Development of Risk Reduction Strategies for Priority Chemicals

A Guidance Document (Pilot Version)

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Note to Reviewers

The present pilot version of this document is being tested through country-based pilot case studies in the context of the Training and Capacity Building Programme on Risk Assessment and Risk Management Decision Making. The guidance contained in the document is intended to be flexible, and countries are encouraged to adapt it to their particular needs and circumstances. Following the outcomes of the pilot case studies and based on feedback from the participating countries and others, the document will be revised in order to better meet the needs of its intended users. Representatives of the pilot countries as well as other interested parties are invited to provide their comments to UNITAR (please see contact information, inside front cover). Feedback on the following points is specifically requested:

- Is the step-wise framework presented in the document useful? Is it relevant and readily applied to the development of risk management strategies in your country?

- Are the suggested steps presented in a logical order? In working through the suggested process, were there any additional steps which needed to be taken which are not presently reflected in the document?

- From the guidance, is it clear what activity(ies) might need to be undertaken at each step, as well as what should be the expected output of the respective steps?

- Are there suggested steps or concepts which are difficult to implement or apply? Would it be useful to have supplementary explanations or examples of certain aspects of the suggested process, and if so, which ones?

- Was it difficult to obtain the information and data needed to carry out the suggested process and, if so, what types of information/data were most difficult to obtain?

- Is the suggested format for the submission of the risk reduction strategy (as outlined in Step 6) considered useful?

- Is the language used in the document user-friendly? What specific improvements might be made in this regard?

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Preface

This document is based on a document entitled *Technical Guidance Document on Development of Risk Reduction* Strategies, which was developed for the European Commission to aid in the preparation of risk evaluations and risk reduction strategies for priority substances under the Council Regulation on the evaluation and control of existing substances. While the original guidance was developed specifically for the European Union context, it was felt that the suggested stepwise approach which the guidance describes could be of potential value to any country interested in working through a systematic process to develop a risk reduction strategy. To this end, the text has been modified to make it generally applicable and, it is hoped, to make it relevant to the needs and circumstances of developing and industrializing countries.

This revised document, entitled *Development of Risk Reduction Strategies for Priority Chemicals: A Guidance Document,* is a pilot version which will serve as the main guidance document for country-based pilot case studies to be undertaken in the context of the Training and Capacity Building Programme on Risk Assessment and Risk Management Decision Making. The programme, support for which is provided by Directorate General XI of the European Commission, is implemented by UNITAR jointly with the IPCS and with the involvement of UNEP Chemicals, the European Chemicals Bureau and other interested partners. Through this programme, task forces in participating countries will select a chemical substance and, starting from the risk assessment stage, will work through the process of identifying risk reduction options and developing a proposed risk reduction strategy, with input from concerned parties. In addition to this guidance document, other risk assessment and risk management materials from various countries and international organizations, including existing guidance and methodologies as well as relevant tools such as software and databases, will be utilized in the context of the pilot case studies.

It is expected that at the country level, the pilot case studies will serve to:
increase familiarity with various existing methodologies and tools for risk assessment and risk management decision-making;
strengthen capabilities and skills needed for carrying out risk assessment and for developing sound risk reduction strategies;
foster an understanding of how risk assessment and risk management decision-making approaches can best be applied taking into account national needs and circumstances; and
foster interaction among the various concerned and interested parties which are likely to be involved in the risk management decision-making process at the country level.

At the international level, it is expected that the outcomes of the pilot country case studies will:
indicate the relevance and utility to the needs and circumstances of developing countries of the guidance contained in this pilot version document;
indicate the potential utility of existing tools -- such as the EUSES software developed by the European Commission -- in supporting risk assessment within a developing country context;
provide input into the *Thematic Session on National Capacity Building for Risk Management Decision-Making for Priority* Chemicals, to be held during the third quarter of 1999 with financial support from the Swiss Agency for Development and Cooperation (SDC); and
provide experiences gained and lessons learned to be shared with other interested countries through (sub-) regional workshops to be organized in late 1999.

Introduction

This document provides guidance on the development of a risk reduction strategy for a chemical substance of concern, in the context of a national programme for chemicals management and safety. It covers that part of the process from the identification, through risk assessment, of risks which need to be limited to the submission of the risk assessment and the proposed risk reduction strategy to the appropriate decision-making body. Whereas the document outlines possible risk reduction measures and implementing instruments as well as criteria for selecting the most appropriate approach, it is understood that this analysis will be carried out taking into consideration the particular needs and circumstances of the country as well as the principles of precaution, of preventative action, that the polluter pays and source oriented management.

The document is intended for use by a national task force or committee which has been charged with the responsibility of developing a proposed risk reduction strategy for a specific chemical of concern (or particular category of chemicals).

Developing a Risk Reduction Strategy

The starting point for development of a risk reduction strategy is to conduct a risk assessment of the substance. If the risk assessment concludes that there is a need for limiting the risks and that risk reduction measures are necessary in relation to one or more adverse effects, human populations and/or environmental spheres, the development of a risk reduction strategy becomes necessary.

At this point, the task of the task force is to develop a risk reduction strategy tailored to the circumstances of the individual chemical. The task force should consult industry and others so that the strategy is developed through an interactive process making use of all the main sources of information on the substance and possible control measures. To help the task force in this process, much of this document is concerned with describing the wide range of risk reduction options available, and on guiding the task force on the factors to take into account when selecting the most appropriate strategy. While the approach that is suggested in this document is a generic one, it is recognized that each case will be different. Thus the task force evaluating a given substance may therefore find only parts of the document to be of relevance.

Some of the key actions and considerations which a task force is likely to undertake during the process of developing a risk reduction strategy include the following:

Summarizing any risks identified by the risk assessment which need to be limited, the magnitude of these risks and the particular activities that give rise to concern;

Consulting on an informal basis with industry and other interested parties;

The Importance of a Multi-Stakeholder Approach

A key to the development of a sound risk reduction strategy is the involvement of the various groups and actors which will be potentially affected by and/or involved in its implementation. Typically these include relevant government ministries/agencies as well as industry, public interest groups, workers' unions and other non-governmental actors. In light of the expertise and knowledge which they can provide, members of the research/academic community should also be involved. Each of these various entities is likely to be able to provide useful substantive input into the strategy development process, as well as to help focus attention on the full range of concerns and factors to be considered.

Consulting with and involving all stakeholders early on in the process can help to ensure that the resulting risk reduction strategy will be practical and feasible, and that important socio-economic issues as well as the input and perspectives of the various groups, can be taken into account in an open and transparent way.

Considering whether risks could be effectively reduced by increasing the effectiveness of existing controls;

Identifying and listing further measures which have the potential to effectively limit the risks in question;

Identifying the most appropriate tools for implementing these potential risk reduction measures;

Identifying the most appropriate risk reduction measure or measures by evaluating the list of potentially effective risk reduction measures and means of implementation against the following criteria: effectiveness; practicality; economic impact; and monitorability;

Considering whether the selected measures will effectively limit the risks without significantly increasing risks elsewhere or otherwise imposing disproportionate burdens on society;

In the case that controls on marketing and use are envisaged, drawing up an analysis of the advantages and drawbacks of the substance and of the availability of appropriate replacement substances;

Outlining any uncertainties in the information and methodologies on which the strategy is based;

Drawing up recommendations, where appropriate, for monitoring effectiveness of the strategy;

Describing how the recommended strategy offers a significant net risk reduction;

Consulting with those who have relevant technical and economic expertise, industry, and other interested parties as appropriate; and

Submitting the recommended strategy to the decision makers;

Considering, on a periodic basis, whether a new strategy should be considered in light of technological breakthroughs or new knowledge on potential risks to human health or the environment which significantly change the risk assessment.

While the exact nature of the activities and decisions to be taken by a task force will vary from one case to the next, an attempt has been made to capture the above-outlined sequence into a generic step-wise process comprising six basic steps, as shown in Figure 1. Guidance and practical suggestions on working through each of these steps are provided in the following sections of this document. In addition, several annexes are included which provide case examples as well as further explanation of specific aspects of the risk management decision-making process.

The suggested output of this step-wise process is a concise document, to be presented to decision makers, which outlines the task force's recommended risk reduction strategy. It is suggested that the initial sections of the document would provide background on the chemical substance, including the concerns which have led to the development of the proposed risk reduction strategy as well as the summary results of the risk assessment. It should also identify the current risk reduction measures which are in place, if any, as well as an indication of their effectiveness. Following this, the document should outline the various possible risk reduction measures the task force has identified, together with the administrative, legal and other tools with which each could potentially be implemented. An explanation should also be provided of the outcomes of the task force's deliberations regarding the potential effectively, practicality, economic impact and monitorability of the various risk reduction measures which have been considered. The document should then provide a recommendation regarding the most preferred risk reduction measure. In the case that the recommended approach involves a restriction in the marketing/use of the substance, an analysis of the advantages and drawbacks of the restriction as well as the availability of alternatives should be provided. The document should also explain the possible arrangements for monitoring the implementation and effectiveness of the proposed measure. Finally, a listing of the organizations consulted during the process should be included, followed by concluding remarks. Further guidance on drawing up the formal risk reduction strategy paper, including an annotated outline, are provided under Step 6.

Figure 1: Developing a Risk Reduction Strategy

Step 1	**Assessing Potential Risks**
	Objective: Identify which specific stages in the manufacture, storage, distribution, use or disposal of the substance give rise to risks which need to be limited.

Step 2	**Identifying Risk Reduction Options**
	Objective: Taking account of any existing risk reduction measures, identify a wide range of available options for reducing the risks which need to be limited.

Step 3	**Identifying Possible Tools for Implementing Risk Reduction**
	Objective: Identify the administrative, legal and/or other tools with which any recommended action could be taken.

Step 4	**Recommending the Most Appropriate Approach**
	Objective: Select the most appropriate risk reduction strategy by evaluating the list of potential effective measures and implementation methods against the following criteria: effectiveness; practicality; economic impact; and monitorability.

Step 5	**Analyzing Advantages and Drawbacks if Marketing and Use Restrictions are Under Consideration**
	Objective: If marketing and use restrictions are recommended, draw up an analysis of the advantages and drawbacks as well as availability of alternatives.

Step 6	**Drawing up a Formal Risk Reduction Strategy**
	Objective: Submit the risk assessment and any recommended risk reduction strategy to decision makers.

Step 1: Assessing Potential Risks

Objective: Identify which specific stages in the manufacture, storage, distribution, use or disposal of the substance give rise to risks which need to be limited.

1.1 Introduction

The basis for drawing up a risk reduction strategy is the risk assessment. Indeed, it is only when the risk assessment concludes that there is a risk that needs to be limited that the task force should develop a risk reduction strategy. The risk assessment will identify the magnitude and character of the risks foreseen for a substance, derived from, for example:

any significant hazardous effects and any significant routes of exposure;
the severity, reversibility and imminence of any critical effects;
the likelihood of specified effects occurring; and
the populations and/or ecosystems at risk.

In this way, the risk assessment will identify not only the risks which need to be limited: it will also identify where such risks arise, and which exposure routes the risk reduction strategy will need to address.

Guidance documents are available which explain how a risk assessment is conducted, thus the process is not examined further here. However, to assist task forces in identifying the range of options available for risk reduction, this section briefly outlines some major potential sources of risk to human health and/or the environment. This document addresses the reduction of risks arising from the normal production, storage, distribution, use and disposal of a substance, and does not include the reduction of risks arising from major releases as a result of catastrophic accidents or deliberate abuse.

1.2 Identifying Potential Sources of Risk Throughout the Life Cycle

Risks can arise at any or all of the stages, of a substance's life cycle, for example, during:

manufacture and industrial use;
distribution and storage;
professional and domestic use; and/or
disposal.

Risks can arise either directly or as a result of the subsequent environmental distribution and/or transformation of a substance, for example, through its inclusion in the food chain. Risks can also arise from the exposure of populations and/or the environment to

substances incorporated in finished products. As with the substance itself, such risks can arise at any of the above stages of the product's life cycle.

Risks can arise from both point and diffuse sources, and from both one-time and repeated exposure. It is also possible that while emissions from individual sources do not give rise to concern, cumulative emission levels represent major risks to the environment or human health.

1.2.1 Potential risks from manufacture and industrial use

Risks can arise from exposure due to:

emissions to atmosphere, including within the workplace (e.g. controlled releases from vents and chimneys; fugitive emissions, e.g. from valves and joints or when sampling takes place; venting from pressure relief systems; handling of powders; and evaporation from non-catastrophic liquid leaks and spills;

emissions to water or soil (e.g. authorized discharges to water courses or sewage treatment works; leaks from drains; leaks, spills and washwater from processing plant and storage facilities); and

direct exposure (e.g. contact with skin or eyes; by inhalation; or by ingestion).

1.2.2 Potential risks from distribution and storage

Similar exposure can occur at this stage. There are also risks from vapour and dust emissions from filling and emptying containers; breathing or venting of storage tanks; spills from container failures; releases during transit, loading or unloading, or during cleaning of tanks; spills from improper handling or failure to store under the correct conditions.

1.2.3 Potential risks from professional and domestic use

Risks can arise from exposure during initial use and subsequent maintenance or replacement due to:

emissions to atmosphere (e.g. solvents from drying and curing of paints, resins, adhesives, and polishes; and spray applications);

emissions to water and soil (e.g. through over-use, spillage or disposal to sewage treatment plants of substances such as detergents and disinfectants);

direct exposure (e.g. contact with skin or eyes, by inhaling, or by mouth); and

aging or weathering in use of products such as paints and coatings.

Spills, leaks and other accidents arising from professional use may be on a smaller scale than in industrial premises, but are likely to occur more widely. Compared to industrial use, it is more difficult to ensure that the substance is safely stored and properly used.

It is even more difficult to enforce similar controls on domestic use, and unlike professional users, domestic users are not covered by occupational safety legislation. Therefore, when assessing risks arising from domestic use, and as a reasonable worst-case scenario, the task force should assume that exposure will in general be uncontrolled, and that susceptible individuals - for example very young or very old people - are involved. The task force should consider whether in certain circumstances the same assumptions should be made about exposure from use in small and medium-sized enterprises.

1.2.4 Potential risks from waste management

Risks can arise from exposure due to:

emissions to atmosphere (e.g. incineration; poor handling techniques or inadequate ventilation; decomposition in landfills; direct evaporation; and air stripping in waste water treatment plants);

emissions to water or soil (e.g. leachate run-off from landfills; spreading sludge containing metals or persistent organics onto land; residues from incomplete decomposition in waste water treatment plants); and

direct exposure (e.g. inhalation by, or dermal exposure of, workers at waste management facilities).

Step 2: Identifying Risk Reduction Options

Objective: Taking account of any existing risk reduction measures, identify a wide range of available options for reducing the risks which need to be limited.

2.1 Introduction

Taking into account the outcomes of Step 1, as well as any risk reduction measures which may already be in place for the substance of concern, the task force at this stage should identify a range of possible options for reducing the risks which need to be limited. A wide range of risk reduction measures are available, which generally fall into a number of generic categories: for example, information requirements; restrictions on marketing and use; and controls on emissions. Once the task force has identified a full range of options, further guidance on selecting which of these measures may be appropriate in a particular case is given under Step 4. Ultimately, the aim of the task force will be to recommend the measure or measures considered most appropriate to the individual substance and the specific risks which need to be limited.

This section provides examples of risk reduction measures that may be appropriate at each of the stages of a substance's life cycle. These examples are not intended to be exhaustive or prescriptive, and the order of measures within each section does not imply that any particular measure is in any sense preferable to any other.

Some of the measures listed below have the potential to reduce risks at several stages of a substance's life. Labeling requirements, for example, can create the conditions in which risks can be reduced during handling, transport, use and disposal.

Controls on emissions to air, soil and/or water may be appropriate if the risks which need to be limited arise from a relatively limited number of point sources. Where risks arise from both point and diffuse sources, it is in general easier to introduce risk reduction measures at the point source stage. Such controls are, for example, easier to enforce, and their effect can be more closely monitored. As diffuse sources may represent a considerable contribution to overall emissions, it is necessary to investigate the possibilities to reduce diffuse emissions.

Where risks arise from cumulative emissions, rather than from individual stages of a substance’s life, the task force should first consider controls on the most significant remaining source of emissions (taking into account any existing risk reduction measures). Where there are a number of significant sources, the task force should aim to control emissions where this can be done most cost-effectively. Environmental quality standards may also be appropriate in such circumstances.

2.2 Risk reduction measures related to manufacture, industrial and professional use

Controls on manufacture, industrial and professional use may include:

controls on manufacture;
restrictions on the marketing and/or use of the substance;
re-designing the process itself, or changing the substances or materials used in it;
safe systems of work, such as specified standards of physical containment or extraction ventilation;
application of good manufacturing practice, for example, under ISO standards;
classification and labeling;
separation of personnel;
monitoring and maintenance of equipment;
dust suppression methods, such as the use of substances in tablet or pellet form;
occupational exposure limits and/or air monitoring in the workplace;
accurate hazard information (for example, safety data sheets), and/or better delivery of safety, information, such as clearer labeling or the provision of warning signs in the workplace;
biological exposure indices and/or biological monitoring of workers;
medical surveys of workers;
training;
use of personal protective equipment;
licensing of operators or of certain operations;
"end-of-pipe" controls to minimize, neutralize or render less harmful any emissions that cannot practicably be avoided otherwise;
limit values for emission and effluent monitoring; and
environmental quality standards, and/or environmental monitoring.

2.3 Risk reduction measures related to packaging, distribution and storage

Controls on packaging, distribution, transfer and storage can minimize the risk, for example, by specifying:

minimum standards for container size, shape and strength;
maximum concentrations in the formulation;
loading and unloading controls;
controls on storage (for example, floating roofs on tanks);
requirements for emptying and cleaning tanks;
vehicle standards, use of approved haulers and designated distribution routes or methods;
driver training;
hazard warning signs on packages and/or vehicles;
classification and labelling;
addition of stabilizers;
proper segregation;

criteria for storage such as security, fire resistance, and containment for firefighting water so as to prevent water pollution;
introduction of reuseable and recycleable packaging; and
use of less harmful substances in packaging.

2.4 Risk reduction measures related to domestic and consumer use

The task force should assume that exposure from domestic or consumer use will in general be unsupervised. Controls or restrictions on such use should therefore assume that:

susceptible individuals, for example, the very young or the very old will be exposed;

not everybody will read, understand and/or act according to the use and handling instructions provided; and

a significant amount of the substance will be released into the environment.

Restrictions on the sale to the general public of substances, mixtures or products which give rise to risks which need to be limited may sometimes be appropriate. Options include prohibiting the sale of the substance to specified vulnerable groups; prohibiting the sale of the substance through self-service vending machines; licensing vendors; or restricting the marketing of the substance to specified applications and/or formulations. Some substances can be restricted to industrial/professional use where risks can be better managed. But dependent on the identified risk, there may be alternatives to controls on marketing and use, including:

restrictions on size of container;
design of containers including non-spill or narrow-neck containers;
limits on concentrations of components;
product design changes, e.g. encapsulation to eliminate consumer exposure to dust;
limits on the overall quantity available to each user;
addition of an emetic, a stenching agent or a colorant;
restrictions on use (as scope for enforcement is limited, clear labelling is essential);
classification and labelling;
hazard warnings and/or use instructions on packaging;
tactile danger warnings; and
child-resistant closures.

2.5 Risk reduction measures related to waste management

Waste management controls may be difficult to enforce, particularly if a substance is used domestically. In this area, the most effective way to reduce risks from waste substances will therefore often be to introduce controls at an earlier stage of the substance's life cycle - for example, through encouraging cleaner technology or placing restrictions on product content to minimize the generation of waste, for example, at production sites. Re-use and recycling should also be promoted where possible to reduce the amount of hazardous waste sent for final disposal.

On the other hand, controls imposed earlier in the cycle may lead to a temporary increase in risks arising at the waste management stage - for example, restrictions on marketing and use may have implications for the disposal of any existing stocks. The task force should also consider whether controls are needed on the disposal of any potentially-contaminated packaging.

Controls to reduce the final release of a substance into the environment include:

classification as hazardous waste;
labelling which encourages responsible disposal;
producer responsibility schemes;
the use of recycling "banks";
duty of care systems;
compulsory acceptance of returned products;
specified disposal methods and/or conditions, for example, incineration (temperature and time); and
end of pipe controls.

Controls to reduce risks from direct exposure at waste management facilities include:

classification as hazardous waste;
secure containers;
controls on movements (including exports);
detailed labelling;
use of personal protective equipment;
staff training;
requiring the use of licensed contractors; and
setting standards for emission and monitoring of environmental quality.

Step 3: Identifying Possible Tools for Implementing Risk Reduction

Objective: Identify the administrative, legal and/or other tools with which any recommended action could be taken.

3.1 Introduction

The risk reduction measures outlined under Step 2 above can be implemented using a range of policy instruments, including, for example, voluntary approaches, economic instruments and regulation. These instruments are not mutually exclusive, and a combination of different instruments may often be the most effective approach: for example, a voluntary agreement may need to be underpinned by regulation.

This section considers the most common policy instruments through which the risk reduction measures outlined in Step 2 could be implemented. Guidance on selecting the most appropriate risk reduction strategy is given under Step 4 below.

3.2 Information programmes and other government initiatives

Better information, or improved communication, can reduce risks if those at risk are exposed through their own ignorance, and if they could take relatively simple precautions to limit the risk to themselves and others. Initiatives such as those outlined below can also play a useful role in increasing the effectiveness of other instruments, for example, economic instruments.

Information programmes can encourage the spread of best environmental practice, particularly of cleaner technology and/or techniques that can generate efficiency savings. Trade associations and other bodies may be prepared to assist in developing and/or running such awareness-raising programmes. Overcoming the difficulties of disseminating information to small and medium-sized enterprises may require special consideration.

Marketing incentives can promote and reward less environmentally harmful products and production. Examples include systems of certifying products or producers and the eco-labeling of product groups.

Investment in infrastructure, including the provision of training and/or research facilities, can also stimulate and facilitate the spread of good risk reduction practices.

3.3 Unilateral action by industry

Industry is increasingly aware of its environmental responsibilities and may be willing to implement certain risk reduction measures voluntarily. Encouraging such action is likely to be of particular relevance where risks are limited to a few specific industrial locations. Examples include setting company performance targets, establishing product stewardship schemes, providing specific information or training, or restricting a substance to specified uses under specified conditions. The chemical industry's "Responsible Care" programme is a good example of how much can be achieved in this area. Additional risk reduction measures may be necessary unless such unilateral action is taken by the majority of firms involved.

3.4 Voluntary agreements

Voluntary agreements are a relatively new approach, but experiences of countries indicate that they have considerable potential for risk reduction. Agreements typically embody a commitment made by an industrial sector in negotiation with Government to meet specific emissions and/or other targets within a certain time scale; or to accept specified voluntary limitations on the manufacture, marketing and/or use of a substance or its products. There is often an unwritten assumption that the regulatory base will not be moved unless the sector fails to honor its commitments.

Voluntary agreements can preserve flexibility in areas where regulation can be rapidly outdated by developments in scientific understanding or by technological breakthroughs. They can be implemented relatively quickly, and can offer cost savings to both industry and the regulator - though negotiation can take time and require significant resources. In some cases, agreements have been used to provide valuable practical experience on which to base subsequent regulations. However it should be noted that monitoring of voluntary agreements may be time-consuming and that they may best work as implementing tools where there is a legislative framework and policy objective whose realization they can achieve.

Effective voluntary agreements would probably need to meet the following conditions:

well defined targets, including time scales, that can be easily monitored;
a limited number of contracting participants with well defined responsibilities;
many, if not all, affected industries willing to participate in an agreement; and
transparency to the public and political institutions.

Voluntary agreements incorporating limitations on marketing and use are more likely to be appropriate where the full range of the substance's uses is easily identifiable, and where effective substitute substances or alternative techniques are readily available or in development and can be introduced without excessive cost.

3.5 Technical standards and authoritative guidance

Codes of practice embodying technical standards and/or authoritative guidance can help to achieve specific improvements. They can also help to prepare for regulation, for example, to bring all businesses into line with those utilizing good practice. Codes can take several forms:

Statutory Failure to comply is an offence unless it can be shown that other means are equally effective;

Advisory While there is no obligation to follow such codes, the extent to which they have been followed may be used as evidence if a prosecution is brought under general legislation; and

Voluntary Failure to follow the code has no direct or indirect legal consequences.

Trade associations and other bodies may be prepared to take the lead in devising and/or enforcing such codes, which are especially appropriate for spreading best practice. However, compliance with advisory or voluntary codes is likely to be uneven, and there may be particular problems in sectors with a large number of small and medium sized businesses (though these are also the sectors where regulation and its enforcement are most difficult).

3.6 Economic instruments

A broad range of measures could be described as economic instruments: emissions charges; product charges; deposit/refund schemes; etc. Most fall into three broad categories: taxes, subsidies and tradeable permits. Economic instruments can prove cost-effective, since they allow business more flexibility, bringing differential costs into play. They can provide an incentive for producers, suppliers and customers to continue to reduce risks beyond levels that might otherwise be accepted. Pollution charges in particular have the potential to raise considerable sums of public revenue.

Economic instruments can be particularly appropriate for controlling pollution from diverse sources. The main drawbacks result from a lack of practical experience, particularly with tradeable permits. For example, there is as yet little understanding of the number of participants necessary to create a functioning market in permits. A further question is whether such a system might act as a barrier to new entrants to a particular field. There may also be considerable costs in setting up a market or monitoring transactions. And there is as yet little guidance on relating the level of charges to the environmental goal to be achieved. Economic instruments may therefore not be suitable where risks must be reduced considerably within a short time-frame.

3.7 Regulatory controls

Regulation's major advantage is its relative certainty of outcome. It will therefore generally be the most effective approach to reducing risks such as those arising from consumer use. Regulation can also in some circumstances be a powerful driving force for the development of less hazardous alternatives and new techniques. Regulatory options include:

more effective enforcement of existing controls;
amending existing legislation, for example by changing a substance's classification and labeling requirements or changing existing limit values; and
new legislation, introducing:

- uniform controls and setting precise standards, such as specific controls on individual uses of a substance quality requirements, child-fast enclosures etc; or
- target-based controls, such as maximum amounts of a substance that can be emitted to air; or
- restrictions on the manufacture, marketing and/or use of the substance.

Even the threat of regulation may be sufficient to prompt industry to take unilateral voluntary action. In extreme cases, this can lead to proposed regulations being made redundant even before they can be brought into force. New legislation in particular can also be time-consuming to negotiate and implement and difficult to update quickly in response to scientific or technical advances.

Step 4: Recommending the Most Appropriate Approach

Objective: Select the most appropriate risk reduction strategy by evaluating the list of potential effective measures and implementation methods against the following criteria: effectiveness; practicality; economic impact; and monitorability.

4.1 Introduction

In selecting the most appropriate risk reduction strategy, the task force should:

- identify the range of possible options from the inventories of risk reduction measures and methods of implementation provided in under Step 2 and 3; and

- assess this range of options to identify the most appropriate approach taking into account criteria such as effectiveness; practicality; economic impact; and monitorability.

This section provides guidance on both stages of this process.

4.2 Identifying the options

A risk reduction strategy should aim to reduce the risks which need to be limited while imposing the minimum necessary burdens on society as a whole. It should therefore be targeted at those significant hazardous effects and routes of exposure where risks that need to be limited have been identified by the risk assessment.

The task force should pay special attention to the imminence and degree of any risks identified. Where delay could lead to large-scale pollution, ill-health or loss of life, or if any damage is likely to prove irreversible, the task force may need to recommend measures that could be implemented quickly. Where there are relevant threats of serious or irreversible damage, the task force should also consider whether precautionary action is necessary, even where scientific knowledge is not conclusive, if the balance of likely advantages and drawbacks justifies it.

The task force may consider any relevant risk reduction measures already in place. If adequate information is available, the task force is advised to assess the effectiveness of existing measures, taking into account any relevant practical experience. The task force should if possible consider if the implementation of existing controls could be made more efficient, and, if so, whether this would remove the need for further controls.

If further measures are needed, discussions with relevant parties will help identify which risk reduction measures are likely to prove effective in individual cases. Depending on the substance in question, relevant parties could include, for example, those with relevant technical and economic expertise, manufacturers, suppliers, processors and users of the substance, consumer groups, labour organizations and environmental organizations. One option producers or users could be asked to consider is voluntarily eliminating the risk altogether, for example, by redesigning the process or moving to an alternative substance.

4.3 Identifying means for implementation and choosing the most appropriate approach

Having identified a number of measures and implementation methods that would effectively reduce the risks that need to be limited, the task force should select the measure (or combination of measures) that can most effectively reduce the risks while imposing the least burden on society. Before recommending new or amending legislation, the task force should consider whether existing legislation already provides any necessary powers.

The task force can use any available information, the professional judgement of its members and any relevant practical experience. The possible options may be evaluated considering the following criteria:

Effectiveness The measure (or measures) must be targeted at those significant hazardous effects and routes of exposure where risks that need to be limited have been identified by the risk assessment and must be capable of reducing the risks that need to be limited within and over a reasonable period of time;

Practicality The measure (or measures) should be implementable, enforceable and as simple as possible to manage (such that smaller enterprises are able to comply). Priority should therefore be given to consideration of commonly used measures that could be properly carried out within existing infrastructure (though not to the exclusion of novel measures);

Economic impact The task force can make a rough qualitative estimate of the impact of the measure on producers, processors, users and other parties on the basis of experience and judgement. However, regarding restrictions on marketing and use, the task force should provide a more detailed analysis of the advantages and drawbacks of the measures (see Step 5).

Monitorability Monitoring possibilities should be available to allow the success of the risk reduction to be assessed.

The degree of detail and the accuracy of the task force's assessment will depend on the extent of the information available. The task force should therefore consult industry and other interested parties during the evaluation, so that the strategy recommended is chosen through an interactive process making use of all the main sources of information on the substance and possible control measures.

Some account should also be taken of any uncertainties in the information and/or the methodologies on which the strategy is based, for example, by testing the robustness of key findings against alterations in any initial assumptions.

In making the assessment, the task force may also take into consideration — if appropriate and to the extent possible — whether any potential measures:

are in line with other existing commitments;
take adequate account of any existing stocks;
are sufficiently flexible to allow account to be taken of scientific or technological breakthroughs;
provide sufficient time scale for establishing necessary changes in technology, process, equipment, etc; and
could provide for exemptions if this would significantly reduce the burden without undermining their overall effectiveness.

Monitoring will allow the success of the risk reduction strategy to be assessed to inform future decisions on whether further measures are necessary and provide experience which may be useful in developing future strategies on other substances. The strategy will therefore also need to anticipate monitoring possibilities and may consider their effectiveness and cost.

If the risk reduction measures selected by the task force include restrictions on the marketing and use of the substance in question, the task force should also analyze the advantages and drawbacks of the substance as well as the availability of replacement substances. Guidance on these additional requirements is given under Step 5.

Step 5: Analyzing Advantages and Drawbacks if Marketing and Use Restrictions are under Consideration

Objective: If marketing and use restrictions are recommended, draw up an analysis of the advantages and drawbacks as well as the availability of alternatives.

5.1 Introduction

If the task force concluded that the most appropriate approach to risk reduction is the restriction of marketing and use of the substance, the task force should carry out an analysis of the advantages and drawbacks of the substance and of the availability of replacement substances.

Although the restriction is an efficient measure in terms of risk reduction of the substance in question, it usually raises concerns in relation, for example, to the possible risks of the replacement substances, their technical feasibility, and consequences to the industry and society in general. The aim of the task force's analysis of advantages and drawbacks is to provide available information and to compare different aspects for and against the restriction, in order to demonstrate whether sufficient justification for the restriction exists. The extent of the task force's analysis should be decided case by case. Therefore, in this chapter only the lower limit of the task force's analysis is suggested, and the upper limit is left open.

The approaches and techniques outlined in this section are aimed at aiding decision making, not replacing it. The task force's analysis should transparently indicate how the data were produced, which methods were used, and how the conclusions were drawn, in order to enable other parties to critically review the analysis and to make their own judgement of it. Also the uncertainty of the analysis should be reflected when drawing up the actual recommendation.

5.2 Scope of the analysis

The advantages would be the benefits to users from the use of products containing the substance, to producers and processors from the profits generated by sales of the substance, and to society e.g. in terms of employment and the general economy. The drawbacks would be the risks to human health or the environment as identified in the risk assessment.

The task force's analysis should also cover the advantages and drawbacks of adopting the recommended restrictions on marketing and use. Following this broadening of the scope of the analysis, the appraisal would then not only cover the risk reduction of the substance, but also the possible adverse effects of the substitutes (net effect on risk). Similarly, the positive and negative consequences to industry and society in general that may be caused by the restriction, such as loss or increase of market and jobs (net social and economic effects). This deliberate broadening of the analysis is recommended because the question of substitutes and the concern of economic consequences will always be raised when proposals for restriction are discussed.

5.3 Appraising advantages and drawbacks

It is not presently possible to recommend any particular approach or methodology that should be used in the appraisal. The task force can choose the approach that best suits the specific circumstances of the substance in concern. However, some basic principles are described in the following in order to help the task force in planning and performing the analysis, and other partners in reviewing it.

In decision making three levels of difficulties can be encountered:

- problems due to lack of information (some consequences of the decision are not known enough in detail);
- problems due to different understanding of the information; and
- problems due to different values (parties have different preferences and weigh the likely impacts of the decision differently).

The aim of systematic and analytical decision aiding is to remove or reduce the two first types of difficulties as much as possible, and to make value conflicts visible, in order to focus the efforts towards the relevant aspects of the decision process.

The advantages of the restriction may include reduction in the risk posed by the substance, which leads to better quality of human health or of the environment, and may also lead to reduction of current or future costs in, for example,

- health care (calls by and consultation of doctors, medicines, hospital treatments, insurance compensation, rehabilitation);
- establishment, administration and enforcement of other control measures (e.g. limitation of discharges) in relation to the substance;
- monitoring the substance in the environment and workplace in order to ensure that current limit values are followed;
- establishing and running clean-up operations; or
- costs of treatment and disposal of hazardous wastes.

Positive economic effects of the restriction may result from:

- the production, marketing and use of the substituting chemicals;
- technical innovations; and
- improved efficiency of new processes or products

which may lead to increased profits or better employment, and possibly also to competitive advantage in the long run.

The drawbacks of the restriction may include:

new risks created by introducing the substituting chemicals and subsequent costs;
costs to the industry (producers, processors, users), public sector and consumers following the shift to substitutes, due to e.g. higher price, poorer performance, adapting process facilities, or closing down of facilities before their actual life time would be over;
loss of amenity to the consumers;
costs to the society, e.g. in terms of administrative burden of preparing and enforcing the restriction, or unemployment; and
transfer of benefits to other countries/regions.

The analysis of advantages and drawbacks can be divided into the following phases, which are discussed in detail below:

a) choice of alternative control measures;

b) choice of decision criteria;

c) collection and presentation of data;

d) comparison of advantages and drawbacks;

e) drawing the conclusions.

The above steps can be taken iteratively, with the aim being of finding a sound basis for decision-making with optimal use of resources.

Usually, it is appropriate to start with a qualitative analysis, and to move to semi- or fully quantified analysis, if necessary and possible. A qualitative analysis can be regarded as a minimum requirement for the task force. The extent of the analysis shall be decided case-by-case, on the basis of, for example:

- the severity and extent of the risk;
- the scale of the drawbacks;
- the balance between the likely advantages and drawbacks;
- the information available within reasonable cost and within a reasonable time frame; and

- dealing with uncertainty.

The members of the task force should consult widely amongst relevant parties during their appraisal. Depending on the substance/substitutes in question, relevant parties could include, for example, those with relevant technical and economic expertise, manufacturers, suppliers, processors and users of the substance/substitutes, labour and environmental organizations and consumer groups. Industry in particular will be a vital source of information on various aspects of the substance/substitutes and on the likely economic effects any proposed restrictions might have. Such information will be of most value when it is verifiable and its derivation is transparent, for example, when it is supported by appropriate technical references.

Close co-operation between risk assessors and persons analyzing advantages and drawbacks is necessary. It is important to acknowledge the nature of the underlying risk assessment, including its strengths and limitations, in order to understand what conclusions can be drawn from it. This will be of special importance if monetarisation or other quantification of the risks is under consideration.

5.3.1 Choice of alternative control measures

Basically, the purpose of the analysis is to compare the advantages and drawbacks of a marketing and use restriction with the current situation, since the restriction was chosen as the most appropriate control measure on the basis of the process described in the previous chapters.

It is also possible to distinguish among and analyze different restriction alternatives. For example, it may be useful to compare the balance of advantages and drawbacks between a total ban and a restriction covering only certain uses of the substance.

The current situation (substance as currently used and controlled) is used as a reference when defining the advantages and drawbacks of a potential restriction. In some cases, however, it might be appropriate to also include alternative control measures to the analysis of advantages and drawbacks. The current situation is usually not a real decision alternative, since some risk reduction measures in any case need to be recommended. Therefore, it could be useful to compare the costs of the restriction to those of alternative risk reduction measures which were identified as most promising according to Step 4. It is to be noted, however, that the aim is to analyze advantages and drawbacks only in relation to a proposed restriction and that the broadening of the analysis probably requires considerable amount of new data, e.g. on the costs of the alternative control measures.

5.3.2 Choice of decision criteria

In risk management the decision maker is confronted with different impacts and consequences resulting from the decision. These impacts can be various and difficult to measure and to compare. Some of them may be of minor importance, and thus can be ignored during the decision process. The impacts that finally affect the decision are called decision criteria. In a broad sense, the decision criteria in this context are advantages and drawbacks, but it is practical to have a more detailed description of criteria that should be considered.

The criteria should be chosen so that they describe different key impacts of the restriction, in order to make the comparison of alternatives possible. In the criteria, the individual endpoints of the evaluation are already to some extent aggregated. For instance, from the total hazard profile of the substance/substitute, only those triggering the actual risk will be chosen as a criteria. The impacts can be described qualitatively or quantitatively. The criteria may vary from case to case, but in this context they usually fall into the following categories:

- risks of the substance to human health and the environment;
- risks of the substitute(s) to human health and the environment;
- costs and benefits to the producer of the substance;
- costs and benefits to the producer of the substitute;
- costs and benefits to the user or other stakeholders; and
- other factors, such as administrative burden, employment, etc.

5.3.3 Data collection

For the analysis of advantages and drawbacks the risk assessment of the substance of concern is a vital source of information. In addition, further data need to be collected, concerning

- the alternative substances (both in relation to technical/economical feasibility and possible hazard/risk posed by the substitutes); and
- economic impact and socio-economic consequences.

The data should, as far as possible, reflect the situation throughout the country. Therefore, the task force is recommended to consult both authorities and industry widely during the data collection process. If the analysis is restricted to cover only certain regions, this should be clearly stated.

Alternative substances

Restrictions on marketing and use can encourage the use and the development of alternatives. Instead of substituting chemicals, it may also be possible to develop and use other techniques. Any such change is likely to affect the balance of advantages and drawbacks of the recommended restrictions.

Ideally, the task force should try to characterize to what extent the risk posed by the substance will be reduced, taking into account the possible new risks caused by the substituting chemicals or alternative techniques. In practice, this is a demanding task, and due attention must be paid to how far the task force should proceed with the assessment of substitutes. A step-wise approach is recommended, in order to move no further than necessary for the demonstration of the likely risks of the alternative substances.

In all cases, the available information of the hazard profile of the substitutes should be assessed and described. To what extent the exposure to (and consequently the risks of) the substitutes should be evaluated, is a matter of case-by-case judgement.

The technical and economic aspects of the substitutes also need to be addressed in order to define their performance and economical feasibility. It can be useful to carry out a rough ranking on the basis of these aspects in order to restrict the number of substitutes that should be studied more closely.

When evaluating the substitutes, it is important to take into account the dynamic nature of the situation: technical progress and development of the market can be rapid. For example, it is useful to consider whether the substitution has already taken place in other countries and, if so, what experience is available.

Sources of information on potential alternatives include industry, the relevant technical and scientific expertise, material safety data sheets, the IUCLID database[1], and other databases or literature.

Economic impacts

The goal of appraising the economic impact is to identify the extent and distribution of the economic consequences the restriction is likely to have. In this context the economic impacts are understood to cover both the direct impacts to industry and consumers involved, and their indirect consequences, such as effects on employment. The economic benefits of risk reduction are dealt with later on in this section. The data used for the appraisal can be both qualitative and quantitative. It may be enough to start with a qualitative, or only partly quantified data, and further quantification will be performed only if necessary.

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1 The International Uniform Chemical Information System Database (IUCLID) is a database developed by the European Chemicals Bureau of the European Commission on so-called “existing chemicals”.

A restriction on marketing and use may cause loss in sales to the manufacturer of the substance; additional costs or savings to users; increase in sales of the producer of the substitute; and increase or decrease in administrative costs.

The economic impact of the restriction can be roughly evaluated by identifying:

the direction and the extent of the impact; and
the type of the additional costs or savings (e.g. investment, operating cost, maintenance).

The following list of questions may be helpful in carrying out a more thorough appraisal of economic consequences.

- Impacts on the producers of the substance and of the substitute(s)

What is the annual turnover (i.e. sales) of the substance in the country?
What could it be for the substitute?
What is the number of companies producing the substance/substitute, what is the size distribution of the companies, and in which regions are they located?
What percentage of the total annual value added or turnover of the companies is from the substance?
Is the substance/substitute exported from or imported to the country?
What are the likely prospects of demand for the substitutes?
If the substitutes are not yet commercially produced, does a commercial manufacturing process exist? Is product or process development needed?

- Impacts on the users:

Are the substitutes already in use in the country or elsewhere?
What is the number of companies using the substance/substitute, what is the size distribution of the companies, and in which regions of the country are they located?
What percentage from the total production costs relate to the cost of the substance?
Is there a need for new investments?
Are development of new processes or modifications of the present ones needed?
Will there be a change in operating costs or operating margin, and what will cause that change?
If new processes are needed, what is the likely time perspective before they will become applicable and commercially viable?
What are the differences between the substance and the substitute in terms of price, technical properties, and usability of the final product (e.g. performance, safety, longevity) from the point of view of professional user or consumer?

- Impacts on the regulator:

What are the administrative costs, including inspection, enforcement and development of new test methods?

Like other impacts, the economic analysis involves multiple assumptions and extrapolations. For instance, prediction of changes in a dynamic market situation can be a complex undertaking. Hence, it is important to make the analysis transparent by providing clear presentation of data used and thorough explanation of methodologies, and by pointing out uncertainties.

5.3.4 Presentation of data

The task force should try to present and summarize the data which is being used in the analysis of advantages and drawbacks as clearly as possible. The data sources, estimation techniques, assumptions and extrapolations should be presented for the sake of transparency.

One possibility for summarizing the data is to use a matrix, which includes a cross-tabulation of alternative control measures and decision criteria. This type of matrix can be used to structure and summarize the data that have been collected and the evaluations performed. The decision matrix should always be accompanied with an explanation of how data were derived and processed, and what uncertainty is involved. Below is an example of a possible matrix.

	ALTERNATE CONTROL MEASURES		
CRITERIA	Current Situation	OPTION 1	OPTION 2
Environmental risk of the substance			
Environmental risk of the substitute			
Health risk of the substance			
Health risk of the substitute			
Cost or benefit to the producer			
Cost or benefit to the user			
Cost or benefit to the producer of the substitute			
Other factors (administrative burden, employment etc.)			

5.3.5 Comparison of advantages and drawbacks

Qualitative analysis

Once the data collection has been completed and the data are described and summarized appropriately, a first attempt can be made to compare the balance of advantages and drawbacks. A qualitative assessment means that:

the data are presented in a qualitative manner, although some of the data may well be expressed in quantified form;
the comparison of advantages and drawbacks is carried out to determine if the advantages outweigh the drawbacks, or vice versa.

A qualitative description of risk is useful in addition to the quantitative outcome of the risk assessment, especially if no quantitative risk characterization of substitutes has been carried out. The human health or the environmental risk/hazard of the substance can be described for example by expressing:

the severity of the hazard, identification of critical effects (reversibility/irreversibility); and
extent, frequency and duration of the exposure (e.g. local - global; sporadic - continuous).

One possibility for characterizing the likely impacts of the control measure is a trend analysis, indicating the direction of changes rather than e.g. the actual cost in money terms. An example on how to perform a trend analysis is presented in Annex C.

It might be possible to draw firm conclusion from the analysis, if, for example,

some of the alternative control measures lead to clearly unacceptable consequences (e.g. immediate severe environmental or human health damage is likely to occur, the likely economic impacts are too severe); or
it is possible to define an acceptable order of preference for the criteria; then the alternative with the best value in the most important criteria will be chosen (e.g. if one must choose the most effective alternative in terms of risk reduction).

Qualitative data usually contain a considerable amount of uncertainty, and it might be difficult to comprehend their practical importance and to compare the different criteria to each other. Therefore, it may be difficult to assess the balance of advantages and drawbacks purely on a qualitative basis.

Quantitative analysis

Quantification of data can be used to make the different impacts more understandable, to simplify the comparison of advantages and drawbacks, and to reduce the uncertainty. Quantification means the assignment of a quantitative (numerical) value (or a set of values or a distribution) for a certain impact. Quantification can be partial (semi-quantitative), or cover the whole data (full quantification). In a semi-quantitative assessment usually only some of the decision criteria, such as certain economic impacts, are quantified.

Although quantification can help decision-making, quantified information should not be automatically given a greater weight in relation to impacts described qualitatively.

Furthermore, quantification usually implies additional assumptions which can also give rise to additional uncertainties.

Quantified data can be expressed in different ways. A distinction can be made between physical units and commensurate units. Physical units (also sometimes called "natural units") describing the risk can be, for example, the PEC/PNEC ratio, the margin of safety, the excess probability of an adverse effect, or numerical values describing the extent of the exposure (such as amount of emission or number of exposed workers). When using physical units, the task force will still face the problem of valuation, which makes the comparison of advantages and drawbacks complex. Valuation techniques have been developed to overcome this problem, which makes it possible to express different impacts in uniform and commensurate units. Valuation is about measuring preferences. The most usual commensurate unit is the monetary value, but it is also possible to create commensurate units using different scoring techniques in order to compare trade-offs between, for example, economic aspects and risks to human health and the environment.

Monetarisation is an essential part of cost-benefit analysis. Monetarisation of human health risks can be used to give a money value for avoided costs (like reduction in medical costs or loss of working days due to illness) or also for so-called statistical life. Likewise, the environmental impacts can be quantified to describe, for example, the loss of use value of nature resources (like a fishery, clean air or water), or the reduction in costs caused by pollution (remediation costs). In principle, it is easier to assess the (objective) use values or avoided costs than the (subjective) non-use values.

There are, however, several limitations in the applicability of valuation. The outcome of the risk assessment is expressed as a ratio of exposure level and no-effect level together with other factors, whereas a fully quantified risk estimation would require that the outcome is presented as a probability of a certain effect with the current exposure. The risk assessment is a so-called generic assessment, which is not directly connected to specific time or place. This makes it rather difficult to communicate the risk in concrete and understandable terms, which is usually the condition for using monetarisation techniques. This, however, should not lead to the conclusion that the risk assessment should be further amended.
Two possible approaches to carry out a (semi-)quantified analysis are risk-benefit analysis and cost-benefit analysis. These are described in more detail in Annex C.[2]

Dealing with the uncertainty

A certain amount of uncertainty is inherent in all available information for the analysis of advantages and drawbacks. In principle, this uncertainty should be acknowledged when comparisons of alternative control actions as well as of advantages and drawbacks

[2] See also: Risk-Benefit Analysis of Existing Substances, Guidance produced by a UK Government/Industry Working Group (Department of the Environment, February 1995). An overview of environmental techniques is provided in: The Economic Appraisal of Environmental Projects and Policies: A Practical Guide (OECD, 1995). More technical guidance is given in: Project and Policy Appraisal: Integrating Economics and environment (OECD, 1994).

are made. For instance, the task force should know how great a difference between two impacts should be regarded as meaningful.

Some simple procedures based mainly on expert judgement can be used to characterize the magnitude of uncertainty. For example, the task force may express different impacts in the form of ranges rather than one exact figure. Another possibility is to use threshold values. A threshold value describes the range wherein a change in a certain impact is considered insignificant. It is also possible to perform a coarse sensitivity analysis in order to determine how susceptible the outcome of the analysis is to changes if its variables.

A systematic description of uncertainty is recommended both in qualitative and quantitative analysis. However, it is not recommended, for example, to revise the risk assessment in order to get a more accurate (i.e. probabilistic) measure of the risk.

5.3.6 Outcomes

Once the advantages and drawbacks of the possible restriction of the substance have been appraised, the task force needs to judge whether the advantages of adopting the restriction outweigh its likely drawbacks. This assessment may for example, conclude that either

- the proposed restriction is not likely to result in significant drawbacks and its adoption is clearly justified by the probable advantages;
- the proposed restriction is likely to result in significant drawbacks, but its adoption is justified by the probable advantages; or
- the proposed restriction is likely to result in significant drawbacks which are not justified by the probable advantages.

Because of the complexity of the appraisal to be made and for reasons of fairness the task force is recommended to discuss its appraisal with representatives of all interest groups and try to achieve a consensus. The result of the discourse should become part of the report. This includes the main lines of reasoning especially in cases of dissent.

When considering the outcome of the appraisal, the task force should pay attention to the uncertainties in the data, especially when considering how definite the restriction proposal should be. In the case of threats of serious or irreversible damage a precautionary approach should be applied. Lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[3]

[3] See: The Rio Declaration on Environment and Development; Principle 15.

If further information is needed in order to more accurately determine the scale of the probable advantages and drawbacks, or their balance, the task force should specify what information is needed and to what purpose.

If the balance of advantages and drawbacks does not justify restriction of marketing and use, the task force should reconsider other risk reduction options which were identified as potentially effective, but did not initially seem as appropriate as the proposed restriction when assessed against the criteria set out in Step 4 above.

Step 6 : Drawing up a Formal Risk Reduction Strategy

Objective: Submit the risk assessment and any recommended risk reduction strategy to decision makers.

6.1 Introduction

Having identified the risk reduction measure or measures that will most effectively reduce the risks which need to be limited while imposing the minimum necessary burden on society, the task force will be in a position to draw up a risk reduction strategy for submission to decision makers.

The level of detail of any recommendations for further action will in part depend on the complexity of the problem and the information available to the task force. However, while the task force is encouraged to analyze the available data, the action suggested will usually be of a generic nature. For example, in recommending a risk reduction measure such as exposure or emission limits, the task force should not seek to prescribe the level at which any such limit should be set. The task force should also state clearly the degree of uncertainty in the information and methodologies on which the analysis is based.

Task forces should consult with those with the relevant technical and economic expertise, industry and other interested parties, as appropriate, on the draft strategy. The task force should then submit the risk reduction strategy and risk assessment to the decision makers.

6.2 Suggested Format for the Submission of Risk Reduction Strategies

An outline of a common format for the submission of risk reduction strategies is given below, and examples of how it could be used are provided in Annex A. The format is not intended to be prescriptive since risk reduction strategies tailored to individual substances are likely to need different emphases. The task force should therefore exclude any of the details suggested below if these are irrelevant to the specific substance, and include additional material where this is appropriate. It is also possible that the task force will not have sufficient information available to complete all the suggested fields. However, the analysis submitted to the decision makers should contain sufficient detail to allow scrutiny of both the data and any underlying assumptions on which the task force's conclusions are based.

SUMMARY

In this section, the task force should outline the main points of the strategy, i.e. the extent and nature of the risk to be reduced; the risk reduction measures recommended; how they are to be implemented; and the likely overall impact of adopting the strategy. The task force should also briefly discuss the degree of uncertainty in the information and methodologies on which the strategy is based.

If the substance gives rise to risks that need to be limited in more than one field (i.e. consumer protection, worker protection, environmental protection, etc), the task force should also state whether the risk reduction measures recommended tackle these risks separately or together.

1. BACKGROUND

In this section, the task force should describe the basic use pattern of the substance, the past control of the substance, and the concerns which led to the substance being selected as a priority for risk assessment.

2. THE RISK ASSESSMENT

This section of the strategy should summarize the key findings of the risk assessment, with appropriate cross-references to the assessment itself.[4] If possible, the task force should set out:

a) any significant hazardous effects and routes of exposure;

b) which populations and/or ecosystems are exposed and/or are likely to be exposed to the risks which need to be limited;

c) the imminence- and degree of any risks which need to be limited. If precautionary action is recommended before the risk assessment can be completed, the task force should explain why this is necessary; and

d) the degree of uncertainty in the results of the risk assessment.

3. CURRENT RISK REDUCTION MEASURES

This section should list any risk reduction measures identified during the risk assessment phase which are currently in place, and, if possible, assess their impact on the risks identified in section 2 above. If the desired reduction in risk could be achieved by

[4] The task force could complete this section by including a copy or summary of Section 0 of the Summary Risk Assessment Report, as explained in Annex II "Guidance on how to complete the (Summary) Risk Assessment Report" in Technical Guidance Document XI/919/94 "Risk Assessment of Existing Substances."

increasing the effectiveness of current measures, the task force should explain how this could be achieved.

4. POSSIBLE FURTHER RISK REDUCTION MEASURES

The task force may list the possible measures considered likely to be effective in reducing the risks identified in section 2 above. In making this selection, the task force may give special consideration to any practical experience of the control of similar substances or of similar measures. Any relevant legislation under which action could be taken may be identified.

5. ASSESSMENT OF POSSIBLE FURTHER RISK REDUCTION MEASURES

The task force should assess the measures and implementation methods listed in section 4 in terms of their likely effectiveness, practicality, economic impact and monitorability.

6. FURTHER RISK REDUCTION MEASURES RECOMMENDED

The task force should outline which of the measures assessed in section 5 are recommended, how and when these should be implemented, and their likely impact on the risks identified in section 2. The task force should explain why the other measures and methods of implementation considered were rejected. In particular, if restrictive measures are recommended, the task force should explain why non-restrictive approaches were judged likely to be ineffective.

7. MARKETING AND USE RESTRICTIONS

If marketing and use restrictions are recommended, the task force should also provide analyses of the advantages and drawbacks as well as the availability of alternatives.

a) Advantages and drawbacks of the substance

In this section, the task force should set out to the extent possible and on the basis of available information:

I) the net advantages provided by the substance as it is currently used, in terms of the benefits provided to users, producers and processors and society as a whole;

ii) the drawbacks arising from the current use-pattern of the substance, in terms of the risks to human health and the environment; and

iii) a brief description of the industry branches and others involved.

b) Advantages and drawbacks of the proposed restriction

In this section, the task force should set out:

I) the net advantages of the proposed restriction (taking into account the effect of any likely increase in the use of alternative substances), in terms of, for example, benefits to amenity, welfare or quality of life; enhanced protection of ecological systems, clean air, soil or water; the likely fall in the number of units of pollution emitted; and the probable effect on the risk characterization; and

ii) the net drawbacks of the proposed restriction (taking into account the effect of any likely increase in the use of alternative substances), for example, to industry, the regulator, consumers and the society as a whole.

Advantages and drawbacks should be appraised as far as is needed to make clear how the benefits to human health and the environment compare with the costs to industry, consumers and society as a whole.

c) Availability of alternatives

The task force should assess the extent to which the recommended strategy could lead to the marketing or use of alternative substances, whether suitable alternatives are available or are in prospect, and, if adequate information is available, the extent to which the use of alternatives would lead to a net reduction in risk.

8. POSSIBLE MONITORING ARRANGEMENTS

The task force should describe how the effectiveness of the recommended measure(s) could be monitored and/or reviewed.

9. ORGANIZATIONS CONSULTED

The task force should list the people and organizations who have been consulted on the draft risk reduction strategy, and attach the comments of those (including industry representatives and enforcement agencies) who will be directly affected by the recommended measures, indicating any views that have not been taken into account.

10. CONCLUSION

In the concluding section, the task force may wish to use to introduce issues not covered above, or to discuss the key issues and considerations which led to the task force's recommendations.

ANNEXES

Annex A Examples of Current Risk Reduction Strategies

This annex contains two fictitious examples of risk reduction strategies drawn up according to the suggested format set out in Step 5. The first of these is based on a case in the European Union which led to the introduction of restrictions on nickel to reduce the risk of skin sensitisation. The remaining two are based on purely imaginary substances: XYZ, a cleaning agent, and ABC, an ingredient in the perfume industry.

The three examples have been selected to show both a range of possible outcomes, and how the level of detail of the task force's work will depend on the circumstances of the individual substance. The nickel example illustrates a case where restrictions are recommended which would have a serious economic impact. For XYZ, while restrictions were again recommended if a voluntary agreement could not be reached, the existence of alternatives with similar performance and cost suggests the economic impact will not be significant. For ABC, the risk reduction measures have been voluntarily accepted by industry. It is clear that the respective task forces would need to pay more attention to the economic impact for nickel than for ABC or XYZ, while for ABC more attention would need to be paid to demonstrating that the voluntary measures had effectively reduced the risk.

These examples have been provided to guide the task force on how to use the suggested format outlined in Step 6: they are not intended to prescribe the level of detail or to limit the subjects addressed. For example, any real strategy would be expected to be more fully referenced and accompanied by supporting documents, as appropriate. However, in all three cases sufficient information was available to allow the task force to reach a decision: and in all three cases the value of adequate consultation with industry and other interested parties is clear. In deciding whether or not such information should be included in strategies, the task force should first consider whether the information is relevant, and secondly whether it is helpful in allowing the task force’s recommendations to be understood.

An Example of a Risk Reduction Strategy

Nickel

Summary

The risk assessment concluded that there was a need for limiting the risks with respect to consumers from skin sensitisation resulting from exposure to nickel.

Prolonged skin contact with articles containing nickel metal, certain nickel alloys or nickel-containing solutions can result in contact dermatitis. Some 1% of men and 10% of women in Europe and the USA have become sensitized and are hence potentially susceptible to this complaint.[5] 3000 new eczema cases are reported in Denmark each year, suggesting 250,000 per year in the EC. Nickel is the most common cause of allergic contact dermatitis.

Whilst the problem was first observed in certain industrial situations modern work practices have minimized occupational exposure. Today, nickel contact dermatitis occurs most frequently as a result of domestic exposures from close and persistent contact of the skin with nickel-plated articles or with certain nickel alloys.

Restricting the use of nickel-containing alloys for post assemblies inserted into pierced ears and other pierced parts of the human body and restricting the use of alloys or coatings in which the release rate of nickel in synthetic sweat exceeds a specified threshold in other items that come into prolonged contact with the skin will contain the problem and reduce its future incidence.

Given the high percentage of costume jewelry that is imported, the dominance of SMEs within the sector, and that those at risk include many young adults unlikely to take adequate account of the risks even if they were better informed, it is recommended that the risk reduction strategy be implemented through restrictions on the marketing and use of the items concerned.

1. Background

Nickel is widely used in costume jewelry and other personal items. Not only is it cheap but it is also especially resistant to corrosion that may result from human perspiration. However, it is known that prolonged skin contact with articles containing nickel metal, certain nickel alloys or nickel containing solutions can result in contact dermatitis. Some 1% of men and 10% of women in Europe (c 30 million people) have become sensitized and are hence potentially susceptible to this complaint. 3000 new eczema cases are reported in Denmark, suggesting 250,000 per year in the EC. Nickel is the biggest allergen, and second only to detergents as a cause of dermatitis.

[5] "Nickel Contact Dermatitis from Consumer products." A study prepared for the EC by the European Environmental Contact Group, 1990.

Whilst the problem was first observed in certain industrial situations, modern work practices have minimised occupational exposure. Today, nickel contact dermatitis occurs most frequently as a result of domestic exposures from close and persistent contact of the skin with nickel-plated articles or with certain nickel alloys. Although not a fatal disease, it can be very unpleasant and disfiguring.

2. The Risk Assessment

I) any significant hazardous effects and routes of exposure;

Persons who are sensitised to nickel are likely to develop dermatitis at areas of the skin that are exposed to solutions of nickel compounds or that come into direct and prolonged contact with nickel metal or with those nickel containing alloys that can react with sweat and generate soluble nickel ions.

The initial sensitisation to nickel requires a substantial exposure to nickel ions but once sensitised a much lower degree of exposure may elicit an allergic reaction.[6] The initial sensitization most frequently arises from domestic exposure to jewelry that is either nickel plated or made of certain nickel alloys such as nickel silver.[7] A particular cause of sensitization is the piercing of ears or other body parts and the use of suspect nickel containing studs during epithelisation of the wound. Since these are worn continuously for a period of several weeks, it is possible for protective coatings on nickel-plated or nickel alloy studs to erode and for corrosion to occur. The soluble nickel compounds which are generated can be present for a sufficient time to cause sensitisation.

In the metallic form neither nickel nor nickel alloys are sensitising substances. It is the soluble corrosion product resulting from the reaction of the metal or of some nickel alloys with sweat that is able to penetrate the skin, resulting in sensitisation and subsequent dermatitis. Moreover, where contact is of short duration there is insufficient time for nickel metal and nickel alloys to react with sweat and produce the damaging corrosion product. As a result of these factors, people are able to handle many nickel-plated or nickel containing articles on a regular basis without suffering from contact dermatitis. Familiar items include pins, keys, handles, coins and kitchenware.

ii) which populations and/or ecosystems are exposed and/or are likely to be exposed to the risks which need to be limited;

About 1% of the male population and 10% of the female population in Europe and the USA are affected by nickel sensitization.

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[6] T Fischer, "Occupational Dermatitis: Nickel an& the Skin in eds H. I. Maibach and T. Menne, Immunology and Toxicology (CR9 Press, Florida, 1989) p. 117.

[7] P. A. Grandjean et al, "Human Nickel Exposure and Chemobiokinetics' in eds H. I. Maibachand T. Menne, Immunobay and Toxicology (CRC Press, Florida, 1989) p.9.

iii) the imminence and degree of any risks which need to be limited. If precautionary action is recommended before the risk assessment can be completed, the rapporteur should explain why this is necessary;

No special considerations apply.

iv) the degree of uncertainty in the results of the risk assessment.

The results reported above are generally accepted.

3. Current Risk Reduction Measures

I) European Community

There are no current Community measures that are relevant to the problem of nickel dermatitis amongst the general public.

ii) Member States

Sweden has a regulation requiring that materials used for earring posts should contain less than 0.05% nickel.

On 27 June 1989 Denmark adopted a law providing for a ban on the use of nickel in a wide range of jewelry and other personal items where the rate of nickel release may exceed a certain threshold value. The purpose of the law was to protect the health of consumers from the possible sensitizing effects of nickel items coming into contact with the skin.

On 21 March 1991 Germany notified the Commission and other MS of its intention to regulate in the same field. The approach proposed was to ban the use of nickel in posts for ear-piercing and to require labeling of all nickel containing jewelry coming into contact with the skin.

iii) Elsewhere

No relevant information has been received

4. Possible Further Risk Reduction Measures

Prevention of the initial sensitisation to nickel provides the most effective way of reducing the incidence of nickel contact dermatitis. This can be achieved by controlling the use of nickel in articles that come into direct and prolonged contact with the skin.

A number of possible solutions are available to avoid or limit the likelihood of nickel sensitisation and contact dermatitis resulting from products designed for continuous skin contact or which are likely to be the subject of frequent or prolonged handling, including the following:

requiring the use of adequate protective coatings over products;

limiting the nickel content of products;

labeling;

requiring the use of alloys which do not react with sweat;

prohibiting the use of nickel in specified products;

specifying the use of products which conform with specified maximum release limits for nickel from products.

5. Assessment of Possible Further Reduction Measures

In deciding on the most appropriate course of action, due recognition should be given to the differing degree of risk posed by different products. The risks presented by many consumer articles involving only transient contact with the skin are insufficient to require risk reduction. However, risk reduction is required in the case of certain products coning into direct and prolonged contact with the skin.

It is also necessary to take account of the nature of the industry concerned. Much of the cheap jewelry concerned and many of the garments are imported into the Community from third countries, e.g. South-East Asia, the former Soviet Bloc, the US and Canada. Only roughly 50% of these industries are Community based. The importers of costume jewelry say they are in a weak bargaining position with overseas suppliers: the latter are thought unlikely to want to bother with separate nickel-free production to meet EU requirements unless the US and Japan were to also restrict the use of nickel.

Within the Community, the costume jewelry sector is dominated by SMES. For example, total employment in the U is around 3,000 divided between roughly 100 firms, but this is supplemented by an unknown number (up to 10,000) of "outworkers" working from home. One firm has recently invested 1.75 million ecu in new machinery to produce nickel-free jewelry. Central Statistical Office data suggests that sales to the end consumer in the UK amount to 235 million ecu a year, about three quarters being imports.

The likely purchasers of costume jewelry include a high proportion of young adults, who are judged unlikely to heed warnings provided by labeling requirements. A voluntary agreement is unlikely to prove effective given the large number of potential players and the high percentage of imports. It is hard to see how an economic instrument could be devised to target this specific problem, without unnecessarily penalising the wider nickel or costume jewelry industries.

Therefore, given the nature of the industry and of the consumers at Risk, it is considered that only regulation can effectively reduce risks in this area. It is possible that enforcement may prove complicated, in particular because of the large number of street traders potentially affected. However, none of the alternative risk reduction measures are considered to be more enforceable.

To limit the adverse economic effects to industry, implementation should be delayed to allow for the use of existing stocks and for the installation of new machinery.

6. Further Risk Reduction Measures Recommended

It is recommended that post assemblies inserted into pierced ears and other pierced body parts should have their nickel content restricted, whilst certain other listed products, such as earrings, wrist watch cases or straps and rivet buttons, should meet specified release limits under standard test conditions.

It is recommended that these risk reduction measures be introduced through restrictions on the marketing and use of the products concerned, by an amendment to Directive 76/769/EC, specifying:

a maximum limit for nickel content in post assemblies that are inserted into pierced ears and other pierced parts of the human body;

a maximum nickel release rate for products intended to come into direct and prolonged contact with the skin such as earrings, necklaces and zip-fasteners;

a maximum nickel release rate for products with a non-nickel coating which will not be exceeded within a specified time-period.

The evidence made available to the rapporteur suggests limits in the region of 0.05% and a release rate around 0.5 ug/cm^2/week should prevent primary sensitisation from occurring and only cause reactions in the extremely sensitized. However, there is as yet no accurate and reliable test for measuring such a release rate. It is therefore also recommended that the European Standards organisation CEN should be asked to develop test methods needed to check that the nickel-containing personal goods meet the requirements of the Directive.

7. Marketing and Use Restrictions

a) Advantages and Drawbacks

I. Of the substance:

I) the advantages provided by the substance as it is currently used, in terms of the benefits provided to users, producers and processors and society as a whole;

Nickel is widely used in costume jewelry and other personal items. It is technically superior to alternative materials in terms of brightness, ability to correct surface defects, ease of deposition and control, strength, and colour. It is also especially resistant to corrosion that may result from human perspiration. It can also be used to add strength to items coated with softer metals. Total sales of products likely to be affected by the proposed strategy were worth some 850 million ecu in 1992.

ii) the drawbacks arising from the current use pattern of the substance, in terms of the risks to human health and the environment;

Persons who are sensitised to nickel are likely to develop dermatitis at areas of the skin that are exposed to solutions of nickel compounds or that come into direct and prolonged contact with nickel metal or with those nickel containing alloys that can react with sweat and generate soluble nickel ions.

The initial sensitisation to nickel requires a substantial exposure to nickel ions but once sensitised a much lower degree of exposure may elicit an allergic reaction. The initial sensitization most frequently arises from domestic exposure to jewelry that is either nickel plated or made of certain nickel alloys such as nickel silver A particular cause of sensitization is the piercing of ears or other body parts and the use of suspect nickel-containing studs during epithelisation of the wound. Since these are worn continuously for a period of several weeks, it is possible for protective coatings on nickel-plated or nickel alloy studs to erode and for corrosion to occur. The soluble nickel compounds which are generated can be present for a sufficient time to cause sensitisation.

In the metallic form neither nickel nor nickel alloys are sensitising substances. It is the soluble corrosion product resulting from the reaction of the metal or of some nickel alloys with sweat that is able to penetrate the skin, resulting in sensitisation and subsequent dermatitis. Moreover, where contact is of short duration there is insufficient time for nickel metal and nickel alloys to react with sweat and produce the Damaging .aging corrosion product. As a result of these factors, people are able to handle many nickel-plated or nickel-containing articles on a regular basis without suffering from contact dermatitis. Familiar items include pins, keys, handles, coins and kitchenware.

Some 1% of men and 10% of women in Europe and the USA have become sensitized and are hence potentially susceptible to this complaint. 3000 new eczema cases are reported in Denmark, suggesting 250,000 per year in the EC. Nickel is the biggest allergen, and second only to detergents as a cause of dermatitis.

The UK Department of Health has calculated that the cost to date of treating nickel dermatitis in the UK alone is in the order of 150 million ecu with recurring annual costs in the order of 3 - 6 million ecu, arising mainly from women who have become newly sensitized to nickel, but also dealing with recurrent problems

from people already sensitized. There are also thought to be costs (very difficult to quantify) to the general economy due to work absences by those sufficiently badly affected by nickel dermatitis.

iii) a brief description of the industry branches and others involved.

The proposal is unlikely to significantly affect the industries producing nickel or possible alternatives, since only a tiny fraction of current nickel production is intended for the end uses to be restricted.

The proposal will have a far greater impact on the producers of costume jewelry and garment manufacturers using nickel fixtures. Only roughly 50% of these industries are Community based. Imports into the Community of goods likely to be affected By the recommendations were implemented were worth some '432 million ecu in 1992.

Within the Community, the costume jewelry sector is dominated by SMEs. For example, total employment in the UK is around 3,000 divided between roughly 100 firms, but this is supplemented by an unknown number (up to 10,000) of "outworkers" working from home. Central Statistical Office data suggests that sales to the end consumer in the UK amount to 235 million ecu a year, about three quarters being imports.

II. Of the Proposed Restriction

I) The net advantages will be in terms of the improvement to human health through a significant reduction in cases of nickel dermatitis. The UK Department of Health has calculated that the cost to date of treating nickel dermatitis in the UK alone is in the order of 15C million ecu with recurring annual costs in the order of 3 - 6 million ecu, arising mainly from women who have become newly sensitized to nickel, but also dealing with recurrent problems from people already sensitized. There are also thought to be costs (very difficult to quantify) to ,he general economy due to work absences by those sufficiently badly affected by nickel dermatitis.

ii) The net drawbacks of the proposed restriction will be largely the additional costs to industry from moving to alternative substances, resulting in some prices in' the shops going up and so me fail in demand. The main businesses to be affected by the measure are custom jewelry and clothing. Different firms have suggested the rise in prices might be in the range 3 - 15% - which for the UK market would represent a per annum recurring cost to the consumer of between 3.1 and 32 million ecu.

There is also the cost of new machinery: one large firm is investing 1.75 million ecu in new equipment to produce nickel-free items. The cost of modifying a nickel-plating line is estimated at around 700,000 ecu. For UK industry, assuming

30 firms investing 600,000 ecu each, total new investment would be in the region of 18 million ecu.

Industry will also have to meet the costs of testing the different lines of costume jewelry to ensure these are within the recommended release rate. Testing may cost about 30 ecu per test given the vast number of different lines produced, this may be a significant impact for some firms.

However, these costs may be partly offset by a tall in imports into the Community of the items covered by the recommendations, which were estimated at 432 million ecu in 1992. Overseas suppliers are thought unlikely to want to bother with separate nickel-free production to meet EU requirements unless the US and Japan were to also restrict the use of nickel.

For garment manufacturers, the main costs will result from the increase in component price resulting from the use of more expensive alternative metals. For the UK Market, it has been estimated that initial capital costs would be in the region of 3.5 million ecu, with additional recurrent annual running costs of 7 million ecu.

No significant new administrative expenditure is foreseen, beyond that resulting from the need for implementation. However, the Commission would be expected to grant financial support to standardisation organisations if new tests for nickel release rates are developed. The necessary mandate for this task comes under the Framework Contract signed on 10 October 1985, which provides for just such financial support from the Commission. The average cost to the Commission of each new standard is 50,000 ecu. As three standards would need to be introduced, the impact should be about 150,000 ecu.

There will also be some additional expenditure from enforcement. This will depend heavily on how individual Member States choose to Implement the proposed Directive, and cannot be quantified at this stage. However, as noted above, enforcement is likely to be complicated.

b) Availability of Alternatives

Substitutes are available in all the nickel applications restricted by this proposal. In the case of posts for pierced body parts the preferred substitute is titanium though silver might also be used. The most suitable substitutes for nickel in uncoated nickel items contacting the skin are stainless steel and white gold. Other alternatives, such as copper and zinc plating, would be cheaper than nickel, but are not used because of inadequate performance in terms of brightness, levelling, strength, colour and corrosion resistance. The solution in the case of coated items is to replace with bronze coatings or to use thicker top coats on nickel substrates or top coats containing a barrier layer or to use special lacquers. The use of these alternatives wold eliminate or reduce the risk of nickel contact dermatitis.

The use of these substitutes would eliminate the risk of nickel dermatitis, and available information suggests there would be no significant rise in other risks arising from their increased use. However, while supplies of these substitutes are readily available, they are relatively expensive compared with nickel.

Other potential substitutes, such as cobalt, would give rise to significant risks to human health. However, cobalt is judged to be too expensive to be a viable alternative.

8. Possible Monitoring Arrangements

The Committee set up under Directive 76/769/EEC would be responsible for monitoring the application of the Directive.

The European Standards organisation CEN should be asked to develop test methods needed to check that the nickel-containing personal goods meet the requirements of the Directive. Evaluation of the Directive's effectiveness would then be carried out annually via the progress reports on the adoption of the standards drafted by CEN.

9. Organisations Consulted

The following were consulted during preparation of the proposal:

Competent Authorities	All Member States
Industry	European Association of Metals Jewelry Distributors Association British Clothing Industry Association British Retail Consortium
Consumers	BEUC Local Authorities Co-ordinating Body on Food and Trading Standards
Relevant Experts	Prof A Sewart (Royal Albert Hospital, Bristol)

An Example of a Risk Reduction Strategy (fictitious)

Chemical: XYZ

Summary

XYZ is a colourless liquid which is used as a reaction intermediate by the chemical industry and a component of cleaning agents which are solely used for professional cleaning of buildings.

XYZ is regarded as genotoxic because of positive results in different mutagenicity tests (in vitro and in vivo). It is strongly suspected of being carcinogenic. SAR supports the findings of the tests. As a component of cleaning agents for professional cleaning of buildings a workforce of c. 100,000 people (in country A) is potentially exposed to XYZ. The exposure is inhalative and dermal and it differs considerably depending on individual working sites. For this reason, and in absence of epidentiological or long-term carcinogenicity studies, the health risk cannot be precisely quantified. However, the risk assessment concluded that there is a need for limiting the risks.

Beyond classification and labelling no further risk reduction measures need to be established when XYZ is used as an intermediate, because exposure does not occur. When used as a component of cleaning agents, conventional risk reduction measures are either not applicable (exposure limit) or not enforceable (personal protective equipment). It is therefore suggested to restrict the use of XYZ as a component of cleaning agents for professional cleaning of buildings.

A regulatory measure is suggested because of the seriousness of the risk and the use of the chemical by many small professional cleaning businesses, who add the chemical themselves to their cleaning solutions. Adopting the recommended strategy is likely to have little overall economic impact. Under certain conditions a voluntary agreement might also be an effective way of reducing risk.

1. Background

a) Use pattern. XYZ has two areas of application. It is used by the chemical industry as an intermediate for the synthesis of polymers in continuous processes. Secondly, a small fraction of XYZ serves as a component of cleaning agents used for the professional cleaning of buildings.

b) Current controls. To date, since its hazardous properties were unknown, XYZ has been handled according to the rules of good manufacturing practice. With respect to its use as an intermediate, occupational health and safety measures as well as environmental measures have been dictated by other agents of the syntheses. The reaction parameters result in virtually no emissions of XYZ. There are no specific provisions for handling XYZ as a component of cleaning agents.

c) Why selected for assessment. The chemical structure and A recent findings of a research institute on the basis of mutagenicity tests prompted the selection of XYZ as a priority chemical.

2. The Risk Assessment

The risk assessment concluded that there was a need for limiting the risks to human health arising from inhalative and dermal exposure.

I) any significant hazardous effects and routes of exposure

Positive mutagenicity tests (in vitro and in vivo) relevant for this class of chemical strongly suggest that XYZ is genotoxic and is therefore to be considered a suspected carcinogen. The use of XYZ as a component of cleaning agents gives rise to inhalative and dermal exposure. XYZ is being resorbed by the skin. There are no indications of ecotoxicity.

ii) which populations and/or ecosystems are exposed and/or are likely to be exposed to the risks which need to be limited;

In country A, approximately l00,000 workers employed in the professional cleaning of buildings are potentially exposed to the chemical. XYZ is a component of cleaning agents, added in concentrations of 1-5% to the mixtures ready for application. Users prepare those mixtures themselves, starting from the pure additives and water. The other additives give no cause for concern. XYZ is not used in cleaning agents for private purposes.

Workers employed in the professional cleaning of buildings must be considered as being at risk because of inhalative and derinal exposure when preparing the cleaning liquid and because of dermal exposure when applying it. The extent of exposure varies considerably depending on the individual cleaning sites.

No special precautions are taken by professional users with respect to the disposal of the used cleaning liquids. However, XYZ is biodegradable and has no observed ecotoxicological properties, and no ecosystems appear to be at risk.

iii) the imminence and degree of any risks which need to be limited. If precautionary action is recommended before the risk assessment can be completed, the task force should explain why this is necessary; and

Because of the nature of the tests which have identified the genotoxic potential of XYZ the potency of this chemical as a carcinogen can not be exactly assessed. XYZ belongs to a class of chemical which by recent findings is now known to include strong carcinogens, yet in the absence of a dose-response relationship the health risk cannot be quantified.

iv) the degree of uncertainty in the results of the risk assessment.

The uncertainties have been addressed under i) to iii).

3. Current Risk Reduction Measures

Because of its inconspicuousness which existed for XYZ until recently there are no risk reduction measures in place so far.

4. Possible Further Risk Reduction Measures

Possible measures to be considered are the following:

hazard information;
training;
use of personal protective equipment;
occupational exposure limits;
restrictions on marketing and use.

The situation in the professional cleaning of buildings in Country A is among other things characterized by a great number of small enterprises (approx. 5 - 10,000) on average employing between 10 and 20 workers with relatively high fluctuation, a high proportion of immigrant workers, and competitive pressure among the enterprises.

The personal capacity of the inspection authorities is too small to visit all enterprises regularly. Efforts to improve the awareness of risks and to encourage risk reduction measures such as personal protective equipment have not had encouraging results over the last 10 - 20 years. For example, there is still a high rate of sensitization to be observed as an indicator that gloves are not been used sufficiently.

The setting of an occupational exposure limit is also unlikely to improve the situation markedly. It would only be useful during the preparation of the cleaning agent starting from pure XYZ to avoid exposure to XYZ vapours. Exposure to XYZ vapours from the prepared cleaning agent is negligible in most cases. The cleaning agent is being prepared at the site of cleaning because of transportation costs. The working conditions when preparing it differ considerably, thus the use of exhausts becomes difficult.

We therefore conclude that only a restriction on the marketing and. use of XYZ as a component of cleaning agents could effectively reduce the risks of inhalative and dermal exposure to workers employed in the professional cleaning of buildings. We suggest the introduction of a restriction on a national level.

Alternatively, a voluntary agreement with industry could be considered. Given the large number of independent small firms using the chemical, any voluntary agreement would need to be

negotiated with the producers and/or distributors. To decide whether this would be practicable, more information is needed on the distribution cf the chemical from producer to user.

5. Assessment of Possible Further Risk Reduction Measures

As to the effectiveness and practicality of the risk reduction measures, see discussion above.

The monitorability of a restrictive measure is considered as being given. Depending on how the chemical is distributed, the inspectorates would have to control either the producers or the distributors of the substance. In either case, this would be a small number of companies.

For economic impact see Section 7 below.

6. Further Risk Reduction Measures Recommended

For the recommended measure see Section 4.

For questions related to implementation see Sections 4,5 and 7.

For rejection of non-restrictive approaches see Section 4.

7. Marketing and Use Restrictions

I) Advantages and Drawbacks

The risk described for professional users under Section 2 would be eliminated by replacing XYZ with substitutes already on the market. Though no long term studies have been performed with the substitutes, they belong to classes of chemicals of which individuals closely related to the substitutes have shown no effects after adequate testing. No other acute or chronic effects of the substitutes are known at relevant doses.

Both XYZ and the substitutes on the market show no adverse effects to the environment.

As pointed out in Section 1, only a small fraction of XYZ is produced for the purpose of being used as a component of cleaning agents. The producer has alternative additives on the market. This leads to low transitional costs, though production capacities would have to be readjusted. There would be no change in overall production costs.

No additional costs are to be expected for the users. The substitute containing cleaning agents show the same performance, and would be prepared in the same way. XYZ is somewhat cheaper than the alternatives: however, lower concentrations of the alternatives in the cleaning agents would achieve the same cleaning efficiency.

In the light of genotoxic properties of XYZ, its continuing use would result in considerable efforts of the inspection agencies. The enforcement of a restriction on XYZ would however concentrate on the producer and possibly on a small number of distributors.

The reduction of risks should have a positive effect on costs for health care. However, insufficient information is available to allow these costs to be quantified.

ii) Availability of alternatives

The substitutes ABC, HIJ, and MNO are already on the market for a long time. They belong to one class of chemicals. ABC, HIJ and MNO have shown no acute or chronic toxic or ecotoxic effects at relevant doses after adequate testing. No carcinogenicity long term tests have been performed on these substitutes. However, ABC, HIJ and MNO belong to a class of chemicals of which individuals closely related to the substitutes have shown negative results. Short term tests were also negative for ABC, HIJ and MNO.

In view of the fact that a restriction of XYZ as component of cleaning agents would result in the elimination of an additional cancer risk (though this risk can not at present be precisely quantified) almost without economic impact, the task force on the basis of the information available recommends the adoption of this risk reduction strategy at the national level.

8. Possible Monitoring Arrangements

See Section 5 above.

9. Organisations Consulted

The producer, the association of users, and the inspectorate have been consulted. The producer and the association of users furnished the necessary verifiable data on which the basis of the qualitative assessment was performed. They had no substantial arguments against the conclusions. The inspectorate confirmed the task force's professional judgement that the other risk reduction measures discussed in Section 4 would be unenforceable.

An Example of a Risk Reduction Strategy (fictitious)

Ingredient ABC

Summary

ABC is a skin sensitiser. It is a synthetic chemical widely used in the perfume industry in both fine fragrances and n industrial perfumes. The two most significant routes of exposure are to workers in the plants that manufacture or use ABC, and to the general public from use of fine fragrances or household cleaning products containing ABC.

Worker Protection. Measures already voluntarily implemented by the two manufacturers of ABC in the country appear to have reduced occupational exposure to acceptable levels. Monitoring under national legislation will ensure that these measures are properly implemented and maintained. No FURTHER risk reduction measures are recommended, though this conclusion should be reviewed if FURTHER sensitisations occur.

Consumer Protection. Based on the apparent safe use of the. substance in preparations sold to the public for many years, there appears no reason to suspect that risk reduction measures are needed. As a precaution however, we recommend that use in fine fragrances should be limited to 10% until more representative exposure data is available. The conclusion that no further action is needed should be reviewed after the manufacturers of fine fragrances have generated this exposure data. If this data is not available within two years, use of ABC should be reconsidered in preparations sold to the general public.

1. Background

ABC is a synthetic chemical widely used in the perfume Industry in both fine fragrances and in industrial perfumes. No specific regulatory controls are in place for ABC, although its use is covered in a general way by existing occupational health and safety provisions

It has not been widely studied in the past, but recent tonnage increases have triggered a need for deeper study. ABC was selected for priority risk assessment after manufacturers notified the regulatory authorities that sensitisation had occurred in plants producing ABC in other countries.

The information that ABC is a skin sensitiser is available to the public and calls for its immediate Elimination from all consumer products have been:. made by green consumer organisations. These calls are consistent with a growing level of consumer concern that"perfumes" may be associated with allergic reactions. Dermatologists are hesitant to conclude that the very wide range of different chemical substances used in perfume formulas should be grouped together in this way, and rely on specific patch testing of individual substances to assess whether sensitisation has occurred and what caused it in each case.

2. The Risk Assessment

In guinea-pig (Buhler) tests, the pure substance ABC was shown to be a sensitiser. There is clear evidence that workers in plants manufacturing and using ABC have been sensitized by skin contact, but no cases have yet been reported which suggest that users of perfumes or of cleaning products containing ABC have been affected.

Workplace exposure takes place when liquid ABC or mixtures containing ABC are handled during routine production. Particular concerns have been noted during pumping operations and in filling of drums for onward shipment. Splashes appear to be the major route of exposure. This applies both to producing plants and to using plants. Dermatological testing has shown in the past that about 10% of workers who have worked for more than one year in the plant areas where splashes can occur are sensitized to ABC. Symptoms among sensitized individuals include rashes and itching when skin exposure occurs.

Since ABC is not very volatile, respiratory exposure is of low concern, and structure-activity relationships (SARs) show no reason to expect respiratory sensitization to occur. Despite the appearance of skin sensitisation in a number of workers, neither these individuals nor other workers have shown any signs of respiratory sensitisation despite exposure to ABC for extended periods of time in the plants.

Extended (up to 24 hours) consumer skin exposure occurs in normal use when me fragrances are applied to the skin, and shorter (up to half an hour) exposure when household cleaning product solutions come into conta ct with the skin during normal use.

Skin sensitisation testing of perfumes containing up to 10% ABC and cleaning products containing up to 0.5% of perfumes which themselves contain up to 10% ABC have been negative both on guinea-pigs and human volunteers.

3. Current Risk Reduction Measures

No regulatory measures are in place. However, within the last two years, the two companies manufacturing ABC within the country have voluntarily implemented industrial hygiene guidelines to minimise, the risk of worker exposure. These include splash proof pipe connections between tanks and drums, warning placards at all points where exposure might occur, and wearing of protective clothing including gloves whenever ABC is being handled. The two companies also agreed that ABC should be classified as ....? This information, and recommended handling procedures are now included in the material safety data sheets issued to customers by both Companies. No new cases both worker sensitisation have been reported since these measures were implemented. This suggests that the risk reduction measures already adopted voluntarily provide adequate protection for the workforce.

4. Possible Further Risk Reduction Measures

Three possible routes to further risk reduction were consider red:

ban on the manufacture and use of ABC within the country;
further restrictions on occupational exposure;
ban or restrictions on use of ABC in preparations sold to the general public.

5. Assessment of Possible Further Risk Reduction Measures

All of these measures are practical. Banning the substance eliminates all risk. Appropriate further restrictions on occupational exposure will be effective provided they both reduce the possibility of future exposure and are reliably implemented by the relevant manufacturers. Whether or not bans or restrictions on use in preparations sold to the general public are effective depends on whether or not there is in fact a significant risk.

The manufacturers advise, that ABC is a substance of considerable importance to the perfume industry. Although other substances with fairly similar odour are known, none of these has been thoroughly tested either for performance as a perfume ingredient or for sensitisation. Significant expense will be necessary.

6. Further Risk Reduction Measures Recommended

Since it appears that the measures already implemented by the manufacturers have reduced the occupational exposure risks to an acceptable level, neither a ban on manufacture and use nor further occupational exposure restrictions seem necessary. However, we recommend that the national regulatory authority should routinely monitor the relevant plants to ensure that the current standards are maintained.

The substance ABC has been safely used by consumers in both fine fragrances and in household products for many years. In the absence of any indication that the risk has changed significantly, no restrictions on the use of ABC in preparations sold to the general public seem necessary. However, we recommend that representative exposure data be collected to allow a data-based risk assessment to be carried out by the manufacturers of these preparations to confirm the assumption that the risk to consumers remains negligible. When this risk assessment is available, we recommend a further review. Exposure via fine fragrances is more crucial than via cleaning products, since the extent of the exposure is greater. The relevant industry association has agreed to develop this data. If not available within two years, use of ABC in preparations sold to the general public should be reassessed.

Furthermore, we recommend that during this period, no use at levels above 10% in fine fragrances be permitted, since this is the highest level so far tested for sensitisation potential of preparations. This is also the maximum level which has been used in preparations sold to the general public in the past.

7. Marketing and Use Restrictions

See final paragraph of Section 6.

Advantages and Drawbacks. As noted above, industry has advised that ABC is a substance of considerable importance to the perfume industry. Although other substances with fairly similar odour are known, none of these has been thoroughly tested either for performance as a perfume ingredient or for toxicity. Significant expense will be necessary.

At this time, it is not possible to draw a firm conclusion that reduction of risk would be achieved by further restrictions on the use of ABC in consumer products, since little information is available about the sensitisation potential and other toxicological properties of the potential substitutes. To avoid the possibility that reduced risk from restrictions on the use of ABC would cause increased risk from substitutes, we recommend that industry should generate and submit data for alternative substances DEF and GHI comparable to that already available for ABC. This data will only be useful if available before the new exposure data is reviewed.

8. Possible Monitoring Arrangements

Routine monitoring under national occupational health and safety legislation at production sites will be used to confirm that worker exposure is being properly controlled.

9. Organisations Consulted

Manufacturer A

Manufacturer B

Industry Association representing manufacturers of household cleaning products

Industry Association representing fine fragrance manufacturers

Chemical Industry Workers Union

Consumers Association

Annex B: List of Potential Consultees For Development of a Risk Reduction Strategy

Following is a list of some of the concerned and interested parties which the task force may wish to consult during the process of developing a risk reduction strategy. The following is intended only as a starting point: not all of the stakeholders listed below may be relevant depending upon the substance in question and the specific circumstances in the country. Similarly, the task force may identify additional groups/actors which should be consulted.

relevant government ministries;
inspectorates;
customs officials;
relevant experts (e.g. from research/academia);
industry associations;
individual companies/firms which manufacture/use the substance in question or which otherwise are potentially affected;
consumer groups;
environmental and other public interest groups;
labour unions;
regional/local authorities;
other countries;
international organizations (e.g. for relevant data/information).

Annex C: Suggested Guidance for the Determination of Costs and Economic Consequences

1. Introduction

Economic assessment of risk reducing measures should be an integral part of the task force's work, assuring that any net negative impact of a measure will not be out of proportion to the benefits of reducing risk. The assessment can be quantitative, but also more qualitative, depending on the availability of the data.

There are different methods available for quantification and even monetarisation of the costs and the benefits of risk reducing policies.[8] Following is a suggested approach based on that of the Netherlands in which the costs of a policy are as much as possible expressed in monetary terms, making a clear distinction between the direct costs of a measure and the economic consequences which follow from a cost rise. The benefits of the policy are generally not expressed in monetary terms, but in units which directly describe the physical effects on humans and the environment. As such they can also be related to the targets the policy is aiming for. Costs as well as economic consequences can arise for each of the relevant actors in the risk reduction process: business sector/producers of the substance, private sector/consumers of the substance and the government sector as regulator.

2. Key considerations

Following are some guidance questions to assist a task force in determining costs and economic consequences:

1. What kind of activities/measures are expected from the various actors in order to reduce the risks?

   Activities should be separated into policy instruments and measures. Policy instruments are in general activities introduced by the government which as such do not have a direct risk reducing effect. They are intended to bring other actors to risk reducing measures. The use of policy instruments generally involves costs for the government.

   Measures which have a direct reducing effect on the risk of a substance for humans and the environment, are taken by producers and/or users of the substance. They can be technical, organizational or administrative.

[8] Risk-Benefit Analysis of Existing Substances Guidance produced by a UK Government/Industry Working Group (Department of the Environment, February 1995).

2. Related to the use of instruments by the government: what are the (extra) yearly budget expenditures for activities such as research, registration, legislation, surveillance, enforcement, etc?

3a Related to the producing (including distributing) sector: which categories of firms will be affected by the policy and how many firms in each category are effectively influenced?

3b What, for the firms concerned, are the probable net costs of the policy?

These costs are assessed by firstly appraising the eventual direct cost rise per annum and secondly by determining the, economic consequences of that cost rise. Therefore, the analysis has to find out for each of the measures whether the policy will lead to extra investment and/or running costs compared with. the situation without regulation.

Investments are converted into annual costs over the life of the investment. Annual investment costs are built up of depreciations and interest costs and can be calculated by the annuity method, resulting in constant capital costs over the life of the investment. Operational costs are also assured to be constant. Total annual costs are the sum of annual capital and running costs. Such annual costs are determined for different sectors or branches of producers. In this approach there is no need for discounting a stream of future costs to a present value. The methodology of cost accounting is elaborated in "method for Environmental Costing".[9]

4. What are the direct costs of risk reducing activities by the users?

Risk reducing activities falling under this heading include the purchase of more expensive alternatives, more expensive ways of using the substance, the installation of protective facilities or clothing, etc.

Higher prices for improved substances as a result of passing higher production costs onto the users should be treated as an economic cost for the users, not as a direct cost.

Users include not only private consumers (as distinguished from producers) but also all kinds of professional users.

5. What are the socio-economic effects of the policy in question on different levels and different time scales?

In this question we are asking for the consequences of the cost rise on economic variables such as profits; future investments, employment, economic structure, price level, purchasing power, etc.

[9] Method for Environmental Costing Background Document (Ministry of Housing, Spatial Planning and the Environment of the Netherlands, March 1994)

As far as producers are concerned the most important question is about the affect of the regulation on the continuity of the firm. Will the firm be able to bear the costs or not? Can the rise in costs be seen as reasonable or not?

The depth of the investigation needed will depends on the extent of the likely cost rise. In many cases with a moderate cost rise, a simple and qualitative approach will be sufficient. With a more extensive cost rise a more elaborate and quantitative analysis may be needed.

The direct costs of risk reducing activities undertaken by a producer can have economic effects for the users (higher prices, loss of purchasing power, compensating expenditures etc) as well as for the producer itself (loss of sale, profit employment, etc). But in the case of alternatives also positive economic effects are in play, which must be weighed against the negative impact.

The costs of activities by the users will have in a comparable way effects on the users themselves as well as on the producers of the substance.

Annex D: Use of Risk-Benefit Analysis[10]

1. Introduction

Risk-benefit analysis is an art as much as a science. The objective is to identify and reduce the uncertainty confronting the decision-maker. There will often be room for debate about the measurement of particular parameters. In such circumstances one of the most important functions of risk-benefit analysis nay be to raise the level of debate in international negotiations. It is not however a substitute for decision-making.

The identification and weighing of the costs and benefits associated with the different risk reduction options can be carried out to various levels of detail and precision ranging from the completely qualitative to the fully quantitative. Three examples of options along this spectrum could be identified for the analysis of advantages and drawbacks.

I) a qualitative risk-benefit analysis - where risks and benefits can be described but not quantified or valued;

ii) a quantified risk-benefit analysis where risks and beef its can be quantified but only benefits can be valued; and

iii) a cost-benefit analysis where both risks and benefits can be quantified and valued.

The following criteria will help the task force determine how far to go along this spectrum:

can a sensible and logical way forward be found?
is the required data available or can they be made available at reasonable cost?
how expensive are FURTHER investigations and data collection likely to be in terms of skilled manpower, etc, in relation to the intrinsic importance of the issue to be addressed?

In general, the analysis of advantages and drawbacks should include a systematic qualitative risk-benefit analysis. In some cases it will involve a quantitative risk-benefit analysis and it may occasionally require a cost-benefit analysis. However, no matter how far the analysis is taken, the central question remains: how do the benefits to human health and the environment expected from introducing risk reduction measures compare with the socioeconomic costs to industry and consumers?

[10]Drawn from Risk-Benefit Analysis of Existing Substances Guidance produced by a UK Government/Industry Working Group (Department of the Environment, February 1995).

2. Risks to Human Health and the Environment and their Valuation

A significant problem in characterising risks is that the output of risk assessment will generally be in the form of risk quotients that compare expected doses and environmental concentrations with predicted no effect levels, ie the ratios PEC/PNOAEL and PEC/PNEC. It is important to try to translate these ratios into expressions of probability that harmful effects will occur, and if possible to evaluate the costs attributable to those harmful effects. The extent to which this can be done will depend on the quality of the information that is available about the harmful effects of the substance, about the exposure response relationships of exposed human groups or environmental targets, and whether there is a rational basis for assigning monetary values to the harmful effects. The types of conclusions that may be drawn will range from:

I) a qualitative statement about the nature of the risks to human health or the environment from the substance and how the control measures are expected to reduce those risks;

ii) quantified estimates of risk probabilities and the amounts by which they are expected to be reduced by the proposed risk reduction measures; to

iii) monetary valuation of the risk estimates and the savings that would be expected if the proposed risk reduction measures were adopted, in terms of monetary valuation of the estimated statistical reduction of harm to people or the environment.

3. Costs to industry and consumers

The extent to which economic effects can be quantified will depend on the information available about the ways that the risk -reduction measures are likely to influence the markets for products affected by controls on the substance. The types of conclusion that may be drawn will range from:

I) a list of the qualitative advantages and disadvantages of the substance as currently used, for the substance with the proposed controls measures, and for any substitute substance(s);

ii) quantitative estimates of the consequent changes in amounts of products demanded and supplied;

iii) the financial consequences of these changes in the market for the products in terms of changes in producer and consumer surpluses.

Consultation with producers and consumers is very desirable at this stage to check that all significant uses of the substance have been taken into account and that all the consequences of the control measures or substitutes have been considered.

When estimating costs to industry and consumers, it the substance is a minor component of the costs of production of the product to be controlled, it will usually only be necessary to estimate changes in producer surplus: however, if the substance is a major' component of the costs of

production of the product to be controlled, it will be necessary to estimate changes in both producer and consumer surplus.

4. Comparing Risks and Benefits

Once the likely reductions in risks to human health and the environment from the risk reduction measures have been established, described and possibly valued, they can be compared with the consequences of those control measures for producers and consumers. A decision must be made on whether the overall changes that would result from the adoption of the proposed risk reduction measures are justified by the reduction in risks to people and the environment. The basis for this decision will range from a purely subjective comparison between qualitative statements of changes of risks and effects of control measures to a clear financial difference between monetary values Of risk reduction and monetary estimates of net changes in producer and consumer surpluses.

Three generic case examples of likely options can be identified along the spectrum from qualitative risk benefit analysis to fully quantitative cost-benefit analysis. Example I is an essentially qualitative and subjective risk-benefit analysis that might be standardised at a later date in the light of experience. Example II is a more quantitative risk-benefit analysis that can be made more objective if applied in a comparative way. Example III is a fully quantitative cost/benefit analysis which is likely to be rarely applied but may be more common where there are concerns about human health since full valuation of health risks is more straightforward than the valuation of harm to the environment.

Example I

If the risk quotient(s) is based on data of poor quality, there may be little point in spending time, effort and money to obtain detailed economic data. A similar view might be taken if the risk quotient is much greater than 1, indicating with reasonable confidence a very high and clearly unacceptable risk, in which case all that may be needed is an order of magnitude assessment to check that the proposed control measures would not lead to any enormous disadvantages.

If the above criteria apply, the appropriate form of risk-benefit analysis is a qualitative risk-benefit analysis (i.e. a systematic description but not quantification of risks and benefits). Lists of advantages and drawbacks should therefore be drawn up for:

I) the substance as currently used;

ii) the substance with the proposed control measures; and

iii) any proposed substitute substance.

All the economic consequences of the proposed control measures and/or substitutes should be described for comparison with the environmental and human health consequences. A subjective judgement can then be made on whether the overall changes that would result from the proposed

risk reduction measures are acceptable in comparison with the reduction in risks that would be achieved.

Example II

This is a quantitative risk-benefit analysis which is likely to be applicable when more confidence can be put in the risk quotient(s) and when there is a finer difference between the quotient(s) for the substance under consideration and the value of 1, and/or between the quotient for the substance under consideration and potential alternative substances. Under these conditions, there will be more justification in putting resources into the costing of the proposed risk reduction measures.

So the information used here includes:

i) a risk quotient which is not a fully quantified assessment of risk and which therefore cannot readily be converted into a monetary value; and

ii) A PNEC used in the risk quotient which gives target levels for control and from which their economic consequences can be assessed.

The outcome of this exercise will be a statement of reduction in risk expressed in terms of a reduction in quotient and a statement of the net consequences of the risk reduction measure in terms of changes in the product quantities demanded and supplied. If this were available across a range of options a quantitative comparison could be made of the reduction of risk per loss of economic benefit for each.

Example III

This is a full cost-benefit analysis, which is likely to be appropriate either when there is a fully-quantified, probabilistic statement of risk for human health and the environment; and/or when an example II analysis leads to the need for judgements that are so fine and yet potentially of such great economic importance that it is worth investing the time, effort and finance in a complete cost/benefit analysis.

Economic values can be applied to the risks using one or more of the range of environmental and human health valuation techniques available. The economic advantages associated with the substance under consideration can be valued by estimating producer and consumer surpluses. The cost-benefit analysis can then be carried out with the substances under consideration or in a comparative way on it and its substitutes. The optimum level of safety will be when the risks have been reduced up to the point where the cost of any further reduction just equals its benefit.