Annex XIV substance (for the uses for which he has applied) outweigh the risks to the environment and human health.

The "socio-economic route" to obtaining an authorisation will **need an SEA** to demonstrate that the benefits of continued use of the Annex XIV substance outweigh the risks (Articles 60(3) and 60(4) of the REACH Regulation). In other words a key decision criterion in determining whether an authorisation to use an Annex XIV substance will be granted under the socio-economic route relates to whether the socio-economic benefits of using the substance outweigh the risks to human health and the environment. The SEA is a process that the applicant or third party follows to assess whether this is the case and thereby to put forward their case that the authorisation should or should not be granted.

The socio-economic route will always apply to applications for authorisations for Annex XIV substances that are PBT, vPvB, non-threshold CMRs and non-threshold substances of equivalent concern. This is because REACH defines that such substances cannot be 'adequately controlled' in accordance with section 6.4 of Annex I to the REACH Regulation. In addition, it also applies to CMRs and substances of equivalent concern that do have an effects threshold, but where it is not possible to reduce exposure below these threshold levels.

Under the socio-economic route, applicants should explain as part of the analysis of alternatives the actions that would be required, as well as the time-lines, to switch to an alternative substance/technique. This should apply in particular in cases where there is an alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") by the applicant, or another operator in the same market has already switched or will switch in the near future to alternatives. Having a robust analysis of the alternatives is critical for the application under the socio-economic route to be considered favourably and the absence of a justification as to the existence and suitability of alternatives may lead to a negative decision, particularly if third parties (who may provide information under Art. 64(2) or other applicants have already switched. Absence of research and development activities should lead to fixing shorter review periods.

[2] In accordance with section 6.4 of Annex I to REACH. It is set out in {Article 60(2)} of REACH.

1.1.2 Adequate control route

If the applicant **can demonstrate adequate control**[2] of risks arising from the use of the Annex XIV substance in his CSR (for the uses for which he has applied), then he can be granted an authorisation if:

- There are no alternatives to the Annex XIV substance; **or**
- There are suitable alternatives to the Annex XIV substance, for which he is providing a substitution plan.

This is called the "adequate control route" to authorisation.

To be granted an authorisation, the applicant must have demonstrated in the CSR which forms part of the application that the Annex XIV substance can be adequately controlled[2] (see Chapter 2 of the Guidance on the preparation of an application for authorisation).

The adequate control route will apply to applications for authorisations for Annex XIV substances that are CMRs for which a threshold can be established (i.e. a DNEL) and substances of equivalent level of concern for which a threshold can be established (i.e. DNEL or PNEC) and where the implemented and recommended Exposure Scenarios can be demonstrated to control risks below these levels. If the analysis shows that there are suitable alternatives available, then the applicant must prepare and submit a substitution plan. The substitution plan details how and in what timetable the applicant will conduct the transferral to the substitute. (See also Guidance on the preparation of an application for authorisation).

An SEA is not mandatory for applications that follow the adequate control route. However, the applicant is strongly advised to submit an SEA to support his application where he believes that socio-economic information is relevant; for instance in setting the time-limited review period or for defining any conditions in the authorisation decision.

1.2 Who is the guidance for?

This guidance is aimed at anyone who is intending to undertake a socio-economic analysis to develop information in support of an authorisation application or provide input on the socio-economic consequences of granting or refusing an authorisation. Within the authorisation process there are two types of actors who may conduct an SEA and submit the output of SEA to the Agency, and these are:

- **the applicant** i.e. the manufacturer/importer (M/I) or downstream user (DU), individually or jointly submitting an application for authorisation of use(s) of an Annex XIV substance; and
- **third parties** (an actor that is not the applicant and not the Agency) who have an opportunity to submit information on alternatives, as well as an opportunity to describe socio-economic benefits and costs arising from continued use or a refusal to authorise an Annex XIV substance. This is done in response to the publication on the Agency's website of broad information on uses for which applications have been submitted.

The guidance aims to describe ***good practice*** and is therefore also expected to be a useful reference document for the Agency's SEA Committee which is responsible for the review and drafting of opinions on (among other things) the socio-economic factors, as well as availability and suitability of alternatives, within an authorisation application and any third party contributions. The guidance

may also assist the Commission who will make the final decision on authorisation of the use of an Annex XIV substance via the Comitology procedure (see glossary).

Most of the guidance describes what needs to be done from an applicant's perspective. If a third party wants to submit a full SEA, they should follow more or less the same steps as an applicant, although they may have access to different types and levels of information which they may want to submit. If a third party only wants to submit input on certain aspects of an SEA, they should follow the guidance relevant to those aspects.

1.3 The aims of socio-economic analysis (SEA)

1.3.1 Why is an SEA important?

REACH Title VII sets out the process of how an authorisation is granted. The applicant will want to make sure that the Agency Committees for Risk Assessment and for Socio-Economic Analysis as well as the Commission can act swiftly following their application. This can best be done where a good quality application is produced, which includes the justification for granting an authorisation and provides a clear view of the costs and benefits of a granted authorisation.

The SEA facilitates a systematic and comprehensive comparison of the relevant costs/benefits of continuing to use an Annex XIV substance with the costs/benefits of no longer being able to use the substance. It can be used by the applicant or third party to provide information on whether the authorisation should or should not be granted on the basis of socio-economic arguments (as well as the other aspects included within the application or other submission). (See also Guidance on the preparation of an application for authorisation.)

The situations in which the **applicant** (i.e. Manufacturer/Importer (M/I) and/or Downstream User (DU)) may need or may wish to submit an SEA as part of their application are addressed below:

Socio-economic route

- **Purpose 1:** Where adequate control of risks arising from the use of the Annex XIV substance cannot be demonstrated in accordance with Annex I, section 6.4[3] for a particular use(s) of the Annex XIV substance and there are no suitable alternative substances or technologies.

  In this situation an authorisation can only be granted if it is shown that that the socio-economic benefits outweigh the risks to human health and the environment arising from the use of the substance {Article 60(4)}. In these cases, submission of an SEA is, in practice, a compulsory part of an authorisation application. This is because presenting an SEA with the application is the only way for the applicant to demonstrate that socio-economic benefits outweigh the risks.

  This purpose will be the main focus of the guidance. However, the guidance and its methodologies can also be used for other types of Authorisations as outlined below.

Adequate-control route

- **Purpose 2:** Applicants can, if they wish, support their application with an SEA under the adequate control route for authorisation, where their analysis of alternatives shows that there are

[3] This may be either because adequate control is not demonstrated for threshold CMRs or other threshold substances, or cannot be demonstrated for non-threshold CMRs, other non-threshold substances and PBT/vPvBs.

no suitable alternatives. The SEA may provide additional socio-economic information, which can be used by the Agency Committees and the Commission in setting conditions for the authorisation or defining the review period.

- **Purpose 3:** Applicants can, if they wish, submit documentation of an SEA in support of a substitution plan.

Previously-granted application

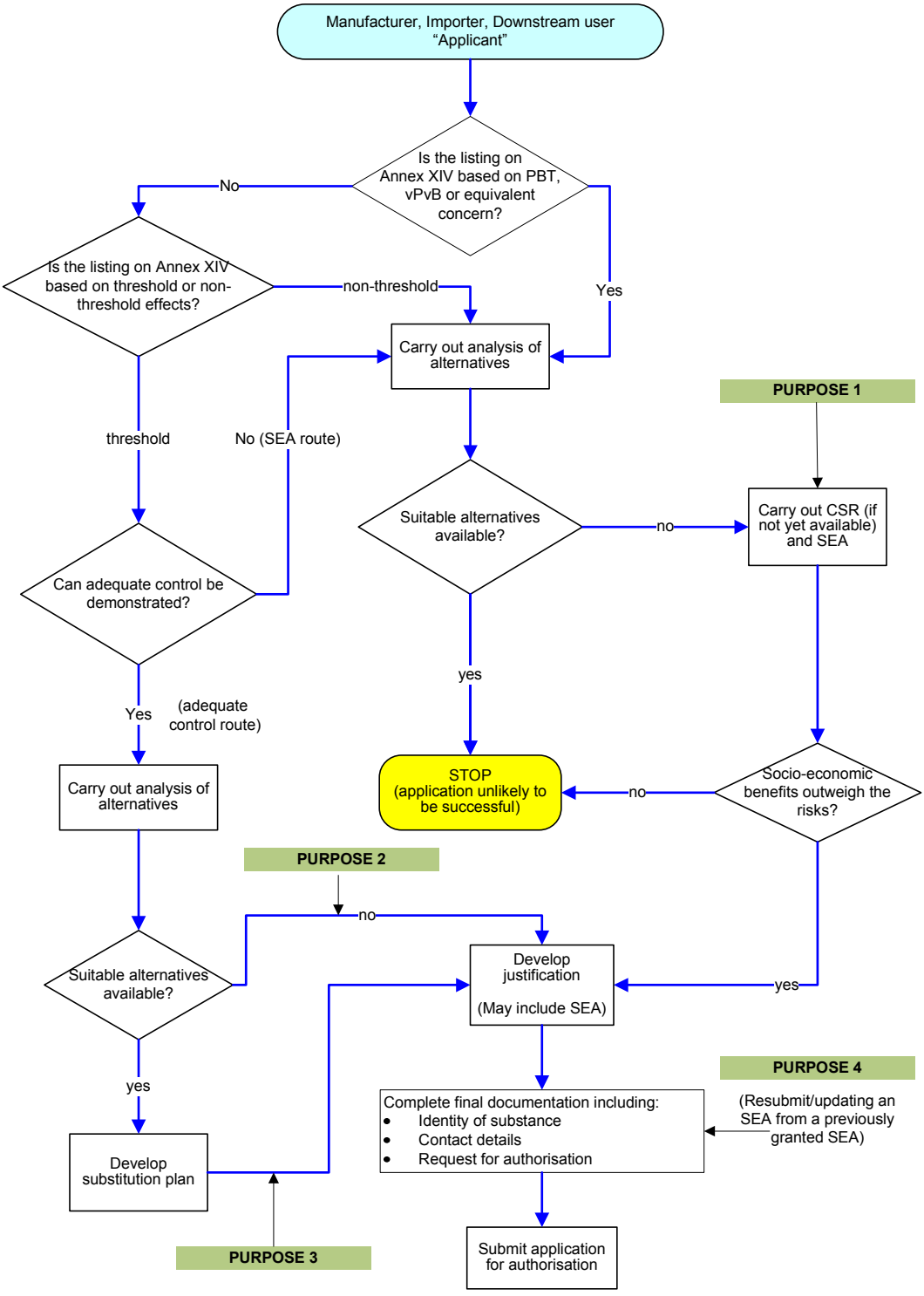
- **Purpose 4:** An applicant for an authorisation may use or refer to the output of an SEA (and/or other parts of the application) of a previously granted application (with the previous applicant's permission) and update this as necessary {Article 63(2)}.

  This purpose is not explained further in this guidance, as it should be obvious to the applicant what parts of the previously-granted application should remain, be updated or taken further.

The Commission can also use the SEA parts of the authorisation application when deciding on the timing of the review, on any conditions under which the authorisation is granted and on any monitoring arrangements.

Figure **1** summarises these circumstances in a flow diagram.

Figure 1 Flow diagram for Authorisation



In Figure **1** the parts of the authorisation process that are relevant to this guidance are highlighted in green.

1.3.2 Purpose 1: SEA supporting an application under the socio-economic route

The documented output of the SEA is an essential part of the application in order for the applicant to put forward their case that the socio-economic benefits outweigh the risks to human health and the environment. The analysis of alternatives (Chapter 3 in Guidance on the preparation of an application for authorisation) will have demonstrated that the applicant considers there to be no suitable alternatives available to him and therefore the documentation of the SEA is used by the applicant to set out the socio-economic arguments in order to justify continued use of the substance.

For **non-threshold substances**[4] there is no theoretically safe exposure level (i.e. adequate control of risks arising from the use of the Annex XIV substance can not be demonstrated according to REACH Annex I, section 6.4). Therefore, the demonstration of the level of control (Risk Management Measures and Operational Conditions) and resulting residual risk as set out in the chemical safety report (CSR) needs to be balanced against the socio-economic benefit of continued use.

For **threshold substances** (e.g. CMRs for which a threshold can be determined) for which adequate control of risks arising from the use of the Annex XIV substance {Annex I (6.4)} can not be demonstrated; the arguments and analysis may additionally include the socio-economic implications of actions required to adequately control the risks (comparing with control measures set out in the CSR). In these cases, the SEA should also demonstrate that the residual risk from the continued use (when not adequately controlled) is outweighed by the benefits of continued use.

Robust arguments will need to be presented in the documentation of the SEA that compare the risks with the benefits and show how the continued use of the substance will continue to benefit society. Consideration will also need to be given to how this may change over time.

The Commission, based on the opinion of the regulatory committee[5] will make the final decision on whether to grant or refuse an authorisation (taking into account the opinions of the Agency Committees). It is therefore of utmost importance that the applicant transparently documents not only his own conclusions, but also how he came to those conclusions, including for example assumptions, data collected, assessment and methods applied.

The authorisation may be reviewed at any time on the basis of changed circumstances or new information on substitutes {Article 61(2)} including the socio-economic impacts.

Where the SEA is required for an authorisation by the socio-economic route, the aim is clear:

To assess whether the socio-economic benefits of continued use[6] of the Annex XIV substance outweigh the risks to human health and the environment.

[4] Non-threshold CMR, other non-threshold substances, PBT or vPvB and substances identified as a SVHC on the basis of PBT / vPvB properties.

[5] See also glossary: *comitology procedure* and *regulatory procedure*.

[6] A use is defined as the use under the conditions set out in the Exposure Scenarios in the applicant's CSR. The SEA will cover the specific uses that are included in the authorisation application (see Guidance on the preparation of an application for authorisation).

The documentation of the SEA should present the socio-economic benefits arising from continued use (for the uses for which the applicant has applied) and socio-economic implications of a refusal to grant the authorisation.

If the SEA does not demonstrate that the socio-economic benefits outweigh the risks, then the application process should be terminated. Therefore, work on the SEA should preferably be undertaken at an early stage, typically concurrently with the analysis of alternatives.

If the analysis of alternatives uses arguments of economic infeasibility (to demonstrate that a potential alternative is not suitable), an applicant might want to further develop this reasoning in the SEA.

1.3.3 Purposes 2-3: SEA supporting an application under the adequate control route

This is the situation in which adequate control of risks arising from the use of the Annex XIV substance **can** be demonstrated {Article 60(2)}. The documentation of an SEA **may** be used in support of the application. SEA could account for the commitments laid out in the substitution plan and include analysis and evaluation of the socio-economic implications of the transfer from the Annex XIV substance to the alternative.

Purpose 2

Under the adequate control route, where the applicant finds from his analysis of alternatives that there are no alternatives, the applicant may still wish to support his application with an SEA providing additional socio-economic information, which can be used by the Agency Committees and the Commission in setting conditions for the authorisation or defining the review period[7].

The aim for an SEA supporting an application by the adequate control route (where there is/are no alternative/s) is to provide additional socio-economic information, which can be used by the Agency Committees and the Commission in settings conditions for the authorisation or defining the review period.

Purpose 3

The substitution plan is a **commitment** to take actions needed to substitute the Annex XIV substance within a given timetable. It has to indicate the steps that will be taken to substitute the Annex XIV substance as well as the specific deadlines for such actions. SEA may, in this case, play an important role in determining the justifications for the steps and in particular the timing presented in the plan. The Commission will take into account information in the substitution plan when deciding on the duration of the time-limited review period. Details of how to produce a substitution plan are set out in Guidance on the preparation of an application for authorisation (Chapter 4).

[7]In this case the granting of an authorisation is not dependent on the applicant showing that the socio-economic benefits of continued use outweigh the risks. However, he may wish to support the argument by demonstrating that the use of possible alternatives will lead to unacceptable socio-economic impacts. Therefore, the analysis will be similar to that presented under the socio-economic route. In addition, the arguments set out in the SEA report can be used to give the Agency and Commission information and context to assist in setting the review period and/or any conditions.

The aim for an SEA supporting an application by the adequate control route where there is/are alternative/s is to assess the socio-economic benefits of a phased transition to the alternative/s.

The applicant will need to show in their substitution plan a commitment to transferral to the alternative(s). Therefore the timing of the transferral is critical. The function of the documentation of the SEA in this case is to set out clear socio-economic arguments that support a proposed timescale. These analyses may, for example, be based on the development of the market for the alternative(s) and accounting for the barriers to (such as costs of) transferral.

1.4 "Quick Guide" - How should the Socio-economic Analysis (SEA) be undertaken?

This section provides a brief overview of the aim of and process for developing and documenting an SEA. Whilst this document is intended to provide guidance (and not a prescribed approach), **it is strongly recommended that the user should familiarise themselves with the whole document prior to developing their SEA**.

1.4.1 The overall SEA process

The main purpose of the SEA report is to support the basis for decision making on an authorisation application under REACH. The key challenge when developing an SEA is being able to use the information available to identify (and where possible quantify) the impacts that could occur under a refused authorisation in a proportionate and robust way.

One of the main challenges encountered when undertaking an SEA is the definition of the "non-use" scenario(s) (i.e. "what happens" if an authorisation is refused), particularly in relation to what the likely response of relevant actors (manufacturers, downstream users, consumers, suppliers of alternatives, etc.) would be if the substance is no longer available for a given use. A scenario is made up of the likely response for each actor in relevant supply chains. Because there can be multiple responses to a refused authorisation by any actor, it may be necessary to have more than one possible response scenario to a refused authorisation. There is then a further challenge in being able to find and use the right data to estimate the impacts under each of these foreseen responses.

What makes a 'good' SEA? - Key features of undertaking an SEA

The following are key features of the SEA approach described in this guidance. The guidance sets out a systematic approach, helping the user to produce a proportionate and unbiased SEA. The applicant or a third party can choose to follow a different approach if they wish.

- Undertake the SEA as an **iterative process**. Start with a qualitative assessment based on readily available data and then in additional iterations (if these are considered to be required) aim to provide more detail and a more quantitative assessment until all key impacts are covered in a sufficiently robust way to draw a conclusion.
- Identify the "non-use" scenario (or scenarios) early in the process. It is important to consider all possible types of responses to non-availability of the substance (though those most likely

to occur will obviously need most detailed assessment) and this is likely to be best done in consultation with the relevant parts of the supply chain and possibly also consumers/customers using the articles produced by using the substance. The scenarios that are considered relevant determine the scope of the SEA regarding the types of impacts to be included and factors such as time period and geographical coverage.

- Undertake the SEA in five stages:
    - Stage 1: Set the aims of the SEA (why is the SEA being developed?)
    - Stage 2: Set the scope of the SEA (what are the "applied for use" and the "non-use" scenarios and what are the supply chains involved)
    - Stage 3: Identify and assess the impacts (what are the expected impacts of being granted the authorisation compared a refusal to grant it – i.e. what are the differences between the "applied for use" scenario and the "non-use" scenario)
    - Stage 4: Interpretation and drawing conclusions (bring the human health, environmental, economic, social and other impacts together to assess the net benefits and net costs of granting/refusing the authorisation)
    - Stage 5: Present the results (prepare a report that transparently documents the results and assumptions used in the analysis)
- Remember to **consider uncertainties** that may arise during the SEA process:
    - Consider uncertainties throughout the SEA process (not just at the end of the analysis)
    - Minimise uncertainties where possible
    - Assess the importance of the uncertainties to the outcome of the SEA. This may be used to decide what further collection of information can best reduce the uncertainties and therefore lead to a robust outcome of the SEA
    - Keep track of/document all uncertainties
- Transparently present and document the main decisions/assumptions made during the development of SEA, including 'negative' decisions on, e.g. why the scope was restricted to a certain geographical area or to a certain part of the supply chain and why certain impacts have not been considered.
- There is no golden rule as to how long the SEA report should be, but a summary of the SEA should be provided and this should in general be restricted to no more than 10 pages.

An illustration of the iterative nature of undertaking an SEA is shown in Figure 2.

Figure 2 Simple flow chart of the process of developing an SEA

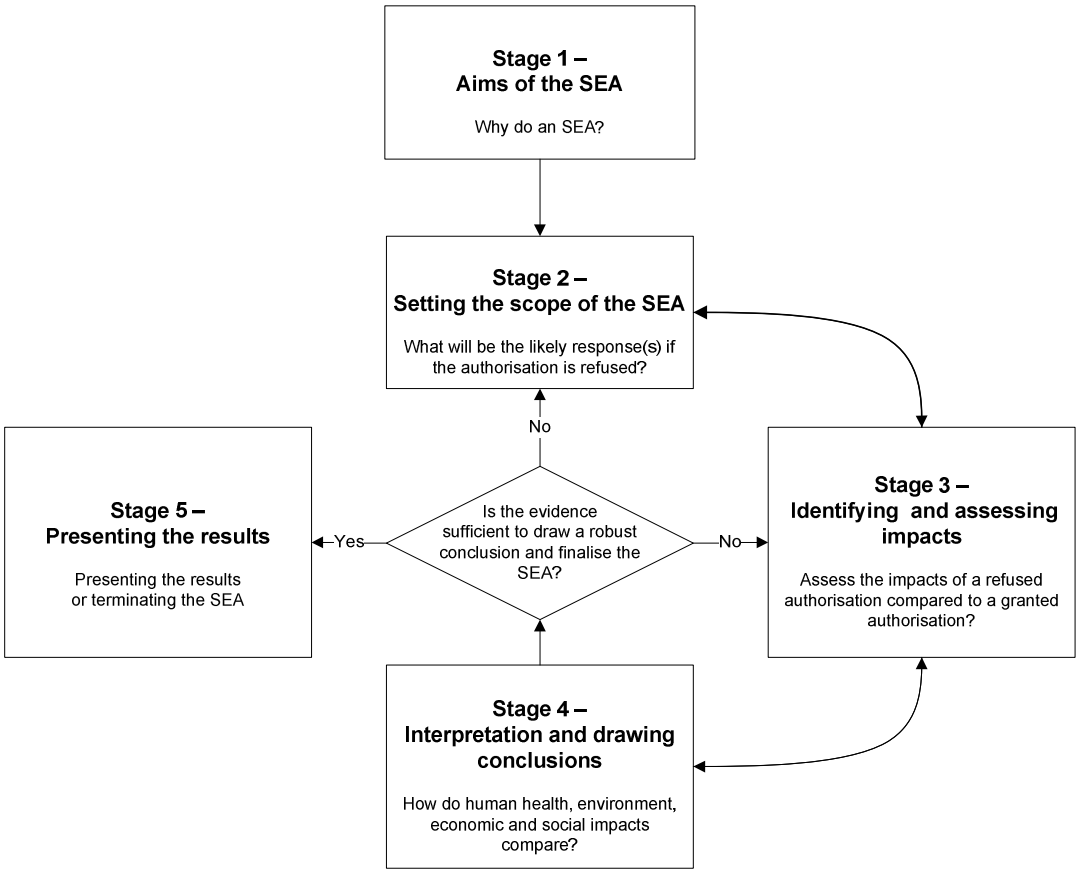
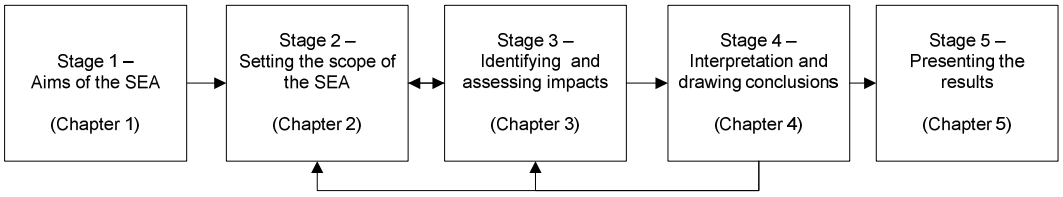


Figure 2 shows the five proposed stages and the suggested iterative approach whereby an SEA is first undertaken based on available data from the development of the other parts of the authorisation application and – where considered necessary and proportionate – further qualitative, quantitative and/or monetised assessments are produced. During Stage 4, the evidence is evaluated allowing the applicant to consider whether a robust conclusion can be drawn. The applicant might decide:

- To collect more data and undertake more analysis in order to draw a conclusion (go to step 2 or 3);
- That the socio-economic benefits do not outweigh the risks to human health and the environment and that the application is not likely to be successful. The applicant would then be expected to terminate the application process;
- That the socio-economic benefits do outweigh the risks to human health and the environment. The applicant then continues to Stage 5 to report the findings of the SEA and include it as part of the authorisation application.

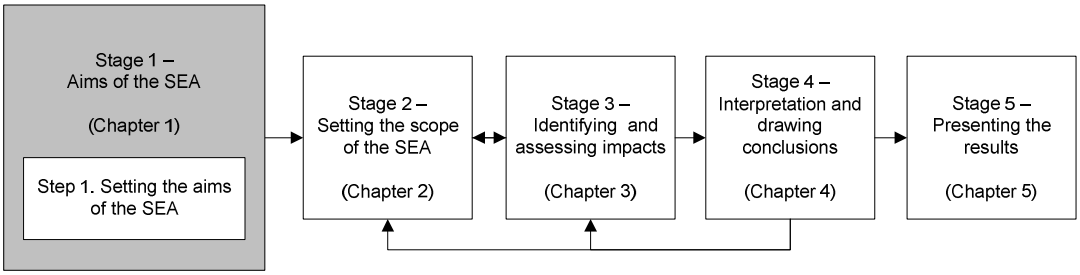
The next sections describe each of the five stages in brief (detailed guidance is provided in Chapters 2 to 5). Throughout the guidance a simple illustration of the five stages is used to indicate where each chapter fits in. This is shown in Figure 3 listing also the chapter number where the detailed guidance on each stage is presented.

Figure 3 SEA process simplified with reference to guidance chapters



1.4.2 Stage 1: Setting the aims of the SEA

Figure 4 SEA process - Stage 1



What is Stage 1: Setting the aims of the SEA?

The purpose of Stage 1 -"Setting the aims of the SEA" - is to provide the entry point to the SEA. It is where the user answers the question: Why is the SEA or input to one being developed? In most cases, it will be clear to the applicant why the SEA is needed or useful but specifically defining the aims early in the application process will help to focus the SEA.

Input from a third party could address any or all aspects. A third party therefore needs to define specifically what it wants to achieve by providing input.

How is Stage 1 undertaken?

The reasons for conducting an SEA were explained in section 1.3, while the main objectives for the applicant and a third party are set out below.

The Applicant

Socio economic route (where the SEA is the only means of providing the necessary evidence that the socio-economic benefits of the continued use outweigh the risks):

- The aim for an SEA supporting an application by the socio-economic route is to assess whether the socio-economic benefits of continued use of the substance outweigh the risks to human health and the environment.

Adequate control route (where the SEA can be submitted to support the application):

- The aim for an SEA supporting an application by the adequate control route where there is/are no available alternative/s can be to provide additional socio-economic information, which can be used by the Agency Committees and the Commission in setting conditions for the authorisation or defining the review period (Purpose 2).
- The aim for an SEA where there is/are available alternative/s can be to support the proposed substitution plan by setting out the socio-economic benefits of a proposed phased transition to the alternative/s (Purpose 3).

As the SEA is not required for applications following the adequate control route, the applicant should consider specifically what aspects of the application the SEA should support.

Third party

Third parties may submit an SEA or input to one regarding any aspects of the application. It is therefore important that they clearly define the aim of their submission. They might, for example, focus the SEA on:

- Providing information on an Annex XIV substance and the socio-economic implications of its use or of a withdrawal of such a use if it would no longer be possible.
- Providing information on a potential alternative and the socio-economic implications of using the alternative.

Furthermore, a downstream user may wish to support an authorisation for his own use of an Annex XIV substance but not want to share information with the applicant. Therefore they can submit a separate SEA. In this case, the aims for the downstream user will be the same as for the applicant.

Further details related to third party submissions

Interested third parties are invited to submit information on alternatives on the basis of broad information on uses applied for published by the Agency on its web site {Article 64(2)}[8]. The timing of the submission of comments to the Agency is set out in Section 1.5.3 and Figure 6 of the Guidance on the preparation of an application for authorisation.

[8] Recital 81 of the REACH Regulation also refers to SEAs submitted by third parties that should be taken into account by the Agency in its opinions.

The comments and information submitted by a third party could include an SEA or information that may contribute to one demonstrating socio-economic benefits and costs arising from a use or a refusal to authorise use of an Annex XIV substance[9].

Interested third parties can be any organisation or individual and a third party may submit information in response to information published by the Agency {Article 64(2)} regarding the uses of the Annex XIV substance that have been applied for. A third party may also provide information on alternatives, which might affect the conditions of the authorisation through consideration of the information by the Agency committees. The importance of socio-economic information from third parties in the context of an authorisation is that the Agency Committee for SEA takes the information into consideration in determining its opinion on the authorisation {Article 60(4)(b) and Article 64(3)}.

However, a key consideration for third parties is that, in general, they will have less information on which to base their analysis than the applicant. In particular they will normally have less precise information on the uses applied for and related conditions (indeed they will only be able to view broad information on the uses applied for on the Agency's web site).

The third party will therefore have to consider the purpose of submitting an SEA or contribution to one, and the type and robustness of the data that they should submit to support this. The setting of the boundary for the analysis will be a key aspect, as this will determine the focus of and extent of the analysis. Therefore, analysis of uncertainties and deficiencies in data may be particularly important.

A key aspect for third parties is the need to make the best use of the information and to make their case as robust as possible (see also the Guidance on the preparation of an application for authorisation Chapter 5 for guidance for third parties in relation to information on alternatives). Thereby, the SEA Committee can clearly see how the information contributes to the opinion development and how the information supports or refutes the arguments being put forward by the applicant.

Third parties' submissions may include an analysis related to feasibility or non-feasibility of transferring to alternatives based on information available to them.

The third party may be providing information to supplement an application on the basis that there are no suitable alternatives to the Annex XIV substance and continued use is of particular importance to the economy or the society as whole. Thus the SEA or information supporting one may focus on the wider impacts of the substance not being granted an authorisation.

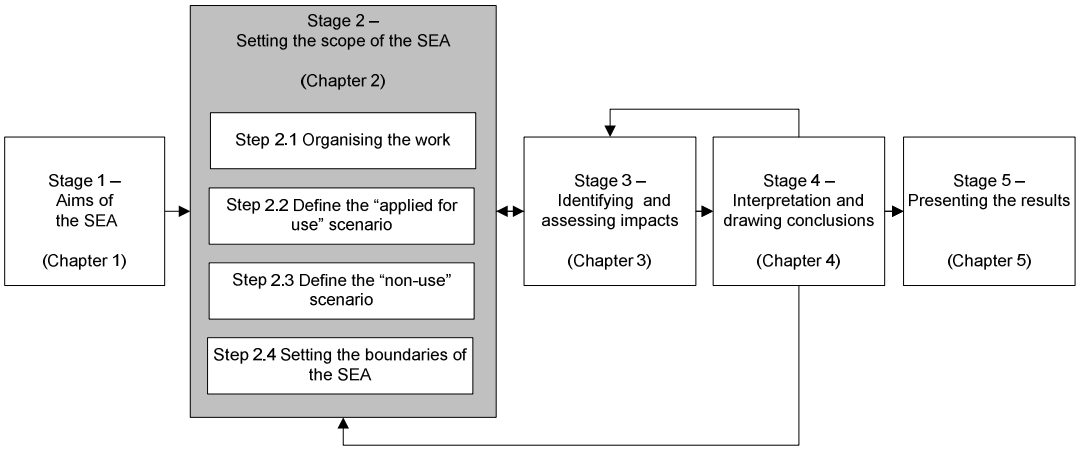
[9] Although Article 64(2) refers only to 'information on alternative substances or technologies' it is assumed that this information could include an SEA (or a contribution to one). Further to this, Article 64(3) states that: "The Committee for Socio-economic Analysis may, if it deems necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies" and "Each committee shall also take into account any information submitted by third parties". Again it is assumed that this additional information could include an analysis of the socio-economic advantages and drawbacks of the use of substance and/or the alternative substance or technology. Furthermore, Article 60(4)(b) mentions information on socio-economic benefits from the use of an Annex XIV substance and socio-economic implications of a refusal to authorise such a use, as demonstrated by "other interested parties", that should be considered by the Commission when deciding whether or not to grant an authorisation. This guidance focuses on information related to socio-economic aspects. Guidance for third parties in relation to submitting information on other aspects is in Guidance on the preparation of an application for authorisation.

For applications using the adequate control route, third parties may wish to provide information on alternatives and the socio-economic implications of their use.

Furthermore, a downstream user may wish to provide information in relation to an authorisation for his use of a substance on the basis of lack of alternatives and the socio-economic benefits of using the substance in cases where he is uncertain whether adequate control of risks arising from the use of the Annex XIV substance can be demonstrated (i.e. through the socio-economic route).

1.4.3 Stage 2: Scoping phase

Figure 5 SEA process – Stage 2



What is Stage 2: Scoping phase

Setting the scope of the SEA (the "scoping phase") is where it is defined what will happen if the authorisation is refused. The analysis of alternatives must have shown that there are no suitable and available alternatives for the applicant[10]. It is therefore important to predict how the supply chain will react if the authorisation is refused and what further impacts this will have in other supply chains and for society as a whole. The scoping stage thus involves identification of possible responses to the non-availability of the substance. Following on from the identification of the possible responses, it should be possible to define some of the boundaries of the SEA in terms of the time period covered, the geographical areas and the types of impacts to be assessed.

The scoping stage involves identifying the likely response(s)[11] and first considerations of the related impacts if the authorisation is refused. Initial feedback from consultation with the supply chains will be vital to understanding how relevant supply chains will react to a refused authorisation. When

[10] In the case of an SEA following the adequate control route and where the SEA supports a substitution plan, the applicant considers that an alternative exists.

[11] Responses here mean the behavioural responses of actors in the supply chain and of the markets associated with the supply chain.

relevant impacts are analysed in more detail (in the next stage) further iterations of the SEA process may be required to adjust the boundaries of the SEA.

If there is more than one possible response and if there are a range of possible impacts (these are both very likely), the applicant should consider the likelihood of the different responses and the importance of the impacts of those responses in setting a defined scope of the SEA. It is important to make sure that all relevant impacts are considered systematically and not omitted without any consideration. Undertaking an SEA has the potential to be much more time and resource intensive (and could include unnecessary data collection and analysis) in cases where the scope is not clearly outlined.

How is Stage 2 undertaken?

There are four proposed steps in the scoping phase:

- Step 2.1: Organising the work. When preparing to carry out an SEA it may not initially be clear how much work will be involved (this will vary on a case-by-case basis). It is advisable to have an initial kick off meeting or 'brainstorming' session with a multidisciplinary team to help decide what is required in order to develop the SEA, how this can be achieved with the resources available. The brainstorming session can also consider what type of consultation would be useful for the development of the SEA. In general, such consultation should take place as early as possible. Appendix A provides guidance on how to develop a consultation plan.

- Step 2.2: Define the "applied for use" scenario. This scenario is typically the continued use of the Annex XIV substance for those uses that are being applied for under conditions described in the applicant's Chemical Safety Report (CSR) – in particular in the Exposure Scenario(s)(ES).

- Step 2.3: Define the "non-use" scenario. This is a key element of the SEA. In the event that the authorisation application is refused, how will the supply chain react? In determining the answer to this question, consultation with the supply chain will generally be very important. There may be more than one possible "non-use" scenario and, in such cases, they may all be taken forward to the next stage involving assessing the impacts. Alternatively, the user may decide not to consider some scenarios further because they are considered too improbable; similarly those scenarios considered to be most likely may be analysed in more detail than those that are less likely. However, it is advisable to document them all, including reasoning for not considering certain scenarios further.

- Step 2.4: Set the scope of the SEA by defining time periods and geographical boundaries and the types of impacts to be covered in the SEA. Having defined the "applied for use" and the "non-use" scenarios, it may be possible to determine these factors (e.g. competitiveness and trade impacts might be relevant / not relevant depending on what type of behavioural responses are considered most likely). When relevant impacts are analysed in more detail (in the next stage) further iterations of the SEA process may be required to adjust the boundaries of the SEA.

"Applied for use" and "non use" scenarios

The two situations are as follows: i) the authorisation is granted and the applicant/his DUs can continue using the substance for the specific uses covered by the authorisation; and ii) the authorisation is refused and the substance can not be used. In this guidance these two situations are called the **"applied for use"** and "**non-use"** scenarios.

The "applied for use" scenario could in most cases also be called the *baseline scenario* while the

"non-use" scenario is the *response scenario*. There are two exceptions: The application could be for a new use or for reintroducing a use that is not currently taking place. Such situations would occur if an applicant identifies a need for a (new) use of the substance after the Application deadline for that substance has expired.

The situation where the application is for an existing use is expected to be the most common situation. Hereafter in this guidance, this is generally assumed to be the "applied for use" (baseline) scenario. Specific reference to the two other situations is only made where this distinction is important; for example in defining the baseline in the scoping phase.

What is the "non use" scenario(s)

Characterising the response to a refused authorisation application is a key element in the SEA. The following types of responses should typically be considered, in close consultation with the supply chain:

Use of an unsuitable alternative (see section 2.3.2 for details);

Changed quality of the goods that the substance is used for or quality of processes the substance is used in;

Certain goods or services no longer being provided by the applicant (or his customers);

Relocation of certain production activities outside of the EU; or

Any other relevant "non-use" scenarios.

It might not be clear from the consultation and from available information which scenario is the more likely. In such cases, all relevant scenarios should be taken forward. In the next stage – Assessing impacts – collection of more information may allow for the SEA to be focused upon the most likely "non-use" scenario(s).

In identifying the possible "non-use" scenarios, it might be useful to conduct a "brainstorming" type of meeting/workshop/conference call involving key experts from the relevant stakeholders. Such an event could focus on firstly determining the possible "non-use" scenarios and secondly, help identifying the likely impacts of the scenarios (identifying impacts are described in the next stage). The relevant stakeholders could be representatives from the supply chain for the Annex XIV substance but also those from other supply chains if the "non-use" scenario potentially involves other substances or technologies.

What are the SEA boundaries?

The scoping of what needs to be covered in terms of supply chains, time period, geographical area and types of impacts is highly dependent upon what has been identified as the likely response(s) under the "non-use" scenario.

Some indications of the considerations to be taken into account are provided below:

Relevant supply chains:

Effects can appear both upstream (suppliers) or downstream from the uses included in the authorisation application. The industries directly affected by a refused authorisation will have to use other substances, technologies or products or modify the characteristics of the product, all of

which have effects on different supply chains. Also other connected supply chains may be affected by the refused authorisation. An important element of setting the boundaries is to identify which supply chains would be affected.

The identification of relevant supply chains can be supported by drawing a process tree of each scenario. The process tree should include all relevant processes related to material and energy flows going into and out of the process(es) in which the substance (or alternative) is used, including related up- and downstream processes and material flows.

Time boundaries of the SEA:

Several considerations should be given to the time boundaries of the SEA, including:

- The time period considered that triggers the impacts (impact *triggering* period). This should be representative for the changes that will happen when the non-use scenario(s) are introduced – as compared to the applied for use scenario.

- The time period over which these impacts will materialise (impact *realisation* period).

- The issue of how impacts are compared over time.

See Section 2.4.2 and 3.7 for further explanation and details.

Geographical boundaries:

All significant impacts should be included independently of where they occur. It should be clearly stated whether impacts occur inside or outside the EU.

General considerations:

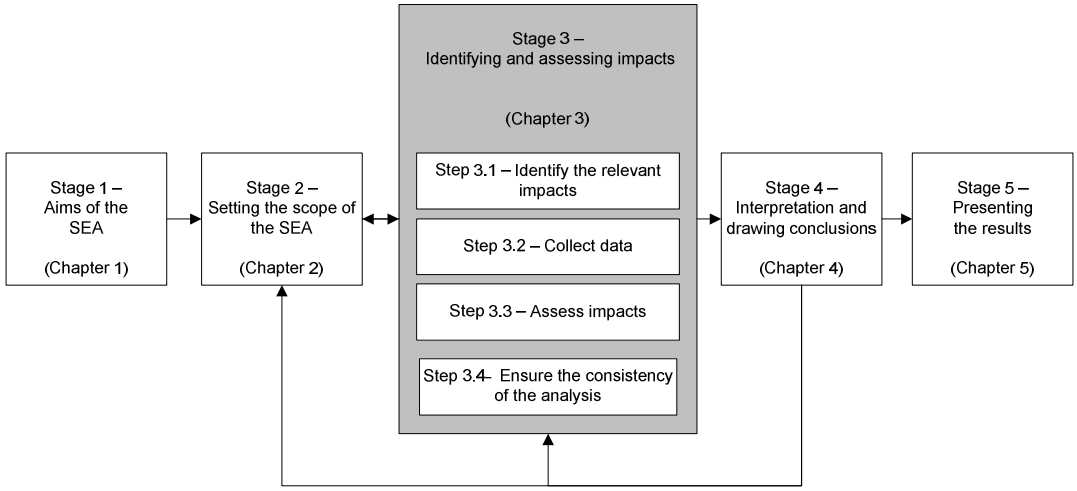
It should be noted that there are no prescribed boundaries on the types of impacts to be considered. All types of impacts (human health, environmental, economic and social) should be considered. Stage 3 includes the guidance on how to identify potential impacts within each type and how to assess their importance.

Setting the boundaries will involve giving some – at least qualitative - consideration to the impacts foreseen as this will implicitly steer what is considered important to include and what need not be included. Likewise, the further identification and assessment of impacts in Stage 3 may trigger the need to revisit the boundaries of the analysis as certain issues may turn out to be more significant than originally envisaged.

The outputs from Stage 2 include firstly an identification and description of the “applied for use” and the “non-use” scenarios. Secondly, they define the scope of the SEA in terms of relevant supply chains, types of impacts, time period and geographical boundaries.

1.4.4 Stage 3: Identifying and Assessing Impacts

Figure 6 SEA process – Stage 3



What is Stage 3: Identifying and Assessing Impacts?

This stage involves the identification and assessment of impacts. The aim is to answer the question: What are the impacts of the "non use" compared to the "applied for use" scenario? The human health, environmental, economic, social and other impacts are determined as the differences between these two scenarios. If there is more than one likely response under the "non use" scenario, the differences in the impacts between each response and the "applied for use" scenario should be identified and analysed.

How is Stage 3 undertaken?

Stage 3 includes four generic steps:

- Step 3.1: Identification of impacts. The potential impacts of a granted or refused authorisation are identified through data already collected as part of the authorisation application and through further data collected based on the baseline and non-use scenarios defined in Stage 2. This involves, where needed, consultation with relevant supply chains and with other relevant stakeholders.
- Step 3.2: Collection of data. Having identified the most relevant impacts, the data necessary for undertaking the assessment needs to be collected. Most data on the human health and environmental risks of the Annex XIV substance will already be available as part of the authorisation application. In situations where the likely response from the supply chain to the refused authorisation would be to use an alternative that is considered unsuitable by the applicant in the analysis of alternatives, some data on the alternative will also have been collected and analysed as part of the analysis of alternatives. Responses involving use of alternative substances or techniques that in the Analysis of Alternatives were quickly identified to be unsuitable (i.e. technically and/or economically unsuitable and/or not reducing health and environmental risks) for the applicant will often require additional data on health and the

environment[12]. There can also be cases where there are no alternatives (not even unsuitable ones). In such cases the likely response may be that the service/function the substance provides would no longer be available for society. Additional data on health and the environment would need to be collected for that situation as well. Similarly, data will need to be collected in order to understand and analyse the economic and social aspects. Key sources of economic and social data will include (but are not limited to) statistical and market reviews, the supply chain and trade associations.

- Step 3.3: Assessment of impacts. The assessment of impacts can be done at different levels of quantification or may only be done qualitatively. Following the suggested iterative approach to conducting an SEA, a first assessment may be undertaken building on immediately available data which is likely to lead to a mixture of quantitative and qualitative results. In subsequent iterations (if these are undertaken) more detail and further qualitative, quantitative and monetised information may be added.

- Step 3.4: Ensure the consistency of the analysis. Before a robust conclusion can be drawn, a series of good practice checks should be carried out on the analysis undertaken. This will include checks to make sure that the results are not misleading to the reader and that impacts are not over/under estimated.

It is important to emphasise that the assessment of impacts should **focus on the *difference* between the "applied for use" scenario and the possible "non-use" scenario(s)**. For example, what are the changes in costs associated with a "non-use" scenario compared to the "applied for use" scenario? How much are the health and environmental impacts changed in the "non-use" scenario compared to the "applied for use" scenario? Please note that for situations where there are no differences between the scenarios for some types of impacts assessed, this could still be important to document; i.e. to document that those impacts are not likely to be significant for that SEA.

[12] This would likely be the case for potential alternatives that were quickly identified to not deliver the functionality (technical suitability) provided by the Annex XIV substance, and therefore not (or not in great detail) analysed in relation to health and environmental impacts.

How to identify and assess impacts?

Consultation with Member State authorities, relevant supply chains and with other organisations is likely to be a key component of identifying all relevant impacts. This guidance includes a suggestion for a **consultation plan** that is developed in Stage 2 and revised in this stage to reflect the needs for data.

The guidance also includes several **check-lists** (a non-exhaustive lists of possible impacts, see Appendix G) which may be relevant to consider and which can be documented to demonstrate that all relevant impacts have been considered.

Most data on the risks to human health and the environment related to the Annex XIV substance will have been included in the CSR (see Guidance on Information Requirements and Chemical Safety Assessment). Where use of alternatives is considered as a likely response under the "non-use" scenario, information on the impacts and risks of potential alternatives may also be available from the analysis of alternatives (see Guidance on the preparation of an application for authorisation).

Impacts will ideally be described by quantitative data where suitable data sources exist and where such an analysis is proportionate. For impacts that are difficult to quantify and monetise, for example the environmental and human health risks, this guidance includes suggestions on how to take the analysis of those elements as far as practicable. This will depend on the level of certainty in assumptions as well as availability of techniques and of resources. References and links to possible external sources of data and valuations that can be applied are provided.

In many cases the impacts will have to be assessed by using **expert judgement**. The nature of expert judgements is such that it is difficult to provide guidance on how to make such judgements. What is important is **transparency**. If judgments are made, the assumptions behind the judgements should be clearly stated.

The types of impacts to consider include the following:

- Human health and environmental impacts: These impacts cover all possible effects directly related to the toxic, eco-toxic or physiochemical properties of the Annex XIV substance or any alternative substance. These impacts also cover any other health and environmental impacts occurring in all affected supply chains with respect to the Annex XIV substance or introduction of alternative substances or technologies. In such cases the alternative is assessed to be the likely "non-use" scenario. These impacts can therefore include for example differences in emissions from raw material extraction or processing or from the disposal of final products. Information on changes to emissions of and exposure to the substance in question, and other related human health and environmental risks (including those for potential alternatives) may have been generated already (see Guidance on the preparation of an application for authorisation). For the purposes of the SEA, more analysis might be useful, focusing on both the severity of the effects and the exposure, e.g. assessing how many people or what environmental populations are exposed, in order to describe the impacts on human health or the environment (what happens as a result of the exposure).
- Economic impacts: These are the costs or savings to manufacturers, importers, downstream users, distributors and consumers in the supply chains when comparing the "applied for use"

and the "non-use" scenarios. Economic impacts to society of for example health care costs caused by human health effects or reduced crop yield due to acidification are covered under "human health and environmental impacts".

- Social impacts: These are all relevant impacts which may affect: workers, consumers and the general public and are not covered under health, environmental or economic impacts (e.g. employment, working conditions, job satisfaction, education of workers and social security). Impacts on certain social groups may need to be considered.

- Trade, competition and economic development (in short referred to as wider economic impacts): Wider economic impacts are impacts that have macro-economic implications such as economic growth, inflation, and taxes. These types of effects follow from the distribution of the economic effects and how the relevant markets function. For example, additional costs could mean that certain businesses or industries might face trade or competition issues that will reduce their business. The production of alternatives is likely to induce business opportunities, which also need to be included in the analysis of wider economic impacts, unless they were already covered earlier under economic impacts.

The definition of the different types of impacts follows what is set out in the legal text as well as the standard categories used the EU impact assessment guidance. Health and environmental impacts as well as social impacts can incur costs, for example increased health care costs. The latter should be included as costs triggered by health or environmental impacts not as economic impacts.

However, in general, no matter under which heading any significant impact is categorised, the most important thing is that it is included in the SEA, but only included once (to avoid double counting). It is furthermore crucial that the associated documentation is clear and transparent in order for the reader to understand what is addressed under which impact heading.

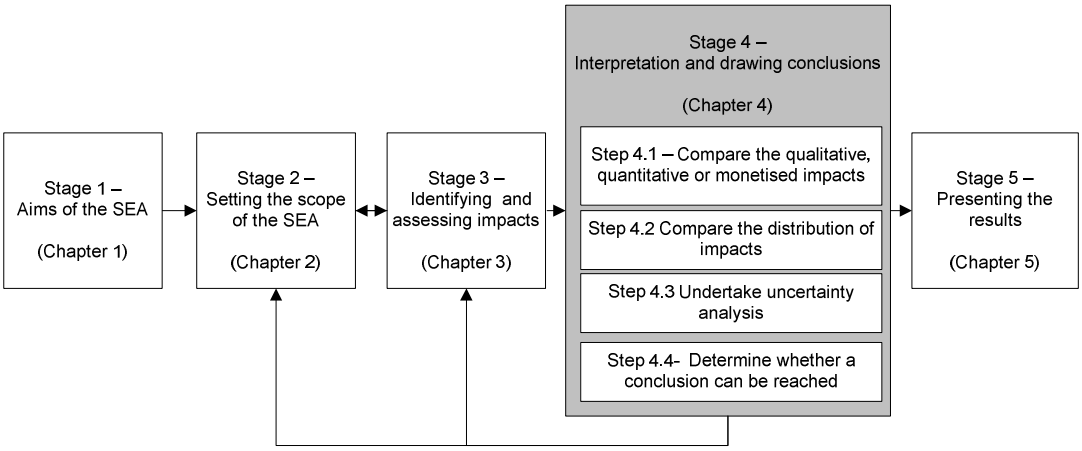
The human health, environmental and economic impacts are often the most significant and therefore should be assessed first. Social and wider economic impacts can, if relevant, be assessed in a second step. This analysis would logically build on and reuse relevant data already gathered.

The output from Stage 3 is a description of all the impacts, either qualitative or quantitative. It is important for all relevant impacts identified to be included. There should be no bias towards impacts that are quantitatively described simply because it has been possible to quantify them (as impacts that cannot be described quantitatively may be of equal or greater importance).

It is likely that the work in this phase will trigger the need for further refinement of the description of the responses under the "non use" scenario as well as the boundaries for the SEA (Stage 2).

1.4.5 Stage 4: Interpretation & conclusion drawing

Figure 7 SEA process – Stage 4



What is Stage 4: Interpretation and drawing conclusions?

Stage 4 focuses on interpreting the impacts identified and assessed in Stage 2 and Stage 3. It is about bringing the information on different impacts (e.g. both qualitative and quantitative and on different receptors, to the economy, on environmental and human health and to society in general) together and undertaking an uncertainty analysis to test the robustness of the SEA.

Based on the assessment and uncertainty analysis, the applicant would decide to either conclude the SEA or to undertake more analysis by reverting back to Stage 2 or 3. This stage also includes making an assessment of the distributional effects. In summary Stage 4 addresses:

- How to compare the "applied for use" and the "non use" scenarios;
- How distributional effects should be addressed;
- How uncertainty analysis of the main impacts should be undertaken; and
- How to determine whether the SEA can be concluded or whether there is a need to go back to Stage 2 or 3 to collect more data on certain impacts.

Comparing the impacts is necessary in order to draw conclusions about the socio-economic benefits of continued use compared to the risks of continued use. This can be done in different ways, ranging from simply listing and discussing pros and cons to using more sophisticated methodologies for aggregating impacts in a way they appear in similar physical and/or monetised units. However, in case of aggregation, it is of crucial importance that the reader of the SEA can easily follow how the aggregation has been done, including being able to trace back the original non-aggregated impacts.

How is Stage 4 undertaken?

Stage 4 comprises the following steps:

- Step 4.1: Compare the different types of impacts using an appropriate SEA assessment tool (e.g. ranging from a qualitative assessment to a fully monetised cost benefit analysis). The

level of quantification undertaken should be proportionate to the problem at hand. A number of risks and impacts will generally not be quantified (e.g. where the data is not available or it is deemed unnecessary to quantify in order to show the severity of these risks and impacts) and qualitative conclusions on these will be needed instead. Regardless of the level of quantification, a transparent presentation of all important impacts is crucial for the quality of the SEA.

- Step 4.2: Assess the distribution of impacts. The impacts will affect different actors in the supply chains and other industrial sectors, as well as geographical distribution of health and environmental impacts. A description of who is affected and how should be included in the SEA. The assessment of the distribution of the impacts should also consider possible differences across social and income groups.

- Step 4.3: Undertake an uncertainty analysis, where needed – for example in the form of sensitivity analysis of key assumptions. The uncertainty analysis aims to test whether different (reasonable) assumptions or estimates could affect the conclusions and, if this is likely, how significant any such difference is. A sensitivity analysis could effectively be carried out by estimating "switch values" (the value at which the conclusion of the SEA is changed) and the likelihood of those values. The results of the uncertainty analysis may result in having to revisit earlier stages such as data collection.

  It is important that uncertainties are identified and described throughout and when carrying out the various stages and steps of an SEA. This will help to ensure that good quality data is used to conduct uncertainty analysis. During the SEA, the uncertainty analysis can be used as a tool to identify what further information generation would reduce uncertainties most and therefore be applied to decide on the most cost-effective iteration strategy in order to arrive at a robust SEA.

- Step 4.4: Decide whether a conclusion can be reached or if there needs to be more data collection or analysis. The suggested iterative approach implies that an initial SEA is done using immediately available data. By comparing impacts, the applicant has to make a judgement about the need for further refinement of the analysis.

Stage 4 is therefore concluded by either:

- Going back to do more analysis (a further iteration of the SEA process);
- Finalising the SEA process and reporting the analysis and findings (Stage 5);
- Exiting the SEA process.

How detailed should the SEA be?

The SEA should be as robust as needed to support the conclusion reached. A better understanding of the consequences of a refused application is essential for the decision making process. Therefore, it is highly recommendable for the applicant to include adequate assessment and information of socio-economic impacts in the authorisation application. The applicant should also note that there are very limited options and time available for providing additional information.

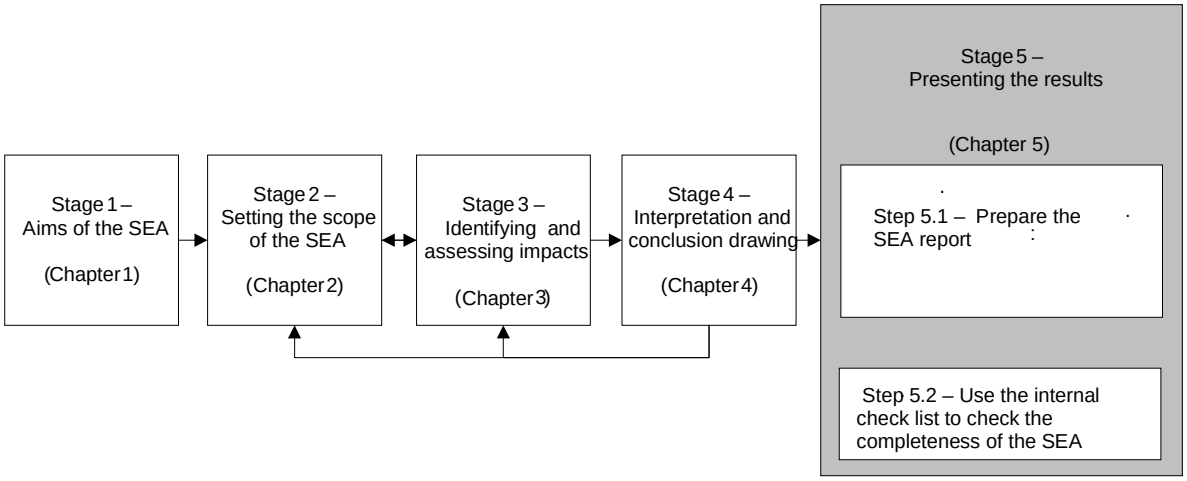
How much detail needs to be included in the SEA will be a case-by-case judgement.

In general the applicant should seek to build as robust a case as possible but, as there are limited resources available to develop SEAs, the level of detail should be proportionate to the problem in hand.

If a qualitative assessment shows that the main impacts are all positive, all negative or all neutral, it might be possible to argue the case based on a predominately qualitative basis. Similarly, if for example the SEA indicates that there are significant benefits of the authorisation while the costs/risks are low, a conclusion might also be drawn on a more qualitative basis. The closer the balance between benefits and costs is the more detail (and frequently quantification) will be required.

1.4.6 Stage 5: Presenting the results

Figure 8 SEA process – Stage 5



What is Stage 5: Presenting the results?

Stage 5 is the final stage in the SEA process. In this stage the main findings and results of the analysis are summarised. For transparency and reliability of the results, the key assumptions used and uncertainties involved should be presented with the final results.

It is important to present all data in a systematic and transparent manner in order to aid the decision-making process. Given that the information in the SEA submitted is one part of an authorisation application it is an important opportunity for the applicant to justify granting an authorisation[13], the argument needs to be presented in a convincing but also unbiased way. For any third party providing comments to an SEA or their own SEA during the consultation period, a transparent and unbiased presentation will facilitate the use of the information being submitted.

How is Stage 5 undertaken?

The output of this stage is the SEA report. This can be presented using a template and checked against an internal checklist to check that the key aspects of an SEA report have been included. Reporting the results of the SEA includes:

- Presenting the "applied for" scenario, the "non use" scenario. This should include the main assumptions made / decisions taken when the scenarios were defined.
- Presenting all the key assumptions/decisions on the time and geographical boundaries of the SEA, supply chains covered and impacts which are covered by the assessment. If relevant, this should also include information on why certain issues are not covered.
- All the key decisions/assumptions including justifications that have been used to estimate and describe impacts should be presented in order for the SEA to be transparent. These could be presented in an appendix to aid readability of the main SEA report.
- Presenting all the key impacts and the SEA results. If impacts are aggregated using a cost-benefit approach or a multi-criteria approach, it is important to present the individual impacts. Chapter 5 indicates what could be reported in an SEA following the structure of the SEA format published on the Agency's website.. **Appendix G** includes several non-exhaustive checklists that could be used to demonstrate which impacts have been considered and which have not been included.
- Presenting the results of the uncertainty analysis: Having undertaken sensitivity analysis or an alternative form of uncertainty analysis to test the robustness of the SEA, the results of this analysis should also be presented.
- Presenting the main conclusions: The applicant or third party should summarise the results of the analysis and provide their conclusions. The implications of uncertainties for the conclusions should be clearly set out.

1.4.7 Pitfalls to avoid

Following the recommendations in this guidance the applicant or third party preparing an SEA should consider the issues outlined in the following text box.

[13] Since the time available for revising an SEA at later stages will be more limited.

Examples of issues that will decrease the quality or credibility of an SEA

Boundary restrictions:

- Not using the most realistic behavioural responses to a refused authorisation;
- Lack or no consideration for all impacts that are either significant or are perceived by some to be significant;
- No attempt to account properly for geographic and temporal limits;
- No consideration of future trends and implication of existing legislation;

Use of poor quality inputs:

- Use of outdated information;
- Lack of awareness of respected data sources;
- Lack of consultation to obtain relevant data

Poorly thought out methodology:

- Not documenting assumptions;
- Not documenting and justifying the key decisions made during the development of an SEA
- No attempt to quantify effects where this is possible and appropriate to do so;
- No attempt to qualitatively assess impacts that cannot be quantified;
- No, or inadequate, account given to the uncertainties in the analysis;

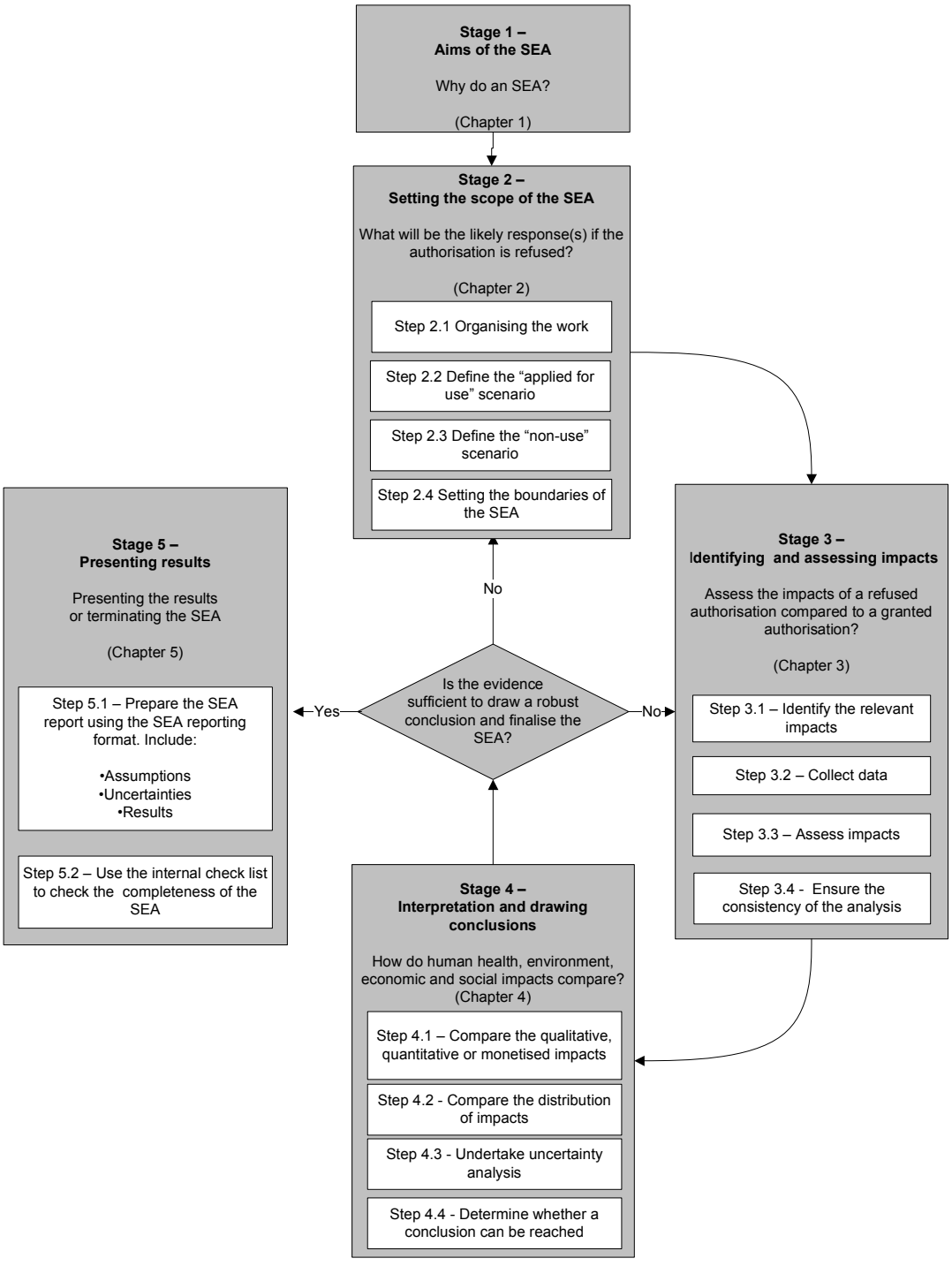
Failure to properly explain the rationale for conclusions:

- Lack of clear explanation for the conclusion reached based on the information provided;
- Lack of account of uncertainties in drawing conclusions;
- Lack of account in the conclusion making process for un-quantified effects;
- Lack of transparency in how the results were derived.

1.4.8 Overview flow chart

The flowchart below provides an overview of all of the stages and steps in the process.

Figure 9 Flow diagram for the process of conducting an authorisation SEA

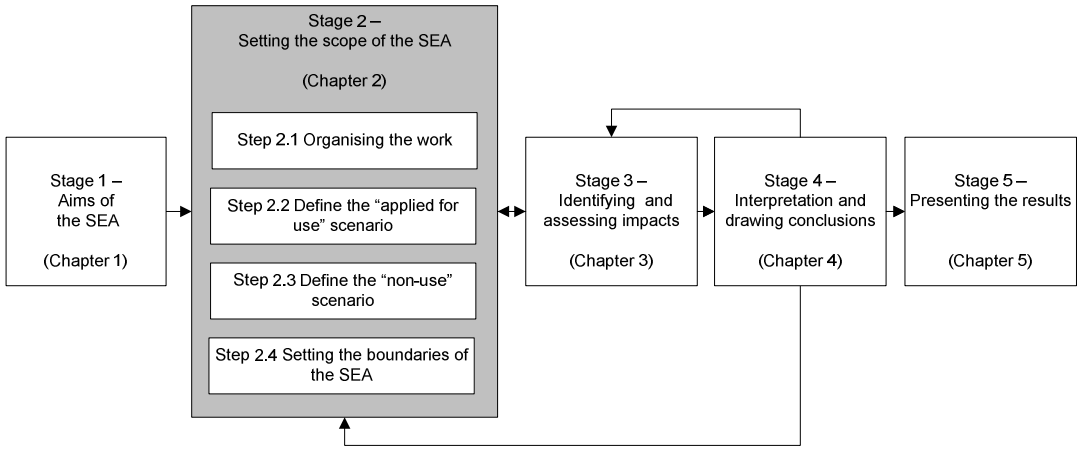


2 THE SEA PROCESS – STAGE 2: SCOPING PHASE

2.0 Introduction to the scoping phase

The scoping phase is the second stage of developing an SEA as part of the authorisation application or for a third party[14] to input to an SEA.

Figure 10 Flow chart for the scoping phase



The scoping phase deals with how the relevant scenarios and boundaries for the SEA should be defined. The process for identifying and describing impacts is covered in Chapter 3.

The scope of the SEA (the "scoping phase") is determined by identifying the response to a refused authorisation. It is a key stage in the SEA as all the socio-economic impacts are defined as the difference between the authorisation being granted and it being refused. By defining the possible responses to a refused authorisation the boundaries of the SEA can be defined.

This section describes the proposed approach to this stage of the SEA in detail. It is recognised that the overall approach to the SEA should be an iterative one and the applicant should undertake this stage at a level of detail appropriate to that of the SEA iteration being undertaken.

Defining a scenario involves assessing the expected behaviour of the supply chain and potentially other actors and implications resulting from non-use or continued use of the Annex XIV substance. For example, if a certain use of the substance is no longer possible then a downstream user might choose to import articles or to apply another substance or process. There will potentially be a range of different implications for different actors and processes.

[14] The role for third parties is described in Section 1.2 and 1.4.2.

2.1 Step 2.1: Organising the work including, work plan, consultation plan and start-up meetings

The SEA will require expertise in a variety of fields: technical (use of the substance and possible alternatives), safety/impact assessment, operations (e.g. costs of production), markets (e.g. on demand or competition) and economic (e.g. cost-benefit analysis). Most of this expertise might be found in-house or within the supply chain. The need for external expertise will depend on the complexity of the SEA. Developing a work plan based on the stages and steps outlined in this guidance will help to identify any such need.

Some of the key elements that may be involved in organising the work for the SEA include:

- Identifying in-house expertise (skills);
- Identifying the relevant supply chain and individual contacts;
- Establishing contact and agreeing involvement with each key person;
- Organising a start-up/inception meeting or briefing;
- Developing a work plan based on the stages and steps as set out in this guidance;
- Developing a consultation plan; and
- Considering the need for external support (e.g. due to lack of skills or resources).

CASE STUDY EXPERIENCES

Experiences of those carrying out a case study SEA as part of the development of this guidance found that:

1) Coordination of work is one of the main challenges in developing an SEA. The project leader should have a good understanding of the authorisation process, the development of an authorisation application and the expertise fields covered by the SEA.

2) It is important to establish early a multidisciplinary team and hold an internal kick-off or brainstorming meeting so that all understand what the scope of the study is, and that all understand the assignment in the same manner.

Appendix A contains more details of how to prepare a consultation plan.

TIP BOX

Key reasons for supply chain contacts:

Engaging with the supply chain is important as it enables you to explore the implications resulting from not granting an authorisation for different stakeholders/organisations.

Engaging with the supply chain is also often the only way to get accurate and specific information regarding the "applied for use" and "non-use" scenarios.

Contact with the supply chain is important for identifying what would happen if the Annex XIV substance is no longer available. This is because there are many possible responses through the supply chain to the substance not being available; for example, this may be changing the end products by using an alternative, halting production of products or moving product production outside the EU. Different uses will prompt different expected responses from different downstream users (DUs) or consumers.

The accuracy of the SEA will depend on the plausibility of the judgements of what will happen if the Annex XIV substance is not available. For anything but the most simple supply chains where the applicant is already fully engaged, additional communication and consultation with the supply chain will be the only way to get accurate information on certain aspects.

If the applicant is a DU, it is more likely that the applicant will have a lot of the information necessary for predicting what would happen if the substance is no longer available for this particular use after the Sunset Date. If the applicant is further 'upstream' in the supply chain, consultation with the DUs will be vital for understanding the socio-economic benefit of the substance in each of the uses being applied for.

If commercial confidentiality restricts the DU's willingness and ability to provide information, expert judgement may need to be applied (unless the SEA is being compiled by an independent party with suitable confidentiality agreements in place).

2.2 Step 2.2 - Define the "applied for use" scenario

If the application is for **an existing use**/s of the Annex XIV substance, then the "applied for use" scenario will be the baseline. If the application is for **new use/s** of the Annex XIV substance, the baseline will be the "non-use" scenario (in both cases the baseline is related to the current situation, though it is not necessarily just a simple continuation as explained below).

Applying for a new use is similar in most aspects to applying for an existing use and the guidance can be used to support both types of application. In case of applying for a new use, it is likely that the applicant would have undertaken some kind of feasibility study to determine that this new use would be advantageous from both a technical and an economic perspective. It would be advantageous if such a feasibility study would give an indication at this early stage what kind of environmental and health consequences the use could have. This would form the basis for defining the "applied for use" scenario in that situation.

The methodologies set out in the guidance document can be used for both types of applications, but for simplicity, the terminology used from here on assumes that the application is for an existing use.

The activities or sub-steps in defining the "applied for use" scenario include:

- Definition of the supply chain; and
- Assessment of possible changes or trends in the use patterns and volumes.

2.2.1 Definition of the supply chain

The applicant should already have defined the specific use/s that is/are being applied for as a starting point for developing the application (see Guidance on the preparation of an application for authorisation Chapter 2). The key information to be used for the SEA includes:

- A description of each use being applied for; and
- A description of the functionality being delivered by each use.

The first issue is how to define the supply chain in which the Annex XIV substance is used. In identifying the "applied for use" scenario and the "non-use" scenario(s), the starting point will be the supply chain of the Annex XIV substance as any change in behaviour as a result of the Annex XIV substance no longer being available originates from that supply chain. (Note that it is relevant to consider other supply chains in relation to identifying impacts; inclusion of other supply chains depends on the definition of the "non-use" scenarios, see Section 2.3.2.2 and Section 2.4.1).

The part(s) of a vertical supply chain requiring authorisation will start from the importer, first downstream user (as manufacture does not require authorisation) or manufacturer (if he places on the market or uses himself the substance) and include the last downstream user that uses the Annex XIV substance as such or in a mixture. However, as the value to society of any intermediary goods is based on the value of the final consumer goods/service and as upstream impacts might also be relevant (Section 2.4.1), **the supply chain needs to be considered from manufacturing of raw materials for the Annex XIV substance all the way down to production of a consumer good/service and the benefit derived from those goods and services.**

Supply chain illustration

This text box illustrates two aspects of the supply chain considerations:

- Supply chains are often complex. A vertical supply chain can have many formulators and downstream users from the manufacturer/importer all they way to the final product (a mixture or an article). There are also typically several vertical supply chains for a given substance;
- For which uses/processes an Authorisation is required to maintain a vertical supply chain.

The supply chain for a given substance can be very complex covering a large number of process steps and uses. The illustration in this example sets out a relatively simple supply chain which includes 15 different main stages. The manufacturer/importer (M/I) supplies a number of DUs/actors; some use the substance as part of an article and others use it to manufacture an intermediate product e.g. a formulation.

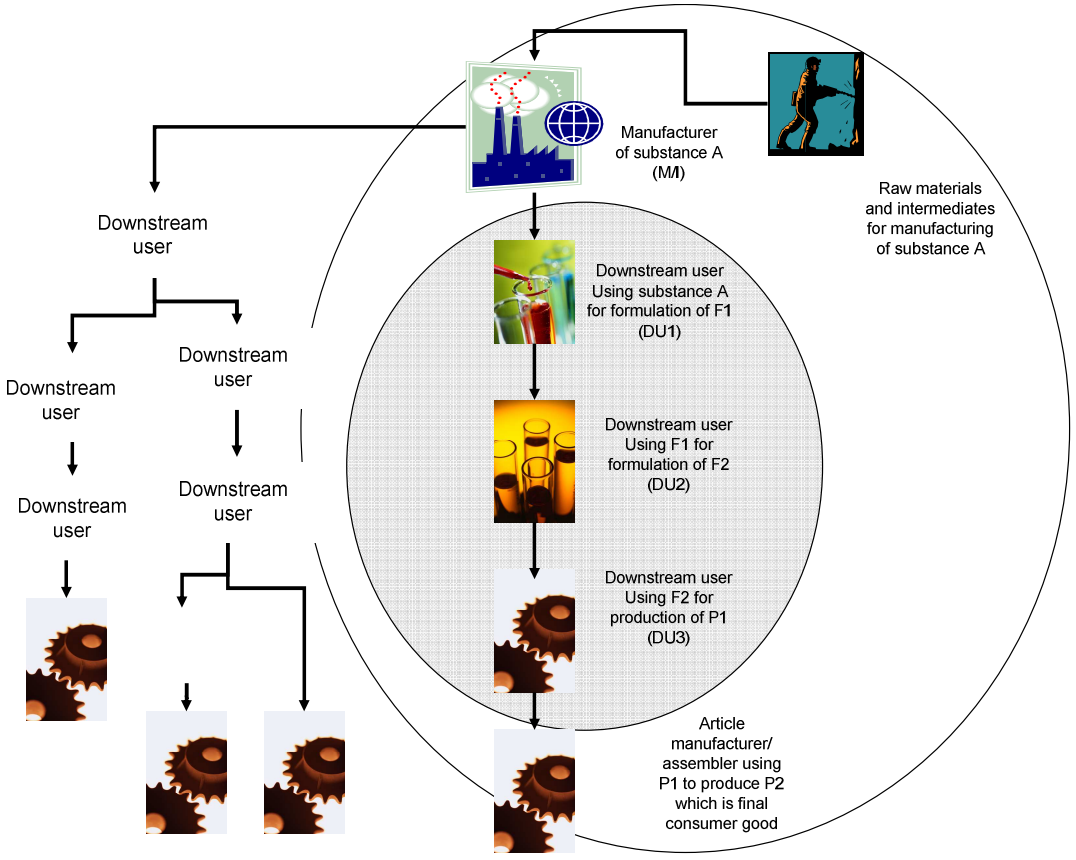
In this example, there are four end-uses and a sub-section of the supply chain – from suppliers of raw materials to a final product which in many cases might be an article – is here called a vertical supply chain. This is marked with the large light grey circle in the illustration below. The dark grey section of the vertical supply chain is an example of where there are three stages in the supply chain that need to have an authorisation.

The M/I can specify one downstream use as the use in making the formulation F1. The reason for using the particular substance A in the formulation F1 is likely to be because it needs certain properties when it is used in

F2 and these properties are again required due to the needs of the last DU that requires authorisation in their production of the article P1. Similarly the requirements for article P1 could be caused by the demand of the article assembler that produces the article P2 which for example could be a consumer good.

When arguing why these properties are necessary and in assessing the socio-economic impacts of not having the substance A, the applicant will often have to refer to the manufacturing of the article P2 irrespectively of whether it is for any the three uses (DU1, DU2 or DU3) that is applied for.

This means that the SEA for each of the three uses will have to be based on similar arguments all related to the functionality being delivered in the production/assembling of P2. The SEA will have to be based on how the end-user – in this example the article producer/assembler (and the downstream uses leading up to the end use) – can react if the substance is no longer available to that supply chain. In other words, the main socio-economic benefits of continued use are likely to come from the end-use rather than from each of the intermediate uses (though there will be socio-economic benefits to the organisations and communities involved for firms in each of the intermediate stages). This indicates the advantages of submitting an application that covers all the uses within each supply chain. The end-user in this example is not a downstream user who requires an authorisation but there could be examples where the end-user would actually use the substance and therefore be a downstream user.



2.2.2 Assessment of changes or trends in use pattern or volumes

It is important to recognise that the "applied for use" is not necessarily a simple continuation of the current situation. There could be changes/trends in the use or uses that should be carefully considered.

- Trends in the quantity of the substance in the use/s caused by:
  - Technological developments that reduces or increases the need for the Annex XIV substance;
  - Future changes due to forthcoming legislation; or
  - Future changes in demand for the end-use product.
- Additional/different Risk Management Measures (RMMs) or Operational Conditions (OCs) that are expected to be applied according to the applicant's Chemical Safety Report (CSR).

In the SEA report, the definition of the "applied for use" scenario can be very brief referring to the use/s and the associated function/s as described in other parts of the application (see Guidance on the preparation of an application for authorisation, Chapter 2 and 3). These uses and functions can also be briefly summarised for clarity in the SEA report.

Table 1 presents a simple format for defining the "applied for use "scenario for one vertical supply chain related to one particular end use. In this supply chain there are three (downstream) uses requiring Authorisation: two formulation stages (DU1 and DU2) and use of the substance for producing the article/product P1 (DU3).

All of the uses in a supply chain will have to be defined in relation to an end-product, which in many cases will be an article. Note that the relevant supply chain can include additional actors that do not require an authorisation, typically actors assembling or using articles (because they do not use the substance on its own or as part of a mixture).

Table 1 "Applied for use" definition for supply chain (example)

Supply chain	Uses	Expected trends
	Does not need authorisation	
M/I	Manufacturing of x tons/year of substance A (Substance A is the substance being placed on Annex XIV). Please note that the manufacturing itself does not need an Authorisation. However, the manufacturer cannot place a substance on the market for a use or use it himself, unless the use(s) has been authorised. An Authorisation can be granted directly to the Manufacturer or to his downstream user in cases where the substance is placed on the market. According to Article 3(12) of REACH, import shall be deemed to be placing on market and always needs authorisation.	No information about overall trend in production of substance A and not important for the SEA for this particular supply chain. However, the trend of the manufacturing for the uses included in the Authorisation application would need to be considered in the SEA. In this case that would be 1% annual increase for supplying the supply chain in this example.
	Needs authorisation	
DU 1	1. Use y kg of substance A in formulation F1	1% annual increase of demand for substance A.
DU 2	2. Use z kg of F1 to produce v kg of formulation F2	1% annual increase of F1. New technology for making the mixture with less work place exposure.
DU 3	3. Use w kg of F2 as coating to provide long life time for component C1 of article P1 in the manufacturing of q units of article P1	Annual increase in demand for P1 of 1%. No change in technology means that demand for substance A will increase by 1% upstream.
	Does not need authorisation	
Article assembler 1	Use q units of article P1 to produce q2 units of article P2	Increase in demand for P2 by 1% per year as there is efficiency gain of about 2% less P2 per unit of P3.
Article assembler 2	Use q2 units of P2 to produce article P3 which is a consumer good	Increase in demand for P3 by 3% per year

In the above example the function provided by the substance is related to article assembler2's article and how it used. The information gathered as part of the application and for the analysis of alternatives might not have covered the actors further down the supply chain (article assemblers in the above example).

For the applicant whether M/I or DU, this kind of information should be collected for each use being applied for. It could therefore be a substantial effort to characterise the "applied for use" scenario and the applicant will need to decide upon the level of detail that they think is appropriate for their application (i.e. the analysis should be subject to the aforementioned considerations on proportionality). For DUs that are not the end users of the substance, a similar exercise of gathering information about all the end uses will generally be needed.

2.3 Step 2.3 - Define the "non-use" scenario(s)

2.3.1 Overview

The activities or sub-steps in defining the "non-use" scenario include:

- Identifying the relevant "non-use" scenarios; and
- Describing the "non-use" scenarios.

The nature of the possible "non-use" scenarios depends on whether the application is done along the socio-economic or the adequate control route and the two situations are covered in turn in the following sections.

2.3.2 Non-use scenario where the SEA supports an application using the socio-economic route

The definition of the possible "non-use" scenario is closely linked with the analysis of alternatives, (see Guidance on the preparation of an application for authorisation Chapter 3). Under the socio-economic route, the applicant will have to transfer to the suitable alternative and should not proceed with the application, unless the analysis of alternatives concludes that there are **no suitable** alternatives.

There could be different reasons for the analysis of alternatives to conclude that there are no suitable alternatives. For each of these reasons a number of generic "non-use" scenarios need to be considered. Examples of these are shown in Table 2.

Table 2 Generic types of "non use" scenarios (examples)

Reason for the analysis of alternatives to conclude: No suitable alternative available	Generic types of non-use scenarios (not exhaustive)
1. There are no technically feasible and available alternatives	• Increased import of articles from outside EU (where the substance is being used) to maintain the function(s) for the end users; • Lower quality delivered to the end users as the function imparted by the substance is no longer fully being delivered (e.g. lower quality of articles); • Functions for end user (e.g. consumer articles or similar end use products) no longer provided by the supply chain in question.
2. There are technically feasible potential alternatives but they are not economically feasible for the applicant	• Use of the alternative substances or technologies without or with less profit ; • Increased import of articles from outside EU, where the substance is being used; • Lower quality of functions delivered to end users (e.g. lower quality of articles); • Function for end users (e.g. consumer articles or similar end use products) no longer provided by the supply chain in question.
3. There are technically and economically feasible potential "alternatives" but they do not reduce the risks	• Use of the alternative substances or technologies (without reducing the risks).

Referring to the supply chain illustration the "non-use" scenario has to be defined with respect to what will happen at each stage in the vertical supply chain.

For example, if a lower quality end-product would be produced, the upstream suppliers might still supply their intermediate products without the Annex XIV substance (through the same or an alternative supply chain).

With regard to scenarios where the most likely response from the supply chain would be to use the alternative that is considered unsuitable by the applicant, the following situations may occur:

- The analysis of alternatives has shown *that a potential alternative does not reduce the overall risks*, i.e. the applicant has concluded that there are no suitable alternatives. However, this would not prevent the downstream users from using such potential alternatives (provided that the potential alternative substances are not on Annex XIV and therefore also would require authorisation).
- The analysis of alternatives has shown that *a potential alternative is economically unfeasible* from the perspective of the applicant. From the point of view of the downstream users or an

article manufacturer/assembler it might be feasible and therefore be used instead of the Annex XIV substance.

- The analysis of alternatives has shown that *a potential alternative will not deliver the functionality* and will therefore result in reduced performance of a downstream product or article. If the supply of the Annex XIV substance stops, the downstream users might anyway switch to the alternative although it will cause drawbacks in terms of technical performance and socio-economic impact.

When it is a likely response, the SEA therefore covers use of potential unsuitable alternatives as one or more "non-use" scenarios. It could thereby in some situations provide additional support to the conclusions from the analysis of alternatives.

2.3.2.1 How to determine which responses to consider and include in the SEA?

If one "non-use" scenario represents the obvious response from the supply chain then the focus can be on that non-use scenario. In most cases, however, there could be more than one response. Different DUs could choose different responses.

The situation for the downstream users should be analysed with respect to:

- Likelihood of the different "non-use" scenarios (e.g. is relocation or abandoning the functionality being performed by the substance likely?);
- Costs to and other implications for the downstream users of the different responses that are likely.

The downstream users can be expected to switch to the least cost alternative to the current use of the Annex XIV substance, subject to technical feasibility/quality/availability (though they will also consider other factors such as public perception of the substances used). That could include ceasing production of the end-use article.

Guidance on how to assess the cost implications is provided in Chapter 3 on assessing impacts.

If the applicant is not the downstream user, consultation with downstream users will be necessary for defining the "non-use" scenario. Commercial confidentiality could limit the data and information that the downstream users are willing to provide.

If the required information cannot be provided, the applicant has to apply expert judgement on what situation is most likely to occur. If there is no clear conclusion, the applicant should include all relevant generic "non-use" responses in the analysis. If the later screening of impacts indicates that there is not much difference between the scenarios, it may be appropriate to choose the one with the lowest additional costs to the supply chain as representative for the "non-use" scenario.

2.3.2.2 What should be included in the definition of the "non-use" scenarios?

The definition should include a description of how each link in the supply chain would react to the non availability of the Annex XIV substance.

Type of "non-use" scenarios

The possible "non-use" scenarios described above relate to the end use. If the supply chain is long - for example with the substance being used in a sequence of formulations - the description should

include indicators such as (broadly) how much of M/Is' or DUs' turnover relates to the end-use in question. This would be necessary for making an assessment of the impact of the "non-use" scenario. The information could be presented as shown in Table 3.

Table 3 Supply chain reaction

Supply chain	Applied for use scenario	"Non-use" scenario 1 Relocation (to outside EU)	"Non-use" scenario 2 Use of another end-product
	Does not need authorisation[15]		
M/I[15]	Manufacturing of x tons/year of substance A.	M/I will no longer supply A to DU1.	M/I will no longer supply A to DU1.
	Needs authorisation		
DU 1	Use y kg of substance A in formulation F1	DU1 will no longer supply F1 to DU2	DU1 will no longer supply F1 to DU2
DU 2	Use z kg of F1 to produce v kg of formulation F2	DU2 will no longer supply F2 to DU3	DU2 will no longer supply F2 to DU3
DU 3	Use w kg of F2 as coating to provide long life time for component C1 of article P1 in the manufacturing of q units of article P1	Will import the component where F2 is used and continue producing q units of P1	DU3 will no longer supply P1 to DU4
	Does not need authorisation		
Article assembler 1	Use q units of article P1 to produce q2 units of article P2	No change	DU4 substitute P1 with Px to produce article P2
Article assembler 2	Use q2 units of P2 to produce article P3 which is a consumer good	No change	No change

If it is not clear which "non-use" scenario is most likely, all of the relevant scenarios should be described. However, it is recognised that not all of the information may be available and an analysis at a lesser or greater level of detail may be appropriate to the circumstances of the application in question.

[15] Please note that the manufacturing itself does not need an Authorisation.

However, the manufacturer cannot place a substance on the market for a use or use it himself, unless the use(s) has been authorised. That Authorisation can be granted directly to the Manufacturer or to his downstream user in cases where the substance is placed on the market.

According to Article 3(12) of REACH, import shall be deemed to be placing on market and always needs authorisation.

2.3.3 "Non-use scenario" in case of an SEA supports an application following the adequate control route

If the SEA supports an application following the "adequate control route", it may account for the commitments laid out in the substitution plan and provide additional socio-economic information, which can be used by the Agency Committees and the Commission in setting conditions for the authorisation or defining the review period. The definition of the "non-use" scenario includes one of the following options:

- Where there is/are alternative/s: an accelerated phase-in of any alternative as compared to the substitution plan; or the use of a less suitable alternative.
- Where there is/are no suitable alternative/s: use of an unsuitable alternative; changed quality of the goods that the substance is used for; certain goods or services no longer being available; relocation of certain production activities outside of the EU.

The first type of scenario might in most cases be unrealistic if the substitution plan sets out the minimum technically feasible time period for introduction of the alternative. If in principle it would be possible to accelerate the phase-in of an alternative, this scenario would address the question of the additional costs of doing so. Guidance on assessment of impacts including economic impacts is provided in Chapter 3.

If it is not technically feasible to phase-in the alternative in a shorter time frame than set out in the substitution plan, a realistic "non-use" scenario would be the second bullet point, which is similar to the type of "non-use" scenarios covered above under the socio-economic route. Similarly if there are no suitable alternatives under the adequate control route, the "non-use" scenarios include those listed in Table 2.

2.3.4 What to do if you are a third party?

A third party should have defined its aims as part of Stage 1, relating to what sorts of information will be provided and what the analysis is intended to achieve. Similarly to an applicant, the information needs to be robust and presented in a transparent way. Thus, the third party would be expected to provide details on the implications of, for example, use of an alternative, such as the responses of various actors in the supply chain and alternative supply chains.

Information on a specific alternative should be described in a similar way to the description of a "non-use" scenario by an applicant. What potential alternative is considered? How would it be applied? What is the expected reaction throughout the supply chain?

If the third party is only providing information on certain specific impacts of the Annex XIV substance or of an identified alternative, Step 3 (assessing impacts) is the next activity to undertake. The third party should, in identifying and assessing impacts, follow the same guidance as for applicants.

If the third party is submitting a full SEA, the next section on boundaries could also be relevant.

2.4 Step 2.4: Setting boundaries for the SEA

Understanding what needs to be included in the SEA is the last step in the scoping phase. It is likely that the boundaries setting out what should be included in the SEA will change to some

extent as a result of the next stages in the SEA process when the impacts are further identified and assessed (Stage 3) and compared (Stage 4). This is another reason why it is advisable to conduct the SEA in an iterative way (e.g. having assessed the impacts in more detail it may be necessary to update the time and geographical boundaries of the SEA).

The boundaries of the SEA are determined by:

- The relevant supply chains affected by a not granted Authorisation;
- The time period for the analysis; and
- The geographical coverage of the analysis.

The identification of impacts is described in more detail as part of Stage 3. There are no boundaries in regard to the **types** of impacts to be covered. Any difference – whether this be environmental, health, economic or social – between the "applied for use" scenario and the "non-use" scenario should be included if it is likely to be significant.

2.4.1 Relevant supply chains

The possible "non-use" scenarios are all defined based on expected responses from the main supply chain(s). As discussed in the previous sections, this vertical supply chain needs to be considered all the way to the supply of consumer goods or services.

It is likely that impacts resulting from the responses as defined by the "non-use" scenarios will affect other supply chains. It is therefore a key consideration for the applicant which other supply chains to include.

The main driver for identifying affected supply chain is to get a thorough understanding about "what happens" if the Annex XIV substance is no longer available for the use applied for.

The relevant supply chains can be identified by determining:

- The physical flow related to inputs to and outputs from the uses covered by the authorisation application; and
- Economic flows through affected markets.

With regard to looking at physical flows of materials, one approach would be to draw up a process diagram/tree showing all processes related to material and energy flows in the supply chains to and from the production process related to each use covered by the authorisation application (for the "applied for use" scenarios), as well as one for the "non-use" scenarios (in this case related to use of possible unsuitable alternatives). The figure in the example box in Section 2.2.1 could be a good starting point for a more complete diagram for the "applied for use" scenario.

The process trees should focus on processes giving rise to differences, for example if the use of an alternative substance means use of different raw materials, then the supply chains covering the extraction and processing of raw materials are likely to be different and needs to be considered for both scenarios. Description of the material flows is important in relation to being able to identify the health and environmental impacts (and sometimes also in relation to direct costs). Guidance on how to identify human health and environmental impacts are included in Section 3.

There could be situations where the response in the "non-use" scenario would result in an increase in the price of the product (for example if an alternative more expensive technology were to be

used). Such a price increase could result in consumers switching to other products. In such a situation the supply chains delivering the other products should be included as a relevant supply chain.

Through the process of identifying impacts it might be necessary to include more supply chains. It is therefore necessary also to consider the coverage of other supply chains as part of Step 3.1 Identification of impacts (see Chapter 3). The analysis of impacts might also show that impacts coming from other supply chains are of less importance and therefore need less weight in the analysis.

Table 4 indicates four different types of "non-use" scenarios. The list can be used as a starting point, but identification of relevant supply chains will always involve case-by-case considerations. Furthermore, it should be reconsidered during the iterative SEA, where for example the identification and assessment of impacts (in Stage 3) might trigger iterations and reconsiderations of the scope of the analysis.

Table 4 Hints on which supply chains to include (non-exhaustive)

Generic "non-use" scenario[16]	Additional relevant supply chains to consider
Use of substance or technology considered to be "unsuitable" (See Section 2.3.2.1)	The supply chain that delivers the unsuitable alternative needs to be included. Potentially supply chains that provide raw materials (for either the Annex XIV substance or to the alternative) if there are any major changes (use of different raw materials)
Increased import of articles from outside EU where the substance is still being used	Even though the main focus is on impacts inside EU (See section 2.4.3), it is important that significant impacts outside the EU are identified at least qualitatively (e.g. whether they use more or less of the substance and on the way they control the use).[17]
Lower quality of downstream article(s)	In this case additional supply chains may need to be considered if the lower quality of downstream article leads the consumers of that article to substitute to a different product or to change consumption of other products. For example if the article is less energy efficient the supply chain delivering that additional energy needs to be considered (that could for example be a fuel or electricity supply chain). Also upstream, processes related to manufacturing/producing the Annex XIV substance and alternatives may differ and are therefore important to consider.
Some articles no longer being provided by the supply chain in question	The implications for those actors that are further downstream (including end-users/consumers), should be included. The result of an article no longer being provided by the supply chain could be substitution with another article which implies that the supply chain for that other article should be included.

[16] The full scenario will obviously be defined in more detail, including predicted responses of the various actors within the supply chains.

[17] In case of relocation, it might not be known to where such relocation will happen. The analysis will therefore have to apply assumptions. It could for example consider whether relocation would be to another industrialised country or to a developing country. The levels of control of emissions could be different but also the possible economic benefit to country of relocation will be different.

2.4.2 Time period for SEA

There are several aspects to consider in relation to setting the appropriate time period. All of these aspects are related to how data for the analysis are collected and assessed and are therefore important to decide on or at least consider at this stage of the analysis.

Initially, it is important to define the *impact triggering period* and to distinguish it from the *impact realisation period*. This differentiation relates to the fact that impacts are a result of potentially long-term cause-effects relationships. The impact triggering period is the time period within which impacts are *triggered* (i.e. the "*cause*" in the cause-effect chain), whereas the impact *realisation* period is the period within which impacts occur/are materialised (the "*effect*"). In particular the environmental and health impacts could appear long after they have been triggered by emissions taking place (certain substances may persist in the environment for many years or where the effects associated with exposure are not manifested within the time period, such as for carcinogenicity).

The impact triggering period

The "cause" represents the changes introduced under the “non-use” scenario, for example, the use of an alternative substance or technology, as compared to the “applied for use” scenario. When conducting the SEA, it is important to choose an impact triggering period that is representative for this cause. Key issues to consider are:

- Will the non-use scenario trigger one-off investment costs in new/additional equipment/facilitates? In this case, the analysis should appropriately take into account the investment cycle, i.e. the period in which the new equipment will operate. Note that the investment cycle refers normally to equipment which produces goods or substances.

- Are there foreseen (increasing or decreasing) trends related to the demands for function provided by the substance? And therefore: are there foreseen trends in the demand for the substance under the applied for use scenario and thereby for any alternative substance or technology considered under the non-use scenario.

The methodological choice is whether to base the assessment over a cumulative time period of, for instance, 20 years or use an annual basis based on a representative year of, for instance, 2030 (where all relevant numbers are expressed as equivalent annual costs or annual benefits in 2030).

For the practical organisation of the analysis, the first step would be to define the Applicant's investment cycle (for example 20 years). Thereafter the following consideration should be made in relation to choosing between the two basic methodological approaches to carrying out the analysis:

- If there are no major trends expected in the future, a representative year can be defined, for instance 2030, as the basis for the analysis as it will make it relatively simple to conduct. This representative year should likely represent a "steady-state" situation.
- If significant changes in the trends are foreseen, it would often be relevant to choose a representative cumulative period of, for instance, 20 years (covering e.g. 2010-2030).

NB! If the SEA supports a substitution plan, the length of the phase-in period for the substitute should most likely be the relevant impact triggering period for the SEA.

In any case, key requirements for the impact triggering period is that it is *representative* for the foreseen changes between the non-use scenarios(s) and the applied for use scenarios. Therefore the period chosen has to be also *the same for both scenarios* to ensure that they are comparable.

The impact realisation period

As already noted, impact may materialise after the impact triggering period. A key principle is that all these impacts should be included in the analysis and at least described qualitatively, and to the extent possible and proportionate, further assessed and quantified.

Often long-term impacts can only be described qualitatively. For example, the impact from accumulation of persistent substances will be very difficult to quantify. However, it is generally not difficult to qualitatively describe how a substance could accumulate and therefore could have increasing effects over time.

Another key issue to consider is whether the substance applied for ends up in an article. In that case, it is relevant to consider the impacts that may materialise throughout the entire life time of the article. If, for example, a substance is used for coating wires used in washing machine motors, it is relevant to consider the entire life time of the washing machines, e.g. whether alternatives considered under the non-use scenario would lead to changed energy efficiency of the motors and thereby washing machines.

Comparing impacts over time

Impacts may appear at different points in time. This includes impacts that may appear after the impact triggering period. Furthermore, in case a cumulative impact triggering period has been chosen (see above), impacts will appear at different points within this period.

For impacts that are monetised, different tools/methodologies exist for making such monetised impacts comparable in relation to a price level in a given year. This includes so-called 'discounting' (covering calculation of 'net present value' (NPV) and 'annualisation'), as well as how to correct for inflation. These methodologies are further described in Section 3.7.

For impacts that are not monetised, a qualitative description and consideration about when these occur in time should be given.

2.4.3 Geographical area covered by the SEA

The applicant should already have attempted to describe the likely responses to not granting the authorisation – the “non-use” scenario. Such responses may cause changes and have impacts that occur outside as well as inside the European Union.

In setting the geographical coverage and undertaking the assessment of impacts, it should be kept in mind that the final comitology decision (see Comitology procedure and Regulatory procedure in glossary) on whether or not to grant an authorisation will most likely focus mainly on impacts inside the EU.

As a consequence, it is recommended that the emphasis be placed on describing and possibly quantifying what happens inside the EU. However, responses/impacts outside the EU should not be neglected and significant impacts should as a minimum be described qualitatively.

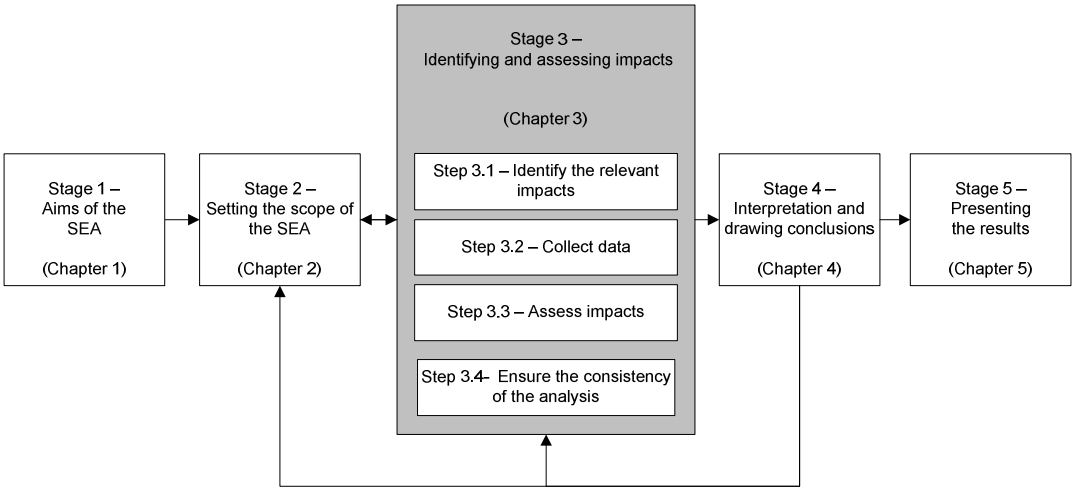
A clear distinction should be made between impacts inside and impacts outside of the EU boundaries, whenever reporting on impacts.

3 THE SEA PROCESS – STAGE 3: ASSESSING IMPACTS

3.0 Introduction

The assessing impacts stage is the third stage in the SEA process.

Figure 11 The SEA process – Stage 3



This chapter provides guidance on how to assess impacts. It is supported by Appendix B which contains potential sources of data / further information and more detailed guidance on how to use specific methods.

The four steps shown in Figure 11 are applied to each type of impact. It is suggested that impacts be assessed in the following order:

- Human health and environmental impacts;
- Economic impacts;
- Social impacts; and
- Wider economic impacts (which includes trade, competition and economic development).

Human health, environmental and economic impacts are likely to be the most significant impacts. Social and the wider economic impacts will follow on from the assessment of economic impacts as economic data gathered provides the starting point for further analysis on employment, trade, competition and wider economic impacts.

The structure of this chapter includes a section covering general issues related to identifying and screening impacts followed by sections covering each type of impact structured around the first three steps (steps 3.1-3.3).

This section describes the proposed approach to this stage of the SEA in detail. It is recognised that the overall approach to the SEA should be an iterative one and the applicant should undertake this stage at a level of detail appropriate to that of the SEA iteration being undertaken.

The approach in Stage 3 can be broken down into the following key sections:

Section 3.1 How to identify the main impacts

Section 3.2 Important considerations when collecting data and assessing impacts

Section 3.3 Human health and environmental impacts

Section 3.4 Economic impacts

Section 3.5 Social impacts

Section 3.6 Trade, competitiveness and economic development

Section 3.7 Consistency of the analysis (currency, price level, discounting, etc.)

Section 3.8 Summary of key issues for the generic "non-use" scenarios

As with all stages in the SEA process, the applicant should give consideration to the uncertainties present in available data. The implications of uncertainties should be considered and acknowledged in the presentation of the assessment of impacts.

3.1 Step 3.1 - How to identify the main impacts

The steps below outline a proposed approach to identifying the main differences in impacts between the scenarios. This process is summarised in Figure **12**. This work should of course build on the relevant supply chains and other boundaries as identified and defined in Stage 2.

Step 3.1 a Create a list of impacts

Appendix G of this guidance contains a non-exhaustive checklist of questions that may lead to the identification of impacts. Any consultation already undertaken during the preparation of the other parts of the application for authorisation may assist in identifying relevant impacts.

The checklists can be used to assist the screening process i.e. to show that all the impacts have been considered and either taken forward or not considered further, but not missed. Submitting the completed checklists as part of the documentation would therefore improve the transparency of the analysis. In any case, it is of key importance to ensure that any decisions made and assumptions used are documented.

The EU Impact assessment guidelines also introduces a useful approach to identify impacts which may support the screening of impacts (Step 3.1.b) by building causal conceptual models. These models can be built in the form of a diagram or matrix and should be able to identify impacts and their interrelations.

Step 3.1 b Screen the impacts (only consider the major impacts)

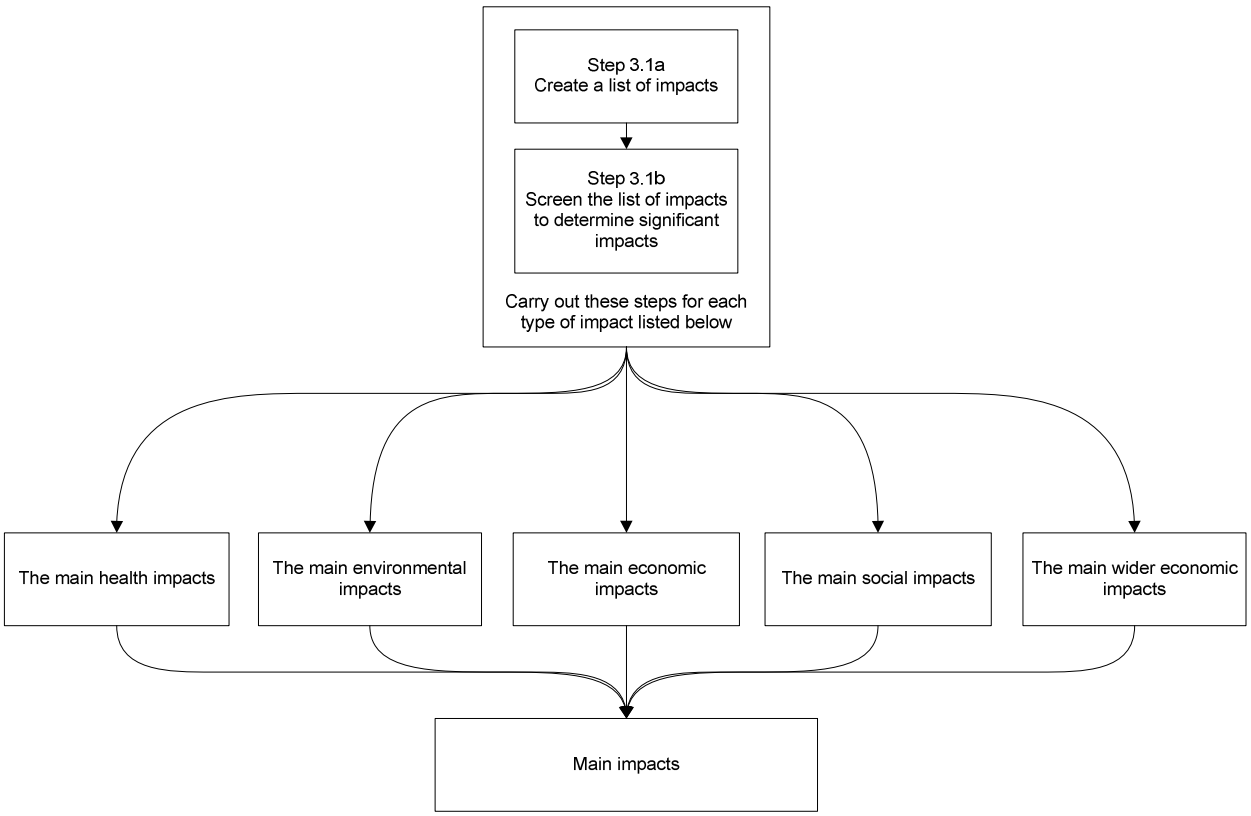
Guidance on how to determine whether an identified impact is sufficiently significant

for it to be brought forward is presented as part of the guidance on each type of impact.

All impacts considered a 'main impact' in the checklist should be considered further but if it is not possible to determine whether some of the impacts in the checklist should be considered further, there are several approaches which may help:

- Consult with relevant experts within the supply chain (See Appendix A);
- Gather more information (through a desk based study);
- Gain opinions from external experts (remember to document their opinion and any assumptions that may have been used in the SEA report). This could for example be experts from various trade associations.

Figure 12 How to determine the main impacts



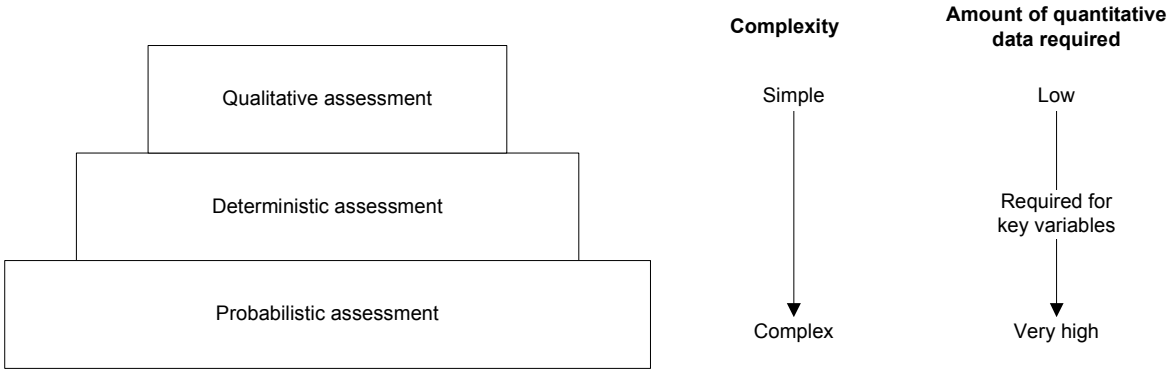
3.2 Important considerations when collecting data and assessing impacts

3.2.1 Consider using a stepwise approach

The level of resources devoted to analysing impacts should be proportionate to the level of analysis required in order to be able to produce a robust basis for decision making process on granting or not granting an authorisation. A stepwise approach is recommended, starting with a qualitative analysis of impacts. This is illustrated below in Figure **13**. The applicant will need to decide whether the

value of this supporting information could be improved by further quantifying and monetising the impacts.

Figure 13 Stepwise approach to analysing impacts



It is important to stress that these three steps can be undertaken as part of an iterative process. The applicant may wish, as a first iteration, to produce a qualitative SEA. The results of this qualitative SEA may then help the applicant to decide whether a robust conclusion can be reached and therefore whether further iterations are required (i.e. undertake the SEA process again but trying to quantify the main impacts). An advantage of this iterative approach is that resources are not used unnecessarily in undertaking a detailed analysis of all impacts as the applicant can focus the detailed analysis on those areas of most significance or greatest contention. The applicant should also gain a better understanding of the main impacts (i.e. a more precise list of impacts and/or a better estimation of the main impacts) which will make it easier to develop a robust conclusion.

3.2.2 Focus on the difference between scenarios rather than absolute values for each scenario

It is important to emphasise that the assessment of impacts should **focus on the *difference* between the "applied for use" scenario and the possible "non-use" scenario(s)**. For example, what are the changes in costs associated with a "non-use" scenario compared to the "applied for use" scenario? How much are the health and environmental impacts changed in the "non-use" scenario compared to the "applied for use" scenario? Please note that, for situations where there are no differences between the scenarios for some types of impacts assessed, this could still be important to document; i.e. to document that those impacts are not likely to be significant for that SEA.

The assessment of impacts can be done by estimating the absolute values for each scenario or by focusing on the differences. The following principles are suggested:

- An impact should be included in the SEA if there is a difference between the "applied for use" and "non-use" scenarios;
- Describe or quantify the difference. Only where absolute values for each scenario are immediately available should these values be used or where understanding the total values are important for the assessment (e.g. total costs borne by a particular actor in a supply chain, particularly if these occur over different timeframes to any benefits derived or where the

differences in environmental and health impacts can only be determined by assessing the total impacts for both scenarios and then comparing the total values to estimate the difference). Otherwise it will normally be easiest to identify and describe any differences between the scenarios.

- Describe the consequences - what are the implications of the differences in costs and benefits of the "applied for use" scenario compared to the "non-use" scenario.

3.2.3 Minimise key uncertainties that arise in the analysis (if it is feasible to do so)

The SEA is likely to be partly based on assumptions, projections and predictions about the likely behavioural response of actors in relevant supply chains, on their future usage (of the substance or an alternative substance) and the significance of each impact under the relevant scenarios. During the analysis it should become more apparent what the key uncertainties are.

The greater the uncertainty, the less confidence there will be in the predicted impacts. The applicant or third party should try to minimise these key uncertainties during their data collection process and should demonstrate the implications of uncertainties in their analysis. As part of the analysis, the applicant or third party should focus on uncertainties that are likely to have the greatest impact i.e. those that prevent the applicant or third party from developing a robust conclusion.

It is important to realise that some uncertainties will be impossible to eliminate (e.g. due to a lack of scientific knowledge about the effects of a substance). These are known as residual uncertainties. Guidance on how to analyse uncertainties is provided section 4.3.

3.2.4 Avoid double counting

It will be necessary to determine the likely response of *each* actor along the supply chain in the "non-use" scenario(s). This is likely to be best achieved through consultation with affected actors along each relevant supply chain (see the previous chapter for further details).

When determining the real cost of the "non-use" scenario it is important to avoid double counting impacts along the supply chain, so as not to exaggerate an impact. E.g., if a manufacturer can pass on any additional cost along the supply chain, the applicant should not consider this a cost to that actor.

There is another aspect of potential double counting that should be considered. Payment of environmental charges and taxes sometimes constitutes internalisation of external environmental costs. If that is the case, then these environmental costs should not be covered under the environmental and human health impacts. In practice, this aspect should be dealt with by considering if any of the environmental costs are already covered under the economic impacts.

Another example is that the costs associated with worker health are only covered under health and environmental impacts, and are not additionally included under economic and/or social impacts.

In general, it should be assured that a given impact is only counted under one impact heading.

By being transparent about how impacts are allocated and calculated (e.g. the methodology, what factors make up the estimate and what variables were used), it should make it clear to the reader that impacts have not been double counted. This will improve the credibility of the SEA.

Example - Analysing impacts along the supply chain

If it costs a manufacturer an additional €10m a year to use an alternative, but that manufacturer is able to pass on €4.5m a year to downstream user A and €4.5m a year to downstream user B through higher prices, then the net cost impact on the manufacturer of using the alternative is only €1m. For downstream users A and B, this €4.5m a year should only be considered to be an additional cost if they are unable to pass on the costs in their end-product through a higher market price. Therefore the cost of using the alternative to the whole supply chain is still €10m, although in this example the majority of the burden of additional costs of using the alternative occurs to downstream users A and B.

3.3 Human health and environmental impacts

Please note, that as part of developing this guidance, a need was identified for further development of methodologies for appropriately describing and assessing the human health and environmental impacts in an SEA context in order to assess the change in impacts comparing the "applied for use" and "non-use" scenarios. In particular this concerns the quantification and valuation of impacts in order to compare the impacts identified, assessed and described in the context of this guidance. This section may therefore be updated at the time such developments become available.

3.3.1 Introduction on human health and environmental impacts

The purpose of the SEA is to investigate whether the benefits from continued use of the Annex XIV substance outweigh the risks from its continued use. To determine the latter, it is necessary to assess the health and environmental impacts of the "applied for use" scenario as compared to the "non-use" scenario(s). If it has been justified when describing the "non-use" scenarios (under Stage 2) that unsuitable alternatives are likely to be used if the authorisation is not granted, this includes addressing impacts of these alternatives as well as other changes in impacts in the supply chains of these alternatives. If the likely "non-use" scenario is not to have the function/service available anymore, this should also be considered carefully in relation to human health and environmental impacts (recognising that the function fulfilled by substances in their end uses may provide protection against human health and environmental impacts).

This section describes how the impacts of manufacture, import and/or use of the Annex XIV substance are compared to not using the Annex XIV substance in terms of impact on human health and the environment. It is important to understand what the changes in health and environmental impacts will be (i.e. the *difference* between the "applied for use" and "non-use" scenario) in order to be able to draw conclusions on what will be the net impacts on human health and environment of the refused authorisation, if these are to be compared to the net socio-economic benefits of granting an authorisation of the Annex XIV substance for the applied for uses.

The basis for the identification and assessment of health and environmental impacts is a proper understanding of the changes that the refused authorisation is expected to cause (i.e. the "non-use" scenario):

- on the manufacture, use or placing on the market of the Annex XIV substance;

- on the manufacture, use or placing on the market of unsuitable alternative chemicals, processes or technologies[18], if identified as a likely response when defining the non-use scenario; and/or
- on any other affected process upstream or downstream in relation to the Annex XIV substance and alternative substance, process or technology.

This should already to a large extent have been described as part of definition of the "applied for use" and "non-use" scenarios and the related scoping of system boundaries. As discussed below, the assessment of health and environmental impacts may, however, lead to revisiting parts of the SEA (iterations) in relation to the understanding of the "non-use" scenario and the original scoping of the SEA.

The assessment of the health and environmental impacts of the reduced/abandoned manufacture, use or placing on the market of the Annex XIV substance under the "non-use" scenario will mean, in the first place, reduced adverse effects caused by that substance. The starting point for assessing these impacts will be information contained in the applicant's CSR.

The SEA should furthermore address impacts related to possible unsuitable alternatives. As part of the preparation of the analysis of alternatives in the Authorisation application, the applicant may have already compared the risks of the Annex XIV substance with possible alternatives as well as assessed the availability and technical and economic feasibility of alternatives (see Guidance on the preparation of an application for authorisation). For SEA purposes, the applicant will however often need to consider a more detailed description of significant health and environmental impacts related to the "applied for use" and "non-use" scenarios, including impacts of reduced/abandoned manufacture, use or placing on the market of the Annex XIV substance and impacts of the anticipated implementation of the identified alternative substance or technology or other significant health and environment impacts. This section is aimed at assisting the applicant in presenting a robust and transparent SEA in relation to covering all relevant Health and Environmental impacts (see also Chapter 2 scoping phase).

In general, for impacts associated with unsuitable alternative substances or techniques and the associated relevant supply chains, the information can be scarce. This may particularly be the case for impacts not directly linked to use of the substance/alternative (for instance changes in energy consumption up or down the supply chain).

When assessing health and environmental impacts, a stepwise approach is proposed, whereby the assessment focuses on those health and environmental impacts that are considered to be significant outcomes of the "non-use" scenario, with the level of detail and quantification applied determined by the extent to which further information will contribute to developing a robust SEA. Throughout the process, judgements will need to be made (drawing on the expertise of others as appropriate) on what impacts are likely to be significant and how these can best be assessed.

The two main challenges are to identify the scope of relevant impacts (i.e. what range of different impacts to cover) and the extent to which impacts should be quantified (i.e. the level of detail and analysis). In relation to the latter, it should be borne in mind that the outcome of this chapter will be compared to the changes in impacts identified in other parts of this guidance.

[18] Note that the SEA non-use scenario may be based on the use of an alternative that the applicant has found to not be suitable and/or available in his analysis of alternatives, see Section 2.3.2.

A particular problem with regard to determining and quantifying human health and environmental impacts is that Annex XIV substances will often have properties for which a Derived No-Effect Level (DNEL) (e.g. non-threshold CMR substances) or a Predicted No-Effect Level (PNEC) cannot be determined (substances with PBT or vPvB properties). For some substance not having a threshold[19], it may be possible to (semi-)quantitatively assess the dose-response behaviour, including e.g. establishing a Derived Minimum Effect Level (DMEL) for non-threshold carcinogens[20]. When no dose-response information can be established, it is more difficult to estimate and quantify the possible toxic impacts. Therefore, it may only be possible to assess these impacts on a qualitative level for certain non-threshold substances.

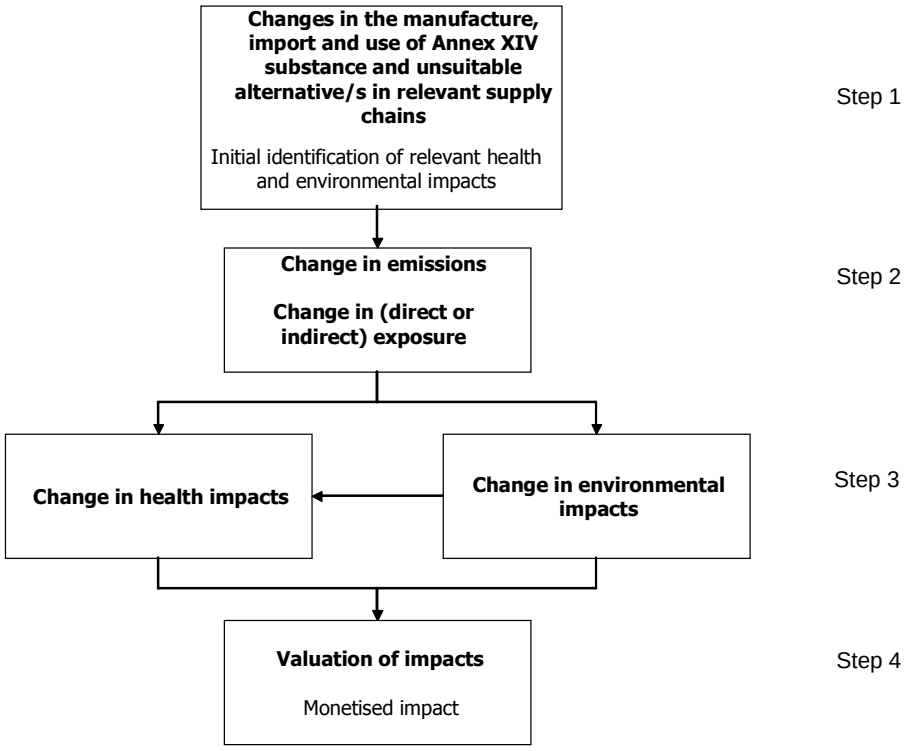
This will also become evident when preparing the Chemical Safety Report (CSR) for these types of substance (See Chapter R.8 and R.11 of Guidance for preparing a Chemical Safety Report). In particular for PBT/vPvB substances, the emphasis of REACH is on reducing emissions throughout the life-cycle of the substance and of characterising remaining emissions. What can be done in an SEA context is to recap all relevant scientific information, to record volumes used and to characterise (estimate) emissions. Most of this information can be found in the CSR. In drawing conclusions on the SEA, this information will need to be compared to the other impacts as part of the overall comparison of the "applied for use" and "non-use" scenarios.

Figure **14** and the related text below describe the steps that can be taken to identify, assess and valuate the impacts.

[19] And therefore only eligible for authorisation under the socio-economic route.

[20] It is important to stress that a DMEL is not equivalent to a DNEL. A DNEL expresses a derived value below which exposures should be controlled – with the underlying assumption that such an exposure level would be below a no-effect-level. For non-threshold effect, the underlying assumption is that a no-effect-level cannot be established and a DMEL therefore expresses an exposure level corresponding to a low, possibly theoretical, risk. Please refer to Chapter R.8 in the Guidance on Chemical Safety Report for further information on how to derive and use DMELs.

Figure 14 Scheme for assessment of health and environmental impacts



Step 1. Changes in the manufacture, import and use of substance and unsuitable alternatives in relevant supply chains. Initial identification of relevant health and environmental impacts.

A refused authorisation of a use of the Annex XIV substance will eliminate or reduce emissions of and exposure to that substance. However, if an unsuitable alternative is likely to be used under the "non-use" scenario, emissions of and exposure related to that alternative could increase. Changes in relevant supply chains may also result in changes in emissions/exposure of various other substances from other processes in the affected supply chains, i.e. upstream or downstream processes related to the manufacture or use of the Annex XIV substance or alternative substances or techniques. This may also include impacts or substances created unintentionally, e.g. increased or decreased emissions from energy generation, or exposure to physical factors (e.g. vibration, heat or explosion) as well as increased or decreased consumption/production of other things such as waste production and water use. Potential impacts upon any/all environmental compartments and human health (such as impacts on workers, consumers and general population indirectly exposed though the environment) should be considered. At the end of this step the purpose is to identify all the health and environmental impacts that are likely to be of significance, based on the changes that will occur to relevant supply chains.

Step 2. Changes in emissions and exposures

Based on the initial identification of relevant supply chains, exposures and impacts, the next step is to summarise the associated changes in emissions and exposure in a quantitative or at least a qualitative way.

Step 3. Change in Health and Environmental Impacts

The exposure may lead to – depending on the characteristics of the substance and the level of exposure – an unwanted impact of the substance on human health or the environment. Examples of unwanted human health impacts are skin irritation and cancer, and for environmental impacts, toxic impacts on populations and secondary impacts at ecosystem level, deterioration of habitats and ultimately extinction of species and/or other environmental impacts not directly related to the toxicity of the substance (e.g. global warming). When assessing impacts, one needs initially to assess qualitatively how the changes in emissions and exposure (that result from a refused authorisation – i.e. the "non-use" scenario) may affect the impacts. Note that 'impacts' may be 'positive' (in cases where emissions/exposures are avoided/reduced) or 'negative' (in cases where emissions/exposures are generated/ increased).

In some cases the identified changes in impacts can be quantified in physical terms (e.g. by assessing how many cases of skin irritation or cancer would be reduced per year as a result of the refused authorisation or introduced by an unsuitable alternative, or the expected impact in a population of a certain species in a specific local environment), while in other cases they can only be described in qualitative or semi-quantitative terms (e.g. number of workers exposed to a carcinogen or the percentage of species in an environmental compartment that are likely to be affected).

To the extent the impacts can be quantified, it is possible to move to the next step; the valuation/monetisation of impacts.

Step 4. Valuation of impacts

The final step is to give a further interpretation of the changes in impacts. This may be done by using damage indicators and/or by assigning monetary values to the identified impacts.

It is possible to give monetary values for several quantified human health impacts. In some cases it is also possible to give monetary values for environmental impacts. By applying these values, one can monetise the human health and the environment impacts resulting from a refused authorisation (allowing comparison with other monetised impacts in the SEA).

The above outline is used as the conceptual framework for identifying, assessing and, if possible, quantifying, and ultimately valuating health and environmental impacts.

Section 3.3.2 describes how to identify relevant supply chains affected and how to make an initial identification of relevant health and environmental impacts; section 3.3.3 further addresses how to identify changes in emissions and exposure. Section 3.3.4 addresses how to determine, assess and if possible quantify impacts; and Section 3.3.5 deals with the valuation of impacts. Possible sources of data are highlighted and example boxes provided. Finally, section 3.3.6 describes how results may be reported.

As indicated above, it will rarely be possible to quantify (in Step 3) or give values for (Step 4) all impacts. However, the aim should be to at least qualitatively describe the main changes in health and environmental impacts foreseen as the difference between the "applied for use" and the "non-use" scenarios.

Some iteration may be needed as the data collection takes place throughout the exercise. This may, for example, point to new relevant emissions that were not thought of initially, or it may turn out that during quantification of impacts an emission initially considered important is found to be of less relevance. Therefore, as a starting point, the scope of the exercise should be as broad as possible. In this way, one can make sure that important aspects are not overlooked. The scope

should cover changes in the entire supply chain(s) of the Annex XIV substance and possible alternatives and include direct and indirect emissions/exposures and impacts.

3.3.2 Changes in the manufacture, import and use of substance and unsuitable alternatives in relevant supply chains and initial identification of relevant impacts

3.3.2.1 Relevant supply chains

The relevant supply chains are those where there will be a difference between the "applied for use" and the "non-use" scenarios i.e. 'what will be different if an authorisation is not granted. These should already have been largely identified and described in the scoping and definition of the "applied for use" and "non-use" scenarios (Stage 2). At this point it should be considered in more detail what the changes in emissions/exposures/impacts will be in the affected supply chains and whether all relevant supply chains were initially identified. In other words, the activities may lead to iterations of the SEA. The following gives some idea of the type of questions/considerations that are relevant at this stage of the assessment.

Consider all those emissions/exposure/impacts that will be reduced/eliminated as well as new/increased emissions/exposure/impacts caused by a refused authorisation:

- Upstream: For example, if another (unsuitable) alternative substance fulfils the function(s) of the Annex XIV substance, will that lead to differences in emissions/exposure/impacts upstream from the Annex XIV substance (e.g. lower emissions) as well as upstream from the alternative (e.g. higher emissions)?

- Manufacture: There will of course be lower emissions/exposure/impacts of the Annex XIV substance and other substances used/generated during its manufacturing process. If, for example, an unsuitable alternative substance fulfils the function(s) of the Annex XIV substance under the "non-use" scenario, higher emissions of that substance will occur, as well as higher emissions of other substances used/generated during that manufacture.

- Downstream: Consider the health and environmental impacts of not using the Annex XIV substance and, if use of an unsuitable alternative substance/technology is a likely response, to which extent that will trigger lower, higher or new emissions and/or different resource consumption and/or different consumer/worker exposure?

- Other affected supply chains: For example, will it require less or more energy or reduce or increase other emissions in the processing steps needed to produce a different technology fulfilling the function(s) of the Annex XIV substance?

- Overall, there will be reduced emissions/exposure/impacts for the Annex XIV substance and increased emissions directly related to the possible alternative(s). However, for emissions of other substances and for other types of impacts (e.g. energy use), impacts at all supply-chain stages may potentially increase or decrease, depending upon the particular circumstances.

If not granting an authorisation will lead to the use of an unsuitable alternative substance, then the supply chains producing and using that alternative should be considered (including end-of-life stages). The procedure will be, subject to the need for and accessibility of information, to look at raw material production, production of the two substances and use of the two substances throughout the supply chains and final disposal of any downstream user products. Note that there may be more than one alternative substance under the "non-use" scenario.

If the “non-use” scenario implies use of alternative technology, the procedure is similar. The supply chain for the alternative technology should be included. For example, it should include considerations of whether there is equipment which causes any significant emissions or other impacts during manufacture (including the raw material use for the equipment).

If non-use is loss of functionality, it should be considered whether there would be any human health and environmental impacts from not having this functionality (as e.g. increased risk for fire and accidents).

The extent to which the analysis of different supply chains needs to be conducted should depend upon the overall level of detail that is likely to be practicable and proportionate to demonstrating the relevant impacts of the “non-use” scenario.

3.3.2.2 Initial identification of relevant health and environmental impacts

Since the basis for the SEA in an application for authorisation relates to evidence that the socio-economic benefits outweigh the risks to human health and/or the environment arising from the use of the Annex XIV substance, the starting point in identifying relevant health and environmental impacts will relate to the risks associated with that substance. There should already be a good understanding of the properties and emissions/exposures of the Annex XIV substance and therefore the associated risks.

Given that starting point, one important purpose of the SEA is to analyse whether refusing an authorisation would lead to other disadvantages, including other significant health and environmental problems. Depending on the identified "non-use" scenario (Stage 2), these may be triggered by unsuitable alternatives fulfilling the functionality of the Annex XIV substance or by the fact that the functionality will no longer be available.

For example, where there is a ‘drop-in’ alternative substance with a similar production and use pattern to the Annex XIV substance, a comparison of the hazardous properties of the two (or more) substances may provide useful information on determining what types of impacts are likely to be relevant. This will be conducted in the analysis of alternatives. However, for the SEA, consideration should also be given to the impacts of other substances used in the production of the Annex XIV substance and possible alternatives and of unwanted by-products to which relevant exposure conditions might occur.

A refused authorisation may result in wider changes to the supply chains that could have other impacts on human health and the environment. This should in all cases be considered when the alternatives are alternative processes or technologies.

Consideration should be given to the types of impacts that may occur at each stage of the supply chains (from raw material extraction to ultimate disposal).

A non-exhaustive list of the types of health and environmental impacts that may be relevant is provided in the following box.

Human health and environmental impacts that may be relevant (examples)

Human health

- Morbidity
  - o Acute effects (e.g. skin or lung irritation)
  - o Chronic effects (e.g. asthma or reproductive disorders)
- Mortality (e.g. premature death due to cancer)

Environmental

- Ecological impairment, i.e. biodiversity and functioning
- Habitat destruction
- Water quality impairment
- Air quality impairment
- Soil quality impairment
- Other impacts, such as
  - o Climate change (e.g. greenhouse gas emissions)
  - o Water consumption/abstraction
  - o Landscape/aesthetic quality of environment
- Resilience and vulnerability to environmental impacts

3.3.2.3 Determining significance

The toxic and ecotoxic impacts of the Annex XIV substance are of key importance because this is the reason it has been listed on Annex XIV. Such impacts should always be considered in determining the impacts of continued use compared to the non-use scenario. In relation to other health and environmental impacts, a judgement will have to be made regarding which are relevant and consequently which should be investigated in more detail.

It is not appropriate to provide hard and fast rules for determining which impacts are likely to be significant, but some guidance is provided in the examples below on narrowing or widening the scope. The process may be an iterative one and it may be necessary to consider other issues that were not originally identified once the impacts have been further characterised.

Example 1 Initial considerations about significance of health and environmental impacts

Each authorisation application will be different and the changes to the supply chains and health/environmental impacts that are of relevance to determining the net benefits of a refused authorisation will also be different.

Identifying and understanding the changes to the supply chains is the starting point for understanding which impacts are relevant and which are not. It may be helpful to construct process trees/flow diagrams for the use of the substance and possible alternatives, including the physical flows throughout relevant supply chains (see also Section 2.4.1).

The significance of the impacts will be determined by their relative size compared to other impacts. For example, if refusal of the application leads to a first crude estimate that an additional 200 tonnes per year of CO_2 emissions will occur, one can use the information about market price of CO_2 (which at the time of writing is about €20/tonne CO_2) and deduct the significance of reducing emissions by 200 tonne CO_2 being worth about €4,000. Even though the 200 tonne CO_2 estimate may be highly uncertain at this point of the analysis, it may give a feel for whether this impact is significant.

The decision on what impacts are significant will be based on judgement. These judgements can be informed by information from and discussion with other experts (e.g. on particular impacts such as waste generation or on particular sectors within the supply chains). Such expert judgements should be justified and documented.

It will always be possible to return to this stage later if other health and environmental impacts are identified as being relevant following more detailed analysis. The aim at this stage should be to *demonstrate* an appreciation of what is likely to be significant, as well as what is not likely to be significant (and why not).

Example 2 Substance specific examples of identifying wider significant impacts

There may be possible wider impacts connected with the use of an alternative substance. Consider for instances a historical example relating to the replacement of tetraethyl lead (TEL) as an anti-knocking (burning control) agent in petrol engines for cars, with methyl tertiary butyl ether (MTBE) being one of the possible alternatives.

MTBE is a technically feasible alternative to TEL and in addition MTBE also reduces the formation of the other polluting gases carbon monoxide and nitrogen oxides. However, the very wide and dispersive use of petrol means that MTBE (indeed any additive) has great potential to get into the environment. Because of possible spillages and leaks from containers (especially where petrol is stored underground), it has great potential to get into groundwater and although it is not particularly toxic (compared to TEL), it is not very biodegradable and it can taint the taste of potable water at very low concentrations. In a case like this, the scope of the analysis would need to include the consideration of the potential impacts of the alternatives on groundwater and potable water supplies. This would form part of the assessment of the alternative in order to establish whether or not risks would be reduced.

(Whilst this example relates to a substance, TEL, that was *restricted*, the principle under the Authorisation procedure is the same.)

3.3.2.4 Outcomes

The analyses described above should provide an understanding of what health and environmental impacts are relevant for the supply chains in question and which of these are likely to be of most significance. This will provide a scope for more detailed analysis.

It may be possible at this stage to take a decision that sufficient information is already available to analyse the impacts of the "non-use" scenario compared to the "applied for use" scenario. For example, if the alternative most likely to be used under the "non-use" scenario would be a 'drop-in' substitute, it may be possible to infer that changes relevant for health and environment do not go beyond the same supply chain and thus the scope of the analysis can be narrowed to this.

In many cases it will be necessary to give further consideration to the emissions, exposure and impacts of the changes to the supply chains as these determine the actual impacts on health and the environment. This should certainly be the case where the overall level of health and environmental impacts (toxic/ecotoxic or otherwise) are likely to be extensive.

3.3.3 Changes in emissions and exposure

3.3.3.1 Background

In order to determine the consequences of changes to the supply chains (in terms of the relevant health and environmental impacts), it is necessary to gain an understanding of the extent to which the humans and the environment will be exposed to the various factors considered. In this context, 'exposure' may include direct or indirect exposure to substances or exposure to physical changes (temperature, noise, resource use, waste generation, etc.).

This section provides an overview of how the extent of such potential changes may be characterised.

The relevant emissions/exposures are all types of emissions to air, water and soil that can lead to human health or environmental exposures and impacts.

In addition, resource consumption should be considered, particularly when resource consumption leads to emissions, e.g. as a result of mining or as emissions from energy consumption.

Human health impacts may follow from:

- Exposure of workers (e.g. via inhalation, dermal or ingestion exposure in the workplace);
- Exposure of consumers (e.g. via inhalation, dermal contact or ingestion following use of consumer products); or
- Exposure of man via the environment (e.g. via inhalation of ambient air and consumption of contaminated food and drinking water).

Humans can also be exposed to physical impacts associated with the physicochemical properties of chemicals (including flammability, explosion, etc.) and with the properties of (alternative) processes/technologies (e.g. risk of accidents, vibrations, noise).

Environmental impacts may follow from emissions to the environment that may lead to pollution of different compartments (e.g. air, water, soil, sediment) and eventually to impacts on living

organisms. Environmental impacts may also follow from physical changes (e.g. temperature, resource use, waste generation) which may affect habitats and lead to landscape impacts.

3.3.3.2 Data collection on emission and exposures

A considerable amount of data is collected for the Annex XIV substance in the development of the CSR (see Guidance on Information Requirements and Chemical Safety Assessment) and for possible alternatives in the analysis of alternatives (see Guidance on the preparation of an application for authorisation). This includes data on the emission, exposure and impacts. These are key data for the analysis to be done in the SEA. However, these data might not fully reflect all relevant emissions and impacts on heath and environment; therefore further data collection may be considered. For example, it is unlikely that the CSR or the analysis of alternatives will have provided details of the numbers of workers or consumers exposed. However, in the CSR for the Annex XIV substance there will be important information on emissions and how they are controlled as well as consideration of the conditions under which exposure occurs (such as in operating conditions and exposure scenarios) and the environment into which releases occur.

Applicants will have considered in the scope of the SEA and in other parts of the application the number of sites where the applied for use(s) take(s) place. In some cases this may be at a single site and therefore site-specific data can be gathered that will allow a more accurate and specific assessment to be made of emissions and control of emissions, as well as the exposures in terms of the number of workers affected and details of the environment into which releases occur.

The assessment of emissions and exposure from the various relevant supply chains (see Section 3.3.2.1) can be based on data on the processes, including use of materials and inputs such as energy, water and raw materials and outputs (via products and emissions). Such data might be sourced from manufacturers and other organisations involved in the supply chains. If suitable data are not available directly, it may be possible to use information from the literature or databases, such as that outlined in the following box.

Examples of possible data sources on emissions and exposure

Examples of the types of data sources that could be used in estimating emissions of and exposure to the relevant environmental and health endpoints are set out below. In practice, the data that will be needed for each application will depend upon the specific substances and technologies relevant to that particular case.

- Emissions and exposure estimates developed for other substances under REACH (and other legislative regimes in the EU and elsewhere).
- Emission scenario documents developed by the OECD (www.oecd.org).
- US EPA exposure assessment tools and models (www.epa.gov/oppt/exposure/).
- Reference documents on Best Available Techniques under the IPPC regime (eippcb.jrc.es).
- Emission inventories, such as those for greenhouse gas emissions or air pollutant emissions (rod.eionet.europa.eu/index.html).
- Emissions register for chemical substances, such as the European Pollutant Emissions Register (www.eper.ec.europa.eu/eper/).

- Statistics on e.g. specific energy consumption of fuels and industrial processes (e.g. DUKES in the UK).
- Assessments of risks to human health and the environment through industrial accidents in relevant supply chain stages (e.g. under the Seveso II regime).
- Life cycle assessment databases may provide average emission data related to the impacts of various materials and processes
  (see e.g. as a starting point http://lca.jrc.ec.europa.eu/lcainfohub/datasetArea.vm)
- Population data based on population censuses as well as aggregated data from Eurostat. (http://epp.eurostat.ec.europa.eu/)
- Information about occupational distribution of workers from industrial statistics
- Environmental data on ecosystems from the European Environmental Agency (http://www.eea.europa.eu/)

3.3.3.3 Characterisation of changes in emissions and exposures

At this stage, it should be possible to at least provide a qualitative description of the extent of exposure that is likely to occur at relevant stages in the supply chains of interest. This should include all of the health and environmental impacts that are likely to be of significance. The data sources detailed in the previous section may allow certain emissions and exposures to be quantified. The extent to which this is done should depend upon the overall level of quantification that is likely to be practicable and proportionate to demonstrating the impacts.

It will be up to the applicant developing the application for authorisation to determine the extent to which the emissions and exposures are quantified. Presentation of the outcomes of this stage in a tabular format including emissions/exposure for each relevant health/environmental issue at each relevant supply chain stage may aid comprehension.

The characterisation of emissions, exposure and impacts at this stage could be qualitative or quantitative (or a mixture of the two). The procedure would be to start with qualitatively identifying where there might be differences in emission between the “applied for use” and “non-use” scenarios. It might be possible to quantify the emissions and this should be done if practicable as it will be an important factor in determining significance of the impacts.

Key aspects to consider for emissions and exposures are:

- Duration – i.e. how long the emission/exposure lasts for. This should include consideration of whether the exposure is continuous or intermittent.
- Frequency – i.e. how often emission/exposure happens.
- Population or compartment exposed – for humans the exposed population may include particular groups (some of which may need special consideration e.g. young children or the ill). The numbers of exposed may be estimated (although this information is not normally reported in standard safety/risk assessments). For the environment this should include consideration of what environmental compartments are exposed, the spatial distribution of

chemicals and particularly vulnerable parts of the environment (sensitive species, protected habitats, etc.).

- Exposure route: for human health this will determine the exposures of individuals; analogously, the extent of exposure of environmental organisms will depend on the environmental compartment in which they live and their behaviour (e.g. diet).

3.3.4 Changes in health and environmental impacts

3.3.4.1 Relating emissions/exposures to impacts

Having identified the difference in emissions and exposures, the possible impacts following from the emissions/exposures should be identified.

The following should be taken into account:

- One type of emission can lead to different types of impacts (some chemical substances may, for example, cause cancer as well as impacts on aquatic organisms; emissions of ammonia can cause human health impacts through particulate matter formation, and also contribute to euthrophication and acidification).
- Several types of emissions may contribute to the same type of impact (e.g. different substances may lead to the same toxic response).
- Impacts can be described and subsequently quantified at different stages in the pathway between causes and impacts (between emission and eventual consequence in terms of e.g. skin irritation, sickness or lost lives).

There might be great uncertainty with regard to the possible impacts and this should be reflected in the description within the SEA. It may be that a description of impacts, such as e.g. contamination of certain environment compartments, will be the best that can be achieved if it is considered that the uncertainty related to estimating an impact (e.g. for human health sickness or death, and for the environment extinction of certain populations or accumulation in particular species) is high. Nevertheless, relating emissions/exposures to impacts should be attempted because the long-term and wide reaching potential for impacts of Annex XIV substances is the reason that such substances require authorisation and it is the aim of the SEA to demonstrate that that the socio-economic benefits of continued use outweigh these impacts.

The level of detail may also depend on how far impacts can actually be quantified. Identification and description of impacts is therefore related to the activities outlined in Section 3.3.4.4 on quantifying impacts.

Examples of the types of impacts that it may be possible to estimate are outlined in the following box.

Examples of types of impacts that it may be possible to estimate

Human health

- morbidity or mortality through exposure to a toxic substance;
- morbidity or mortality due to different explosive characteristics of the substance;
- morbidity through exposure to noise, vibration radiation; and
- other human health impacts (which should be specified in the SEA).

Environmental

- eco-toxic impacts (including accumulation) upon ecosystems/species/populations;
- euthrophication or acidification of water or soil;
- amount of waste generation; and
- other environmental impacts (e.g. on habitat, natural resources supply, landscape).

The potential impacts will generally need to be further assessed and, where possible, adequate and proportionate, they should be described qualitatively, quantitatively or as a mixture of the two. It will be a matter of judgement for the applicant in determining how far the assessment should involve quantification and monetisation of impacts. The overall aim should be to have gained, and be able to communicate, an understanding of (or a 'feel for') the significance of the impacts.

3.3.4.2 Data on impacts assessment

Understanding the likely impacts from each exposure requires expertise in toxicology and eco-toxicology and in other health and environmental impacts. As with other parts of the SEA, depending on the case in question, it is likely to be appropriate to consult with relevant experts in the fields concerned.

See the Guidance on Information Requirements and Chemical Safety Assessment in relation to assessment of toxic risks from substances.

In cases where several emissions not related to (eco)-toxicity have been identified, Life Cycle Impact Assessment (LCIA) methodologies may be applied to get an idea of the likely resulting impacts. See for example http://lct.jrc.ec.europa.eu/assessment/partners for links to some organisations providing such methodologies. These methods may also be used for the further quantification of impacts (described below). See also Guidance on the preparation of an application for authorisation for determining the 'non-toxic' risks of alternatives.

3.3.4.3 Qualitative assessment of impacts

Toxic impacts to human health

When a quantitative measure of impacts is not feasible, qualitative criteria can be used to characterise impacts.

The human health and physical impacts can be characterised by means of criteria of potency (hazard) and exposure. For example, it may be possible to come to a qualitative description of the likely impacts by considering the following criteria (in practice, other criteria may be appropriate):

a) the potency of intrinsic properties of concern e.g. no-effect-level or other indicators of dose-response (median or other percent effects levels); potency could also be indicated descriptively (e.g. mild, moderate or severe);

b) the potential for effects to be transferred to future generations (i.e. for mutagens and reprotoxins);

c) severity of the effect (i.e. the type of effect and whether it can lead to morbidity and/or mortality) for example skin irritation would, at an individual level, be considered less severe than asthma and both considered less severe than cancer;

d) exposure characteristics, including which populations are exposed (workers, consumers, man via environment), number of exposed and to what extent/level (concentration/dose), how often (frequency) and for how long (duration). This could also consider the likelihood of failure of risk management measures (different performance, likelihood of non-application).

In cases where a risk characterisation ratio has been estimated as part of a safety/risk assessment, the value can be used as an indicator of whether the exposure exceeds a derived or predicted no-effect level. The potency of the intrinsic property of concern (criterion a) will be expressed by the no-effect level used to calculate the risk characterisation ratio. The ratio should not be used as the only criterion, because it does not include information about the severity of effects (which is important when comparing two or more substances) and the exposed populations. Furthermore, the quantitative interpretation of the risk characterisation ratio is only possible if the dose-response curve is defined. Note that it will not be possible to do this for the Annex XIV substance if it is a non-threshold CMR or PBT/vPvB.

Qualitative conclusions can then be drawn as to the expected severity and extent of the impacts. This exercise would be repeated for each relevant exposure situation and end-point.

Health impacts caused by physicochemical properties and other physical forces

It will generally only be possible to describe in qualitative terms the impacts caused by the physicochemical properties associated with a substance and physical forces associated with alternative technologies. To the extent possible, the types of impacts should be described, including increased/decreased likelihood of e.g. flammability/explosion, vibration/noise and the associated numbers of workers/consumers affected in a particular way. This may already have been done to a large extent in previous steps.

Environmental impacts

Similar criteria as for human health can be used to describe the expected impacts on the environment. In general terms, eco-toxicological and environmental impacts are more usually characterised by means of criteria of magnitude and significance, where magnitude is the intensity

of the potential effect and significance indicates the foreseeable damages of the receptor (population, community, ecosystem, and natural resources). Examples of criteria that may be used include the following:

- frequency of impact;
- duration (will the impact be temporary or permanent; how long will it last);
- extent, e.g. the percentage of a habitat that may be lost, geographical scale of exposure;
- sensitivity/vulnerability of the receptor affected;
- resilience of the receptor affected; and
- ecological, economic or cultural relevance of the impacted receptor.

At this stage, it may be possible to describe the likely magnitude and extent of the expected environmental impacts, not forgetting that – as explained previously – the presence or accumulation of the Annex XIV substance in an ecosystem may also be considered to be an impact. For example, this may include, for each relevant endpoint, a description of the types of ecosystems (or organisms) likely to be affected, how widespread the impacts are likely to be and what the effect on those ecosystems will be.

In order to aid presentation, it may be appropriate to rank the magnitude and significance of impacts (e.g. as high, medium or low), according to set criteria, provided that these are set out transparently and the decision-making processes can be followed.

3.3.4.4 Quantitative assessment of impacts

Overview

It is important to attempt to quantify the human health and environmental impacts to the extent possible, practicable and proportionate. The more the health and environmental impacts can be quantified, the more solid the case can be made for the application for authorisation. One should not forget to take into account and document uncertainty related to the quantification.

N.B. It is vital that greater weight is not given to quantitative data in the overall assessment simply because quantification has been possible for a particular impact. There may be other impacts of significantly greater importance that cannot be readily quantified for reasons of data availability or uncertainty.

Human health toxic impacts

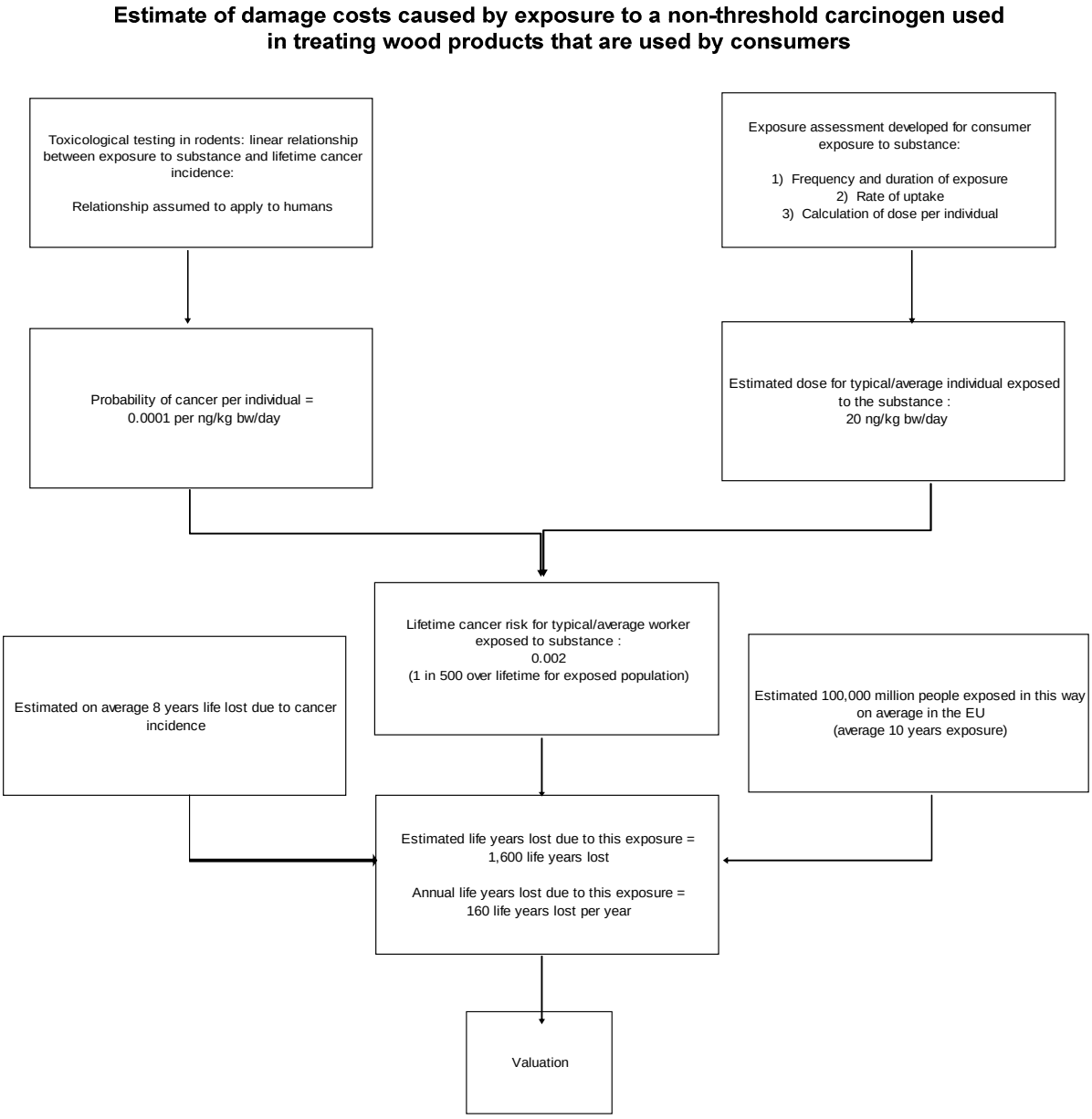
In order to quantitatively analyse the total health impacts, the applicant needs to have predictive estimates of exposed population (e.g. number of persons) and consider the type of severity of the health impairment that is likely to occur (e.g. in terms of reduction in life expectancy or degree of health impairment). Such data are not normally reported as part of chemical safety assessments. Therefore, it is highly recommended that such data are collected – to the extent possible – as early as possible and reported in the SEA accompanying the application for authorisation.

In order to be able to quantify the impacts upon human health, a number of types of data are likely to be needed:

- Quantitative estimates of the relationship between individual exposure and the incidence of a defined health effect (e.g. skin irritation, respiratory illnesses, cancer) and derivation of a probability of that effect being manifested (i.e. a dose-response relationship);
- Assessment of exposure, including e.g. the frequency and duration of exposure, the rate of uptake of the substance by the relevant route (e.g. inhalation, oral, dermal) in order to be able to estimate and average dose or a range of doses;
- A measure of actual impact of the health effect (e.g. numbers of life years lost due to contracting cancer);
- An estimate of the total population exposed (and if possible the distribution of exposure within that population).

Figure **15** provides an illustration of how these types of data could be used to quantify the risks associated with cancer from the exposure to a non-threshold carcinogen released from a consumer (or other) product and to which a defined population is exposed. The specifics of the example are not important (e.g. it is recognised that carcinogens should be prohibited from use in such consumer products) and the figure is only intended to illustrate a possible process for quantifying impacts.

Figure 15 Illustration of quantification of health impacts for consumer exposure to a carcinogen



Environmental impacts

Environmental impacts could involve ecosystem impacts (including toxicological effects on ecosystem structure and function) and impacts like reduced quality of soil, air and water (e.g. for drinking or recreation) influencing human use of these resources.

In the case of impacts on ecosystems, the analysis may involve the quantification of the damage from the level of populations to the full ecosystem level. How to quantify these impacts, especially at ecological community and ecosystem level, based on observed effects on some species is a challenge that is not supported by any established scientific method so far, but operational methods might be developed in the future.

Alternatively, the assessment can be focused on the impact on particular populations or species, based on their sensitivity or economic or cultural/symbolic value. The impacts on these species can possibly later be valuated (see section 3.3.5) and the outcome can be regarded as a quantitative or semi-quantitative assessment, depending on whether the impact on those species is representative of the overall impact on the environment.

The feasibility of a (semi)quantitative impact assessment is normally higher where applied to a local environment, e.g. to a specific industry site.

Based on the extensive work carried out under the Convention on Long-range Transboundary Air Pollution of the UNECE, the European Commission applied in its Thematic Strategy on Air Pollution, the latest scientific findings of the critical levels and loads of acidifying and eutrophying substances, as well as the effects of ozone on ecosystems[21]. Furthermore several activities have focused on identifying the impacts of heavy metals on the environment[22]. Thus, a lot of existing knowledge can be used concerning the impacts of releases of heavy metals, ammonia, volatile organic compounds, NOx and SO_2 to the environment.

Other useful methodological references for the application of (semi)quantitative environmental impact assessment can be found in the assessment of potential accidental releases of dangerous substances for Seveso Directive[23] (2003/105/EC) sites.

3.3.5 Valuation of impacts

3.3.5.1 How and what to value

The valuation of human health impacts is based on the prediction of the total health damage, i.e. number of persons that might be affected by a certain health effect, ranging from morbidity to mortality. Depending on the extent to which such quantification has been carried out (see previous section) it may be possible to aggregate the health impacts. Two possible methodological approaches can be used.

One possibility is to use weights based on disability or quality adjusted life years (DALY or QALY), in order to aggregate health impacts. Appendix B1 gives further information on how this could be carried out. With DALYs and QALYs it is possible to carry out cost-effectiveness analysis as the benefits are in the units of “years” and costs in the units of “euros”.

A second method is to use the willingness-to-pay estimates (WTP) of people for reducing the risk of dying or avoiding illness. Such values have been estimated both in the EU and other parts of the world. For instance, the most recent estimate used at the EU- level for the value of gaining a “life year” was €55,800 (in 2003 prices). The example below shows how such a value can be applied.

[21] For details see, e.g. the Coordination Centre for Effects available at http://www.mnp.nl/cce/

[22] For details, see e.g. the integrated assessment of heavy metal releases in Europe (ESPREME) available at http://espreme.ier.uni-stuttgart.de/

[23] See http://ec.europa.eu/environment/seveso/index.htm

EXAMPLE: How to apply a value of life year

Continuing with the example of Figure **15**, using the value of life year in Appendix B.1.2, it is possible to estimate the benefit of reduced exposure to the carcinogenic substance, with the assumption that the alternatives do not have such properties. Given that the benefit of not using the substance would be 160 life years per year and given that the value of the life year is €55,800, the monetised value of the benefit would be €8.9 million per year. This could be compared against the costs of the non-use scenario in a cost-benefit analysis.

Changes in healthcare costs (hospital costs, medicine, etc.) and changes in production due to sick-leave are means of valuing the impacts of improved health. This has been the basis for estimating the value of avoiding a "minor restricted activity day" at €41/day (in 2003 prices). Appendix B.1.2 gives more details; including values for reducing the emissions of main air pollutants. Such values are likely to be helpful when different kinds of health end-points are valued.

It is possible to value the external effects of air pollutants, which will mainly be caused by burning of fossil fuels. For example, for particular air pollutants, the European Commission – as part of the Clean Air for Europe programme – has estimated the value of the impacts for releasing one tonne of $PM_{2.5}$ (particulate matter with a diameter smaller than 2.5 μm), NH_3, SO_2, NO_x and VOCs in different Member States. Concerning the valuation of the impacts of greenhouse gases, the current or predicted market price of CO_2 (being about €20/tCO_2 at the time of writing) is likely to be a helpful source to value the changes in greenhouse gas emissions. Such reference values can also be found from other sources. These are likely to be helpful in undertaking a quantitative analysis of air pollution or externalities of energy production. See Appendix B.1.2 for further details.

Ecosystem services contribute to economic welfare by, for instance, the generation of income (e.g. crops, fisheries) or wellbeing (recreational values and non-use values, e.g. existence values) and through the prevention of damages resulting in costs for society (e.g. water regulation, erosion control). Therefore, for environmental impacts, the costs and benefits could be described as the value of changes in the services provided to society by the natural environment.

Valuation of impacts should be carried out when possible and proportionate. Valuation helps in making the comparison between different types of impacts easier by giving an indication of the magnitude of the impacts in a form that allows like-for-like comparison. As with the analysis of other impacts, the valuation of impacts has various associated uncertainties. Therefore, the assumptions and sources of the values need be reported transparently.

If there are no values that can be used, it is possible to undertake a specific valuation study. It should be noted that such studies require multi-disciplinary expertise and are usually resource intensive.

However, there are many techniques that can be applied to valuate environment degradation in more general terms and the reduction of environmental services. The example below includes several applications of such approaches.

EXAMPLE: Valuation of environmental and health impacts

Some examples of assessing environmental impacts resulting in monetary appraisal can be found in

a study conducted for the European Commission analysing benefits of REACH on the environment. The benefits have been calculated by three different approaches: via the willingness-to-pay (WTP) for avoiding the environmental damage, via an identification of costs caused by environmental damages, and via an estimation of the current costs that could be avoided if the release of chemical substances were better controlled (e.g. less expensive drinking water purification).

Among those three approaches, the damage function approach was applied based on case studies of selected substances (already restricted in the EU). While the value of the overall benefit of REACH presented in this study is subject to significant uncertainties due to certain assumptions and extrapolations, and while different approaches can also be applied, the substance-specific case studies can give some indications for an appraisal of environmental benefits in the context of REACH SEA.

The extracts of the case studies are presented below. The detailed calculations can be found in the above-mentioned report, referenced at the foot of this example.

1,2,4-trichlorobenzene in drinking water

An EU risk assessment has been conducted for 1,2,4-trichlorobenzene (1,2,4-TCB) and in particular the contamination of drinking water was considered. It is estimated that 1.3 million people are exposed to concentrations in drinking water exceeding the WHO-limit of 20 μg/l, which is estimated to result in 582 cancer incidents per year in the EU-25. The WTP to avoid a cancer case is €400,000 per non-fatal case and €1 million per fatal case. It was not known whether the incidents caused by 1,2,4-TCB would be fatal or non-fatal, which meant that the incidents correspond to a cost in the range €98 to €582 million per year. Thus the monetised benefit of not using 1,2,4-TBC were estimated to be in this range. The cost of cleaning the drinking water is estimated to be €14-89 million per year.

Nonylphenol in sewage sludge

Nonylphenol may accumulate in sewage sludge in concentrations higher than a limit value which is set for protection of the soil environment at farmlands. It is estimated that between 1.1 and 9.1 million tonnes (dry weight) of sewage sludge contains nonylphenol in concentrations exceeding the limit causing it to be unsuitable for use as a fertiliser on agricultural land. Therefore, the sludge is often incinerated and, in addition, other fertiliser has to be supplied to farmlands. The total cost of these alternative controls is estimated to be €229-1,829 million per year.

Tetrachloroethylene in ground water

Tetrachloroethylene (PER) is classified as carcinogenic category 3 and intake of drinking water with a concentration of 1 μg/l causes an extra lifetime cancer risk of 1.5 in 1 million. It is estimated that 0.8% of drinking water is contaminated in concentrations exceeding 10 μg/l, but it is not known what percentage exceeds 1 μg/l. However, it is estimated that 3.6 million people in the EU-25 would be exposed to PER in concentrations exceeding 10 μg/l and, assuming a linear dose-response relationship, this would on average result in 0.8 extra cancer incidents per year. The cost is estimated to €0.3-0.8 million per year for non-fatal (€400,000) and fatal (€1 million) incidents, respectively.

Polychlorinated biphenyls (PBC) in fish

PCB levels are still elevated in the environment and in particular in biota despite the ban on manufacture of PCBs more than 20 years ago. Concentrations in fish are so high that the number of cancer incidents is estimated to be 194-583 per year in the EU-25. As no information is available on whether these cancer cases would be fatal or non-fatal, the cost is given as a range at €78-583

million per year.

The full study and case studies can be found on:
http://ec.europa.eu/environment/chemicals/reach/background/docs/impact_on_environment_report.pdf.

3.3.5.2 Data collection

In many cases the applicant may not have enough information i) on the values themselves and ii) on quantification of the environmental impacts. Lack of such information hampers the possibility to monetize environmental impacts. However, there exist valuation studies containing values of ecosystem services. These can be used with a technique called "benefit transfer". In this technique, values of an environmental asset can be transferred from an existing study to a similar context. Thus, the value of benefit can be derived. For instance, the Environmental Valuation Reference Inventory (EVRI) database of valuation studies (http://www.evri.ec.gc.ca) contains detailed information on environmental valuation studies, primarily from North America but with about 460 studies from Europe. In addition, market-based methods, describing straightforward commercial and financial gains and losses, such as lost productivity (e.g. crop production) or additional costs to recreation and leisure, could be used in this context. Appendix B.1 gives further details on data sources.

3.3.6 Reporting the results

It is most likely that the results of the assessment of changes in health and environmental impacts will not be one aggregate number but rather a mixture of qualitative, semi-quantitative and quantitative information.

It is therefore recommended that the reporting of the outcome of the assessment of the human health and environmental impacts should always comprise a comprehensive narrative description of **all** foreseen changes in impacts including:

- The human health and environmental endpoints being affected both qualitatively and quantitatively;
- The possible unit values used for monetising environmental and human health impacts (e.g. the value of life year) and the estimate total values (e.g. number of life years lost multiplied by value of life year);
- The significance of the impacts;
- The certainty and confidence in the description and possible quantification of the impacts; and
- All relevant assumptions/decisions and estimated uncertainties relating to what has been included (measurements, data sources, etc.).

3.4 Economic impacts

Economic impacts are concerned with costs or savings comparing the "non-use" scenarios with the "applied for use" scenario. Economic impacts comprise the net costs to manufacturers, importers,

downstream users, distributors, consumers and society as a whole. “Net costs” should take into account both additional costs to actors if an authorisation is not granted and possible cost savings caused by the transfer to alternatives.

Economic impacts include, for example:

- Cost of new equipment or production process necessary to comply if the authorisation is not granted or ceasing use of equipment/facilities before the end of their intended life:
- Operation and maintenance costs (labour costs, energy costs etc);
- Cost differences between different substances due to different production costs and purchase prices of the substances;
- Cost differences due to differences between the two scenarios (due to reduced or improved efficiency for example)
- Changes in transport costs; and
- Design, monitoring, training and regulatory costs.

Appendix I gives practical information and further guidance on how to calculate compliance costs in the application for authorisation. This annex is also helpful when the economic feasibility is assessed in the analysis of alternatives (see section 3.8 *How to determine economic feasibility of alternatives in the Guidance on the preparation of an application for authorisation*).

In much literature, e.g. the EU guidelines for Impact Assessment (available via: http://ec.europa.eu/governance/impact/index_en.htm) a distinction is made between economic, environmental and social impacts, where health impacts are covered usually under either “environmental” or "social" impacts. Here, human health impacts are covered separately as part of human health and environmental impacts. The EU Impact Assessment guidelines also consider costs that arise from environmental or human health impacts as part of environmental and human health category. It means that economic impacts are primarily impacts on business and consumers. This guidance follows the same approach.

Economic efficiency and equity

Economic analysis makes a distinction between efficiency and equity. Efficiency relates to the most efficient use of scarce resources. For instance, if using a potential alternative technology requires more labour or energy input and therefore increases production costs, this is considered as a negative impact. This is because the overall efficiency of society to produce the same amount of goods and services is reduced. On the other hand, if a given new technology requires less labour input it is a benefit to society as there would be resources freed for a different use. In this case, the overall efficiency (also called productivity) increases.

Full utilisation of all factors of production (labour, capital, etc.) is often assumed in cost-benefit analysis. So if the “non-use” scenario results in more capital and labour being used, then these additional scarce resources can not be used for different uses. In economics these costs are called “opportunity costs” and refer to the costs of the “non-use” scenario to society. If there are a lot of free resources (e.g. a lot of unemployment) the opportunity costs would be low. In a full employment situation the opportunity cost would equal the market rate of labour costs. As it is difficult to measure the effect of unemployment on real labour costs, market-based labour costs are usually used in economic analysis.

The equity rationale relates to the distributional impacts of a scenario. If certain groups are affected by increased unemployment, this is seen as a negative distributional impact, even if employment is offset (to some degree) elsewhere. However, this situation is less evident when the overall level of employment in society increases but there is still a reduction of employment for some sections of society (e.g. a reduction in demand for a particular type of worker skill/occupation). These issues are usually dealt by under the heading social impacts (see Section 3.5).

In all cases, it is important to state the assumptions that are being used for the assessment and the conclusions that are drawn. In summary, economic impacts can be assessed based on:

- Efficiency: Changes in resource use (equal to changes in the use of production factors such as raw material, energy, labour or capital);
- Equity: Distribution of economic impacts on different industries or social groups.

The efficiency rationale is covered in this section. The distributional aspects should be integrated into the assessment with a clear identification of who will be affected by the impact (see section 4.2 for more information).

3.4.1 Distinction between private costs and social costs[24]

In any assessment, an important distinction is made between costs to the private sector (often called "private costs") and costs to society as a whole (often called "social costs"). In order to compare the "applied for use" scenario with the "non-use" scenario, it is necessary to know the costs to society as a whole under each scenario. Part of the overall cost of a scenario is made up of private costs but only part of these costs is used in the economic analysis that is concerned with the societal point of view.

There are also situations where the social costs could be higher than the private costs leading to an upwards adjustment of estimates based on private costs. The prices of exhaustible resources do not always reflect the long term scarcity of the resource. In such situations, the price should be increased in order to reflect that the resource is non-renewable. It is generally a case by case judgement as to whether there are any changes in consumption of a non-renewable resource that need to be taken into account beyond what is reflected in the existing market price of that resource.

Private costs are the costs incurred by the identified actors in relevant supply chains. Economic analysis needs to strip out any parts of the private cost from these companies which are actually 'transfers' from one section of the economy to another. The reason is that such costs are not additional for society as a whole. These include first of all taxes and subsidies. Transfer payments or 'transfers' refers to the transfer of value between sections of society. They do not represent an overall cost to society, simply a redistribution of value (notwithstanding the equity issues described above). Significant transfer payments should be discussed when considering the distributional impacts (see section 4.2).

If any cost element in either scenario is partly paid for through a subsidy the costs to society of that subsidy need to be included in the analysis – even though the subsidy does not represent a cost to the private sector.

[24] Private costs are also referred to as financial costs while social costs are referred to as economic costs.

If costs include taxes, these should be removed. The reason for this is that taxes represent a transfer from those paying the tax to those who receive the tax revenues. Taxes overstate the costs of the measure to society as a whole (by the amount of the tax paid). Value added taxes and excise duties are examples of taxes that can be relatively easy to remove from the analysis. However, labour taxes and indirect business taxes (such as social security charges) are less straightforward. In instances where it has not been possible to remove taxes (or deemed not appropriate to do so) this should be documented in the SEA report whether an estimate includes specific taxes or not.

There is an important special case regarding taxes – if a tax is charged to cover the damage of an environmental or another externality (e.g. a landfill tax) the tax is not a transfer, but rather a reflection of (or attempt to reflect) the true costs of the resource to society. Such taxes should be included, but should not be double-counted when analysing environmental impacts.

The issue of adjusting the private costs correcting for transfer payments is most relevant if the assessment of costs is based on reported accounting data. If the costs of a measure are calculated from scratch based on estimations of capital costs and operational costs, there will not be any transfer payment included and no adjustment will be needed.

As general guidance the following recommendations are made when carrying out economic analysis: 1) avoid using costs that include taxes and subsidies, and 2) state clearly what kinds of costs have been included (e.g. what taxes and subsidies may be included in the costs).

3.4.2 Step 3.1 Identifying economic impacts

A practical way of identifying and screening impacts is to use checklists. The checklist presented in Appendix G (Initial checklist) includes questions such as:

- Are there any significant changes to operating costs?
- Are there any significant changes to investment costs (e.g. costs to avoid risks to human health such as waste and waste water handling)?
- Are there likely to be any significant changes to administration costs?

The checklists set out in this guidance provide pointers to the types of effects that could be considered. They can also be used to document the analysis and can be included in the reporting of the SEA to show that all relevant impacts have been considered.

The following set of specific examples of investment, operational and maintenance costs or savings cover some of the more important economic impacts. By considering each type in consultation with the supply chain the most important economic impacts can be identified.

If a “non-use” scenario would imply that a certain consumer good is no longer provided by the supply chain in question or the quality has changed, the consumers might face additional costs or they might incur a loss of welfare. In some cases there is direct financial effect, for example lower energy efficiency increasing the consumer’s expenditure on energy, the additional costs to the consumers can be estimated similar to changes on operational costs for industries. If there is loss of welfare when one consumer good replaced by another the economic impact could be a loss of welfare. This will have to be estimated by assessing the willingness to pay both for the consumer good that is no longer available and for the most likely substitute. It is a specialist analysis to undertake such valuation; see Appendix C that includes guidance on relevant valuation techniques.

Different types of costs and savings

Examples of investment costs

□ Change in innovation and research & development costs

□ Change in performance testing costs

□ Change in property rights costs

□ Change in equipment costs

□ Change in modification costs

□ Change in decommissioning costs

□ Equipment down-time costs

□ Change in value of production equipment (machines, buildings etc as a result of the "non-use" scenario)

Types of operating costs or savings

Energy costs

□ Change in electricity costs

□ Change in fuel costs

Materials and services costs:

□ Change in transportation costs

□ Change in storage and distribution costs

□ Change in replacement part costs

□ Change in auxiliary costs, such as chemicals, water

□ Change in environmental service costs, such as waste treatment and disposal services

Labour costs:

□ Change in operating costs, supervisory costs and maintenance staff costs

□ Change in training costs of the above staff.

Maintenance costs

□ Change in sampling, testing and monitoring costs

□ Change in insurance premium costs

□ Change in marketing costs, license fees and other regulatory compliance activities

□ Change in other general overhead costs (e.g. administration)

Appendix B.2 includes more details on different types of costs.

What about costs in other supply chains?

If a downstream user is assumed to change to an alternative technology as a response in the "non-use" scenario, the difference in production costs is measured from the perspective of the downstream user. The supplier of the alternative technology will have an income from selling this technology, whilst the previous supplier has a loss of revenue. The costs for each supplier represent an important distributional effect, but there is no net cost from the perspective of society (assuming all other factors remain the same e.g. customers pay the same price, product quality is the same) but just a redistribution of income.

However, the response of the supply chain in the "non-use" scenario may result in certain companies in the original supply chain having relevant resources that become redundant (e.g. capital – such as equipment and labour – skills and experience) and thus a proportion of the original investment will not be recoverable. This will entail a cost to the original supply chain, even if the income from the supply of the alternative balances out the income foregone by the ban of the original substance. It might be necessary to consult suppliers in order to obtain an estimate of the price of the alternative technology. Therefore it is advisable to consider and report both the net economic costs to society and also the distributional effects to different actors in all the relevant supply chains.

It is normally assumed in economic analysis of this type that changes in the activity within one sector will not affect prices throughout the economy. So if the downstream user in a "non-use" scenario purchases an alternative substance/technology, it is assumed that it does so at the "normal" market price. Generally, it can therefore be assumed that the changes in the supply chain in question will not affect prices of any inputs (e.g. raw materials) and it will therefore not result in either costs or savings in other supply chains[25].

Appendix I gives practical information and further guidance on how to calculate compliance costs in the application for authorisation.

Presenting the identified economic impacts

The results of the identification of economic impacts can be presented in a table that describes the possible economic impacts through the supply chain and by "non-use" scenario (the difference between each "non-use" scenario and the "applied for use" scenario). Where presenting the results in the form of tables, the data included should be supported by appropriate documentation of analysis and conclusions.

The example in Table 5 is just for illustration of how impacts are identified and described. It relates to the example in Table 3.

[25] This assumption will need to be tested on a case by case basis, as in some instances changes in demand may affect other supply chains. For example, if refused authorisation leads to the use of an alternative substance and the additional demand for the alternative substance can not be satisfied through additional supply, higher prices for the alternative may have impacts on the current users of that alternative (e.g. they can not afford the higher price and cease making their product). It is also possible for there to be a decrease in the price of the alternative as extra demand makes it viable for manufacturers to take advantage of "economies of scale" (e.g. cost savings of mass production, bulk purchases of raw materials, etc). However in most cost benefit analysis the assumption of normal market price is a valid assumption.

Table 5 Example of presentation for identification of economic impacts

Supply chain	Description of the "applied for use" scenario	Scenario 1: Relocation (outside the EU)		Scenario 2: Use of another end-product	
		Impacts in the EU	Impacts outside of the EU	Impacts in the EU	Impacts outside of the EU
Uses which do not require authorisation					
Suppliers	Suppliers of raw material and intermediates	Possible distribution effect from lower operational income s	Possible distribution effect from increased operational income	Possible distributional impacts (some suppliers will see reduced operating income while other will see an increase)	No change
M/I[26]	Manufacturing of x tonnes/year of substance A	Decreased operating income (distrib-utional effect); pos-sible costs due to low reuse value of capital assets for EU Manufact-urers of substance A;	Increased operating income for non-EU manufacturers of substance A	Decreased operating income for the manufacturers and im-porters of substance A (if they do not make the alternative); possible costs due to low reuse value of capital assets	No change
Article assembler	Use q units of article P1 to produce q2 units of article P2	No change		Additional costs of substituting P1 with Px to produce article P2	No change
Article assembler	Produces Px	No change		Increased operating income due to sales of Px	No change
Article assembler	Use q2 units of P2 to produce article P3 which is a consumer good	No change		No change	
Uses which require authorisation					
DU 1	Use y kg of substance A in formulation F1	Decreased operating income; possible costs due to low reuse value of capital assets	Increased operating income for non-EU DU	Decreased operating income; possible costs due to low reuse value of capital assets	Increased operating income for non-EU DU
DU 2	Use z kg of F1 to produce v kg of formulation F2	Decreased operating income; possible costs due to low reuse value of capital assets	Increased operating income for non-EU DU	Decreased operating income; possible costs due to low reuse value of capital assets	Increased operating income for non-EU DU
DU 3 (end user)	Use w kg of F2 as coating to provide long life time for component C1 of article P1 in the manufacturing of q units of article P1	Additional costs of importing the component C1, which may (partly) be passed on	Not applicable (end users assumed to be in EU)	Decreased operating income; possible costs due to low reuse value of capital assets	Increased operating income for non-EU DU

[26] Please note that the M/I may/should sometimes apply for an authorisation for uses for which the substance is placed on the market. See further explanations in Table 1.

In the example shown in Table 5, the M/I and some of downstream users will lose part of their business (decreased operating income) as the Annex XIV substance will no longer be used and the alternatives involve supply from other supply chains. Therefore in this example the supply chain for the alternative will gain most from a refused authorisation. The occurrence of costs and benefits in and outside the EU should be presented separately.

The relevant costs are related to lower or no utilisation of the production factors previously used for the production of the substance or the formulations where the substance was a key component. If any employees become unemployed as a result of the outcome of the application it is a cost for society. This aspect is covered under social impacts. The economic impact for the businesses concerned will relate to the use of their production facilities. The relevant costs to include in the SEA are the losses in asset value estimated as the previous value minus the value in best alternative use.

3.4.3 Step 3.2 - Data collection

The analysis of economic impacts is best achieved by using estimates for specific types of costs and benefits. Appendix B2 provides a non-exhaustive list of information that may be relevant to collect and analyse further. The information on economic impacts should be collected in consultation with relevant supply chain actors and possibly trade associations. When confidential data is a particularly important issue, the use of independent parties could be used to facilitate the data collection and analysis process by ensuring the confidentiality of information provided by actors in the supply chain. Table 6 lists types of information required on economic impacts for a typical SEA.

Table 6 Types of information required on economic impacts for a typical SEA

Types of information to gather for a typical authorisation SEA		Why is it important to gather this information?
About the industry affected	• Number of companies along the supply chain • Total turnover and employment for affected companies/industries	• As reference information for understanding the supply chain (may not always be needed)
Economic effects of difference between "applied for use" and "non-use" scenarios	• Cost difference of using a potential unsuitable alternative (substance or technology) compared to the Annex XIV substance • Cost difference in case of relocation of production (costs of establishing production facilities, transport costs, etc.) • Cost difference in the case of purchasing the product containing the substance • Cost differences in case of change in quality difference in end-product (e.g. end product less energy efficient) • Loss in asset value based on best alternative use of production facilities that become redundant in a "non-use" scenario	• To understand the direct cost implication of refusal of the authorisation for the supply chain • These could help determine the scale/severity of the economic impacts • Scale of employment
Economic importance of the substance	• The share of turnover related to the applied-for use(s) for each company in the supply chain • Value added by end product and in intermediate steps	• To understand the distributional impacts along the supply chain and to the end customer if this substance is no longer available
What are the costs to downstream users and end consumers	• Lifetime of the end product • Market price • Details of any loss of function and costs of searching for alternatives	• Cost implications and distributional impacts to downstream users and the end product consumers.

3.4.4 Step 3.3 - Assessing economic impacts

Following the principle of the SEA as an iterative process, the assessment of the economic impacts starts with a qualitative description. Having identified the main impacts, a qualitative assessment would identify and describe the most important elements.

Further quantification can be achieved based on the data collected from the supply chain or suppliers of possible alternatives.

The key economic impact data such as the additional cost of using alternatives or the possible relocation of production will have to come from the supply chain supported by data from suppliers. If a company has not considered the costs of using an alternative or the possible relocation of production, expert judgement or other assumptions may be required.

Estimates of the implications of using alternative substances or technologies or of relocation of production will generally be based on either previous experience or knowledge of technical

requirements building on engineering designs. The rationale behind decisions, expert judgements, and assumptions should always be documented in the SEA report.

A systematic approach to identification and assessment of economic impacts should avoid costs and benefits being counted more than once.

The estimation of economic impacts should focus on the additional costs and benefits rather than absolute values (see Section 3.2.2) such as the additional resources required to produce a good or service. If the additional costs incurred by an actor in the supply chain can be passed on down the supply chain then there is only a cost to the actor in the supply chain who cannot pass those increased costs on (either in full or partly). The additional costs might ultimately be borne by the final consumer. It will be important for decision makers to understand how the authorisation application outcome will affect different sections of society (see section 3.2.4 for further details).

Table 7 is an example of a helpful and transparent way to record the economic cost impacts and to demonstrate how they are distributed along the relevant supply chains.

Table 7 Additional annual costs or savings of "non-use" scenario vs "applied for use" scenario by supply chain in a given year

Supply chain stage	Additional costs/cost savings (incurred by own activity)	Cost/savings passed on	Accumulated costs/savings	Costs or savings financed by this stage of the supply chain
Manufacturer/importer	0	0	0	0
Downstream user 1	Additional annual costs €0.15 million	No costs passed on	€0.15 million	€0.15 million
Downstream user 2	Additional annual costs €0.45 million	No costs passed on	€0.60 million	€0.45 million
Article manufacturer 1	Additional annual costs €2.5 million	All passed on	€3.1 million	0
Article manufacturer 2		All passed on	€3.1 million	0
Consumer	0		€3.1 million	€2.5 million
Totals supply chain costs/savings	**€3.1 million**		**€3.1 million**	**€3.1 million**

The total costs increases of additional resource requirements should be distributed throughout the supply chain according to who bears the costs. The total supply chain costs/savings (second column) and the total costs/savings financed should be the same.

Appendix I gives further practical information on how compliance costs can be analysed and synthesised in the application for authorisation.

3.4.5 Outcome of assessment of economic impacts

Having assessed the economic impacts the applicant (or third party) should document the individual cost elements that have been identified and assessed. Table 7 is an example of how the economic impacts can be summarised. When each individual impact is reported in the SEA report it may be useful to consider including: an estimate or description of the impact, any key assumptions used, any uncertainties surrounding the estimate and the data sources used to derive the estimate. To improve the readability of the SEA report, some of this information might need to be reported in separate tables or within an appendix.

3.5 Social impacts

Social impacts are taken to include all relevant impacts which may affect: workers, consumers and the general public where these are not analysed under human health and environmental impacts and economic impacts. For most SEAs this will mainly be impacts on employment and any major impacts that result as a consequence of changes in employment (e.g. changes in working conditions, job satisfaction, education of workers and social security), as well as changes to quality of life (such as change in availability and quality of consumers products). Further details on social impacts can be found in chapter 4 of the EC Impact Assessment guidelines[27].

3.5.1 Step 3.1 Identification of social impacts

When should employment effects be considered in the SEA?

Employment effects are important from a distributional point of view. If certain groups would be affected by increased unemployment (for example when some business activities close down or are relocated to outside of the EU) this could be seen as negative distributional impact. Whether the total level of employment would be affected is a macro-economic issue. Here the following is suggested:

- Minor employment effects that arise from "marginal" changes in the activity of a given company (for example using one substance instead of another) should not be included as they are covered by the analysis of the economic impacts.
- Employment effects that are caused by a given activity, e.g. a production line or company closing down, or relocating production outside of the EU, should be estimated and included as a distributional impact.

Are there other relevant social impacts?

If there are major effects on employment which will affect certain regions and certain social groups, it could be relevant to consider these impacts[28]. A non-exhaustive list of impacts includes: educational level of workers, family support, child work, forced labour, wages and salaries, good labour criteria of International Labour Organisation (ILO), quality factors, supplier evaluation,

[27] EC Impact Assessment Guidelines (p31-32) 15 June 2005

[28] Chapter 4 of the EC Impact Assessment Guidelines (p31-32) 15 June 2005 provides a more comprehensive range of social impacts which may be relevant to consider in order to be to able to produce a robust conclusion.

social security, part-time workers, gender equality, trainees, strikes and lockouts and employee qualifications.

Another important social impact to consider is changes to the "welfare" of consumers. Economists use this term to describe the wellbeing of an individual or society, so naturally many factors could be included. For example, some consumers may miss the satisfaction (economists prefer the term – utility) they derive from the use of a product, or a change in the quality of the product (e.g. if it is not as durable, or can not be used it in the same way as it was previously used) can result in a loss of consumer welfare (e.g. the utility of an individual).

For example, if paint used to decorate a house is now less durable, the utility an individual gains from having an attractive-looking house will diminish sooner than it would had they used the previous product which was more durable. **Appendix C** provides some further details of some non-market valuation techniques (goods/services that do not have a value in the market place) which can be used to value losses/gains in utility. However in most cases, it will be very difficult and perhaps not necessary to go beyond a qualitative assessment of consumer welfare.

3.5.2 Step 3.2 Collection of data to assess social impacts

The number of people potentially affected is likely to be estimated through consultation with relevant actors in the supply chain. Relevant data will include the number of staff affected and their respective skills / job types. Data on employment in the area or region affected can be obtained from sources such as:

- Relevant supply chain actors;
- National statistical data;
- Local authority / regional government reports and websites;
- Statistical services such as Eurostat (the statistical office of the European communities);
- Published information such as Employment in Europe and the quarterly EU labour market review;
- Trade associations.

National population survey (census) data is likely to be a key source of information for social impacts. One potential problem with national census data in general is that they are only updated periodically and therefore may not accurately reflect the true socio-economic demographic in an area if significant changes have occurred after the census survey was carried out. Another potential problem with census data is that the categories and labelling of data (e.g. qualification and occupation groups) will vary for each Member State, although in general it should be possible to collate and compare the information. Nevertheless the census data are likely to be the best source of publicly available information on social impacts.

Appendix B.3 provides references to literature on estimating social impacts and possible sources of data and information.

3.5.3 Step 3.3 Assessing social impacts

Regardless of the complexity of the analysis (i.e. qualitative or quantitative) the approach to determining employment impacts is likely to be similar. A suggested approach is outlined below:

Task 1 Estimate the change to direct employment

Estimate the change in employment based on the best available information. In most cases the supply chain should be able to provide data on the number of people that could be affected if certain areas of their business are scaled down or closed.

If the supply chain is very complex with many suppliers of the substance or formulation (for example) it may be possible to estimate the change in the typical number of people required within the process using a representative firm(s), followed by up-scaling to cover the whole supply chain based on the proportion of volumes of the substance/formulation/article produced (or other suitable metric). Some form of sensitivity analysis should be carried out when up-scaling the results.

Task 2 Estimate the types of jobs and skills level in the local region

Estimate the skills (and qualifications, age, gender) of people in the region where these industries are located and the types of businesses located within the local region. This information should be available in national census data.

Task 3 Estimate the effect on the location of these jobs

Determine what type of jobs may be lost / created in the region and how this relates to the types of businesses located in these regions, to determine how significant these jobs are within those regions affected.

TIP BOX – Some useful social indicators that can be found in national census data

- Number of people employed relative to the working age population in the local area
- Relevant employment sector distribution in the local area e.g. manufacturing, construction, transport storage and communication
- Job occupation type in the local area e.g. managers and senior officials, plant and machine operatives
- Qualifications of people in the local area who are of working age

Outcome

By the end of Stage 3 possible social impacts should be identified with considerations on whether certain regions or social groups will be adversely affected.

3.6 Trade competition and other wider economic impacts

3.6.1 Step 3.1 Identifying trade, competition and wider economic impacts

The starting point for the identification of potential impacts on trade, competition and economic development is the estimate of economic impacts. If the difference in costs between the "applied for

use" scenario and the "non-use" scenario is very significant this might lead to significant wider economic effects. There could also be a situation where a relatively small decrease (or increase) in costs will impact on industries' competitiveness. Therefore a case by case assessment is necessary.

Appendix G includes a checklist[29] with questions to support the identification of wider economic impacts. It includes questions such as:

- Are there likely to be changes to competition within the EU? (For example, changes in the number of products available to downstream users and consumers and changes to the numbers of manufacturers/importers supplying these products.)
- Are there likely to be changes to competitiveness outside of the EU? (For example, would the effect in the "non-use" scenario give an advantage to manufacturers outside of the EU?)
- Are there likely to be changes to international trade? (For example trade flows between EU and non-EU countries.)

To answer these questions it will typically be necessary to undertake some analysis of the relevant markets. Section 3.6.3 includes a description of the kind of analysis that can be used for understanding whether wider economic impacts on trade, competition and economic development could be relevant for the SEA.

As a rough indicator only, as each use in an authorisation application will vary on a case-by-case basis, competition and competitiveness impacts will generally be important (a main impact) to assess further given that most substances are traded globally. Impacts such as changes in investment flows and international trade will only be relevant to analyse further if there are likely to be significant impacts on the competitiveness of EU manufacturers (e.g. when there becomes a significant advantage/disadvantage to being located in the EU, which will give EU manufacturers an advantage/disadvantage over manufacturers outside of the EU, as a result of not granting the authorisation – the "non-use" scenario(s)).

3.6.2 Step 3.2 Collecting data on trade, competition and other wider economic impacts

The starting point for gathering information on these impacts is identifying information not collected during the economic impacts analysis which is relevant for analysing the possible impacts on trade, competition and wider economic impacts.

The relevant types of data may include:

- What is the geographical extent of market (e.g. national, EU or global)? (It may be useful to gather statistics on import and exports to determine where the key markets are.)
- How many competitors are there (and where are they located)?
- How price-sensitive is the demand for the product?
- What is the profitability of companies at the market?

[29] The checklists are neither exhaustive nor definitive. They are intended to guide you towards ensuring that impacts and issues that are particularly relevant are considered during the analysis. Types of impacts falling outside those listed in these checklists but are relevant for the authorisation application should be considered.

Information on these aspects can be provided for example by the supply chain, trade statistics, financial statistics (profitability of individual companies or industry sectors) or through market reviews which are publicly available.

3.6.3 Step 3.3 Assessing trade, competition and wider economic impacts

The objective will be to analyse the extent to which any additional costs that would occur in a "non-use" scenario compared to the "applied for use" scenario can be passed on further down the supply chain. If a cost at given stage in the supply chain can be passed on down the supply chain there are likely to be limited impacts to trade and competition at that stage in the supply chain. If costs can not be passed on, these companies might face difficulties to compete which in turn might affect trade and further economic development. Therefore, the analysis of an industry's resilience is important for making a judgement on wider economic impacts.

The majority of these impacts will only be analysed qualitatively and supported where possible by quantitative data. A proposed process for analysing trade, economic and wider economic impacts is outlined below:

- Task 1 – Analyse the market to determine the ability to pass through additional costs
- Task 2 – Determine the resilience of the industry using financial ratios

Task 1 - Analyse the market to determine the pass through of additional costs

Use the data gathered on the level of competition and possible price sensitivity of the demand to make a judgement on whether additional costs at any part of the supply chain can be passed on further down the chain. The assessment of whether costs can and will be passed through depends on aspects such as:

- Extent of the market – size of the market
- Price elasticity - how sensitive demand for the product is to changes in price
- Competitive rivalry – competition both between manufactures and between products

There are several established methodologies that have been developed for analysing markets. One commonly used methodology is 'Porter's five forces theory'. Competitive forces determine industry profitability because they influence the prices, the costs and the required investments of firms in an industry. See Appendix D.4 for further details on this methodology.

Task 2 - Determine the resilience of the industry using financial ratios

The resilience of the industry can be calculated using financial ratios of the applicant's firm (specific to the Annex XIV substance) and the industry average. Sensitivity analysis should be carried out. Appendix D provides a list of useful financial ratios which describe for example the profitability of a firm.

Note of caution when using financial ratios

1. Data on profitability may be difficult to obtain under joint applications
    a. If there are joint or multiple applicants (e.g. manufacturers and downstream users collaborating to develop an application), it may be difficult to obtain profitability data for specific uses of the Annex XIV substance. It may be worth getting an independent party to develop this section of the application or to submit this data independently of the main application.
    b. Industry averages specific to the uses of the Annex XIV substance may be difficult to obtain.
2. It will be necessary to obtain a series of profitability data (e.g. data over at least a 5 year period) as some industries profitability can vary significantly in different market conditions.
    a. One year's profitability in most cases cannot be used as a representative year for future years.
    b. Trends in profitability based on past years performance may not necessarily give a true representation of future conditions faced by these industries, especially under the new conditions of the application.
3. It will be important that the analyst is comfortable reading and understanding financial ratios to be able to understand what "message/signals" they are showing.

When describing the resilience of a sector, the consideration of longer-term trends (5-10 years) is useful to ensure that short-term fluctuations are not allowed to distort the long term resilience of the sector.

Appendix D provides further details on financial ratios

3.7 Ensuring the consistency of the analysis

This section includes guidance on how to ensure a consistent analysis and it applies to all types of impacts (environmental, human health, economic, social and wider economic impacts).

As a general rule, sources and origin of all data should be recorded. This will allow the data to be traced and validated at a later date if necessary. If the data source is a published report or database, then a standard bibliography will normally suffice for this purpose. If the data source is a verbal or some other form of non-public communication, this should be clearly stated and the source and date recorded. **It is also very important that all assumptions that are made during the analysis are documented in a transparent way.**

It is recommended that (where possible), costs and benefits be described in similar terms.

- Monetary estimates: these should be expressed in a common currency e.g. Euros (€) and they should be in the price level of a common year (e.g. all prices quoted in 2008 prices).
- Quantitative estimates: these should be expressed in physical terms e.g. man hours saved, amount of energy saved in kWh.

- Qualitative estimates: these should be as similar to the quantitative estimates as possible e.g. qualitative description of how man hours and energy saved could change.

The applicant should strive to identify and use the most recent valid data available. The year to which the cost data apply and any currency exchange rate applied should always be stated. This ensures transparency and allows other users to reproduce (confirm the validity of) the analysis if necessary. These aspects are discussed below.

3.7.1 Exchange rates

Where prices are quoted in different currencies, they need to be converted to a common currency, i.e. Euros. When making this conversion, the applicant will need to specify the exchange rate used in the calculation as well as the source and date of that exchange rate. Market exchange rates are likely to be sufficient in this work.

3.7.2 Inflation

The general price level and the relative prices of goods and services (e.g. cost of investment equipment, market price for raw materials) in an economy will change over time because of inflation. There will often be a need to use estimates for costs and benefits found in literature sources that were based on findings in different years and in such cases inflation will need to be taken into account.

For example, if the cost of investment equipment was quoted in 2001 prices this is likely to be an underestimate compared to the cost in today prices. It will be necessary to adjust prices into equivalent base year prices (which in most cases would be the present year[30]).

Establishing prices in the base year

To adjust the cost data into an equivalent price in a selected year (the nominal price), it is necessary to use a price adjuster, which can be derived by the following two steps:

Step 1:

$$\text{price adjuster} = \frac{\text{appropriate price index for the 'base year' of the analysis}}{\text{appropriate price index for the year to which the raw cost valuation relates}}$$

Step 2:

$$\text{adjusted cost} = \text{original cost valuation } x \text{ price adjuster}$$

What is the appropriate price index?

An important source of European price indices is Eurostat. It is suggested that the GDP deflator be used as the price index for adjusting data into a common base year (see http://epp.eurostat.ec.europa.eu/portal/page/portal/national_accounts/introduction).

[30] Making the distinction between real and nominal prices is unlikely to be necessary if the base year is the present year.

3.7.3 Discounting

Discounting is only relevant:

- For impacts, which have been monetised;
- If the timing of costs and monetised benefits is known (within an acceptable level of uncertainty)

Introduction

The decision whether or not to grant an authorisation is likely to have consequences (i.e. costs and benefits) now and in the future. The current and future costs and benefits to those people in society affected by the decision need to be taken into account in the SEA (i.e. including impacts which are not immediately priced through markets such as health and environmental effects). A mechanism is therefore required to compare costs and benefits occurring at different times.

In economic analyses the most common method used to compare costs and benefits over time is called discounting. Discounting makes it possible to calculate equivalent amounts in today's terms, i.e. the 'present value', or at any other fixed point in time. The further away in time a cost or benefit occurs, the lower its present value becomes. The size of the reduction in the present value depends on the discount rate: future costs or benefits estimated using a higher discount rate will have a lower present value.

The net present value (NPV) of an option, for example, is the net value today of the present value of the benefits of a continued use minus the present value of the costs, i.e. a positive net present value means that the socio economic benefits of continued use outweigh the costs (it is important to note however that the net present value is not necessarily the criterion with which the final decision is made as some impacts can not be monetised).

An alternative to the use of net present value is to provide an equivalent annual value for (or to "annualise") the investment costs and add the annual operating costs (and other recurrent costs), to derive an annualised cost. This approach is often used for environmental policies because the impacts are often assessed on an annual basis (e.g. how many people are affected by a pollutant in a year). The annualised value involves somewhat less work than the net present value approach and is appropriate when the costs and benefits are likely to be relatively stable year-on-year. It can be particularly useful when comparing options against one another where the impacts occur over different lifetimes.

Appendix E.1 provides further information on:

- Why discounting is important;
- Why the choice of discount rate is important; and
- How to determine the discount rate using different approaches.

Approach

The proposed approach to discounting future costs and benefits is described below.

Task 1 **Apply the formula for discounting to calculate the present value of costs and benefits**

In order to discount and calculate the present value of a future cost or benefit it is necessary to know**:**

- **The various issues related to the time boundaries of the SEA** – this should have been determined in Stage 2 of the SEA (see Section 2.4.2.
- **The magnitude and timing of specific costs and benefits** over the time period; and
- **The discount rate** – the default discount rate that should be used in the SEA is 4% (as used for Impact Assessment for European Commission proposals). The applicant may wish to *additionally* use different discount rates to test the sensitivity of the results to the discount rate (see task 2).

This information is fed into the annualisation equation below. This reflects the commonly used method for discounting for a time period of up to 30 years[31]. Using this method will make the comparison of scenarios more transparent and allow organisations reviewing the SEA to make their own judgements on the consequences of using an alternative discount rate.

Annualised costs = Annualised investment cost + Annual operating cost

Where:

Annualised investment cost C_t is set out below

$$C_t = \frac{I \cdot s}{1-(1+s)^{-t}}$$

Where Ct is the annualised investment cost in year t
I = Investment
t = year (until year n)
s = discount rate

The equation to use for calculation of the Present Value (PV) of costs is set out below:

$$PV_C = \sum_1^n \frac{C_t}{(1+s)^t}$$

Where PV_C is the present value of the costs
t = year (until year n)

[31] Where it is perceived that a longer time period is required a declining discount rate should additionally be used as part of the sensitivity analysis. This is discussed in task 2 and Appendix D

s = discount rate
C_t = cost in year t

The equation to use when calculating the Present Value of benefits is:

$$PV_B = \sum_1^n \frac{B_t}{(1+s)^t}$$

Where PV_B is the present value of the benefits
t = year (until year n)
s = discount rate
B_t = benefit in year t

The Net Present Value (NPV) is calculated as the benefits minus the costs:

$NPV = PV_B - PV_C$

The benefit/cost ratio is calculated as: PV_B / PV_C

It can be seen from the above equations that the Present Value (PV) is the same as the Investment (I) in the other equation.. In other words, with the above two equations any Investment (I) can be converted to an annual cost (C_t)and any stream of annual cost (C_t) can be converted in to a net present value, i.e. an investment.

Technical note:

When discounting one needs to choose if it starts in the beginning or the end of the year. For instance, the standard net present value (NPV) function used in spreadsheet applications assumes that the discounting starts immediately (i.e. 1 January of the year). If you discount from the beginning of the year, use, NPV function in Excel is (=NPV(4%;<range of values>)). In order to get the annualised stream of from this value one should used the following Excel function (=PMT(4%;year;NPV;0;0)). This function is equivalent to the equation used in this technical guidance document.

If one assumes that discounting starts at the end of the each year, discounting starts one year later Thus, the NPV will be 4% higher (when 4% is the discount rate). The NPV function in Excel would need to be adapted to become (=NPV(4%;<range of values>)*(1+4%)). To annualise this NPV one needs to either use the following Excel function (=PMT(4%;year;NPV;0;**1**)) or to divide Excel function (=PMT(4%;year;NPV;0;0)/(**1+4%**)).

As a general guide it is suggested that discounting starts in the beginning of each year. See also below numerical example.

Numerical Example of Discounting

Table 8 shows a numerical example of a situation where there is a stream of annual costs of €1000 for 10 years with 4% discount rate (*s*). The discounted value of €1000 for the first year is (€1000/1.04^1=) €962, for the second year (€1000/1.04^2=) €925 and for 10th year it is (€1000/1.04^{10}=) €676. Adding these up for 10 years makes the present value (PV_c) of €8111. In spreadsheet programmes, one function calculates this directly. This is shown in the footnote to cell B13.

Table 8 shows also the inverse, i.e. if one needs to annualise an investment (*I*). If the investment is €8111 euros for 10 years (shown in cell B15), the annualised cost (C_t) (with 4% discount rate) is equivalent of €1000 per annum. In spreadsheet programmes, one function calculates this directly. This is shown in the footnote to cell B16.

As can be seen in Table 8, with same discount rate, annualising and taking present value

give the same result. In other words, the company would be equally content to either invest upfront €8111 (for 10 years) or pay €1000 every year (for next 10 years) with a 4% discount rate.

Table 8 Example of taking present value and of annualisation (with 4% discount rate)

Row	*Column A*	*Column B*	*Column C*
1	Year	Nominal value (not discounted) €	Discounted value[a)] €
2	2010	1 000	962
3	2011	1 000	925
4	2012	1 000	889
5	2013	1 000	855
6	2014	1 000	822
7	2015	1 000	790
8	2016	1 000	760
9	2017	1 000	731
10	2018	1 000	703
11	2019	1 000	676
12	Sum	10 000 [b)]	8 111 [c)]
13	Present Value	8 111 [d)]	
14			
15	*Investment for 10 years*	8 111	
16	Annualised cost	1 000 [e)]	

Notes:

[a)] Discounting from the beginning of year

[b)] Using in Excel (=SUM(B2:B11)). This is the sum of the costs if there would be no discounting (i.e. the discount rate would be zero)

[c)] Using in Excel (=SUM(C2:C11)). This is the sum of the costs when the discount rate is 4%

[d)] Using in Excel (=NPV(4%; B2:B11)) This is just a more effective way to calculate the present value (no need to calculate first a separate column of discounted values and add them up as in cell C12).

[e)] Using in Excel (=PMT(4%;10;C15;0;0)) This is an effective way to calculate the annual value of an investment cost.

Task 2 If warranted, carry out a sensitivity analysis on the discount rate and the timing of specific costs and benefits

Consider declining discount rate if cost occur in the far future

In cases where costs and benefits occur beyond 30 years and their timings are very uncertain (and also to take into account different investment perspectives through different discount rates), it is advisable to undertake a simple uncertainty analysis such as sensitivity or scenario analysis in order to gauge how uncertainties could alter the present value of costs and benefits (this is not relevant if costs and benefits can be determined in annual terms). **Appendix E** provides further details on these two techniques.

If costs and benefits occur beyond 30 years a sensitivity analysis should be presented using either a 1% discount rate or declining discount rate over time in addition to the default 4% discount rate. This will allow judgements to be made on the impacts of

using different rates. This issue is discussed further in **Appendix D**.

Sensitivity analysis in the normal case

Also when costs do not occur in the far future, it might be appropriate to conduct a sensitivity analysis with a higher discount rate (e.g. 6-8%) to reflect private opportunity cost of capital. A lower rate might also be applied to test how sensitive the outcome is in relation to the discount rate used. This issue is discussed further in **Appendix D**

3.7.4 Consistency when impacts occur at different times

In Section 2.4.2 it was set out that the impact triggering period for the analysis, would normally either be a representative year or a cumulative time period.

The SEA should consider the difference between the "applied for use" scenario and the "non-use" scenario. For example a "non-use" scenario could imply that a different technology is used which does not result in any significant health impacts. If a 20 year cumulative impact triggering period is taken for the analysis and it is assumed that the health impacts from use of the Annex XIV substance occur approximately 25 years after exposure and exposure takes place when using the substance directly, the impacts can be assessed in the following way.

The 20 year impact triggering period used in the analysis could be from 2010 to 2030, while the health impacts will only be manifested from 2035 to 2055. This can be qualitatively described but it can also be included quantitatively if the impacts are monetised. To calculate economic values, the monetised impacts are discounted to give a Net Present Value as described in section 3.7.3. In this case the monetised values for the period 2035 to 2055 are discounted to give a NPV (noting that an alternative discount rate may be appropriate when considering health and environmental impacts).

If the SEA is based on one year's use of the Annex XIV substance most impacts will occur after that year. An economic impact such as an investment is dealt with by annualising the investment costs. Health and environment impacts that might occur over a longer period are discounted using the net present value formula to give the estimate of value of the impacts that are triggered by one representative years use of the substance or replacement by another substance/technology/product.

Please also note (as set out in Section 2.4.2) that the life time of articles produced by using the substance should be considered. Such monetised impacts should be discounted to NPV.

3.7.5 Presenting costs and benefits occurring over time

Table 9 provides an example of how a summary of costs and benefits occurring over time could be presented. Note that costs and benefits do not have to (and often cannot) be monetised and a qualitative scale could be used instead. The table should be accompanied with a description of the timing of costs and benefits to explain how the results were derived.

An approach such as this is only really relevant where there are significant changes in costs and benefits over time.

Table 9 Summary of costs and benefits over time*

Impact **Time period**	Immediately	Short term (e.g. 1-5 years)	Medium term (e.g. 6-20)	Long term (e.g. >20 years)
Environmental impacts				
Health impacts				
Economic impacts				
Social impacts				
Wider economic impacts				
Total (net impact)				

* Severity of impacts: either monetary, quantitative or using scale high (+++ or ---), medium (++ or --), low (+ or -) or not applicable (n/a)

3.8 Summary of key issues for the generic "non-use" scenarios

This section summarises some specific issues related to each of the generic "non-use" scenarios.

Use of potential alternatives (where the Analysis of Alternatives concludes that alternatives are not suitable)

If the analysis of alternatives has identified potential alternatives but showed that they are not suitable, for example because they do not reduce the risk or they do not deliver the same functionality, the use of these alternatives within the SEA may still be considered if it is well demonstrated that such a substitution could realistically take place. This should be clearly outlined when describing the non-use scenarios (Stage 2).

If a potential alternative involves other substances, the risks to human health and the environment and other impacts from those substances should be considered. If the potential alternative involves another process or technology, the risks associated with this other technology should be assessed.

The relocation of production to outside the EU

If there are no potential alternatives (either substance or technology), then relocation of production and subsequent import of articles is a potential "non-use" scenario.

Costs and benefits to EU operators and to non-EU operators should be demonstrated separately.

This scenario is relevant when the final use is related to production of an article as the substance may be used outside the EU and then the article imported into the EU. The key issues to consider include:

- Costs and savings of relocation on the supply chains within the EU and outside of the EU;
- Gains and losses of economic activity and potential employment within the EU and outside of the EU;
- Changes in environmental and health risks within the EU and outside of the EU.

This "non-use" scenario requires at least some consideration of impacts on regions outside the EU. For the other "non-use" scenarios the main impacts are likely to be within the EU, while this response scenario could mean that some risks are reduced in the EU while increased outside the EU.

It is suggested that impacts that occur outside of the EU should be identified and listed, but not necessarily analysed much further in terms of quantification as it would often be difficult for the applicant or third party to determine the impacts outside of the EU with a high degree of certainty[32]. See also general considerations in Section 2.4.3.

However, demonstrating that there will be impacts outside the EU will allow the overall decision to be made being as informed as possible.

Change in quality of downstream products

In determining whether a reduction in the quality of the downstream products would arise under a non-use scenario, it should be considered whether the function being delivered by the Annex XIV substance is essential to the end product. If it is essential, a lower quality product might result and the implications of this should be considered.

The definition of the scenario should include the type of property/quality that is no longer being delivered and it might be possible to estimate the value of that quality. Examples might include increased casualties from fires through use of a less efficacious flame retardant, increased road casualties or reduced energy efficiency from using an alternative to the Annex XIV substance.

Using the checklists in Appendix G should make it easier to identify the main effects.

Non-availability of the final supply chain product

Where a consumer good or service is no longer provided by the supply chain, a key impact would be loss of welfare by consumers. It is not straightforward to estimate such losses but an approach is included in Section 3.3 on economic impacts.

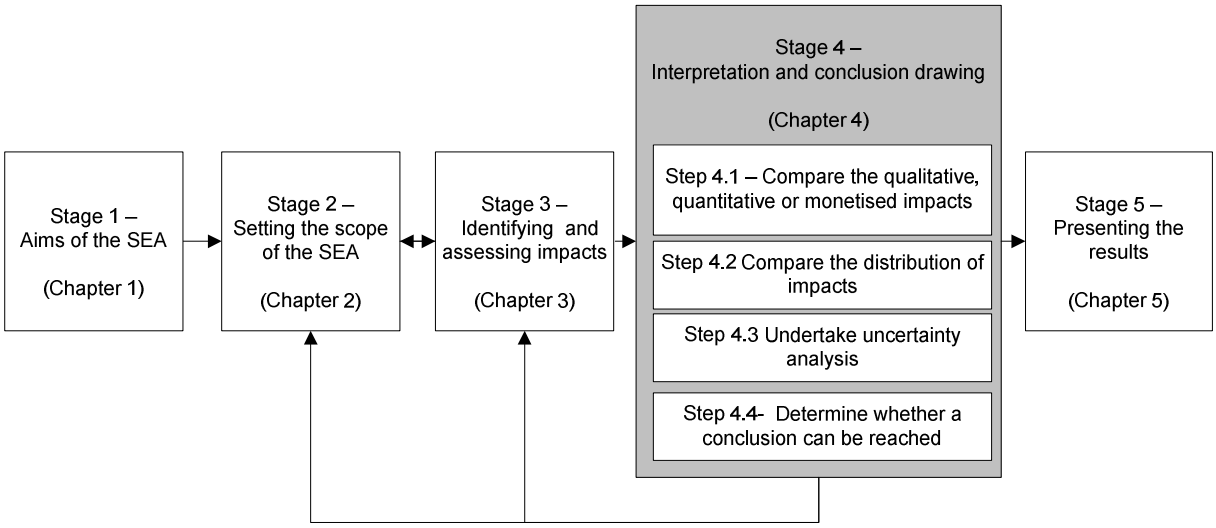
[32] To do this would require knowledge of where these industries would relocate to; the standard of environmental and health legislation in these countries; the quality of available workforce, infrastructure, available land, cost of raw materials, import and export costs and so on. It would therefore be very difficult to estimate, quantify or monetise any of these impacts with a high degree of certainty. However, it may be possible to describe the direction of the impact such as whether the environmental standards are the same and the if salaries are likely to change.

4 THE SEA PROCESS – STAGE 4: INTERPRETATION AND DRAWING CONCLUSIONS

4.0 Introduction

Interpretation and drawing conclusions is the fourth stage in the SEA process, as shown in Figure 16 below. The main aim is to present and compare the qualitative, quantitative and monetised costs and benefits of the difference between the "applied for use" and the "non-use" scenarios.

Figure 16 SEA process - Stage 4



The main steps of Stage 4 are shown in Figure 16. Each step is explained in more detail in the following sections.

This section describes the proposed approach to this stage of the SEA in detail. It is recognised that the overall approach to the SEA should be an iterative one and the applicant should undertake this stage at a level of detail appropriate to that of the SEA iteration being undertaken as a whole.

As with all stages in the SEA process, the applicant should give consideration to the uncertainties present in the data and analysis. The implications of uncertainties should be considered and acknowledged in the presentation of results.

4.1 Step 4.1: Compare the qualitative, quantitative and monetised impacts

There are several SEA tools and comparative techniques which can be applied in order to compare impacts between the "applied for use" and "non-use" scenarios.

It is advisable that the applicant/third party start by reading chapter 5 of the EC Impact Assessment Guidelines (2009) - How do the options compare? Several comparative techniques are provided which could be used regardless of the type of analysis produced in the previous stage (i.e. a qualitative or monetised assessment).

In addition it is advisable that the applicant makes a clear distinction on whether the impacts occur inside or outside of the EU and report this in a clear and transparent fashion.

Determining the level of quantification to be used is best achieved through an iterative process starting with a qualitative assessment of the impacts with further analysis carried out in future iterations if this is necessary to produce adequate information for the decision making. In some cases a qualitative analysis will be sufficient to produce a robust conclusion and, in such cases, further quantification would not be necessary. In other cases quantification brings added value for the decision making process.

When there is a need for monetisation, the appropriate tool for comparing quantified and monetised impacts is cost-benefit analysis (CBA). Cost-benefit analysis uses monetised values. It puts all costs and benefits into standard units (usually Euros) so that they can be compared directly. In reality however, it is unlikely that it will be possible to monetise all impacts (e.g. social and wider economic impacts). In addition, it might be difficult and sometimes impossible to estimate environmental impacts based on the current body of knowledge. Some costs or benefits do not have a market value and, when attempts have been made, there may be a lack of monetised valuation data available that could be used for a benefit transfer. However, market-based methods describing straightforward commercial and financial gains and losses, such as lost productivity (e.g. crop production), costs for the replication of services (e.g. water purification) or additional costs to recreation and leisure, could be used in this context.

This guidance suggests using a cost-benefit analysis type approach which involves recognising that not all impacts can be quantified or monetised. As such, it is proposed that the analysis should involve quantifying and monetising impacts as far as is practicable (and appropriate) and combining the monetised results with qualitative and/or quantitative descriptions of all non-monetised impacts.

The iterative approach to the SEA means that a first “initial” SEA could be undertaken applying immediately available information. This is likely to be made up of predominately qualitative information.

It is therefore suggested that the applicant should:

- Compile all available information and describe all impacts qualitatively; and
- Go through the next steps 4.2 and 4.3 on distributional and uncertainty analysis, then evaluate the results and decide how far it would be appropriate to take the analysis in terms of greater quantification and monetisation.

In **Appendix F** information is provided on cost benefit analysis as well as several other SEA tools such as cost-effectiveness analysis (CEA) and multi-criteria analysis (MCA). Given that not all impacts can be quantified and monetised, the cost-benefit analysis type approach suggested above has similarities with a multi-criteria analysis.

If all the quantitative and qualitative impacts were assigned a score and they were all weighted to give an overall score it would be a formal multi-criteria analysis. The use of a multi-criteria approach including more formalised scoring and weighting could be useful when there is a long list of impacts that are not monetised. More information can be found in **Appendix F**.

4.1.1 Initial (qualitative) comparison of impacts

A first iteration of comparing impacts can be based on the results of step 3.1 (identification of impacts). Assuming that the impacts are either qualitatively described or quantified based on existing information, the results can be reported in form of a table similar to that below.

The impacts are described as the difference between the “applied for use” and the “non-use” scenarios. As illustrated in Table 10 there can be more than one “non-use” scenario. The example addresses a substance (Substance A – included in Annex XV as being carcinogen category 2) for which an Authorisation is applied for. It is used in a formulation, which is used to coat wires. These wires are then used for the production of motors for washing machines. NB! This example would thus require Authorisation for the formulation of the coating and the use of the formulation to produce the wire. In the first non-use scenario a "non-suitable" alternative substance B (which is considered less human toxic, but more ecotoxic than Substance A) is considered. Substance B is slightly cheaper than A, but reduces the quality of the wires (and was therefore considered non-suitable in the analysis of alternatives). In the second non-use scenario it is assumed that use of substance A for producing wires is relocated outside EU and that these wires are then imported by EU washing machine motor producers.

Table 10 Example of qualitative listing of impacts or risks for two potental "non-use" scenarios

Impacts or risks	**Difference between the “applied for use” and the “non-use” scenarios**		
	“Non-use” scenario is “use of another substance B”	**“Non-use” scenario is “relocation of production of article”**	
Risks or impacts on human health	Reduced human health risks from worker exposure as the alternative substance B is less toxic *	Reduced risk of worker exposure (within EU) from 25 people in the applied use scenario to 0 in non-use scenario	Additional risk of exposure to the substance for workers outside EU. It is anticipated that > 25 workers would be exposed; to the same or a higher concentration
Risks or impacts on the environment	Increased risk to the aquatic environment as the alternative substance B is considered more persistent	No change in risk to the aquatic environment as it is a globally significant pollutant	No change in risk to the aquatic environment
Economic impacts	Costs savings in the manufacturing of the unsuitable alternative substance B (being cheaper than A)	Additional costs of transport and quality controls etc for the motor manufacturer when importing the coated wires.	
	One off investment costs for motor producer when using wires coated with substance B Sunk costs as production equipment could not be operated to the end of its technical and economic lifetime.	EU formulator and wire producers will lose market which can result in loss of value of production facilities. Sunk costs as production equipment could not be operated to the end of its technical and economic lifetime.	Non-EU formulators and wire producers will gain.

Impacts or risks	Difference between the "applied for use" and the "non-use" scenarios		
	"Non-use" scenario is "use of another substance B"	"Non-use" scenario is "relocation of production of article"	
	Higher operating (electricity) costs for consumers of washing machines as the motor is less energy efficient.	Higher investment costs for consumers of washing machines as the motor is will become more expensive.	
Social impacts	No significant employment effects expected	Reduction of 25 jobs due to relocation.	Job creation outside the EU
Wider economic impacts such as effects on innovation or trade.	No significant wider economic effects expected (a more firm conclusion on this type of effects requires quantification of the additional production costs)	No significant wider economic effects expected (a more firm conclusion on this type of effects requires quantification of the additional production costs)	

In the first iteration of the SEA this qualitative assessment is taken forward to Step 4.2 on distributional assessment and then to Step 4.3 on uncertainty analysis.

In later iterations the comparison could include the quantitative and monetised impacts.

4.1.2 Comparison of qualitative, quantitative and monetised impacts

After listing qualitatively all impacts, they should to the extent possible and proportionate, be quantified based on additional data that have been collected during the iterative analysis. Costs are usually expressed (directly) in monetary terms. For instance, additional energy consumption (e.g. in kWh) can be expressed in Euros (applying the price per kWh). Some of the quantified impacts (e.g. changes in health status) can be valued (e.g. applying the willingness-to-pay to avoid illness). Using a cost-benefit analysis approach, the monetised impacts can be aggregated into net present values or annualised costs as set out in Section 3.7.

4.1.2.1 List all quantitative, monetised and qualitative described impacts

It is unlikely that all impacts will be quantified and/or monetised. All impacts (whether only described qualitatively, quantified or monetised) should be listed together. However, the impacts must not be counted twice. For instance, if the cost of additional energy consumption is listed (in euros), the consumption itself (in kWh) should not be listed, as this would be double counting.

For quantified impacts, costs and benefits of similar physical characteristics should be presented side by side and where possible costs deducted from benefits. If, for example, there are data for number of workers exposed for both the "applied for use" scenario and the "non-use" scenario and the net number of persons exposed can be estimated, the overall net effect could be calculated (this would require the impacts of the exposure to be comparable).

It should be noted that the gross costs and benefits should also be documented in the SEA as well as their net impacts.

Having aggregated and summarised the impacts, the applicant may feel that there is sufficient information to draw a conclusion. In order to make a decision all impacts will have to be weighed up against each other (either implicitly or explicitly) in order to conclude whether the benefits of continued use outweigh the costs.

4.1.3 Using alternative SEA tools

Given that, in most cases, not all impacts will be quantified and monetised, the cost-benefit approach suggested has similarities with a multi-criteria analysis (MCA).

If all the quantitative and qualitative impacts were assigned a score and they were all weighted to give an overall score it would be a formal MCA.

The use of a multi-criteria approach including more formalised scoring and weighting could be applied when there is a long list of impacts that are not monetised in order for the applicant to get a feel for what is important. However, it is of crucial importance that the reader of the SEA (i.e. for the authority's decision-making process) that it can easily be followed how the aggregation has been done, including the ability to trace back the original non-aggregated impacts. The applicant should therefore rather use the results of applying MCA to discuss which impacts seem to be significant and how the advantages and drawbacks seem to compare rather than only giving the final outcome of the MCA. The latter would be of limited use for the subsequent process.

Guidance on how to apply multi-criteria analysis can be found in Appendix F.

4.2 Step 4.2: Compare distributional impacts

4.2.1 Introduction

In addition to the main SEA results, socio-economic analysis of the distributional costs and benefits should be presented. It is important to consider costs and benefits:

- Along the supply chain – e.g. to manufacturers, importers, downstream users, and upstream suppliers;
- To the end consumer and final product/service – e.g. price and quality;
- To different socio-economic groups along the supply chain – e.g. highly skilled, semi-skilled, manual workers and unskilled workers; and
- To different Member States or regions – e.g. inside the EU and outside the EU.

Table 12 provides an example of how distributional impacts could be presented. In Table 12 distributional impacts can be broken-down along the supply chain and also by socio economic group. It is also possible to show effects on different groups such as age and gender which may be particularly relevant for human health effects. For example, the risks of human exposure to a CMR substance maybe different along the supply chain and therefore could affect a particular gender or age group more than others. Distributional impacts should not just focus on how economic costs change along the supply chain and for all the main types of impacts. It should be considered whether it is important to document all types of distributional impacts (e.g. particular species and

ecosystems may be affected, depending on the outcome of an application, more in one region compared to another).

4.2.2 Approach

One approach to the consideration of distributional impacts is to use a checklist of questions as a prompt for thinking about how different sections of the supply chain, people and regions would be affected by continued use of the substance. Table 11 provides a non-exhaustive list of questions that could be considered – they will not all be relevant to all SEAs.

No further data collection and analysis should normally be necessary to answer these questions. It should be possible, based on the analysis undertaken in Stage 3 (see Section 3.3 to 3.6 of this guidance), to at least go through the questions qualitatively to describe the distributional impacts. If further analysis is required it may be necessary to return to Stage 3 to collect data specifically for analysing distributional impacts.

Table 11 Question for considering distributional effects

Analyse the identified benefits of continued use (the difference between the "applied for use" and each of the "non-use" scenarios) to determine:	
Q1.	Who is most likely to benefit from continued use of the substance? (consider the benefits along the whole supply chain)
Q2.	Which specific sectors are most likely to benefit from continued use of the substance?
Q3.	Which parts of the environment are most likely to benefit from continued use of the substance?
Q4.	Which sections of society are most likely to benefit (human health) from continued use of the substance?
Q5.	Which geographical areas are most likely to benefit from continued use of the substance?
Q6.	Which sections of society are most likely to benefit from continued use of the substance?
Analyse the identified costs of continued use (the difference between the "applied for use" and each of the "non-use" scenarios) to determine:	
Q7.	Who is most likely to suffer from continued use of the substance? (consider the costs along the whole supply chain)
Q8.	Which specific sectors are most likely to suffer from continued use of the substance?
Q9.	Historically how resilient are these industries to enforced changes?
Q10.	Which specific regions / parts of the environment are most likely to suffer from continued use of the substance?
Q11.	Which specific sections of society are most likely to suffer (human health) from continued use of the substance?
Q12.	How reliant is the region for employment by these industries?

Q13. Which sections of society are most likely to suffer from continued use of the substance?

4.2.3 Presenting distributional analysis

A qualitative or semi-quantitative scale could be used to present distributional effects (Table 12). The table would need to be accompanied with a description of the qualitative and quantitative distributional costs and benefits to explain how the results were derived.

Table 12 Distributional impacts*

Distributional analysis	Benefit of continued use	Cost of continued use
EU suppliers		
Non EU-suppliers		
Importers		
EU manufacturers		
Downstream user group 1 – Use A service providers		
Downstream user group 2..etc		
End customer		
Public		
Regulators		
Region x		
Region y		
Socio-economic group[1]		
Group A – Highly skilled		
Group B – Skilled/semi-skilled		
Group C – Manual/non skilled		

* Severity of impacts: either monetary or using scale high (+++ or ---), medium (++ or --), low (+ or -) or not applicable (n/a)

[1] Several occupation group classifications exist. However, the following general approach could be used: Group A: Managers and senior officials, professional occupations and associate professional and technical. Group B: Administrative and secretarial, skilled trades occupations and personal service occupations. Group C: Sales and customer service occupations, process; plant and machine operatives and elementary occupations. This is further discussed in Appendix D.4.

4.3 Step 4.3 Consider how uncertainties in the analysis may alter the outcome of the SEA

4.3.1 Introduction

Throughout this guidance it has been emphasised that uncertainties should be considered and recorded throughout conducting the SEA, whether that be in understanding the response behaviour of actors in relevant supply chains or in estimates valuing the scale of impacts (or any other aspects). The applicant should be able to show the extent to which the outcome of their SEA takes into consideration these potential uncertainties.

The purpose of uncertainty analysis is to test the overall uncertainty in the SEA. This analysis will lead to several possible outcomes:

- Returning to stage 2 and carrying out further analysis on specific behavioural responses e.g. whether it is possible to narrow-down the possible behavioural responses to get a better estimate of the impacts of the "non-use" scenario(s) in stage 3.
- Returning to stage 3 and carrying out further analysis on the assessment of specific impacts to reduce the variability[33] or uncertainty in the estimate.
- Returning to stage 3 and conducting a further iteration of the assessment of the main impacts (deciding that a more quantitative or monetary assessment is necessary in order to be able to produce a robust conclusion).
- Determine that the assessment of the net benefits to manufacturers, importers, downstream users, distributors, consumers and society as a whole of the difference between the "applied for use" and the "non-use" compared to net costs to human health and the environment of the difference between the "applied for use" and the "non-use" is robust enough to conclude the SEA.

For the former three outcomes (leading to iterations), the uncertainty analysis can additionally be used to focus further data collection and assessment of impacts on the major uncertainties, thereby focus the further work in the most cost-efficient manner.

The section below outlines a stepwise approach to conduct an uncertainty analysis.

Upon completion of the SEA, the final uncertainty analysis should be documented in the SEA report (section 4.3.3).

4.3.2 Approach

The level of resources devoted to uncertainty analysis and the level of detail at which it is undertaken should be proportionate to the scope of the SEA. It is proposed that a stepwise approach be adopted, starting with a simple qualitative assessment of uncertainties that may on its own be sufficient to determine whether uncertainties affect the outcome of the SEA and therefore whether further analysis is required. If uncertainties do appear critical to the outcome of the SEA, then a more quantitative assessment is likely to be necessary, using a deterministic approach and then, if necessary and feasible, a probabilistic assessment.

Figure **17** outlines this stepwise approach and Figure **18** illustrates the process in more detail. A deterministic approach typically involves a simplified sensitivity or scenario analysis whereby low and high estimates are determined for each of the main costs and benefits identified in the SEA. A probabilistic approach assigns probabilities to the range of estimated outcomes for each impact (as well as key input parameters).

The different approaches are described in turn below.

Appendix E provides information on several uncertainty analysis techniques and techniques which can help reduce the variability of impacts (i.e. help produce a narrower estimate of an impact).

[33] See Appendix E for definitions of variability, uncertainty and risk.

Figure 17 Step wise approach to uncertainty analysis

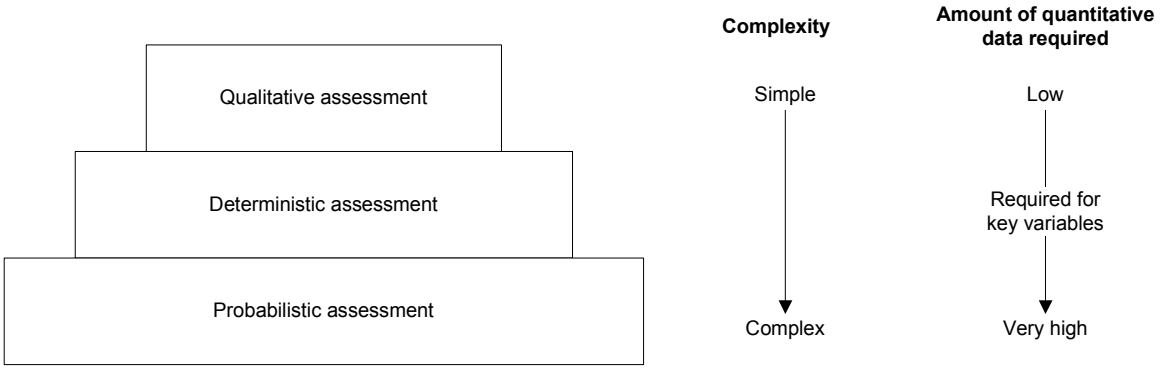
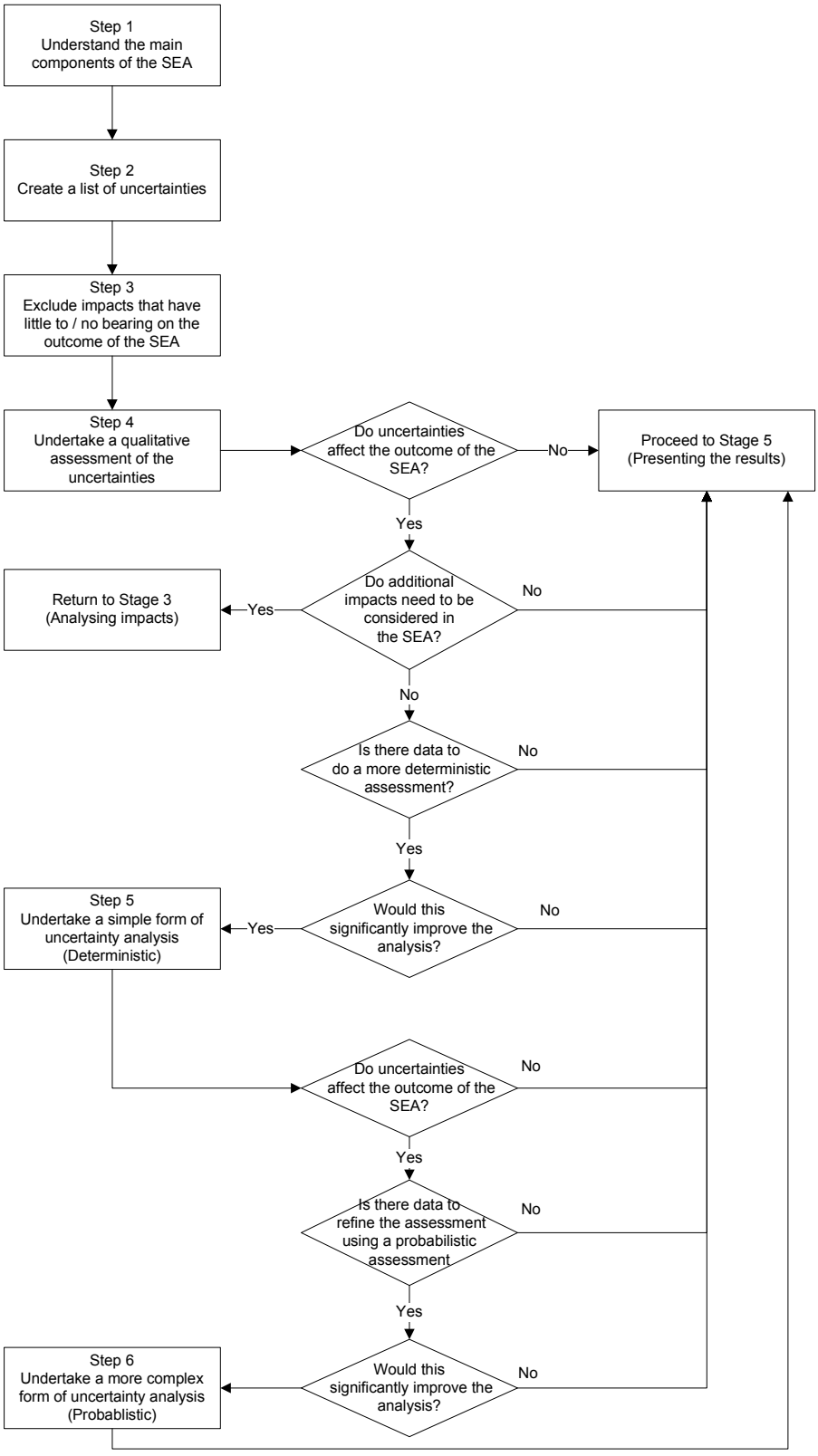


Figure 18 Uncertainty analysis process



The following briefly describes the stepwise approach outlined in Figure **17**.

Step 1 **Undertake a simple assessment of the uncertainties and decide if further analysis is required (i.e. a qualitative assessment)**

Relevant uncertainties should have been identified through all relevant stages in development of the SEA. The next step is to determine the direction and magnitude of each uncertainty. Direction refers to whether the uncertainty is likely to be an underestimate or overestimate. Magnitude refers to the extent to which it may alter the outcome of the SEA (e.g. whether it is likely to have a minor, medium or major effect). A ranking system such as +++, ++, +, -, -- or --- can be used to communicate both the direction and magnitude of each uncertainty (e.g. +++ is a major overestimate).

Estimates that are unlikely to alter the outcome of the SEA (i.e. minor estimates) generally need not be considered further. These minor estimates are likely to contain residual uncertainties that may remain regardless of the level of analysis undertaken.

Step 2 **Undertake an intermediate form of uncertainty analysis (i.e. a deterministic assessment)**

More significant uncertainties can be assessed using either sensitivity analysis or scenario analysis. Using the best available information (e.g. from consultation with the supply chain) low and high estimates are determined for each of the main costs and benefits identified in the SEA.

A sensitivity analysis is undertaken by varying each factor (e.g. quantified value of an impact) at a time and the effect on the overall results are recorded.

A scenario analysis could involve varying several factors at a time.

If it is not possible to determine realistic low and high estimates then no further analysis is possible.

If the benefits of the "applied for use" scenario outweigh costs under both the low and high estimate scenarios, then no further analysis is required. However, if the outcome of the SEA varies, then a more complex probabilistic analysis (Step 4.3c) may be necessary or more consideration should be given to the range of values that the key parameters may actually take. Figure **19** illustrates the process for a deterministic assessment.

Similarly if uncertainties make it more difficult to determine the socio-economic impacts whilst using low and high scenario estimates for each relevant impact, then a more complex probabilistic analysis may be necessary.

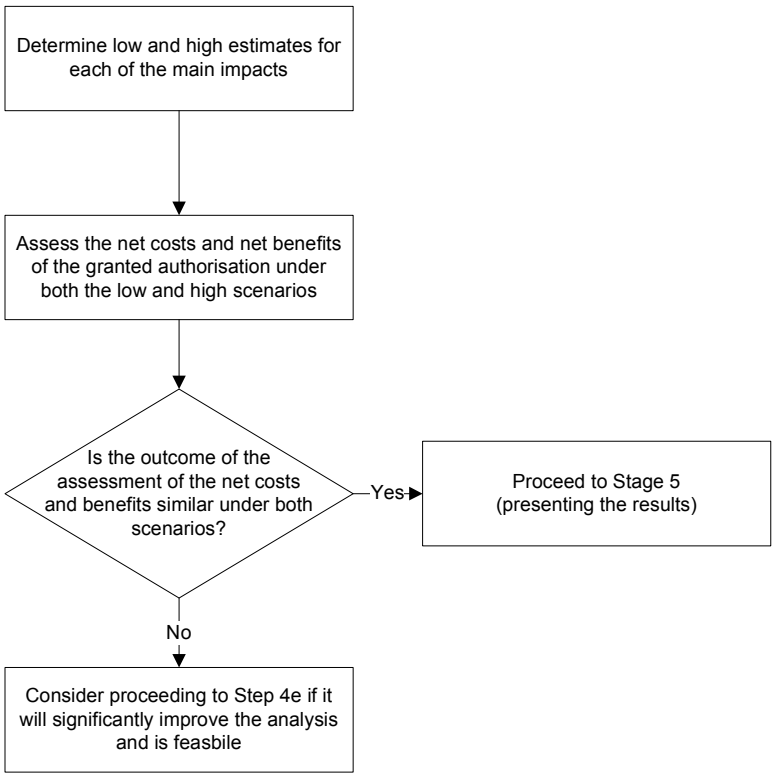
Step 3 **Undertake a more complex form of uncertainty analysis (i.e. a probabilistic assessment)**

A deterministic approach helps to clarify the overall significance of the uncertainties but does not take into consideration the probabilities of a particular estimate or outcome occurring. This is achieved using a probabilistic assessment.

In a probabilistic assessment, probabilities are assigned to the range of estimated outcomes for each impact. The probability of different outcomes is multiplied by the estimate for that outcome to give an expected value for the estimate.

Using the expected value of each impact instead of the low/high scenario estimates, this will involve assessing the main socio-economic impacts. The results should be documented alongside the SEA results so that the SEA Committee can understand how uncertainties could alter the SEA outcome. **If it is not possible to assign probabilities to the range of estimates then no further analysis is possible.** Specialist knowledge is generally required to undertake probabilistic uncertainty analysis.

Figure 19 Process for deterministic uncertainty analysis



4.3.3 Presenting the uncertainty analysis

The applicant or third party should describe the following:

- an appreciation of the overall degree of uncertainty and of the confidence that can be placed in the analysis and its findings;
- an understanding of the key sources of uncertainty and their impacts on the analysis;
- an understanding of the critical assumptions and their importance to the analysis and findings; this should include details of any assumptions which relate to the subjective judgments of the analysts performing the analysis;
- an understanding of the unimportant assumptions and why they are considered unimportant;
- an understanding of the extent to which plausible alternative assumptions could affect any of the conclusions; and

- an understanding of key scientific debates related to the assessment and a sense of what difference they might make regarding the conclusion.

Table 13 provides an example of how assumptions used in the SEA could be presented.

Table 13 Assumptions used in the SEA

Impact/variable	Default assumptions/data/estimates used to assess impact	Justification for using the assumption/data/estimate
Discount rate	4%	This is consistent with the EC Impact Assessment guidelines
Shadow price[34] of CO_2	€20/tonne	Current market price of CO_2

Table 14 provides an example of how the findings of uncertainty analysis could be presented.

Table 14 Uncertainty analysis results

Assumptions/date/ estimates	Default assumptions/data/estimates used to assess impact	Level of uncertainty / alternative assumptions	Potential impact on the SEA outcome
Discount rate	4%	This may underestimate future net benefits of environmental and health benefits which could occur beyond 30 years. As a sensitivity analysis a declining discount rate could be used.	(In this box the Applicant should show the results of applying the declining discount rate)
Shadow price of CO_2	€20/tonne	For sensitivity the UK estimate of the shadow price of carbon in 2008 prices (£26/t) could be used	(In this box the Applicant should show the effects on the outcome of the SEA, using the €20/tonne and the UK £26/t estimate)

[34] The shadow price of carbon captures the damage costs of climate change caused by each additional tonne of greenhouse gas emitted.

4.3.4 Step 4.4 Make decision on how to proceed with the SEA

Having undertaken a comparison of impacts and an uncertainty analysis, all key impacts and the results of the uncertainty analysis can be presented.

It is important to present all the most significant impacts with the key assumptions to provide a transparent account of the analysis. It is also important to present what impacts have been assessed to be of minor importance. This will also show that those impacts have actually been considered.

To derive a conclusion, the positive and negative impacts have to be weighed up against each other and each "non-use" scenario has to be considered. As the SEA may need more than one iteration, this can lead to:

1. No clear conclusion can be drawn before another iteration has been made with a more detailed assessment. Proceed back to Stage 2 and reconsider the scope of the SEA or to Stage 3 for better identification and assessment of impacts.
2. If the benefits (including avoided costs) of the continued use are unlikely to outweigh the (health and environmental) risks of continued use, the applicant should consider whether to proceed with the application, as it would probably not be successful.
3. If the SEA clearly shows that the benefits of continued use outweigh the (health and environmental) risks of continued use, the SEA can be completed without more detailed analysis. In this case proceed to Stage 5 – presenting the results.

Box 1 Tip: Principle of proportionality

It is difficult to give precise guidance on how much detail needs to be included in the SEA before a number of authorisation applications have been processed and decisions made.

In general the applicant should seek to build as robust a case as possible but, as there are limited resources to develop SEAs, they should be proportionate to the problem at hand. The level of detail should thus be sufficient to demonstrate a robust assessment of the costs and benefits but need not include information that does not substantially further aid the assessment.

In taking into account proportionality in the level of detail to be included, the applicant may wish to consider:

1) The higher the absolute level of costs and benefits are, the more details and quantification is required. Alternatively, however, if for example the costs are obviously very large and the benefits very small, this would suggest that significant additional analysis would have little merit.

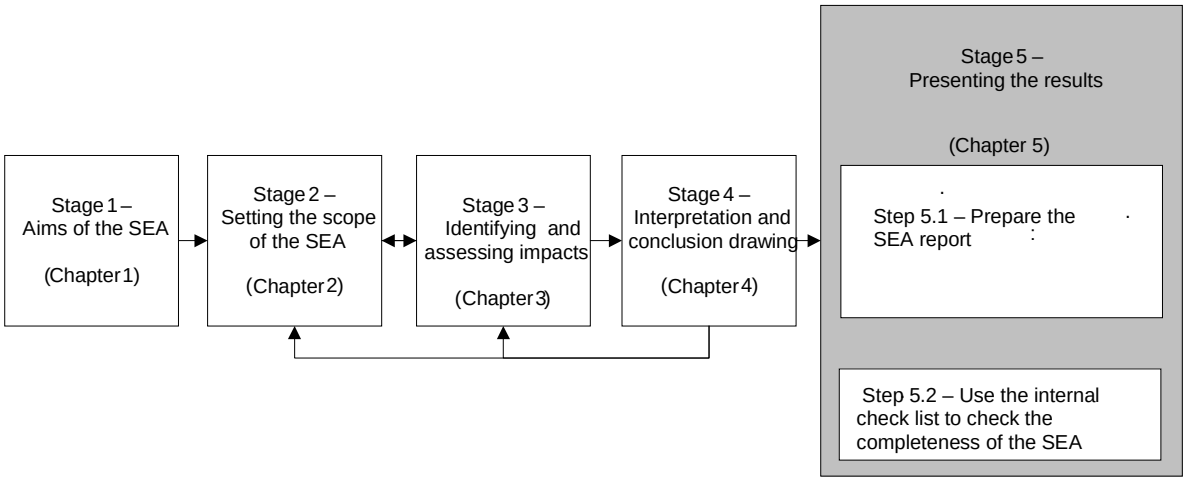
2) The closer the balance between benefits and risks/costs are the more details and quantification is required.

In relation to the different generic non-use scenarios it is likely that if the non-use scenario is applying an alternative which the applicant considers unsuitable (it does not result in an overall improvement) the analysis will require more details and quantification.

5 THE SEA PROCESS – STAGE 5: PRESENTING THE RESULTS

5.0 Introduction

Figure 20 SEA process – Stage 5



Stage 5 is the final stage in the SEA process. **Its aim is to highlight the key findings of the SEA which the SEA Committee should consider when preparing its opinion and the Commission should consider when making its decision.** The results of the analysis are summarised in an SEA report, together with key assumptions used in the SEA and the findings of the uncertainty analysis.

The applicant should document the analytical process and the decisions made with respect to which scenarios and which impacts have been included the SEA. This should be done throughout the process of developing the SEA. This section presents guidance on how to document and present the SEA. The applicant should first refer to the EC Impact Assessment Guidelines (2009) and in particular part II chapter 9 (Presenting the findings: The Impact Assessment Report). The next chapter provides some principles of ***good practice*** which should be adhered to. These are summarised below:

- Prepare a summary report – It is important to distinguish between the work undertaken for the SEA – the 'process' and the final 'report' summarising that 'process'. The executive summary should only summarise the findings of the SEA whilst the SEA report should include the activities conducted and the methodologies applied (e.g. for impacts assessment) during the SEA, as well as the results of the SEA.

- Remember to document all decisions, uncertainties or assumptions used in the final SEA report to improve transparency and traceability. It will also be necessary to specify which methodologies were used to assess and compare the impacts, e.g. cost benefit analysis or multi-criteria analysis.

- Keep it simple – Ideally any non-specialist should be able to follow the arguments and understand the positive and negative impacts of each scenario considered in the SEA. To

enhance the clarity and readability of the SEA report, use tables and diagrams to summarise key points. Examples of such tables can be found in Part III of the EC Impact Assessment Guidelines and some tables have been included stage 4 of this guidance. Note however that simplification does not necessarily mean a very short report. All information necessary to follow the argumentation should be included – where relevant appendices can be applied.

5.1 Step 5.1 Considerations for reporting the SEA

The guidance below is intended to be an indication of what could be reported in an SEA following the structure of the SEA format published on the Agency's website.

5.1.1 Guidance on how to fill in the template

Overview

It is recommended that the user undertakes their SEA using the process outlined within the guidance. This process is explained in detail in chapters 1-5.

For third parties providing input into an SEA it is recommended for transparency to that the format provided by the Agency be followed as relevant, even if the intention is to submit limited information.

Summary of the SEA

This section should be completed once the SEA results and conclusions have been finalised.

Aims and scope of the SEA

It is highly recommended that the user read chapters 1-2 in order to fully comprehend the issues on setting the aims of the SEA, the boundaries, defining the "applied for use" and "non-use" scenario. It is important to be able to define each scenario and list the potential impacts of being granted an authorisation to use a substance for particular uses, against the impacts of not being able to use the substance for these applied uses. It is however unlikely using a step-by-step guide that the user will not have to re-visit earlier steps in the process. Therefore the process used within the 'scoping phase' has been designed so that the user undertakes any necessary iteration in a logical and efficient manner. Including these key iterations in one stage should improve the transparency of the SEA process.

Analysis of the impacts

In the case of the applicant, this section will ideally outline, using a cost benefit approach (this is explained in chapter 4), all the net impacts of the authorisation compared to the "non-use" scenario (i.e. the differences between the two scenarios). It may not be possible or necessary to quantify all impacts. This may be due, for example, to a lack of data to convert environmental risks into impacts (which can then be assigned a monetary value), or it may be that certain impacts are so severe that a qualitative assessment will be considered appropriate for the problem being considered. The user should refer to Chapter 3 of this guidance.

As well as considering the scale of the impact, it will also be necessary to explain how these impacts affect different sections within society (i.e. the distributional impacts to the local/regional economy such as employment, crime and regeneration). The user should refer to chapter 4 of this guidance.

For interested parties submitting specific information rather than a complete SEA, it may not be necessary to reproduce the whole analysis. The focus is likely to be on the analysis of alternatives. However it is recommended that the impact of this 'new' information be reported in the context of how the outcome of the applicant's SEA is affected by this 'new' information.

Interpretation and conclusions drawing

Here the user should present the findings of their SEA, or input into an SEA. These should include any assumptions used (including the methodology that has been applied) and how uncertainty may affect the outcome of the SEA. The user should refer to Chapter 4 of this guidance.

The user should outline their case for authorisation, or in the case of some interested parties, present arguments for the application to be refused or present arguments to support the application.

Appendix

It is highly recommended that the user document within their SEA, or input into an SEA:

- Data sources;
- How the data was obtained; and
- Who was consulted.

This will improve the transparency of the results and will facilitate an assessment of whether the data has been obtained from reliable sources. For example this may include any questionnaires used and literature sources for any monetary valuations of impacts.

5.2 Step 5.2 Check that assumptions and uncertainties have been included

The following tables can be used both as an issues log to keep track of the analysis and decisions made during the development to the SEA as well to document the process.

The first table is to document the analysis and arguments for including "non-use" scenarios in the SEA.

Table 15 Audit trail for "non-use" scenarios

Name of "non-use" scenarios	Considered in scoping phase Yes/ No	Included in final SEA Yes/No	If no, please give your reasons - Description/arguments
Use of an unsuitable alternative 1 Use of an unsuitable alternative 2			
Use of an unsuitable alternative 3			
Production relocated			
The function not being delivered and reduced quality/availability of down stream consumer good/services			
Any other relevant "non-use" scenarios			

The next table is for an audit trail for impacts. There needs to be a table for each "non-use" scenario taken forward for impact assessment.

Table 16 Audit trail for "non-use" scenarios

Impact	No*	Assumptions/ description	Level of certainty	Effect on estimated impact	Effect on overall SEA result	Need for further data collection?
Impact 1	1 2 3					
Impact 2	1					
Impact 3	1 2					
Impact N						

Notes *) Iteration no

5.3 Step 5.3 Internal check list before submission of an SEA

This section contains an internal checklist of information which the applicant may wish to use before they submit their SEA report to the SEA Committee (SEAC). It is important to note that the questions in the checklist are non-exhaustive and the checklist is indicative only and also that the applicant is not necessarily expected to answer "yes" to all questions. For transparency, the applicant may wish to attach a completed checklist in an appendix of their SEA report.

It may be useful to submit the checklist (or a similar list) to the SEA Committee to show what information has been included in the SEA[35], along with cross references to where the information that answers each question can be found in the SEA report (this may be particularly relevant for interested parties contributing limited input to a submitted SEA).

A template to support the reporting of the SEA is contained in **Appendix A**. It provides one example of how the findings of the SEA could be organised and presented.

Summary of the SEA

(This section of the SEA report should be completed last)

✓

☐ 1. Have you summarised which uses are included in the SEA?

☐ 2. Have you summarised the main impacts?

☐ 3. Have you presented a summary of the SEA results?

☐ 4. Have you presented your conclusions in a clear and concise manner?

Aims and objectives

✓

☐ 5. Have you set out the aims and objectives of the SEA?

☐ 6. Have you described the "applied for use" and "non-use" scenarios?

☐ 7. Have you considered future trends in the use of the substance?

[35] Completing all the aspects on the checklist does not guarantee a authorisation application will be successful.

☐ 8. Have you set out which uses are included in the SEA?

Analysis of impacts

✓

☐ 10. Have you considered whether it is relevant to analyse and describe the main economic impacts of the "applied for use" scenario compared against the "non-use" scenario? If this is relevant, have you done so?

☐ 11. Have you considered whether it is relevant to analyse and describe the main health risks/impacts of the "applied for use" scenario compared against the "non-use" scenario(s)? If this is relevant, have you done so?

☐ 12. Have you considered whether it is relevant to analyse and describe the main environmental risk/impacts of the "applied for use" scenario compared against the "non-use" scenario(s)? If this is relevant, have you done so?

☐ 13. Have you considered whether it is relevant to analyse and describe the main social impacts of the "applied for use" scenario compared against the "non-use" scenario(s)? If this is relevant, have you done so?

☐ 14. Have you considered whether it is relevant to analyse and describe the main trade, competition and wider economic impacts of the "applied for use" scenario compared against the "non-use" scenario(s)? If this is relevant, have you done so?

☐ 15. Have you ensured the consistency of the analysis e.g. referenced data sources and set prices in a common year (base year). (Consider whether it is possible for the reader to understand the methodology and where appropriate to be able to reproduce the results.)

☐ 16. If relevant, have you discounted any monetised impacts?

☐ 17. Have you conducted sensitivity analysis on the discount rate and when impacts occur over time? (only relevant for monetised impacts)

Comparing scenarios

✓

- ☐ 18. Have you listed the uncertainties in the SEA?
- ☐ 19. Have you provided justification for using the assumptions in the SEA?
- ☐ 20. Have you explained what implications the assumptions might have on the outcome of the SEA?
- ☐ 21. Have you documented assumptions that are considered unimportant in terms of uncertainties and why they are unimportant?
- ☐ 22. Have you discussed the key sources of uncertainty and their impacts on the SEA?
- ☐ 23. Have you discussed the overall degree of uncertainty and of the confidence that can be placed in the SEA findings?
- ☐ 24. Have you shown/discussed the comparison of socio economic benefits and costs?
- ☐ 25. Have you incorporated uncertainty analysis? (i.e. expected values or high/low scenarios)
- ☐ 26. Have you presented and justified the time period of the SEA?
- ☐ 27. Have you determined when costs and benefits are likely to occur over the SEA time period?
- ☐ 28. If possible and relevant to do so, have you shown when costs and benefits occur in time intervals?
- ☐ 29. Have you shown impacts along the supply chain and on the final consumer?

☐ 30. Have you shown the distributional impacts on the environment and human health to different sections of society and in different regions?

☐ 31. Have you shown how impacts affect different groups, age in society? E.g. socio-economic groups, age groups and gender.

☐ 32. Have you shown the geographical location of impacts?

Specific for <u>cost benefit analysis</u> using monetised values only:

✓

☐ 33. Have you shown the present value for all costs and benefits?

☐ 34. Have you calculated either net present value or annualised values?

Specific for <u>multi criteria analysis</u> only:

✓

☐ 36. Have you shown the assigned score for each impact?

☐ 37. Have you shown how impacts have been grouped into separate categories?

☐ 38. If appropriate to do so, have you shown and assigned weighting to each category? If so, have to justified the weightings used for each category?

☐ 39. Have you shown the aggregated score for both costs and benefits?

☐ 40. Have you clearly shown the overall score of the SEA e.g. the benefits minus the costs?

Conclusions

☐ 41. Have you presented your arguments in a clear manner?

☐ 42. Have you made a recommendation to the SEA committee which can be justified by the SEA Committee?

Appendix A

☐ 43. Have you listed the data sources used in the SEA?

☐ 44. Have you included any data collection material? (e.g. questionnaires used)

☐ 45. Have you included a list of organisations consulted?

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APPENDIX A CONSULTATION DURING THE PREPARATION OF AN AUTHORISATION APPLICATION

CONSULTATION DURING THE PREPARATION OF AN AUTHORISATION APPLICATION

APPENDIX A – CONSULTATION DURING THE PREPARATION OF AN AUTHORISATION APPLICATION

A.1 Introduction

Within an analysis of alternatives (see Guidance on the preparation of an application for authorisation), it is likely that some form of consultation or preparation for one will already have taken place. Try to integrate the consultation process to cover aspects relevant for the analysis of alternatives and the SEA. Consultation with downstream users (DU) early on in the process will be crucial in order to get information for an authorisation application.

The benefits of effective consultation can include:

- Permitting greater access to information which may not always be publicly available;
- Improving the understanding on which sectors/actors could be affected by a refused authorisation and how they could be affected;
- Improving the credibility of the SEA findings by consulting a wide range of relevant organisations and drawing upon wide expertise;
- Minimising the risk of potentially confrontational challenges to the SEA findings at a later stage;
- Improving the quality of the analysis; and
- Utilising expertise and skills which may not be available in-house.

Consultation may range from requests for limited and well specified information to wide public consultation. The aims of consultations need to be clear and the consultation should be proportionate to the issue. Further guidance on communicating with the supply chain can be found in Guidance on the preparation of an application for authorisation (section 3.4.2) and Guidance on data sharing and Guidance for Downstream Users.

A.2 Stages in the development of a consultation plan

Set consultation objectives

The plan needs to clarify the objectives of consultation, both for the people involved in preparing the SEA and for stakeholders who will be consulted. Consultation can be a very important part of the SEA process with multiple objectives. It can:

- Help to identify what might be the likely response(s) of all affected parties if the authorisation is refused (this is part of the scoping phase). For example, is it possible for downstream users to use an alterative?
- Help to identify the main impacts/risks of a refused authorisation (again this is part of the scoping phase). For example, what would be the change in occupational risk if downstream users use an alternative substance? What would be the environmental consequences of switching to this alternative?;

- Provide data or information on the changes in costs and benefits to all affected parties if the application is refused. For example, what are the impacts associated with an increase in demand for the alternative substance such as on jobs, energy consumption, product price and in terms of any supply constraints on existing users of the alternative substance;
- Draw upon expertise which may help to reduce uncertainties that may arise during the SEA; and
- Provide feedback on the socio-economic analysis and recommendations.

Those responsible for preparing an SEA should be aware, however, that there is no legal obligation for industry or other stakeholders to provide information. It is especially important to communicate to stakeholders how consultation fits into the overall SEA decision making process and how stakeholder input may affect the outcomes of the SEA. It may sometimes be appropriate to involve stakeholders in the decision on how their input is to be used, especially if they are providing confidential information.

Develop a consultation schedule

The consultation plan should include measures to ensure that time and resources are available to plan, deliver and assess the findings of consultation activities. Stakeholders should be provided with start and finish dates for consultation periods in advance and given enough time to be involved. The consultation should be timed to ensure that its findings can be used to contribute to the SEA being developed as part of the authorisation application: in general, consultation should take place as early in the process as possible. The resources required should be identified early and, ideally, included in the budget for the overall SEA.

Identify who to consult

Applicants should aim to consult all the parties affected or potentially affected by the outcome of the authorisation application.

TIP BOX

Consider consulting (and possibly collaborating where appropriate) with:

- Immediate upstream supplier(s)
- Downstream user(s)
- Other manufacturers/downstream users of the substance
- Trade associations / industrial bodies (think carefully about which industries could be affected)
- Inter-related supply chains (that maybe affected by the authorisation application outcome. For example suppliers, manufacturers and downstream users of a relevant alternative)
- Non-governmental organisations (NGO)
- Labour and trade unions
- Relevant authorities

Make sure that those consulted provide representative views considering possible differences across member states

It could be useful to develop a matrix that shows who is likely to contribute with which type of information (as shown in Table 17). This could be a useful internal planning tool to check with relevant stakeholders who have particular expertise with different types of impacts (i.e. human health and social) if all the relevant impacts have been identified. Any information gathered from stakeholders should help to develop a more complete analysis of impacts. It is also a useful internal check to see if sufficient stakeholders have been identified for each type of impact.

Consultation can be hindered by the time each stakeholder can devote during the consultation period, so where possible do not rely on any one stakeholder to provide input. The level of consultation needed should be proportional to the quality of readily available information. The greater the quality of readily available information, the easier it will be to understand the main issues and to use consultation to gather comments on these identified issues, rather than using the consultation to understand what are the main issues.

Table 17 Mapping of who can contribute with what information

	Identification of "non-use" scenario(s)	**Environmental impacts**	**Health Impacts**	**Economic impacts**	**Trade, competition and economic development**	**Social impacts**
Stakeholder A	✓			✓	✓	✓
Stakeholder B		✓	✓			
Stakeholder C			✓			
Stakeholder D		✓				
Stakeholder E				✓	✓	
Stakeholder F						✓
Applicant	✓	✓	✓	✓		

Chose appropriate consultation methods

The applicant is advised to ensure that the consultation methods used are appropriate for the level of expertise of stakeholders involved. Appropriate methods may include:

- An introductory pack containing background information – this could include information on; REACH, the authorisation process, why the substance is on Annex XIV, its current uses and the reasons for the consultation; and/or
- A one-day stakeholder workshop – an introductory event providing similar information to that suggested above (though there may obviously be problems bringing together widely dispersed stakeholders, such as bias towards the situation in a particular Member State);
- Brainstorming event – gathering stakeholders together with the aim of gathering a consensus on key issues that need to be addressed during the SEA. For example, what are the likely response scenarios for all affected parties if the application is refused and what are the main impacts if the application is refused?; and/or

- Telephone or written questionnaires – these can be used as a means of collecting information from a wide range of stakeholders in a cost-effective manner. They may also be used to reveal the likely response if the application is refused. However the applicant must be careful to avoid bias and ambiguity with how the questions are worded and what possible answers the interviewee can select. In this respect, questionnaires prompting descriptive responses may be more effective than those of a 'tick-box' nature.

For consultation with groups and individuals who traditionally have not participated in the past with such exercises for reasons such as language or location barriers, it is advisable that the applicant include measures to remove barriers to participation. For example, consider having questionnaires written in multiple languages that are common in many member states (e.g. English, French, and German) or holding similar workshops in multiple locations and reimbursing travel expenses. The extra cost of this consultation should be proportional to the level of consultation deemed necessary (i.e. us the value added of this extra consultation justified?)

CASE STUDY EXPERIENCES

Experiences of those carrying out an SEA as part of the development of this guidance found that:

1) A kick-off meeting would be recommended to be held with those key stakeholders that have information that is necessary for a good SEA. In particular, it would be important to invite to a kick-off meeting those stakeholders that would welcome the authorisation (e.g. downstream users), as these are likely to give such information, and in a kick-off workshop other parties would peer review that kind of information.

2) The applicant developing the application has no legal mechanism to require SEA-data from downstream users. A good understanding of the drivers for industry to participate in developing a SEA is needed, although it is in the interests of both the manufacturer and downstream user to co-operate in developing a good SEA.

3) In an early stage of the study stakeholders should be involved in scoping the study and data collection. Much of the data needed for performing a SEA is not available in the public domain. Without stakeholder participation it will be very difficult to write a robust SEA, especially with regard to the economic impact assessment.

Based on a restriction case study by RIVM

Consider what information stakeholders might need

Consultation should be based on informed comment and input. This means making high-quality information available to stakeholders that helps them to understand what is required of them. The type of information given to stakeholders will depend on the audience but in general information should be presented in an easy to understand format, readable and well presented and you should consider the language used, especially if consultation occurs at a Community-wide level.

Consider how outcomes will be collated, reviewed and reported

Documenting, evaluating and reporting the views expressed through consultation activities are essential steps in demonstrating that the SEA has been a transparent and robust process. Feedback should be provided to stakeholders showing how their views have influenced the SEA and hence why their involvement was worthwhile.

CHECKLIST

The following checklist can be used to evaluate a consultation plan.

CONSULTATION PLAN CHECKLIST

Explain the consultation process

□ Have you explained the purpose of this consultation?

□ Have you clearly outlined the consultation period and key milestones?

□ Have you explained specifically how the consultation may improve the SEA?

Consider who to consult and how to get them involved

□ Have you identified the key areas, relevant stakeholders and their role within the SEA?

□ Have you identified whether there are any groups of stakeholders who are difficult to access?

□ Have you developed a communication plan to ensure that the views of these stakeholders can be heard?

□ Have you considered hosting a meeting/conference to discuss the findings?

Consider what stakeholders might need

□ Have you provided the necessary information to those people who are participating?

□ Have you provided adequate information to ensure that they can express an informed opinion?

□ Have you provided information in a way which is easily understandable and meaningful?

□ Have you provided adequate opportunity for people to receive the information and not just a "one-off" item?

Consider when to carry out the consultation

□ Have you considered when consultation is occurring at each stage of the process?

□ Is it early enough to help identify all the issues or are you merely seeking comment on already identified issues?

□ Is it sufficiently early in the SEA process for people to feel that you are genuinely interested in their opinions?

□ Have you considered whether consultation is occurring at appropriate times of the year? Usually December and August are bad times for consultation.

Remember to provide feedback to stakeholders

□ Have you explained the decision-making process clearly and how their information will be used to all the stakeholders?

□ Have you planned to provide feedback including reasons why particular items were not incorporated?

Consider the resources needed to facilitate consultation

□ Are there adequate resources in-house for the consultation?

□ Have you explored the cost of getting external help with the consultation?

□ Have you considered sharing some of the consultation responsibilities with consortium members?

FURTHER READING LIST

EC Impact Assessment Guidelines (p 9-12) 15 January 2009

Communication from the Commission - Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission. COM(2002) 704

General consultation plan guidelines:

Consultation Guideline: for the Ministry of Health and District Health Boards relating to the provision of health and disability services August 2002. New Zealand

Victorian Local Governance Association (VLGA) - Local government consultation and Engagement – Principles

Consultation Guidelines, Our Scottish Borders

South Western Sydney Area Health Service Community Participation Framework: Consultation Guidelines Appendix 16

Public Consultation Policy and Guidelines. Queensland Government, EPA

APPENDIX B ESTIMATING IMPACTS

ESTIMATING IMPACTS

B.1 Human health and environmental risks

B.1.1 "Quality Adjusted Life Year" (QALY) and Disability Adjusted Life Years (DALYs)

The following describes the concept of "Quality Adjusted Life Years" (QALYs) and Disability Adjusted Life Years (DALYs).

The most common of these measures is the "Quality Adjusted Life Year" (QALY). Other measures which are increasingly being used and recommended for use are Disability Adjusted Life Years (DALYs) and Healthy Years Equivalents (HYEs). Each of these concepts can be used to measure the utility of a specified "health profile" (i.e. a time path of health states ending in death) in terms of an equally valuable length of time lived in full health. As greater emphasis is being placed on such measures in recent documents produced for the World Health Organisation, they are briefly reviewed here.

Quality Adjusted Life Year (QALY)

A quality-adjusted life-year (QALY) takes into account both quantity and the quality of life generated by healthcare interventions. It is the arithmetic product of life expectancy and a measure of the quality of the remaining life-years.

A QALY places a weight on the time which a patient spends in different health states. A year of perfect health is worth 1; a year of less than perfect health life expectancy is worth less than 1. Death is considered to be equivalent to 0. However, some health states may be considered worse than death and have negative scores. The amount of time spent in a health state is weighted by the utility score given to that health state. It takes one year of perfect health (utility score of 1) to be one QALY, but regards one year in a health state valued at 0.5 to be equivalent to half a QALY.

There is currently some debate within the field of health economics as to whether or not QALYs are the appropriate unit of output, given its limited applicability to CBA. As a result, there is a growing field of study which is researching and developing approaches for assigning monetary values to QALYs based on the use of value of statistical life (VSL) and value of life year (VOLY) estimates.

This requires information on:

- the QALY value that should be attached to the health effects of concern and the duration of these health effects;
- the money value of the VSL and the appropriate discount rate to provide the basis for calculating the VOLY; and
- the number of QALYs in a statistical life.

For example, the UK Health and Safety Executive calculates the monetary value of a year of ill-health as the product of the number of QALYs lost and the monetary value of a 'full health life year'. They take the component of the UK VSL related to pain, grief and suffering (WTP to avoid the risk of death) and equate this to the value of one QALY. Assuming that the WTP component of the VSL is £550,000 and that an accident results in the loss of 39 years of life, and applying a 4% discount rate, the resulting VOLY is £27,150.

Disability Adjusted Life Years (DALYs)

Disability Adjusted Life Years (DALYs) were developed as a measure of the health of a society (rather than an individual) and have been used to measure the burden of disease in various countries (OECD, 2002). They are similar to QALYs except that they incorporate an age-weighting factor and measure the loss of longevity and health from an idealised health profile. The age-weighting factor represents a judgment that years lived in young adulthood and middle age contributes more to a society than years lived as a childhood or in old age. In other words lower weights are applied to the health of the very young and the very old.

DALYs are the sum of years of life lost (YLLs) and years of life lived with disability (YLDs) (Driscoll et al, 2004). A variety of measures have been developed to measure the stream of life lost due to death at different ages. These measures can be divided into four families: potential years of life lost, period expected years of life lost, cohort expected years of life lost and standard expected years of life lost) (Driscoll et al, 2004).

DALYs and QALYs do not provide any additional information about the magnitude of health impacts or the valuation of the impacts. They only allow different health impacts (different disease and mortality effects) to be aggregated. It could in some cases be useful if an alternative has a different profile in terms of the type of health impacts caused compared with the Annex XIV substance.

Further information can also be found in the WWF study "social costs of chemicals" prepared by D Pearce and P Koundouri: http://assets.panda.org/downloads/1654reachcbafindoc.pdf

B.1.2 Unit costs for mortality and morbidity and external costs of various pollutants

Unit costs for mortality and morbidity[36]

Key unit values on mortality and morbidity are given below based on the latest EU-wide research programmes. The values have been given at 2003 price levels so that they can be scaled to the price level of the analysis.

Table 18 Reference values of effects of exposure on chemicals on mortality (2003 price levels)

	Central value (mean value)	For sensitivity analysis (median value)
Value of statistical life	€1,052,000	€ 2,258,000
Value of life year lost	€55,800	€125,200

Source: NewExt (2003, page III-34)

[36] If you are considering using any of the unit costs used in this section, it is recommended to check if these values have been "superseded" by more recent studies.

Table 19 Reference values of effects of exposure on chemicals on some end points acute effects on morbidity (2003 price levels)

Effect	**Value**[37]
Respiratory and cardiac hospital admissions	€2134/admission
Consultations with primary care physicians	€57/consultation
Restricted activity day*)	€89/day
Minor restricted activity day	€41/day
Use of respiratory medication	€1.1/day
Symptom days	€41/day

*) average value for working adult
Source: Ready et al. 2004 according to CAFE (2005)

For chronic effects on morbidity, a number of US studies exist, but these are related to the most severe definition of chronic bronchitis. Based on these, but adjusted to a case of "average severity" by the scalar estimated by Krupnick and Cropper (1992) the following values are derived in the context of chemicals:

- Low range estimate: €120,000
- Central range estimate: €190,000
- High range estimate: €250,000

The validity of using these values depends on whether the average severity of a case of chronic bronchitis found in the Krupnick/Cropper study is close to how it is defined in the epidemiological literature (or in baseline rates in Europe). A recent study by NEEDS provides analysis that supports the central range.

External costs for selected pollutants

Another type of emission is the by-products from manufacturing or use activities along the supply chain. These could be by-products of combustion activities or additional waste or waste water generated where there would be difference between the "applied for use" scenario and the "non-use" scenario (for example if manufacturing the substance in question is more energy intensive than the potential alternative).

In many cases such indirect emissions are limited and they do not need to be further analysed. Here we provide guidance on how to make that judgement.

- Identify what is the most important of such indirect emissions (e.g. air emissions, greenhouse gases, additional wastewater generation, solid or hazardous waste);
- Estimate the quantity of the emissions;
- Apply unit monetised values to estimate the overall costs;

[37] The values shown here have been adjusted to price year 2003 by dividing the original data for price year 2003 by a factor of 0.937, derived from the harmonised consumer price index for the EU25 for 2000-2003.

- Decide if the costs are likely to affect the overall results and only take them further if this is the case.

Note that care should be taken to avoid double-counting of these costs, as some of them can be (fully or partially) internalised through e.g. emission charges and be included in economic impacts as operational or overhead costs. Also potential changes in emissions or waste generation can be presented under economic headings as, for instance, costs related to waste water and waste treatment or disposal services.

Unit monetary values for the damage from some environmental emissions have been developed at an EU level.

Examples of unit monetary values for air emissions and the link to where more detail can found are given below.

Table 20 Average damages per emission

	Average damages per tonne of emission for EU 25
NH3	€16,000
NOx	€6,600
PM2.5	€40,000
SO2	€8,700
VOCs	€1,400

Note: values derived using median value of Value of Statistical life on PM2.5 mortality and median Value of Life year Lost for ozone
Source: Extract of tables 8-12 of AEAT (2005)

The following table includes estimates of external costs of electricity production in the EU. The table shows averages for the EU (EU-25 except Cyprus, Malta and Luxemburg). More details, such as data for each Member State and key assumptions, can be found at the referred website.

Table 21 External costs of electricity production in the EU (in cent/kWh)

	€cent/kWh
Low estimate	1.8
High estimate	5.9

Source: EEA. (2008). External costs of electricity production

For greenhouse gases, there are no agreed monetary values to be used across the EU. A damage cost value CO_2 and other GHGs would be difficult to estimate. Instead it is suggested to use an estimate of the cost based on the abatement costs. Policies such as the EU Emissions Trading

Scheme are likely to set a cap on the total emission, which means than action that increases or decreases CO_2 emissions will not impact on total EU level of emissions[38].

In the SEA, it is recommended that the reference value for CO_2 unit value is the future price of the relevant period of analysis. For instance, the price per tonne of CO_2 for the period 2008-2012 was at the time of writing this guidance document about €20/tCO_2. However, this value will change depending on the post 2012 overall cap on greenhouse gas emissions in the EU and the world by 2020. For the analysis of effects that occur in the first Kyoto period 2008-2012, the reference value would be €20/tCO2. It is recommended that for sensitivity analysis the price should be varied.

For additional wastewater generated there are no EU wide unit costs to apply. As part of implementing the Water Framework Directive most Member States will develop economic analysis and estimate the unit abatement costs for removal of such substances. The results of these analyses could be used in the SEA.

It is unlikely that there would be many situations where additional wastewater would be generated in amounts significant to affect the outcome of the SEA.

USEFUL REFERENCES

- CAFE (2005)Impact assessment of the Thematic Strategy on Air Pollution

- European Commission (2009),Impact Assessment Guidelines of the European Commission: http://ec.europa.eu/governance/impact/commission_guidelines/commission_guidelines_en.htm

- NewExt (2003) New Elements for the Assessment of External Costs from Energy Technologies: http://www.ier.uni-stuttgart.de/forschung/projektwebsites/newext/newext_final.pdf

B.2 Types of economic impacts and relevant data sources

These checklists support the analysis of economic impacts (see section 3.4). The term 'change' used in these checklists can refer to revenues or costs/cost savings. These checklists should be used for all relevant supply chains (e.g. supply chain of an alternative substance) and not just the current supply chain using the substance.

For those submitting an SEA to support a substitution plan under the adequate control route (purpose 3 – see section 1.3) the timing of the transition will be a critical factor which will need to be taken into consideration when determining the scale of the economic impacts (as well as other types of impacts).

[38] It can be argued that if there is cap and trade policy regarding a certain type of emission that specifically makes sure that a given cap (target) will be achieved, then implication of changes in emissions should be measured by the price of treading emissions.

Investment and sunk costs

What do we mean by investment and sunk costs?

Investment costs refer to the purchase of capital equipment such as plant and machinery. 'Sunk costs' refer to investments which have already been paid for, and cannot be recuperated by selling the investment. Thus, sunk costs no longer figure in the decision making process of the company. For example, once an unpatented product is brought to the market, research and development costs are sunk costs.

Types of investment costs

□ Change in innovation and research & development costs

□ Change in performance testing costs

□ Change in property rights costs

□ Change in equipment costs

□ Change in modification costs

□ Change in general site and operations costs

□ Change in decommissioning costs

□ Equipment down-time costs

□ Change in value of production equipment (machines, buildings etc as a result of the "non-use" scenario)

Operating and maintenance costs

What do we mean by operating and maintenance costs?

These costs often vary in direct proportion to changes in output, such as raw materials, components, labour and energy used in manufacturing (i.e. variable costs), but there will also be fixed operating costs.

Types of operating costs

Energy costs

□ Change in electricity costs

□ Change in natural gas costs

□ Change in petroleum products costs

□ Change in coal or other solid fuels costs

Materials and services costs:

□ Change in transportation costs

□ Change in storage costs

□ Change in distribution costs

□ Change in packaging and labelling costs

□ Change in replacement part costs

□ Change in auxiliary costs, such as chemicals, water

□ Change in environmental service costs, such as waste treatment and disposal services

Labour costs:

□ Change in operating costs, supervisory costs and maintenance staff costs

□ Change in training costs of the above staff.

Types of maintenance costs

□ Change in sampling, testing and monitoring costs

□ Change in insurance premium costs

□ Change in marketing costs, license fees and other regulatory compliance activities

□ Change in emergency provision costs

□ Change in other general overhead costs (e.g. administration)

Subsequent (indirect) costs:

The implementation of a new technique can lead to changes in the production process, which again might lead to increasing costs, for instance, a reduction in system effectiveness or inferior product quality. Derived costs should be assessed as far as possible and clearly identified when reporting the results.

Revenues, avoided costs and benefits

What do we mean by revenues, avoided costs and benefits?

Revenue refers to value received in the market for the quantity of the product sold. Avoided costs are savings in cost which no longer exist due to a change in production and/or output.

Revenue sources:

□ Change in sales

□ Change in production efficiency / downtime

□ Change in interest on working capital

□ Change in residual value of equipment

Types of avoided costs:

□ savings on raw materials

□ savings on auxiliaries (chemicals, water) and services

□ savings on energy use

□ savings on labour

□ savings on worker protection expenses

□ savings on insurance claims and type of insurance coverage

□ savings on the monitoring of e.g. emissions

□ savings on maintenance

□ savings on capital due to more effective use of plant

□ savings on disposal costs

It is recommended that these additional savings should also be stated in physical terms, such as:

□ the amount of energy saved

□ quantity of useful by-product recovered and sold

□ number of man-hours saved

Subsequent (indirect) benefits:
The implementation of a new technique can lead to changes in the production process, which again might lead to lower costs, for instance, a rise in system effectiveness or improved product quality. Derived benefits should be assessed as far as possible and clearly identified when reporting the results.

Regulatory costs (typically not relevant for authorisations)

What do we mean by regulatory costs?

The costs of regulation to the competent authority (or 'regulator') are known as regulatory costs. In the case of authorisation, generally few changes to regulatory costs would be expected (except perhaps for the regulatory role involved in ensuring compliance with the authorisation). There could be situations where it would relevant to consider costs to the regulator. For example if production is relocated outside of EU, there might be additional costs of inspection of the imported articles.

Types of regulator costs?

□ Change in administrative costs associated with, for example, licensing an activity

□ Change in inspection and monitoring costs (e.g. of imports or emissions)

□ Change in costs of any scientific modelling, sampling and testing

□ Change in enforcement costs

□ Change in income stemming from changes in permitting or taxed activities

Downstream user and consumer costs

What do we mean by downstream user and consumer costs?

Consumer costs are costs that affect the consumer of the end product. Some of costs mentioned above are relevant to downstream users (i.e. revenues, avoided costs and benefits) as well as the ones listed below.

Types of consumer costs

□ Change in the lifetime of the end product

□ Change in market price

□ Change in annual maintenance/repair costs

□ Change in effectiveness of the end product

□ Change in the availability and choice

Types of downstream user costs

□ Change in the lifetime of product from upstream users/manufacturer

□ Change in the market price

□ Change in effectiveness of the end product

□ Change in the availability and viability of using an alternative

Subsequent (indirect) costs

A "non-use" scenario may lead to changes in the quality and durability of the end product, which may lead to higher costs, for instance, replacement or repair costs. Derived costs should be assessed as far as possible and clearly identified when reporting the results.

Economic cost data can be obtained from a variety of sources but, whatever the source, the user needs to think critically about the validity of the data. **In most cases the key economic data will come from consulting the supply chain.** It may be possible to gather economic cost data using the other sources listed below.

- The supply chain for the uses(s) applied for
- Other relevant supply chains or suppliers (e.g. of potential alternatives);
- Trade associations;
- Expert estimates;
- Published information, e.g. reports, journals, websites;
- Research groups;
- Cost estimates of comparable projects in other industries or sectors;
- Eurostat or similar statistical services; and

- Financial reporting from industries.

Cost estimates found in the literature may either be over or under estimated as they are likely to be specific for a particular purpose rather than a generic indicator of the cost. The data will also have a 'shelf-life', as costs and prices can vary over time. For example, the price of a technique could increase with inflation or, it could fall as the technology changes from an experimental to a mass-produced technique.

If data are expert estimates, it is important to present all the assumptions that the estimates are based on. As any expert judgment includes an element of subjectivity it is important to transparently show how the estimates have been derived and thereby avoid a biased analysis.

B.3 How to estimate social impacts

The checklists below supports the analysis of social impacts (see section 3.5). The term 'change' used in these checklists can refer to revenues or costs/cost savings. These checklists should be used for all relevant supply chains (e.g. supply chain of an alternative substance) and not just the current supply chain using the substance.

Employment Impacts

What do we mean by employment impacts?

Employment impacts refer not only to the change in total employment but also to the change in the types of jobs and where they are located. It is important to consider both the change in employment for those industries currently using and manufacturing the substance and also changes in employment due to a change in demand for an alternative product or process.

How realistic is it to obtain quantitative information?

In most cases it will not be possible to obtain quantitative information on employment impacts especially on specific issues such as different occupational groups (especially without consultation with industry representatives and trade associations) but a "good" SEA would at least qualitatively consider how a refused authorisation may affect impacts such as different occupation groups (e.g. which kind of jobs and skills could be most affected under the "non-use" scenario).

Number of jobs

□ Change in labour required by upstream suppliers (including upstream suppliers for an alternative)

□ Change in labour required for manufacturers of the substance / alternative

□ Change in labour required for transporting the substance / alternative

□ Change in labour required for distributing the substance / alternative

□ Change in labour required for storing the substance / alternative

□ Change in labour required by downstream users

Occupational groups

□ Change in demand for unskilled workers

□ Change in demand for manual workers

□ Change in demand for skilled and specialist workers (particular relevant for niche industries)

□ Change in demand for management positions

Location

□ Change in employment for each Member State

□ Change in employment overall inside of the EU

□ Change in employment overall outside of the EU

Other relevant social impacts

Working environment

□ Change in job quality

□ Change in training available

□ Change in worker rights and protection

□ Change in job security

□ Change in employment conditions

□ Change in support given to families

Workers

□ Change in the number of children employed

□ Change in the number of forced labour

□ Change in average wages and salary

□ Change in the good labour criteria of the ILO

□ Change in working hours / patterns (e.g. more part time or shift work)

□ Change in equality – gender, race, ethnic origin

Consumer welfare

□ Change in utility (satisfaction) - from loss in functionality of the product

□ Change in utility (satisfaction) - from loss in durability of the product

□ Change in utility (satisfaction) - from product no longer being available

□ Change in utility (satisfaction) - for any other reason

Outlined below is a more detailed approach to analysing employment. This should only be considered if the simple approach shown in section 3.5 indicates that further analysis is required.

Task 1	**Estimate the change to employment**
	Estimate the change in employment based on the best available information. It may be possible to estimate the change in the typical number of people required within the process using a representative firm(s), followed by up-scaling to the relevant geographic area. Some form of sensitivity analysis should be carried out when up-scaling the results (uncertainty analysis techniques is discussed in the Appendix E).
Task 2	**Estimate leakage effects**
	The change in jobs occurring outside of the geographical scope of the SEA should be excluded from the change in employment. The geographical scope of the SEA should have been determined in stage 2 (Setting the scope of the SEA).
Task 3	**Estimate the displacement effects**
	The change in employment should consider any redistribution or substitution of jobs elsewhere within the geographical scope of the SEA. It may help to consider what type of jobs may be lost / created. Consider the skills required for these jobs to determine whether these skills are in demand elsewhere within the local region area.
	TIP BOX If industries downscale or relocate, consider: • Will industries take some of the employees with them i.e. highly skilled specialist workers, long serving workers who have a lot of experience and are well trained • Redistribution - Can employees find jobs easily within the local area (consider the types of jobs available and the skills of these workers) • Substitution of jobs – e.g. change from manufacturing jobs to jobs related to distribution and storage and service. Similarly if demand for an alternative products increases, consider: • Will demand result in more labour or more investment in capital • Redistribution of resources – will current employees change working hours/practices to meet the extra demand (e.g. longer shifts rather than extra workers) • Redistribution within the local economy – will these jobs be taken up by those unemployed or will they be taken up by people already employed within the area (this is a transfer of labour and should not be considered an additional social benefit); Tip - Consider the skills level of unemployed people in the area and whether it is sufficient for the jobs being created.
Task 4	**Estimate the types of jobs and skills level in the local region**
	Estimate either the skills (or qualifications) of people in the region where these industries are located and the types of businesses located within the local region. This information should be available in national census data.
	TIP BOX **Use the Travel to Work Area (TTWA) to define the local region**

	The TTWA represents the area in which the majority of the people that could work on a manufacturer's site would live. The fundamental criteria for the TTWA are that, of the working population in the area, at least 75% actually work in the area. For example if over 75% the working population work within 20km of the site, this can be used as the TTWA. In order to collect and analyse data using national census data, the TTWA can be approximated using for instance Super Output Area boundaries[39].
Task 5	**Estimate the effect on the area of these jobs**
	Determine what type of jobs may be lost / created in the region and how this relates to the types of businesses located in these regions, to determine how significant these jobs are within those regions affected.
	TIP BOX – Some useful social indicators that can be found in national census data • Number of people employed relative to the working age population in the local area • Relevant employment sector distribution in the local area e.g. manufacturing, construction, transport storage and communication • Job occupation type in the local area e.g. managers and senior officials, plant and machine operatives • Qualifications of people in the local area who are of working age
Task 6	**Estimate other relevant social impacts**
	Determine what impact changes in net employment have on other relevant social impacts such as job security and working hours. In most cases it may only be possible to qualitatively infer these impacts.

B.4 How to estimate trade, competition and wider economic impacts

This section supports the analysis in section 3.6

In particular:

Task 1 – Analyse the market to determine the ability to pass through additional costs

Extent of the market

A good starting pointing point is being able to identify the size of the market. The size of the market can be broadly defined as a:

[39] Super Output Areas are a geographic hierarchy used by UK government to report small area statistics in England and Wales. There are three layers of Super Output Area – lower, middle and upper –typically the middle layer is used i.e. areas with a minimum population of 5,000 people and mean population of 7,200.

- Local market – this is where there is a need for goods and services to be near to the customer. This can be limited to a region or regions within a single member state.
- Regional market – this is generally limited to a few neighbouring Member States.
- EU market.
- Global market – this is where firms are competing against competitors from all over the world.

Understanding the extent of the market is important as it may determine the power that the downstream user and end product customer (final buyer in the supply chain) have over the price of the commodity. In a local market, the downstream user and end product customer might rely on one manufacturer and may have limited control over the purchase price of raw materials. This will be less so in a global market, where prices are determined on the open market and European firms need to remain competitive against manufacturers and importers from outside Europe.

TIP BOX

Information that could be useful to help determine the size of the market

- The location of manufacturers
- Where the main upstream suppliers are located
- Import/export trade data to understand the flow of materials and the size of the market
- Sales data to determine the value of the market and where the main downstream users and end customers are located
- Physical characteristics of the product – is it easy to transport the substance & feasible to do so over long distances?

Price elasticity

Price elasticity is a term used to describe how sensitive downstream users and the end product customers are to changes in the manufacturer's price. If a product is price sensitive – demand is price elastic – then any increase in the price due to additional production costs will result in a decrease in demand. If the manufacturer is a "price taker" his/her demand is described as perfectly elastic and any increase in price will eliminate the sales.

Some issues that might affect the elasticity of the price of a commodity include: the level of competition in the sector, the power of downstream users and buyers, the power of suppliers (upstream), and the ease with which downstream users and end product customers can switch to an alternative product.

TIP BOX

Information to assess price elasticity

Each company in the supply chain is likely to be able to make an expert assessment of how price sensitive their product is and thereby how likely it is that costs can be passed on without a significant reduction in sales.

If a more quantified estimate is needed it is advisable to consult with an economist to determining the price elasticity. The main information considerations are explained below. It is quite a comprehensive list of information (although not exhaustive) which may not be relevant for all types of authorisation applications.

1. Information about the bargaining power of downstream users and the end product consumer to dictate the price that a manufacturer can charge.

Try to find information about the rivalry within the sector, economists typically try to use the concentration ratio (CR) (or the Herfindahl-Hirschmann Index which is more difficult to find). The CR indicates the percent of market share held by the four largest firms (although it maybe possible to find data for the largest 8, 25 and 50 firms in an industry). National census and other forms of statistical reporting often report the CR for major Standard Industrial Classifications (SICs).

2. Information about the bargaining power of suppliers to charge a high price for raw materials required by manufacturers.

This will affect the operating costs of the manufacturer. These costs can either been absorbed by the manufacturer or passed on to downstream users in the market price.

3. Information about the threat of new entrants

The threat of new entrants to the market could reduce prices. If manufacturers (or the industry in general) are making large profits this would encourage new firms to 'enter the market' and try to take a share of the profits being made. Several factors would influence the decision of a potential new entrant and in general a lot of this information can be obtained through desk based research and the use of sector /industry experts.

4. The threat of alternatives

The threat of alternatives could reduce prices depending on how real the threat is. A real threat is likely to make the price elastic, whereas when the threat of alternative is low then the price is more likely to be inelastic. Some of the information can be obtained from sector/industry experts or by consultation with downstream users.

Competitive rivalry

In a sector where there is little or no differentiation between the products that are supplied by a large number of manufacturers then there will be a high degree of competition. It will therefore be more difficult to pass on any additional costs to downstream users or the end product customer where cost increases are not borne by competitors. When the effect (i.e. legislation) takes place across the whole of the EU, it may be possible for EU firms to pass on costs so long as the market is not exposed to competitors who can import from outside of the EU. The more international competition there is, the more difficult it could be for EU firms to pass on the costs to their consumers.

Alternatively, if the sector is characterised by more specialist products, and where there is an opportunity to differentiate one manufacturer's product from that of the competition, then there may be more flexibility on the price. In these situations there is more opportunity for the operator to pass on the costs to the customer. Similarly, the less exposed the firm is to international competition, the easier it may be for the firm to pass on costs to their customers.

TIP BOX

Information that could be useful to assess competitiveness

Competitiveness is a comparative concept of the ability and performance of a firm, sub-sector or country to sell and supply goods and/or services in a given market. Information that may be relevant in assessing competitiveness is listed below. Generally some of this information can be obtained from desk based research, although the majority of this information can only be obtained from manufacturers and trade associations.

- number of competitors in the market
- market share of competitors
- rate of growth in the industry
- exit barriers – i.e. costs to leave the industry
- diversity of competitors – is this the only substance they make/sell?
- product differentiation
- cost of manufacturing per unit (alternatively the cost of value added)
- level of advertising expense
- labour costs
- expenditure on research and development

Resilience of the industry

'Resilience' describes the supply chain's ability to absorb any increase in costs while ensuring that it remains viable in the short, medium and long-term. In order to ensure this viability, manufacturers and downstream users in the sector will need to be able to generate sufficient financial returns on an ongoing basis to be able to invest in, for example, process development, product development or safety and environmental improvements. Any increased costs will either need to be absorbed along the supply chain (i.e. by the manufacturer or downstream users) or passed on to the customer.

The **main sources** of trade, competition and wider economic costs and benefits are likely to be from:

- Statistical services and in particular Eurostat
- Member State specific trade data e.g. uktradeinfo in the UK (part of HM Revenue & Customs)
- Financial reporting to shareholders and company credit reports
- Published information i.e. websites, journals and reports
- Consultation with industry (trade associations and individual companies)
- Research groups
- Expert estimates

Analyse the market using 'Porter's five forces theory'

There are several established methodologies that have been developed for analysing markets. One commonly used methodology is 'Porter's five forces theory'. Competitive forces determine industry profitability because they influence the prices, the costs and the required investments of firms in an industry. Specifically it will help to determine whether additional costs be passed on to downstream users and consumers

According to Porter's view, the rules of competition are embodied in five forces that shape the structure and intensity of competition:

1. rivalry among existing firms
2. the bargaining power of suppliers (upstream supply chain)
3. the bargaining power of buyers (downstream users and the end product customer)
4. the threat of alternative products or services
5. the threat of new entrants

The strength of these five forces varies from industry to industry, and can change as an industry evolves over time. **In most cases undertaking a five forces test will require specialist economic expertise, although it will not require any economic modelling capabilities.**

Rivalry among existing firms

Strong rivalry in a sector (i.e. between competing manufacturers, or competition within each downstream user market) is likely to result in strong competition on price and may possibly constrain profit margins and, therefore, the sector's ability to absorb or to pass on any costs of the "non-use" scenario. The concentration, or number of players in the market, can indicate the level of rivalry in the sector (the concentration ratio (CR) can give an indication of the concentration in the sector). If overcapacity exists, then there will be limited opportunity to gain market share (this can sometimes be the case in sectors where products are sold to a standard specification, such as cement). Also, if there are high exit barriers (i.e. high shutdown costs) then these factors are likely to lead to strong rivalry within the sector.

Bargaining power of suppliers (upstream supply chain)

If there are a large number of manufacturers/importers in a sector or a small number of downstream users and end product consumers, then there is likely to be keen competition on price. Upstream suppliers might also be in a powerful position if the manufacturers / importers are constrained by high switching costs (e.g. re-tooling or increased transport costs) and cannot switch upstream suppliers easily. A good indication of this is the size of the market i.e. an international market would imply that switching costs are low. If a sector is only a small outlet for an upstream supplier, then the supplier is again in a powerful position and can dictate the price and reduce the manufacturer's ability to bargain for lower costs.

Bargaining power of buyers (downstream users and the end product consumer)

If a sector is characterised by a small number of buyers (downstream users and the end product consumer) taking a significant market share of the sales, then the buyer tends to be in a strong position and can exert more influence on the price. The ability of existing manufacturers in the sector to pass on any additional costs may, therefore, be constrained. However when the product is a small fraction of the buyer's costs, there may be more flexibility to pass the costs on.

The buyer may also be able to influence the market price, if the cost of switching to an alternative (i.e. process/substance) is low. Similarly, if a competing manufacturer uses a more expensive alternative (i.e. process/substance) it may not necessarily be able to charge a higher price, because of significant buyer power, forcing the manufacturer to absorb the higher cost of the alternative.

Threat of alternative products or services

Where the buyer has the option of switching to an alternative product, then this may present a threat to the sector (for example, aluminium and plastics are increasingly being used as raw material in the production of cars, as a substitute for steel), then the opportunities to pass on increased costs to the buyer are limited. The buyer may initially be reluctant to make the switch because of the cost of investment cost of modifying their process that they would have to make to accommodate the switch, but as the cost increases and these costs are reflected in product price increases, the threat of buyers switching to substitute products may become more of an issue. Switching to an alternative product means distributional changes but if it results in activities relocated outside of EU it could have impacts on the overall economic activity.

Threat of new entrants

Highly profitable markets tend to attract new entrants. This threat tends to be constrained if there are high entry barriers (new equipment, access to distribution channels, customers switching costs, legal permits, etc.). An important consideration is increased costs (i.e. from using an alternative product, change in process) which could make non EU companies more competitive in the market, prompting EU industries to consider relocating outside of the EU.

This section supports the analysis in section 3.6

In particular:

Task 2 – Determine the resilience of the industry using financial ratios

Determine the resilience of the industry using financial ratios

For a firm to be economically viable it must be able to adapt and grow under varying economic conditions and fluctuations within its industry. Analysing the viability of an industry using financial ratios will help to determine whether additional costs on the industry will limit any further growth in industry or even put part of the industry out of business.

To be economically viable a firm must maintain sufficient:

- Liquidity;
- Solvency; and
- Profitability.

Liquidity is a short-term measure of the health of a company and describes the company's ability to pay off its immediate liabilities. This appendix includes a method for calculating both the 'current ratio' and the 'quick ratio', which are routinely used to describe liquidity.

Solvency of a company describes the company's ability to fulfil its obligations in the longer term. Solvency is when a firm's assets exceed its external debt (liabilities). Therefore the firm has a good financial basis or stability and, as such, solvency is a good measure for the overall wellbeing of the company. If external debts are greater than the asset values, a state of insolvency exists. Calculations for 'debt/asset ratio' and 'interest coverage', which are routinely used to describe solvency, are included in this appendix.

Profitability: Companies with higher profit margins and overall profits will find it easier to absorb any increase in production costs (this is mostly a distributional impact to society). A business that is both solvent and liquid will not necessarily be profitable. A simple definition of profit is revenue after costs have been deducted. More importantly profit can also indicate the return on capital invested i.e. it compensates the owner of the capital for the loss of the capital for any other potential use. This is usually a good basis for investors to determine whether the return on their investment will yield an adequate return relative to the solvency risk of the company as well as alternative investments elsewhere including risk-free investments. There are various measures of profitability. Financial ratios for 'gross profit margin', 'net profit margin' and 'return on capital employed' are discussed in this appendix.

This section includes several financial ratios for each of these key indicators.

Liquidity

$$\text{Liquidity ('Current') Ratio} = \frac{\text{Current Assets}}{\text{Current liabilities}}$$

This is considered the main test for liquidity. There is no exact value for this ratio which can be used as a guide to a firm's health as it will depend on the industry and the particular circumstances. Generally figures of around 1.5 are recommended though the trend is more important. A value at or below 1.0 indicates concern (can not meet short term debt) and values greater than 2.0 may mean that too much finance is tied up in short term assets.

$$\text{Acid Test ('Quick') Ratio} = \frac{\text{Current Assets – stock}}{\text{Current liabilities}}$$

Under the acid test stock is deducted because it can be hard to quickly convert stock into cash due to various factors such as the weather or legislation. Accountants recommend that the acid test ratio should be around 1 i.e. that there should be about €1 of liquid assets for every €1 of short-term debt.

Solvency

$$\text{Debt/asset ratio} = \frac{\text{total firm liabilities}}{\text{total firm assets}}$$

Debt/asset ratio is a common measure of business solvency. Generally smaller debt/asset ratio values are preferred to larger ones. Smaller values indicate a better chance of maintaining the solvency of the business should it be faced with a period of adverse economic conditions. Low debt/asset ratios may also indicate that the firm is reluctant to use debt capital to take advantage of profitable investment opportunities. Values which are less than 1 indicate a solvent business.

Profitability

There are various measures of profitability. This section focuses on gross and net profit margins as well as return to capital employed (ROCE):

$$\text{Gross profit Margin} = \frac{\text{Gross Profit}}{\text{Sales}} \times 100$$

The gross profit margin is the percentage of sales revenue before other expenses are considered.

$$\text{Net profit margin} = \frac{\text{net (operating) profit}}{\text{Sales}} \times 100$$

Net gross profit margin is generally considered more significant because, unlike gross margins, fixed overheads are taken into account.

$$\text{Return to capital employed (ROCE)} = \frac{\text{Profit before tax and interest}}{\text{Capital employed}} \times 100$$

The ROCE is the percentage of return the firm is able to generate on its long-term capital employed in the business. It is also sometimes used as a measure of efficiency. A firm's ROCE allows investors to judge the financial effectiveness of the company action and it possibly be used for growth forecasts. A high ROCE indicates that a significant proportion of profits can be invested back into the company for the benefit of shareholders. The reinvested capital is employed again at a higher rate of return, which helps to produce higher earnings-per-share growth. A high ROCE is, therefore, a sign of a successful growth company.

If the ROCE is lower than the rate of a risk-free investment such as a fixed savings account, then the firm maybe better off closing down, selling its assets and putting the money in this fixed savings account. Investors can use the ROCE to other potential investments to see who is likely to generate the best return.

Consistency is a key factor of performance. Sudden changes in the ROCE could indicate a loss of competitiveness in the market or that more assets are held as cash. There are no firm benchmarks because ROCE can be low during periods of recession, but as a very general rule of thumb, ROCE

should be at least double the current interest rate. An ROCE any lower than this suggests that a company is making poor use of its capital resources.

APPENDIX C VALUATION TECHNIQUES

VALUATION TECHNIQUES

Introduction

This appendix outlines alternative valuation techniques for estimating the monetary values of human health or environmental impacts. The Commission's Annexes to Impact Assessment Guidelines (chapter 11) provides information on a range of valuation techniques.

This appendix provides a few more details on most of the techniques including how they could be used in an SEA. The appendix is intended to provide only an introduction to the different techniques available. More detailed information and specialist expertise should be sought before carrying out the valuation of impacts.

The valuation techniques described in this appendix present several alternative approaches to establishing monetary values for impacts or changes where there is not market price that can be applied. The valuation techniques will therefore primarily be relevant for human health and environmental impacts. They could however also be relevant in situations where a "non-use" scenario will result in a quality change to a good or service.

Traditionally in chemicals risk management, value transfers have often been used to value impacts such as environmental and human health impacts. The remaining techniques presented in this appendix have not usually been used partly because it is more difficult to apply them to chemical risk management but also because they require a lot of resources to be devoted to gathering data. The applicant should take this into consideration when planning their resources and budget.

It should also be kept in mind that valuation techniques such as avoided costs and in some cases resource costs are not providing valuation of the impacts as such and there they should be applied with care making it clear why they are used.

Where can I find <u>more information</u> about valuation technique?

Economic literature on valuation techniques is plentiful. A couple of more recent books include:

- Freeman, A. Myrick; "The Measurements of Environmental and Resource Values: Theory and Methods", Resource for the Future Press, 2003
- Carson Richard: "Contingent Valuation: A Comprehensive Bibliography and History", Edward Elgar Pub, 2008.

C.1 Value transfers

<u>What</u> is this technique?

Value or benefit transfer is the process of taking information about monetary values (which can be benefits or costs) from one context (the 'study site') and applying it to another context (the 'policy site').

Due to constraints on time and resources, it is unlikely to be practicable to conduct new valuation studies when developing an SEA. Therefore, estimated values can be transferred from previous studies with similar characteristics. The context in which the original valuation study was conducted is often termed the 'study site', and the site where the new value estimate is needed is termed the 'policy site'. Value transfer can be used across different sites (spatial value transfer) or at one specific site over time (temporal value transfer). The main assumption with value transfers is that estimates of the value of an impact at one site are able to provide a reasonable approximation to the value for another site with similar conditions.

How is this technique used?

Typical steps in value transfer are as follows:

- Determine the type of value required (e.g. cost associated with a particular health impact)
- Conduct a literature review to identify relevant valuation studies
- Assess the relevance of study site values for transfer to the site in question
- Assess quality, consistency and robustness of study site data
- Select and summarise the data available from the study site
- Transfer values from study site to the policy site in question, adjusting as appropriate (e.g. for purchasing power)
- Determine how to aggregate impacts in relation to site in question, e.g. households affected, area of influence, and so forth.

The key step is transfer from the study site to the policy site. There are different ways to do this transfer depending on the differences in the characteristics of the study site and the policy site. The following types of transfer can be applied:

- Single value transfer (e.g. the willingness to pay for protecting a natural site estimated at €100/person surveyed in the original study is used irrespectively of the size or qualities of the site)
- Marginal point value transfer (the value of €10/ha/person is used taking account of the size of the area)
- Benefit function transfer (the transfer includes several attributes, size of area, number of species, income of surveyed population, etc)
- Meta value analysis (a number of studies are used to estimate a value to be used for the benefit transfer)

What difficulties can arise when using this technique?

- The quality and/or availability of existing studies is often insufficient. A value transfer is only as reliable as the original study;
- The expected change of new projects or policies is outside the range of previous experience;
- Problems occur with converting a discrete change (i.e. in environmental quality) into marginal values to value the new policy;
- Problems occur trying to value a gain (i.e. in environmental quality) when the valuation relates to a loss (in environmental quality);
- Differences in the study site(s) and the policy site cannot be or are not accounted for in the transfer model or procedure.

When could this technique be used? (within the SEA process)

It is not feasible to estimate all impacts in a typical SEA using the data that will typically be available. Value transfer methods may be particularly useful for an SEA where a 'rough and ready' indication of impacts may be sufficient to reach a judgement. They are also particularly relevant when time and financial constraints rule out the use of other valuation techniques.

Appendix B on impact assessment includes examples of tables with benefit transfer values that has been developed as part of EU initiatives. They cover some health and environmental impacts and have been developed through a meta analysis approach and agreed amongst the Member States.

Example of how to use this technique

There are some existing databases of valuation studies and it can be expected that further databases will become available in the future. Currently, the EVRI database is one example of a valuation study database. EVRI includes about 1500 to 2000 valuation studies and new studies are added regularly. Whilst use of valuation studies are likely to be relevant for an SEA in only a limited number of cases, the example below shows how one can use benefit studies to get an understanding of the likely order of magnitude for certain impacts.

Valuation of recreation benefits are particularly well covered as this type of use value has been subject to many studies. One of the studies that can be accessed in the EVRI database is a study that summarised values available for recreation benefit[40], drawing upon values from a number of primary studies. It is therefore a meta study and provides the basis for using meta value benefit transfer. The meta analysis is likely to provide a more robust basis for the benefit transfer than transfer from studies covering individual sites.

This study summarises the value of different recreational activities. It includes, for example, the value attributed to swimming and fishing. A monetary welfare value is given in $ per activity day per person. The mean value for swimming is $21 per day per person, while the mean value for fishing is $36 per day per person. The uncertainty is given by the gross range of values; for fishing the range is from $2 to $210 per person. (This highlights the uncertainties inherent in such an approach and uncertainty analysis – see Appendix F – is likely to be a fundamental part of any SEA using value transfer techniques. Where possible a more plausible range could be used i.e. weighted average or confidence interval around a mean value)

Before using such values, the issues listed above, regarding considering whether the benefit values are suitable for transfer, need to be addressed.

In this case, most of data are from North American studies. One needs to consider whether this affects the applicability for use in the EU. This covers two aspects: i) Are there differences in income levels and ii) are there differences in preferences for recreational activities.

[40] Rosenberger Randall S.; Loomis, John B. 2001. Benefit transfer of outdoor recreation use values: A technical document supporting the Forest Service Strategic Plan. Gen. Tech. Rep. RMRS-GTR-72. Fort Collins, CO: U.S. Department of Agriculture.

In this example, the difference in income levels can be measures as by the difference in GDP/capita in EU and in the US. The GDP values needs to be based on purchase power parity (PPP)[41]. It means that there is accounted for differences in price level (if the nominal income/capita in country A is twice that of country B but all prices of goods and services are also twice as high in country A, then the PPP adjusted income/capita will be the same).

If it is further assumed that there is no reason to believe in any particular difference in preferences for these recreational activities the values can be used.

The conversion of the above willingness to pay results from $ 1996 values to € in 2007 prices includes the follow steps:

- Conversion of $ to € based on 1996 exchange rates;
- Adjustment of the values by the difference in household income in 1996;
- Adjustment of 1996 value to 2007 price level by using EU inflation rates for the period 1996 to 2007.

The conversion of estimates from one currency to another and from prices in the year of the study to present prices is described in Section 4.8. In this example there a few complications. In 1996, the € was not established as real currency but existed in the form of ECU. Its value are comparable to the € and it is therefore used. Based on the Eurostat database the exchange rate is estimated at 0.79 € per $. (average exchange rate for last quarter of 1996)

Adjustment for the effect of different levels of wealth is complicated by the fact that EU in 1996 was only EU15. The new member states have GDP levels that are relatively low but they experience high annual growth. It is therefore a question how to account for that. GDP/capita figure for 1996 show a difference at 70 to 80% between US and EU while the more recent figures are down to about 50%. Here the adjustment is based on 2007 data.

	GDP per capita (PPP) 2007 estimates
European Union	28 213
United States	43 444
Ratio	1.54

Based on Eurostat data the EU inflation (EU 27) from 1996 to 2007 is about 40%.

All three steps in adjustment of the original willingness to pay estimate are illustrated below.

	Original estimate	Currency adjusted	Adjusted for EU income and price level	Final adjusted value
	$ in 1996 prices	€ in 1996 prices	€ in 1996 prices	€ in 2007 prices
Swimming	21	17	11	15
Fishing	36	28	18	25

[41] This adjustment can be found using the OECD PPP: (if this web-page has moved, use the statistical portal of the OECD site and look for the PPP topic in the topics list)

http://www.oecd.org/department/0,3355,en_2649_34357_1_1_1_1_1,00.html

As it can be seen this conversion it not straightforward and it is therefore recommended to consult economic expert advise in the case of this kind of benefit transfer.

If in an SEA a number of natural sites in the EU were expected to be affected, recreational values could be used to develop estimates of the order of magnitude for the possible loss (or gain) that would be expected to occur. The values could be used through an assessment of how many people currently undertake recreational activities and whether those activities would be prevented due to contamination (or improvement) of the sites. If in total 500,000 person days of fishing would be affected, the potential loss would be €14 million per year with range of €1 million to €82 million.

If the number of people affected were not known, a sensitivity analysis could be undertaken. If the total economic cost difference between the two SEA scenarios was estimated to be €100 million per year, a sensitivity analysis could show that if more than 3.7 million recreational fishing days were potentially affected, the loss would exceed the economic costs (€100 million divided by €27/fishing day equals 3.7 million days). If additional information indicated that the total fishing activities in the areas potentially affected was only 100,000 recreational fishing days, it could be concluded that this loss would be unlikely to exceed the economic costs. In most cases there would be other types of environmental effects to consider, making this kind of analysis more complex.

Where can I find more information about this technique?

EC Impact Assessment Guidelines Annexes (see chapter 11) 15 January 2009

UK Treasury Greenbook (Chapter 5)

The Environmental Valuation Reference Inventory is a searchable database of valuation studies of environmental benefits (and human health) and is intended as a tool for facilitating benefits transfer. http://www.evri.ca/

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

Central Queensland University: A Systematic Database for Benefit Transfer of NRM Values in Queensland

Cost-Benefit Analysis and the Environment Recent Developments (Chapter 17) -OECD 2006

C.2 Stated preference

What is this technique?

The basic idea behind any stated preference (SP) technique for estimating impacts which are typically not assigned a value through the market (non-market prices) is to quantify a person's willingness to bear a financial cost in order to achieve some potential (non-financial) improvement or to avoid some potential harm. SP approaches are based on hypothetical markets and rely on asking people hypothetical questions utilising questionnaires. These questions can ascertain the economic value people attach to certain goods and services. With any study conducted using questionnaires, the reliability of the valuations are only as good as the actual questions and the language used (i.e. any bias in the language or options available will affect the usefulness of the

results).

Within the class of SP methods, there are two alternative groups of techniques: the contingent valuation method (CVM) and choice modelling (CM).

Contingent valuation method (CVM)

When deploying the CVM, the examiner constructs a scenario or hypothetical market which is then posed to a random sample of the population to estimate their willingness to pay (WTP) for an improvement or their willingness to accept (WTA) monetary compensation for the decline in quality (e.g. in terms of environmental quality). Based on survey responses, examiners estimate values such as the mean and median WTP for an improvement or willingness to accept compensation for a decline in quality.

Choice modelling (CM)

In applying CM goods are described in terms of their attributes (quality, price etc) and of the levels that these attributes take. Respondents are presented with various alternative descriptions of a good, differentiated by their attributes and the levels of these attributes, and are asked to rank, rate or choose their preferred alternative with respect to the set of attributes. WTP can be indirectly recovered from people's choices as long as price is one of the attributes, with the advantage of avoiding an explicit elicitation of WTP itself.

How is this technique used?

Expert guidance is recommended when utilising SP techniques. The following steps are needed for a successful SP study (Pearce et al., 2002):

- Initial Research – What question is being answered? What is the object or impact being valued?
- Choice of survey method and valuation technique – Is the survey method face to face? Mail? Internet? Will it be CM or CV?
- Choice of population and sample – What is the target population, and what kind of sample should be selected?
- Questionnaire design – Payment vehicle (Tax, Price, Donation etc.)? Elicitation format? Form of question? (Avoid wording questions which steer the audience in a particular direction.)
- Testing the questionnaire – Focus groups, pilot surveys, redesign.
- Conduct the main survey – Redesign questionnaire and conduct main survey.
- Econometric analysis – Construct a database of results and pass to econometrics experts.
- Validity and reliability testing – Do the results meet validity and reliability tests?
- Aggregation and reporting – Aggregating from the sample results to the target population.

When could this technique be used? (within the SEA process)

It is generally not expected that an SEA would include primary valuation work. If however, the values at stake are sufficiently high it could be decided to undertake primary valuation. Such valuation studies could be relevant for different types of impacts. Monetary valuation techniques are often considered in the relation to environmental and health impacts. They could also be used to assess whether a "non-use" scenario would result in a changed quality of an end product. The choice modelling (CM) technique was originally designed to gain understanding of consumers'

willingness to pay for changes in quality and other attributes of consumer goods. By designing a questionnaire covering the different qualities of the end-product, the willingness to pay for a change in those qualities due to ban of the substance could be estimated.

A valuation study could also be designed to specifically analyse the willingness to pay for the change in risks between the two scenarios. This could enable the willingness to pay for reducing the risks(s) to be analysed even if only a qualitative description of the risks is available.

Undertaking a primary valuation study would require expert input. There are organisations specialised in design of (unbiased) questionnaires, selection of representative samples and implementation of surveys.

What difficulties can arise when using this technique?

- Respondents may not offer a genuine response because they do not believe in the scenario
- Results obtained are not based on actual behaviour and can therefore miss factors present in markets
- It is possible for respondents to agree with the bid offered without properly considering the magnitude of the bid or other considerations
- Social desirability bias occurs if respondents give responses in such a way as to portray themselves in a favourable light with respect to social norms
- Statistical analysis of data can be very complex and requires expert assistance and specialist software
- The payment vehicle used and framing of the questions can greatly influence results
- The technique can be very costly and time consuming

Where can I find more information about this technique?

Ecosystem Valuation, Methods chapter 6: Contingent Valuation

DTLR: Economic Valuation with Stated Preference Techniques Summary Guide (March 2002)

NOAA Coastal Services Center - Environmental Valuation: Principles, Techniques, and Applications:

DEWR - The Economic Value of Biodiversity: a scoping paper (October 2003)

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002):

Cost-Benefit Analysis and the Environment Recent Developments (Chapter 8-9) -OECD 2006

C.3 Revealed preference

What is this technique?

Revealed preferences (RP) are uncovered through actual choices made by individuals in the marketplace and share the common feature of using market information and behaviour to infer the monetary value of an associated non-market impact. In some instances, replacement costs have been used as a form of revealed preference (e.g. the restoration of earlier damages). The three main revealed preferences approaches are introduced below.

The **hedonic price method** of environmental valuation uses surrogate markets in order to ascertain values for environmental quality. The real estate market is the most commonly used surrogate market used in hedonic pricing of environmental values. Property prices are affected by different pollutants such as air and noise and this as a direct impact on their value. By comparing properties with otherwise similar characteristics and correcting for all non-environmental factors, information on the housing market can be used to estimate people's willingness to pay for environmental quality.

Under the **travel cost method**, a demand curve for a non-marketed recreational/tourist asset that is dependent on the condition of its environment can be inferred from an estimated relationship between visitation rates and the costs of travelling to a site. In other words, by investigating how much people are willing to pay to get to a site, it is possible to infer the value they enjoy from being at the site.

Averting behaviour and defensive expenditure approaches are similar to the previous two, but differ to the extent that they refer to individual behaviour to avoid negative intangible impacts. People might buy goods such as safety helmets to reduce accident risk and double-glazing to reduce traffic noise which in turn reveals their valuation of these negative impacts. Avoided cost approach is explained in section B.5.

When could this technique be used? (within the SEA process)

Techniques based on revealed preferences are less likely to be useful in an SEA context. In terms of preferences for avoiding exposure to chemicals in the work place or in during consumer use, there may be examples that could be used to assess how a population at risk would be expected to choose to avoid or reduce the risks and their willingness to pay for that. To undertake a revealed preference study, one would need to identify a situation where workers or consumers have a choice between different levels of exposure to a chemical/chemicals and where the choices have a financial implication, such as on salary or product price. As with the stated preference techniques, specialist input would be required.

(Benefit transfer values are often based on revealed preference studies.)

What difficulties can arise when using this technique?

- Coefficients on attributes in models estimated from choices in actual settings provide only limited predictions of the impact of changing policies
- Statistical analysis of data can be very complex and requires expert assistance
- Co linearity among multiple attributes is common in revealed preference data, making it difficult to separate the effects of attributes and creating implausible results
- Revealed preference methods are relatively complex to implement and interpret, requiring a high degree of statistical expertise
- The techniques requires a large amount of data gathering and manipulation is required and can therefore be costly depending on data accessibility
- Problems with hedonic pricing include
- The scope of impacts that can be measured is limited to things that are related to the surrogate markets involved
- The method only takes into account perceived impacts so impacts that individuals are unaware of will be missed
- Problems of the TCM include

  - The travel itself may have a value

  - The same costs might be incurred to access more than one site

  -Some of the costs are intangible (e.g. opportunity costs of time)

- Averting behaviour has the difficulty that the market goods may have more benefits then just reducing the intangible negative impact being measured

Where can I find more information about this technique?

Energy, Transport And Environment Center For Economic Studies: the development and application of economic valuation techniques and their use in environmental policy – a survey (2003)

NOAA Coastal Services Center - Environmental Valuation: Principles, Techniques, and Applications:

DEWR - The Economic Value of Biodiversity: a scoping paper

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002):

Cost-Benefit Analysis and the Environment Recent Developments (Chapter 7) -OECD 2006

C.4 Resource cost approach

What is this technique?

The resource cost approach can be used to make monetary valuations of health effects such as illness. The resource costs of an illness consist of two components. The first is the actual costs of illness, which are the easiest to measure. Estimation of these costs is based either on the actual expenditure associated with treating different illnesses, or on the expected frequency of the use of different services for different illnesses together with the costs of those services. The key problem in assessing the direct costs is the ability to collect data on the actual costs associated with a particular health end-point, given that accounting practices adopted by health practitioners have not generally been developed with this in mind.

The second component of resource costs is that of lost earnings and/or time, often referred to as indirect productivity costs. The costs of lost earnings are typically valued at the after-tax wage rate (for the work time lost), and lost home time at the opportunity cost of leisure (for the leisure time lost). However, a basic drawback of including these indirect costs is that, although well established, the approach does not necessarily provide a reliable estimate in times of high unemployment (OECD, 2002). Total resource costs are then estimated as the sum of:

- actual expenditure (e.g. medicines, doctor and hospital bills) per day, i.e. direct costs; and
- the value of lost earnings and leisure time per day, i.e. indirect costs; and

These are then multiplied by the number of days sick and number of cases of sickness for the illness.

It needs to be recognised that, because the resource costs approach focuses only on the more tangible costs avoided, it does not necessarily reflect an individual's full WTP to avoid an illness (Freeman, 1993, in OECD, 2002). Care is needed when WTP values include the costs incurred by the individuals for treating an illness, in order to avoid double counting.

When could this technique be used? (within the SEA process)

The resource costs approach is similar to any cost assessment and it could be relevant to use in the SEA context. If health impacts are identified and the use of benefit transfer is not suitable, an estimation of the resource costs related to the health impact would be useful.

What difficulties can arise when using this technique?

- The technique is limited to specific situations which involve health impacts and therefore the technique will have limited applicability
- The approach does not necessarily reflect an individual's full WTP to avoid an illness as it just focuses on the resource costs e.g. losses in utility associated with the pain the individual suffers
- Obtaining data on actual costs for a specific analysis may be difficult given the accounting practices generally adopted by health services

Where can I find more information about this technique?

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002):

Cost-Benefit Analysis and the Environment Recent Developments (Chapter 14) -OECD 2006

C.5 Avoided cost approach

What is this technique?

This technique assesses the cost of measures that have been introduced with the purpose of preventing, avoiding, or mitigating the damages caused by, for example, use of a substance with non-threshold effects. Instead of providing a strict measure of monetary values based on people's willingness to pay for a product or service, the approach assumes that the costs of avoiding damages to ecosystems or their services provide useful estimates of their respective values. This is based on the assumption that, if people incur costs to avoid damages caused by lost ecosystem services for example, then those services must be worth at least what people paid to avoid the damage.

How is this technique used?

The initial step for the avoided cost approach involves assessing the environmental services or other services which are provided. This consists of specifying the relevant services, including how they are provided, to whom and at what levels. The second step is to estimate the potential damage which could occur, either annually or over some discrete time period. Finally the monetary value of potential damage, or the amount that people spend to avoid such damage, is calculated.

What difficulties can arise when using this technique?

- Costs incurred are usually not an accurate measure of the benefits derived which contradicts one of the main assumptions of this approach. This approach should, therefore, be used as a last resort as social preferences for ecosystem services or individuals' behaviour in the absence of those services are not considered.
- The methods may be inconsistent because few environmental actions and regulations are based *solely* on benefit-cost comparisons, particularly at the national level. Therefore, the cost of a protective action may either exceed or fall short of the benefits to society.
- These approaches should be used only after society has demonstrated their willingness-to-pay for the investment in some way (e.g., approved spending for the investment). Otherwise there is no indication that the value of the good or service provided by the ecological resource to the affected community is greater than the estimated cost of the investment.

When could this technique be used? (within the SEA process)

The avoided cost approach could be used to value impacts where an EU wide target means that increasing or decreasing emissions of a substance would have to be offset by changes in other sectors. The avoided cost approach is suggested in relation to the emissions of CO_2 and other greenhouse gas where it is almost impossible to derive a useful damage estimate; see Section 3.4.4of the guidance.

Where can I find more information about this technique?

Ecosystem Valuation, Methods, Section 5: Damage Cost Avoided, Replacement Cost, and Substitute Cost Methods

APPENDIX D DISCOUNTING

DISCOUNTING

DISCOUNTING – APPENDIX D

This appendix aims to give supporting guidance to section 3.7 on how to carry out the discounting of costs and benefits in a SEA. This appendix provides information on:

- The reasons for discounting
- Choosing the discount rate
- Discounting rate approaches
- Other key considerations;
    - market rates vs. social time preference rate
    - environmental and health issues
    - intergenerational issues
    - Future generation's valuation of health and the environment

D.1 The reasons for discounting: 'valuing the future less than today'

The two main, non-exclusive reasons why the large majority of economists argue that costs and benefits should be discounted over time are:

- A time preference reason, which could have two components:
    - Individuals are 'impatient'. Although most individuals may be (almost) indifferent as to whether they receive a gift in a year's time compared to a year and one day, people will generally clearly prefer to have their gift today rather than tomorrow, even if both gifts are equally guaranteed. Economists term this 'pure time preference'. Some economists have argued that society as a whole does not or should not have the impatience that single individuals have.
    - Individuals are 'mortal'. Individuals may not be around to benefit from future consumption and so place greater value on present consumption (that is not to say they do not consider the future as many individuals have for example pensions and leave bequests for future relations). Government though will need to consider future generations and human/environmental/social catastrophe. This will be discussed later in more detail.
- Capital is 'productive'. Productive capital implies that current consumption is more expensive compared to future consumption. When you save /invest your money, you receive a positive return (interest) that allows you to consume more in the future. This premium for not consuming now is a concept also referred to as 'marginal productivity of capital'. An individual can earn 'interest' on their money invested in a savings account. This interest in the 'marginal productivity of capital' of the savings account.

  Similarly, if a company invests in updating its existing machinery, the value of any additional output, is the 'marginal productivity of capital' for that particular investment. If we continue with this analogy, new investment in say public education may result in a better educated society and workforce. Here the 'marginal productivity of capital' could be a more productive workforce or savings from less training required. If we assume consumption continues to

growth (as historical trends over the past century show) diminishing marginal utility of consumption implies that additional consumption in the future is less valuable than consumption today.

Often, risk is mentioned as a third reason for discounting. It concerns the uncertainty related to specific costs and benefits (incurred by a specific party), which is often reflected in a surcharge on the interest rate required for getting the financial means to incur costs and benefits at different points in time. Discounting implicitly assumes that such spreading out is possible. In the evaluation of investment projects such a risk mark-up is commonly used. For an SEA, however, it is recommended to book such costs as a separate item, and not through the discount rate as the latter reflects the general price of waiting and the risk is related to specific costs of benefits only.

As said above, the consequences of discounting are that the impacts that occur further away in the future have a lower PV compared to impacts that occur in the short term. It has therefore been argued that discounting should not be used for certain environmental, health and intergeneration impacts. Many of the arguments brought forward are essentially moral in character; for instance, is a fatality over 5 years less grave a matter than one over 2 years time? Should one refrain from any such comparison through economic evaluation?

These considerations are valid and merit therefore separate consideration in the appraisal and reporting activities. However, it is also true that in practice people, companies and governments make such trade-offs in everyday decisions. Rather than doing so implicitly we recommend doing so explicitly so as to gain insight on the (possible) consequences and the trade-offs related to the decision at hand.

D.2 Choosing the discount rate

The choice of discount rate can alter the comparison between various impacts within the SEA. For example, if some costs mainly accrue in the future, the mere use of a high discount rate would reduce the PV of these costs. This is of particular importance when the time period under consideration has to be rather long; a relatively high discount rate effectively gives a weight of practically zero to effects in the further future.

The table following shows the benefit of one sick day avoided using a hypothetical estimate of €200. The table shows how the discount factor changes depending on the discount rate and the timing of the impact. It shows that when using a 4% discount rate the estimated savings of one sick day avoided in the 10th year is valued at € 135.11 whereas the savings is only € 3.96 in the 100th year (all other things being equal). This is a mere € 0.59 in the 100th year if a 6% discount rate is used.

Table 22 Example of why the timing of the impact matters

Year	**10**	**20**	**30**	**50**	**100**
Discount factor using a **4%** discount rate	0.6756	0.4564	0.3083	0.1407	0.0198
Benefit of one sick day avoided (€200)	€ 135.11	€ 91.28	€ 61.66	€ 28.14	€ 3.96
Discount factor using a **6%** discount rate	0.5584	0.3118	0.1741	0.0543	0.0029
Benefit of one sick day avoided (€200)	€ 111.68	€ 62.36	€ 34.82	€ 10.86	€ 0.59

Unfortunately, there is no consensus on a uniformly applicable standard value of the discount rate. Partly this reflects heterogeneity: different groups and different societies may have a different time preference; moreover, the appropriate discount rate may depend on the scope and running time of the specific appraisal exercise. For example, if a substance has PBT or vPvB properties and ceases to be produced after the sunset date, there may still be environmental impacts resulting from production which lingers for beyond 30 years. Therefore for sensitivity the use of declining discount rates may be appropriate to use in addition to the 4% discount rate.

Moreover, for some types of problems it matters whether the actual preference of the involved economic agents as expressed as market behaviour is taken as a point of reference or an ethical principle; for other type of problems it does not.

Setting of the discount rate, in particular over a longer period of time, adds to the complexity of choosing the discount rate and because there is also no full consensus among economists, it is highly recommended to run a sensitivity analysis comparing a few different discount rates.

It is recommended that the user undertake a sensitive analysis of the effect of alternative discount rates. It is unlikely that a consensus on discounting will emerge among experts as the trade-off between the welfare of current and future generations is political. By analysing the implication of alternative discount rates, the use presents the evidence in the most transparent manner allowing any reader of the SEA to make own judgements about the trade-off.

Following on to the arguments for why to discount the following list includes alternative ways to determine the discount rate:

- Social time preference based on ‘actually observed behaviour’ usually combines the ‘impatience’ argument of people preferring consumption now for consumption later, a pure time preference usually estimated to be around 1.5 %, with the effect of the prospect of higher future consumption due to economic growth (about 2–3%). This results in an overall time preference and thus a discount rate typically in the range level of 3% to 5%.
- Intergenerational equity is another argument to base the time preference rate on. The intergenerational equity argument suggests that the opportunities for consumption should be equal over time. The basis for this rate would therefore be expected real per capita growth rate in the economy. The real growth per capita rate is difficult to predict over a long time period and it has historically and regionally varied significantly. Currently the real growth rate forecast for EU for 2007 is around 2% and real growth has been in the range of 1-3 % over the last years.
- Lastly, the discount rate could be based on the return on capital. This is the opportunity cost argument that money used to invest in risk reductions could alternatively have received the average return for private investments. A discount rate based on this type of argument would be in order of 5%-8%. Here, it matters for the choice of discounting rate which economic agent specifically is incurring the cost or benefits in the course of time. For consumers this may be the relevant market interest rate; for industry, this may be the (required) return on investment.

Some possible discount rates are shown in Table 23. If the impacts are likely to occur over a long period of time, it is recommended to include in the sensitivity analysis a discount rate scheme that allows for a falling rate after 30 years.

Table 23 Discount rates

	Discount Rate (%)	Comments
EU Level		
Impact Assessment guidelines EU Commission	4%	Based on the average real yield on longer term government debt in the EU over a period since the 1980's. This is intended to reflect the social time preference. Allows for setting the discount rate at different levels when appropriate.
Financial discount rate	6%	For projects financed from EU Structural funds. This rate may increase to 8% for new member states or current candidates where they would have difficulty obtaining finance at a lower rate.
Some EU MS		
Denmark – Environment Ministry	3%	This is based on the social time preference rate[42]
Denmark – Finance Ministry	6%	This reflects the opportunity cost from other projects before tax and depreciation (OCC approach). Given the two rates, a sensitivity analysis is usually conducted to consider the impacts of using both discount rates.
France	4%	That is for costs and benefits accruing within 30 years; the rate falling to 2% beyond 30 years.
Germany	3%	Time period: 20-40. After 40 years it is recommended to use a declining discount rate
Ireland	5%	Called the 'test discount rate' which is used in all CBA and CEA of public sector projects. Can be adjusted when there are significant changes in real interest rates and in the rate of return on investments in Ireland.
Slovak Republic	5%	The Slovak Republic Ministry of the Environment employs a 5% discount rate for the evaluation of environmental impacts, as indeed it is for other impacts in society. 30 years is set as the maximum horizon for which economic benefits and costs are considered, with no special discount rates for projects or policies with very long-run impacts.
Spain	5%	Water infrastructure projects however use a 4% discount rate
Sweden	4%	
UK	3.5%	This is based on the social time preference rate over a 30 year period. Thereafter a declining discount rate; 3% for 31-75yrs, 2.5% for 76-125 yrs, 2%for 126-200 yrs, 1.5% for 201-300 yrs and 1% for 301+ yrs.

Source: Based on information in Hepburn (2006)

D.3 Discounting rate approaches

Introduction

The main arguments for discounting are either the time preference argument for consumption now to consumption later or the opportunity costs of capital from private investments. It can theoretically be demonstrated that in an economy with no risks, taxes or other "distorting" factors, the two rates would converge to an equilibrium rate and that equilibrium rate would then be the social discount rate.

[42] Samfundsøkonomisk vurdering af miljøprojekter, Miljø-og Energiministeriet, 2000.

In the real world economy the two might differ for several reasons and also arguments about specific characteristic of health and environmental impacts might lead to deviation from any of the two theoretically based discount rates.

In the guidance text, a practical approach has been suggested applying the discount rate recommended by EC for impact assessments and undertaking sensitivity analysis. In cases where the decision is not influenced by the choice of discount rate there is no need to focus on the discounting issue. In other cases where the timing of costs and benefits imply that discounting has an impact on ranking of alternative outcomes, it might be relevant to further explore the discounting issue.

This appendix provides more guidance on how to undertake a more detailed analysis. It does not contain a detailed theoretical coverage of all aspects[43].

Discounting rate approaches

There two main competing theories for determining the discount rate, which are summarised below include:

- Consumption rate of interest (CRI) or social time preference rate (STPR)
- Opportunity costs of capital (OCC).

Each theory is described in the subsequent sections including how to find data to support to use of each argument.

Consumption Rate of Interest (CRI)/Social time preference rate (STPR)

As mentioned earlier people are impatient. The rate at which an individual is willing to forgo consumption now, for future consumption is known as the CRI. It reflects the income that a consumer would require in the future to compensate for surrendering a unit of income today. The term CRI is sometimes used to denote the individual time preference rate while the social time preference rate is called STPR. They are both based on the same theoretical arguments. The social rate is an aggregation on the individual rates. The relevant social discount rate to use in the SEA is the social rate and we will use the term STPR to describe the time preference based rate. The STPR can be broken down in two components as illustrated in Equation 4.

$$s = \delta + \mu g \qquad \textbf{Equation 1}$$

s = social time preference rate

δ = utility discount rate

μ = income elasticity of marginal utility

g = long-run average rate of growth of consumption per capita = that of income (GDP) as well

[43] For a comprehensive theoretical elaboration of the issues of discounting the reader is referred to Groom et al (2005) and Hepburn (2006)

The variable δ is the rate that future utility is discounted. For example setting $\delta=0$ would imply that utility today is valued the same as utility in the distant future. Some economists would argue for this based on ethical grounds that utility should not fall just because they occur in the future.

Some researches have further split the δ, the utility discount rate, in two components: the pure time preference rate element and the "changes in life chances" element[44]. There is some empirical evidence for determining these elements. Oxera (2002) contains a review of the literature which subsequently was used to form the basis for the UK Treasury's guidance on discount rates, see Example 3.

Example 3 Illustrative use of STPR

Using the UK Treasury Greenbook, they have calculated their STPR of 3.5% in the following way:

δ – The evidence suggests that these two components (catastrophe risk and pure time preference) indicate a value of δ of around 1.5 per cent a year for the near future.

μ – The available evidence suggests the elasticity of the marginal utility of consumption (μ) is around 1. This implies that a marginal increment in consumption to a generation that has twice the consumption of the current generation will reduce the utility by half.

g- Maddison (2001) shows growth per capita in UK to be 2.1 per cent over the period 1950 to 1998. Surveying the evidence, the Treasury paper *Trend Growth: Recent Developments and Prospects* also suggests a figure of 2.1 per cent for output growth to be reasonable. The annual growth of g is therefore put a 2 per cent per year.

The calculated STPR:

So with g=2 per cent, δ = 1.5 per cent, μ = 1, then using STPR equation, the STPR to be used as the real discount rate is

$$0.015 + 1*0.02 = 3.5 \text{ per cent}$$

Source: HM Treasury (2003) Green Book, Appraisal and Evaluation in Central Government

Approach to determine the STPR based discount rate

The ideal approach is determining the discount rate is to estimate the STPR. This can be split into three stages:

1. Develop several scenarios for the values of δ, μ and g
2. Assign a probability (expected outcome) to these scenarios
3. Using equation 2, determine the expected (or average) discount rate based on the scenarios

However, in practice it is extremely difficult to determine the values for δ and μ (and less so for g) because these are social preference variables and not individual preferences. Using revealed preference at an individual level to determine the social preference would need to be well justified.

[44] See Oxera (2002). In the UK Treasury's Green Book (the reference guide for economic assessment of public projects), the second term is called "catastrophic risks" (as it takes a societal point of view), see also Example 2. Note it can also be justified by an option value of waiting (i.e. in the future one may obtain better information / technology currently fully unforeseen)

If the issue of discounting is crucial for the result of the SEA and the user would like to consider the determination of the discount rate further, review of the most up to date literature is recommended as starting point. That might provide more empirical data on δ, μ. The expected growth rate could be explored further by analysis of the growth in EU per capita consumption. Though the historical trend would provide some insight the variable to use is the expected/projected growth rate. It will require an advanced macro economic model to make new projections and it is therefore unlike to undertaken as part of an SEA. Still if it should be required, specialist institutions operating macro-economic models covered the EU should be contracted to undertake such work.

For more in-depth theoretical analysis, the user may wish to refer to Groom et al (2005) and Hepburn (2006).

Opportunity Cost of Capital (OCC)

The concept behind OCC is that public investment can 'crowd out' private investment. It sets the discount rate at the real rate of return (to society) forgone in the private sector. Often the OCC rate is different for each sector or industry group. The discount rate is based on the return of the next best investment of similar risk within ones own sector/industry group. If for example the biotech sector can earn a 10% return on its capital investment, then it may wish to also include as part of their sensitivity analysis, what the effects of using a 10% discount rate are within the SEA when applying for authorisation. It is advisable to seek further advice before using OCC as it may not be appropriate to use different discount rates of different impacts and is not necessarily a discount rate which represents societies view.

Combining the two approaches

In an economy with no 'distortions' such as risks, taxes, eternal effects etc an equilibrium interest rate would emerge where the two types of discount rates would be equal. This rate would be determined by the spilt of total production in the economy between consumption and investment through the supply and demand for capital.

Because of these 'distorting' factors the two discounting rates are not equal. It has been argued that a social discount rate could then be calculated as a weighted average of the two. The weight would be determined by the split between consumptions and savings. However for the majority of SEA it is recommended to use the appropriate approach suggested rather than the weighted average of the two.

Market interest rates

Risk free market interest rates are sometimes used as an approximation to the social time preference rate. This is discussed in the next section. The following table includes actual long term interest rates from EU member states.

Table 24 Harmonised long term interest rates[45] within the Euro Area

Countries	Jan. 07	Feb. 07	Mar. 07	Apr. 07
Belgium	4.06	4.11	4.01	4.22
Germany	4.02	4.05	3.94	4.15
Ireland	4.04	4.07	3.97	4.19
Greece	4.28	4.3	4.2	4.4
Spain	4.07	4.1	4.01	4.21
France	4.07	4.1	4	4.21
Italy	4.26	4.28	4.18	4.37
Luxembourg	4.17	4.19	4.12	4.33
Netherlands	4.05	4.07	3.98	4.19
Austria	4.05	4.09	3.98	4.19
Portugal	4.18	4.19	4.1	4.3
Slovenia	4.23	4.34	4.34	4.41
Finland	4.05	4.08	3.98	4.2

Source: ECB and European Commission.
See: http://www.ecb.int/stats/money/long/html/index.en.html#fn1

D.4 Other key considerations

Market interest rate vs. STPR

STPR is meant to reflect the rate at which society discounts the future whereas the risk free market rate might represent the rate at which individuals discount the future. Hepburn (2006) argues there are at least four reasons to use the STPR over the risk free market interest rate:

- Market imperfections – the market price may not truly reflect the social opportunity costs of the resource. The market price can result in sub optimal resource allocations due to various distortions such as asymmetric information, taxation, market power and externalities. For example many goods do not take into consider in their price the environmental 'externalities' caused by its use and manufacture.
- Super-responsibility – market rates only reveal the preferences of the current generation. Although consumers may weight current consumption over future consumption, the government in principal has a responsibility to both the current and future generations.
- Dual role – Due to asymmetric information it is uncertain if the present generation are more concerned about future generations than their day-to-day activities on current markets would reveal.
- Isolation – Based on arguments by Sen (1892) individuals may be more willing to invest for the future under a collective contract even though they are unwilling to invest in as much in isolation.

[45] for convergence assessment purposes (percentages per annum; period averages; secondary market yields of government bonds with maturities of close to ten years)

However, it can be argued that the lowest risk-free market rate, i.e. the one on the market for long-running government bonds (which are corrected for inflation), meets the first and fourth criteria above in a satisfactory way. The market for such bonds is deep and liquid and the issuers of this paper, governments, have negligible default risks and many buyers have long run perspective. For example those who are close to retirement will convert the majority of their pension fund into government bonds to protect the value of their retirement fund, whilst those with a wishing to diversify their portfolio may also have a proportion of the assets as government bonds due to the low risks associated with these bonds.

The other arguments also seem to ignore that the present generation has preferences for the next generation as people do save and consider the welfare of their children and their future offspring. It is important to realise that discounting on the long run attempts to take intergenerational effects on board but that unavoidably it can only do this through the preferences of the current generation.

Environmental and health issues

For consistency all impacts which can be monetised should be discounted whether they are health, financial or environmental impacts. Sunstein and Rowell (2005) for example argue although human lives can not be invested in the same way as capital can, the resources used to save lives (or to reduce risk) can indeed be invested in a variety of ways. Therefore there is no reason not to discount such impacts. Some economists such as Revesz (1999) have argued though that environmental and health impacts should be discounted at a lower rate compared to economic impacts because they are different.

Often the arguments used are actually about the valuation of environmental and health impacts and not necessarily about their discount rate. For example it has often been argued that environmental goods are luxury goods, implying that as people's income increases, their desire for environmental protection/preservation increases. Adjusting the discount rate to reflect for expected growth in income is therefore not the appropriate response. Instead valuations over the lifetime period should be adjusted to reflect their value over time as income increases (i.e. increasing WTP for environmental protection/preservation). Therefore it is not appropriate to use lower discount rates to compensate of uncertainties and differing intergenerational valuations of these impacts.

Using a simple example, where a new piece of equipment is being proposed to reduce the level of emissions exposure, this would result in improvements in the health of workers using this chemical. If the benefits over the lifetime of the equipment are based on the sum of each years discounted benefits (based on using the NPV approach), and societies income was expected to increase, future generations may then value these benefits more than the present generation. To account for this the approach should not be to reduce the discount rate but to incorporate future generations, by increasing the valuation of these benefits in the future.

Intergenerational issues

The concept of capital is 'productive' implies nicely to intergenerational issues. Without using discounting, a life saved today would be valued the same as a life saved in 2050. However discounting would take into consideration that the investment today would save €X today and be used to save more lives by 2050. However a balance or compromise needs to be made as benefits that occur in the future should not be overly penalised because of our impatience.

Dealing with impacts that occur over a long period of time (especially relevant for PBTs and vPvB substances) makes determining the discount rate very difficult. The main reasons are that we do not know the preferences of future generations and the rate of income and economic growth are uncertain. This has lead to the idea of decreasing discount rates gaining more prominence (Groom

et al 2005). For example the uncertainty of economic conditions was the basis for the UK government to incorporate declining social rates in the HM Treasury Green Book which is their official guidance on government project and policy appraisals.

Incorporating declining social rates over time could allow for:

- Changes in future preferences – individuals and societies preferences are likely to change throughout their lifetime and there attitudes to future generations and potential human catastrophe may change.
- Uncertainty about future economic conditions – It is very difficult to predict the future especially those beyond 30 years and very controversial to do so. An economic optimal growth model can be adapted to introduce a 'prudence' effect which will require several assumptions of the future. A prudent society is one where individuals save because the future is uncertain and are taking precautions. Gollier (2002) argues that a prudent society should care more about the future when it is more uncertain, and this is achieved by reducing the discount rate, so that more investment (favouring the future) becomes profitable. Using an optimal growth model and developing the necessary assumptions for the model is likely to be beyond most SEA with some form of sensitivity analysis of using different declining discount rates more appropriate.
- Intergenerational equity – Using a declining discount rate is likely to result in higher values for impacts on that occur to future generations compared to using a single discounting rate over the whole period (if the declining rate is set below the single constant rate).

However the use of declining discount rates is problematic in practice because there is no universally accepted guide for:

- At what point in time is it appropriate to start using declining discount rates. As shown in Table 23 some member states have chosen to use declining discounting rates for impacts that occur after 30-40 years.
- The speed (in terms of time) at which the rates fall. Again as shown in Table 23 the rate of decline used by several member states varies.

Overall, there is no definitive approach for the treatment of intergenerational effects within SEA. The clearest way to actually understand any implications for future generations are to present the stream of costs or benefits undiscounted on a year by year basis and then to undertake sensitivity analysis using both the default 4% discount rate and a decreasing discount rate.

Future generation's valuations of health and environment

A solution to some of the concerns about the use of positive discount rates for long term health and environmental effects lie in the way these effects are valued or monetised. Valuations of health or environmental effects has to be based the current generations preferences. It is however possible to make a correction for the possible changes in these valuations over time. It may be possible, based on the assumption that health and environment quality are so called 'luxury' goods where their marginal utility increases with income, that valuations should be increased if the income is expected to grow. This will require specialist input to implement.

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APPENDIX E UNCERTAINTY ANALYSIS TECHNIQUES

UNCERTAINTY ANALYSIS TECHNIQUES

E. 1 Introduction

This section contains an overview of several uncertainty analysis techniques which supports section 4.3 where the aim is to determine whether uncertainties in the estimation of impacts could affect the overall conclusions made about whether to grant the authorisation. More accurately the techniques shown in this appendix can be used to either reduce the variability of estimates, or to help test whether uncertainties affect the conclusions being drawn in the SEA. The only way to actually reduce uncertainty is through better data, better understanding and knowledge of the uncertainties and through further analysis. However in most cases residual uncertainties will always remain. This appendix is intended to provide only an introduction to several different techniques available. More detailed information and specialist expertise should be sought before using any of the techniques.

The following techniques are covered in this section:

- Sensitivity analysis–used to test whether uncertainties affect the conclusions being drawn;
- Scenario analysis –used to test whether uncertainties affect the conclusions being drawn;
- Expert judgement – used to reduce the variability of an estimate; and
- Monte Carlo simulations – used to reduce the variability of an estimate.

There are other less commonly used techniques such as risk-risk analysis, Delphi techniques and portfolio analysis which can be used to help reduce the variability of estimates but are not discussed in this guidance[46].

Definitions of risk, uncertainty and variability

Risk: Risk is the combination of the probability of a consequence and its magnitude. Therefore risk considers the frequency or likelihood of occurrence of certain states or events (often termed 'hazards') and the magnitude of the likely consequences.

Uncertainty: Uncertainty exists where there is a lack of knowledge concerning outcomes. Uncertainty may result from an imprecise knowledge of the risk, i.e. where the probabilities and magnitude of either the hazards and/or their associated consequences are uncertain. Even when there is a precise knowledge of these components there is still uncertainty because outcomes are determined probabilistically[47].

Further information can be found at: http://www.ukcip.org.uk/images/stories/Tools_pdfs/HCTN_44.pdf

Variability: The size (scale) of the range of estimates for a particular risk or impact due to uncertainties. Techniques such as Monte Carlo analysis can be used be reduce the variability of estimates (given there is sufficient data to run a Monte Carlo simulation).

[46] For further guidance on these techniques, refer to the: Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

[47] The term 'aleatory uncertainty' is sometimes used where probabilities and dependent consequences are **precisely** known. 'Epistemic uncertainty' is used to describe situations in which probabilities and consequences are **imprecisely** known.

E.2 Sensitivity analysis

What is sensitivity analysis?

Adopting only the most likely value (estimated or average) of each impact within a SEA provides no indication of the level of uncertainty surrounding the analysis and hence has implications for any decisions based on the conclusions. Instead, it is recommended that information be developed on the range of plausible outcomes associated with a given option.

This type of information is developed through the use of sensitivity analysis, which is a generic term for the techniques that involve identifying key assumptions (or variables) for which uncertainty as to their values could significantly affect the conclusions drawn on costs or benefits. Sensitivity analysis is therefore used to identify the variables that contribute most to uncertainty in predictions.

How is this technique used?

The basic principles of sensitivity analysis (whether in relation to industry estimates, expert judgment or models) are to:

- Focus on key variables: Often a full sensitivity analysis is not feasible (due to time or data constraints) and the analyst must limit the analysis to those assumptions that are considered key.
- Identify a plausible range for the key variables: The analyst should be careful to determine what is considered a plausible range of values for the key variables and to document the rationale behind the range assigned and the level of certainty associated with this range.
- Determine the impact upon the overall conclusions using the ranges for each of these variables: This can provide an understanding of how sensitive the overall results are to differences in each of the key variables.
- Identify switching points, break-even values or threshold values: Switching points, break-even values or threshold values are those values at which the results of the SEA would change from selection of one scenario to another (for example, benefits minus costs changing from being positive to negative or the net benefits of one scenario become greater/less than those of another); they can often provide an indication of the robustness of choosing one scenario over another;
- Clearly present the results: The results of the sensitivity analysis should be presented clearly and with accompanying descriptive text. The results might be presented in terms of (a) conclusions under basic assumptions; (b) description of parameters varied for sensitivity testing and impact on the conclusions.

What difficulties can arise when using this technique?

- Generally this is a fairly simple process, although it can become more complicated depending on the number of variables considered at one time.
- The main difficulty is in being able to identify a plausible range using the data available. This is a range of possible values that could occur e.g. it may be possible for a manufacturer to pass on between 5 and 10% of the additional costs incurred under a scenario to downstream users through higher prices.

When could this technique be used? (Within the SEA process)

- Scoping phase: This technique can be particularly useful when trying to determine whether an impact is an important impact which should be analysed further.
- Analysing impacts: For the estimates of the main impacts a sensitivity analysis could be carried out to determine switching points.

What can be achieved using this technique?

- Identification of switching points or threshold values to see whether an impact could alter the SEA outcome
- Assessment of whether there is a need for more detailed analysis: sensitivity analysis can also be used as a screening device to determine if more extensive analysis is required.
- Ideally, the end result of an uncertainty analysis should be a probabilistic range resembling a confidence interval.

Where can I find more information about this technique?

EC Impact Assessment Guidelines Annexes (chapter 13) 15 January 2009

UK Treasury Green book (Chapter 5)

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

E.3 Scenario Analysis

What is scenario analysis?

For most decisions characterised by uncertainty, there will be more than one uncertain variable affecting the choice of options. Instead of examining the uncertainty associated with each of these variables separately (e.g. by using sensitivity analysis), a fuller picture of the implications of the combined uncertainty affecting a particular decision may be gained through the simultaneous variation of the key uncertain variables. This approach is often referred to as scenario analysis, or 'what if' analysis.

Scenario analysis is one of the more useful and simple methods for assessing the importance of uncertainty inherent in a decision based on SEA. It can be used to provide an understanding of what could happen without the need to specify probabilities; it can be applied quickly and does not have as significant data requirements as the more probabilistic approaches. Scenarios can be used to represent both qualitative and quantitative types of uncertainty. Scenario analysis is also often the starting point for the use of many of the more advanced techniques for uncertainty analysis – such the Delphi technique or Monte Carlo analysis – when there are numerous scenarios to be considered.

Scenario analysis involves defining a range of possible outcomes based on the uncertainty surrounding key variables. Values of uncertain inputs are selected (e.g. best and worst cases), which give rise to the specified outcomes. These are then modelled deterministically (i.e. without

assigning probabilities to the likelihood of these inputs) to indicate the range of likely outcomes.

How is this technique used?

The types of scenarios that may be appropriate include: worst case; best case; business-as-usual; best guess; trend analysis; low, medium and high; different periods in the future; different scales of effect, etc.

- Focus on key variables: Often a full scenario analysis is not feasible (due to time or data constraints) and the analyst must limit the analysis to those assumptions that are considered key.
- Identify the estimated costs and benefits of scenarios by varying the key variables: The user should identify appropriate values for each of the key variables under each scenario considered and then determine the overall costs and benefits (as well as any relevant intermediate results) of each scenario.
- Clearly present the results: The results of the scenario analysis should be presented clearly and with accompanying descriptive text.

What difficulties can arise when using this technique?

Generally this is a fairly simple process although it can become more complicated depending on the number of variables considered at one time. Care is required to avoid excessive scenario testing as this may introduce additional uncertainty (for example, if no conclusion is drawn as to which scenario(s) is (are) considered most likely to occur. There are other problems associated with scenario analyses, including:

- maintaining consistency when specifying the scenarios; and
- preventing emphasis being placed on average values to ensure that a sufficiently wide range is considered.

When could this technique be used? (Within the SEA process)

- Scoping phase: This technique can be particularly useful when trying to determine whether an impact is an important impact which should be analysed further.
- Analysing impacts (stage 4) using a deterministic approach: For the estimates of the main impacts low and high scenarios could be analysed (i.e. selecting values of input parameters that tend to give a low result for one scenario and a high result for another scenario) to determine whether the SEA outcome would be different using different plausible assumptions for input values.

What can be achieved using this technique?

Low and high scenarios can be used to determine whether the SEA outcome would be different if various input parameters are varied within a plausible range. If the results of the SEA differ under each scenario, further uncertainty analysis may be justified to determine which scenario is most likely to occur. If the SEA outcome is the same under all the scenarios, then it is reasonable to

conclude that the uncertainties considered will not alter the outcome of the SEA (hence increasing the level of certainty in the final results).

Where can I find more information about this technique?

UK Treasury Green book (Chapter 5)

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

E.4 Expert Judgement

What is expert judgement?

Because the possible implications of an application may be very uncertain, it is likely that expert opinion is needed in order to determine not only what the impacts might be, but also to judge how likely it is that those impacts will be realised as estimated.

Such experts might include, *for example*, specialists in particular chemicals, products or sectors; economic analysts; or market analysts.

When is it appropriate to use this technique?

Experts can be used to develop data related to the likelihood of future events or scenarios, ranges or probability distributions for model parameters, potential impacts and more qualitative views on the relative significance of such impacts. Expert judgment may also be important to understanding and bridging conflicting opinions on the interpretation of models or other results.

What difficulties can arise when using this technique?

- Time constraints: It will be important to contact experts as early as possible in the process to ensure that they are available when you foresee the need for their services. Consider including experts at key stages in the development of the SEA, such as during any brainstorming meetings/workshops.
- Budget constraints: Consider what role experts may have in the SEA. Try to make best use of their available time in areas where their expertise is most required.
- Experts may not be independent but represent certain interests.

When could this technique be used? (Within the SEA process)

Use of expert judgement necessarily involves identifying the most appropriate experts to provide advice and input into the SEA. These experts may be in-house or may be specialists brought in from outside.

If you intend to carry out the SEA internally with input from experts, then consider including them

in:

- Brainstorming sessions or workshops
- During the scoping phase, when determining the main impacts and the likely response by industry and other affected organisations if the application is refused.
- Reviewing/inputting on important analytical sections of the SEA report
- Data collection and analysis – this is likely to be the main need for expert input
- Consultation process

What can be achieved using this technique?

Experts – by definition – have a better understanding of a particular subject than others. Utilising this knowledge should help to minimise knowledge uncertainties, providing a more realistic estimate of expected behavioural change, values for key parameters in the analysis and various other factors. The use of expert judgement can thus significantly reduce the time needed for data collection and analysis.

What help should I get to use this technique?

It will be important early on in the process to identify what skills will be needed to carry out the SEA and then consider to what extent may internal or external expertise be required. Consider whether you have sufficient expertise with:

- The markets involved for the chemicals and associated products and services, including historical and likely future behavioural change in the event of unavailability of substances.
- Stakeholder engagement – an important source of information will be cost data directly obtained from industry. Therefore effective consultation and engagement is crucial to the quality of data available to make an informed decision and to reduce uncertainties.
- Impact assessment – those familiar with using the EC impact assessment guidelines should be well placed to conduct an SEA. It would be advisable to have a team capable of assessing impacts on the environment and human health as well as social and economic impacts (including wider economic impacts such as trade, competition, viability and profitability).

E.5 Monte Carlo Analysis

What is Monte Carlo analysis?

Monte Carlo analysis is a further step in the analysis of uncertainty than the previous mentioned techniques. It is a probabilistic tool, which is particularly useful since it explicitly characterises the uncertainty of input parameters by use of probability density functions (PDFs). A PDF provides an indication of the range of likely values for a particular parameter and the probabilities of different values within that range (e.g. uniform, normal, triangular distribution). There must, therefore, be some sort of information on the uncertainty of the input data to use this tool. This may include defining the likely ‘shape’ of the PDF (such as ‘normal’ or skewed distributions) together with an

indication of mean values and associated variance or range of possible values.

How is this technique used?

- Collect sample values from each input value and combine them to generate numerous possible output values and the likelihoods of those values occurring (for example, this could involve estimating the mean and standard deviation values for a particular parameter). Parameter or model probability distributions may be derived empirically (for example from population data or indirectly from regression of other statistical models) or by using appropriate assumptions based on available data or expert judgement.
- Document all assumptions and model specifications: The quality of the overall analysis is only as good as the quality of its components; therefore all assumptions or model specifications should be justified and well documented.
- Run the simulation: The accessibility of software to undertake Monte Carlo simulations is now widespread, with many add-ons available for spreadsheets. However, it is important to recognise that such analyses require knowledge of the shape of the probability distribution functions for the uncertain input variables as well the degree of interdependence amongst the input variables (which can be readily incorporated into the analysis). The analysis itself is generally an automatic process whereby different values for each parameter of interest are selected according to their probability in the PDF; the overall results are computed using the selected values and the process is repeated – often using several thousand iterations. The number of iterations that are required to ensure that each PDF is adequately sampled is an important consideration (sometimes 10,000 or more).
- Documenting the results: After sufficient iterations, the result of a Monte Carlo analysis is a probability distribution of the final output value(s). The analyst can therefore make determine, for example, the degree of confidence (e.g. as confidence intervals) that the results will fall within a certain range, such as below a switching point for the final results, or the most likely value of the final result.

When is it appropriate to use this technique?

Where there are numerous uncertainties affecting the assessment, it may be important to go beyond a scenario analysis and to consider the probabilistic distributions of possible values. Where this is the case, then a Monte Carlo analysis may be valuable.

What difficulties can arise when using this technique?

- Finding a significant volume of data on the uncertainties
- Appropriate computer software is required. The accessibility to Monte Carlo simulations is now widespread, with many add-ons available for spreadsheets. However, it is important to recognise that such analyses require knowledge of the shape of the probability distribution functions for the uncertain input variables as well the degree of interdependence amongst the input variables (which can be readily incorporated into the analysis).
- Good understanding of statistics and the outputs of the program i.e. probability density functions

(PDF) are required in order to understand and present the results in a meaningful way.

When could this technique be used? (Within the SEA process)

Given the level of expertise and data required to use this technique, it should only be used if the results of a sensitivity or scenario analysis indicates that further analysis is required on the uncertainties and how they could affect the SEA. If the SEA is conducted in an iterative process (i.e. starting with a simple low tier qualitative assessment which is built up to a more developed assessment) then a Monte Carlo analysis should only be carried out if a high tier (fully quantitative) assessment is required.

What can be achieved using this technique?

The main benefit to using a Monte Carlo analysis is the results are presented as a PDF. Therefore it is possible to present the results in various ways - for example, the 'best' (median) estimate of the cost is €6.5m but there is a 10% chance that the cost will exceed €8.5m.

Where can I find more information about this technique?

UK Treasury Green book (Chapter 5)

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

APPENDIX F SOCIO-ECONOMIC ASSESSMENT TOOLS

SOCIO-ECONOMIC ASSESSMENT TOOLS

Introduction

This appendix provides more details on the main socio-economic tools likely to be used in undertaking an SEA. Socio-economic tools can be used to bring risks/costs and benefits (disadvantages and advantages) together to allow for an overall conclusion to be made.

The tools covered in this appendix are:

- Cost benefit analysis
- Multi-criteria analysis
- Cost-effectiveness analysis
- Compliance cost analysis
- Macro-economic modelling

F.1 Cost benefit Analysis (CBA)

What is Cost Benefit Analysis?

CBA provides a framework for comparing the costs and benefits of each risk management option (RMO). The nature of the analysis may range from one which is mainly qualitative to one which is fully quantitative (and monetised).

Traditionally CBA has been used to determine whether an investment is worthwhile from the perspective of economic efficiency. This normally means that there is an emphasis on placing a monetary value on as many of the impacts of a proposed measure as possible and allows a more transparent comparison to be made of the implications of more than one measure. The underlying principles, however, can be more generally applied by valuing all of a measure's effects in economic opportunity cost terms. One can thus determine the trade-offs that society would be willing to make in the allocation of resources amongst competing demands. As a result, a robust CBA can indicate whether or not a particular measure is 'justified' in the sense that the benefits to society outweigh the costs to society.

How is this technique used?

Six steps need to be carried out in order to complete a full CBA (Moons, 2003):

1. Definition of the project/policy and of the relevant population of interest

2. Identification of relevant impacts

3. Quantification of relevant costs and benefits

4. Valuation of relevant costs and benefits in money terms

5. Aggregation of benefits and costs over time by discounting

6. Comparison of total discounted benefits with total discounted costs, to produce a net present value (NPV)

7. Conduct uncertainty analysis on important parameters such as the discount rate, investment

lifetime and cost and benefit estimates.

These steps are similar to the structure of the SEA technical guidance document. Guidance on the above steps can be found in chapters 2-6 respectively.

When is it appropriate to use this technique?

The CBA is the approach which underpins this guidance. In line with other guidance document it takes a pragmatic approach where CBA is understood as the aim but realising that often many important impacts can not be quantified. They will have to be presented alongside the quantified impact in an equal manner. When drawing a conclusion and considering all impacts either an implicit or explicit weighting is necessary. From that perspective the CBA analysis becomes almost similar to what is described in the next section under multi-criteria analysis.

What difficulties can arise when using this technique?

The main guidance deals with the different difficulties such as quantification of impacts, monetisation of impacts, discounting and uncertainties.

Where can I find more information about the technique?

EC Impact Assessment Guidelines Annexes (chapter 13) 15 January 2009

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

DTLR: Economic Valuation with Stated Preference Techniques Summary Guide (March 2002)

Energy, Transport And Environment Center For Economic Studies: the development and application of economic valuation techniques and their use in environmental policy – a survey (September 2003)

Cost-Benefit Analysis and the Environment Recent Developments -OECD 2006

F.2 Multi Criteria Analysis (MCA)

What is Multi Criteria Analysis?

MCA describes any structured approach used to determine overall preferences among alternative options, where the options have several types of impacts and/or accomplish several objectives.

In MCA, desirable objectives are specified and corresponding attributes or indicators are identified. The actual measurement of indicators is often based on the quantitative analysis (through scoring, ranking and weighting) of a wide range of qualitative and quantitative impact categories and criteria. This need not be done in monetary terms. Different environmental and social indicators may be developed side by side with economic costs and benefits and MCA provides techniques for comparing and ranking different outcomes, even though a variety of indictors are used. Explicit recognition is given to the fact that a variety of both monetary and non-monetary objectives may influence policy decisions.

The key features of multi criteria analyses are the identification of criteria to provide a means of measuring the degree to which the various objectives are met, and the relative weighting of the objectives which directly incorporates their value judgements in the assessment of options. This contrasts to economic analysis (particularly the efficiency based approaches of CBA and CEA) which is aimed at providing an objective measure of the net value (or social worth) of a proposed option.

How is this technique used?

Step 1– Identify criteria by which the impacts will be assessed

The criteria and sub-criteria are the measures of performance by which the impacts will be judged. A large proportion of the 'value-added' by a formal MCA process derives from establishing a soundly based set of criteria against which to judge the impacts.

A MCA manual developed for Department of Transport (DTLR 2000) argues the perspective(s) of interest groups may be important. One way to include them is to directly involve the affected parties in some or all stages of the MCA. A second approach is to examine policy statements and secondary information sources from the various interest groups and to analyse these to derive criteria to reflect their concerns. A third, if suitable experience resides within the decision making team, is to encourage one or more of its members to role-play the position of key interest groups, to ensure that this perspective is not overlooked when criteria are being derived.

Step 2 – Grouping the criteria

It can be helpful to group together criteria into the main types of impacts: generally economic, environmental, health, social and wider economic impacts for an SEA. This is particularly helpful if the emerging decision structure contains a relatively large number of criteria (say eight or more) and if a weighting is being assigned to each criterion.

Step 3 – Assess the criteria

Before finalising the choice of criteria the provisional set needs to be assessed against a range of qualities:

- Completeness - Have all important criteria been included?
- Redundancy and double counting – Remove any criteria which are unnecessary and avoid having similar criteria.
- Operationality – It is important that each option can be judged against each criterion. The assessment may be objective, with respect to some commonly shared and understood scale of measurement, like human health risk or cost. It may also be judgmental, reflecting the subjective assessment of an expert.
- Mutual independence of preferences – It should be possible to assign scores to impacts without knowing the scores given to other impacts.
- Size – An excessive number of criteria leads to extra analytical effort in assessing input data and can make communication of the analysis more difficult. But a criteria which is too small, may

result in the underestimation of important impacts (or giving greater weight to lesser impacts).

Step 4 – Set up a scoring system

Set up a scoring system whereby qualitative, quantitative and monetary impacts can be scored against the criteria. Often scoring is normalised with a scale between 0-1. However a key aspect is that the scoring system is transparent and that the scoring system is consistently applied to all scenarios. By introducing transparent, unbiased and well justified criteria, the rationale behind the SEA results can be clearly interpreted by the SEA committee and third parties, and the decision of whether socio-economic benefits outweigh costs should be easier to make.

Step 5 - Weight criteria and compare scenarios

It is optional to apply a weighting to each impact. It will often involve a subjective perspective and is hence often sited as a drawback to MCA. If a weighting system is applied then the justification and rationale should be clearly set out. Once each cost and benefit has been assigned a score (and weighting applied if appropriate) then the sum score of costs should be deducted from the sum score of benefits. A positive score would indicate that the socio-economic benefits outweigh the socio-economic costs.

When is it appropriate to use this technique?

MCA is a type of decision analysis tool that is particularly applicable to cases significant environmental and social impacts cannot be assigned robust monetary values. Most SEAs will include a combination of impacts that are measured in qualitative, quantitative or monetary terms. It could therefore be argued that MCA could be applied to any socio-economic analysis although it is not formalised with scoring and weighted criteria as described above.

What difficulties can arise when using this technique?

Similar to CBA assessing the various impacts is subject to difficulties. The specific issues with MCA are the choice of the score for each impact and the choice of weights for each criterion. Scoring of impacts that are described in qualitative terms is subjective as are the choice of weighting. If an formal MCA is applied it is important to list all assumptions so that the scoring and weighting are presented transparently.

Where can I find more information about this technique?

EC Impact Assessment Guidelines Annexes (chapter 13) 15 January 2009

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

DTLR (2002) multi-criteria analysis manual

The encyclopaedia of earth: Multi-criteria analysis in environmental decision-making

UNFCC brief summary of MCA

Example of MCA approach developed by BASF

F.3 Cost Effectiveness Analysis (CEA)

What is Cost Effectiveness Analysis?

CEA is widely used to determine the least cost means of achieving pre-set targets or goals, with these targets defined by government guidelines or legislation. A CEA is often defined in terms of finding the minimum cost of meeting a specified physical outcome.

The CEA can be aimed to identify the least option among a set of alternative options that all achieve the targets. In more complicated cases, the CEA is used to identify combinations of measures that will achieve the specified target.

Compared to the CBA, the advantage of the CEA is that there is no need for monetisation of the benefit of achieving the target but is disadvantaged where a specific level of abatement has/can not been defined.

When is it appropriate to use this technique?

As part of an application, it may be necessary to determine the impacts of different "non-use" scenarios. This requires comparing each "non-use" scenario against continued use of the substance. Here the use of CEA can be helpful in comparing these scenarios.

What difficulties can arise when using this technique?

- When the cost estimates do not reflect the full social costs of the measure (i.e. are financial costs rather than economic costs), then it may not be possible to compare RMOs on an equal basis;
- Where the proposed measure would not achieve a continuous level of effectiveness per unit of expenditure (e.g. there is a limited number of individuals who can benefit from the proposed measure), then comparing this measure against others on an equal basis becomes difficult;
- When different measures would lead to varying levels of risk reduction, with some measures meeting targets and others falling short but involving significantly lower costs, conflicts may arise between strictly adhering to the target and finding an economically efficient solution; and
- When the proposed measure has more than one target objective, for example, achieving health benefits in addition to saving lives, or environmental benefits across more than one environmental end-point, then measures may vary in their cost-effectiveness with regard to different targets.

There is an underlying assumption that the benefits of achieving a target outweigh the costs. This assumption gives rise to one of the key limitations concerning the use of CEA for regulatory analyses: it does not explicitly address the question of whether the benefits of regulation outweigh the costs.

Other problems have arisen in the healthcare field over the failure of CEAs to adopt a common or standardised approach that would allow for the results of different studies to be compared. In

particular, a panel on cost-effectiveness analysis stressed the importance of adopting a societal perspective when undertaking such analyses to ensure that estimates reflect the full resource costs of adopting a given option (Russell *et al*, 1996).

Where can I find more information about this technique?

EC Impact Assessment Guidelines Annexes (chapter 13) 15 January 2009

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

Global Environment Facility (GEF) Cost Effectiveness Analysis in GEF projects. GEF Council Meeting June 6-8, 2005

F.4 Compliance cost assessment

What is compliance cost assessment?

Most SEAs begin with the assessment of compliance costs. Essentially, this type of analysis focuses on the direct costs associated with the adoption of a particular measure, although it should also identify any savings in costs due to changes in processes, etc. At a minimum, such assessments will identify the capital and operating (non-recurring and recurring) costs that would accrue to the sectors directly affected by the measure. They may also examine the indirect costs to other sectors where the impacts are expected to be significant (e.g. costs falling on downstream users, for example, due to the need to make process or other changes). They may also identify costs that cannot be easily quantified, such as those related to changes in product quality or product performance (further guidance can be found in chapter 3).

These analyses tend to focus on the financial costs rather than on economic costs. Financial analysis is aimed at determining the impact that a proposed regulation will have on a company or sector and its cash flow. Financial analyses may provide the starting point for a Cost Effectiveness Analysis (CEA) or Cost Benefit Analysis (CBA), particularly where compliance costs are used as a proxy for economic costs. It differs from formal CEA and CBA, however, as these focus on the economic or resource costs associated with a measure rather than simply financial costs. As a result, financial analyses will ignore the health, environmental and other social costs and benefits that would arise from a measure and will, therefore, not provide any comparison of the full economic costs and benefits of adopting different measures.

Where can I find more information about this technique?

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

F.5 Macro-economic modelling

What is macro-economic modelling?

Macro-economic models are mathematical models that aim at describing the interactions in the economy. They allow for all economic effects including all feed backs responses on different markets to be covered in a consistent way. There are different types of models that are suited to answer different types of questions. In relation to SEAs, the use of macro-economic modelling is less likely to be relevant. Only if there are economic impacts that affect all sectors of the economy in a significant way the use of macro-economic modelling could become useful. Applying a macro-economic approach will require the use of a suitable model and given that it is very resource demanding to develop macro-economic models their applications in SEAs would have to be based on existing models. It would therefore require expert advice on which model to apply and similar expert input to undertake the analysis. The EU impact guidance includes more details on the different type of macro-economic models and lists some of the more used models which has been developed through EU funding and therefore typically cover the whole of EU.

Where can I find more information about this technique?

EC Impact Assessment Guidelines Annexes (chapter 7) 15 January 2009

Technical guidance document on the use of socio-economic analysis in chemical risk management decision making (OECD 2002)

APPENDIX G CHECKLISTS – IDENTIFICATION OF IMPACTS

CHECKLISTS – IDENTIFICATION OF IMPACTS

APPENDIX G CHECKLISTS

This appendix contains five checklists to help determine the main impacts of the "non-use" scenario compared against the "applied use" scenario, during the **assessing impacts stage** (a more comprehensive checklist is used later on in the SEA process). The checklists are for:

- Human health risks;
- Environmental risks;
- Economic impacts;
- Social impacts; and
- Wider economic impacts.

The checklists are intended to be used as an internal decision-making tool to facilitate the process of determining the main impacts and do not constitute a comprehensive list of impacts. They cover only some of the impacts identified in the EC Impact Assessment guidelines (2009). It is therefore recommended that the guidelines for impact assessment are referred to for more information. Completed checklists can be submitted with the SEA to improve the transparency of the analysis.

HOW TO USE THE CHECKLISTS

If the risk assessment (see Guidance on Information Requirements and Chemical Safety Assessment) indicates that risks for a particular endpoint are not significant (or possibly not relevant) then the answer in the checklist should be **No**. Impacts that are not significant should be acknowledged in the SEA report, but there is no need to analyse the impact any further as it is unlikely to alter the outcome of the SEA However, risks should be considered where there is no concern identified in the risk assessment (under the "applied for use" scenario) but where the "non-use" scenario introduces new risks.

If a risk has been identified, then the answer in the checklist could be **Yes** or **unknown**. It is necessary to try to establish whether this is:

- **Yes - a significant impact (main impact)** – This impact must be analysed further in the SEA process; or
- **Unknown** – With the information available at this stage in the SEA process, it may not be possible to determine whether an impact is a significant (main) impact. In this instance, more information is required to determine the relevance of the risk.

It may be helpful to complete the checklists during a brainstorming workshop or meeting, at which internal/external experts and relevant stakeholders are invited to participate. In completing the checklists, it may be appropriate to draw upon sources of information such as the EC Impact Assessment guidelines. In particular, pages 29-32 of the EC Impact Assessment guidelines contains questions aimed to the guide the reader towards ensuring the impacts and issues that have particular relevance are considered during stage 3 (Identification and Assessment of Impacts). Note though, these questions (as with the questions in the checklists in this appendix) are neither exhaustive nor definitive. They are meant as an aid to facilitate the reader to consider a wider range of potential impacts under the "applied for use" scenario that may have otherwise been ignored at the beginning of the SEA process.

The intention is to help the applicant consider a wide range of possible impacts so that the analysis does not immediately concentrate on a few core impacts that have already been identified during the development of the authorisation applicant. Thus, this exercise should result in a more comprehensive picture of the potential impacts of granting the authorisation.

Table 25 Initial checklist for human health risks

Potential Impacts – **Changes between the "applied for use" and the "non-use" scenario"**	**Likely to be a significant impact that requires further assessment? Yes/No/unknown**	**If 'no', reason why impact is excluded (e.g. not relevant for this application)**
Are there any changes in risks to workers health associated with using the substance? (E.g. changes in number being exposed, type of exposure, severity of exposures etc?)		
Are there any changes in risks to consumer's health associated with using the substance?		
Are there any changes to public health and safety risks?		
Are there any changes in risks to workers health associated with known substitutes?		
Are there any changes in risks to consumer's health associated with known substitutes?		
If there are any changes in the process used, would these changes have an impact on worker health and safety?		
If there are any changes in the process used, would these changes have an impact on consumer health and safety?		
Are there any significant changes in emissions to air, water, land and/or any significant changes in raw material usage, which could have potential implications for human health?		
Are there any other risks/impacts that need to be considered?		

Table 26 Initial checklist for environmental risks

Potential Impacts – **Changes between the "applied for use" and the "non-use" scenario"**	**Likely to be a significant impact that requires further assessment? Yes/No/unknown**	**If 'no', reason why impact is excluded (e.g. not relevant for this application)**
Are there any changes in risks in air quality? (e.g. any effect from emissions on acidifying, eutrophication, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (polluted soil or rivers etc)		
Are there any changes in risks to water quality and/or the quantity of water and drinking water?		
Are there any changes in risks to soil quality and/or the quantity of available soil and usable soil?		
Are there any changes in risks to the emission of ozone depleting substances (CFCs, HCFCs, etc.) and greenhouse gases (e.g. carbon dioxide, methane etc) into the atmosphere?		
Are there any changes in demand/usage of renewable resources (fish, freshwater) or changes to rate of demand/usage of non-renewable resources (groundwater, minerals etc)?		
Are there any changes in risks to biodiversity (e.g. the number of species and varieties/races), flora, fauna and/or landscapes (e.g. the scenic value of protected landscape)?		
Are there any changes in risks to land use which may affect the environment? (e.g. affect the balance between urban and rural land use, reduction of 'greenfield' sites, etc)		
Are there any changes to waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of or recycled?		
Are there any changes in the risks to the likelihood of the prevention of fire, explosives, breakdowns, accidents and accidental emissions? Any changes risks to the likelihood of natural disasters?		
Are there any changes to mobility (transport modes) and the use of energy? (e.g. is the a change in the consumption of energy and production of heat, demand for transport and change in vehicle emissions)		
Are there any changes in the environmental consequences of firms' activities? (E.g. does this change the use of natural resources required per unit of output and will the process becoming more or less energy intensive? Will this change the operating behaviour of firms to pollute more or less?)		
Are there any changes in risks to animal and plant health, food and/or feed safety?		

Potential Impacts – **Changes between the "applied for use" and the "non-use" scenario"**	**Likely to be a significant impact that requires further assessment? Yes/No/unknown**	**If 'no', reason why impact is excluded (e.g. not relevant for this application)**
Are there any changes in environmental risks associated with substitutes?		
Are there any changes in the process used that may have an impact on the environment? (e.g. alternative process uses a different amount of natural resources or amount of energy used)		
Are there any significant changes in emissions to air, water, and land or in raw material usage, which could have potential implications for the environment? (e.g. change in raw materials which need to be imported from outside of the EU which leads to additional emissions from transport)		
Are there any other risks/impacts that need to be considered?		

Table 27 Initial checklist for economic impacts

Potential Impacts – **Changes between the "applied for use" and the "non-use" scenario"**	**Likely to be a significant impact that requires further assessment? Yes/No/unknown**	**If 'no', reason why impact is excluded (e.g. not relevant for this application)**
Are there any changes to operating costs?		
Are there any changes to investment costs? E.g. costs to avoid risks to human health such as waste and waste water handling.		
Are there likely to be changes to profitability? E.g. costs of using an alternative substance can not be passed on along the supply chain.		
Are there likely to be changes to sales and turnover? E.g. a loss of functionality leads to reduction in demand		
Are there likely to be changes to administration costs?		
Are there likely to be changes to innovation and research?		
Are there likely to be changes to the market price?		
Are there likely to be changes to the quality of the final product?		
Are there likely to be changes to employment?		
Are there likely to be changes to monitoring, compliance and enforcement?		
Are there likely to be changes to the trend in sales and production?		
Are there likely to be changes to the cost associated with		

Potential Impacts – Changes between the "applied for use" and the "non-use" scenario"	Likely to be a significant impact that requires further assessment? Yes/No/unknown	If 'no', reason why impact is excluded (e.g. not relevant for this application)
substitutes?		
Are there likely to be changes to the performance and product quality associated with substitutes?		
Are there likely to be any changes in the process used that may have an impact on economic costs?		
Are there likely to be any changes in emissions to air, water, land and/or any changes in raw material usage, which could have potential economic costs?		
Are there any other risks/impacts that need to be considered?		

Table 28 Initial checklist for social impacts

Potential Impacts – Changes between the "applied for use" and the "non-use" scenario"	Likely to be a significant impact that requires further assessment? Yes/No/unknown	If 'no', reason why impact is excluded (e.g. not relevant for this application)
Are there any likely to be changes in employment at an EU level?		
Are there any likely to be changes in employment at a MS level?		
Are there any likely to be changes in employment outside of the EU?		
Are there any likely to be changes in the type of job occupations?		
Are there any likely to be changes in the working environment? (e.g. working hours, job satisfaction, training available etc)		
Are there any likely to be changes to employment to other sectors within the community? i.e. local restaurants, retail shops and other service industries.		
Are there any other risks/impacts that need to be considered?		

Table 29 Initial checklist for competition, trade and wider economic impacts

Potential Impacts – **Changes between the "applied for use" and the "non-use" scenario"**	**Likely to be a significant impact that requires further assessment? Yes/No/unknown**	**If 'no', reason why impact is excluded (e.g. not relevant for this application)**
Are there any likely to be changes to competition within the EU? (e.g. changes in the number of products available to downstream users and consumers)		
Are there any likely to be changes to competitiveness outside of the EU? (E.g. would a refused authorisation give an advantage to manufacturers outside of the EU?)		
Are there any likely to be changes to international trade? (e.g. trade flows between EU and non-EU countries)		
Are there any likely to be changes in investment flows? (e.g. businesses deciding to locate outside of the EU)		
Are there any likely to be changes on EU and MS finances? (e.g., changes in revenue from corporation taxes)		
Are there any likely to be changes to the labour market? (e.g. demand for specialist skills, job migration outside of the EU)		
Are there any other risks/impacts that need to be considered?		

APPENDIX H: TYPES OF INFORMATION A THIRD PARTY MAY WISH TO SUBMIT TO THE SEA COMMITTEE CONCERNING A SUBMITTED SEA

TYPES OF INFORMATION A THIRD PARTY MAY WISH TO SUBMIT TO THE SEA COMMITTEE CONCERNING A SUBMITTED SEA

Introduction

The following checklist has been designed for **third parties** who wish to submit comments or socio-economic analyses regarding an authorisation application submitted to the SEA committee. For example, a third party may wish to provide cost information on the use of an alternative, which they wish to keep confidential.

Third parties should clearly indicate within their submissions the information that they wish to remain confidential and the reasons for not disclosing information submitted. The Agency may grant access to documents under specific circumstances (see section 5.4 in the Guidance on the preparation of an application for authorisation). Therefore, if clear reasons for not disclosing information are not provided, the Agency reserves its right to decide that access can be given to your comments.

Third parties who have requested that information remains confidential may still decide to make available:

- certain parts of the document to anyone requesting access to it or
- Certain parts, or all, of the document to a restricted number of actors requesting access to it.

In chapter 6 a separate checklist is included for those preparing an authorisation application. That checklist is intended as an internal audit check and it is not necessary to include it with the submission of an authorisation application. Further guidance is provided in chapter 6 for those preparing an authorisation application.

In most instances, given the limited time (and/or resources) available for third parties to comment on a submitted authorisation application, conducting a complete SEA and subsequently producing a report is unlikely to be feasible. A third party may only have enough time to submit partial information using predominately in-house expertise. Submitting this information using the checklist, along with any comments, should help the SEA committee easily identify and organise all the information submitted to them, without the need for the third party to produce a detailed report.

Checklist for third party submission to the SEA Committee

✓

Type of information

- ☐ Information on the "non-use" scenario
- ☐ Information of the "applied for use" scenario
- ☐ Information on changes to the uses of the "applied for use" scenario
- ☐ Information on environmental risks/impacts
- ☐ Information on human health risks/impacts
- ☐ Information on economic impacts
- ☐ Information on social impacts
- ☐ Information on competition, trade and other wider economic impacts
- ☐ Information on uncertainties and assumptions used in the submitted SEA
- ☐ Information on distributional impacts; e.g. impacts for a particular region/industry
- ☐ Information on recommendations for the authorisation applicant
- ☐ Any other SEA information relevant for the SEA Committee to consider

APPENDIX I: CALCULATION OF COMPLIANCE COSTS

CALCULATION OF COMPLIANCE COSTS

Contents

1 INTRODUCTION

This appendix provides supplemental information and further guidance on the calculation of costs resulting from regulating a substance through the authorisation process for the substances of very high concern, i.e., substances included in Annex XIV of REACH. The appendix is also applicable when the applicant carries out the analysis of the economic feasibility of the alternatives to the substance.

The appendix is intended to be used in conjunction with other sources of information. It builds on:

- Chapters 3.4 (Economic impacts), to some extent 3.5 (Social impacts) and Appendices B, C, D, E and F of this guidance; as well as
- Chapter 3.8 (How to determine the economic feasibility of alternatives) in the Guidance on the preparation of an application for authorisation.

This appendix focuses on compliance costs[48]. Administrative costs also need to be analysed, where relevant. However, these issues are covered in Chapter 8.4 of the EU Impact Assessment Guidelines[49] and Chapter 10 of Part III of Annexes to the EU Impact Assessment Guidelines[50]. **Therefore, to avoid duplication, administrative costs are not presented in this appendix**.

The distribution of compliance costs between groups is an important issue. This is discussed in section B.3 (Social impacts) of Appendix B.

All market prices are distorted to some degree. In practice, the prices of all marketed goods or services incorporate elements of taxation, such as value-added tax, taxes on labour inputs, and taxes on some material input. However, in the cost calculations in conjunction with the applications for authorization, it is rare that such considerations would need to be addressed. Thus, this appendix does not address the possible correction of market prices as this is considered unnecessary in most cases and very difficult to do in practice even if such corrections would be warranted.

In practice – taking also into account that the VAT varies between Member States – the applicant is likely find it easy to use **"ex-factory prices" without value added taxes (VAT)**. Therefore, it is recommended that the applicant used such prices in its application unless it specifies them differently.

In this appendix costs are given usually in annual form (i.e. annualised costs) as this is considered standard when the application for authorisation is made. These annualised costs can be aggregated to net present values, and applicants are encouraged to present the net present value of the costs during the relevant period. This appendix shows also how to do this aggregation

[48] Issues relating to "deadweight loss" are not addressed in this appendix. The reason is that they are normally very small compared to the compliance costs and their estimation would require additional information (e.g. price elasticities) which the applicant would have often difficulties in obtaining.

[49] See http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

[50] See http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_annex_en.pdf

2 ECONOMIC COSTS

2.1 What are costs

Economics starts from the assumption that resources are scarce and that it is therefore important that they are used sensibly. By “resources” we mean things such as labour input, capital goods and land. We can also consider the environment and human health to be a scarce resource that is “used up” when we generate pollution.

In considering the “costs” in a “non-use” scenario (if authorization is not granted) we are really asking what society has to pay in terms of the other resources such as labour and capital in order to secure a cleaner environment or improved human health. Therefore, at the most fundamental level, the economic cost of an “non-use” scenario is the value to society of these other resources that are used up in order to implement it. This is counted as a cost because the resources that are used up are then not available for other purposes.

By using up resources to implement a “non-use” scenario we give up the opportunity to use the resources to do something else. For this reason we say that a “non-use” scenario has an 'opportunity cost' (See chapter 3.4 in Guidelines on SEA –Authorisation process). Using this terminology, economic cost is then a sum of the opportunity costs of all inputs used in the production. When summing up cost of production one needs to take into account opportunity costs, not only market prices of inputs.

2.2 Types of costs

2.2.1 Distinguishing between social and private costs

As the ultimate focus of a socio-economic impact assessment is to determine the costs (and benefits) to society of a “non-use” scenario, an important aspect of the cost calculation process is the distinction between private and social costs. Therefore, the starting point for assessing the costs to society of a “non-use” scenario is usually to look at the impact on those particular groups or sectors affected. The costs incurred by a particular sector or group as a result of a “non-use” scenario are called the private costs. By contrast, the social costs are the costs of a policy to society as a whole – from an EU perspective this includes all 27 Member States, although costs to non-EU members need to be reflected, as relevant. These concepts are discussed in Chapter 3.6 (Trade, competition and other wider economic impacts) of the Guidance on SEA – Authorisation process.

When market prices reflect scarcity, private costs provide a good estimate of the costs to society as a whole. For example, consider the case of installing equipment to a factory to reduce workers’ exposure to chemicals. In this case expenditure incurred by the firm to buy and operate the equipment could be used as a good first estimate of the value to society of the resources used to improve workers’ health. This is because the price of the equipment would normally reflect the amount of labour, capital and energy required to make it.

In authorisation applications **private costs are usually a good proxy for social costs** as long as the effect of any major distortions (e.g. monopoly pricing) is removed from prices.

A straightforward approach can be the following:

(1) estimate the private costs to the supply chain in question

(2) estimate the private[51] costs or savings to any other relevant supply chains

(3) add the resulting figures from different groups or sectors up to give the total cost to society as a whole.

Where there is a clear difference between private and social costs, this needs to be reflected at least qualitatively. The overall focus of a cost analysis should ultimately be on costs to society. This is the appropriate level of analysis as required by the REACH regulation. Therefore, where it is clear that there is a difference between private and social costs this needs to be taken into account during the analysis.

Another important issue related to social costs are the effects on different groups. These should be explained, particularly if one group, sector or region is affected in a disproportionate way.

2.2.2 Investment and operating costs

Investment and operating costs need to be treated differently in any cost calculation. Investment costs show up only once, or relatively infrequently. As an example of an investment cost is the cost of new equipment needed to change the production process if an authorisation is not granted. Investment costs are also called “one-off” or “capital” costs.

Operating costs are incurred each time a good is produced or consumed. An increase in the price of a raw material is an example of an operating cost, as the higher price has to be paid each time this input is used. For further details on investment and operating costs, see section B.2 (Economic impacts) in Appendix B (Estimating Impacts) as well as Appendix D (Discounting).

A distinction between investment and operating costs needs to be made whenever the production costs change. However, there are cases where the production costs remain unchanged while the characteristics of the goods produced change. In such cases investment and production costs of the downstream users may change, too, and thus, the distinction needs to be made. Below, both changes in production costs and the effects of the changes in the characteristics of goods are addressed.

2.2.3 Changes in production costs

If the production costs of the substance, mixture or article change in the non-use scenario, the market price of the good would change accordingly. This cost is often referred to as ”direct cost”. Such costs trickle down the supply chain either directly or with some delay. In economics, this would be called ”the price effect” of the change in the price of a good, assuming that the characteristics of the good do not change.

In almost all cases the compliance costs incurred by producers will eventually be passed on to consumers as higher prices for consumer goods, though this may only happen after a time lag. For instance, in the long run the increase in the costs reducing the SVHC content in an article would be passed on to downstream users of these articles. However, in the short run increases in compliance costs may be absorbed by the suppliers of goods or services as reduced profits. Double counting

[51] In rare cases (i.e. if prices are distorted e.g. due to monopoly pricing) adjust estimates of private cost, if necessary, to take into account any differences between private and social costs (essentially by removing the effect of taxes)

needs to be avoided, though: Costs that are passed on to consumers as higher prices should not be counted as a cost to both consumers and firms.

2.2.4 Changes in the characteristics of the good

In a typical compliance cost analysis it is assumed that the goods are homogeneous. If this is not the case due to changes in the characteristics of the good, this second category of costs needs to be estimated and taken into account.

In chemical regulation it is common, that the characteristics[52] of the good change due regulation. Main examples of these are the quality or the lifetime of the good. The quality could be different (e.g. in a non-use scenario the composition of a good (such as paint) may change such that the it needs to be applied three times instead of two), the operation conditions could be different (e.g. more electricity would be required when using the good) or one might need to replace the good more often (e.g. if it wears out faster than the good it is replacing).

While there can be a deterioration in the quality/lifetime or characteristics of the good, the change can be positive, too. For instance, the application times can become shorter, energy efficiency may improve or the product may last longer. The production cost and the price of the good could also increase while the characteristics of the product would do so, too. Thus, the applicant needs to analyse the combined effects to the downstream users.

The changes in the characteristics of the good trickle down the supply chain so that there would be an increase or decrease in (usually) operating costs of the downstream user. A decrease in operation costs is a saving and needs to be estimated, too.

Examples of such effects are

– more or less labour input (paint more/less often),

– higher or lower other operating costs (more/less paint needed, higher/lower energy consumption etc.) or

– higher/lower replacement rate (change equipment more often).

In some cases it is easy to estimate such costs while in other cases it may only be possible to give the direction (increase or decrease) and perhaps some order of magnitude of such costs.

3 CALCULATING COSTS

In this section the general approach as well as some specific issues are discussed when calculating compliance costs. A specific issue is how to deal with a situation when a “non-use” scenario would make existing capital redundant. In other words, how to treat “residual capital” will be discussed. In addition, some issues concerning the estimation of other compliance costs (through the characteristic of the good) are discussed. The last section focuses on the issue that only additional costs should be calculated.

[52] If the price changed the applicant would see this in compliance costs (see above).

3.1 Changes in production costs

Changes in production costs can be calculated by multiplying a change in the unit cost of using or providing some good or service by the quantity of the good used or produced. The cost of replacing a substance (which is in Annex XIV) by another (more expensive) substance in the production process is an example of an increased production cost. The compliance costs can show up as increased expenditure and therefore, the starting point for an assessment of compliance costs is to look at the effects a "non-use" scenario has on the production costs.

To estimate the compliance cost the applicant needs to know at least the change (usually increase) in the price of the good and the change in the quantity demanded (i.e. used).

Compliance cost (**C**) is the change in the price of the good from the price in the baseline scenario between the "applied for use" scenario ($\mathbf{p_1}$) and the price in the "non-use" scenario ($\mathbf{p_2}$) multiplied by the number of units placed on the market in the "non-use" scenario ($\mathbf{q_2}$), as stated in equation 1:

$$\mathbf{C = (p_2 - p_1)\ q_2} \qquad \mathbf{(1)}$$

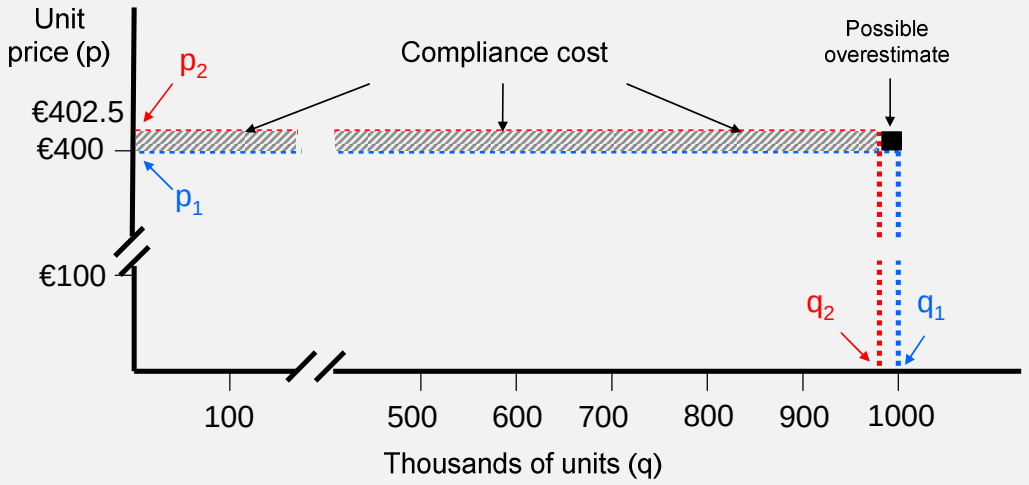
If the applicant does not have a reliable enough estimate of the annual number of goods sold on the market in the "non-use" scenario ($\mathbf{q_2}$), it can use instead the quantity in the "applied for use" scenario ($\mathbf{q_1}$). In this case the compliance cost can be calculated as stated in equation 2:

$$\mathbf{C = (p_2 - p_1)\ q_1} \qquad \mathbf{(2)}$$

The following box gives an example of compliance costs. Note that the example contains only compliance costs accruing from changes in production costs. It also shows how a (usually small) overestimation of compliance costs takes place when using equation 2.

Example of compliance costs: Changes in production costs

Consider that in the "non-use" scenario the cost of producing a good increase from €400 to €402.5 as a result of using e.g. a different production process. The compliance cost is the additional cost per unit (€2.5) multiplied by the number of goods sold on the market. This can be represented on a chart as follows:



The chart presents the number of units sold per year (**q**) at prices in the "applied for use" scenario (**p_1**) and "non-use" scenario (**p_2**). In this example, if the market price of the unit is €400 (**p_1**) then the number of units bought would be 1 million (**q_1**). If the price rises to €402.5 (**p_2**), the applicant estimated that the number bought drops to 992 500 (**q_2**).

If the applicant knows that the number of units sold annually would be reduced from 1 million (**q_1**) to 992,500 (**q_2**) in the "non-use" scenario, the similar estimation of compliance cost (using the equation 1) is €2.5x992500=€2,481,250, i.e. €2.48 million.

If the applicant does not know what the quantities sold would be in the "non-use" scenario, he can use equation (2) and estimate the costs to be €2.5x1million=€2.5 million.

If the applicant does not know the quantity of units sold in the "non-use" scenario, he is likely to overestimate the compliance cost, to some extent. In this case the overestimation would be €0.02 million (i.e. 0.75%) i.e. rather small. Thus, in practice, it is sufficient to use the equation 1 when lacking information on (**q_2**).

3.2 Change in the characteristics of the good

There are other compliance costs that are not necessarily linked to expenditure of the supplier but to the characteristics of the good. Thus, the costs of the downstream user or the consumer may be affected indirectly due to the change in the characteristic of the good.

For example, if a measure increases the time spent on the activity (e.g. painting) it has a direct additional labour cost (to painters[53]). In this case the compliance cost can be converted into money terms by multiplying time lost by the downstream user (e.g. in minutes) by an estimate of the money value that people attach to time (e.g. in the case of painters the hourly wages[54]). This additional cost could be linked to the overall product that is being analysed (e.g. litres or tonnes of paint) and used in the cost calculation. The example in the box illustrates the issue.

Example: Change in the characteristics of a paint

As an example, let's assume that if an authorisation was not granted an alternative substance would be used. As a consequence, the characteristic of an end product (e.g. paint applied by professional painters) would change so the paint would take 10 hours to dry instead of 1 hour.

It has been estimated that on average all painters would spend an additional 2 hours (**h**) per working day for applying the paint. The wages (**w**) are estimated to be €20/hour. A painter is estimated to use 4 liters of paint a day (**q**). In the "applied for use" scenario 1 million liters of paint would be used per year. In this example, the price of the paint would not change in the "non-use" scenario (only the characteristic of the paint)

The applicant needs to estimate the compliance costs (**C**) of the downstream users in the EU due to change in the characteristics of the paint. He needs to know how long it took to paint 1 million liters (**Q**) in the "applied for use" scenario. This is 1 million liters / 4 liters/working day, i.e. 250.000 working days. If the authorization is not granted, the additional amount of labour required is 2 hours per day (**h**), i.e. 250.000 working days x 2 hours/working day = 500.000 hours.

The hourly wages (**w**) of painters are estimated to be €20/h. Thus, the additional cost to the downstream users would be €20/hour x 500.000 hours, i.e. €10 million per year. In other words, the "non-use" scenario would increase the demand for painters by 500.000 hours[1] with a cost of €10 million. Formally the above is given in the following equation:

$$\mathbf{C = (Q/q)} \times \mathbf{h} \times \mathbf{w}$$

Where

Q = 1 million liters

q = 4 liters of paint per working day

h = 2 hours working day

w = €20 per hour

[53] There could also be an indirect cost to "do-it-yourself" consumers who would use the paint.

[54] In the case of consumers, one would normally estimate the "opportunity cost" of free time. Often a certain fraction (e.g. 50%) of salary is used as an estimate for this.

Compliance costs to the downstream users and or consumers arise due to reductions in: i) product quality (including, e.g. reliability) or ii) product life. These types of changes are normally associated with changes to product standards or the inputs that can be used for a process or the technology that can be used. As far as possible these types of direct costs should be quantified and then valued. The precise procedure followed will vary from case to case. Where it is not possible to quantify these effects it is nevertheless important to list them in qualitative terms and give an indication of their importance.

It is important to note that the compliance costs of downstream users may change (increase or decrease) either because the costs of the (upstream) producers are passed on to downstream users or because the characteristics of the good change (become better or worse for the downstream user). It is quite possible that the price increases and the quality improves at the same time.

Often the substance itself has characteristics that are desirable and thus embedded in the product. Therefore, it is likely that when calculating the compliance costs of the "non-use" scenario the effects of changes in the characteristics of the goods are important. Thus, these costs would need to be analysed.

3.3 Treatment of residual value of capital

Residual value of capital relates to investment costs (e.g. buildings or equipment) that a firm has had to make to produce a good or a service prior to the introduction or knowledge of the "non-use" scenario whose impact is being analysed. The analysis of residual value of capital is straightforward to the extent that the capital can be sold on the market or retrofitted for a new production process. In such a case the original investment costs would not be included in the analysis (as the company can offset the cost by the revenue gained from selling the building, land or equipment). However, a problem may arise if the capital is bound to the production process in such a manner that it does not have any value on the market.

A difficulty arises if a "non-use" scenario leads to a significant reduction in the value of existing (capital) assets because they cannot be reallocated to some other function. An example of this is the closing down of a production line if an authorisation is not granted.

The applicant could make an estimate of the net revenues (i.e. revenues minus operating costs) that the specific residual capital could bring to the company. In this manner the applicant could estimate the foregone net revenues and thus, include this in the analysis.

It may prove to be difficult to estimate the foregone revenues (partly because the applicant may have difficulties in linking the revenue to the specific residual capital), even more difficult to verify (e.g. for the Socio-Economic Analysis Committee of the European Chemicals Agency when it gives an opinion) and is prone to overestimation. Thus, the applicant could estimate the residual value of the capital stock instead of the forgone revenues. This estimate is likely to be easier to make and verify.

The reduction in the value of this productive capital is part of the cost of the "non-use" scenario. For example, suppose that an authorisation is not granted and this would lead to plant closure. The owner of the plant is unlikely to be able to recoup the value of the invested capital by selling off the equipment second hand. In such cases the residual value of the capital should be estimated.

In practice, a good source for such estimates would be the book value of the residual capital. This can be retrieved, e.g. from the annexes of the financial statement of the company. However, the book value does not always reflect the true value of the asset to the company. This situation could

arise, for instance, if the company has depreciated the asset in its books faster than what the economic lifetime of the investment would have warranted. In such situations, another way of estimating the residual value of capital could be used. Estimating the market value could be the solution.

The residual value of the capital stock can then be annualized so that they can be compared with other costs. Examples of such calculations are given in Table 8 in Scenario 3 in the chapter 5.3.4.

3.4 Ensuring that only additional costs are included

There are a number of ways in which the costs can be incorrectly estimated. One important case is where one forgets that it is only the additional (i.e. incremental) effects of a "non-use" scenario that should be estimated. It is important to make sure that the costs identified are really attributable to the scenario if no authorisation is granted. This means that it is important to pay attention to what would have happened in the absence of any "non-use" scenario (i.e. the "applied for use" scenario).

The following example illustrates the issue. Suppose that a "non-use" scenario requires a company to replace a piece of equipment with a more up-to-date, modern appliance. Suppose that emission controls lead to the closure of old, polluting filtering equipment in a plant and the installation of a new one that costs €1 million. At first sight the cost of this "non-use" scenario is the cost of installing the new equipment less any difference in operating costs between the old and new equipment.

For simplicity, it is assumed that the operating costs of the two filters are the same. It appears then that the cost of the "non-use" scenario is €1 million.

But it needs to be considered that the old filter would have been replaced at the end of its lifetime, e.g. in five years time. Therefore, the cost of the "non-use" scenario is **the cost of bringing forward the expenditure on the new filter by five years** and not the full cost of the new filter.

The applicant can estimate the cost of this very simply by using the annualised cost approach, which is equivalent to having to pay an additional five years "rent". This cost can easily be calculated (Table 1).

Table 1: Annualising costs and calculating the additional cost of bringing forward an investment by 5 years

Investment cost			€1000000				
Discount rate			4%				
Lifetime of filtering equipment			20	Years			
Annualized cost:			€73582	(using =pmt(4%;1000000;0;0)			
		Year:	**1**	**2**	**3**	**4**	**5**
a. Cost			€73582	€73582	€73582	€73582	€73582
b. Discount factor			0.9615	0.9246	0.8890	0.8548	0.8219
c. Discounted cost (axb)			€70752	€68030	€65414	€62898	€60479
d. Total cost (Present value)			€327573				

Note: Discount rate is 4%. Discounting starts from the beginning of the 1st year.

Using the above assumptions on the lifetime (20 years) of the filtering equipment and discount rate (4%) the annualized cost is € 73582 per annum. Therefore, the cost of the "non-use" scenario would be €73582 per year for the next five years as the old filter could have been used in the "applied for use" scenario. This series of payments has a present value. With 4% discount rate the present value is €327573. Thus, **the cost of this policy is €0.33 million and not €1 million** as an applicant may have estimated incorrectly.

4 STEPS TO ASSESS THE COSTS

4.1 Introduction and caveats

This section discusses the approach to assessing the compliance costs with the following caveats

- All costs refer to those incurred after the "non-use" scenario has taken place.
- If the applicant has information about projections of quantities (e.g. input to the process or output of the process)[55] demanded in the future, he should use them.

The analysis of issues identified above can be quite complex and is often plagued by lack of information. Therefore, it is not expected that changes in future demand (due to price changes) are analysed in standard cases. Thus, the steps below do not include such complications.

All prices need to be adjusted to one currency (Euro) and one price level (e.g. 2009). Market exchange rates should be used for the current year (e.g. 2009) and GDP deflator in the EU for other years. These steps are not covered in this chapter, as such conversions are explained in detail in the Guidance on SEA – Authorisation process, Chapter 3.7.

In addition to the steps presented below, the cost analysis can include a sensitivity analysis or other analytical methods to test how uncertainties may alter the conclusions of the analysis. Chapter 4.4

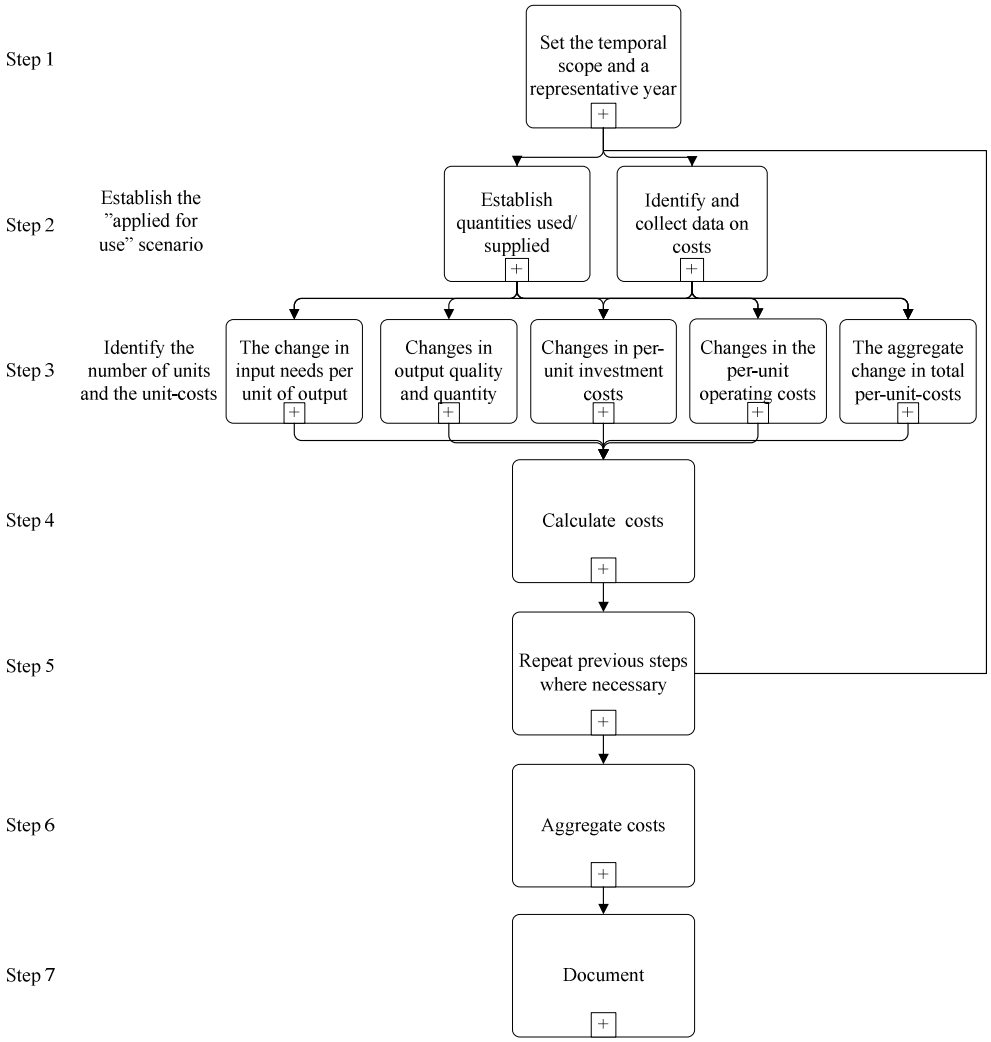
[55] Inputs are used in the production process, e.g. materials (e.g. Substance A to produce coated wire), to produce intermediate goods (e.g. coated wire), which is used in another production process (e.g. motors to washing machines) to deliver outputs, i.e. goods (e.g., washing machines) or services.

and Appendix E of the Guidance on SEA – Authorisation process describe different techniques for conducting uncertainty analysis.

Each step has been illustrated by examples on the basis of Chapter 5.

4.2 Steps

The following graph presents practical steps that would be taken in a cost calculation.



In the table below the practical steps have been identified to help when carrying out a cost calculation. As shown in the graph above many steps are likely to be carried out in parallel (e.g. projections of quantities produced are linked with to prices).

Step	Description	Example(s) or comments
Step 1	**Define the temporal scope of the analysis and choose a representative year (steady state) for the analysis**	(e.g. 2020 when all factors affecting relevant costs under "non-use" scenario would have taken place. If net present value is calculate e.g. 2010-2024)
Step 2	**Establish the applied for use scenario (i.e. the baseline)**	This is the starting point against which the scenarios are compared with.
2.1	Establish the number/quantity of input and output units today. Based on anticipated trends project future demand to the representative year	(e.g. 0.58 kg of Substance A per washing machine is used in the coating of wire) (e.g. 1 million washing machines placed on the market per year). (e.g. with 3% annual growth 1 million machines in 2010 would be 1.34 million machines in 2020).
2.2:	Identify and collect data on costs	
2.2.1	Collect investment cost (i.e. capital expenditure) per unit of output	(e.g. €400 per machine);
2.2.2	Collect operating costs (usually for one year). These include maintenance, labour, monitoring, compliance and other costs	(e.g. €40 operating costs per machine per year);
Step 3	**Identify the number of units and the unit cost associated with the "non-use" scenario. i.e. additional (incremental) costs due to compliance with non-use" scenario**	
3.1	Estimate the change in the number of input units required to produce one unit of output	(0.058 kg of Substance B per washing machine is used in the coating of wire)
3.2	Identify changes in the number of output units	(e.g. 1.34 million washing machines established above would not change.) The detailed example

	produced if relevant for the analysis (e.g. change in production of goods)	assumes that there is no change in the number of washing machines placed on the market.
3.3:	Assess changes in investment costs per unit of output	Investment costs are also called “capital” costs or “one-off” costs
3.3.1	Estimate investment cost of producers and, as relevant,	Note that the increase can be to the producer (in which case the cost will be passed on to the consumer) or to the consumer itself. (e.g.. plant retrofitting capital costs, building of a new waste water facility, R&D investment, etc.) For instance, €1 million investment in production facilities to accommodate the replacement of Substance A with substance B. (e.g. the price of washing machine would increase by €2.5,) Note that the washing machine is a durable good having an economic lifetime of 10 years on the average.
	the residual value of capital	(e.g. an old plant would still have a lifetime of 8 years but can no longer be used for producing the good. The residual capital is €1 million.)
3.3.2	Estimate the direct price increase related to the good placed on the market and annualise these additional investment costs using 4% discount rate and calculate the cost per unit	(e.g. if lifetime of the €1 million investment is 15 years for producing 1 million washing machines per year, the annualised additional cost is €89941 per annum or **€0.09** per washing machine) (e.g. the annualised cost of an increase of the price of a washing machine by €2.5 with a lifetime of 10 years and 4% discount rate is (using =pmt(4%;10 years; €2.5;0;0)) **€0.31** per washing machine per annum.) (e.g. the annualised cost of residual capital of buildings (€1 million) to wire producer (8 years lifetime left) [using =pmt(4%;8 years; €1million;0;0)/1 million] **€0.149** per washing machine per annum.)

3.3.3	(If relevant) estimate any changes in the investment costs to the downstream users that are due to the changes in the **characteristics** of the good.	(e.g. if the characteristic of the good implied that the lifetime of a washing machine[56] reduce from 10 years to 2 years. In both cases the cost of the washing machine is the same. i.e. €400).
3.3.4	Estimate the difference (price increase) due to the change in the characteristics of the good. Annualise these additional investment costs using 4% discount rate and calculate the cost per unit	(e.g. the reduction of the lifetime of a washing from10 to 2 years implies that the annualised cost of a €400 investment cost would increase from €49.32 (using =pmt(4%;10 years; €400;0;0) to €212.08 (using =pmt(4%;2 years; €400;0;0). The difference between the two (€212.08 -€49.32=) **€162.76** is the annualised increase of investment cost that is related to the reduction of the lifetime of the washing machine.)
3.4.	Assess changes in the operating costs[57] per unit of output:	
3.4.1	Estimate changes in unit costs for the producer. Evaluate potential cost savings due to the "non-use" scenario.	(e.g. Imported wire will cost 50% more than wire bought in the EU. Thus the price of the motor (and thus the washing machine) would increase by €2.5 per unit.) (e.g. the price of Substance B in coating wires is 10% cheaper than Substance A leading to a saving of **€0.058** per machine). In this case ask the applicant should ask himself why these savings are not materialising now. The most likely reason is higher investment cost (see above) related to the "non-use" scenario.
3.4.2	Estimate the costs due to changes in the characteristic of the good.	(e.g. the operating costs of one washing machine would increase by **€2.4** per year. because of additional energy costs)

[56] Note that the company may produce goods that have a long life time (like washing machines) or consumables (like washing powder).

[57] Operating costs may increase e.g. because the alternative materials/substances are more expensive, it is more complicated/time consuming to use the alternative substance/technique (i.e. labour costs increase). The action could also introduce new expenditures such as expenditures to operate waste management facility. For details, see Chapter 3.5 and Appendix G of the Guidance on SEA – Authorisation process.

		(e.g. if the application time would be longer and thus the consumers would spend 0.5 hours per year more using the machine of e.g. €10/hour x 0.5 hours=) €5/year. This is not used in the detailed example in Annex 2).
3.5	Calculate the total per unit costs in the representative year by adding together – as relevant – the annualized investment costs (sections 3.3.3 and 3.3.5) and operating costs (sections 3.4.1 and 3.4.2) Describe (qualitatively) any additional costs that the applicant was <u>not</u> able to quantify which are relevant to the analysis.	(e.g. Annualised investment cost in (Step 3.3.2) €0.09 Saving when using substance B (Step 3.4.1) -€0.058 Operating costs of one washing machine (Step 3.4.2) €2.4 Total €2.432 per washing machine per year (e.g. Scenario of importing coated wire Additional cost per washing machine per year (Step 3.3.2) €0.31 per washing machine per year) (eg. Scenario in the reduction of the lifetime of the washing machine Annualised increase of investment cost (Step 3.3.4) €162.76 per washing machine per year) (Eg. "The additional costs of maintaining the machines using another substance are not known. They are assumed to be small and thus not estimated").
Step 4	**Calculate the compliance cost by multiplying the number of units (in step 3.2) by the cost/prices per unit (in step 3.5)**	(e.g. 1 million washing machines x €162.76/year = €162.76 million euros per annum in 2020 in the scenario of reducing the lifetime of the washing machine). (e.g. 1 million washing machines x €0.31/year = €0.31 million euros per annum in 2020 in the scenario of importing wire). Note that the costs of complying with the "non-use" scenario depend on the response of the producers of motors. From the above it can be deducted that the option for importing wire would

		be cheaper. The €0.31 million is considered the compliance cost and is taken further in the aggregation of the results. However, the costs of the alternative scenario should be reported. too.
Step 5	**Repeat steps 2-4 for any other services/goods affected.**	
Step 6	**Calculate <u>total</u> compliance costs by aggregating the costs for all services/goods affected (i.e. add together the compliance costs of step 5).**	Avoid double counting.
Step 7	**Document the results according to the reporting format**	(see technical guidance document or specific reporting format) Consider reporting annualised costs in a given year without discounting to present date. The applicant can also calculate the net present value (using the cumulative year approach) during the relevant time period (as established in Step 1).

5 EXAMPLE – COST OF SUBSTITUTING "SUBSTANCE A"

Caveat

This example is purely illustrative and should not be taken as representing a real world situation. Inclusion of this example does not therefore in any way imply that production of washing machines involves any undesirable impacts.

5.1 Introduction

5.1.1 The problem

This example concerns "Substance A" which has adverse impacts on workers' health at manufacturing sites when wire is coated. The applicant is asked to estimate compliance costs if (i) Substance A was no longer available from 2010 onwards or (ii) how much if would cost to eliminate workers' exposure (through filtering the emissions from the process) from 2010 onwards.

5.1.2 Main drivers of the analysis

Manufacturers supply Substance A to formulators who incorporate it into a mixture. The mixture is used by downstream users for coating wires, which in turn are used in motors for washing machines. Substance A allows the wire to be coated in a manner that prolongs significantly the lifetime of the wire and thus, of the motor. Consequently, the lifetime of the washing machine is about 10 years. If the wires were not coated at all, the lifetime of the engine would be only two years.

5.1.3 Scope of the analysis

This example is an illustration of compliance costs for the purpose of continuing to use Substance A (because it has been placed on Annex XIV). It focuses on social (i.e. welfare) cost calculation of substituting Substance A or reducing the process emissions to non-existent. In the process a number of costs have not been addressed for simplification purposes. These include the regulatory cost for authorities and companies.

This example illustrates only the compliance costs of a "non-use" scenario. Thus, health impacts (change in worker health risks) of the "non-use" scenario have not been estimated, nor have distributional or other socio-economic impacts (e.g. possible employment effects) been estimated.

It is (realistically) assumed that the applicant has access to real prices for the cost calculations. In other words, this example is not addressing the issue of how to get real prices from the market.

Throughout the analysis a 4% discount rate is used to assess costs occurring at different points in time. This is in line with the SEA Guidance document as well as the European Commission's Impact Assessment Guidelines.

As most data are available for current production and consumption levels, it will be easiest to undertake the analysis using the current year. What is important is that all cost and price data refer to the same year. Using the current year would be the simplest approach. Here in this illustrative example the analysis is undertaken as all figures are scaled as a first step to 2007 and the analysis starts from the assumption that the "non-use" scenario would start from 2010 onwards.

All values used in this example refer to 2007 price level. In other words, the prices are 'real' as the effect of inflation has been removed from the prices.

5.2 The "applied for use" scenario

To simplify the example, the current production and consumption volumes of (e.g. 2007 at the time of writing this example) Substance A is used as the basis for the cost calculations as it is assumed that there are no trends in the use of the substance[58]. Consequently it is assumed that there is no change in the demand for Substance A in coating wires for washing machines either. In the EU, some 1 million electrical motors (using wire coated with Substance A) are used as components in the production of 1 million household washing machines[59].

5.3 "Non-use" Scenarios

5.3.1 What would happen if Substance A was not available

If wires were not coated at all, the lifetime of the motor would be reduced from 10 to two years on average. Not coating wires would imply that washing machines would need to be replaced every second year, implying an increased annual cost of €162.76[60] per washing machine. Such an analysis could have been made in the analysis of alternatives. In sum, not coating wire is so costly that this option is not analysed further.

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[58] Otherwise the analysis would need to take into account the increasing or decreasing trend in demand for the substance or the end product (i.e. washing machines).

[59] Thus, the human health related problem of workers using Substance A during manufacturing of coated wire (which are not discussed in this example) would remain unchanged in the "applied for use" scenario, too.

[60] With 4% discount rate and the price €400 of a washing machine, the following annualised costs can be calculated:

Lifetime with coating of wire with Substance A	10	years
Lifetime without coating of wire	2	years
Annualised cost with coating of wire with Substance A	€49.32	per year
Annualised cost without coating of wire	€212.08	per year
Difference	€162.76	per year

In Step 3.5.2 it has been shown to what extent this is an overestimate, and how it is possible to correct for this, assuming that the price elasticity is known.

As a result of the regulation of Substance A, the following "non-use" scenarios were identified as possible:[61]

(1) The producers of the wire would use an alternative substance – called Substance B – to coat the wires. Using Substance B would require a change in the design of the motor including an investment of €1 million in the production facilities for the engine and would reduce the energy efficiency of the motor by 10%. The investment would have a lifetime of 15 years. However, Substance B is 10% cheaper than Substance A.

(2) The producers of the wire could invest in filtering equipment that would reduce workers exposure to a non-existent level. The investment of the equipment costs would be € 10 million with a lifetime of 20 years.

(3) The production of the coated wires (using substance A) would cease in the EU and coated wires would be imported to the EU. This would result in additional transportation costs. In this scenario, the wire would have the same quality and product specifications as the wire produced in the EU with Substance A. Therefore, there would be no impact on the energy efficiency.

(4) The producers of electrical motors would cease production in the EU and the motors would be manufactured outside of the EU.

(5) Consumers would purchase household appliances produced outside of the EU[62].

To simplify this example the costs of only Scenarios 1, 2 and 3 are analysed further. The analysis of the import of motors (Scenario 4) or washing machines (Scenario 5) would be similar to Scenario 3 (import of the wires coated with Substance A).

It should be noted that Scenarios 1 (using substance B) and 2 (filtering equipment) would be carried out under the economic feasibility study of the analysis of alternatives.

However, Scenario 3 (import of wire) would not be carried out under the analysis of alternatives. Rather, it would be carried out under socio-economic analysis, as in this case neither a substitute substance nor technology is analysed.

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61 These are the most realistic "non-use" scenarios. The following responses could also be considered:

i) Consumers would buy household appliances without the coated wires and they would therefore have to replace the motor five times during the lifetime of the washing machine.

ii) The producers of household appliances would change from electrical motors to another type of motor or another type of washing machine not requiring such a motor.

The scenario where the lifetime of the motors is significantly reduced is an unlikely response as replacing a motor in an existing household appliance would be expensive and cumbersome for consumers. Replacing the electrical motor (that requires the wiring) with another type of engine (e.g. combustion engine) that would not require this type of wiring could in principle be an alternative. However, combustion engines cannot be used in apartments for safety reasons. Other types of engine technologies are not known to exist.

In addition, it is assumed that washing machines will be needed in the future and thus a scenario with "no washing machines" was not considered realistic and not analysed further.

62 In other words, production of washing machines using coated wires would cease in the EU. Note that EU consumers can purchase washing machines from abroad (without the restriction).

Having said this, the methodologies to analyse the three scenarios are the same.

5.3.2 Relevant time period

In this example, the relevant time period is dependent upon the investment cycle, i.e. the one-off costs for process improvements required to substitute Substance A with Substance B. The investment related to the use of Substance B is assumed to be €1 million investment cost for new equipment with a lifespan of 15 years. The capacity to produce motors and thus, washing machines is assumed to be 1 million machines per year.

As the lifespan of the investment is 15 years, **in this example, the relevant time period is 15 years.** For the purposes of this analysis, the same investment cycle of 15 years is also used for the second (filtering) and third scenarios (import of coated wire).

A longer time period would be warranted if a significant change in technology (e.g., to produce washing machines) or in the demand for the product/service (i.e. washing of clothes) occurred**.**

In this example, costs are calculated in two ways:

In the *representative year approach* (i.e. where all costs are expressed as equivalent annualised costs) these effects will be analysed for a particular year during this investment period. In this example, 2020 is selected as the representative (steady state) year.

In the *cumulative approach,* the net present value of socio-economic costs of using Substance B will be analysed over the next 15 years (between 2010 and 2024).

The lifecycle of the washing machine (10 years in the baseline) is assumed to be the same for washing machines using motors with domestically produced wire coated with Substance B (Scenario 1) or with Substance A (Scenario 2) or with imported wire coated with Substance A (Scenario 3).

5.3.3 Scenario 1: Costs if Substance B is used

In this example, the consultation with the supply chain gave the following estimates which are the basis for making the cost calculations:

- Change in investment cost
    - Substituting Substance A with Substance B costs of € 1 million (with a lifespan of 15 years and assuming bringing forward a reinvestment in the equipment by 10 years (i.e. the investment needed to use substance A has been already used for 5 years));
- Change in recurrent costs due to price change
    - Substance B is 10% less expensive than Substance A;
    - Price of Substance A is €10 per kg;
    - Quantity of Substance A (or its substitute. Substance B) used per motor and therefore, per washing machine is 0.058 kg;
- Change in recurrent cost due to increased energy consumption

- Additional electricity consumption with washing machines with motors using Substance B of 20 kWh/year; and
- Price of electricity of €0.12 per kWh in 2007.[63]

The additional cost of substituting Substance A with Substance B is a one-off investment cost of €1 million for changing the production facilities. The new equipment is estimated to have a lifespan of 15 years. Using the annualising function [with 4% discount rate and 15 year lifetime, i.e. =PMT(4%;15;1;0;0)] the annualised investment costs will be €89941 or €0.0899 per washing machine (in 2007 price levels). **The "non-use" scenario on Substance A would result in an increase of investment costs of €0.0899 per washing machine per annum.**

Substance B is 10% less expensive, i.e., there are savings in the material cost of €58000 per year[64]. **Given that each year 1 million machines are produced, the recurrent cost of producing one washing machine would decline by €0.058 per annum.**[65]

Additional electricity consumption of washing machines with motors using Substance B is 20 kWh/year over the 10 year life time of the washing machine. The average EU electricity price for consumers was about €0.12 per kWh in 2007[63]. Thus, **the additional recurrent costs to consumers would be €2.4**[66] **per washing machine per annum.**

Table 2 summarises the additional costs per washing machine

Table 2: Scenario 1: Additional cost per washing machine if Substance A is substituted by Substance B (2007 price level)

	€ per washing machine produced
Annualised investment cost to shift from A to B (lifetime of equipment 15 years)	0.089
Annualised effect of Substance B being 10% less expensive	-0.058
Annualised energy cost per washing machine (€0.12 / kWh x 20 kWh)	2.400
Total	**2.432**

Given that the cost per annum in 2010 was €2.43 (measured in 2007 price level) per washing machine. Table 3 shows the costs of using Substance B instead of A. The impact for 10 million washing machines in 2020 would be **€24.32 million** (measured in 2007 price level). This would be the costs using the *representative year approach*.

Concerning the investment cycle of 15 years for 1 million washing machines produced each year between 2010 and 2024 the present value of these costs are **€175.26 million in 2010** (see Table 3) (measured in 2007 price level). This would be the costs using the *cumulative approach*.

[63] Eurostat: Consumer price EU-27 average 1st January 2007; see: http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-SF-07-080/EN/KS-SF-07-080-EN.PDF

[64] Total expenditure on using Substance A is 0.058 kg/motor * €10/kg * 1,000,000 motor = €580,000. Taking 10% of €580,000. gives €58,000

[65] €58,000/1,000000=€0.058

[66] (20 kWh x €0.12/kWh=) €2.4

As discussed earlier there is some uncertainty about how many washing cycles would be carried out and thus, the related electricity consumption. Assuming that this uncertainty is in the range of 25% this range can be applied to the energy costs. Given that the additional electricity cost per washing machine was 2.4 per annum, the uncertainty range for 10 million machines would be €6 million per annum[67]. Thus, the costs would be either lower (i.e. **€18.32 million per annum**) or higher (i.e. **€30.32 per annum**) using the representative year approach.

Table 3 Scenario 1: Cost of using Substance B instead of A in 2020 and during 2010 and 2024 (measured in 2007 price level)

	Cost per one washing machine per annum (€)	Number of new washing machines marketing use (millions)	total cost (€millions)
2010	2.43	1	2.43
2011	2.43	2	4.86
2012	2.43	3	7.30
2013	2.43	4	9.73
2014	2.43	5	12.16
2015	2.43	6	14.59
2016	2.43	7	17.02
2017	2.43	8	19.46
2018	2.43	9	21.89
2019	2.43	10	24.32
2020	2.43	10	**24.32**
2021	2.43	10	24.32
2022	2.43	10	24.32
2023	2.43	10	24.32
2024	2.43	10	24.32
Present Value for 2010-24			**175.26**

The present value of the uncertainty of 25% in energy costs is €43.24 per annum (this calculation is not shown). Thus, using the cumulative approach, the present value would range **from €132.02 to €218.50 million for 2010-2024**. These uncertainty ranges will be used when the results are summarised.

5.3.4 Scenario 2: Cost of installing filtering equipment

It is possible to invest in filtering equipment in the manufacturing site where the wire is coated. In this case the health risk for the workers would become redundant. However, the investment cost of the equipment is €10 million and the lifetime of the equipment is 20 years. Using the annualising function [with 4% discount rate and 20 year lifetime, i.e. (=PMT(4%;20;10;0;0)] the annualised investment costs will be €735818 or €0.735818 per washing machine (in 2007 price levels). **The "non-use" scenario on Substance A would result in an increase of investment costs of filtering of €0.7358 per washing machine per annum.**

[67] (25% x €2.4 x 10 million=)

The operating costs of the filtering equipment consist of labour costs of ½ person per annum (i.e. 900 hours per annum) and additional energy costs concerning 300 MWh. **Additional labour costs** are calculated using average industrial wages of €20/hour i.e. 900x€20= €18000 or **€0.018 per washing machine per annum. Additional energy cost** of the filtering equipment are (€0.12 / kWh x 300000 kWh) €36000 or **€0.036 per washing machine per annum.**

In Table 4 the annualised investment and operating costs are aggregated per one washing machine. Given that the additional cost of filtering equipment was €0.7898 per washing machine Table 5 gives the compliance cost in 2020 for 10 million washing machines (€7.90 million) as well as the present value for the stream between 2010 and 2024 (€56.92 million). All these costs are measured in 2007 price level.

Table 4: Scenario 2: Additional cost per washing machine if filtering equipment is installed (2007 price level)

	€ per washing machine produced
Annualised investment cost of €10 million (lifetime of equipment 20 years)	0.7358
Annualised effect higher labour costs	0.0180
Annualised energy cost per washing machine (€0.12 / kWh x 300 000 kWh)	0.0360
Total	**0.7898**

Table 5 – Scenario 2: Cost of installing filtering equipment in 2020 and during 2010-24(measured in 2007 price level)

	Cost per washing machine per annum (€)	Number of new washing machines in use (million)	Total cost (€million)
2010	0.7898	1	0.7898
2011	0.7898	2	1.5796
2012	0.7898	3	2.3694
2013	0.7898	4	3.1592
2014	0.7898	5	3.9490
2015	0.7898	6	4.7388
2016	0.7898	7	5.5286
2017	0.7898	8	6.3184
2018	0.7898	9	7.1082
2019	0.7898	10	7.8982
2020	0.7898	10	**7.8982**
2021	0.7898	10	7.8982
2022	0.7898	10	7.8982
2023	0.7898	10	7.8982
2024	0.7898	10	7.8982
Present Value for 2010-24			**56.92**

Sensitivity analysis

It seems clear that the discount rate of the investment cost in Scenario 2 is important. Therefore, Table 6 is reproduced below with 6% discount rate (instead of 4%). The annualised cost of the

investment would increase from [=PMT(4%;20;10;0;0)] €0.7358 to [=PMT(6%;20;10;0;0)] €0.8718 per washing machine. The additional labour and energy costs are unaffected.

Table 7 gives the compliance cost in 2020 for 10 million washing machines with 6% discount rate (€9.26 million) as well as the present value for the stream between 2010 and 2024 (€66.72 million). Given higher discount rate, the costs in tables 6 and 7 are higher than in tables 4 and 5, respectively.

Table 6: Scenario 2: Sensitivity analysis – Additional cost per washing machine if filtering equipment is installed (2007 price level) – using 6% discount rate

	€ per washing machine produced
Annualised investment cost of €10 million (lifetime of equipment 20 years)	0.8718
Annualised effect of higher labour costs	0.0180
Annualised energy cost per washing machine (€0.12 / kWh x 300 000 kWh)	0.0360
Total	**0.9258**

Table 7 – Scenario 2: Sensitivity analysis – Cost of installing filtering equipment in 2020 and during 2010-24 (measured in 2007 price level) – using 6% discount rate

	Cost per washing machine per annum (€)	Number of new washing machines in use (million)	Total cost (€million)
2010	0.9258	1	0.9258
2011	0.9258	2	1.8517
2012	0.9258	3	2.7775
2013	0.9258	4	3.7034
2014	0.9258	5	4.6292
2015	0.9258	6	5.5551
2016	0.9258	7	6.4809
2017	0.9258	8	7.4068
2018	0.9258	9	8.3326
2019	0.9258	10	9.2585
2020	0.9258	10	**9.2585**
2021	0.9258	10	9.2585
2022	0.9258	10	9.2585
2023	0.9258	10	9.2585
2024	0.9258	10	9.2585
Present Value for 2010-24			**66.72**

5.3.5 Scenario3: Costs if coated wire is produced outside the EU

In Scenario 3, the costs include any additional costs of the wires or the motors being produced and imported from outside the EU. In this scenario the higher costs to use imported wire relate to higher quality control and additional transportation costs.

The following is the basis for making the cost calculations for the EU motor producers:

– Cost of production in the EU of coated wire for one motor is €5;

– The motor producers in the EU estimate that they would have to pay 50% more for coated wire if it was imported into the EU. These comprise of additional quality control and transportation costs.

The additional cost of purchasing coated wired from outside the EU would be equal to €2.5[68] per motor and thus per washing machine. Given the lifetime of the washing machine (10 years) this additional cost of €2.5 can be annualised. **The annualised additional cost[69] of importing the wire is thus €0.308 per washing machine per year**.[70]

The following are used in cost calculations (in 2007 price level) for the EU wire producers:

– an estimated loss in buildings of €1 million with 8 years remaining lifetime.

– an estimated loss in equipment of €2 million with 5 years remaining lifetime.

Using the annualising function [with 4% interest rate and 8 years of remaining lifetime i.e. =PMT(4%;8;1;0;0)] the annualised costs for the buildings is €148500. **This would be equal to €0.149 per washing machine** (measured in 2007 price level).

Using the annualising function [with 4% interest rate and 5 years of remaining lifetime) i.e. =PMT(4%;5;2;0;0)] the annualised costs for remaining equipment is €449254. **This would be equal to €0.449 per washing machine** (measured in 2007 price level).

Table 8 summarises the additional costs of Scenario 3.

Table 8: Scenario 3: Additional cost per washing machine in 2010 if the coated wire is imported (measured in 2007 price level)

	€ per washing machine produced
Annualised cost of wire being €2.5 more expensive (10 years lifetime)	0.308
Annualised cost of residual capital of buildings (€1 million) to wire producer (8 years lifetime left)	0.149
Annualised cost of residual capital of scrapped equipment (€2 million) for wire producer (5 years lifetime left)	0.449
Total	**0.906**

[68] 50% x €5=€2.5

[69] Additional cost compared to the "applied for use" scenario (continued use of Substance A in the coating of wire).

[70] Use the Excel function PMT(4%;10;2.5;0;0), where 4% is the discount rate, 10 is the lifetime of the motor (in years), 2.5 is the cost per motor (in euros), the first 0 is the resale value amount (in euros) at the end of the lifetime of the investment (it is zero because the washing machine has come to end of its lifetime and has no commercial value) and the last 0 indicates that one starts to discount from the beginning of the year

Table 9: Scenario 3: Cost of relocating wire production outside the EU in 2020 and during 2010-24(measured in 2007 price level)

	Cost per washing machine per annum (€)	Number of new washing machines in use (millions)	total cost (€millions)
2010	0.91	1	0.91
2011	0.91	2	1.81
2012	0.91	3	2.72
2013	0.91	4	3.62
2014	0.91	5	4.53
2015	0.91	6	5.44
2016	0.91	7	6.34
2017	0.91	8	7.25
2018	0.91	9	8.15
2019	0.91	10	9.06
2020	0.91	10	**9.06**
2021	0.91	10	9.06
2022	0.91	10	9.06
2023	0.91	10	9.06
2024	0.91	10	9.06
Present Value for 2010-24			**65.29**

Given that the cost per annum in 2010 was €0.906 per washing machine Table 9 gives the costs of discontinuing wire production in the EU. The impact for 10 million washing machines would be **€9.06 million** in 2020. This would be the costs using the *representative year approach*.

Considering the placing 1 of million washing machines each year on the market during the investment cycle of 15 years (from 2010 to 2024) the present value of these costs is **€65.29 million** in 2010 (see Table 9). This would be the costs using the *cumulative approach*.

5.4. Summary

Table 10 summarises the annualised and cumulative costs of the scenarios.

There are some uncertainties relating to the analysis. The main one relates to the actual energy consumption related to the use of washing machines. In Section 3.3 it was assumed that the uncertainty range was 25% around the energy efficiency loss if Substance B was used instead of Substance A.

Table 10: Summary of the costs of three scenarios in 2020 (measured in 2007 price level), millions of euros – 4% discount rate used unless specified otherwise

	Scenario 1	Scenario 2	Scenario 3
Annual cost in 2020			
Minimum estimate (25% lower energy costs)	€18.32	n.a.	n.a.
Central estimate	€24.32	€7.90	€9.06
Maximum estimate (25% higher energy costs)	€30.32	n.a.	n.a.
Using 6% discount rate	n.s.	*€9.26*	n.a.
Cumulative cost in 2010-24 (Present Value)			
Minimum estimate (25% lower energy costs)	€132.02	n.a.	n.a.
Central estimate	€175.26	€56.92	€65.29
Maximum estimate (25% higher energy costs)	€218.50	n.a.	n.a.
Using 6% discount rate	*n.s.*	*€66.72*	n.a.

Scenario 1: Substance B is used instead of Substance A;
Scenario 2: Substance A is used but filtering equipment is installed
Scenario 3: Suitable coated wire is imported into the EU (changing the discount rate would not change the results)

The cost of Scenario 2 was estimated to be €7.9 million per annum in 2020. Cumulatively the present value of the costs for 2010-24 is €56.92 million.

The cost of Scenario 3 was estimated to be €9.06 million per annum in 2020. Cumulatively the present value of the costs for 2010-24 is €65.29 million.

The costs of Scenarios 2 and 3 are much lower than the cost of Scenario 1.

The likely response to a regulation concerning the human health impacts of Substance A is either that the EU producer invests in filtering equipment in its site or his customers import the coated wire from outside the EU. In the former case the compliance cost would be €7.9 million and in the latter case €9.06 million per annum in 2020. However, with 6% discount rate the compliance cost of Scenario 2 would be €9.26 million, i.e. slightly higher than in Scenario 3. **In sum, the compliance cost is estimated to be between €7.9 and €9.06 million per annum in 2020. This is equivalent of the compliance costs being (cumulatively) between €56.9 and €65.3 million during 2010-24.**

If the company in the EU invested in filtering equipment the risks would be reduced to non-existent while if the downstream user imported the wire from outside the EU. The risks would be taken by the workers that coat the wire there (assuming that the non-EU producer does not have filtering equipment).

As a reminder Scenarios 1 (using substance B) and 2 (filtering equipment) could have been carried out under the study of the economic feasibility in the analysis of alternatives. However, Scenario 3 (import of wire) would not be carried out under the analysis of alternatives but under socio-economic analysis. This is due to the fact that in this case neither a substitute substance nor technology is analysed.

European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki
http://echa.europa.eu